Appeal Nos. 23-1509, 23-1553

United States Court of Appeals
for the
Federal Circuit

ALIVECOR, INC.

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee,

APPLE INC.,

Intervenor.

APPLE INC.

Appellant,

v.

INTERNATIONAL TRADE COMMISSION

Appellee,

ALIVECOR, INC.,

Intervenor.

On Appeal from the United States International Trade Commission
Inv. No. 337-TA-1266

NONCONFIDENTIAL RESPONSE AND REPLY BRIEF OF APPELLANT ALIVECOR, INC.

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Pursuant to Federal Circuit Rule 25.1(e) and the Protective Order issued in the International Trade Commission on May 26, 2021, and amended on August 18, 2021, AliveCor, Inc. is filing a confidential version of this brief that highlights the material marked confidential, and a non-confidential version including appropriate redactions. In the non-confidential version of this brief, confidential material has

been deleted on pages 5, 6, 7, 9, 10, 11, 12, 14, 16, 16, 17, 24, 25, 26, 27, 28, 31, and 50. The general nature of the deleted material is (1) confidential business information of AliveCor, Inc. regarding its finances, product information, and agreements with a third party not involved in this litigation; and (2) confidential business information of Apple Inc. regarding its internal communications and product information.

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INTRODUCTION AND SUMMARY OF ARGUMENT

Weaved throughout Apple's brief is the troubling view that its smartwatches are so successful and important that they are effectively beyond the Commission's reach. That cannot be correct. And though Apple touts its own successes in helping users of its smartwatches detect and confirm AFib, those self-promotions bury the critical fact that it has done so only by ***copying and infringing*** AliveCor's patented inventions while acting to exclude AliveCor from the market. AliveCor invented the AFib-detection-and-confirmation technology at issue here, not Apple. And AliveCor invested heavily domestically in that technology. The Commission was thus correct to find a Section 337 violation as to AliveCor's '731 and '941 patents, and it should have reached a similar determination as to AliveCor's '499 patent. None of Apple's arguments (or the Commission's arguments in defense of its '499 determination) counsel otherwise.

First, Apple wrongly attempts to shut the Commission's gates to startups like AliveCor based on an unduly narrow view of a domestic industry. AliveCor—a pioneering American company that has developed life-saving cardiac monitoring technology—is exactly the type of entity that Congress intended for the Commission to protect. The Commission thus correctly found a domestic industry because of AliveCor's domestic R&D contractor expenses. That finding is grounded in substantial evidence. Despite Apple's contentions, the R&D contractor expenses

pertain to a domestic-industry product, have a nexus to the asserted patents, and are substantial.

Second, the '731 and '941 patents are valid and infringed. On validity, Apple largely focuses its attack on the Commission's finding that secondary-considerations evidence showed copying and industry praise. Apple tries to downplay the praise and dismiss the copying as irrelevant, but it cannot overcome the high industry praise (including by Apple itself) and has no answer to its shelving of its ECG functionality in 2013, only to pick it back up around AliveCor's release of the KardiaBand in 2017. On infringement, Apple fares no better in challenging the Commission's construction of the "confirm" limitation in the asserted claims. That limitation simply does not require comparing the PPG data or results to the ECG data or results, nor does it require using the PPG data as an "input" to the ECG confirmation of an arrhythmia.

Third, Apple and the Commission both fail to explain how, at *Alice* step one, claims 16 and 17 of the '499 patent cover an abstract idea when those claims, in light of the specification and other evidence, are directed to a particular improvement in cardiac technology—an improvement that saves lives in the real world and had never before been implemented in a wearable device such as a smartwatch. Even if the claims were directed to an abstract idea, they would still pass *Alice* step-two muster because they contain an inventive concept. Apple and the Commission both argue

that ECGs and smartwatches were known, but they do not dispute that AliveCor's particular combination of PPG sensors and ECG sensors in a smartwatch with a machine-learning algorithm was a novel combination. AliveCor's patented combination pushed the field forward by solving the discrete medical problem of detecting and confirming AFib, particularly in ambulatory environments. Likewise, Apple and the Commission fail to justify the Commission's late-breaking claim construction of the "alert" limitation. When the limitation is not cabined to a literal message to take an ECG (as Apple wrongly argues) but instead given its full scope consistent with the original claim-construction order, the evidence indisputably shows that the Accused Products infringe.

Finally, the Court should decline to undo the Commission's exclusion order. The Commission properly considered and weighed all the public-interest factors—finding that there are many available alternatives to the excluded Apple Watches and that the exclusion would not impact any on-going medical studies. This determination is subject to extremely deferential review, and Apple offers no basis for this Court to set it aside.

ARGUMENT

I. THE COMMISSION CORRECTLY FOUND THE EXISTENCE OF A DOMESTIC INDUSTRY

Contrary to Apple's arguments (Br. 31-43), substantial evidence supports the Commission's determination (Appx11-23) that a domestic industry exists because

AliveCor made—"with respect to" the KBS[1]—"substantial investment in [the asserted patents'] exploitation, including … research and development." 19 U.S.C. § 1337(a)(3)(C). Through subparagraph (C), "Congress, believing the Commission's application of the domestic industry requirement had been too rigid, liberalized the domestic industry requirement by allowing that requirement to be satisfied by proof of non-manufacturing activity, such as licensing and research." *John Mezzalingua Assocs., Inc. v. Int'l Trade Comm'n*, 660 F.3d 1322, 1327 (Fed. Cir. 2011). While this liberalization was intended to protect American companies engaging in research and development of intellectual property, *see, e.g.*, OMRON HealthCare Br. 14; MDMA Br. 7-11, Congress still sought to "bar the use of section 337 by patent holders with no connection to the U.S. other than their ownership of a U.S. patent," *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1302 (Fed. Cir. 2013).

AliveCor's domestic R&D represents a classic example of investments falling within subparagraph (C). AliveCor is an American company, with an American founder, headquartered in America. It has poured millions into domestic research

[1] As the Commission explains (Br. 3-4), the KBS, or "KardiaBand System," is made up of the KardiaBand, the Apple Watch's PPG and motion sensors, and the KardiaApp, which includes AliveCor's KardiaAI and SmartRhythm algorithms. The ALJ found that the KBS practices the asserted patents. *See infra*, p. 9. Apple does not challenge that finding on appeal.

and development to create innovative solutions and products for a complex and life-threatening problem: AFib detection. None of Apple's challenges to the Commission's domestic-industry determination have any merit.

A. Substantial Evidence Supports The Commission's Determination That A Domestic Industry Exists Under Section 337(a)(3)(C)

1. AliveCor's R&D Contractor Expenses Are With Respect To The KBS

Apple wrongly faults (Br. 35-40) the Commission for crediting [redacted] Dollars of AliveCor's R&D contractor expenses because those expenses were "associated with" the [redacted] Product 1, which, unlike the KBS, is not a domestic-industry product ("DI product"). Contrary to Apple's view, an investment does not stop being "with respect to" a DI product simply because it also relates to and benefits a non-DI product. Apple cites no decision holding that the investments must relate exclusively to the DI product. In fact, Apple's cited Commission decision (Br. 35) holds the opposite. *See Certain Integrated Circuit Chips*, Inv. No. 337-TA-859, 2014 WL 12796437, *28 (I.T.C. Aug. 22, 2014) (the fact that domestic investment relates to non-DI articles "does not diminish that Realtek's investment is also with respect to the domestic-industry articles"). And, as this Court has put it, the investments simply "must ***pertain*** *to* products covered by the [asserted] patent." *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1361 (Fed. Cir. 2019) (emphasis added). That "pertaining" requirement is met when, as here, *see infra*,

pp.6-8, the investment is in technology that is used in a DI product. *Roku, Inc., v. Int'l Trade Comm'n*, ___ F.4th ___, 2024 WL 202033, *4 (Fed. Cir. Jan. 19, 2024).

Thus, the relevant question is whether the Dollars [redacted] in R&D contractor expenses that Apple claims pertains to the Product 1 [redacted] ***also pertains to the KBS***. Substantial evidence supports the Commission's determination that it does.

For starters, substantial evidence topples the core pillar of Apple's argument—that a wall of separation exists between investments in the KBS and the Product 1 [redacted]. Apple disregards the close relationship between the two products and to the asserted patents. Developing the Product 1 [redacted] became necessary only because Apple altered the way that its smartwatches report heart-rate data. Appx30083-30085. This change stopped AliveCor's SmartRhythm algorithm in the KBS from working. Appx30083-30085; Appx30198-30200. Undeterred by that anticompetitive conduct, AliveCor began developing the Product 1 [redacted] and Product 2 [redacted] to deploy the same technology in the KBS in form factors free of the Apple Watch. Appx30085-30086; Appx30200-30201; Appx30091-30092. The Product 1 [redacted] is thus a continuation of the patented technology in AliveCor's KBS.

The guts of the two products punctuate that point. As the ALJ found, both products include a smartwatch, activity sensor, PPG sensor, and ECG sensor. Appx110-11; Appx3083-30086; Appx30132-30135; Appx30070-30071;

Appx30101-30102. Both use the KardiaApp software, which includes AliveCor's SmartRhythm and KardiaAI algorithms. Appx30198; Appx30565-30566. Those two algorithms in particular embody "the core part of the invention." Appx30292-30293; *see* Appx30212. Given this overlap, advances to the KardiaApp, SmartRhythm, and KardiaAI made when AliveCor was developing the Product 1 [redacted] Product 1 [redacted]—technology that is also used in the KBS—pertain to the KBS. *See also* ITC Br. 24-26 (explaining additional technological overlaps between the Product 1 [redacted] and KBS). Indeed, based on that extensive overlap, the Commission found the Product 1 [redacted] would practice the asserted patents. *See infra*, p. 9.

Those advancements pertain to the KBS for an additional reason: They were actually rolled out to current KBS users. Even after Apple's anticompetitive conduct forced AliveCor to discontinue the KBS in 2019, AliveCor has continued to serve current KBS users. As part of that service, AliveCor updates the KardiaApp in the KBS, such that current KBS users benefit from the advances in the KardiaAI and SmartRhythm algorithms made while developing the Product 1 [redacted]. Appx30210-30211; Appx30227. And current KBS users continue to take ECGs using KardiaAI and receive SmartRhythm alerts. Appx30201-30202; Appx30227. As the Commission correctly found, investing in technology that is actually used in the DI product—the KBS—and that benefits current users of that product is an investment that pertains to the KBS. Appx16-19.

Nor is Apple correct (Br. 38-39) that the Commission's determination should be set aside because it treated the R&D contractor expenses differently under subparagraph (B) (employment of labor and capital) and subparagraph (C) (investment in exploitation of the patents). The question before this Court is whether substantial evidence supports the Commission's finding that AliveCor's R&D contractor expenses qualify under subparagraph (C). As explained, there is. Any error that the Commission made in excluding those same expenses from subparagraph (B) has no bearing on its determination under subparagraph (C).

The two cases on which Apple relies (Br. 39) do not suggest otherwise. *LePage's 2000, Inc. v. Postal Regulatory Commission*, 642 F.3d 225 (D.C. Cir. 2011), involved an agency's unexplained departure from its precedent. *See id.* at 233. Here, in contrast, the Commission's decision under subparagraph (C) ***is consistent*** with its prior decisions. *See supra*, p. 5. And in *Colorado Interstate Gas Co. v. F.E.R.C.*, 850 F.2d 769 (D.C. Cir. 1988), an agency issued irreconcilable decisions on the same day in two cases involving different parties. *See id.* at 744. Here, in contrast, there is a single decision involving one set of parties that is now before this Court on direct review.

2. AliveCor's R&D Contractor Expenses Have A Nexus To The Asserted Patents

Apple's nexus challenge largely relies (Br. 40-41) on the faulty premise that the Commission's determination rested solely on an AliveCor internal spreadsheet

describing the R&D contractor expenses. Although the ALJ's nexus finding was primarily based on the spreadsheet itself, the Commission additionally relied on testimony from Dr. Albert, Dr. Vander Veen, Mr. Raghavan, and Mr. Somayajula and also documentary evidence to conclude AliveCor had established that the R&D contractor expenses in the spreadsheet went to the "core part of the invention." Appx16-19; *see* ITC Br. 23-29. Based on that evidence, the Commission found that the R&D contractor expenses "are directed to the sensors, circuitry, and the housing structure of the AliveCor wristbands, *i.e.*, the KardiaBands." Appx18. That finding is thus well supported by the record.

The nexus is further shown by Apple's admission that [redacted] Dollars of the R&D expenses relate to the [redacted] Product 1. The Commission affirmed the ALJ's finding that the [redacted] Product 1 would practice the asserted patents because of the overlap in technology with the KBS—a product the ALJ also found practices the asserted patents. Appx3; Appx151-166; Appx214-219; Appx245-246; *see* ITC Br. 7-8. Apple contests neither finding on appeal. Under Commission precedent, a "nexus may readily be inferred based on evidence that the claimed investment is in the domestic industry article, which itself is the physical embodiment of the asserted patent." *Certain Integrated Circuit Chips*, 2014 WL 12796437, at *23; *see Certain Non-Volatile Memory Devices*, Inv. No. 337-TA-1046, 2018 WL 6012622, *25 n.11 (I.T.C. Oct. 26, 2018) ("Here, the nexus requirement of subsection (C) can be

presumed because the research investment is in the article protected by the patent."); *Certain Elec. Digital Media Devices & Components*, Inv. No. 337-TA-796, 2012 WL 6738157, *234 (I.T.C. Oct. 24, 2012) ("[I]f a product practices (*i.e.*, exploits) the patented technology then naturally any investments in said product also promote the exploitation of the patented technology."). That precedent hews to subparagraph (C)'s text because '"exploitation' is a generally broad term that encompasses activities such as efforts to improve, develop, or otherwise take advantage of the asserted patents." *Certain Integrated Circuit Chips*, 2014 WL 12796437, at *22.[2]

Even using a line-by-line-item approach, as Apple suggests, all the R&D activities were indisputably efforts to improve and take advantage of the asserted patents. Appx11717-11718. The few entries that Apple calls out (Br. 41) on their face show the nexus to the asserted patents. Expenses for "Confidential product information," "Confidential product information," or "Confidential product information" for the very products found to embody the asserted patents—the KBS and the Product 1—are investments designed to

[2] Apple appears to suggest (Br. 33-34, 40) that AliveCor failed to meet its burden because it did not have a witness testify directly about the spreadsheet. Apple cites no authority for this argument, and the Commission itself found that the spreadsheet "on its face provides at least some description of the activity beyond each cost that suggest a nexus to sensors, circuitry, and housing structure relating to AliveCor's wristbands, *i.e.*, the KardiaBands." Appx18. As explained in text, testimony from several witnesses also supported the nexus determination, even if that testimony did not explicitly address the spreadsheet.

exploit the patents.[3] Likewise, research and development into the [redacted] of the KardiaBand or its [redacted] relates to the exploitation of the asserted patents because the watchband portion of the KBS houses AliveCor's ECG acquisition and transmission module. Appx30101-30102.

This evidence of nexus is more than substantial. But if the Court were to conclude otherwise, the Commission's domestic-industry determination may be affirmed under subparagraph (B)—which does not have a nexus requirement to the asserted patents—because AliveCor engaged in, "with respect to" the KBS, "significant employment of labor or capital." 19 U.S.C. § 1337(a)(3)(B). As explained, the Commission determined, in its analysis of subparagraph (C), that the R&D contractor expenses pertain to the KBS (*see* Appx16-19), but it did not correct the ALJ's exclusion of those same R&D investments under subparagraph (B), which evaluates significant labor or employment costs pertaining to an article protected by the asserted patents (*see* Appx23-26; Appx270-275). Because those investments are significant (as explained *infra*, Part I.A.3), a domestic industry exists even in the

[3] Many entries are for the "[redacted] project." *See* Appx11717-11719. "[redacted]" was an earlier name of the [redacted] *See* Appx916.

absence of a nexus between AliveCor's R&D contractor expenses and the asserted patents.[4]

3. AliveCor's R&D Contractor Expenses Are Substantial

Contrary to Apple's arguments (Br. 42-43), the Commission correctly found that AliveCor's [redacted] Dollars in domestic R&D contractor expenses constitutes a "substantial investment" by comparing it to AliveCor's [redacted] Dollars in foreign R&D contractor expenses. Appx19-23. That ratio of domestic-to-foreign contractor expenses mirrored AliveCor's own allocation of internal R&D labor, which was over 80 percent U.S. based. Appx21.

Citing no authority, Apple claims (Br. 43) that this finding is "obviously flawed" because the analysis supposedly must focus on whether the domestic expenses themselves are substantial. But subparagraph (C) does not dictate such a circumscribed approach. Rather, as this Court has explained, "substantial" refers to a "quantitative analysis" that looks to "an increase in quantity, or to a benchmark in numbers," *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883 (Fed. Cir. 2015), such

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[4] As an alternative ground for affirmance, this issue did not need to be raised in AliveCor's opening brief on its appeal and is properly raised in response to Apple's brief. *See, e.g.*, *Aventis Pharma S.A. v. Hospira, Inc.*, 637 F.3d 1341, 1343 (Fed. Cir. 2011); *Nautilus Group, Inc. v. Icon Health & Fitness, Inc.*, 437 F.3d 1376, 1378 (Fed. Cir. 2006). Nor would affirming on this basis run afoul of the *Chenery* doctrine because the Court would not be making "a determination of fact not previous made by the agency." *In re Comiskey*, 554 F.3d 967, 974 (Fed. Cir. 2009) (quotation omitted). The Commission already found that the R&D contractor expenses pertain to the KBS and that those expenses are substantial. Appx16-23.

that a qualitative analysis alone is not sufficient. But, within that framework, as the Commission explains (Br. 30 n.12), "the appropriate context for evaluating whether domestic investments are significant or substantial may vary depending upon the facts of a particular investigation." *See, e.g.*, *Certain Carburetors & Prods.*, Inv. No. 337-TA-1123, 2019 WL 5622443, *6-7, *10-11 (I.T.C. Oct. 28, 2019).

The domestic-to-foreign comparison is a quantitative analysis because it is a benchmark in numbers and shows an increase in quantity of domestic investment over foreign investment. Indeed, in *Roku*, this Court recently affirmed the Commission's finding of substantiality based on "the amount of [the complainant's] domestic R&D investments relative to its total R&D expenditures." 2024 WL 202033, at *5, *affirming Certain Elec. Devices*, Inv. No. 337-TA-1200, 2021 WL 3185836, *89 (I.T.C. July 9, 2021) (comparing domestic-to-foreign R&D in the disputed technology).[5] The Commission undertook the same domestic-to-foreign analysis here.

[5] The Commission has long used that comparison as one way among many to evaluate the substantiality of an investment. *See, e.g.*, *Certain Carburetors*, 2019 WL 5622443, at *13 ("Commission has also assessed the relative domestic contribution to the protected article by comparing complainant's product-related domestic activities to its product-related foreign activities."); *Certain Integrated Circuit Chips*, 2013 WL 6858006, at *9 ("Realtek's domestic investments related to the domestic industry products do not appear to be 'significant' or 'substantial' when considered alone or when compared to Realtek's foreign investments.").

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The Commission, moreover, supplemented that quantitative analysis with an assessment of qualitative factors, which it determined also weigh in favor of finding substantiality. *Certain Elec. Candle Prods.*, Inv. No. 337-TA-1195, 2022 WL 5241198, *7 (I.T.C. Oct. 4, 2022) ("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.") (quotation omitted). The Commission found that the "record certainly evidences a qualitative effort on the part of [AliveCor] to refine and improve the KBS features like SmartRhythm and KardiaAI—which have a clear nexus to the heart rate and ECG analysis limitation received in the Asserted Claims." Appx19. Apple leaves this finding unchallenged.

The Commission thus acted well within its discretion and the statutory mandate in determining, based on quantitative and qualitative considerations, that AliveCor's investment was substantial under the circumstances of this case. Appx19-23.[6]

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[6] As the Commission showed (Br. 31), Apple waived its argument (Br. 43) that AliveCor's [redacted] investment is not substantial because it "represent[s] roughly [redacted] of AliveCor's revenue for the same time period." That standard of measurement also makes little sense. Apple itself had revenue of over $383 billion in 2023. *See* https://www.macrotrends.net/stocks/charts/AAPL/apple/revenue. By any measure, R&D investment of [redacted] of that revenue to exploit a patent would be substantial. Regardless, the Commission's decision is supported by substantial evidence—the domestic-to-foreign comparison and qualitative factors discussed in text.

B. In Any Event, A Domestic Industry Exists Under Section 337(a)(3)(B)

Even if Apple were correct that the Commission erroneously found a domestic industry under subparagraph (C), the Court should not reverse on that basis. The Commission made multiple errors that led it to mistakenly conclude that AliveCor did prove a domestic industry under subparagraph (B)—errors that either provide an alternative ground for affirmance or necessitate a remand for further proceedings.

Specifically, the Commission should have considered the Product 1 [redacted] and the Product 2 [redacted] as DI products because they were "in the process of being established." 19 U.S.C. § 1337(a)(2). The Commission has held that "the process of being established" requires (1) taking "necessary tangible steps to establish an industry in the United States," and (2) a "significant likelihood that the industry requirement will be satisfied in the future." *Certain Non-Volatile Memory Devices*, Inv. No. 337-TA-1046, 2018 WL 6012622, *18 (I.T.C. Oct. 26, 2018) (quotation omitted).

The Commission recognized that AliveCor was taking steps to establish the Product 1 [redacted] and Product 2 [redacted] but found no significant likelihood that the economic component would be satisfied in the future. Appx289-293. That latter determination is not supported by substantial evidence. AliveCor presented detailed production plans for the Product 1 [redacted] (Appx30207-30208; Appx3072 (describing contents of CPX-045C, a spreadsheet laying out production plans)), purchase orders with AliveCor's manufacturer of the Product 1 [redacted] (Appx16386), and documents

showing AliveCor was seeking FDA approval for the product (Appx30178). Additionally, at the time of the hearing, AliveCor was testing Product 2 [redacted]s in preparation for an FDA submission. Appx30216-30217.

The Commission's determination is also legally erroneous to the extent it was based on AliveCor's failure to prove a significant likelihood that these products would reach commercial production. Appx289-293. The Commission has previously reversed an ALJ's initial decision that assessed the likelihood of future "commercial production." *Certain Non-Volatile Memory Devices*, 2018 WL 6012622, at *27 (I.T.C. Oct. 26, 2018). Prototypes and even a "precursor of what may someday be a prototype" are sufficient to establish a domestic industry so long as sufficient investment goes toward them. *Id.* at *20, *27. Here, AliveCor did not just have plans to produce prototypes; it actually created them by the time of the hearing. Appx30207-30208; Appx30216-30217. And the ALJ found that those prototypes practice the asserted patents. Appx161-166; Appx218-219; Appx245-246. That by itself shows an industry in those products is in the process of being established. As was true in *Certain Non-Volatile Memory Devices*, simply "because [AliveCor] has not yet arrived at the final stages of commercializing [the products], does not mean that [AliveCor] does not have a domestic industry in the process of being established with respect to the [prototypes] protected by the asserted patents." *Certain Non-Volatile Memory Devices*, 2018 WL 6012622, at *27.

The Commission's errors have two important implications. If the [redacted] is a DI product, then the challenged [redacted] in R&D contractor expenses necessarily relate to a DI product and cannot provide a basis for reversal. *See supra*, Part I.A. And if the [redacted] is a DI product but the Court were to hold that the Commission erred in finding the [redacted] in R&D contractor expenses to be substantial under subparagraph (C), then the Court should remand so the Commission can determine whether the [redacted] in R&D contractor expenses related to the [redacted] and the additional excluded R&D regulatory labor expenses are nevertheless significant for purposes of subparagraph (B). In assessing subparagraph (B), the ALJ had excluded all regulatory labor expenses and R&D contractor expenses related to the [redacted] (Appx270-275)—an error the Commission did not correct (Appx23-26).

Apple and the Commission both wrongly suggest (Apple Br. 32; ITC Br. 7-8) that AliveCor needed to appeal these issues and argue them in its opening brief. A party may appeal a judgment only if the party "seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment." *Raytheon Co. v. Gates*, 318 F. App'x 890, 890-91 (Fed. Cir. 2008) (quotation omitted). Thus, a party must file an appeal or cross-appeal only when "acceptance of the argument it wishes to advance would result in a reversal or modification of the judgment rather

than an affirmance." *Bailey v. Dart Container Corp. of Mich.*, 292 F.3d 1360, 1362 (Fed. Cir. 2002).

Here, AliveCor is not seeking to enlarge its own rights or lessen Apple's rights—AliveCor is simply presenting additional grounds to support the Commission's domestic-industry determination. No party's rights depend on the *reason* that a domestic industry exists; it matters only that one exists, as the Commission found. Nor is AliveCor seeking to reverse or modify the Commission's final determination based on any domestic-industry argument. It is Apple that seeks to do that. These contingent issues are properly raised now in response to Apple's and the Commission's principal briefs.

II. THE COMMISSION CORRECTLY DETERMINED THAT THE ACCUSED PRODUCTS INFRINGE VALID CLAIMS OF THE '731 AND '941 PATENTS

The Commission correctly determined that the Accused Products infringe valid claims of the '731 and '941 patents. Appx27-47; Appx136-151; Appx211-214. Apple's obviousness (Br. 59-75) and noninfringement (Br. 44-59) arguments have no merit.

A. Substantial Evidence Supports The Commission's Nonobviousness Determination

Although obviousness is ultimately a question of law, "it is based on underlying questions of fact, including the level of ordinary skill in the art, the scope and content of the prior art, the differences between the claims and the prior art,

motivation to modify or combine with a reasonable expectation of success, and objective indicia of nonobviousness." *Acorda Therapeutics, Inc. v. Roxane Lab'ys, Inc.*, 903 F.3d 1310, 1328 (Fed. Cir. 2018). This Court reviews factual findings underlying an obviousness determination for substantial evidence. *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1357 (Fed. Cir. 2019).

Here, the Commission correctly found that Apple had not met its prima facie burden of showing the prior art, AMON, rendered obvious certain dependent claims. Appx203; Appx232-233; Appx257. And for the other claims in which the Commission did find that Apple had met its burden, the Commission nonetheless correctly concluded that the patents were not obvious after a thorough consideration of the required secondary considerations. Appx203; Appx232-233; Appx257. These findings are supported by substantial evidence and outweigh Apple's prima facie case.

1. Apple Failed To Show Prima Facie Obviousness For Some Dependent Claims

Apple largely focuses (Br. 60-67) on one piece of prior art, AMON, and despite what the Commission found, argues that AMON renders obvious certain dependent claims in all the asserted patents. Apple is wrong as to each claim:

ECG-Rhythm-Strip-Display Claims. Claim 21 of the '941 patent and claim 15 of the '731 patent both require a smartwatch that "display[s] an ECG rhythm strip" from electrical signals sensed by the ECG. Appx10092; Appx10073. To show

AMON disclosed these claims, Apple plucks (Br. 61-64) one figure in AMON—figure 4, which is a sample ECG measurement—out of context.

But as the Commission correctly found, "[t]here is no disclosure in AMON that the rhythm strip illustrated [in figure 4] was ever on a device driven by AMON's processor." Appx198. Apple asks this Court to hold that because the AMON article shows a theoretical prototype watch with a display and a separate figure labeled "ECG measurement" (Figure 4), an ECG rhythm strip must be displayable to the user of the AMON device. But nothing in AMON or elsewhere in the record mandates this inferential leap. In fact, for at least three independent reasons, the record provides substantial evidence that the ECG rhythm strip was *not* displayed on the AMON device.

First, AMON teaches using ECG data to determine heart rate and QRS durations. Appx198. Nothing requires displaying the ECG rhythm strip in reaching these calculations. Appx198-199. Instead, AMON teaches the "average RR, QRS, and QT distance values" as being displayed. Appx199 (citing Appx11969). Nowhere does AMON disclose displaying an ECG rhythm strip in communicating these values. Appx198-199. In fact, the only time figure 4 and its ECG rhythm strip are mentioned is to show that the ECG sensor on the AMON device would work. Appx11969; *see* ITC Br. 49. Thus, despite Apple's contention (Br. 63), figure 4 does not describe "the output" of the AMON device. Moreover, and as confirmed

by Apple's expert and AMON itself, AMON's ECG provided poor or no results and did not disclose a wrist-monitoring device that performs any detection of any medical condition on its own. Appx31160-31161.

Second, outside of AMON itself, the Commission credited the testimony of AliveCor's expert Dr. Efimov that he did not find any disclosure in AMON of displaying a rhythm strip as required by the claims. Appx197-199; Appx31269; *see* ITC Br. 48. Instead, Dr. Efimov testified that figure 4 was simply a "plot for publication purposes" to demonstrate the efficacy of the single lead ECG sensor, not something to be displayed on the device. Appx31269-31270. While Apple's expert testified to the contrary (Appx31129; Appx31141-31142), the Commission was free to credit Dr. Efimov over Apple's expert—especially given the lack of link in the text of AMON between the ECG rhythm strip in figure 4 and the display.

Third, Apple offers no reason why a patient/user of the AMON system would have needed to view an ECG recording. As the Commission correctly found, while such recordings are useful for a doctor/cardiologist, there is no evidence that displaying such a recording would be useful to a lay person who has no experience analyzing or interpreting ECG rhythm strips. Appx199. Indeed, Apple concedes (Br. 63) "that ECG devices have been creating digital rhythm strips for many years, so that ***physicians can use the data*** to diagnose heart problems" (emphasis added).

The Court likewise should not accept Apple's argument that a POSITA would modify AMON to require such a display. As the Commission explained, other than being "attractive imagery," displaying those strips would not benefit a lay person wearing the AMON device. Appx199.

Machine-Learning Claims. Claims 3 and 5 of the '731 patent and claim 17 of the '499 patent each disclose machine-learning algorithms to detect arrhythmia. Appx10039; Appx10072. But Apple concedes (Br. 64) that in AMON, ECG inputs are fed into an algorithm only to determine what those signals are, not to detect arrhythmias. That alone is dispositive substantial evidence supporting the Commission's finding that AMON does not render these claims obvious. Moreover, to the extent Apple argues (Br. 64-65) that a POSITA would have background knowledge of machine learning generally to detect arrhythmia, that argument is contradicted by Apple's own expert who testified that, even today, physicians are skeptical of using machine learning for arrhythmia diagnosis due to its lack of transparency, which teaches away from using machine learning. Appx15792; Appx30923; *see* AliveCor Br. 51-52.

Additionally, Apple waived any separate basis that claim 5 of the '731 patent is obvious, as Apple did not distinguish between claims 3 and 5 of the '731 patent in arguing obviousness below. *See* Appx227; Appx1300; *see also* ITC Br. 50-51.

Mathematical-Analysis Claims. As to the mathematical-analysis limitations in claims 9 and 10 of the '731 patent, Apple fails to offer (Br. 66-67) any evidence indicating that a POSITA—when viewing AMON in light of Almen—would have been motivated to use PPG data in AMON's ECG algorithm. Indeed, the Commission found that even accepting Apple's expert's opinion "that the claimed technique was well-known, the one reference Apple cites as disclosing the transform discusses it as applying to ECG data, not PPG data, as the claim requires." Appx229. Apple's assertion (Br. 66) that the '731 patent discloses this limitation as "known in the art" is likewise incorrect, as that disclosure is also directed to ECG data, not PPG data. *See* ITC Br. 52.

2. Secondary Considerations Overcome Any Prima Facie Showing Of Obviousness

For any claim that the Commission found Apple to meet its prima facie burden of obviousness, it found that secondary considerations of nonobviousness overcame that showing. Appx44-47; Appx203. That conclusion is correct and supported by substantial evidence.

(a) Apple Copied AliveCor's Patented Technology

A determination of copying is "strong evidence of nonobviousness." *Volvo Penta of Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1213 (Fed. Cir. 2023). Although a finding of copying requires more than just similarities between a product and the claimed invention, *In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995), Apple

did much more than that. Apple actively met with AliveCor for years, examined AliveCor's products numerous times, and changed its [Confidential product information] strategy *after* AliveCor announced the release of SmartRhythm. *See* Appx201-202 (collecting evidence); *see also* ITC Br. 42-44 (cataloging evidence in timeline). This is far more than a scintilla of evidence, and the Commission rightly found this substantial evidence of copying supported the conclusion that the claimed inventions would not have been obvious. Appx44.

Apple asks (Br. 71) the Court to disregard much of this evidence because it pre-dates the November 2017 public release of the KardiaBand with SmartRhythm. Yet Apple fails to cite any authority holding that this public-release line is dispositive, particularly where, as the Commission found (Appx201-202; Appx44), Apple indisputably obtained confidential information about the KBS from AliveCor and the FDA in developing its infringing Series 4 Apple Watch (*e.g.*, Appx31202-31213; Appx40001-40002). As the Commission explains (Br. 43 n.15), "that Apple used information that predates the [KardiaBand] shows the lengths that Apple went to obtain information about and ultimately copy AliveCor's [KardiaBand]."

When all the pre-2017 evidence is considered, the copying conclusion is overwhelming. But even considering just the post-release evidence, there remains substantial evidence of copying.

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Specifically, after the public release of the KardiaBand, Apple met with AliveCor executives and inventors to learn about the KBS, and Apple engineers used AliveCor's SmartRhythm as a guide in developing its own product. Appx201-202; Appx16285 ([redacted] circulating one of AliveCor's blog posts discussing motivations behind SmartRhythm's development and how it worked with the KBS (Appx12007) and comparing SmartRhythm with Apple's [redacted] alert); *see* ITC Br. 42-43 n.15.

Just as importantly, Apple shelved developing its ECG functionality in 2013 only to pick it back up in 2017. Appx40001-40004; Appx31210. What else happened around that time? AliveCor publicly released its KardiaBand with SmartRhythm. *See* Appx15925; Apple Br. 14-15. The Commission reasonably found that this timing was no coincidence and was probative of Apple's copying. *See, e.g.*, *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1329 (Fed. Cir. 2009) (holding that the defendant's initial attempts at one design together with the "prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness").

Apple attempts (Br. 73-74) to explain away this evidence (and delay) as caused by regulatory, rather than technical, challenges. But testimony from Apple's own witnesses shows otherwise. For example, Dr. Waydo admitted the [redacted] that Apple was considering as late as 2014 "offered poor [redacted] and generated very high [redacted]." Appx30790; *see* Appx12026. He further

testified that it took Apple "a lot of work for many, many years" to incorporate the Confidential product information [redacted] sensors with the [redacted] algorithm and to incorporate the Confidential product information [redacted] sensors with the classification algorithm to reliably detect the presence of AFib. Appx30810. Apple's expert, Dr. Stultz, testified that he had no reason to dispute that testimony. Appx31151-31152.

Moreover, Apple's contention that "regulatory challenges" delayed the incorporation of the ECG functionality into the Apple Watch defies the evidence and common sense. Apple began development to incorporate ECG functionality into the Apple Watch in 2012 (Appx30738) but did not release the ECG app until 2018 (Appx11738). This six-year delay in releasing the ECG functionality supports the Commission's reasonable inference that Apple did not believe it was worth doing so until it saw AliveCor blaze a trail in wearable and mobile health technologies. Recall that when the Apple Watch was first released in 2015, Apple marketed it as a fashion accessory—not a health device. Appx16341; Appx13201-13208 ("Apple's new smartwatch was designed to be a fashion accessory."); *see* Appx13209-13210 (Director of Apple Watch Product Marketing testifying Apple did not conduct any research or analysis to determine whether Apple Watch customers would want an Confidential product information [redacted] or the [redacted]). This development timeline thus does not weigh against copying; it supports it. *See, e.g.*, Appx30812-30815; Appx16356; Appx11652.

Indeed, the relatively short time Apple took to overcome these regulatory challenges further suggests that it was AliveCor's products that drove Apple to release the Accused Products when it did.[7] Dr. Waydo testified, for example, that Confidential product information the [redacted] was not released along with the HHRN in September 2017—five years after Apple started working on the feature—because the Confidential product information [redacted] hardware was "still in active development," Apple was "approaching [its] clinical validation trials," and Apple would still need to "get through the regulatory clearance process before [it] could release those features." Appx30745. Apple then released the ECG app in December 2018. *Id.* If incorporating ECG technology into the Apple Watch was so technically simple, and Apple was able to obtain regulatory clearance in such a short period of time, it should not have taken the world's most valuable company six years to complete this process.

Furthermore, the evidence shows that Apple was not merely "benchmarking" its products, as it now maintains (Br. 72), but that Apple piggybacked off AliveCor's inventions. When it discovered how AliveCor used SmartRhythm in the KBS, Apple deviated from its original plan to release the Confidential product information [redacted] and [redacted] as standalone Confidential product information features, and instead decided to [redacted] the two features. Appx11499; *see* Appx2882-

[7] It is undisputed that Apple obtained confidential information from the FDA about AliveCor's KardiaBand and that Apple researched and compared its software with Software in AliveCor's KBS. *See* ITC Br. 42-43.

2886. Likewise, after it found out about SmartRhythm, Apple began tracking how many users took an [Confidential product information] after receiving an [Confidential product information] (Appx11499; Appx16346-16355) and prepared a presentation stating that a goal of its [Confidential product information] classification algorithm was to confirm [Confidential product information] alerts (Appx11499). That presentation also proposed providing [Confidential product information] "similar to AliveCor." Appx11492. And just before Apple released the IRN and ECG, it updated its presentations to reflect that using the [Confidential product information] as a [Confidential product information] for the [Confidential product information] app was "done." Appx16365.

Finally, in its post-2017 FDA submission, Apple stated that the KardiaBand was "the most similar product on the market." Appx202. This submission, when coupled with the ongoing relationship with AliveCor and Apple's many internal emails saying that it was tracking and benchmarking AliveCor, provides still further substantial evidence of copying.

(b) The Industry Praised AliveCor's Patented Technology

Like copying, substantial evidence of industry praise, including by Apple itself, supports the Commission's finding of nonobviousness. *See* Appx200. The Commission has thoroughly shown (Br. 44-45) the extensive praise from the industry (including from Apple itself) that AliveCor received for the KBS. Apple focuses on just a few examples of industry praise while ignoring the rest.

Specifically, Apple attacks (Br. 69) the 2018 medical journal article praising the accuracy of the KardiaBand's ECG algorithm for detecting atrial fibrillation.

Apple characterizes the article as self-serving because the lead author was on the advisory board of AliveCor. But the article was published in the *Journal of the American College of Cardiology*, a ***peer-reviewed, preeminent*** medical journal, was collectively authored by nine doctors, and was reviewed through the American College of Cardiology's normal procedures. Appx11644-11651; Appx31198-31199; *see* ITC Br. 45-46. That is industry praise at its finest.

Similarly, Apple discounts (Br. 69-70) another article praising AliveCor's KBS (Appx11632-11643) because the doctor quoted therein "helped test the KardiaBand" and otherwise relies heavily on information from AliveCor's then-CEO. Praise from someone who actually tested and used a product, however, is highly probative. *See* ITC Br. 46.

Finally, Apple claims (Br. 70) that the Commission should have discounted the industry praise because much of it focuses on the ECG function of KardiaBand and its associated software. But, as the Commission recognized, the ECG functionality is an element of the claimed invention, and the industry praise is not for the ECG alone, but for how the ECG is used in the KBS. Appx200; *see* ITC Br. 46. In any event, the articles are not limited to the ECG feature in the context of KBS; they also discuss SmartRhythm. *See* Appx11629-11631; Appx11999-12004; Appx11632-11643; Appx11644-11651.

Apple's argument (Br. 70-71) that "AliveCor failed to connect the evidence of industry praise to the novel elements of the claims" is thus simply wrong. It is difficult to conceive of praise that is more exacting in its acclaim of the claimed features, and Apple cites no authority requiring industry praise be rendered with "limitation by limitation" precision. This Court has held that "[o]bjective evidence of nonobviousness need only be reasonably commensurate with the scope of the claims." *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013). This means that "industry praise is probative of nonobviousness ***even if it was not precisely limited to the point of novelty of the claimed combination***." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1334 (Fed. Cir. 2019) (emphasis added).

All the above suffices to show why Apple's industry-praise arguments fail. But what is even more telling is that Apple ignores the substantial evidence of industry praise for KardiaBand ***from Apple itself and consumers of Apple products***. *See* ITC Br. 45-46. Praise from competitors is highly probative evidence of nonobviousness because they are not likely to praise an obvious advance over the prior art. *See Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016) (en banc) ("[P]raise in the industry for a patented invention, and specifically praise from a competitor tends to indicate that the invention was not obvious.").

For example, Dr. Waydo, Apple's Director of Health Algorithms, testified that he and others at Apple "tried out" the KardiaBand because they had some

"excitement about these products, because [Apple] like[s] it when people build innovative things on [its] platform." Appx30784. Dr. Waydo further testified that Apple Watch users could benefit from combining ECG and PPG technologies in the context of the KardiaBand. Appx13667. Another Apple employee wrote that KardiaBand was "a high quality accessory and works really well with the Watch" and that "[w]ith a few small tweaks this could be a great experience for Apple Watch customers." Appx16279-16280. And in a November 2017 email discussing SmartRhythm's release, yet another Apple employee, in comparing AliveCor's SmartRhythm with Apple's Confidential product information, explained that AliveCor's use of Confidential product information sensing would increase the likelihood that users could confirm the presence of arrhythmias with Confidential product information recordings for "a ***higher chance*** of catching paroxysmal a-fib (with their Confidential product information) than our Confidential product information." Appx12010. This praise from Apple is striking not only because it comes from one of AliveCor's direct competitors, but also because it specifically relates to the claimed features (*i.e.*, detecting arrhythmias with PPG and confirming them with ECG).

(c) The Commission Properly Weighed The Evidence Of Copying And Industry Praise

Apple's challenge to the Commission's weighing of secondary considerations evidence against any prima facie case fails for two reasons.

First, contrary to Apple's characterization (Br. 67-69), the Commission expressly concluded that "the secondary considerations are … strong," not weak.

Appx200-203; Appx42-47; *see* ITC Br. 47. That finding is supported by substantial evidence. *See supra*, Part II.A.2(a)-(b).

Second, Apple's argument rests on the erroneous premise (Br. 67-69, 74-75) that AliveCor was required to make an "extremely strong" showing on secondary considerations to prevail over Apple's prima facie case. "Evidence of secondary considerations may often be the most probative and cogent evidence in the record." *Apple Inc.*, 839 F.3d at 1052 (quotation omitted). It can "establish that an invention appearing to have been obvious in light of the prior art [*i.e.*, a strong prima facie case] was not" actually obvious after all. *Id.* And it is not just to be considered "when the decisionmaker remains in doubt after reviewing the art." *Id.* at 153. Rather, it is critical evidence that can "guard against slipping into use of hindsight." *Id.* at 152 (quotation omitted). Plainly then, and as the Commission correctly found here, strong evidence of secondary considerations ***can*** overcome even a purportedly strong prima facie case.[8]

Apple's cited authority does not suggest otherwise. In *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997), the Court said that only a jury "***may***" still find a claim obvious in light of strong secondary

[8] Indeed, this Court just recently remanded a case to the PTAB for further consideration of secondary considerations even though the Court found a strong prima facie case. *See Volvo Penta*, 81 F.4th at 1215. It imposed no super showing of secondary consideration in so doing.

considerations. It does not say that a factfinder ***must*** do so. If anything, *Motorola* suggests some deference is owed to the factfinder and that courts should not quickly "second-guess" the factfinder's weighing of secondary considerations against the prima facie case. The other cases that Apple cites are also distinguishable because they either involved minimal evidence of secondary considerations, *see Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373-75 (Fed. Cir. 2018), or similar to *Motorola*, ***upheld*** fact findings based on weighing the secondary considerations, *see Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

B. Substantial Evidence Supports The Commission's Infringement Determination

Each of the infringed claims of the '941 and '731 patents requires the smartwatch's PPG sensor "detect the presence of an arrhythmia" and the ECG sensor "confirm the presence of the arrhythmia." Appx10072; Appx10092. As relevant to Apple's appeal, the Commission construed the phrase "confirm the presence of the arrhythmia" to '"not require a comparison of the ECG sensor results' to the 'discordance determination' in the '941 patent or the 'PPG data' in the '731 patent." Apple Br. 45 (quoting Appx127; Appx207). Apple has identified no error in the Commission's construction and thus no basis to set aside its infringement determination.

1. The Commission Properly Construed The Claim Term "Confirm The Presence Of The Arrhythmia"

The Commission correctly construed the phrase "confirm the presence of the arrhythmia" as not requiring a comparison of ECG results to PPG data or results. Appx127; Appx207; Appx326-328; Appx330-332. Apple challenges (Br. 46) that construction by arguing the claims do, in fact, require a "correlation between the PPG and ECG results." Yet it strains to find that correlation in the actual text of the claims and likewise finds no support in the specification or extrinsic evidence.

For example, Apple's textual argument is so thin that it is relegated (Br. 48-49) to trying to squeeze significant meaning into the claims' mundane choice of articles. Apple points out that the claims first require the PPG sensor to detect "***an***" arrhythmia and only then confirm "***the***" arrhythmia using an ECG. But nothing about this article choice shows the claims require the PPG and ECG to run on the same data or to compare their results to each other. A person could take an ECG well after the PPG sensor detected "an" arrhythmia and still confirm "the" arrhythmia that the PPG sensor detected. The article choice imparts no requirement that it be the same episode of arrhythmia, nor that it even be the same species of arrhythmia.[9] After all, "arrhythmia" was construed broadly (by agreement) to be

[9] Of course, an instance where the PPG detects, and the ECG confirms, the same episode and/or the same species of arrhythmia falls within the scope of the claims. For example, the PPG sensor might detect an episode of AFib from an irregularly

any "cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx127; Appx145.

Apple also wrongly contends (Br. 46-48) that the Commission's construction conflates "confirming" and "detecting" because the ECG would simply be "detecting" ***another*** arrhythmia, not confirming "the arrhythmia" that the PPG technology detected. In pursuing this argument, Apple resorts to unsupported and context-bereft attorney argument regarding the supposed meaning of the term "confirm." Apple contends (Br. 46) that something can be "confirmed" only when that same specific thing, or a hypothesis regarding that thing, came before it. Its examples include confirming a doctor appointment, or experimentation confirming a hypothesis. Although conceptually simplistic, these examples are irrelevant because they have nothing to do with how "a person of ordinary skill in the art would have understood claim terms at the time of the invention." *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1372-73 (Fed. Cir. 2005); *see, e.g.*, *Unitherm Food Sys., Inc. v. Swift–Eckrich, Inc.,* 375 F.3d 1341, 1351 (Fed. Cir. 2004) (proper definition is "definition that one of ordinary skill in the art could ascertain from the intrinsic evidence in the record").

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irregular heart rhythm, and an ECG taken shortly thereafter could then confirm AFib from the absence of P-waves in measurements from that same episode. *See* Appx30324; Appx30447-30448; Appx30456.

The proper context of the claimed invention—as shown in the intrinsic record—is cardiac monitoring, and more particularly the usage of an on-demand ECG technology that measures the electrical signals across a user's heart to confirm a suspected arrhythmia. *See* Appx10064 (10:10-28); Appx10069-10070 (20:62-21:19); Appx10072 (25:25-46); Appx10083 (fig. 7); Appx10085 (4:14-32); Appx10090 (13:29-51); Appx10091 (15:22-43, 15:49-59); Appx30292-30293; *see also* AliveCor Br. 7-14. It is through this lens, *and only through this lens*, that the scope and meaning of the claim terms should be determined.

As disclosed in the patents, ECG provides a superior cardiac measurement tool to determine whether a user has an arrhythmia. *See* AliveCor Br. 6-9, 24-25 (collecting evidence). For example, it is well known to those of ordinary skill in the art that the absence of P-waves in an ECG—a critical portion of the electrically generated PQRST waveform across the human heart, representing atrial depolarization—is a strong medical indication that a user/patient is experiencing AFib. Appx30049-30050; Appx30290-30293; Appx30324; Appx30343-30344; Appx30350-30352. It is likewise well known to those of ordinary skill in the art that PPG-based detection mechanisms cannot detect the presence or absence of P-waves, because PPG uses "optical" technology to detect changes in blood-volume and derive/compute heartrate; it is *not* an electrical measurement. Appx30049; Appx30066; Appx30292-30293; Appx30324; Appx30343-30344; Appx30351-

30352. Thus, a person of ordinary skill in the art, considering the claim term "confirm the presence of the arrhythmia" within the context of the intrinsic record and field of technology, would know that ECG provides a *clinically-understood confirmatory* measurement tool. The claimed inventions' use of ECG as a confirmation of the arrhythmia is therefore necessarily distinct from the "detection" of an arrhythmia provided by PPG-based technologies.[10]

On top of the claim language, nothing in the specification requires comparing the ECG data or results with the PPG data or results, as Apple wrongly contends (Br. 49-50). In fact, the Commission dutifully compiled all the provisions in the specification showing the ECG is meant to be taken later in time than the PPG. *See* Appx132-135. Indeed, the provisions cited by Apple also confirm that the ECG is to be taken *after* the PPG-based detection of arrhythmia. *See* Apple Br. 47-50 (citing Appx10072 (26:42-46); Appx10092 (18:12-18); Appx10091 (15:27-32, 15:39-43, 15:55-59)). This sequential timing—as opposed to simultaneous occurrence—reinforces that the PPG and ECG functions do not have to be based on the same data and that the claims require no comparison or correlation between the two.

[10] Apple's cited cases, including *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000), are therefore inapposite. "Detect" and "confirm" inherently have different meanings in the context of the intrinsic record and as understood by a person of ordinary skill in the art, and there is no basis to conclude that the Commission construed "confirm" to "equate" the two terms, as Apple wrongly argues.

Turning from the intrinsic record to extrinsic evidence, even Apple's invalidity expert Dr. Stultz—the only practicing cardiologist testifying as an expert—agreed with AliveCor and its expert Dr. Jafari, testifying that the "confirm" limitation entails *an underlying arrhythmia* being "confirmed" by *a subsequently-taken* ECG. Appx31154-31156.[11] Dr. Stultz's testimony was consistent with an earlier opinion he offered during claim construction, where he stated that a person of ordinary skill "would have understood that after the claimed method and the system determine a possibility of 'an arrhythmia,' the claims require obtaining ECG data 'to confirm the presence of the arrhythmia.'" Appx3008. Thus, both experts agreed—as the Commission found—that the claims do not require simultaneously-occurring PPG and ECG cardiac measurements for the ECG to "confirm" the arrhythmia.

2. Apple's Noninfringement Argument Fails Under The Proper Construction

Apple does not dispute that, as the Commission found, the Accused Products meet the "confirm the presence of the arrhythmia" limitation under the Commission's construction. Appx148-150. Instead, Apple argues (Br. 51-54) only that the Accused Products do not infringe under its preferred "correlation"

[11] It is immaterial that Dr. Stultz was testifying about claim scope from an invalidity standpoint. *See, e.g.*, *Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009) ("It is axiomatic that claims are construed the same way for both invalidity and infringement.").

construction. Because Apple's sole noninfringement argument rests on its flawed claim construction, the Commission's infringement finding as to the '941 and '731 patents should be affirmed.

III. THE COMMISSION ERRED IN DETERMINING THAT CLAIMS 16 AND 17 OF THE '499 PATENT ARE INVALID AND NOT INFRINGED

Claims 16 and 17 of the '499 patent are valid, and the Accused Products infringe them. None of Apple's (Br. 75-85) or the Commission's (Br. 52-61) arguments on appeal can save the Commission's contrary determinations.

A. Apple Failed To Prove Patent Ineligibility

1. The Claims Are Not Directed To An Abstract Idea Or A Known Diagnostic Process Using Generic Technology

At *Alice* step one, a plain reading of the claim language, particularly viewed in light of the specification, reveals that claims 16 and 17 of the '499 patent are drawn to specific improvements in cardiac monitoring technology. These improvements allow a user of a mobile computing device having a specific combination of sensors to detect the presence of an arrhythmia, such as AFib, and alert a user to record an ECG, in an ambulatory setting. *See* Appx10019; Appx10025; Appx10026 (2:30-55), Appx10027 (3:50-4:7); Appx10037-10038 (23:1-27; 24:58-25:48); Appx10039). As the Commission found with respect to the '941 and '731 patents (Appx31-34), these improvements constitutes patent-eligible subject matter.

Here, neither Apple (Br. 76-77) nor the Commission (Br. 53-54) analyzes the claims of the '499 patent "as a whole," as required by this Court. *See, e.g.*, *McRO, Inc. v. Bandai Namco Hames Am. Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016); *CardioNet, LLC v. InfroBionic, Inc.*, 955 F.3d 1358, 1367 (Fed. Cir. 2020). Instead, they focus on individual claim elements in isolation, omit specific claim language, and characterize the claimed elements as "generic and conventional," without even considering the specification of the '499 patent and how the written description illuminates what the claims are directed to. *See, e.g.*, *CardioNet*, 955 F.3d at 1368.

Take the preamble, for example. Apple and the Commission ignore that it was construed below as limiting the claim to "[a] system for determining the presence of an arrhythmia of a first user." Appx234. They also overlook that the processor "receive[s] a heart rate," "determines a heart rate variability," "compares said activity level of said user to said heart rate variability," and "alerts said first user to record an electrocardiogram using said mobile computing device," and that the "mobile computing device" is specifically "configured to sense an electrocardiogram of said first user." Appx10039 ('499 patent claims 11, 16, 17). In addition to overlooking critical language, Apple goes further (Br. 76)—mischaracterizing the "mobile computing device ***configured to sense*** an electrocardiogram of said first user" (Appx10039) as "'a mobile computing device' ***capable of 'sens[ing]*** an electrocardiogram'" (emphasis added).

Contrary to Apple's (Br. 76-77) and the Commission's (Br. 53) arguments, the record does not reflect that doctors have long used the claimed elements of (1) a motion sensor to determine activity level, (2) a computer program to determine heart rate variability and compare a user's activity level to heart rate variability, (3) a smartwatch (claim 16), or (4) a machine-learning algorithm (claim 17) to determine the presence of an arrhythmia, particularly in an ambulatory environment. Rather, as AliveCor's expert Dr. Efimov testified, combining PPG and ECG was a specific improvement over conventional arrhythmia detection devices. *See* Appx31994 (agreeing with testimony of Apple's Dr. Waydo and recognizing value of "using those two things [PPG and ECG] together."); *see also* Appx31153-31154.

Just as importantly, Apple and the Commission ignore that an advancement captured by the '499 patent claims is the detection of paroxysmal AFib. Both Apple and AliveCor experts testified that such episodic AFib is hard to predict and diagnose because it may not present itself during a doctor's office visit (*i.e.*, in non-ambulatory environments). Appx31096-31097; Appx31145-31146; Appx31216-31218; Appx31228-31231; Appx32123. Indeed, this is one advantage of the inventions of the '499 patent that is repeatedly touted in the specification. *See, e.g.*, Appx10019 (fig. 10); Appx10025 (fig. 14); Appx10026 (2:30-55); Appx10027 (3:50-4:7); Appx10037-10038 (23:1-27, 24:58-25:48). Further, Apple's expert Dr. Stultz conceded that paroxysmal AFib detection is very challenging (Appx31096-

31097; Appx31146), and that a company with unlimited resources like Apple needed many years to develop this technology (Appx30745-30746; Appx31151-31152). This ability to detect paroxysmal AFib outside the presence of a doctor during everyday life was a revelation that saves lives and something that had never been done before in a wearable device such as a smartwatch.

Apple's and ITC's arguments regarding claims 16 and 17 specifically also fail. On claim 16, Apple (Br. 77) and the Commission (Br. 57) ignore the claim language in asserting that the smartwatch limitation does not benefit or affect any other limitations. If the claimed "mobile computing device" "comprises a smartwatch," then the "heart rate sensor," "motion sensor," "non-transitory computer readable medium …" and ECG sensor would all be directly affected by being in such a form factor, and further limited in sensor type and size. *See* AliveCor Br. 44-45.

Similarly, in arguing that the machine-learning limitation of claim 17 only adds "generic machine learning" and is "simply an extension of a mental process or mathematical algorithm" directed to an abstract idea, Apple (Br. 79) and the Commission (Br. 58) ignore the specification's description of how machine-learning algorithms can be trained and used to better detect arrhythmias. *See, e.g.*, Appx10027 (3:50-4:7); Appx10028 (5:6-10); Appx10029-10030 (8:65-9:19). They also fail to account for the expert testimony of Dr. Efimov, who explained the

benefits of using machine learning to better detect arrhythmias in real time and without the need for a medical professional. Appx31243-31244; *see* AliveCor Br. 45-46.

Apple's attempt to distinguish *CardioNet*, 955 F.3d 1358, misses the mark. Even under Apple's view (Br. 79-80) that the *CardioNet* claims "recited a different form of data analysis than a human doctor would use," claims 16 and 17 similarly do just that. A doctor would not use a smartwatch on a patient or a motion sensor to detect her activity level or "determine a [user's] heart rate variability," and would not use a machine-learning algorithm to determine a presence of arrhythmia. *See* AliveCor Br. 39-43.

The Commission fares no better in arguing (Br. 54-55) that a different, non-precedential *CardioNet* decision, *CardioNet, LLC v. InfoBionic, Inc.*, 816 F. App'x 471 (Fed. Cir. 2020), is more analogous to the '499 patent's claims. There, this Court held patent-ineligible claims that were "not directed to specific methods for identifying cardiac events or determining correlation between machine- and human-identified events" and instead "essentially recite[d] and [were] directed to collecting, analyzing, and displaying data by conventional means." *Id.* at 475, *quoted in* ITC Br. 55. But, contrary to the Commission's suggestion, claims 16 and 17 collect and analyze cardiac data by unconventional means, *i.e.*, using a smartwatch and specific sensors thereon to collect and analyze data to determine the presence of an

arrhythmia (claim 16) and analyzing data using a machine-learning algorithm to do the same (claim 17). Appx10039; *see* AliveCor Br. 39-43.

2. The Claims Contain Inventive Concepts

At *Alice* step two, Apple (Br. 82-85) and the Commission (Br. 59-61) again focus on addressing the claim elements individually—not as *an ordered combination*—and ignore the specification to argue that known components are used for known purposes to perform known diagnostic purposes. But "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces." *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016); *see* AliveCor Br. 46-47. And, as explained above, doctors have not and would not have used the claimed elements in a smartwatch or used machine-learning algorithms to determine the presence of an arrhythmia, particularly not in ambulatory patients. *See supra*, Part III.A.1; *see also* AliveCor Br. 50-52. Further, the undisputed evidence shows that one problem solved by the '499 patent, reducing false positives caused by motion artifacts in a wrist-worn device, required significant time and resources to resolve. *See* AliveCor Br. 49. None of Apple's or the Commission's responses overcomes this evidence.

First, in asserting (Br. 59-60) that the claim is not innovative because "physicians have been using ECGs to record heart activity for decades," the Commission overlooks that using an ECG in the claimed ordered combination with

a motion sensor and heart rate sensor in a smartwatch (*i.e.*, in an ambulatory patient, outside the physician's presence) allows the patient to capture more-relevant data. *See, e.g.*, Appx31228-31236.

Second, Apple wrongly argues (Br. 83) that AliveCor does not identify any unconventional arrangement of sensors and algorithmic steps. But this ignores both the claim language and the specification. *See supra*, Part III.A.1. Apple also incorrectly asserts (Br. 84) that an inventive concept is lacking because ECG watches and at least one smartwatch were known. The inventive concept is the combining of existing mobile continuous monitoring technologies (*e.g.*, PPG and motion sensors) and newly developed mobile ECG technologies in a unique and novel way in a day-to-day, wearable platform. Further, Apple's (Br. 85) and the Commission's (Br. 60-61) arguments that a smartwatch is the environment in which the abstract idea is carried out ignores that the claim language, specification, and preamble—which was held to be limiting—all dictate the type and size of the sensors that can be used in the claimed invention. *See supra*, Part III.A.1.

Third, contrary to the Commission's argument (Br. 61), the machine-learning algorithm limitation of claim 17 is not itself an abstract idea. It is a concrete inventive concept because, as claimed, it used a particular novel manner to "determine a presence of said arrhythmia." Appx10039. *SAP America, Inc. v.*

InvestPic, LLC, 898 F.3d 1161, 1163 (Fed. Cir. 2018), is inapposite, as that case did not involve a machine-learning algorithm.

Finally, Apple's assertion (Br. 66) that no expert testimony is needed "to recognize the preemption risk" is no response to AliveCor's argument (Br. 51) that there was ***no evidence***—expert or otherwise—in support of the Commission's preemption conclusion. Likewise, Apple misplaces reliance (Br. 85) on *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759 (Fed. Cir. 2019). That case is inapposite because the claims there were directed to "communications over a network for device interaction" that would "preempt the use of any networked charging stations." *Id.* at 769. Here, there would be no preemption of smartwatches with ECG capabilities, or even doctors' non-ambulatory practices using ECG devices. *See* AliveCor Br. 49-52 (discussing industry skepticism confirmed by Apple's own expert Dr. Picard).

B. Apple Failed To Prove That Claim 17 Is Obvious

Although the Commission erred in ruling that claim 17 of the '499 patent is patent ineligible, it correctly determined that Apple had failed to prove that the claim is obvious. Appx42. Apple's contrary arguments (Br. 64, 67-75) fail for the same reasons as its arguments on the '731 and '941 patents. *See supra*, Part II.A.

C. The Commission's Noninfringement Determination Lacks Substantial Evidence

Both Apple and the Commission largely try to brush aside the Commission's erroneous construction of the "alert" limitation to require a literal message to take an ECG. For starters, the Court should reject Apple's (Br. 54-56) and the Commission's (Br. 37-38) contention that the Commission did not alter the claim construction after the evidentiary hearing. A comparison of the Claim Construction Order (Appx322-323) to the ALJ's initial determination (Appx243-244) shows that it did.

Apple argues (Br. 55) that the original "not limited to a message" construction is not at issue because the Commission found that the IRN alert to "talk to your doctor" is, in fact, a message. *See* Appx244. But that misses the point. The Claim Construction Order rightly construed the "alert" limitation as not limited to a message ***to literally take an ECG*** and requiring only that it "alert" the user that an ECG is appropriate. *See* AliveCor Br. 53-54 (collecting intrinsic evidence). That the IRN alert is a message is not reason to conclude—by itself—that the message does not "alert" the user that an ECG is appropriate, consistent with the original construction.

For the Commission's part, it seeks to avoid the claim-construction issue (Br. 37-38) by faulting AliveCor for choosing the term "alert" rather than some other term to define the scope of its claimed invention. But this, too, misunderstands

AliveCor's argument. It is precisely the term "alert"—a term broader than merely "inform"—that AliveCor argued, and the Commission originally correctly found, covers more than just a message to literally take an ECG. *See* Appx322-323.

Under the correct claim construction, there is no substantial evidence of noninfringement. In fact, the evidence conclusively establishes that Apple did infringe—literally or under the doctrine of equivalents. But at minimum, Apple's admission (Br. 56) that the Commission dismissed as irrelevant much of the critical evidence under the correct claim construction would be reason alone to remand to the Commission for consideration of that evidence in the first instance. Here, however, no remand is necessary because when all the evidence is properly considered, it leads to only one permissible conclusion: infringement.

Apple's IRN feature literally "alerts" the user to an opportune time to take an ECG to capture the presence of a transient and potentially deadly arrhythmia (AFib), just as the claims require. *See* AliveCor Br. 56-62 (collecting evidence). It is of no moment that the words of the IRN alert tell the user to "talk to [their] doctor" rather than instructing them to record an ECG, as Apple (Br. 55-56, 58) and the Commission (Br. 12-13, 38-40) both argue. The literal function of the AFib alert in the IRN feature is to alert the user to the opportune time to take an ECG, and the evidence cited by AliveCor fully supports that finding.

The context in which the alert appears further supports this conclusion. The IRN's AFib alert, which takes the form of a surfaced pop-up, is delivered to the user with a chime and/or haptic feedback (*e.g.*, vibration) that normally accompanies alerts on the smartwatch and paired iPhone. Appx11879; Appx13637. This is especially significant given that the IRN's user base is restricted to persons not previously diagnosed with AFib. *See, e.g.*, Appx13909-13917; *see also* AliveCor Br. 60. Thus, for IRN users in particular, an AFib alert after meticulous yet unknown background monitoring by the IRN app (*see* Appx13911) would understandably be both surprising and jarring to the user receiving that alert. This context—along with other circumstantial evidence of infringement, *see* AliveCor Br. 57-62 (collecting evidence)—is highly relevant for understanding the nature of the "alert" and how its in-the-moment delivery constitutes an alert for the user to take an ECG exactly as the claims require.

Apple does not directly address this critical context. Instead, it dismissively addresses other evidence that AliveCor cited. For example, Apple tries (Br. 56-57) to dismiss the statements of third parties and Apple itself encouraging users to take an ECG after receiving an IRN notification, arguing that it is the user's choice to take an ECG in response to the IRN alert, and that the Apple Watch therefore does not contain computer-executable instructions to take an ECG, as the claims require. But the IRN alert is itself surfaced to the user pursuant to computer-executable

instructions stored in the watchOS software. *See* Appx31713-31714; Appx13744; Appx13776-13777. Moreover, AliveCor established that upon receiving the unexpected AFib alert from the involuntary IRN software, a user would be "alerted" within the context of the asserted claims to take an ECG using the watch's ECG software to confirm whether the user has AFib. *See* AliveCor Br. 57-62.

Apple likewise gives (Br. 57) short shrift to the strong evidence that it tracks and benefits from the IRN and ECG being used sequentially. The tracking-and-benefit evidence is potent circumstantial evidence that the underlying IRN alert is literally an "alert" for the user to take an ECG, considering that users in fact do take an ECG following the IRN alert. Otherwise, why would Apple be tracking its use as such?[12]

Equally unavailing is the Commission's effort (Br. 39) to relegate to irrelevance Apple's public encouragement that users take an ECG. As AliveCor

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[12] Apple wrongly accuses (Br. 57) AliveCor of mischaracterizing the record regarding the CPI design. Despite not tying the CPI and CPI together, the software as designed and implemented by Apple does "CPI" a user to take an CPI upon receiving the CPI alert, and Apple knows this to be true. Apple's design intention that the CPI be a CPI" for CPI stands in stark contrast, however, to what Apple told the FDA about the features while its regulatory approval was pending. *See* Appx13704 (Apple document for engineers prior to FDA meetings, listing as a "Thing[] to avoid/look out for … ***do not talk about using [the*** CPI ***alert] as a*** CPI ***for [the*** CPI ***]***"). And *after* receiving FDA's clearances and mere weeks before launch of IRN/ECG, Apple internally assured its Health team that the CPI alert] CPI for [CPI] was "Done" and ready to go. Appx15988; *see* Appx30745-30746.

explained (Br. 58-59), these public endorsements are like instruction manuals that are "circumstantial evidence of infringement." *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1204 (Fed. Cir. 2017). The Commission has no answer.

Even if there were no literal infringement, the IRN alert serves a substantially equivalent purpose to—or at minimum, is insubstantially different from—alerting a user to record an ECG under the doctrine of equivalents. *See* AliveCor Br. 62-64 (collecting evidence). The only evidence that Apple musters (Br. 58) in support of the Commission's rejection of the doctrine of equivalents is Dr. Picard's testimony. Apple points (Br. 58) to her explanation that the differences between the IRN message and the "alert" limitation are substantial because the IRN message simply does not instruct the user "to record an ECG" (quoting Appx30907-30908; Appx30973-30974).[13] Similarly, the Commission (Br. 40) relies on Dr. Jafari's testimony that the message "would send a user to the doctor" (quoting Appx243-244; Appx30380). But these snippets of testimony are relevant only if the Commission's narrow claim construction is correct. They provide no basis to reject a doctrine-of-equivalents theory grounded on a correct construction of the "alert" limitation. That correct construction would not cabin the claim to "informing" the

[13] It is of no consequence, as Apple argues (Br. 56), that the "desire to take an ECG would need to come from the user" rather than via an automatic process initiated on the smartwatch. The IRN alert—provided via computer-executable instructions—serves the purpose of alerting the user to take that ECG.

user to literally take an ECG and instead would include "alerts" that prompt him/her to the opportune time to do so—something that the "go see a doctor" message accomplishes, at least equivalently.

IV. THE COMMISSION PROPERLY EXERCISED ITS DISCRETION IN ISSUING A LIMITED EXCLUSION ORDER

Upon finding a Section 337 violation, the Commission "is required to issue an exclusion order … absent a finding that the effects of one of the statutory-enumerated public interest factors counsel otherwise." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) (citing 19 U.S.C. § 1337(d)(1)).[14] An exclusion order is intended "to be the normal remedy" for a Section 337 violation. *Id.* Thus, as Amici MDMA et al. explain (Br. 20), it is unsurprising that the Commission has declined to issue an exclusion order only three times—this "consistent approach provides certainty to U.S. innovators, while implementing the will of Congress to broaden access to Section 337."

This Court reviews the Commission's decision to issue an exclusion order only "as to whether it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Spansion*, 629 F.3d at 1358. That review "necessarily is limited" because the Commission "has broad discretion in selecting the form,

[14] The four public-interest factors are "(1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production of like articles in the United States, and (4) United States consumers." *Spansion*, 629 F.3d at 1358.

scope, and extent of the remedy." *Philip Morris Prods. S.A. v. Int'l Trade Comm'n*, 63 F.4th 1328, 1339 (Fed. Cir. 2023). If "the Commission has considered the relevant factors rationally and not made a clear error of judgment, the determination will be affirmed." *Fuji Photo Film Co., Ltd. v. Int'l Trade Comm'n*, 386 F.3d 1095, 1106-07 (Fed. Cir. 2004).

This standard is so deferential that Apple did not cite—and AliveCor could not find—a single case from this Court reversing an exclusion order based on the four public-interest factors. In contrast, the reporters are filled with cases affirming the Commission's exclusion orders.[15]

This case is not the one to break new ground. Here, the Commission dutifully considered each factor in over thirty pages of analysis. It determined that the public interest did not overcome its statutory duty to exclude the infringing Apple Watches. Appx47-88. That "normal" conclusion was well within the Commission's discretion and was not arbitrary or capricious.

[15] *See, e.g.*, *Philip Morris Prods.*, 63 F.4th at 1340; *Comcast Corp. v. Int'l Trade Comm'n*, 951 F.3d 1301, 1310 (Fed. Cir. 2020); *Cisco Sys., Inc. v. Int'l Trade Comm'n*, 873 F.3d 1354, 1363 (Fed. Cir. 2017); *Organik Kimya, San. v. Tic. A.S.*, 848 F.3d 994, 1006 (Fed. Cir. 2017); *Spansion*, 629 F.3d at 1360.

A. Other Suitable Products Can Remedy Any Potential Health Concerns From The Exclusion

Contrary to Apple's suggestions (Br. 89-95), the Commission correctly found that a bevy of alternative products can replace the infringing Apple Watches and alleviate any potential health concerns.

First and foremost, Fitbit offers watches cleared by the FDA for AFib detection using ECG- and PPG-based algorithms. *See* Appx74-75; *see also* Apple Br. 92. Next, Apple's own Apple Watch SE comes fully equipped with HHRN notifications and FDA-approved IRN functionality. *See* Appx75; Appx2777. Users could easily combine the Apple Watch SE with a mobile ECG device to confirm AFib. For example, AliveCor's KardiaMobile Card is an FDA-cleared, credit-card-sized ECG reader. *See* Appx2913. With that product in hand, a consumer with an Apple Watch SE who receives an IRN notification could reach into her wallet and take an immediate ECG. The KardiaMobile Card could likewise be combined with the Garmin Venus 2 and Amazfit GTS4, both of which boast HHRN and IRN capabilities. Appx2913-2914; Appx3122-3127; *see* Appx75-77. Then there are the many Samsung Galaxy watches, which can provide "an on-demand 30 second ECG that can detect the presence of AFib and that also provide continuous heart rate 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." Appx76; Appx3085. The Samsung Galaxy Watch 3 and 5 both have FDA approval for the ECG functionality.

Appx2777; Appx2913. Other examples abound. *See* Appx2913-2917 (AliveCor brief listing more).

Apple thus plainly overreaches in asserting (Br. 88) that the Commission's reasonable-substitute decision is "contrary to all record" evidence. The Commission acted well within its expertise and discretion to find that many other products could alleviate any public-health concerns that the exclusion order might cause.

Indeed, Apple itself admits (Br. 92) that the Fitbit Charge 5 and Sense 2 models have FDA-approved ECG and IRN functionality, as well as an HHRN feature. Those models thus do exactly what the excluded Apple Watches do—measure heart rate, provide irregular heart rate notifications, and take ECGs to detect AFib, all with the FDA's approval. This alone dooms Apple's arguments regarding suitable alternatives. Apple tries to get around this Fitbit problem in two ways. Neither argument works.

First, Apple claims (Br. 92) that Fitbit's watches do not offer the same range of features as the infringing Apple Watches. Things like the ability to "place and receive phone calls, exchange messages, stream music, and access a wide range of apps such as navigation, mobile banking, and e-commerce." Appx1478. Consumers prefer the Apple Watch for those features, or so Apple says. Appx1478; *see* Appx58.

This argument is nothing more than a plea to Apple's dominant market share in the industry. And Apple's market share is not a public-interest issue. *See* MDMA

Br. 20-21 ("The sheer magnitude of [Apple's] infringement should not exempt it from the consequences of its decision to manufacture infringing products outside of the United States."). That is especially true here because Apple gained its market share in part by infringing AliveCor's patents. Apple's argument is essentially that because its Apple Watch is ***so*** successful and does ***so*** many things, infringing any one patent for any one feature can never justify exclusion. That cannot be correct. And it is certainly not an abuse of discretion or arbitrary for the Commission to conclude otherwise.

Likewise, these other features, such as the ability to make cell-phone calls or listen to music, are not public-health issues. As the Commission recently determined in another case excluding versions of the Apple Watch for infringing a patent relating to the blood-oxygen feature, the connection between the public health and welfare to these "smart" features is "too attenuated to rise to the level of a public-interest concern." *Certain Light-Based Physiological Measurement Devices*, Inv. No. 337-TA-1276, 2023 WL 8109999, *57 (I.T.C. Nov. 14, 2023).

Apple, moreover, cites no authority to support its view that only products having all the features—even unaccused features—of an infringing product qualify as reasonable alternatives. As the Commission explains (Br. 62), this stretches the public health and welfare factors too far. The Commission considers "other non-infringing alternatives in the market, even when those alternatives are not exactly

the same as the accused products." *Certain Tobacco Heating Articles*, Inv. No. 337-TA-1199, 2021 WL 2333742, *70 (I.T.C. May 14, 2021); *accord Certain Table Saws*, Inv. No. 337-TA-965, 2017 WL 1476193, *5 (I.T.C. Feb. 1, 2017). Nothing in Section 337 required the Commission to go further.

Second, Apple wrongly contends (Br. 93-94) that Fitbit's watches should not be considered reasonable substitutes because Fitbit supposedly could not ramp up production to meet demand. As the Commission found, Apple offered no evidence to support that assertion. Appx75-76. In fact, the evidence shows the opposite. Fitbit had annual sales of 10.6 million to 25.4 million devices from 2016 through 2021. *See* Appx2915. This suggests that Fitbit could replace all of Apple's excluded watches. Appx2712 (Apple's witness stating that Apple shipped 10 million infringing Apple Watches in 2021).[16] Additionally, Apple does not grapple with the Commission's decision to temporarily suspend its limited exclusion order pending appeal of the PTAB's Final Written Decisions, which will provide additional time to ramp up production. Appx75. It likewise fails to acknowledge that even if Fitbit could not by itself meet the new demand, Apple (through its Apple Watch SE),

[16] Apple complains (Br. 94) that the Commission did not let it subpoena Fitbit and Samsung to get manufacturing data. But the Commission's control of its docket and the scope of discovery is committed to its sound discretion.

Samsung (through the Galaxy), and other smaller manufacturers of smartwatches could meet the demand together.

Apple does not meaningfully address those non-Fitbit products. For example, Apple fails to explain why its own Apple Watch SE when paired with an ECG monitor would not be a reasonable substitute.[17] Instead, it generally faults (Br. 90) the Commission for adopting a two-device solution. But as the Commission recently explained, while "it is not ideal for an individual or research participant to wear two wearable electronic devices to obtain all of the desired features, the inconvenience of doing so is not significant enough to rise to the level of a public interest concern, especially in view of the countervailing interest of protecting intellectual property rights." *Certain Light-Based Physiological Measurement Devices*, 2023 WL 8109999, at *57.

Apple's only real response on this score (Br. 90) is that consumers are unlikely to purchase a separate ECG monitor because they do not know that they have a heart condition. That misses the point. The Apple Watch SE itself or Apple's redesigned Watch[18] would motivate the user to buy the ECG monitor by providing the IRN or HHRN notification to the user. And of course, Apple could obviate the need for a

[17] The same is true for other watches with HHRN and IRN capabilities.

[18] Ruling Letter (CBP, EOE Branch July 18, 2023), available at https://rulings.cbp.gov/ruling/H329187

two-device solution altogether by simply reversing its anti-competitive conduct to allow the KBS to work with the Apple Watch SE. Appx75-76.

Finally, Apple wrongly suggests (Br. 91-92) that many of the alternatives cannot be reasonable substitutes because they do not have FDA approval for both IRN and ECG functionality. Its primary authority for this supposed FDA-approval requirement is not even the FDA; it is a third-party organization that asserts, without support, that the FDA-approved devices are more accurate. *See* Appx1389-1391. The Commission was well within its discretion to classify those comments as "general admonition[s]" that are not entitled to weight and thus to reject Apple's argument that only devices with FDA-approved ECG and IRN capabilities could qualify as suitable substitutes. Appx74. In any event, Apple overlooks that the Samsung Galaxy Watch 3 and Watch 5 *have* FDA approval for their ECG functionality. Appx2777; Appx2913. Those approvals make Apple's point (Br. 91) about Class II controls on ECG software irrelevant for those models.

B. The Exclusion Will Not Impact Any Research Studies

Apple's invocation (Br. 95-97) of research studies using its infringing watches likewise provides no basis to set aside the Commission's exclusion order. Apple does not maintain that any future studies would be affected by the exclusion order and instead relies solely on the order's supposed effects on ongoing studies. As the

Commission found, however, the exclusion order will have little, if any, effect on those studies. Appx71-72.

That is due in large part to the Commission's exemption of the 30 million (and counting) Apple Watches already purchased in the United States. Appx80. The Commission's remedial order expressly allows Apple to repair and serve those already circulating watches. Appx80-81. Thus, the limited exclusion order would not bar current participants in research studies from using their current Apple Watches or repairing them.

As for ongoing studies that may recruit new participants, the Commission correctly noted that Apple did not raise in its briefing any ongoing studies requiring additional Apple Watches for additional participants, nor quantify that number. Appx71. On appeal, Apple cites (Br. 97) pages in its Commission briefing purportedly doing so. But those pages only baldly assert that ongoing studies will be adversely affected and provide the general amount of new participants those studies may enroll. Those pages do not, as the Commission recognized (Appx71), claim that ***the new participants will need additional Apple Watches***. Nor could Apple so claim. Ongoing studies that are recruiting new participants could easily provide the many alternatives listed above or draw from the 30 million strong pool of existing Apple Watch users. As the Commission recently explained, "to the extent any studies depend on having a large number of participants with infringing

Apple Watches, infringing Apple Watches have already been broadly sold in the United States such that there are already a large number of potential study participants." *Certain Light-Based Physiological Measurement Devices*, 2023 WL 8109999, at *61.

CONCLUSION

The Commission's determination should be affirmed as to the '731 and '941 patents and reversed as to the '499 patent.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Counsel for Appellant AliveCor, Inc. certifies that the brief contained herein has a proportionally spaced 14-point typeface, and contains 13,942 words, based on the "Word Count" feature of Word for Microsoft 365 MSO, including footnotes and endnotes, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b).

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