UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF	**Investigation No. 337-TA-1266**

COMMISSION OPINION

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I. INTRODUCTION

On September 22, 2022, the Commission determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on June 27, 2022. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). On review, the Commission has determined to affirm, with modifications, the ID's finding that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Having found a violation of section 337, the Commission has determined to issue a limited exclusion order and a cease and desist order as set forth below. The Commission finds that the public interest does not preclude the issuance of remedial orders. The Commission has determined that a bond in the amount of $2 per imported article is required for infringing products imported during the period of Presidential review.[1] The Commission, however, has determined to suspend enforcement of the orders, including the bond provision, pending final resolution of the U.S. Patent and Trademark Office, Patent Trial and Appeal Board's ("PTAB") Final Written Decisions finding all asserted patent claims unpatentable. *See Apple, Inc. v. AliveCor, Inc.*, IPR2021-00970, Patent 9,572,499, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00971, Patent 10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, Patent 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022) (collectively, "Final Written Decisions" or "FWDs").

This opinion sets forth the Commission's reasoning in support of that determination. The Commission adopts the remainder of the ID that is not inconsistent with this opinion.

[1] Commissioners Schmidtlein and Stayin disagree with the Commission's determination regarding the amount of the bond required for infringing products imported during the period of Presidential review as provided in section (V)(D) of the Commission's Opinion concerning bond. *See infra* note 41.

II. BACKGROUND

A. Procedural History

On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California ("AliveCor" or "ALC"). 86 Fed. Reg. 28382 (May 26, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG[2] functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 ("the '731 patent"); claims 1-23 of U.S. Patent No. 10,638,941 ("the '941 patent"); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 ("the '499 patent"). *Id.* The Commission's notice of investigation named Apple Inc. of Cupertino, California ("Apple") as the sole respondent. The Office of Unfair Import Investigations ("OUII") is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor's motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the '499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the '731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the '941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

The ALJ held an evidentiary hearing from March 28-April 1, 2022, and received post-hearing briefs thereafter.

[2] ECG stands for electrocardiogram.

On June 27, 2022, the ALJ issued the final initial determination ("ID"), finding a violation of section 337 as to the '941 and '731 patents, and no violation as to the '499 patent.[3] The ID found that the parties do not contest personal jurisdiction, and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. § 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)). Regarding the '941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98, 187-88. For the '731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127, 188. For the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. § 101. *Id.* at 129-138, 140-152, 188. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. § 1337(a)(2). *Id.* at 152-180, 188. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and a cease and desist order would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. *Id.* at 194-95.

On July 11, 2022, Apple filed a petition for review of the final ID and AliveCor filed a

[3] The ALJ issued a corrected final ID on July 26, 2022, correcting the table of contents.

combined petition and contingent petition for review.[4] On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.[5]

On September 22, 2022, the Commission determined to review the final ID in part. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). Specifically, the Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. § 101 and obviousness under 35 U.S.C. § 103, and the economic prong of the domestic industry requirement for all three patents. *Id.* The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *Id.*

On October 6, 2022, the parties filed initial submissions in response to the Commission's request for briefing.[6] On October 14, 2022,[7] the parties filed reply submissions.[8] On October

[4] *See* Respondent Apple Inc's Petition for Review of the Initial Determination on Violation of Section 337 ("Apple Pet."); Complainant AliveCor, Inc.'s Combined Petition for Review and Contingent Petition for Review of the Initial Determination ("AliveCor Pet.").

[5] *See* Respondent Apple Inc.'s Response to the Complainant's Petition for Review of the Initial Determination ("Apple Rep."); Complainant AliveCor Inc.'s Response to Respondent Apple Inc.'s Petition for Review of the Initial Determination on Violation of Section 337 ("AliveCor Rep."); Combined Response of the Office of Unfair Import Investigations Response to the Private Parties' Petitions for Review of the Final Initial Determination on Violation ("OUII Rep.").

[6] *See* Respondent Apple Inc.'s Opening Brief in Response to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("Apple Sub."); Complainant AliveCor, Inc.'s Submission in Response to the Commission's September 22, 2022 Notice of a Commission Determination to Review in Part ("AliveCor Sub."); Brief of the Office of Unfair Import Investigations on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("OUII Sub.").

[7] On October 12, 2022, the Chair granted the parties' request to extend the due date for their reply briefs by one day. *See* Commission Letter Granting Request for Extension of Time to File Replies to the Commission's Request for Written Submissions; *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Inv. 337-TA-1266 (Oct. 12, 2022).

[8] *See* Respondent Apple Inc.'s Reply Brief to AliveCor and OUII's Response to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the

21, 2022, Apple moved for leave to file a sur-reply to AliveCor's reply submission.[9] On October 24, 2022, AliveCor filed an opposition.[10] OUII filed a response in opposition on November 2, 2022.[11] The Commission has determined to reject Apple's motion for leave to file a sur-reply to AliveCor's reply submission. The Commission finds that Apple has not shown AliveCor's reply submission contains errors that warrant a sur-reply.

On December 7, 2022, Apple filed an emergency motion, asking "the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions."[12] Apple Emergency Motion at

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Public Interest, and Bonding ("Apple R.Sub."); Complainant AliveCor, Inc.'s Reply Submission in Response to the Commission's September 22, 2022 Notice of a Commission Determination to Review in Part ("AliveCor R.Sub."); Reply Brief of the Office of Unfair Import Investigations on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("OUII R.Sub.").

[9] *See* Respondent Apple Inc.'s Motion for Leave to File Sur-Reply Brief to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[10] *See* AliveCor's Opposition to Apple's Motion for Leave to File Sur-Reply to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[11] *See* Response of the Unfair Import Investigations to Respondent Apple Inc.'s Motion for Leave to file Sur-Reply Brief to AliveCor's Reply to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding.

[12] *See* Respondent Apple Inc.'s Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of any Appeal of the Patent Office's Decision that United States Patent Nos. 10,638,941, 10,595,731, and 9,572,499 Are Unpatentable ("Apple Emergency Motion").

1. On December 9, 2022, AliveCor filed an opposition to Apple's motion.[13] On December 16, 2022, OUII filed a response to the motion.[14]

B. Overview of the Technology

The technology at issue generally relates to systems, devices, and methods for monitoring cardiac health and managing cardiac disease. ID at 3.

The '941 patent entitled, "Discordance Monitoring," issued on May 5, 2020. '941 patent (JX-0003). The patent describes systems, devices, and methods that can be used to "conveniently sense the presence of an intermittent arrhythmia in an individual." '941 patent, Abstract. The systems, devices, and methods can also "be configured to sense an electrocardiogram." *Id.*

The '731 patent entitled, "Methods and Systems for Arrhythmia Tracking and Scoring," issued on March 24, 2020. '731 patent (JX-0002). The patent describes "a dashboard centered around arrhythmia or atrial fibrillation." '731 patent, Abstract. "The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors." *Id.* "The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score." *Id.*

The '449 patent, also entitled, "Methods and Systems for Arrhythmia Tracking and Scoring," issued on February 21, 2017. '449 patent (JX-0001). The patent also describes "a

[13] *See* AliveCor's Opposition to Apple's Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings ("AliveCor Opposition").

[14] *See* Response of the Office of Unfair Import Investigations to Respondent Apple Inc.'s Emergency Motion to Suspend any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of any Appeal of the Patent Office's Decision that United State Patent Nos. 10,638,941, and 9,572,499 Are Unpatentable ("OUII Reply to Emergency Motion").

dashboard centered around arrhythmia or atrial fibrillation." '449 patent, Abstract. "The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors." *Id.*

C. The Accused Products

The accused products consist of four generations of Apple smartwatches:

Apple Model(s)	Category
A1975, A1976, A1977, A1978	Series 4
A2092, A2093, A2094, A2095	Series 5
A2291, A2292, A2293, A2294	Series 6
A2473, A2474, A2475, A2477	Series 7

ID at 6. The parties explained that the "Apple Watch Series 6 is sufficiently representative from a hardware standpoint of all other Accused Products" and they describe the "salient features of the Accused Products via the Series 6 as 'a motion/activity sensor known as an accelerometer, a photoplethysmography ('PPG')[15] sensor, an electrocardiogram ('ECG') sensor, a display screen, a processor, and memory.'" ID at 6 (citing Hr'g Tr. (Jafari) at 303:19-24; JX-0221C (Waydo) at 207:10-14, 208:14-209:11; CX-0107). The ID further found that the "software running on these devices is also important, taking the form of Apple's operating system, WatchOS" and that "[a]s with hardware, the parties have agreed that version 7.6.2 of WatchOS is representative of all other versions that contain the diagnostic tools implicated by the Asserted Claims." *Id.*

[15] PPG is used to sense the amount of oxygen in the blood.

D. Domestic Industry Products

The domestic industry products include "wearable electronic devices, being developed, manufactured, and/or sold by AliveCor under the tradenames KardiaBand System, [[ ]]." ID at 4. "Each product includes, 'among other things, a smartwatch, activity sensor, PPG sensor, and ECG sensor.'" *Id.* at 4-5. "The KardiaBand System ('KBS') comprises the KardiaBand watch band, and an Apple Watch (Series 1, 2, 3) with Watch OS 5.0 or earlier running a program called KardiaApp." *Id.* at 5 (citing Hr'g Tr. (Jafari) at 385:16-386:15). Complainant relies on its KBS product for its domestic industry that exists and relies on its [[ ]] products for its domestic industry in the process of being established.

III. COMMISSION REVIEW OF THE ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 4 (May 1, 2015). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9-10 (July 1997) (quoting *Certain Acid-Washed Denim Garments & Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). With respect to the issues under review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS

A. Economic Prong of the Domestic Industry Requirement

The Commission determined to review the economic prong of the domestic industry requirement for all three patents and asked the parties for briefing. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

On review, the Commission has determined to affirm the ID's findings that AliveCor failed to establish the economic prong of the domestic industry requirement as to a domestic industry in the process of being established, and an existing industry under subsections (A) and (B), but proved the existence of a domestic industry under subsection (C). With respect to the industry in the process of being established and an existing industry under subsection (A), the Commission affirms the ID for the reasons stated therein. Regarding subsections (B) and (C), the Commission affirms the ID as modified below.

1. Legal Standard

In patent-based proceedings under section 337, a complainant must establish that a domestic industry "relating to the articles protected by the patent . . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this domestic industry requirement consists of an "economic prong" and a "technical prong." *See Alloc, Inc. v. Intl Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003). To satisfy the "technical prong," the complainant must establish that it practices at least one claim of each of the asserted patents. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 at 17-18 (Apr. 11, 2005). To satisfy the "economic prong," paragraph (3) of section 337(a) provides:

> For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Expenditures in each of the above three categories under section 337(a)(3) must "pertain to the complainant's industry with respect to the articles protected by the asserted IP rights." *See, e.g.*, *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68 (Oct. 30, 2015); *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 40 (Jan. 6, 2016).

Under subsection (C), a domestic industry will be found to exist if, "with respect to the articles protected by the patent," a complainant can show "substantial investment in *its exploitation*, including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3)(C) (emphasis added). For this provision, the Federal Circuit has interpreted "its" to mean the patent (or other enumerated IP right in subsections 337(a)(1)(B)-(E)), so there must be a nexus between the domestic investments and the exploitation of the asserted patents, beyond showing that those investments relate to the protected domestic industry ("DI") articles. *InterDigital Communications, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1297-1301 (Fed. Cir. 2013).[16] To establish the nexus, the complainant must show the connection between its

[16] The ID states that "[u]nlike subsections (A) and (B), where a connection is made between an alleged investment and a patent-practicing product, a subsection (C) analysis requires a connection between the R&D investment and the asserted patents (*i.e.*, nexus)." ID at 170 (citation omitted). We clarify that while subsection (C) requires a nexus between the claimed investments and the asserted patents, the requirement that investments be "with respect to articles protected by the patent" applies with respect to subsections (A), (B), and (C). *See* 19 U.S.C. § 1337(a)(3); *see also InterDigital,* 707 F.3d at 1298 ("Thus, just as the 'plant or equipment'

investments and the patented aspect(s) of the invention that it is exploiting. *See Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 49-50 (Aug. 2014) ("As a matter of statutory construction, an investment in the article is not automatically an investment in the asserted patent."). It is not enough for a complainant to assert that it generally conducts research and development, or that its R&D relates to non-patented features incorporated into articles that also practice the patent at issue. *Id.*

Depending on the particular facts of a case, a complainant's domestic industry with respect to articles protected by the asserted IP rights may extend beyond the protected article, to include those additional parts or components that are necessary to use or exploit the patented invention. *See Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1351 (Fed. Cir. 2013) (explaining that "nothing in § 337 precludes a complainant from relying on investments or employment directed to significant components, specifically tailored for use in an article protected by the patent"). However, there may be investments that are too far removed from the articles protected by the asserted intellectual property rights to be considered part of the complainant's domestic industry. *See Certain Video Game Systems and Wireless Controllers and Components Thereof*, Inv. No. 337-TA-770, Comm'n Op. at 66 (Oct. 28, 2013) ("[W]e agree with the ALJ that the language of the patent is directed to the toy wand and not the toy wand plus the entire MagiQuest attraction."). Nevertheless, for subsection (C), the focus remains on whether the claimed investments are related to the exploitation of the patent and whether those investments in the exploitation of the patent are substantial.

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referred to in subparagraph (A) must exist with respect to articles protected by the patent, such as by producing protected goods, the research and development or licensing activities referred to in subparagraph (C) must also exist with respect to articles protected by the patent, such as by licensing protected products.").

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007). The Commission decides the domestic industry requirement has been established in each investigation based on "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* A complainant does not need to show any "minimum monetary expenditure," and does not "need to define or quantify the industry itself in absolute mathematical terms." *Stringed Musical Instruments,* Inv. No. 337-TA-586, Comm'n Op. at 16-17 (May 16, 2008) ("A precise accounting [of the complainant's domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation."). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *See Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011).

To satisfy the domestic industry requirement, section 337(a)(3) requires that a complainant's asserted investments must be "significant" or "substantial." The Federal Circuit has held that "qualitative factors alone are insufficient" to show that domestic industry investments are significant or substantial. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 885 (Fed. Cir. 2015). The statute "requires a quantitative analysis to determine whether there is a 'significant' [or 'substantial'] increase or attribution by virtue of the claimant's asserted commercial activity in the United States." *Id.* at 883. "[T]he terms 'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers." *Id.* at 885; *see also Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 15-16 (Oct. 28, 2019). While significance may not be established on qualitative evidence alone,

"qualitative evidence may still be relied upon to support a finding that a complainant's investments are significant." *Carburetors*, Comm'n Op. at 24; *see also id.* at 23 ("There may be facts and circumstances where, based on an assessment of quantitative information, it remains unclear whether a complainant's investments are significant or not. In such cases, resorting to qualitative factors that may indicate significance could be relevant to the evaluation."). In this regard, the Commission considers the "nature and significance" of a complainant's activities with respect to the protected articles. *Certain Printing and Imaging Devices*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011). The Commission may consider, *inter alia*, whether the "activities were important to the articles protected by the asserted patents in the context of the company's operations, the marketplace, or the industry in question, or whether complainant's undertakings had a direct bearing on the practice of the patent" or "whether and to what extent [] domestic activities added value to the imported products." *Id*.

2. Economic Prong of the Domestic Industry Requirement Under Subsection (C)

a) Background

AliveCor is a U.S. company based in California that designs and develops wearable electronic devices to help diagnose heart conditions. *See* Compl. at ¶ 11; CDX-005C.13; Tr. (Albert) at 53:22-54:20; CDX-005C.29; Tr. (Albert) at 77:24-78:14. AliveCor developed the inventions claimed in the Asserted Patents in the United States and introduced the "technology to consumers through the KBS, a system that included an app and watchband accessory for the Apple Watch," clearing the KBS with the U.S. Food and Drug Administration ("FDA") for use in connection with the Apple Watch. ID at 4-5; Tr. (Albert) 83:8-85:19; 199:3-201:21; CDX-0005C.34-36. There is no dispute that the KBS domestic industry product was developed in the United States and the [[ ]] products are also being developed in the United States.

Although AliveCor ceased to manufacture and sell the KBS product in 2018, AliveCor continued to invest in the technology of the patents through the date of the complaint filing. Under Commission precedent, past expenditures in R&D can be counted towards establishing a domestic industry in a product that exists but has been discontinued, like the KBS, if there are continuing investments. *See, e.g.*, *Certain Marine Sonar Imaging Devices*, Inv. No. 337-TA-921, Comm'n Op., at 59 (Jan. 6, 2016) (crediting "labor and capital expenditures related to . . . software updates" used in a discontinued but practicing product), *affirmed*, *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361-2 (Fed. Cir. 2019) ("[P]ast expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted [intellectual property] rights and the complainant is continuing to make qualifying investments at the time the complaint is filed.").

b) AliveCor Established the Nexus Requirement for Both Past Investments and Continuing Investments

AliveCor has established both (1) that its past investments in R&D were directed to each of the asserted patents to develop the KBS and to use the technology of the patents to develop [[ ]]; and (2) that after AliveCor ceased manufacture and sales of the KBS in 2018, AliveCor continued to make on-going R&D domestic investments directed to exploiting the asserted patents and these continuing investments benefit current users of the KBS. Moreover, the evidence shows that, since 2018, AliveCor has continued to incur ongoing expenditures to address customers' concerns for the KardiaBand through its customer service contractor iQor which benefits current KBS users. *See* RX-0484C.48.

AliveCor proffered evidence of its internal costs as well as contractor costs to support its claim that DI was met under subsection (C). The ALJ did not credit the majority of AliveCor's

internal labor R&D expenditures because they were not sufficiently reliable to determine the quantitative amount that could be properly allocated to the domestic industry products. ID at 170-75. The ID found the evidence of payments to outside contractors to be reliable and sufficient to show AliveCor's investments in R&D of [[ ]] from 2017 through 2020. The Commission agrees with these findings.

The evidence of record establishes that these payments were directed to exploitation of the patents. *See, e.g.*, CPX-0048; CX-09236C; ID at 175-76; Tr. (Albert) at 176:22-177:3 ("We didn't just stop KardiaBand. [[

]]; AliveCor Rep. at 3-6. Accordingly, AliveCor's past R&D expenditures to exploit the patents in the KBS, together with continuing R&D investments in the [[ ]] that benefit KBS users support AliveCor's claim that it has established the requisite nexus exists for purposes of a domestic industry under subsection (C). Further, as noted AliveCor has made continuing investments in the KBS through its customer service contractor iQor.

Apple persists in its argument that the ID erred in finding that AliveCor established a nexus between the alleged R&D contractor expenditures and the Asserted Patents for purposes of subsection (C). Apple Pet. at 19; Apple Sub. at 24-26. We disagree. In finding the nexus

requirement for these contractor investments met, the ID stated, with respect to a physical exhibit recording these contractor expenditures, that "CPX-0048C [on its face] provides at least some description of the activity behind each cost that *suggests* a nexus to sensors, circuitry, and housing structure." ID at 175-76 (citing CX-09236C (presenting totals for "DI Contractor R&D Labor"). Under Commission precedent, the nexus requirement can be inferred under these facts. *See, e.g.*, *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 42 (Aug. 22, 2014) ("[A] complainant's evidence of its investment in a protected article that practices the patent ordinarily also can support the inference that the investment was itself an exploitation of the patent.").

The record evidence shows that "the core part of the invention" claimed in the Asserted Patents is "technology that measures heart rate and heart rate parameters in the background," that "use[s] … AI [artificial intelligence] and machine learning algorithms to mine that data and" when it "identif[ies] irregularities that are suggestive of atrial fibrillation, provide[s] a trigger to the user to take an ECG" and allows "the user [to] take on-demand ECG on the wrist." Tr. (Jafari) at 292:17-293:2; AliveCor Rep. at 11. As the ID found, the evidence shows that the contractor expenditures are directed to the sensors, circuitry, and the housing structure of the AliveCor wristbands, *i.e.*, the KardiaBands. CPX-0048; CX-09236C; ID at 175-76. Further, as AliveCor explained, this "development work for the SmartRhythm algorithms, described above, is directed to the technology in the KBS that identif[ies] irregularities that are suggestive of atrial fibrillation, provide[s] a trigger to the user to take an ECG." AliveCor Rep. at 11 (citing Tr. (Somayajula) at 198:13-227:20). Moreover, the "development work for KardiaAI is directed to technology that allows [existing] KBS users to take an on-demand ECG." *Id.*; Tr. (Albert) at 64:1-67:8. That is, the record evidence shows that the development work undertaken by the

contractors pertains to the patented features of the domestic industry products for the benefit of current users of the KBS. As the Commission has held, '"[e]xploitation' is a generally broad term that encompasses activities such as efforts to improve, develop, or otherwise take advantage of the asserted patent." *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op., 2014 WL 12796437, at *21 (Aug. 22, 2014).

c) AliveCor's Investment in Exploiting the Patents is Substantial

Having found the relevant nexus between the investments and the Asserted Patents, the ALJ found that the investments, totaling [[ ]] for the technology of each of the three patents, were "substantial" under subsection (C).[17] ID at 180-83. We agree for the reasons stated in the ID, as supplemented below.

As stated above, we agree with the ID's finding that payment to outside contractors show R&D investments of [[ ]] from 2017 through 2020. Beyond these contractors' investments, the ID found with respect to continuing investments in exploiting the asserted patents that the "record certainly evidences a qualitative effort on the part of ALC to refine and improve the KBS features like SmartRhythm and KardiaAI—which have a clear nexus to the heart rate and ECG analysis limitations recited in the Asserted Claims of the 941, 731, and 499 patents." ID at 170-171. The quantitative evidence also shows that, since 2018, AliveCor has continued to incur ongoing expenditures to address customers' concerns for the KardiaBand through its customer service contractor iQor, which as discussed above, has a nexus to exploiting the asserted patents. The table below shows the labor costs related to iQor tickets for KardiaBand or AliveCor's Kardia app:

[17] We note that DI product for each of the three asserted patents is the KBS and thus there is no need to allocate the investments among the three patents. That is, the DI product for each patent standing alone is the KBS.

Year	KardiaBand Tickets	Hardware Unknown Tickets	Total Tickets With Sufficient Information to Code	Cost to AliveCor for KB + Software	Percentage of KB + Software Tickets
2018	[[				
2019					
2020					
Jan-Sept 2021 (Sept)					]]

RX-0484C.48.

Apple separately argues that the [[ ]] expenditures for R&D contractor expenses includes foreign expenditure. Apple Sub. at 27, Apple R.Sub. at 18. The record, however, does not support Apple's argument. As AliveCor explains, its Chief Financial Officer Clyde Hosein testified at his deposition that "he had reviewed the information underlying his declaration and thought it best to remove some expenses paid to one vendor, [[ ]], because it was 'not clear whether those costs were incurred in United States or all of it was incurred in the United States.'" AliveCor Sub. at 24 (citing JX-0229C (Hosein Depo.) at 90:18-92:11). Mr. Hosein submitted the declaration in question with AliveCor's complaint enumerating "expenses related to United States-based consultants and contractors preforming hardware engineering, testing, development, and support work for AliveCor's DI Products from 2016 through 2020." *Id.* (citing Compl. Ex. 20, Hosen Decl. ¶ 14 (EDIS No. 740374); CPX-048C at tabs 2017 QB & NS 2018-2020). AliveCor states that "[i]n accordance with Mr. Hosein's declaration and testimony, [its] economic expert, Dr. Akemann, removed all payments to [[ ]] from his calculations" and that "[w]ith those payments removed, Dr. Akemann determined that AliveCor incurred [[ ]] in qualifying investments to domestic R&D contractors." *Id.* at 25 (citing CX-0925C ("Excludes expenses with Vendor Name of [[ ]] . . . ")). Apple

points to the ID's statement that "ALC's record of R&D contractor payments do suggest a material amount of foreign payments towards the DI Products in 2016-2020 that have otherwise gone unaddressed in ALC's briefing (see CPX-0048C (Tabs [[

]]" and that "they only add up to [[

]]." ID at 182. Apple misapprehends the ID's statement. The ID was contrasting AliveCor's domestic contractor expenditure to its foreign contractor expenditure. The evidence shows that the ID did not find that the credited [[ ]] in domestic R&D contractor payments included the [[ ]] of payments to foreign contractors as Apple contends. *Id.* Indeed, there is no evidence to support Apple's assertion.

As mentioned above, the ID correctly found that the [[ ]] expenditures for R&D contractor expenses is substantial. As an initial matter, the evidence supports the ID's finding that AliveCor's "R&D labor expenses overall, including for the DI Products, are mostly domestic." ID at 181. The ID pointed to Dr. Akemann's opinion that "over the entire DI period [[ ]] of ALC's total headcount was domestic" and that "[a]fter comparing domestic and foreign R&D headcount, especially for the period 2016-19, it is likely that ALC's internal R&D labor expenses for KBS were overwhelmingly domestic, even without allocation." *Id.* (citing CX-0937C). In addition, the ID observed that of the total R&D contractor payments incurred in the development of the KBS, the foreign payments towards the KBS DI Products in 2016-2020 "only add up to [[ ]]" and that "[i]f this is the true extent of foreign R&D payments over this time and dedicated to the DI Products, then it only further supports the substantiality of the [[ ]] domestic spend." *Id.* at 181-82 (citing CX-0935C). In other words, a comparison of the domestic contractor expenses to the foreign contractor

expenses shows that the domestic expenditure is substantial. The Commission agrees with the ALJ's reasoning.

We note the ID's statement that the "overall analysis here is troubling, to be sure" because "[i]t is no secret that a domestic-to-foreign comparison is at least the preferred method of proving economic prong" and that "[t]he parties were even warned at the end of the evidentiary hearing that 'you need to compare foreign and domestic investments.'" *Id.* at 182 (citing *Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 17-19); Hr'g Tr. at 1312:17-18. The Commission, however, has made clear that a domestic-to-foreign comparison is not a requirement, nor is it "preferred" as a general matter to show significance. *See Carburetors*, Comm'n Op at 8-9, 17-19.[18] The appropriate context for evaluating significance may vary depending upon the facts of a particular investigation. For example, significance may be shown, *inter alia,* by demonstrating the value added by domestic activities, by comparing domestic investments to costs or revenues for DI products, or other contextual evidence of significance to the company's operations, the marketplace, or the industry in question. *See id.* Here, the Commission finds that the ID's reliance on the comparison of the domestic contractor expenses to the foreign contractor expenses and Dr. Akemann's "sufficiently detailed and pertinent headcount comparison showing it more likely than not that DI-related R&D labor expenses were substantially domestic" is sufficient to show that AliveCor's domestic expenditure in the exploitation of its patents is substantial under subsection (C) for a domestic industry relating to

[18] In the view of Commissioner Kearns, a proper contextual analysis for "significance" requires some comparison of domestic and foreign activities or investments where the domestic industry products benefit from both. This comparison can be through, for example, a comparison of domestic to foreign expenditures or a value-added analysis. *See Certain Electronic Candle Products and Components Thereof*, Inv No. 337-TA-1195, Comm'n Op. at 38 n.22 (Kearns footnote) (July 14, 2022).

the KBS products that "exists." *See* ID at 183. Moreover, AliveCor's continued activities after the KBS products ceased to be manufactured and sold are sufficient to show an industry that exists as of the date AliveCor filed its complaint.

3. Economic Prong of the Domestic Industry Requirement Under Subsection (B)

The Commission has determined to affirm the ID's finding that AliveCor failed to establish the economic prong of the domestic industry requirement under subsection (B) relating to the KBS products. In support of its assertion that its [[ ]] investments in R&D labor allocated to the KBS products were significant, AliveCor offered a comparison of these investments to its company-wide labor and capital expenditures, as well as a comparison of KBS sales revenue to its company-wide hardware and total sales revenues. ID at 178. Having found AliveCor's evidence of internal R&D labor expenditures to be unreliable, the ID considered instead AliveCor's domestic R&D contractor, customer support, and regulatory expenditures of [[ ]] to evaluate significance and compared that figure to AliveCor's proffered company-wide labor and capital expenditures.[19] The ID found that these investments by AliveCor totaling [[ ]] from 2016 to 2021 were "closer to [[ ]] of its total labor and capital investments from 2016 to 2020, instead of [AliveCor]'s calculated [[ ]]."[20] *Id.* at 178. Although the ID had misgivings about the relevance of comparing domestic industry investments to total company-wide investments to show significance, the ID, nonetheless, considered it and found that "[t]his is not a significant percentage on its own." *Id.* at 178-79. With respect to the comparison of

[19] The Commission agrees with the ID's findings relating to the unreliability of AliveCor's evidence of its internal labor allocations.

[20] It appears that AliveCor expected the ID to credit all of its allocated labor expenses, which would have resulted in a contextual expenditure of [[ ]] of its total labor and capital investments as opposed to the [[ ]] that the ALJ found based on those expenditures supported by reliable evidence.

KBS sales revenue to company-wide hardware and total sales revenues from 2018 to 2019, the ID observed that this proffered contextual analysis "is not material because it does not involve investments at all, and is for a limited range of years." *Id*. at 180.

We find that the contextual analysis relied on by AliveCor fails to support a finding that its domestic industry investments are quantitatively significant. Specifically, AliveCor failed to show how or why its comparison of its domestic labor expenses in the DI product to its overall company-wide labor and capital expenditure showed that its domestic investment was significant. The ID correctly reasoned that "[a] large company with many products may have a domestic industry based on one such product, even though it only accounts for a tiny percentage of the company's expenses; conversely, a small company with a single qualifying product may not have a domestic industry if the bulk of its investments are overseas" based upon the location of its investment. ID at 179. Because of this, while we do not preclude that a complainant may rely on a comparison of its domestic industry investments to company-wide investments in establishing significance given the facts and circumstances of a particular investigation,

AliveCor has failed to explain or substantiate why such a comparison in the context of this investigation nonetheless demonstrates the significance of its domestic industry investments.[21, 22]

Regarding AliveCor's second proffered basis for showing quantitative significance, we agree with the ID that this also falls short. The ID found this basis – a comparison of KBS sales from 2018 to 2019 to its hardware revenues and its total revenues – inapt as "the percentage of

[21] While Commissioner Schmidtlein agrees that AliveCor has failed to demonstrate that the investments as credited by the ID are significant, she does not join the majority's analysis on this point. This is because the majority is applying a recently established additional threshold requirement that complainants must "explain or substantiate" why certain contextual analysis is appropriate before the majority will consider whether that analysis shows the investments are significant. It is a subtle difference, but Commissioner Schmidtlein's decision in this case is based on the failure of AliveCor to demonstrate that its credited investments of approximately [[ ]] percent of company-wide labor and capital investments are significant. In contrast, the majority does not reach whether these investments are significant because AliveCor did not "explain or substantiate" why a comparison of the domestic industry investments to company-wide investments is the appropriate comparison. *See infra* note 22. The majority cites the recent case C*ertain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. (Oct. 4, 2022) (Comm'r Schmidtlein dissenting) (Pub. Vers.) as precedent for the Commission requiring a complainant to explain or substantiate the contextual benchmark upon which it relies. There, under its analysis of complainants' investments in plant and equipment, the majority in that case rejected one of complainants' sub-arguments "that their investments as a percent of gross profits show that their investments are significant" because the complainants did not explain the relevance of that particular benchmark. *Id*. at 37- 38. Commissioner Schmidtlein dissented finding the domestic industry requirement to be satisfied. In considering the complainant's proffer of an alternative contextual analysis, she noted that she saw no reason to discount the comparison using gross profit. *See id., Dissenting Views of Commissioner Schmidtlein* at 18 n.7. Similarly, in this case, Commissioner Schmidtlein declines to join the majority in requiring the complainants to "explain or substantiate" why a certain contextual analysis is appropriate.

[22] In response to footnote 21, the Commission is not establishing a new requirement, or affirming a previously established one, for all domestic industry analyses but instead observes the concerns noted by the ALJ with the particular contextual analysis offered by Complainant here and that Complainant has not, in light of those concerns, explained or substantiated why its proposed contextual analysis establishes that its claimed investments are significant. *See, e.g.*, *Certain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op. at 38 (July 14, 2022) (declining to find complainants' proffered comparison of domestic industry investments to gross profits as a relevant benchmark to assess significance absent an explanation as to how or why that proffered metric is meaningful in relation to the protected articles).

ALC total revenue provided by KBS, is not material because it does not involve investment at all, and is for a limited range of years. *See* CIB at 160 (highlighting that in 2018-2019, KBS supplied "[[ ]] of AliveCor's hardware revenues and [[ ]] of AliveCor's total revenues.")." *Id.* at 180.

Given that these data are the only contextual framework that AliveCor relied on before the ALJ, it has failed to show a domestic industry exists under subsection (B). The headcount and regulatory comparisons that AliveCor now presents in its submission to the Commission were never presented to the ALJ and the Commission declines to consider them because they are waived. *Broadcom Corp. v. Int'l Trade Comm'n*, 542 F.3d 894, 901 (Fed. Cir. 2008).

As discussed above with respect to subsection (C), the Commission notes that certain statements in the ID pertaining to subsection (B) suggest that the Commission prefers foreign comparisons in determining domestic significance of an investment. *See* ID at 179-180.[23] The Commission once again makes clear that it does not require a domestic-to-foreign comparison, nor does it express a general preference for such a comparison to establish significance. *Carburetors*, Inv. No. 337-TA-1123, Comm'n Op at 8-9, 17-19. Thus, the fact that AliveCor did not offer one is not fatal to its efforts to support its claims of significance under subsection (B). However, as discussed above, AliveCor failed to offer a meaningful contextual analysis by which to evaluate the quantitative significance of its investments and thus failed to establish that a domestic industry exists by virtue of significant investments in labor or capital under subsection (B).

[23] Even though the ID contemplated a similar result if AliveCor's investments were compared to its foreign manufacturing costs, the ID did not require such an analysis nor reach its conclusion on that basis. ID at 178.

B. The ID's Patent Eligibility Findings Under 35 U.S.C § 101

The Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. § 101. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

1. Legal Standard

Section 101 limits patent-eligible subject matter to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has held that the statute excludes laws of nature, natural phenomena, and abstract ideas from patentability. *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012). The statute renders these categories unpatentable because "they are the basic tools of scientific and technological work" and "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it." *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

Under Supreme Court precedent, "applications of abstract concepts 'to a new and useful end remain patent eligible." *Alice Corp. Pty. v. CLS Bank Intern.*, 573 U.S. 208, 217-18, 221 (2014). A tribunal, however, must determine whether the claims transform the abstract idea into patent-eligible subject matter. To make this determination, *Alice* prescribes a two-step inquiry: a court must first "determine whether the claims at issue are directed to" a "patent-ineligible concept[]"; if they are, the court must then "determine whether [any] additional elements 'transform the nature of the claim' into a patent-eligible application," requiring an "inventive concept" or "additional features" to "ensure that the patent does not seek simply to monopolize the abstract idea." *Id.* The Federal Circuit has explained that "[t]he 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*,

822 F.3d 1327, 1335 (Fed. Cir. 2016). To save a patent at the second step, the inventive concept or additional features must be evident in the claims themselves. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151-52 (Fed. Cir. 2016).

2. Whether the ID Erred in Finding Claim 12 of the '941 Patent Patentable Under Alice

a) The ID

The ID found that "claim 12 of the '941[24] patent is not invalid under 35 U.S.C. § 101, although it is directed to an ineligible concept under *Alice* step one." ID at 66. The ID explained that claim 12 consists of a first portion reciting "the structure of a smartwatch (found to be limiting, above) loaded with a processor and particular sensors" and a second portion that "refers to instructions causing analysis of the sensors' data and indicating (by any means) at least one result to the user." *Id.* at 67. The ID stated that "[t]he first portion alone typically would be

[24] Claim 12 of the '941 patent recites:

A smartwatch, comprising:
a processor;
a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;
a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;
an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and
a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:
determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;
based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and
receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

'941 patent, col. 17, l. 53-col. 18, l. 19.

considered patent-eligible subject matter (as an apparatus), but the second portion alone typically would be questionable (as a set of algorithms)." *Id.* The ID defined the issue as "whether the claim, in view of the specification, is directed primarily to the apparatus or to the instructions" and found that "[t]he intrinsic evidence supports the latter." *Id.* For support, the ID observed that "[t]he majority of '941 patent claims focus on data analysis and returning results of that analysis to a user (941 patent at cls. 2-9, 13-21), while only a handful recite non-algorithmic features (*id.* at cls. 10, 11, 22, 23)." *Id.* The ID further observed that "[t]he specification similarly speaks at length to diagnostic techniques for arrhythmias, and the benefits of a discordance determination preceding an ECG measurement." *Id.* at 67-68 (citing '941 patent, Title, 1:66-2:3, 2:10-3:12, 12:55-65, 12:66-13:7, 13:67-14:8, 14:8, 14:36-42, Fig. 7). The ID surmised that "it is fair to say that claim 12 is directed to the abstract idea of analyzing a combination of heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis, as medical practitioners have routinely done for years" and thus is "directed to non-patent eligible subject matter." *Id.* at 68 (citing *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314 (Fed. Cir. 2016) ("The Supreme Court has held that 'fundamental . . . practice[s] long prevalent' are abstract ideas.")).

The ID found that "[t]he structural elements within claim 12, however, are sufficient to transform the claim into patent eligible subject matter under *Alice* step two." *Id.* The ID explained that "[t]he claim's recitation of a smartwatch comprising 'a photoplethysmogram ('PPG') sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor,' is particularly specific and structural." *Id.* The ID added that "a PPG sensor on a smartwatch is specific and innovative." *Id.* at 69 (citing Hr'g Tr. (Albert) at 66:2-11; Hr'g Tr. (Jafari) at 513:12-15; Hr'g Tr. (Waydo) at

823:12-824:1). The ID reasoned that the "recitation of a PPG sensor within a smartwatch, while not the entire focus of the claim, does move it away from the ineligible concept of data collection/analysis and towards a specific electro-mechanical apparatus." *Id.* (citing *Alice*, 573 U.S. at 217-18 (asking whether the additional elements "transform the nature of the claim" into patent-eligible subject matter)).

The ID stated that "[t]he claim's 'electrocardiogram ('ECG') sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor' on the smartwatch adds to this finding." *Id.* The ID pointed to record evidence showing that "ECG sensors collect data in a certain way and provide a very particular waveform." *Id.* at 69-70 (citing Hr'g Tr. (Albert) at 48:6-49:24; Hr'g Tr. (Jafari) at 291:4-13; Hr'g Tr. (Stultz) at 1058:16-1059:13, 0195:1-10; '941 patent at Fig. 1, 8:l- 9:23). The ID concluded that "[a]n ECG sensor, in combination with a smartwatch that also includes a PPG sensor, as well as an activity level sensor, amounts to significantly more than a patent on the ineligible concept of analyzing a heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis." *Id.* The ID acknowledged that "[t]aken individually, each separate component may be conventional," but that "combining all the various sensors on a smartwatch, for a specific function that is not traditional for smartwatches, is sufficiently 'unconventional' to satisfy Section 101 under *Alice* step two." *Id.* at 70.

The ID found unpersuasive Apple's main argument that "it is not enough to implement an abstract idea with 'well-understood,' 'routine,' or 'conventional' technology" and that the combined use of PPG sensor data and ECG sensor data for arrhythmia detection was "well-known and not inventive as of 2013." *Id.* at 70 (citing RIB at 57; RRB at 34-35). The test, the

ID stated, "is whether a smartwatch with integrated processor, activity sensor, PPG sensor, and ECG sensor (with at least two electrodes) adds something more than carrying out heart rate discordance determination, user indication of arrhythmia, and arrhythmia confirmation on generic hardware," which, as noted above, the ID found it does. *Id.* at 71.

b) Analysis

The Commission finds that the ID erred in concluding that claim 12 of the '941 patent is directed to an abstract idea under *Alice* step one.[25] As the ID observed, the claim recites "the structure of a smartwatch loaded with a processor and particular sensors." ID at 67. The second portion, referring to instructions, supports the technological advancement of using a smartwatch to detect possible heart defects. *Id.* Indeed, the ID found that the "recitation of a PPG sensor within a smartwatch, while not the entire focus of the claim, does move it away from the ineligible concept of data collection/analysis and towards a specific electro-mechanical apparatus." ID at 68. This finding reflects that the claimed invention passes muster under *Alice* step one. There is no requirement for the entire focus of the claim to be directed to non-abstract concepts. The step-one inquiry is always whether the character of the claims, considered in light of the specification, is directed to excluded subject matter. *Enfish*, 822 F.3d at 1335.

Put differently, the issue is whether claim 12 of the '941 patent is "directed to the abstract idea of analyzing a combination of heart rate and activity, and then measuring and analyzing ECG electric signals for medical diagnosis, as medical practitioners have routinely done for

[25] The ID found that "[t]here is no principled distinction between the claims of the '731 patent and those of the '941 patent under Section 101." ID at 114. The Commission notes that claims 1, 12, and 16 of the '731 patent are similar in substance to claims 12, 13, and 16 of the '941 patent, in that each of the claims are directed to a smart watch with a particular arrangement of sensors to detect the presence of an arrhythmia. Thus, the Commission's analysis applies equally to the asserted claims of the '731 patent.

years," as the ID found (ID at 68); or whether the claim is directed to technological improvements in cardiac monitoring technology, as AliveCor contends. AliveCor Pet. at 16-17; AliveCor Rep. at 41-46. In our judgment, the claim as a whole, considered in light of the specification, supports AliveCor's argument.

The specification of the '941 patent discloses that diagnosing intermittent arrhythmias using conventional methods was "difficult, because, for example, it is not practical to be prepared to apply one of the aforementioned diagnostic modalities at the exact time that an individual experiences an intermittent arrhythmia." '941 patent col. 1, ll. 49-53. The specification explains that by sensing heart rate parameters and activity level, the smartwatch can "determine the future onset of or the presence of an arrhythmia by identifying discordance between these two parameter values" and "[i]n response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed." *Id*. at col.1 ll.61-66, col.2 ll.1-3. That is, the patented invention solves a concrete problem by implementing a particular configuration of sensors and steps on a smartwatch. As AliveCor's expert, Dr. Efimov, testified, by monitoring the user's heart rate parameter in the background and indicating to the user when an arrhythmia may be present, the claimed device allows users to record an ECG outside clinical settings and "confirm" arrhythmias that a doctor would have otherwise missed. Tr. (Efimov) at 1229:24-1231:6. Contrary to the ID's findings, the claimed invention does not simply analyze a combination of heart rate and activity, and then measure and analyze ECG electric signals for medical diagnosis, as medical practitioners have routinely done for years. ID at 68. Rather, the claims recite a specific system that uses a first sensor to sense an activity level value of a user, and a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user so as to alert the user of the possibility of an arrhythmia and to

enable the capture of an ECG. '941 patent col.1 ll.49-57, claim 12. This technological advancement enables the capture of ephemeral cardiac events in a way not possible using prior cardiac monitoring technology. Tr. (Efimov) at 1252:15-1254:18; CDX-002C.45; IA Rep. 22-23.

We agree with AliveCor that the asserted claims are akin to the claims the Federal Circuit found pass muster under *Alice* step one in C*ardioNet, LLC v. InfoBionic, Inc*, 955 F.3d 1358 (Fed. Cir. 2020). In *CardioNet*, the patent "describe[d] cardiac monitoring systems and techniques for detecting and distinguishing atrial fibrillation and atrial flutter from other various forms of cardiac arrhythmia."[26] *Id*. at 1362. In reversing the district court, the Federal Circuit stated that "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." *Id*. at 1368. The Court pointed to the specification's disclosure that the claimed device "more accurately detects the occurrence of atrial fibrillation and atrial flutter—as distinct from [ventricular tachycardia] and other arrhythmias—and allows for more

[26] As the Court stated in *CardioNet*, 955 F.3d at 1365, claim 1 recited:
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 beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

reliable and immediate treatment of these two medical conditions" and "achieves multiple technological improvements." *Id*. at 1368-69. Here too, the evidence shows that claimed device (smartwatch in claim 12) monitors the user's heart rate parameter in the background and indicates to the user when an arrhythmia may be present, allowing users to record an ECG outside clinical settings to "confirm" arrhythmias that a doctor would have otherwise missed. Tr. (Efimov) at 1229:24-1231:6. That is, the claim is directed to technological improvements in cardiac monitoring.

In any event, even if the claims are directed to an abstract idea under *Alice* step one as the ID found, the Commission agrees with the ID that the claims would be patentable under *Alice* step two. Under *Alice* step two, the asserted claims do not merely claim a "generic environment in which to carry out the abstract idea." ID at 70. Rather, the claimed configuration of sensors and other hardware components implemented in a smartwatch is inventive. *Id.* ("Taken individually, each separate component may be conventional, but combining all the various sensors on a smartwatch, for a specific function that is not traditional for smartwatches, is sufficiently 'unconventional' to satisfy Section 101 under *Alice* step two."). As the ID added, "[t]here may come a time when every smartwatch includes the various claimed sensors, and runs the needed algorithms to practice claim 12, but as of the date of the invention the 'ordered combination' of the claim's elements was sufficiently 'transform[ative].'" *Id*. (citing *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) ("The mere fact that something was disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.")).

3. Whether Claims 16 and 17 of the '499 Patent Are Patentable Under Alice

a) The ID

The ID concluded that independent claim 11,[27] from which claims 16 and 17 depend, is directed to the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then alerting the user to 'record an electrocardiogram using said mobile computing device.'"[28] ID at 143. In making that determination, the ID observed that the "bulk of the claim is directed to the data analysis algorithms taking place within the 'processor' and

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[27] While independent claim 11 itself has not been asserted in this investigation, we analyze it because asserted claims 16 and 17 necessarily include the limitations of claim 11, from which they depend.

[28] The claims recite:

> 11. A system for determining the presence of an arrhythmia of a first user, comprising a heart rate sensor coupled to said first user;
>
> a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> a motion sensor
>
> a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.
>
> 16. The system of claim 11, wherein said mobile computing device comprises a Smartwatch.
>
> 17. The system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

according to the 'instructions' saved in memory (*i.e.*, ineligible subject matter)" and that the "bit of apparatus recited (*i.e.*, potentially eligible subject matter) is devoid of specificity, such that it can only be considered generic computer hardware—'a heart rate sensor,' 'mobile computing device,' 'a processor,' 'a motion sensor,' and 'non-transitory computer readable medium.'" *Id.* The ID also pointed to the testimony of Dr. Stultz, who testified that "carrying out these steps is common in medical practice." *Id.* (citing Hr'g Tr. (Stultz) at 1058:13-1059:19, 1077:21-1078:15, 1085:15-22). The ID thus found that "claim 11 is directed to ineligible subject matter under *Alice* step one." *Id.*

The ID then considered claims 16 and 17 and found that they "fare similarly" under *Alice* step one. *Id.* at 144. The ID explained that claim 16 recites that the "mobile computing device" is a "smartwatch" and that "does not materially transform the claim as there is no other limitation that benefits or is affected by the computing device being in this form factor." *Id.* (*comparing* '499 patent at cl. 16 *with* '941 patent at cl. 22 ("wherein the PPG sensor is located on a back of the smartwatch")). Regarding claim 17, the ID noted that it requires the processor to further "determine a presence of said arrhythmia using a machine learning algorithm" but that "[t]his is literally just another algorithm and only deepens the connection between the claim and ineligible subject matter." *Id.*

Turning to *Alice* step two, the ID concluded that "claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept." *Id.* (citing *Alice*, 573 U.S. at 217-18). The ID explained that "there are sensors recited ('heart rate,' 'electrocardiogram,' 'motion'), but they are unrestricted as to structure, arrangement, or data output so long as they relate to 'heart rate,' electrical activity of the heart, or 'activity level,' respectively." *Id.* The ID stated that "an

ECG sensor is rather specific; but unlike claim 12 of the '941 patent, claim 11 of the '499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the 'mobile computing device.'" *Id.* The ID added that "[i]n essence the claim covers the addition of generic sensors to an existing ECG machine, and for no particular purpose" and that "[a]lone or as an ordered combination, all this is equivalent to the basic idea of using such sensors." *Id.* The ID found that "[t]he remaining hardware limitations ('mobile computing device,' 'processor,' and 'computer readable medium') are equally generic, if not more so, and perform their generic functions (be configurable, contain and execute instructions)" and that "there is nothing recited that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.)." *Id.*

With respect to claim 16, however, the ID found the recitation of a "smartwatch" was sufficient to pass muster under *Alice* step two. *Id.* The ID stated that "[u]ndoubtedly claim 16 is more abstract than the claims of the '941 and '731 patents, because no particular kind of heart rate sensor or motion sensor is required" but found that "incorporating even any kind of heart rate sensor into a smartwatch, especially when combined with an ECG sensor, lifts that smartwatch out of the realm of 'well-understood, routine, and conventional.'" *Id.* Regarding claim 17, however, the ID found it failed *Alice* step two because the recited "machine learning algorithm" is an unspecified "algorithmic step." *Id.* at 145.

a) Analysis

The Commission agrees with the ID that the claims are directed to the abstract idea of "taking in heart rate data (of any kind), taking in activity level data (of any kind), calculating heart rate variability, comparing that variability with the activity (by any means), and then

alerting the user to 'record an electrocardiogram using said mobile computing device.'" ID at 143. We also agree with the ID that claims 16 and 17 fare no better under *Alice* step one for the reasons provided in the ID. *Id.* at 144.

The Commission affirms the ID's finding as to claim 17. After finding that claim 11 recited an abstract idea, the ID correctly concluded that "claim 11's non-ineligible elements, either individually or as an ordered combination, do not transform the nature of the claim into something more than a patent on the abstract concept." *Id.* at 144. The ID reasoned that "there are sensors recited ('heart rate,' 'electrocardiogram,' 'motion'), but they are unrestricted as to structure, arrangement, or data output so long as they relate to 'heart rate,' electrical activity of the heart, or 'activity level,' respectively." *Id.* That is, the claims are broad enough to cover any generic and conventional sensor that can carry out those functions. Even when the claims recite a specific sensor, ECG sensor, as the ID observed, "unlike claim 12 of the '941 patent, claim 11 of the '499 patent does not recite the number of leads to further specify the type of ECG sensor, nor does it expressly recite any use for the ECG data—it simply exists within the 'mobile computing device.'" ID at 144.

Under *Alice* step two, the Commission looks for an "inventive concept" or "additional features" to ensure that the patent does not seek simply to "monopolize the abstract idea." *Alice*, 573 U.S. at 221. As the ID found, claim 17 in essence "covers the addition of generic sensors to an existing ECG machine, and for no particular purpose." ID at 144. We adopt the ID's finding that "[a]lone or as an ordered combination, all this is equivalent to the basic idea of using such sensors" in their well-known and conventional manner. *See id.* We further agree with the ID that the "hardware limitations ('mobile computing device,' 'processor,' and 'computer readable medium') are equally generic, if not more so, and perform their generic functions (be

configurable, contain and execute instructions)." *Id.* Indeed, "there is nothing recited that could be viewed as improving the operation of any of these computing elements (*e.g.*, faster, fewer errors, less power consumption, etc.)." *Id.*

As to claim 16, however, the Commission disagrees with the ID that simply reciting a "smartwatch" imbues the recited abstract idea with patentable subject matter. As the ID acknowledged, "[u]ndoubtedly claim 16 is more abstract than the claims of the 941 and 731 patents, because no particular kind of heart rate sensor or motion sensor is required." ID at 145. That is, unlike the asserted claims of the '941 and '731 patents that require specific sensors arranged in a specific configuration, claim 16 simply incorporates generic sensors used in their well-known and conventional manner in a "smartwatch." We disagree with the ID that "incorporating even any kind of heart rate sensor into a smartwatch, especially when combined with an ECG sensor, lifts that smartwatch out of the realm of 'well-understood, routine, and conventional.'" *Id.* The only difference between claims 16 and 17 is the environment in which the abstract idea is carried out. Under Federal Circuit precedent, this is insufficient to confer patentability on claim 16. *See Intellectual Ventures v. Capital One Bank*, 792 F.3d at 1366 ("An abstract idea does not become nonabstract by limiting the invention to a particular field of use or technological environment, such as the Internet."); *Affinity Labs*, 838 F.3d at 1259 ("[M]erely limiting the field of use of the abstract idea to a particular existing technological environment does not render the claims any less abstract."). Moreover, it would stifle innovation to find that at the relevant time a claim that describes generic sensors used in a conventional way is patentable when implemented in a smartwatch. As the Supreme Court has explained, "the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor." *Mayo Collaborative Servs. v. Prometheus Labs.,*

Inc., 566 U.S. 66, 88 (2012) (emphasis in original) (citation omitted). Accordingly, the Commission reverses the ID's finding as to claim 16 and finds it patent ineligible under section 101.

C. The ID's Findings with Respect to Obviousness Under 35 U.S.C § 103

The ID found that Apple failed to show that the asserted claims of the '941 patent are invalid for obviousness. ID at 60-98. For the '731 patent, the ID found that Apple failed to prove that asserted claims 3, 5, 9, 10, and 15 are invalid for obviousness, but proved that asserted claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 113-127. The Commission determined to review the final ID's invalidity findings, including obviousness under 35 U.S.C. § 103, and asked for briefing. 87 Fed. Reg. 58819-20 (Sept. 28, 2022). On review, the Commission has determined to affirm the ID's invalidity findings with the modification below as to secondary considerations.

1. Legal Standard

"Obviousness is a question of law based on underlying questions of fact." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include the so-called "Graham factors": "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The U.S. Supreme Court has held that the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). While specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching,

suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 420.

An obviousness determination should also include a consideration of "secondary considerations," that is, "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham*, 338 U.S. at 17-18; *see Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015). "[I]n order to accord substantial weight to secondary considerations of nonobviousness, the evidence of secondary considerations must have a 'nexus' to the claims, *i.e.*, there must be 'a legally and factually sufficient connection' between the evidence and the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (internal citations omitted).

Under established Federal Circuit precedent, "a patentee is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim if the patentee shows that the asserted evidence is tied to a specific product and that the product '*is* the invention disclosed and claimed.'" *Teva Pharms. Int'l GmBH v. Eli Lilly & Co.*, 8 F.4th 1349, 1360 (Fed. Cir. 2021) (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019)). This presumption applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (internal citations omitted). "Conversely, '[w]hen the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process,' the patentee is not entitled to a presumption of nexus." *Id.* (internal citations omitted). The Court stated that it has "rejected attempts 'to reduce the coextensiveness requirement to an inquiry into

whether the patent claims broadly cover the product that is the subject of the evidence of secondary considerations.'" *Id.* at 1360-61. As the Court explained, rather, "the degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies 'perfect or near perfect correspondence,' and at the other end lies 'no or very little correspondence.'" *Id.* at 1361 (internal citations omitted). "Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention." *Id.* "Whether a product is coextensive with the patented invention, and therefore whether a presumption of nexus is appropriate in a given case, is a question of fact." *Id.*

2. Analysis

For the reasons stated herein, the Commission has determined to affirm the ID's findings that Apple failed to prove that claims 12, 13, 19, and 20-23 of the '941 patent are invalid for obviousness. The Commission has also determined to affirm the ID's findings that Apple failed to prove that claims 3, 5, 9, 10, and 15 of the '731 patent are invalid for obviousness for the reasons stated in the ID. The Commission, however, has determined to reverse the ID's findings that Apple proved that claims 1, 8, 12, and 16 of the '731 patent are invalid for obviousness as explained below. In sum, the Commission finds that none of the asserted claims has been shown to be invalid for obviousness.

a) Record Evidence of Industry Praise and Copying Is Sufficient to Overcome the Prima Facie Showing of Obviousness with Respect to Claims 12, 16, 20, 22, and 23 of the '941 Patent

The ID found that because KBS practices claims 12, 16, 20, 22, and 23 of the '941 patent, AliveCor was entitled to a presumption of nexus where the secondary consideration evidence pertains to KBS. ID at 93. The ID found that AliveCor's evidence and argument as to

commercial success, copying, and industry praise were sufficient to overcome Apple's *prima facie* showing of obviousness.

With respect to commercial success, the ID found that AliveCor's evidence of [[ ]] in funding it received did not have a clear connection to the KBS. ID at 95. AliveCor does not challenge this finding. The ID credited certain evidence "show[ing] that KBS 'was selling very successfully,' as ALC's chief financial officer testified." ID at 95 (citing RX-0384C (Hosein Deposition) at 77:24-78:11; CX-0934C; CX-0935C (showing that KBS revenues for calendar years 2017, 2018, and 2019 totaled over [[ ]]"). *Id.* But the ID found that "KBS' profitability is not clear, though, so the evidence of commercial success is not as persuasive as the evidence of industry praise."

Apple challenged the ID's nexus presumption as to commercial success based on the KBS sales revenues because that evidence pertained solely to the KardiaBand, which lacks the PPG and activity sensors required by the asserted claims. Apple Pet. at 86-87. AliveCor acknowledges that "the KardiaBand is but one element of the KBS" and can be used without SmartRhythm. AliveCor Rep. at 67. AliveCor explains that "because each product was sold by separate manufacturers, AliveCor could not produce evidence of the KBS's commercial success as a whole." *Id.* AliveCor, however, contends that "it is equally true that the KardiaBand could not be used without the Apple Watch" and that "Apple produced no evidence suggesting that consumers who purchased the KardiaBand did not use that accessory with the Apple Watch." *Id.* AliveCor points to its former chief technology officer, Mr. Somayajula, who testified that for "whoever was buying [the KardiaBand], it was obvious that it required the KardiaBand System, which comprised of the Apple Watch, for it to be functional" and that "[o]therwise that hardware would be of no use to the customer." *Id.* (citing JX-0226C (Somayajula Dep.) at 43:12-23).

AliveCor also argues that its commercial success evidence as to KardiaBand undervalues the commercial success of KBS as a whole because it does not account for Apple Watch sales that were made to take advantage of the KBS's features, *id.* at 68; however, AliveCor cites no proof as to revenues or profits associated with its theory of additional Apple Watch sales. *Id.* The Commission finds, based on this record, that AliveCor's evidence of commercial success regarding the '941 patent claims is weak and gives it little weight in determining whether the evidence of secondary consideration is sufficient to overcome the *prima facie* evidence of obviousness. Specifically, the Commission agrees with the ID that KBS' profitability is not clear and AliveCor's evidence of [[ ]] in funding it received did not have a clear connection to the KBS. ID at 95.

The Commission, however, finds that the evidence of "industry praise" and "copying" together, even without commercial success, is sufficient to overcome the *prima facie* showing of obviousness.[29] Apple argues that the ID's findings on "industry praise" and "copying" are in error and that even if they were not, the evidence is insufficient to overcome its prima facie obviousness showing. Apple Sub. at 4-7. The ID's findings as to copying and industry praise, however, are amply supported by the record evidence. ID at 93-96. Moreover, the cases that

[29] Chairman Johanson would not find that the secondary indicia of nonobviousness outweigh the *prima facie* case of obviousness. The ALJ found that "the prima facie case is strong." FID at 97. With respect to claims 12, 16, 20, 22, and 23 of the '941 patent, he found that "except for one element of independent claim 12, every element of every claim is found in AMON." FID at 97. With respect to that one missing limitation ("based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present") the ALJ finds that "[i]n essence, AMON discloses a genus (inform the user of the sensed condition in an appropriate form) of which the 'indicate' limitation is a species . . . . AMON itself implies multiple possibilities, but it surely would have been obvious to that skilled artisan to just program the device to display a plain language description of the detected discordance . . . in fact, it likely would have been the simplest implementation." FID at 76. Given the strength of these findings, Chairman Johanson would not find the evidence of obviousness outweighed by the cited evidence of nonobviousness.

Apple relies on predate the Court's *Graham* 1966 decision. *See* Apple Sub. at 4 (citing *Dow Chem. Co. v. Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 330 (1945); *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 567 (1949)). *Graham* and its progeny make clear "[t]hat evidence is 'secondary' in time does not mean that it is secondary in importance." *Truswal Sys. Corp. v. Hydro–Air Eng'g, Inc.*, 813 F.2d 1207, 1212 (Fed. Cir. 1987). The Federal Circuit has explained that the requirement that courts always consider secondary considerations "is in recognition of the fact that each of the *Graham* factors helps to inform the ultimate obviousness determination." *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016).

b) Secondary Considerations for Claims 1, 12, and 16 of the '731 Patent

The ID stated that the elements of claims 1, 12, and 16 of the '731 patent are disclosed in AMON and that "[b]ecause anticipation is 'the epitome of obviousness' [(*Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019)], claims 1, 12, and 16 are invalid, without regard to secondary considerations of non-obviousness." ID at 126.

In its petition for review, AliveCor asserted that the ID's finding is legal error. AliveCor Pet. at 27-29. Specifically, AliveCor argued that the Federal Circuit "has consistently pronounced that all evidence pertaining to the objective indicia of nonobviousness must be considered before reaching an obviousness conclusion." *Id.* at 28 (citing *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1355 (Fed. Cir. 2013); *Stratoflex, Inc. v. Aeroquip Cor.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) ("[Evidence of secondary considerations] is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.")).

The Federal Circuit has emphasized that "[t]he significance of this fourth *Graham* factor cannot be overlooked or be relegated to 'secondary status.'" *Plantronics*, 724 F.3d at 1355. The

mere fact that anticipation is the "epitome of obviousness" does not make anticipation and obviousness the same. These are two distinct legal doctrines with distinct bodies of law. While secondary considerations remain relevant in an obviousness inquiry, such considerations are absent from anticipation. Thus, the issue is whether the ID was considering obviousness or anticipation when analyzing Apple's invalidity case as to the '731 patent. As AliveCor points out, Apple did not assert anticipation as a defense at the hearing or in its pre- or post-hearing briefing. AliveCor Pet. at 29 (citing Respondent's Initial Post-HB at 95-104 (asserting only obviousness); Respondent's Reply Post-HB at 55-61 (same)). OUII stated that "to the extent that the ID found that each limitation of claims 1, 12, and 16 is found in AMON, those claims are anticipated and secondary considerations of obviousness do not apply," even though OUII did not assert anticipation before the ALJ. OUII Rep. at 42. But relying on a single reference to show obviousness, as here, does not convert the obviousness inquiry into an anticipation inquiry. Indeed, none of the parties made an anticipation argument.

Apple asserts that the "ID did not commit legal error when it determined that Apple's *prima facie* case of obviousness was so strong that it was equivalent to anticipation, and therefore secondary considerations need not be considered." Apple Rep. at 24. We disagree. Apple cites *Planet Bingo, LLC v. GameTech Int'l,* Inc., 472 F.3d 1338, 1346 (Fed. Cir. 2006), as holding that "if an accused infringer makes a non-frivolous argument that 'each and every limitation of a claim is found, expressly or inherently, in [a] single prior art reference,' the accused infringer generally is entitled to have anticipation decided by the finder of fact." *Planet Bingo,* however, is an anticipation case, and says nothing about obviousness. In any event, the Supreme Court's precedent, *Graham*, is clear that a tribunal must consider secondary

considerations of nonobviousness in determining whether an invention would have been obvious to a person of ordinary skill in the art at the time of the invention. *Graham,* 383 U.S. at 17.

We therefore agree with AliveCor that the ID erred in failing to consider the evidence of secondary considerations before concluding the relevant claims of the '731 patent are invalid as obvious. The Commission finds that the ID's secondary consideration findings as to the '941 patent applies to claims 1, 12, and 16 of the '731 patent as well.[30] The Commission thus finds that the secondary considerations of "industry praise" and "copying" are sufficient to overcome the *prima facie* showing of obviousness for claims 1, 12, and 16 of the '731 patent.[31]

V. REMEDY

Where a violation of section 337 has been found, the Commission must consider the issues of remedy, the public interest, and bonding. Section 337(d)(1) provides that:

> If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry

19 U.S.C. § 1337(d)(1); *see also Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) ("[T]he Commission is required to issue an exclusion order upon the finding of

[30] Chairman Johanson would not find that the secondary indicia of nonobviousness outweigh the *prima facie* case of obviousness as to claims 1, 12, and 16 of the '731 patent. The ALJ found that "claims 1, 12, and 16 are disclosed in AMON" in a manner that is tantamount to anticipation. FID at 126. Commissioner Johanson agrees that the Commission must consider evidence of nonobviousness as to these claims but would not find the strong showing of obviousness to be outweighed by the evidence of nonobviousness.

[31] We note that claims 1, 12, and 16 of the '731 patent are similar in substance to claims 12, 13, and 16 of the '941 patent, in that each of the claims are directed to a smart watch with a particular arrangement of sensors to detect the presence of an arrhythmia.

a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise."). The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). The Commission may issue an exclusion order excluding the goods of the person(s) found in violation (*i.e.*, a limited exclusion order) or, if certain criteria are met, against all infringing goods regardless of the source (*i.e.*, a general exclusion order).

In conjunction with (or in lieu of) an exclusion order, the Commission may also issue orders directing persons found in violation of section 337 "to cease and desist from engaging in the unfair methods or acts involved." 19 U.S.C. § 1337(f). The Commission generally issues a cease and desist order ("CDO") when the evidence shows that the respondent maintains a "commercially significant" inventory of imported infringing products in the United States or has significant domestic operations that could undercut the remedy provided by an exclusion order.[32] *See, e.g.*, *Certain Elec. Skin Care Devices, Brushes & Chargers Therefor, & Kits Containing the Same*, Inv. No. 337-TA-959, Comm'n Op. at 26 (Feb. 13, 2017).

A. Limited Exclusion Order

As noted above, the ID included the ALJ's Recommended Determination ("RD") on remedy and bonding. ID/RD at 189-195. In the RD on remedy and bonding, the ALJ recommended that, in the event the Commission finds a violation of section 337, "there is no

[32] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations need(s) to be "commercially significant" in order to issue the CDO. *See, e.g.*, *Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65 n.24 (Apr. 9, 2019); *Certain Table Saws Incorporating Active Injury Mitigation Tech. & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 6 n.2 (Feb. 1, 2017). In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO.

dispute that a limited exclusion order ('LEO') should issue against Apple that covers all infringing products imported by or on behalf of Apple or its agents." ID/RD at 190. The ALJ recommended that the LEO include the Commission's standard certification as "it has been Commission practice for the past several years to include certification provisions in its exclusion orders to aid CBP [Customs and Border Protection]." *Id.* at 92.

AliveCor and OUII agree with the ID's recommendation. AliveCor Sub. at 35; OUII Sub. at 8-9. Apple argues that no remedial orders should issue because it would have an adverse effect on the public interest. Apple Sub. at 37-64. Apple also argues that should the Commission issue an LEO, it should "suspend enforcement thereof for at least two years to allow for sufficient production of adequate replacements to Apple Watch and, at a minimum, until final resolution of the Patent Office's Final Written Decisions on AliveCor's Asserted Patents" and "tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67; Apple Pet. at 98 (citing Apple's Notice of Institution of Petitions for *Inter Partes* Review and noting that "[t]he PTAB's FWDs on each asserted claim is expected December 8, 2022"). We discuss these issues below.

The Commission has determined to issue a limited exclusion order covering the unlicensed importation of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the patents, except

under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts.[33]

The Commission agrees that the LEO should include the standard certification provision under which, at the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles that are potentially subject to the LEO may be required to certify that they are familiar with the terms of the LEO, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under the LEO. Certification is only acceptable for those articles that were previously determined not to infringe. *See Automated Teller Machines, ATM Modules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-972, Comm'n Op. at 27 (June 12, 2017) ("The standard certification language does not apply to redesigns that have not been adjudicated as non-infringing."). As discussed below, the Commission finds that the public interest factors do not counsel against issuance of remedial orders, but warrant an exception for servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts.

[33] Apple also requested an exemption for software updates and personal imports. Apple Sub. at 70-73. Commission exclusion orders, however, do not extend to electronic transmissions. *See ClearCorrect, Inc. v. Int'l. Trade Comm'n*, 810 F.3d 1283 (Fed. Cir. 2015). As to personal imports, the exclusion order here is directed to infringing articles "that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns." LEO ¶ 1. Apple has not shown why an exemption for personal imports is warranted.

B. Cease and Desist Order

The ALJ noted that Apple stipulated that it "'will not dispute that it currently maintains a commercially significant inventory of the Accused Apple Products in the United States at the time hearing evidence is submitted in this Investigation.'" ID/RD at 192 (citing CX-0904C.3). The ALJ found that, "[p]er that stipulation, ALC reports 'a domestic inventory of [[ ]] that cumulatively value at over [[ ]]' and argues it is 'commercially significant' as well as an underestimation." *Id.* The ALJ stated that "[g]iven the stipulation referenced above, this inventory requirement is certainly met for Apple, and it is my recommendation that a cease and desist order ("CDO") issue against this respondent." *Id.* at 193 (citing CX-0904C.3).

AliveCor and OUII agree with the ALJ that a CDO is warranted in this investigation. AliveCor Sub. at 39-40; OUII Sub. at 9. Specifically, OUII notes that "Apple has stipulated that it has an inventory of at least [[ ]] of the Accused Products in the United States valued at over [[ ]]" and that "[t]his inventory is used to support Apple's commercial operations in the United States, and Apple does not dispute that it is commercially significant." OUII Sub. at 9 (citing CX-904C (Import Stip.)).

In light of the undisputed evidence of commercially significant domestic inventory, the Commission has determined to issue a CDO against Apple. [34] The CDO directs Apple to cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation),

[34] In light of the undisputed evidence of domestic inventory, Commissioner Schmidtlein agrees with issuing a CDO as to Apple in this case. *See supra* note 32.

or distribution of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent, and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent.

C. The Public Interest

Prior to issuing remedial orders under section 337, the Commission must weigh the effect the orders would have on four public interest factors: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production of like or directly competitive articles in the United States; and (4) United States consumers. 19 U.S.C. §§ 1337(d), (f). In connection with the statutory public interest requirement and based upon statements on the public interest received from the parties and various third parties, the Commission asked for briefing in its Notice of Review. 87 Fed. Reg. 58819-20 (Sept. 28, 2022).

The private parties and numerous third parties filed public interest statements. Apple argues that the public interest favors suspension of any exclusion order in particular to avoid any adverse impact on public health and welfare for U.S. consumers and researchers that use the Apple Watch with ECG and IRN[35] for early identification of AFib and other health conditions. *See* Respondent Apple Inc's Public Interest Statement at 4; Apple Pet. at 99. According to Apple, there are insufficient substitutes for its accused Apple watches.

The following entities submitted public interest statements in support of Apple's position and presented essentially the same arguments as Apple:

- Statement of Third Parties Computer & Communications Industry Association and Netchoice in Response to the Commission's July 15, 2022, Notice of Request for Statements on the Public Interest (July 26, 2022)
- Dr. Marco Perez, Associate Professor in Cardiovascular Medicine, Stanford School of Medicine

[35] "IRN" stands for Irregular Rhythm Notification.

- Dr. Calkins, Professor of Cardiology, Johns Hopkins School of Medicine
- Dr. Richard Milani, Chief Clinical Transformation Officer, Ochsner Health System
- Mellanie True Hills CEO and Founder of StopAfib.org, an atrial fibrillation patient advocacy organization and patient-to-patient resource
- Members of Congress: Representatives Eric Swalwell, Zoe Lofgren, Donald Beyer, Anna Eshoo, Jimmy Panetta, Linda Sanchez, and J Luis Correa expressed concern that issuing an exclusion order against Apple's wearable devices would present a significant detriment to American consumers

The American Heart Association ("AHA") submitted a statement "not in support of any party," but their position is consistent with Apple. *See* Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party (July 26, 2022). The AHA stated that the "recommended remedial orders would harm scientific research, healthcare consumers, and healthcare providers and in the United States. Accordingly, the AHA urges the Commission to tailor any remedial orders to allow researchers adequate time to complete ongoing research projects and transition to new research protocols with devices that are not subject to any exclusion order."

AliveCor asserts that its requests for an LEO and a CDO will benefit the public in that they "will promote intellectual property rights and continued innovation, and prevent a powerful company from holding health technology hostage simply because it is a large company that has successfully excluded competition." Complainant AliveCor, Inc.'s Statement on the Public Interest at 1-2. According to AliveCor, there is a "diverse field of suppliers" of alternative products that offer the health monitoring technologies of the accused Apple watches. *Id.*

The following entities submitted public interest statements in support of AliveCor's position and presented essentially the same arguments as AliveCor:

- Dr. Swerdlow, Professor of Medicine, Cedars Sinai Clinical Professor of Medicine, UCLA Cedars-Sinai Heart Institute

- Dr. Topol, Executive VP, Scripps Research and Director, Scripps Research Translational Institute

- Dr. Reynolds, Chief of Cardiovasular Section, the University of Oklahoma Health Sciences Center

- Cardiovascular Research Foundation of Southern California ("The answer could not be more transparent and clear that excluding infringing Apple Watches does not harm the public interest.")

- Medical Device Manufactures Association (The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of companies such as Apple who can afford to engage in "efficient infringement" as a business strategy.)

- Members of Congress: Representatives Henry "Hank" Johnson, Jr. and Lucy McBath expressed sentiment that the public interest is best served when the Commission takes action to protect intellectual property, enforce our nation's patent laws, and promote fair and robust competition

1. Apple Submission

a) Public Health and Welfare

Apple asserts that the recommended remedy "will seriously harm the public health and welfare" in three ways: (1) it will "reduce early detection of AFib, a prevalent and life-threatening disease that often goes undetected until a patient experiences serious or fatal complications, and may reduce detection of other cardiac conditions"; (2) it will "irreparably disrupt ongoing research into AFib, depriving the American public of potentially 'breakthrough' treatments for this disease and wasting millions of dollars in public and private investment already devoted to medical research using Apple Watch"; and (3) it will "deprive consumers of Apple Watch's numerous other invaluable health, wellness, and safety functions and disrupt ongoing research on these unaccused features." Apple Sub. at 40.

With respect to the first reason, Apple states that it "recognized the potential for Apple Watch to help detect AFib early, before a user experiences a stroke or other major medical

event" and that after years development, "followed by extensive clinical trials establishing the safety and efficacy of each of ECG app and IRN, Apple received *de novo* FDA authorizations for each separate feature in September 2018." *Id.* at 41 (citing Tr. (Waydo) at 738:6-9). Apple contends that its "ECG app and IRN each help facilitate 'diagnoses that otherwise would have either been diagnosed much later or missed altogether without an Apple Watch.'" *Id.* Apple explains that the "ECG app enables users to record an electrocardiogram on demand using two electrodes on Apple Watch" that "record the electrical activity of the user's heart for a 30-second period." *Id.* at 41-42. The ECG app on Apple Watch then "rapidly analyzes the heart's electrical signals to detect whether signs of AFib are present." *Id.* at 42. Apple points to the FDA's statement in approving its ECG app that "having this 'convenient and readily accessible means to record' an ECG on demand 'is especially valuable for users with recurrent, transient but infrequent symptoms, which can be difficult to catch with traditional cardiac monitors.'" *Id.* Apple further explains that upon activation, the IRN "operates in the background, periodically measuring and analyzing the user's pulse rate using PPG sensors located on the back of Apple Watch to identify irregular heart rhythms" and that "[i]f IRN identifies and confirms heart rhythms suggestive of AFib, IRN will notify the user and prompt them to 'talk to [their] doctor.'" *Id.* at 42 (citing ID at136 (quoting IRN notification)). Once again, Apple notes the FDA's statement that this feature "is an effective device for identifying abnormal pulse rates that may suggest the presence of [AFib]." *Id.* Apple "estimates that there are [[ ]] Apple Watch users in the United States who have activated IRN on their Apple Watch, and a similar number who have activated ECG app." *Id.* at 43.

Regarding the second reason, Apple asserts that remedial orders "will jeopardize ongoing and planned AFib research, depriving the public of critical advances in medical knowledge." *Id.*

at 47. According to Apple, there are numerous ongoing studies related to heart diseases using the Apple Watch. *Id.* As an example, Apple points to the "American Heart Association's collaboration with Northwestern University and researchers from Johns Hopkins University, Stanford University, and the University of California at San Francisco on the REACT-AF study, a seven-year, 5,400-patient research trial that will study the potential of Apple Watch to minimize the amount of time that a patient with AFib needs to take blood thinning medications." *Id.* (citing Kristin Samuelson, *Can Apple Watch reduce patients' reliance on blood thinners*, Northwestern University (Aug. 29, 2022), https://tinyurl.com/bddd9evk). Apple asserts that "[t]he NIH already awarded researchers $37 million to conduct the study" and that '"government support' for research is an important factor "in determining the importance of a public interest."[36] *Id.* (citing *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 16 (Jan. 10, 2020)). Apple asserts that for ongoing studies using the accused Apple Watches, "the recommended remedial orders could jeopardize their scientific merit and cause waste of resources spent for the studies." *Id.* at 48.

As to the third reason, Apple contends that a remedial order "would deprive consumers of numerous other important life-saving features wholly unrelated to AliveCor's Asserted Patents [and not accused by AliveCor], and disrupt dozens of ongoing medical studies involving these features. *Id.* at 49. As examples Apple asserts that (1) "Apple Watch Series 4 and later offer fall detection, which connects wearers with emergency services after detecting a hard fall that has rendered the wearer immobile"; (2) "Apple Watch Series 6 and later include a blood oxygen monitoring feature that allows users to take on-demand measurements of their blood oxygen saturation—the amount of oxygen the red blood cells carry from the lungs to the rest of the

[36] "NIH" refers to National Institute of Health.

body—providing users with insight into their overall wellness; and (3) both Apple Watch Series 8 and Ultra "offer industry-leading crash detection technology," which "can automatically connect the wearer with emergency services, provide dispatchers with the location of the crash, and notify the wearer's emergency contacts." *Id.* at 50.

b) U.S. Consumers

Apple asserts that the recommended remedy will harm U.S. consumers directly by risking serious harm to consumers' health and welfare as discussed above. *Id.* at 52. Apple argues that remedial orders will also harm U.S. consumers "indirectly by disrupting crucial research and hampering the efficacy of the health care available to them." *Id.* Apple further argues that remedial orders will result in a lack of competition that will further harm U.S. consumers. *Id.*

c) Suitable Alternatives

Apple asserts that "there are not alternative smartwatches capable of counteracting the grave damage to public health and welfare and to consumers described above that would result from exclusion of the accused Apple Watches" and that "no new or upgraded product could redress that harm in a commercially reasonable time, because development, regulatory clearance, and production of such a product takes years." *Id.* at 53-54. According to Apple, "[t]he only suitable alternatives, for purposes of remedying the harm from exclusion, are wearable devices with both FDA-cleared ECG and IRN functions." *Id.* at 54. Apple argues that there are only "two options that meet those criteria currently available in the United States, but neither would ameliorate the harm to public health from an exclusion order." *Id.* Apple identifies "Fitbit, maker of the Charge 5 and Sense," as the only other company in the United States that "currently offers wearable products with HHRN and both an FDA-cleared ECG and IRN feature." *Id.* at 55. Apple, however, contends that "neither Charge 5 nor Sense could sufficiently compensate

for the wide-ranging harms to consumer and public health and welfare in the event of exclusion of Apple Watch from the U.S." *Id.* Apple adds that "[e]ven if Fitbit could ramp up manufacturing to fully meet consumer demand in the event of the sudden shortfall that would occur—which it cannot—the Sense and Charge 5 are markedly inferior to Apple Watch in their functionality, breadth of features, and ability to deliver life-saving cardiac and other benefits." *Id.* Apple further argues that "no other product could take the place of Apple Watch in the groundbreaking research" and that "Apple Watch's prevalence is the actual *subject* of some research, which looks to better understand and measure the public health benefits of a device with such widespread adoption." *Id.* at 57.

Apple observes that "[b]efore issuing an exclusion order, the Commission also considers the ability of AliveCor, its licensees, and third parties to satisfy demand for Apple Watch in the event the recommended remedy issues." *Id.* (citing 19 C.F.R. § 210.8(b)(3)). Apple states that "[n]o one, alone or in combination, can substantially replace the sudden supply shortfall that will arise if Apple Watch is excluded." *Id.* Apple explains that "[g]iven the complexities of engineering new electronic wearables, obtaining FDA clearance, and navigating the fragile and intricate procurement and manufacturing process, companies necessarily plan product launch and output years in advance" and that "[h]ere, where the massive shortfall would result from an external market shock, those companies would be caught flat-footed, unable to meet the enormous demand gap within a commercially reasonable time frame." *Id.* at 57-58.

d) Competitive Conditions in the United States

Apple contends that remedial orders "will also harm competitive conditions in the United States by harming third-parties reliant on the accused products and reducing market pressure on Apple Watch's competitors to cut costs and deliver innovative new products" and that "[t]hese

competitive harms will not be offset by any benefit to domestic 'production of like or directly competitive articles,' 19 U.S.C. § 1337(d)(1), because neither AliveCor nor any of Apple's primary competitors manufactures their competitive products in the United States." *Id.* at 61. Apple explains that "various U.S.-based components suppliers for Apple Watch 'have invested heavily in manufacturing to Apple specifications, … as Apple represents a large percentage of their business'" and that "[t]hese companies 'will likely experience negative impacts due to an exclusion order.'" *Id.* at 62. Apple adds that "numerous 'healthcare companies, hospitals, medical researchers and research institutions … have all made investments to work on projects … that rely on and sync with the Apple Watch.'" *Id.* Apple states that "removing a product as popular as Apple Watch, with as many sales as Apple Watch has, would 'weaken a primary force that underlies the current competitive environment'—vigorous competition between Apple and others." *Id.* at 63.

According to Apple, "[t]he substantial competitive harms caused by an exclusion order will not be offset by any benefit to 'the production of like or directly competitive articles in the United States'" because "the handheld ECG products that AliveCor does sell are not produced in the United States." *Id.* (citing 19 U.S.C. § 1337(d)(1), (f)(1)). Apple adds that to its knowledge, "Apple Watch's competitors, such as Samsung, Fitbit, and Garmin, do not produce their products in the United States either" and that it "is not aware of any company that manufactures full-featured smartwatches in the United States." *Id.* at 64.

e) Apple's Position

Against this backdrop, Apple asserts that the Commission should exercise its discretion and decline to issue an exclusion order. Apple Sub. at 65-67. Apple states that "[s]hould the Commission choose to issue a remedy despite the fact that doing so will place American lives at

risk, it should: (A) suspend enforcement thereof for at least two years to allow for sufficient production of adequate replacements to Apple Watch and, at a minimum, until final resolution of the Patent Office's Final Written Decisions on AliveCor's Asserted Patents" and "(B) tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67.

Apple argues that "Fitbit, which is currently the only company with FDA-clearances for an ECG app and an IRN feature," "would have to increase its current production of ECG and IRN-enabled products 'many times over' to replace the excluded Apple Watches." *Id.* at 68. Apple states that "given the existing supply chain issues, chip and neon gas shortages, logistics obstacles, and other issues, there is no reasonable likelihood Fitbit could increase its production to meet that demand in less than two years." *Id.* Apple adds that "[f]or any other company that does not have a current smartwatch with both of the two FDA authorized features in development, releasing such a smartwatch in the United States would require developing a working prototype, receiving FDA authorization, and overcoming the substantial supply chain hurdles currently roiling the global economy." *Id.* Apple states that "just receiving the necessary FDA clearance for any replacement product will likely require at least two years—assuming the product qualifies for the most straightforward FDA clearance pathway, which is no guarantee." *Id.* (citing Ex. 2 (Lietzan Decl.) ¶¶ 24-25). Apple thus asserts that "[d]elaying enforcement by two years is therefore the minimum time necessary for suitable alternative products to become available for sale on a scale sufficient to replace excluded Apple Watches." *Id.*

Apple contends that "[r]egardless of whether the Commission chooses to suspend enforcement of any remedial order until alternatives are ready, it should suspend enforcement

until final resolution of the Patent Office's Final Written Decisions for each of the Asserted Patents." *Id.* at 69. Apple states that it "filed petitions for *inter partes* review alleging that all of the claims asserted in this Investigation are unpatentable and should be cancelled" and that a final decision is expected by December 8, 2022, "*before* the Commission's target date to issue its Final Decision." *Id.* (citing *Certain Unmanned Aerial Vehicles*, Inv. No. 337-TA-1133, Comm'n Op., 2020 WL 5407477, at *21 (Sept. 8, 2020) ("Suspension of [any] remedial orders pending resolution of the PTAB's Final Written Decision[s]" is fully "consistent with the Commission's past practice on this issue.").

Apple also argues that the Commission should "tailor its remedy to allow for support of Apple Watch users, clinical use, certain personal imports, governmental use, and standard certification." *Id.* at 67. Apple explains that "[[ ]] Americans have activated EGC and IRN on their Apple Watches" and that millions more own Apple Watches but have not yet activated these features. *Id.* at 70. Apple states that "[a]n exception permitting software maintenance releases and updates for all Apple Watches, including units with the Accused Features installed" because "[s]uch updates for Apple Watches are important '[t]o make sure that … Apple devices have the latest bug fixes and security enhancements.'" *Id.* (citing RX-644.1). Apple further argues that "[a]ny remedial order should permit Apple to honor all service and repair obligations—including obligations under applicable warranties and law, and other applicable service and repair obligations—by providing technical support, service, repair, and replacement for all permissibly obtained Apple Watches, including models with the Accused Features installed." *Id.* at 71. Apple explains that "[t]he Accused Products are subject to a manufacturer's warranty that requires Apple to repair or replace products for one or two years, depending on the model." *Id.* (citing CX-60C; CX-6; *Certain Liquid Crystal Display Modules*,

Inv. No. 337-TA-634, Comm'n Op., 2009 WL 4087135, at *2 (Nov. 24, 2009) (exempting infringing repair parts from remedial orders and allowing importation of service and replacement parts)).

Apple asserts that it "should also be permitted to continue the sale, replacement, or exchange of bands for the Apple Watches at issue" as well as "charging accessories like charging pucks and compatible adapters." *Id.* at 71-72. Apple asserts that "AliveCor's accusations have nothing to do with watch bands, and the bands are articles in commerce which users may choose to purchase or seek to have replaced." *Id.* Apple further contends that "[a]ny remedy should also include an exemption permitting continued sale of new AppleCare service and repair plans." *Id.* at 72.

Apple states that "[a]ny prohibition on 'marketing' or other customer facing communications in the Commission's Cease and Desist Order should expressly permit Apple to continue to provide and update informational and support materials for users of all Apple Watches on its website, including information specifically on ECG app, IRN, and HHRN." *Id.* at 72. Apple explains that "[i]n some instances, such as instructions for use, Apple is obligated by FDA to keep these materials accessible" and that "[i]n other instances, these materials help educate doctors and others about how to use Apple Watch to achieve better health results." *Id.*

Apple asserts that "[s]eparate from permitting support for existing end users, any remedy should also include an exception for products made, marketed, used, or sold solely for uses reasonably related to the development and submission of information under the FDCA." *Id.* at 73. Apple argues that "[a]n exclusion order should also include a personal importation exemption that would cover (i) American Apple Watch users who travel abroad with an accused Apple Watch and then return with that device; (ii) foreign visitors who enter and then depart the

United States with a personal Apple Watch; and (iii) U.S. travelers who buy an Apple Watch abroad, or have a watch replaced abroad under warranty." *Id.* According to Apple, "[t]hese exceptions are necessary to avoid harming unwitting consumers who are merely traveling with their Apple Watch products or choose to make a purchase decision abroad." *Id.*

2. AliveCor Submission

a) Public Health and Welfare

AliveCor contends that "the requested remedial orders do not raise any public health, safety, or welfare concerns" because there are numerous substitutes (discussed below) available that "will allow consumers to access wearable monitoring devices that can record ECGs and monitor cardiac events." AliveCor Sub. at 48. For support, AliveCor points to the public interest statements submitted by third parties. Specifically, AliveCor points to Dr. Topol's submission that '"[p]ublic health is far more served by encouraging and protecting those who innovate to make better medical technology' rather than by making an exception for large companies like Apple 'because that would be protecting those who use without authorization, simply because they are large.'" *Id.* AliveCor also points to Dr. Reynolds' statement in contemplation of Apple's intended argument that '"as a major seller of smartwatches in the U.S. [that] the public would somehow suffer if the Commission excluded its infringing Apple Watches' is actually 'a situation of Apple's own making'" in that "Apple created this situation by using its power and influence to 'exclude AliveCor and other competitors while Apple simultaneously introduced its infringing Apple Watches.'" *Id.*

In response to Apple's argument, AliveCor asserts that remedial orders will not apply to unaccused watches, including watches from Apple itself. AliveCor R.Sub. at 36. Specifically, AliveCor identifies the Apple Watch SE as a suitable substitute because it "has IRN, HHRN, Low Cardio Fitness Notifications, sleep stages, fall detection, crash detection, cycle tracking,

emergency SOS, noise monitoring, and backtrack." *Id.* Regarding Apple's assertion about the ECG, AliveCor states that "the majority of the testimonials that Apple attached to its brief—over 250 of them, *see* Apple Br., Ex. 8—do not appear to mention ECG functionality at all," and "[s]o there is no reason to think an exclusion order would affect the functionalities being touted." *Id.* AliveCor adds that "the nearly 30 million people who already own infringing devices would not be affected by any remedy in this case" and that "all of these Apple Watches—those unaccused, and those already in the stream of commerce—could be paired with relevant accessories, like AliveCor's KBS, to add functionalities." *Id.* at 36-37. AliveCor states that "[i]f Apple would stop its anticompetitive actions and restore access to the raw PPG data and APIs, AliveCor could make updated versions of KBS for the unaccused Apple Watches." *Id.* at 37.

b) Suitable Alternatives

AliveCor states that "numerous major electronic suppliers market reasonable substitutes for Apple's infringing functionalities." AliveCor Sub. at 44. According to AliveCor, "Apple itself sells and markets the Apple Watch SE series, which, although it provides IRN and HHRN, does not contain an ECG sensor and therefore has not been accused." *Id.* AliveCor adds that "[t]hose unaccused Apple Watches can, moreover, be combined with the KBS to provide ECG functionality" and that "[a]ll Apple needs to do is reverse its anticompetitive changes to watchOS that prevent SmartRhythm from working." *Id.* AliveCor also identifies certain third parties as offering reasonable substitutes. *Id.* Specifically, AliveCor argues that Samsung watches, including Galaxy Watch 5, Galaxy Watch 4, Galaxy Watch 3, and Galaxy Watch Active 2, "provide the capability of an on-demand 30-second ECG that can detect the presence of Afib" and that "[t]hese watches also provide continuous heartrate monitoring using an optical heart rate sensor (*i.e.*, PPG) that detects and keeps track of heart rate and heart rate changes in the

background." *Id.* AliveCor further argues that "Fitbit offers numerous products, cleared by the FDA, that provide AFib detection capabilities using an ECG app13 and a PPG-based background detection algorithm," including the Fitbit Sense, the Fitbit Versa, the Fitbit Versa Lite, the Fitbit Charge 4, and the Fitbit Inspire 2." *Id.* at 45. According to AliveCor, "[t]he substitute Fitbit devices are also capable of tracking elevated heart rates (similar to Apple's HHRN) as well as tracking heart rate variability ('HRV'), which is a measure of the time variances in between heartbeats that can indicate whether the heart is beating irregularly." *Id.* AliveCor also identifies other "wearable smartwatches on the market that have received FDA clearance and have heart-rate monitoring capabilities." *Id.* at 46. These include the "Oppowatch, which contains an optical heartrate sensor and monitors the user's heartrate" and the "Withings Scanwatch, which not only uses ECG and PPG for Afib detection, but specifically highlights those detection capabilities to consumers on its website." *Id.*

AliveCor emphasizes that "[t]he infringing Apple Watches that would be subject to the recommended exclusion order comprise only a subset of Apple's watch offerings; those products that include both **(1)** PPG-based arrhythmia detection features (*i.e.*, the Irregular Rhythm Notification feature ("IRN") and the High Heart Rate Notification ("HHRN") feature) and **(2)** the ECG App." *Id.* at 46. AliveCor states that "Apple offers numerous unaccused Apple Watch products that lack ECG hardware (and thus do not accommodate the ECG App), but which nevertheless offer both the IRN and HHRN features" and that "[t]hese unaccused models would not be subject to the recommended exclusion order." *Id.*

c) Competitive Conditions in the United States

AliveCor asserts that "the requested remedial orders will not, in fact, remove any competitor from the market." AliveCor R.Sub at 45. AliveCor contends that "Apple can

continue offering unaccused watches" and that "Samsung, Fitbit, and others can continue competing with Apple." *Id.* at 46. AliveCor contends that "it is Apple that is engaging in anticompetitive behavior." *Id.* AliveCor explains that "Apple's unfair acts of competition" "are substantial and ongoing: Apple met with, considered acquiring, stole technology from AliveCor and is continuing to infringe AliveCor's patents and exclude AliveCor's products." *Id.* (citing AliveCor Sub at 10-14; OUII Sub at 17 ("This effectively excluded AliveCor from the Apple Watch market," so "[i]t appears likely that the effect of the requested remedial orders would benefit competitive conditions by opening up markets.").

d) AliveCor Position

AliveCor states that the remedial orders should issue immediately and without carveouts. AliveCor R.Sub. at 48. AliveCor asserts that "[t]here is no need for any exception for software updates" as "[t]he investigation Apple itself cites confirms that Customs does 'not [ ] regulate electronic transmissions.'" *Id.* at 49 (citing *Certain Systems for Detecting and Removing Viruses or Worms*, Inv. No. 337-TA-510, Comm'n Op., 2005 WL 8153587, at *3 (Aug. 23, 2005)). Regarding an exception for service and repair, AliveCor asserts that "Apple's corporate designee confirmed under oath that, under its warranty, it can provide a refund in lieu of repairing a broken watch" and that "[i]n such circumstances, a service and repair exemption is not warranted." *Id.* (citing JX-220C (Rollins) at 162:21-163:3, 167:1-9; CX-0060C; CX-0061; *Certain Light-Emitting Diode Products, Fixtures, and Components Thereof*, 337-TA-1213, Comm'n Op. at 13 (Jan. 14, 2022). Finally, AliveCor argues that "Apple's request that any remedy be suspended for two years is based on a claim that 'there are no suitable alternatives to Apple Watch" but that "[t]he record shows otherwise." *Id.* (pointing to immediately available, FDA-cleared alternatives from Fitbit, Samsung, and even Apple itself).

With respect to suspending remedial orders until final resolution of the IPRs, AliveCor states that "[i]n every case Apple cites, the Commission has acted only **after** a FWD decision issues, and only with respect to patent claims actually deemed invalid" and thus "[a] suspension of the remedial orders should therefore not even be under consideration unless every patent claim on which a violation is found has been held invalid in a FWD." *Id.* at 50.

3. OUII Submission

a) Public Health and Welfare

OUII states that on balance, "the requested remedial orders will not adversely affect the public health and welfare" because "[s]imilar irregular rhythm notification and ECG features are available on a variety of other devices." OUII Sub. at 13. OUII asserts that "consumers may purchase existing alternative devices including the Samsung Galaxy 4 smartwatch, the Samsung Galaxy 3 smartwatch, and the FitBit Charge 5 smartwatch." *Id.* OUII explains that the "Samsung Galaxy Watch 4 allows users to monitor for abnormal or irregular heart rhythm and to take electrocardiograms ('ECG') in real time." *Id.* OUII adds that "ECG technology is likely to be introduced in various existing and future products" and that "Garmin has completed clinical trials for its smartwatch ECG technology and is expected to enable such functionality in certain devices (including the Garmin Venu smartwatches) once it has secured necessary FDA clearance." *Id.* OUII states that "various alternative devices are available on the market to monitor heart health, including AliveCor KardiaMobile Card personal ECG device, Oura Ring Gen 3 smart ring, and Prevention Circul+ smart ring with ECG and blood pressure monitoring capabilities." *Id.* at 14. According to OUII, "[g]iven the wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." *Id.*

OUII states that "[w]hile the Apple Watch has certainly been used in various on-going research projects, at this time it has not been shown that alternative products cannot be used in its place." *Id.* OUII contends that "remedial orders would not impact the function of the existing Apple Watch installed base, and would thus appear unlikely to affect on-going research projects in any meaningful way." OUII R.Sub. at 16. OUII observes that "the non-accused Apple Watch SE provides the IRN and HHRN features that work in the background to detect irregular heart rhythms" and that "it appears that all of the research projects identified in public interest comments and briefing could be performed by an Apple Watch SE alone, or in combination with an external ECG device such as AliveCor's KardiaMobile Card." *Id.*

b) Competitive Conditions in the United States Economy

OUII argues that "remedial orders will promote competitive conditions in the United States economy." OUII Sub. at 16. OUII explains that "[i]n 2013, Apple tried unsuccessfully to design a smartwatch with the accused functionality" and that "when AliveCor successfully introduced its technology to the Apple Watch platform, Apple took steps to copy that technology by seeking information from the FDA, by commissioning research on AliveCor's technology, and by requesting meetings and live demonstrations to obtain information from AliveCor." *Id.* at 16-17. According to OUII, "once Apple had successfully implemented the patented technology, Apple revised its watchOS API in a manner such that AliveCor's KardiaBand System was no longer functional," which "effectively excluded AliveCor from the Apple Watch market, leaving consumers with fewer and less effective options." *Id.* at 17 (citing Tr. (Albert) at 83:20-85:19). OUII states that thus "[i]t appears likely that the effect of the requested remedial orders would benefit competitive conditions by opening up markets, allowing wider access to superior

technology, and encouraging innovation." *Id.* OUII also notes the availability of alternatives. *Id.* at 16.

c) Production of Like or Directly Competitive Products in the United States

OUII states that it is not aware of any evidence of record regarding the impact of the requested remedial orders on the production of like or directly competitive articles in the United States. *Id.* at 17.

d) United States Consumers

OUII states that on balance, remedial orders will not adversely impact U.S. consumers, pointing to the availability of alternatives for support. *Id.* at 18-19.

e) OUII Position

OUII asserts that based on the evidence provided in Apple's initial written submission, "any remedial order should be tailored to allow support of existing Apple Watch users." OUII R.Sub at 20. OUII also agrees with Apple's request that any remedial orders be tailored to permit Apple "to provide (1) 'software maintenance releases and updates for all Apple Watches, including units with Accused Features installed' and (2) to honor its service and repair obligations." *Id.* at 21. According to OUII, "Apple has demonstrated that 'Consumers who purchased an Accused Product reasonably expected to get the *full* scope of the accompanying warranty or insurance contract.'" *Id.* (citing JX-220C (Rollins Dep. Tr.) at 79:1-9; 160:9-168:21). OUII proposes an exception to the remedial orders as follows: "except for service or repair of wearable electronic devices with ECG functionality that were imported prior to the Commission's determination becoming final within the meaning of 19 U.S.C. § 1337(j)(4)." *Id.* OUII states that the evidence of record does not support any additional tailoring of the requested remedial orders. *Id.*

4. Analysis

Under Federal Circuit precedent, "the Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise." *Spansion*, 629 F.3d at 1358; 19 U.S.C. § 1337(d)(1) ("If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States …"). The Commission finds that issuance of remedial orders in this investigation will not have such an adverse effect on the public interest factors that would warrant denying a remedy. Thus, the Commission declines Apple's invitation to exercise its discretion and deny a remedy.

a) Public Health and Welfare

The Commission agrees with AliveCor and OUII that remedial orders in this investigation would not raise significant public health or welfare concerns. *See* AliveCor Sub. at 48; OUII Sub. at 13.

Apple identifies three public health and welfare concerns that it contends would be affected by the remedial orders here: (1) the ability of current users to continue to enjoy the health, wellness, and safety features of the infringing Apple watch; (2) the disruption of ongoing research projects into Afib that utilize the infringing watches (no new studies were identified); and (3) curtailing consumer access to unaccused features of the infringing Apple watches and ongoing research projects pertaining to those unaccused features.

With respect to the first concern, the potential impact on existing owners of infringing Apple watches, the Commission finds, consistent with AliveCor's representation, that remedial relief against the infringing Apple watches would not affect current users of Apple's infringing watches as nothing in the relevant remedial orders would prevent them from being able to

continue using all of the features without interruption, which would include software updates and the like to maintain the functional status of the watches that are in the hands of U.S. consumers.[37] *See* AliveCor R.Sub. at 36 ("the nearly 30 million people who already own infringing devices would not be affected by any remedy in this case"). Moreover, the Commission has determined that the evidence of record supports an exemption for service, repair, and replacement of those infringing watches pursuant to Apple's warranty obligations described below. This exemption would enable consumers who possess infringing watches to continue to benefit from the health, wellness, safety and other features that they have accessed since those watches were purchased prior to the orders becoming final.

With respect to the second concern, the effect on ongoing research projects, the Apple infringing watches used in those ongoing projects would likewise be unaffected by the remedial orders. Apple contends that remedial orders will "irreparably disrupt ongoing research into AFib, depriving the American public of potentially 'breakthrough' treatments for this disease and wasting millions of dollars in public and private investment already devoted to medical research using Apple Watch." Apple Sub. at 40. According to Apple, there are numerous ongoing studies related to heart diseases using the Apple Watch. *Id.* Apple does not identify any new studies that would be impacted by the remedial orders here, but rather the issue pertains solely to studies already underway. Remedial orders will not take Apple Watches away from existing study participants, and Apple does not contend that these studies need additional Apple Watches for additional participants, much less quantify that need. Therefore, infringing Apple watches supplied to research subjects at the commencement of those projects would remain

[37] Apple requests an exemption from the orders to account for software maintenance and updates and technical support for current Apple watch owners. Apple Sub. at 70-71. No exemption is necessary as these are not covered by the remedial orders.

available to the persons participating in those studies given that current users can continue to utilize all of the features without interruption as noted above. Moreover, to the extent that study participants' watches malfunction or break, Apple can continue to provide service and repair under its warranty obligations under the Commission's exemption. The service and warranty exception will allow Apple to repair or replace malfunctioning watches for existing participants, and any new studies can utilize any of the numerous alternatives discussed below, including the Apple Watch SE paired with ECG functionality.

As to the third concern, the curtailment of consumer access to non-accused features of infringing watches and ongoing research into those unaccused features, persons who already possess these infringing watches whether for their own use or ongoing research, their continued access is unaffected as explained above. To the extent that Apple's concerns relate to potential new customers of infringing watches, Apple has failed to substantiate or detail its concerns.

With respect to persons who seek to purchase new watches after the orders become final, the parties dispute whether there are suitable substitutes available to address public health, safety, and welfare concerns that may arise due to exclusion of the infringing Apple watches. Apple contends that "suitable alternatives for purposes of remedying the harm from exclusion must (1) include ECG, IRN, and HHRN features; (2) be a wearable; and (3) be FDA-cleared." Apple Sub. at 54. AliveCor responds that "the majority of the testimonials that Apple attached to its brief—over 250 of them, *see* Apple Br., Ex. 8—do not appear to mention ECG functionality at all." AliveCor R.Sub. at 36. OUII states that due to a "wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." OUII Sub. at 14.

The Commission finds that suitable alternatives are available to meet the public health concerns raised by Apple's comments. As to Apple's first and second points regarding suitable alternatives, Apple explains that for substitutability with Apple's infringing watches, portability is key because a device offering IRN functionality without a readily available ECG app "would mean that wearers concerned about their heart health—either because of an IRN alert or because of how they are feeling—would need to go to the hospital or acquire an inconvenient and separate at-home ECG device to accurately detect AFib, by which time their fleeting symptoms may have passed." Apple Sub. at 44. Thus, in Apple's view, wearable devices that have an IRN function and a means by which the user can quickly take an ECG would provide a suitable alternative. In contrast to IRN, Apple explains that HHRN "cannot itself detect any heart conditions, [but] it provides valuable information to users that can encourage them to seek medical care, which can in turn lead to the identification of a range of cardiac conditions that might otherwise have gone undiagnosed. *Id.* AliveCor and OUII concur that a combination of portable devices can readily replace the infringing Apple watches. AliveCor Sub. at 44-47; OUII Sub. at 12-16. In view of these comments, the Commission finds that wearable devices that have IRN and HHRN functionality along with portable ECG devices represent a reasonable alternative to the Apple watches to be excluded under our remedial orders. As discussed in detail below, various portable devices are currently available on the market to provide these functionalities.

With regard to Apple's third point regarding substitutability, FDA clearance, Apple contends that FDA-clearance provides a "rigorous authorization process for software as a medical device (SaMD) [which] requires high-quality validated sensor inputs that have clinical-level accuracy." Apple Sub. at 54. Apple argues that "[no]n-cleared devices that purport to measure cardiac activity through PPG sensors have not been determined to accurately identify

potential AFib" and that decisions as to medications and treatments based on these data would be "ill-advised." *Id.* at 55 (citing StopAfib.org Sub. at 3). Apple's assertion, however, is based exclusively upon the conclusory statement that "non-FDA cleared devices are often inaccurate and may lead to ill-advised decisions about medications and treatment." StopAfib.org Sub. at 3. Aside from this general admonition, Apple provides no evidence showing that particular non-FDA cleared portable devices are, in fact, inaccurate or that doctors or patients have made medical decisions on medications and treatments for AFib based solely on data generated by non-FDA cleared software. Absent such factual basis, the Commission does not credit Apple's conclusory assertion that FDA-clearance is mandatory in order for alternative devices to serve as suitable substitutes for the infringing devices.

Even if suitable alternatives were restricted to the three-part definition that Apple advocates, Apple concedes that Fitbit's Charge 5 and Sense are alternatives currently available in the United States. Apple Sub. at 55-56. According to AliveCor, Fitbit offers "numerous products, cleared by the FDA, that provide AFib detection capabilities using an ECG app13 and a PPG-based background detection algorithm," including the Fitbit Sense, the Fitbit Versa, the Fitbit Versa Lite, the Fitbit Charge 4, and the Fitbit Inspire 2" that "are also capable of tracking elevated heart rates (similar to Apple's HHRN) as well as tracking heart rate variability ('HRV'), which is a measure of the time variances in between heartbeats that can indicate whether the heart is beating irregularly." AliveCor Sub. at 45. Apple, however, asserts that Fitbit cannot ramp up manufacturing to fully meet consumer demand in the event of the sudden shortfall that would occur. *Id.* at 55, 68. Specifically, Apple states that "given the existing supply chain issues, chip and neon gas shortages, logistics obstacles, and other issues, there is no reasonable likelihood Fitbit could increase its production to meet that demand in less than two years." *Id.* at

68 (citing Exh. 6 (Davies Decl.) ¶¶ 17, 22, 37, 53, 90)).[38] Again, Apple (including the cited paragraphs of the declaration), provides no evidence to substantiate its assertions that Fitbit presently lacks the manufacturing capability to produce new products that include FDA-cleared ECG, IRN, and HHRN features in a single wearable device to meet the narrow band of consumer demand for products so defined, and Apple's assumption that consumers would forego all other portable devices that provide some or all these features, which are widely available in the U.S. market as discussed below. In any event, as noted above, the Commission is suspending the remedial orders pending final resolution of the PTAB's final written decisions which will give adequate time for alternatives to be readily available.

Under the Commission's understanding of reasonable alternatives, the record evidence shows that, in addition to Fitbit, there are substitutes that offer a wide range of health, safety, and wellness features including some that "will allow consumers to access wearable monitoring devices that can record ECGs and monitor cardiac events." AliveCor R.Sub. at 36. As AliveCor notes, "Apple itself sells and markets the Apple Watch SE series, which, although it provides IRN and HHRN, does not contain an ECG sensor and therefore has not been accused." *Id.* at 44. The evidence shows that the Apple Watch SE series can be combined with ECG devices, such as the KBS, to serve as an adequate substitute. *See* AliveCor Sub. at 44.[39]

[38] Apple filed a motion for leave to file "further corrected Exhibits 5 and 6" on October 11, 2022, after omitting these exhibits from its October 6, 2022 opening submission, obtaining leave from the Commission to file these omitted exhibits, then served a first corrected version on October 7, 2022, followed by this second set of corrected exhibits filed and served on October 11, 2022. *See* Apple Mot. at 1-2 (Oct. 11, 2022). The Commission has determined to grant Apple's motion.

[39] We note that the KBS was previously pared with the Apple watch series 1-3 to provide ECG functionality in a single device. That situation ended around December of 2018 when Apple changed its software to no longer support the KBS. AliveCor Sub. at 41 (citing RX-0047C; Somayajula Tr. at 84:1-84:3, 199:18-200:20). Apple has not provided evidence that

AliveCor also identifies other third parties as offering reasonable substitutes that carry out the same functions, specifically Samsung watches including the Galaxy Watch 5, Galaxy Watch 4, Galaxy Watch 3, and Galaxy Watch Active 2. The Samsung watches provide "the capability of an on-demand 30-second [FDA cleared] ECG that can detect the presence of Afib" and also "provide continuous heartrate monitoring using an optical heart rate sensor (*i.e.*, PPG) that detects and keeps track of heart rate and heart rate changes in the background." *Id.* Apple does not disagree with AliveCor's statement, nor does it contend that Samsung's products are not competitive with its own smartwatches. Apple R.Sub. at 26. Rather, Apple responds that Samsung products are not "FDA-cleared to continuously monitor for irregular heart rhythms suggesting potential AFib," albeit Apple concedes that Samsung offers a feature comparable to HHRN. *Id.* As discussed above, Apple has failed to substantiate its contention that suitable substitutes must have FDA clearance. Apple also raises the same high level general supply constraints observations as it raises with respect to Fitbit relating to global supply of semiconductor chips in 2021. Apple Sub. at 61.

OUII also points out that "ECG technology is likely to be introduced in various existing and future products," noting that "Garmin has completed clinical trials for its smartwatch ECG technology and is expected to enable such functionality in certain devices (including the Garmin Venu smartwatches) once it has secured necessary FDA clearance." OUII Sub. at 13. Apple responds that it is unaware of the status of Garmin's FDA application, clinical trials, or IRN-type feature under development. Apple R.Sub. at 30.

changing its software to again allow compatibility with the KBS would require a substantial ramp up period, including in light of the suspension of enforcement of the orders.

OUII points to other alternative devices "available on the market to monitor heart health, including AliveCor KardiaMobile Card personal ECG device, Oura Ring Gen 3 smart ring, and Prevention Circul+ smart ring with ECG and blood pressure monitoring capabilities" and states that "[g]iven the wide availability of alternatives, it does not appear to OUII that the public health and welfare would be adversely impacted by the requested remedial orders." *Id.* at 13-14. The table below, submitted by AliveCor, identifies devices that are suitable alternatives:

TABLE 1: SELECTED SMARTWATCH FEATURES PROMOTED BY DEVICE MANUFACTURERS

	Apple		Competitors				
	Apple Watch (Series 8) [A]	Apple Watch (SE 2nd Gen) [B]	Samsung Galaxy (Watch 5) [C]	Fitbit (Sense2) [D]	Fossil (Gen 6) [E]	Garmin (Venu 2 Plus) [F]	Zepp (Amazfit GTS4) [G]
GPS	✓	✓	✓	✓	✓	✓	✓
Emergency SOS Capability	✓	✓	✓	x	x	✓	x
Water Resistant	✓	✓	✓	✓	✓	✓	✓
Speaker and Microphone	✓	✓	✓	✓	✓	✓	✓
24+ Hour Battery Life	✓	✓	✓	✓	✓	✓	✓
iOS Compatability	✓	✓	x	✓	✓	✓	✓
Cellular Connectivity	✓	✓	✓	✓	✓	✓	✓
Personalizable Design	✓	✓	✓	✓	✓	✓	✓
Health Functions							
ECG	✓	x	✓	✓	x	x	x
HHRN	✓	✓	✓	✓	-	✓	✓
IRN	✓	✓	-	✓	-	✓	✓
Low Cardio Fitness Notifications	✓	✓	-	✓	✓	✓	✓
Blood Oxygen	✓	x	✓	✓	✓	✓	✓
Fall Detection	✓	✓	✓	x	x	✓	✓
Crash Detection	✓	✓	✓	x	x	✓	✓
Wrist Temperature	✓	x	✓	✓	x	x	x
Sleep Monitoring	✓	✓	✓	✓	✓	✓	✓

AliveCor R.Sub. at 37.

Apple contends that AliveCor and third parties cannot meet demand within a commercially reasonable time if its infringing watches were to be excluded. Apple Sub. at 57 ("No one, alone or in combination, can substantially replace the sudden supply shortfall that will arise if Apple Watch is excluded."). Apple submitted the following IDC data for imports by U.S. retailers of Apple watches (with and without the infringing functionalities) as well as other smartwatch and fitness trackers for the period 2015 through 2021:[[

]] Apple Sub., Exh. 5 (Dippon Decl.) ¶ 11. The infringing Apple watches comprise [[ ]] of the total Apple shipments listed above in 2021, amounting to [[ ]] infringing Apple watches. *Id.* ¶ 25.

As relevant to Apple's public health and welfare arguments focused on U.S. consumers with Afib, Apple states that of the total number of infringing units sold in the United States, [[ ]] users have activated IRN and ECG on their infringing watches. Apple Sub. at 70. Afib affects up to 6 million people in the United States. Apple Sub., Exh. 5 (Dippon Decl.) ¶ 49. These data indicate that consumers, and particularly those affected by Afib, who need portable devices offering health and safety features discussed above have already purchased and activated IRN and ECG on their Apple watches, Fitbit, or other devices or if they are new purchasers, they would be able to obtain devices that meet their needs from third party suppliers.

Moreover, as noted above, nothing in the remedial orders prevents current users and researchers from continuing to use their Apple watches. We also find Apple's argument that remedial orders "would deprive consumers of numerous other important life-saving features," and "disrupt dozens of ongoing medical studies involving these features" unpersuasive and unsubstantiated. Apple Sub. at 49. Moreover, the available substitutes for the infringing watches can be used for new studies.

b) Competitive Conditions in the United States Economy

In our judgment, the evidence of record shows that the remedial orders would not have any adverse impact on competitive conditions in the United States economy. Apple's argument to the contrary depends entirely on its view that there are no suitable alternatives other than Fitbit. As discussed above, the record evidence shows an abundance of suppliers that offer competing products. With respect to market shares of these competitors, Apple offers the following data from IDC regarding U.S. smartwatch and fitness tracker shipment shares in 2021:[[

]] *See* Apple Sub., Exh. 5 (Dippon Decl.) ¶ 24. As shown in the table above, these suppliers of competitive products include Samsung, Garmin, Fitbit, Fossil, and Zepp, among others. Apple itself can remain a competitor in the U.S. market with products that do not infringe such as the Apple Watch SE.

Apple argues that remedial orders will "harm competitive conditions in the United States by harming third-parties reliant on the accused products and reducing market pressure on Apple

Watch's competitors to cut costs and deliver innovative new products." Apple Sub. at 62. This argument, however, is wholly unsubstantiated.

c) The Production of Like or Directly Competitive Articles in the United States

The record contains no evidence that remedial orders will adversely impact the production of like of directly competitive articles in the United States. We note that neither the infringing products nor the reasonable alternatives are manufactured in the United States.

d) United States Consumers

As to potential effects on consumers, Apple argues public health considerations relating to consumers that the Commission has discussed above. Apple Sub. at 52. Apple further argues that exclusion would likely result in higher prices and poorer quality alternatives diminishing consumer choice. *Id.* Apple's argument, however, is unsubstantiated. Indeed, Apple does not present evidence of a direct price comparison between and among the competing products to support its allegation. *See Certain Audio Players & Controllers*, Inv. No. 337-TA-1191, Comm'n Op. at 32 (Jan. 6, 2022).

The record evidence indicates that [[ ]] own infringing Apple Watches. As discussed above, current owners of the infringing Apple watches will be unaffected by the remedial orders here thus alleviating any concerns regarding current users of these products.

While these consumers will not be affected by any remedy in this case, they bought their watches reasonably expecting to get the *full* scope of the accompanying warranty and insurance contract. JX-220C (Rollins Dep. Tr.) at 79:1-9; 160:9-168:21. For this reason, as well as to allow individuals using the Apple Watch to participate in ongoing studies as discussed above, the

Commission has determined to tailor the remedial orders to allow Apple "to honor its service, repair, and replacement obligations." *See* OUII R.Sub. at 21.

AliveCor suggests that a refund would suffice. AliveCor R.Sub. at 48. However, AliveCor and OUII have not shown that a refund will be adequate to compensate consumers who are seeking to maintain their Apple Watches or to participate in ongoing health-related studies using the Apple Watch. Accordingly, based upon the reasonable expectations of those consumers who purchased infringing Apple Watches and in consideration of ongoing research projects involving infringing Apple Watches that may malfunction or break, the Commission's remedial orders include the following exemption: "except under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts."[40]

e) Summary

In sum, the public interest factors do not compel the Commission to decline to issue remedial orders in this investigation. The Commission, however, has determined to include an exemption to allow Apple to honor its service, repair, and replacement obligations. The orders

[40] Commissioner Stayin does not believe that a warranty or service exception is justified merely because consumers expect the full scope of their bargain, as this would justify such an exception in every case involving a product sold with a warranty or service agreement. Moreover, in his view, it was Apple's burden to show an exception is necessary, and not AliveCor's burden to show a refund was sufficient. *See Certain Audio Players & Controllers, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-1191, Comm'n Op. at 25 (Feb. 1, 2022) (finding respondent failed to show a warranty exception was appropriate, including because respondent could provide a refund in lieu of repair). Nonetheless, given the specific health-related functionality at issue in this case, Commissioner Stayin believes a warranty and service exception is appropriate so that existing consumers do not bear the burden of switching to a new device for monitoring purposes in the event an issue arises with their previously purchased device after the remedial orders go into effect.

also include an exemption for articles imported by or for U.S. Government use, as usual, and include the Commission's standard certification provision.

D. Bond

If the Commission enters an exclusion order and/or cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review subject to posting a bond. 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be sufficient to protect a complainant from any injury. *Id.*; 19 C.F.R. §§ 210.50(a)(3), 210.42(a)(1)(ii). "The Commission typically sets the bond based on the price differential between the imported infringing product and the domestic industry article or based on a reasonable royalty. However, where the available pricing or royalty information is inadequate, the bond may be set at one hundred (100%) percent of the entered value of the infringing product." *Loom Kits*, Comm'n Op. at 18 (citations omitted). A complainant bears the burden of establishing its requested bond amount. *See, e.g.*, *Certain Liquid Crystal Display Devices*, Inv. No. 337-TA-631, Comm'n Op. at 28 (July 10, 2009). Should a complainant fail to meet its burden, the Commission may determine to impose no bond for products imported during the period of Presidential review period. *Id.*

The ALJ recommended that the Commission set no bond for entry of infringing products during the period of Presidential review. ID/RD at 194. The ALJ stated that "[i]t is entirely unclear what competitive harm ALC will face during this time as the KBS product has not been sold for some time (Hr'g Tr. (Albert) at 135:14-136:22) and [[ ]] are, at best, in development." *Id.* OUII and Apple agree with the ID's recommendation. OUII Sub. at 74; Apple Sub. at 21.

AliveCor asserts that "[t]he Commission should impose a bond of $13 per imported article." AliveCor Sub. at 40. According to AliveCor, "[t]he amount of bond to be posted during the sixty-day period for Presidential review must be at least sufficient to 'offset any

competitive advantages resulting from the unfair method of competition or unfair act enjoyed by persons benefitting from the importation.'" *Id.* (citing S. Rep. No. 1298, 93 Cong., 2d Sess. 198 (1974); 19 U.S.C. § 1337(e)(1), (j)(3); *see also Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-432, RD at 7 (Oct. 1, 2001)). AliveCor argues that "Apple's continued patent infringement and unfair competition are harming AliveCor" and that "[t]hrough its unfair acts, Apple excluded AliveCor's KBS from the market." *Id.* AliveCor asserts that the record evidence contains [[

]]. *Id.* at 42 (citing Tr. (Akemann) 638:18-639:24; JX-007C; JX-008C; JX-010C; CX-0872C). AliveCor points to [[

]]." *Id.* (citing Tr. (Akemann) 638:18-639:24; JX-008C.4). Thus, AliveCor argues that the Commission should set the bond at $13 per imported article. *Id.*

The Commission finds that the record evidence supports a bond in this investigation. Apple argues that "AliveCor does not compete with the accused Apple Watches, and has failed to prove that it would be injured by the importation of the accused Apple Watches, or that Apple enjoys a competitive advantage resulting from its alleged infringement," and therefore the Commission should not impose a bond for importation of infringing products during the period of Presidential review. ID at 193. However, Apple is [[

]]. *See* AliveCor Sub. at 40. Thus, the Commission finds Apple's argument self-serving and unpersuasive.

Regarding the appropriate bond rate, AliveCor asserts that "a bond—$13 infringing import—is consistent with [[

]].'" AliveCor R.Sub. at 50. As OUII notes, however, the [[

]]. OUII Sub. at 22; *See* JX-008C.4; Tr. (Vander Veen) at 1048:25-1051:4. The ID also observed that "[w]ith Apple using its own software, the $13 rate is demonstrably too high," and concluded that because AliveCor "has not offered alternative proposals reflecting this reality, it has not met its burden." ID at 194-95. The record evidence, however, includes [[

]]." AliveCor R. Sub. at 50 (citing CX-0872C.16). Accordingly, the Commission has determined to set a bond in the amount of $2.00 per unit article for infringing products imported during the period of Presidential review.[41]

[41] Commissioners Schmidtlein and Stayin agree the record evidence supports a bond in this investigation, but they disagree with the Commission's determination to set that bond in the amount of $2.00 per unit article. While various licenses were cited by AliveCor in its briefing before both the ALJ and the Commission as evidence available for considering a reasonable royalty rate, AliveCor has consistently indicated that "[t]he most straight forward and applicable [[ ]] *See, e.g.*, AliveCor Sub. at 42. And as noted by the Commission, AliveCor also contends [[

]] *Id*. (citations omitted). In Commissioner Schmidtlein and Commissioner Stayin's view, rather than requiring absolute precision, the purpose of the bond determination under the statute and the Commission's Rules is to protect the complainant from harm. *See* 19 U.S.C. § 1337(j)(3) (". . . bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury."); 19 C.F.R. §§ 210.50(a)(3) (". . . [d]etermine the amount of the bond to be posted by a respondent . . . taking into account the requirement of section 337(e) and (j)(3) that the amount of the bond be sufficient to protect the complainant from any injury."). Here, while the cited royalty rate may cover [[ ]], on this record they find the $13.00 [[ ]] sufficient to protect the complainant from any injury. *See, e.g.*, *Certain Audio Digital-to-Analog Converters and*

E. Suspension of Remedial Orders

As noted above, Apple, on December 7, 2022, filed an emergency motion, asking "the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions." Apple Emergency Motion at 1. Apple contends that "suspension is consistent with the Commission's routine past practice" and that "[a] stay will simplify the issues and conserve agency and party resources—by avoiding issuance of a merits determination that is likely to be mooted by an affirmance of the PTAB's Final Written Decisions—without causing any harm to Complainant." *Id.* Apple states that "either a suspension or a stay accords due deference to the Patent Office's role as the lead agency in assessing patentability and honors Congress's intent that invalid patents should not be enforced." *Id.*

AliveCor filed an opposition to Apple's motion on December 9, 2022. AliveCor asserts that "[g]ranting the requested stay would be unprecedented" and that "[t]he Commission has never stayed an investigation that is in this posture pending the appeal of a FWD when the complainant opposes, and Apple cites no authority to the contrary." AliveCor Opposition at 1. According to AliveCor, "[a]t most, the Commission could exercise its discretion to suspend enforcement of any remedial orders" but that "Apple's argument for the Commission to do so is weaker than in any past investigation when the Commission has implemented a suspension." *Id.* at 9. AliveCor explains that "Apple did not file IPRs on those patents until June 2021, six months" after institution of the investigation and that due to "Apple's delay, the FWDs were

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Products Containing Same, Inv. No. 337-TA-499, Comm'n Op. at 28 (Mar. 3, 2005) (Public Version) ("adopt[ing] the ALJ's finding that a bond of 5 percent is adequate to protect the complainant from injury during the 60-day Presidential review period" where "[t]ypical royalty rates in the semiconductor industry range from 0.75 percent - 5 percent.").

expected to issue after the Commission's Final Determination," which was expected on September 28, 2022, before "the Commission extended the Target Date." *Id.*

On December 16, 2022, OUII filed a response. OUII "supports Apple's motion to the extent that it requests that any remedy that issued by the Commission be suspended pending appeal of the PTAB decisions." Otherwise, OUII "opposes Apple's motion." *See* OUII Reply to Emergency Motion at 4.

The Commission has found a violation and determined that issuance of an LEO and CDO is warranted. The Commission agrees with AliveCor and OUII that granting a stay would not be consistent with Commission practice nor has Apple established the requisite showing to justify a stay of the proceedings. *See Certain Magnetic Tape Cartridges and Tape Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 61 (Apr. 9, 2019); *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 3 (July 29, 2009).

However, the Commission has determined to exercise its discretion to suspend enforcement of those remedial orders pending final resolution of the PTAB's Final Written Decisions finding all the asserted claims to be unpatentable. *See Viscofan*, 787 F.2d at 548 (finding that the Commission has "broad discretion in selecting the form, scope, and extent of the remedy"). Suspension of the remedial orders pending resolution of the PTAB's Final Written Decisions is consistent with the Commission's past practice on this issue. *See, e.g.*, *Certain Unmanned Aerial Vehicles and Components Thereof* (*"Unmanned Aerial Vehicles"*), 337-TA-1133, Comm'n Op. at 35 (Sep. 8, 2020); *Certain Magnetic Tape Cartridges and Tape Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 62-63 (Apr. 9, 2019); *Certain Three-Dimensional Cinema Systems and Components Thereof*, Inv. No. 337-TA-939, Comm'n

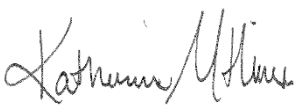
Op. at 60 (July 21, 2016). As the Commission explained at length under similar circumstances in *Unmanned Aerial Vehicles*, suspension of remedial orders is within the Commission's discretion over the form, scope, and extent of its remedy and may be appropriate where, as here, the PTAB issues final written decisions of unpatentability concerning certain claims before the Commission issues remedial orders based on those same claims. *Unmanned Aerial Vehicles*, Comm'n Op. at 35-38. The Commission has determined that it is appropriate under the facts in this investigation to suspend enforcement of the limited exclusion order and cease and desist order, including the bond provision, pending final resolution of the PTAB's Final Written Decisions finding the asserted claims of the '941, '731, and '499 patents unpatentable. AliveCor's contention that Apple delayed in filing its case at the Patent Office is not sufficient to overcome the other considerations warranting suspension of the remedial orders in this case.

VI. CONCLUSION

For the reasons detailed above, the Commission has determined to affirm the ID's finding of a violation of section 337. Regarding the issues under review, the Commission has determined to affirm the ID's economic prong of the domestic industry findings with the modifications described herein. Concerning invalidity, the Commission has determined to affirm the ID's patent eligibility findings under 35 U.S.C. § 101 as modified, but reverse as to one claim; and reverse the ID's decision not to consider objective indicia of non-obviousness for certain asserted claims. For remedy, the Commission has determined to: (1) issue a limited exclusion order prohibiting the unlicensed importation of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the '941 patent and claims 1, 3, 5, 8-10, 12, 15, and 16 of the '731 patent that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated

companies, parents, subsidiaries, or other related business entities, or their successors or assigns, and stating that they are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the patents, except under license of the patent owner or as provided by law, and except for articles or components imported for use in servicing, repairing, or replacing covered articles that were imported prior to the effective date of this Order pursuant to existing service and warranty contracts; (2) issue a cease and desist order directing that respondent Apple, cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of wearable electronic devices with ECG functionality and components thereof that infringe one or more of claims 12, 13, and 19-23 of the ’941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the ’731 patent; (3) find that the public interest factors do not preclude the issuance of the proposed remedial orders; and (4) set a bond in the amount of $2 per unit of article for infringing products imported during the period of Presidential review. The Commission, however, has determined to suspend enforcement of the orders, including the bond provision, pending final resolution of the PTAB’s Final Written Decisions finding the asserted claims of the ’941, ’731, and ’499 patents unpatentable.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

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