Nos. 23-1509, -1553

IN THE

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

NON-CONFIDENTIAL REPLY BRIEF OF INTERVENOR–CROSS-APPELLANT APPLE INC.

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Statement Regarding Confidential Material Omitted

Pursuant to Federal Circuit Rule 25.1(e) and the Protective Order issued in the ITC on May 26, 2021, and amended on August 18, 2021, two versions of this brief are being filed with the Court: a confidential version that notes the material marked confidential, and a nonconfidential version containing appropriate redactions. In the nonconfidential version of this brief, confidential material has been deleted on pages 5 and 7-18. The general nature of the deleted material is confidential business information of AliveCor, Inc., regarding its finances, product information, and agreements with a third party not involved in this litigation.

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INTRODUCTION

Apple demonstrated multiple fatal flaws in the Commission's decision to exclude Apple Watch from importation, based on patents that the Patent Trial and Appeal Board has held invalid and on a handful of contractor payments that, in any event, have no connection to AliveCor's discontinued domestic-industry product or its asserted patents. The Commission and AliveCor have little defense of the Commission's actual rationale for that decision. Both invent new (and equally flawed) rationales for the Commission's domestic-industry finding. AliveCor even asks this Court to "affirm" by making new factual findings on separate domestic-industry grounds that the Commission rejected. Both defend the Commission's claim construction by attacking arguments Apple hasn't made on appeal. They suggest that the mere length of the public-interest analysis somehow justifies the Commission's arbitrary reasoning. They even claim that the secondary considerations the Commission relied on to reject Apple's strong obviousness showing were also "strong," when the Commission's ruling unambiguously says otherwise.

Unable to muster any persuasive defense of the Commission's flawed reasoning, AliveCor suggests that this Court should overlook the Commission's many errors because Apple allegedly anticompetitively excluded KardiaBand from the market. Not only is this allegation irrelevant, but a district court recently rejected AliveCor's similar aspersions, granting summary judgment of no antitrust violation and finding that AliveCor "could enter the [alleged Watch] app market today." *AliveCor, Inc. v. Apple Inc.*, No. 4:21-cv-03958, 2024 WL 591864, at *15 (N.D. Cal. Feb. 13, 2024). AliveCor has chosen instead to wield its invalid patents to "protect" a supposed domestic industry in a product that has long since ceased to exist, to the detriment of millions of Americans who could benefit from Apple Watch's heart-health features. The Court should not sanction this abuse of the Commission's extreme remedial authority.

ARGUMENT

I. AliveCor Failed To Prove A Domestic Industry.

Even under the "liberalized" version of Section 337's domestic-industry requirement, "the Commission is fundamentally a trade forum, not an intellectual property forum." *John Mezzalingua Assocs., Inc. v.*

ITC, 660 F.3d 1322, 1327-28 (Fed. Cir. 2011). The Commission exists to protect "industry in the United States" from unfair competition achieved through importation. H.R. Rep. No. 100-40, at 157 (1987). When the alleged unfair act is patent infringement, the complainant must prove that the "industry" in question relates to "articles protected by the patent." 19 U.S.C. § 1337(a)(2). The Commission acknowledges this limitation along with the "addition[al]" requirement that a patentee who relies on § 1337(a)(3)(C) must show "a nexus between the domestic investments and the exploitation of the asserted patents." CB20-21.[1]

AliveCor touts the "millions" of dollars it has spent on products directed to "AFib detection." RB4-5. But much of that spending relates to products, like KardiaMobile, that have nothing to do with the patents AliveCor asserts. *See* AB13-14; Appx30159-30163. AliveCor's only use of those patents consists of (1) the KardiaBand system that it chose to discontinue years ago and (2) two supposedly in-development products that AliveCor cited to invoke the Commission's jurisdiction but which it seemingly has done nothing with since. The Commission rightly

[1] "CB" refers to the Commission's brief; "AB" refers to Apple's principal brief; "OB" refers to AliveCor's opening brief; and "RB" refers to AliveCor's response-reply brief.

refused to find jurisdiction based on those latter products, given AliveCor's unclear intent to develop them. But the Commission nonetheless relied on AliveCor's spending on those still-nonexistent products to somehow find an existing domestic industry in the discontinued KardiaBand.

As Apple demonstrated, the Commission's finding cannot be sustained for three independent reasons: (1) the Commission improperly credited expenses that do not relate to the KardiaBand system; (2) AliveCor failed to demonstrate a nexus between the expenses and the asserted patents (and none is self-evident); and (3) the Commission's only basis for deeming these domestic expenses "substantial" is illogical. AB31-43.

The Commission and AliveCor defend the Commission's errors by inventing new rationales for its conclusions, pointing to record evidence the Commission did not credit, and mischaracterizing this Court's precedents. These arguments are all meritless. § I.A.

Implicitly recognizing the vulnerability of the Commission's actual finding, AliveCor asks this Court to affirm by reversing several of the Commission's findings that AliveCor failed to show a domestic industry

in other respects. These arguments are not properly before this Court and, in any event, are meritless. § I.B.

A. The Commission erred in finding an existing domestic industry under subparagraph (C).

No nexus to domestic-industry product. AliveCor and the Commission concede that Confidential product information [redacted] "is not a domestic industry product." RB5; *accord* CB23. They nevertheless argue that it was proper to count investments in Confidential product information [redacted] as showing an existing domestic industry related to the KardiaBand system given the "overlapping technology" between the products. CB23-26; RB6-7. The Commission's decision did not adopt this rationale, however. It cited technological overlap as a basis for finding that contractor payments related to Confidential product information [redacted] had a nexus to the *patents*, Appx17-18, but—as the Commission acknowledges (CB21)—that is separate from the requirement that domestic-industry expenses have a nexus to the domestic-industry *product*. Appx12-13 & n.16. This Court is "not free to … uphold the agency's decision" on a ground the agency did not employ. *InterDigital Commc'ns, LLC v. ITC*, 690 F.3d 1318, 1329 (Fed. Cir. 2012).

In any event, AliveCor and the Commission's theory that a complainant can make out an existing domestic industry in a discontinued product based on mere technological "overlap" with another future product would stretch the domestic-industry requirement beyond its breaking point. Under this approach, Ford could show an existing domestic industry in Model Ts based on investments in modern cars with combustion engine technology.

This Court's decision in *Roku, Inc., v. ITC*, 90 F.4th 1367 (Fed. Cir. 2024) (cited at RB6), is not to the contrary. There, unlike here, the domestic-industry products (Samsung televisions) existed in the real world, and the qualifying investments were in a feature that was "installed on" and therefore a "subset of" those televisions. *Roku*, 90 F.4th at 1373-34. That was the basis of this Court's holding that "a complainant can satisfy the economic prong of the domestic industry requirement based on expenditures related to a subset of a product." *Id.* at 1374. That holding in no way suggests that a complainant may count investments in a *different* product as establishing an existing industry in a discontinued product simply because the two products employ overlapping technology. *Contra* RB6.

AliveCor and the Commission fare no better with their defense of the Commission's actual conclusion—that investments in Confidential product information [redacted] Confidential product information [redacted] are investments "with respect" to KardiaBand because they benefit legacy users. As Apple showed, the Commission did not explain its reasoning for this conclusion. AB37-38. AliveCor and the Commission try to supply the missing reasoning on appeal, citing portions of the record that the Commission's decision did not and offering theories the Commission's decision did not adopt. CB25-26; RB7. This Court has "no warrant to 'accept appellate counsel's *post hoc* rationalizations for agency action'" or to adopt "a reasoned justification for an agency decision that the agency itself has not given." *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1326 (Fed. Cir. 2015) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). Doing so would be particularly inappropriate here, given that there is no evidence that the actual investments in Confidential product information [redacted] the Commission credited—such as "Confidential product information [redacted]" and unspecified "Confidential product information [redacted]," Appx282—benefit legacy KardiaBand users in any way.

Even if these investments in Confidential product information [redacted] did indirectly benefit "a very small set" of legacy KardiaBand users, CB25 (quoting

Appx30227), that would not establish an existing domestic industry in the discontinued KardiaBand. AliveCor and the Commission cite no case suggesting that such an incidental benefit from an investment in another product can qualify. The Commission and AliveCor continue to rely on cases where past investments *in a still-existing product* were counted as part of the "industry" related to that product. CB28-29; RB5. Here, the Commission counted expenditures on a non-existent product (Confidential product information [redacted]) to find an existing domestic industry in a separate, discontinued product (the KardiaBand system). Unsurprisingly, neither the Commission nor AliveCor cites any authority endorsing this twisted logic. Nor can any ongoing customer-service expenses for legacy KardiaBand users justify counting its Confidential product information [redacted] expenses. *Contra* CB26. The purpose of the domestic-industry requirement is to ensure that the Commission's drastic remedial power is used only to "protect domestic industries." *InterDigital Commc'ns, LLC v. ITC*, 707 F.3d 1295, 1302 (Fed. Cir. 2013). But where, as here, there is no existing or planned economic activity involving the domestic-industry article beyond dwindling

customer-service expenses related to previously sold products, there is nothing for a remedial order to "protect."

The Commission and AliveCor also fail to defend the inconsistent treatment of Confidential product information [redacted] expenses under subparagraphs (B) and (C). *See* AB38-39. The Commission suggests that the ALJ properly credited the evidence under subparagraph (C) as an "investment in exploitation of the patents." CB27-28. But again, as the Commission itself recognizes, the patent nexus requirement is distinct from the articles nexus requirement. Appx12 n.16; CB21. Thus, the Commission resorts to arguing that "the excluded contractor expenses played no role in the Commission affirming the ALJ's finding under subparagraph (B)." CB28. The Commission's opinion belies this assertion, however. Its subparagraph (B) analysis adopted the $ Dollar amount [redacted] figure the ALJ calculated (and deemed insubstantial)—an amount that properly excludes Confidential product information [redacted] investments. *See* Appx23-24; Appx271-274.

AliveCor does not even try to reconcile the Commission's inconsistent treatment, seeking only to distinguish Apple's cases on the ground that they involved two inconsistent decisions, rather than one internally inconsistent ruling. RB8. But if anything, the fact that an

agency is taking inconsistent positions in a single decision is *more* arbitrary and capricious. AliveCor fails to show otherwise.

No nexus to patents. The Commission also erred in finding that AliveCor met its burden of showing a nexus between the vague research-and-development expenses listed on a single spreadsheet—which AliveCor's expert concededly did not analyze—and exploitation of the asserted patents. *See* AB40-42.

The Commission argues that it was entitled to interpret the spreadsheet "without a witness" because it is "self-explanatory." CB27. But there is nothing "self-explanatory" about whether investments in, for instance, Confidential product information [redacted], Confidential product information [redacted], or general "Confidential product information [redacted]" are investments in "exploiting" patents that claim specific sensors and software for processing data from those sensors. Appx11717-11718. AliveCor claims the Commission looked beyond the spreadsheet, RB9, but the Commission's additional string citation shows only that the technology in KardiaBand and Confidential product information [redacted] generally overlaps. *See* Appx17. None of the cited testimony connects the expenses in the spreadsheet to the asserted patents. *See* RB10 n.2 (admitting the "testimony did not explicitly address the spreadsheet").

Nor did the Commission find that "the R&D contractor expenses in the spreadsheet went to the 'core part of the invention.'" *Contra* RB9. Rather, as Apple explained (AB41), the Commission relied on the ALJ's finding that the spreadsheet entries merely "suggest[] a nexus to sensors, circuitry, and housing structure." Appx281; *see* Appx18. The Commission did not explain how this tenuous "suggest[ion]" shows exploitation of what it called "the core part of the invention," Appx18 (quoting Appx30292-30293): namely, background heart-rate monitoring and analysis of that data to trigger an on-demand ECG.

At bottom, AliveCor and the Commission's position appears to be that *any* investments in KardiaBand or Confidential product information [redacted] must qualify because both products "practice[] the asserted patents." RB9-11. "[A]n investment in the article is not automatically an investment in the asserted patent," however. *Certain Integrated Circuit Chips*, Inv. No. 337-TA-859, 2014 WL 12796437, at *28 (Aug. 22, 2014). While a nexus may be inferred from investments in the domestic-industry article, *id.* at *23, any such inference falls away where the respondent "demonstrat[es] that [the proffered] domestic investment is unrelated"

to the asserted patent—as Apple did here. *Id.* at *28-29; *see* Appx1447-1448.

Insubstantiality. The Commission also erred in concluding that AliveCor's $[redacted] (Dollar amount) in spending on domestic contractors was "substantial" just because it was more than the $[redacted] (Dollar amount) that AliveCor spent on non-U.S. contractors. Appx21-22. As Apple explained (AB42-43), whether AliveCor spent relatively more domestically than it did overseas does not show that its domestic expenses are themselves substantial. By this logic, a dollar of domestic spend is substantial, so long as only 10 cents were spent abroad.

The Commission and AliveCor do not attempt to explain *why* a domestic-to-foreign comparison shows substantiality. They instead chide Apple for "[c]iting no authority" that precludes such a comparison. RB12; CB30. But, apart from a handful of misguided Commission decisions, neither the Commission nor AliveCor cites any authority endorsing such an approach, either. AliveCor notes that *Roku* "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.'" RB13 (quoting 90 F.4th at 1374). But comparing

domestic investments to "total" expenditures is not the same as comparing domestic investments to foreign ones (and, in any event, the issue was undisputed in *Roku*). Nor does characterizing the Commission's comparison of two numbers as a "quantitative analysis" automatically make the comparison sound. *Contra* RB12-13 (quoting *Lelo Inc. v. ITC*, 786 F.3d 879, 883 (Fed. Cir. 2015)).

B. This Court cannot and should not accept AliveCor's invitation to find a domestic industry on grounds the Commission rejected.

Perhaps recognizing the flaws in the Commission's actual domestic industry analysis, AliveCor (but not the Commission) asks this Court to find a domestic industry on grounds the Commission rejected. AliveCor offers multiple theories of what it calls alternative grounds for affirmance: (1) finding an existing domestic industry in the KardiaBand system under § 1337(a)(3)(B), *see* RB11-12; and (2) finding an industry in the process of being established, also under subparagraph (B), based on [redacted] (Confidential product information) or the [redacted] (Confidential product information), *see* RB15-18.[2] The Commission, however, properly found that AliveCor "failed to

[2] AliveCor also hints at affirmance under subparagraph (C) based on [redacted] (Confidential product information), RB17, but does not develop this argument—which is flawed for the same reasons as the arguments it pursues.

establish" the domestic-industry requirement on either basis. Appx11; Appx23. AliveCor's request that this Court revisit those findings in the course of "affirming" the Commission's ruling is both procedurally and substantively flawed.

Procedurally, AliveCor's arguments run afoul of *Chenery*'s rule that a court "cannot affirm [an] agency's decision" on a ground not relied upon by the agency. *Mittal Steel Point Lisas Ltd. v. United States*, 542 F.3d 867, 878 n.1 (Fed. Cir. 2008); *InterDigital*, 690 F.3d at 1329. Contrary to AliveCor's argument (RB12 n.4), this case does not fall into the exception for "when upholding the [agency's] decision does not depend upon making a determination of fact not previously made by the [agency]." *In re Comiskey*, 554 F.3d 967, 974 (Fed. Cir. 2009). Accepting either of AliveCor's arguments would require significant new fact-finding, which is plainly improper. *Id.*

This is transparent in AliveCor's request for a finding of an in-progress industry in the [redacted] and [redacted] design. Confidential product information AliveCor openly asks this Court to review the same evidence the Commission considered and reach a different factual finding: namely, that AliveCor showed a significant likelihood that the still-nonexistent

Confidential product information
[redacted] and [redacted] design would develop into actual products. RB15-16; *see* Appx290-293 (discussing AliveCor's "unclear" plans for development). Even with respect to the KardiaBand system, however, AliveCor's argument would require new factfinding, as shown below (at 16).

AliveCor's bold requests also come too late. AliveCor forfeited these arguments by "failing to raise [them] in its opening brief on the cross-appeal." *Invitrogen Corp. v. Clontech Lab'ys, Inc.*, 429 F.3d 1052, 1077 n.21 (Fed. Cir. 2005); *see also* AB32; CB7. That AliveCor "is not seeking to enlarge its own rights or lessen Apple's," RB18, is beside the point. Under that logic, the arguments AliveCor *did* raise in its opening brief should have been precluded. AliveCor cannot have it both ways.

AliveCor's arguments also fail on the merits. The Commission found that AliveCor "failed to establish the economic prong of the domestic industry requirement under subsection (B) relating to the" discontinued KardiaBand. Appx23. After stripping out irrelevant or unreliable expenditures, the Commission rightly found that AliveCor "failed to show how or why … its domestic investment was significant" by comparing domestic KardiaBand spending to overall, companywide

spending. Appx24. And AliveCor's alternative attempt to show significance—"a comparison of [KardiaBand] sales from 2018 to 2019 to its hardware revenues and its total revenues"—was "inapt." Appx25.

AliveCor does not challenge these findings. Instead, it asks this Court to reverse the ALJ's decision to "remov[e] Confidential product information [redacted] investment" from the calculations, Appx272, then use the Commission's finding that AliveCor's domestic-to-foreign comparison showed "substantial" investment in patent exploitation under subparagraph (C) as a basis for finding "significant employment of labor or capital" under subparagraph (B). RB11-12 & n.4. But the Commission was right to exclude investments unrelated to the domestic-industry product. *See supra* 5-10. And the Commission's domestic-to-foreign comparison is wrong for the reasons discussed above (at 12-13). Moreover, AliveCor "did not offer" any domestic-to-foreign comparison "to support its claims of significance under subsection (B)." Appx26; *see* Appx284. It has therefore forfeited its attempt to do so on appeal.

Substantial evidence also supports the Commission's finding that no domestic industry is in the process of being established with respect to the still non-existent Confidential product information [redacted] and Confidential product information [redacted]

Confidential product information [redacted] To start, even if these products were seriously under development, the Commission found that AliveCor's investment information was "not reliable." Appx290-293. AliveCor does not challenge this finding.

Regardless, substantial evidence supports the Commission's finding that it was "unclear" whether AliveCor would "undertake [the] effort" to develop Confidential product information [redacted] or the Confidential product information [redacted] product, and whether such effort would "take[] place domestically." Appx292. While AliveCor asserts it presented "detailed production plans for the Confidential product information [redacted]," RB15, AliveCor's expert did not dispute that "there are no records of planned investment or forecasting revenue for the project." Appx292; *see also* Appx30686. Without such records, the Commission reasonably inferred that Confidential product information [redacted] "is in more of an exploration phase as opposed to a planned commitment." Appx293; *see also* Appx16387-16388. Likewise, the Commission was not required to credit Dr. Albert's unsupported testimony that AliveCor was "building a big [FDA] submission" for Confidential product information [redacted], Appx30178, over evidence showing Confidential product information "[redacted] and [redacted] of [AliveCor's] own employees working on the project." Appx292; *see* Appx11703.

As for [redacted] (Third party), the only evidence AliveCor cites is unsubstantiated testimony that it planned "to do some [redacted] (Confidential product information) and some [redacted] (Confidential product information)" with its prototype for a possible future FDA submission. Appx30216-30217; *see* RB16. The Commission properly declined to find this evidence sufficient to show a "substantial likelihood" of a future domestic industry, particularly given AliveCor's plan to "contribute [redacted] (Confidential product information) and [redacted] (Confidential product information) already developed and obtained, and otherwise have as [redacted] (Confidential product information) as possible." Appx291.

AliveCor's legal arguments also fail. The Commission's decision did not turn on an assessment of potential "commercial production," RB16, so AliveCor's argument is irrelevant. *See* Appx289-293 (recognizing that a complainant "need not establish that its practicing article is a product that has been or will be commercialized"). And AliveCor is wrong to suggest that merely having a prototype automatically shows an industry in the process of being established. RB16. Such an extraordinary rule would allow a complainant with no actual intent to build a domestic industry to invoke the Commission's jurisdiction based on de minimis investments in a barebones representation of a theoretical product. AliveCor may have hoped to

secure the Commission's jurisdiction in this way, but the Commission rightly rejected the attempt.

II. AliveCor Failed To Show Infringement Of Valid Patent Claims.

A. Under the proper claim construction, Apple does not infringe the '941 and '731 patents.

The asserted claims of the '941 and '731 patents require executable instructions that use ECG data to "confirm the presence of the arrhythmia" detected based on PPG data. As Apple's opening brief demonstrated (AB44-51), the plain meaning of "confirm," the definite article "the," the specification, and the purpose of the invention all show that executable instructions on the smartwatch must confirm *the same* arrhythmia that was detected. Neither the Commission nor AliveCor disputes Apple's showing that there is no infringement under that construction. *See* AB51-54.[3] Claim construction is therefore the only question this Court need decide.

The bulk of the Commission's argument is devoted to a strawman. The Commission acknowledges that there were "two disputes" about the

[3] Neither party, for example, defends the ALJ's suggestion that infringement might occur through a user's mental processes, despite the claim requiring executable instructions. *See* Appx149-150; AB51-52.

claim language before the Commission—one about "what was being detected and confirmed," and one about the timing of confirmation. CB33. Apple has pressed only the first issue on appeal. *See* AB46-51. Yet the Commission almost exclusively addresses the now-irrelevant timing point. *See* CB32-36. Even when it briefly acknowledges Apple's actual argument in a footnote, the Commission immediately returns to timing. *See* CB35-36 n.14 (arguing that Apple's specification cites support the Commission because they show "later-in-time ECG measurements"); *see also* RB38 (AliveCor similarly making a non-responsive timing argument, citing testimony from Dr. Stultz). The Commission thus has no substantive response to Apple's claim-construction showing.

AliveCor does respond, but it offers no basis on which to affirm the Commission's reading of the claim to not require any link between the arrhythmia that is "detect[ed]" and the one that is "confirm[ed]." AliveCor does not dispute the ordinary meaning of "confirm" to mean "verifying" a prior hypothesis. AB46-50. It instead suggests that a skilled artisan would not understand "confirm" according to this "simplistic" ordinary meaning, RB35, but rather would understand

that, in the "context" of the patent, ECG is a "clinically-understood confirmatory measurement tool." RB37 & n.10. In effect, AliveCor's theory is that a skilled artisan would understand any ECG as inherently "confirmatory," regardless of whether the ECG result has any connection to an arrhythmia previously detected using PPG. RB35-37.

This argument fails on several levels. To start, AliveCor's theory fails to distinguish between "confirm" and "detect"—a distinction AliveCor itself has recognized as necessary in the related Board proceeding. *See* AB47 n.7; *Helmsderfer v. Bobrick Washroom Equip.,* 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("[D]ifferent claim terms are presumed to have different meanings.").

Moreover, AliveCor offers no evidence that a skilled artisan would, in fact, read the claims as it proposes. On the contrary, AliveCor's cited evidence establishes that skilled artisans would understand "confirm … the arrhythmia" according to its ordinary meaning: verifying the same arrhythmia that was previously detected. The specification describes the smartwatch using ECG data to "verify" the arrhythmia previously detected using heart-rate data, Appx10069-10070 20:62-21:9, and to

provide "more accurate analysis" following PPG-based detection, Appx10064 10:25-26. *See* RB36 (citing these portions). It likewise describes how heart rate data may be used to "determine[]" a "discordance," which must then "be confirmed with the ECG." Appx10091 15:22-43, 49-59; *see also* Appx10090 13:29-51; Appx10072 25:25-36. These descriptions are consistent with the plain meaning of "confirm," not any special meaning—and they are consistent with the core insight of the invention, which is to screen for potential arrhythmias using continuous PPG monitoring and then, when an arrhythmia is detected, prompt an ECG to confirm. *See* AB49-51.

AliveCor's theory that skilled artisans would ignore the plain meaning of "confirm" is also belied by AliveCor's expert, who testified that "the word confirm" involves "compar[ing]" the ECG to the PPG data "to confirm if … the suspected AFib condition is indeed an AFib condition." Appx30364-30365. Indeed, in the portion of his testimony cited by AliveCor (RB36), Dr. Jafari embraced the exact definition that AliveCor disparages as "conceptually simplistic" (RB35): "within the context of this invention," he explained, PPG data "establish[es] the

hypothesis, and the suspicion that something is wrong," while ECG data "confirm[s] it." Appx30292-30293; *see also* Appx30365-30368.

Apple also demonstrated how the claims' reference to "*the* arrhythmia" (not "*an* arrhythmia") shows that the ECG must confirm the same arrhythmia detected by the PPG. AB48-49. AliveCor dismisses this as a "mundane choice of articles," RB34, while ignoring this Court's frequent reliance on the principle that "use of the definite articles 'the' or 'said' in a claim refers back to the same term recited earlier in the claim." *Wi-Lan, Inc. v. Apple Inc.*, 811 F.3d 455, 462 (Fed. Cir. 2016); *see, e.g.*, *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 954 (Fed. Cir. 2006); *Process Control Corp. v. HydRe-claim Corp.*, 190 F.3d 1350, 1356 (Fed. Cir. 1999).

AliveCor next suggests (RB34-35) that any textual requirement that the smartwatch confirm "the same episode of arrhythmia" or "the same species of arrhythmia" can be ignored because the Commission construed arrhythmia as "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx127; *see also* CB35 & n.14. But the specification itself identifies different irregular heart rate patterns as "different arrhythmias."

Appx10085 3:40-45; *see also* Appx10085 4:14-32; Appx10078 (Fig. 2); Appx327; Appx10083 (Fig. 7); Appx10091 15:27-59; AB49-50. And nothing about construing arrhythmia as a "condition" supports the Commission's reading of "confirm" to encompass identifying any type of arrhythmia, with no comparison or correlation of the PPG and ECG readings.

Imagine, for instance, claims requiring "detecting a cancer" using magnetic resonance imaging (MRI), then "confirming the cancer" using a biopsy. If "cancer" were construed to mean "a condition in which cells divide more rapidly than normal," that would not justify reading the claims to encompass detecting a brain tumor using an MRI and, separately, taking a biopsy of a mole and finding melanoma. That an "arrhythmia" is a "condition" likewise does not change the fact that the claim language, the specification, and the purpose of the patented invention all require some connection between what is initially detected (using PPG) and what is ultimately confirmed (using ECG).

B. All asserted claims are obvious.

1. The secondary consideration evidence does not overcome Apple's strong prima facie obviousness showing.

Improper weighing. Even if the Commission's findings about secondary considerations were supported by the evidence, *but see infra* 27-34, Apple demonstrated that they were not enough to overcome Apple's strong prima facie obviousness showing. *See* AB74-75. The Commission and AliveCor do not dispute that Apple's showing was uniquely strong. Instead, they falsely claim that the Commission also found "strong" evidence of nonobviousness. RB31-32; *see* CB47. That is incorrect. While the *ALJ* found "strong" evidence of secondary considerations, the Commission chose to "modif[y]" the secondary-considerations findings. Appx203; Appx40. It excluded entirely the supposed "commercial success" evidence the ALJ had found noteworthy, deeming it "weak" and omitting it from the final analysis. Appx44.

As to copying and industry praise, the Commission majority found the ALJ's findings "amply supported by the record" but did not suggest, let alone state, that they amounted to a strong showing of nonobviousness. Appx44. Contrary to the Commission's attorney

argument that there was "strong evidence of copying," CB47, even the ALJ had deemed that evidence "not especially impressive." Appx201-203. AliveCor is wrong to suggest that copying is categorically "'strong evidence of nonobviousness.'" RB23 (quoting *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1213 (Fed. Cir. 2023)). As the Commission acknowledges, *Volvo Penta* merely held that copying "can be 'strong evidence of nonobviousness,'" not that it always is. CB41; *see also Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000) ("copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia"). And while the ALJ did deem the industry-praise evidence "impressive," it also disparaged the same evidence as "admittedly" "not … unqualified … and generally focus[ed] on [KardiaBand's] ECG function." Appx200.[4]

Even if this tepid assessment of the secondary considerations were supported by substantial evidence, it could not overcome Apple's strong prima facie obviousness case. *See* AB74-75. AliveCor (but not the

[4] The Commission is wrong to claim (CB46) that "praise from Apple" supports the Commission's balancing. Neither the Commission nor the ALJ relied on supposed praise from Apple in their industry-praise analysis.

Commission) argues that it was not required to make an "extremely strong" showing. RB32. But in all this Court's "history …, [it] ha[s] only once held that evidence of secondary considerations outweighs strong evidence of obviousness." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1068 (Fed. Cir. 2016) (Prost, C.J., dissenting) (citing *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340 (Fed. Cir. 2012)). In that case, there were "seven types of objective" indicia that supplied "extensive," "compelling objective evidence of nonobviousness." *Transocean*, 699 F.3d at 1349, 1354. The Commission did not find anything close to that extraordinary showing here. Again, *Volvo Penta* (cited at RB32 n.8) is not to the contrary. There, the Court primarily faulted the Board for insufficiently explaining its secondary-considerations analysis, and remanded for "further consideration" and "additional findings." 81 F.4th at 1215.

Insubstantial evidence. Even apart from the improper weighing of obviousness factors, no substantial evidence supports the Commission's findings that there was any copying or industry praise. *See* AB69-74.

No copying. Both the Commission and AliveCor insist that Apple copied KardiaBand. CB41-44; RB23-28. But they fail to cite any evidence supporting that assertion. They claim, for example, that Apple "admit[ted] that it obtained confidential information about the [in-development KardiaBand]" through FOIA requests that predated the public release. CB43 (citing Appx1297); RB27 n.7. That is false. The cited FOIA requests involved an entirely different product, the AliveCor Heart Monitor, which is an ECG device with no PPG functionality used with mobile phones, not smartwatches. Appx1297; *see* Appx30159; Appx14652; Appx13695-13700. Furthermore, consistent with FOIA's exemption for confidential information, *see* 5 U.S.C. § 552(b)(4), any AliveCor confidential information was redacted from the FOIA productions. Appx1298; *e.g.*, Appx15411-15412; Appx14390-14402. These redactions belie Dr. Efimov's baseless assertion (Appx31202-31213) that Apple obtained AliveCor's confidential information using FOIA. That Apple received public information about a different, non-practicing product has no bearing on whether Apple copied KardiaBand. *See* AB71-72.

The Commission and AliveCor also divine copying from the fact that Apple temporarily "'back burner[ed]'" development of Watch's ECG functionality. CB42 (quoting Appx40003); RB25-26; *see* Appx202. But Apple did so due to "regulatory challenges," not technical ones. Appx11038-11039; *see* AB73-74. AliveCor responds (RB25-26) with citations showing only that Apple's ECG technology was not perfect during early tests, Appx30790, and that Apple worked for "years" to develop the technology, Appx30810. It requires quite a leap to infer from Apple's work to perfect its ECG technology that Apple shelved ECG for anything other than its stated regulatory reasons.

AliveCor therefore resorts to pretending that the Commission "infer[red] that Apple did not believe it was worth [adding ECG functionality] until it saw AliveCor blaze a trail." RB25-26. But the Commission did no such thing. *See* Appx200-202. For good reason: The undisputed evidence shows that Apple began developing ECG functionality for Watch in 2012, *before* the asserted patents' priority dates, Appx30738-30743; Appx12029; Appx12206, and that Apple resumed development long before KardiaBand's release, "when it became clear that we were doing … a physical update" to Watch Series

4. Appx11039; Appx13213; Appx30744-30745. None of AliveCor's citations suggests otherwise. *E.g.*, Appx16341-16345 (news article stating that Watch was originally "designed to be a fashion accessory as well as a gadget"); Appx30744-30745 (testimony that Apple was "approaching … clinical validation trials" for ECG in September 2017, before AliveCor's KardiaBand release); Appx13209-13210 (Apple employee did not recall Apple conducting research to "determine whether Apple Watch customers would want an ECG app").

None of the post-KardiaBand-release evidence shows copying either. The Commission and AliveCor note that one Apple employee "compar[ed] SmartRhythm in the [KardiaBand] with" Apple's IRN software. CB43 n.15 (citing Appx16285); RB25. But the mere fact of comparison cannot be inherently suspect. *See* AB72-73. Tellingly, the Commission cites no caselaw for its assertion that such a commonplace practice "can later be used as evidence of copying." CB43-44. And it identifies nothing in Apple's assessment of AliveCor's product that comes close to evidence previously treated as copying. *See, e.g.*, *Transocean*, 699 F.3d at 1352 (internal documents stated, for example, "we have to incorporate" competitor's technology).

AliveCor also argues (RB27-28) that Apple "decided to link" ECG and IRN after AliveCor publicly released KardiaBand with SmartRhythm. The Commission did not cite or credit any such evidence, however. *See* Appx202; OB59-60 & n.4 (AliveCor faulting Commission for "disregard[ing]" this evidence in infringement analysis). Apple affirmatively chose *not* to link the two features, and its separate FDA clearances for ECG app and IRN as "standalone" medical devices depend on that choice. *See* AB53. AliveCor elsewhere insinuates that Apple's "design intention" conflicts with "what Apple told the FDA." RB50 n.12. AliveCor's accusation is baseless. Apple did consider a link, as the cited document reflects. *See* Appx15988; *accord* Appx16365. But it is undisputed that this link "was removed prior to the software release." Appx30859; *see also* Appx30839 (same); Appx30862-30863 (explaining emphasis on keeping the two features separate). And AliveCor's expert conceded that "there's no input from IRN" to the ECG application. Appx30463.

No industry praise. The Commission and AliveCor, omitting crucial context, dispute whether the industry-praise evidence was

biased. *See* CB45-46; RB28-29.[5] But they do not dispute that this praise "generally focus[es] on the ECG function" of KardiaBand. Appx200. They assert that this should not matter because "ECG functionality is an element of the claimed invention." CB46; RB29. But it is undisputed that AliveCor's patents "effectively assume[] [ECG] devices are ordinary" and offer no "information on how to achieve" the reliable ECG measurements praised in industry articles. Appx187.

AliveCor also argues that praise need not be "precisely limited to the point of novelty" of the claimed invention. RB30 (citing *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1334 (Fed. Cir. 2019)). True, but it must at least be directed to *some* novel feature. *See Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364 (Fed. Cir. 2023); *S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015). The Commission and AliveCor identify no such praise. *See, e.g.*, RB29 (stating only that some articles "discuss" SmartRhythm). The evidence the Commission quotes from (CB44-45) is illustrative. One

[5] There can be no dispute, however, that bias infects the amicus briefs nominally supporting the Commission. Signatories on both are "[m]ajor investors" in AliveCor. Appx12212. Omron Healthcare disclosed its interest. Dkt. 80 at 3. Khosla Ventures did not. Dkt. 84 at 3.

reviewer described KardiaBand's "EKG device on the wrist" as a "giant leap in personalized health care," Appx15925-15926, but AliveCor's founder admitted that "ECG watches [have existed] since the early 1990s," Appx10235.

Finally, the Commission and AliveCor cite supposed praise by Apple employees. The Commission did not credit this evidence in its nonobviousness analysis, *see* Appx200, so it cannot serve as a basis for affirmance. *Power Integrations*, 797 F.3d at 1326. Regardless, AliveCor and the Commission mischaracterize these employees' statements. For example, while both parties highlight Dr. Waydo's testimony that he "tried out" a KardiaBand because Apple initially "had some excitement" about the product's potential, Appx30784 (quoted at CB45, RB31), they omit that Dr. Waydo could tolerate wearing the KardiaBand only for "about 30 minutes" and criticized it as "clunky," "awful," and not "acceptable" for a general audience. Appx16282-16284; *see also* Appx13667 (Dr. Waydo testifying that "a user could get value out of using [PPG and ECG] together," without discussing KardiaBand); Appx16279-16280 (Apple employee calling KardiaBand "a high quality accessory" but identifying "problem[s]" and "room for improvement");

Appx12007-12010 (Apple employee citing KardiaBand's "theor[etical]" advantage in catching arrhythmias but noting its "much higher rate of false positives").

2. Apple showed that all asserted claims are prima facie obvious.

Rhythm-strip-display claims. Apple showed that AMON renders the asserted ECG rhythm-strip display claims obvious. AB61-63. AliveCor and the Commission argue that AMON does not literally disclose displaying a rhythm strip. RB19-21; CB48-50. But they have little answer to Apple's showing that this display would have been obvious. *See* AB63.

AliveCor argues only that displaying an ECG rhythm strip on a wristworn device like AMON "would not benefit a lay person wearing the AMON device." RB22. But all agree that rhythm strips are what physicians "use … to diagnose heart problems." RB21; *see* Appx31296-31297; Appx31088. And no one disputes that AMON discloses a built-in display. Appx11967. A skilled practitioner seeking to accomplish AMON's goal of ensuring that high-risk cardiac patients' heart "problems will be detected in time," Appx11966-11967, would have

found it immediately obvious to use AMON's display to show a rhythm strip like the one AMON depicts in Figure 4. *See* AB62-63.

The Commission offers no substantive argument, instead criticizing Apple for presenting only "attorney argument." CB49-50. That is transparently false; Apple cited AMON's teachings, along with testimony from both parties' experts and AliveCor's founder. AB61-63 (citing Appx11967-11969; Appx31129; Appx31141-31142; Appx31088; Appx12171-12172; Appx30114-30115). The Commission ignores this evidence.

Machine-learning claims. Apple also showed that the asserted machine-learning claims would have been obvious in view of AMON's machine-learning teachings and a skilled artisan's background knowledge. *See* AB64-66.

The Commission defends its contrary determination by focusing solely on AMON's literal disclosure. CB50-51. As Apple explained (AB64-65), obviousness "requires an assessment" of a skilled artisan's background knowledge. *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1349 (Fed. Cir. 2010).

AliveCor argues that the Commission properly disregarded this evidence because "Apple's own expert … testified that, even today, physicians are skeptical of using machine learning for arrhythmia diagnosis due to its lack of transparency." RB22. But the Commission did not adopt this rationale. *See* Appx224-226; Appx257; *see also* OB51-52 (AliveCor faulting the Commission for "disregard[ing]" this evidence in analyzing eligibility). Moreover, as the Patent Trial and Appeal Board observed, this purported "skepticism" relates only to "deep learning," not all machine-learning methods. Appeal No. 23-1512, Appx49; *see* Appx31137; Appx15972; Appx30923. AliveCor's patents are not limited to deep learning. *See* Appx10030 9:58-67; Appx10064 9:67-10:3.

Mathematical-analysis claims. Apple also showed that the mathematical-analysis claims would have been obvious in view of AMON's and Almen's teachings about measuring heart-rate variability ("HRV") from PPG data, combined with the '731 patent's admission that nonlinear and geometric means of measuring PPG-derived HRV signals were known. *See* AB66-67.

The Commission disputes that it "acknowledged that AMON in view of Almen 'discloses measurement of HRV' from PPG data." CB51. But it expressly recognized that "Almen discloses use of an optical [i.e., PPG] sensor … to measure heart rate and thereafter process it for determining heart rate variability," and that it would have been obvious to modify AMON to do the same. Appx194-195.

AliveCor and the Commission separately argue that the '731 patent's disclosure was "directed to ECG data, not PPG data." CB51-52; RB23. That is incorrect. The specification recognizes that HRV data, before being analyzed, may be derived using "raw heart rate signals" collected from either an "electrocardiogram" or, "alternatively, or in combination," a "photoplethysmography" sensor. Appx10063 8:45-65.

III. The Commission Abused Its Discretion In Issuing Remedial Orders.

The Commission's decades-long practice of failing to adequately consider the public-interest factors was particularly egregious here, where Apple Watch offers profound health and wellness benefits to millions of Americans that cannot readily be backfilled by other products, along with being a critical tool in medical research. AB86-97.

The Commission and AliveCor ask this Court to overlook the arbitrary reasoning to the contrary, largely because the Commission conducted over "thirty pages of analysis" and this Court reviews the Commission's public-interest findings deferentially. CB61-63; RB52-61. But quantity does not mean quality, and no amount of deference authorizes irrational decisionmaking.

Nothing the Commission or AliveCor says on appeal rehabilitates that reasoning. As to the Fitbit devices, for example, both the Commission (CB62) and AliveCor (RB55-56) criticize Apple for pointing out the differences between those products and Apple Watch. But as one leading cardiologist explains, Apple Watch's "uniquely high adoption rate"—which comes from its full array of features—"is the key to its positive impact on public health and welfare." Saxon Br. 10-11, 2-3; *see* Appx1465; Appx1402-1404; Appx1380-1381; Appx1509. This is not, as AliveCor argues, a matter of "dominant market share" or rewarding "anti-competitive conduct." RB55, 59. Indeed, a district court recently granted summary judgment to Apple on AliveCor's antitrust claims. *AliveCor*, 2024 WL 591864, at *15 (finding "no genuine dispute" that Apple's changes to Watch software were a

"product improvement" and that AliveCor "could enter the [alleged] watchOS [heart rhythm analysis] app market today").

Regardless, AliveCor's citation (RB57) to general sales numbers does not overcome the fact that Fitbit, even if a viable alternative, lacks the production capacity to rapidly meet demand. *See* AB93. And, contrary to AliveCor's suggestion (RB57), it is not rational to suggest that Fitbit "ramp up production" on the chance that this Court overturns the Board's patentability decision. The Commission doesn't even address the supply point, instead faulting Apple for failing to obtain information the Commission itself blocked Apple from getting. CB62-63.

The Commission also does not defend its reasoning about two-device solutions. *See* AB90-91. AliveCor tries, but fails. Its suggestion that a device with only PPG functionality could "motivate the user to buy [an] ECG monitor," RB58, ignores the importance of being able to take an ECG in real time, while the user is experiencing symptoms. *See* Saxon Br. 6-9; CCIA Br. 15-17; Appx1381; Appx1464-1466.

The Commission and AliveCor also fail to offer any persuasive defense of the Commission's arbitrary finding that exclusion will not

jeopardize ongoing and planned research. *See* AB95-97. They argue that the remedial orders will not prevent studies from enrolling new participants "that have already purchased Apple Watches." CB63; RB60-61. But at least one of these studies is recruiting participants who currently "do not own Apple Watches." Appx2782. And it is not up to either the Commission or AliveCor to suggest that new study participants use "substitute" devices, CB63, RB60-61; as the record and common sense reflect, redesigning studies whose protocols have been approved (and funded) based on Apple Watch would be wasteful and threaten the scientific merit of the research. *E.g.*, Appx1403.

CONCLUSION

The Court should reverse the Commission's finding of a Section 337 violation.

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