No. 2024-1285

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

NON-CONFIDENTIAL REPLY BRIEF FOR APPELLANT APPLE INC.

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July 19, 2024

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CERTIFICATE OF INTEREST

Counsel for Appellant Apple Inc. certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Apple Inc.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

[X] Yes (file separate notice; see below) [ ] No [ ] N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

Already filed.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: July 19, 2024

/s/ Mark D. Selwyn

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TABLE OF CONTENTS

CONFIDENTIAL MATERIAL OMITTED

The material omitted from pages 1, 10, and 11 contains information that Intervenors Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order in effect in ITC Investigation No. 1276.

TABLE OF AUTHORITIES

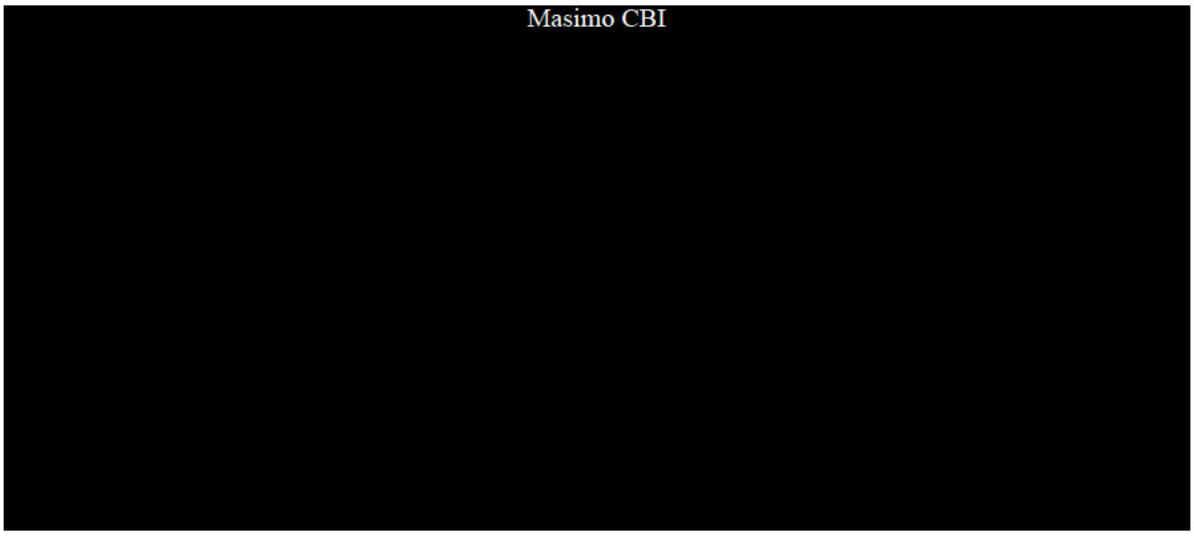
CASES

STATUTES, RULES, AND REGULATIONS

INTRODUCTION

In 135 pages of briefing, Masimo and the Commission fail to identify a prior instance where the Commission exercised its extraordinary powers to protect a patent-practicing "article" that (1) never existed in the form represented in the Complaint, (2) never existed in ***any*** form before the Complaint, and (3) was not clearly the subject of significant employment of domestic labor. Properly interpreted, Section 337 does not permit the Commission to use its draconian remedy—here, against a signature product developed by an American company—to protect a complainant's rudimentary "project" that in no way resembles a domestic industry.

Masimo and the Commission fail to justify imposing an injunction based on a complaint alleging a domestic industry through CAD drawings of a device that was purportedly "available on request"—but which actually did not exist:



Appx2741; Appx2750. Masimo's and the Commission's latest rationale is the CAD drawings were "representative" of—i.e., close to—certain prototype devices. The law and the facts do not support such an approach, which relies on cobbling together fragmentary, speculative developmental evidence for items not identified in the Complaint and calling it a domestic industry. And even the Commission acknowledged in December 2023—years after Masimo needed to show a domestic industry—it was undisputed that Masimo has not sold its commercial "W1" smartwatch "in the United States in any meaningful quantity and also does not intend to widely market that product in the United States, opting instead to market a different, not yet released product." *E.g.*, Appx27241.

In finding a domestic industry where there was none, the Commission departed from its statutory mandate, and Masimo is wrong to suggest (at 23-27) the Commission's domestic industry ruling is only subject to substantial evidence review because the agency "never had to interpret the statute." The Commission necessarily resolved a disagreement over the scope of the statute's technical and economic prongs in applying them, and whether the Commission's determination is "based on a proper interpretation of the [statute] is a question of law." *E.g.*, *Laerdal Medical Corp. v. ITC*, 910 F.3d 1207, 1211 (Fed. Cir. 2018); *accord PS Chez Sydney L.L.C. v. ITC*, 684 F.3d 1374, 1378-1379 (Fed. Cir. 2012) (whether entity qualified as "affected domestic producer" was question of law reviewed *de*

novo). For example, no plausible reading of the statute supports the Commission's conclusion that an item that does not actually practice the asserted patent satisfies the economic prong so long as it is a part of some undefined "'iterative'" chain that eventually resulted in a patent-practicing device. *E.g.*, Masimo Br.29 (quoting Appx373). This Court rejected a similar reading of the statute just two months ago, noting economic prong evidence must "'pertain to products that ***are covered*** by the [asserted] patent.'" *See Zircon Corp. v. ITC*, 101 F.4th 817, 823-824 (Fed. Cir. 2024).[1]

The Commission's brief goes further still, appearing to take the remarkable position (at 25-27) that the only rules limiting its behavior are its own (inapposite) procedural regulations—and not the plain language of its governing statute as interpreted by an Article III court. The Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 144 S.Ct. 2244 (2024), makes clear that the Commission's position is wrong. Judicial review of an agency's statutory interpretation is perhaps *most* important—and "abdication in favor of the agency is *least* appropriate"—when considering "the scope of an agency's own power." *Id.* at 2266 (emphasis in original).

[1] Emphasis added unless noted.

Masimo's and the Commission's responses to the many other flaws in the agency's decisions regarding validity, infringement, and laches fare no better. For example, both lean heavily on arguments that appear nowhere in the decision under review (such as their waiver/forfeiture arguments)—in violation of *Chenery*'s command that "[a]n agency must defend its actions based on the reasons it gave when it acted." *DHS v. Regents of the University of California*, 591 U.S. 1, 23-24 (2020). In other instances, both merely reiterate the agency's justifications (such as on laches) without explaining why they make sense. While the Court need not reach these other issues if it agrees with Apple on domestic industry, each provides an independent ground for setting the agency's decision aside.

Ultimately, affirming the Commission's decision will "open the floodgates" to abuse by patentees without an actual product or true domestic market—a ruling that would harm "innovation[,] … the United States economy," and the American public itself. *See* ACT Amicus Br.2, 8-11. Apple respectfully submits this Court should reject the Commission's significant jurisdictional overreach.

ARGUMENT

I. THE DOMESTIC INDUSTRY REQUIREMENT WAS NOT SATISFIED

A. There Was No Patent-Practicing Item That Existed At The Time Of The Complaint, As The Technical Prong Requires

Section 337 and precedent required Masimo to identify an *actual* physical item that practiced the patents when the Complaint was filed. *See* Apple Br.24-27;

19 U.S.C. §1337(a)(2) (domestic industry must "exist[]").[2] The Commission erred as a matter of law in finding Masimo met its burden, both because the purported article pictured in the Complaint concededly never existed and because the Commission impermissibly relied on speculative evidence to find the "exist" requirement met. Apple Br. 27-31.[3] Regardless, substantial evidence does not support the Commission's ruling. Apple Br. 31-37.

1. The Commission committed legal error by exercising jurisdiction over a complaint that relied on an "article" that undisputedly never existed

Masimo and the Commission first wrongly contend that even if the item pictured in the Complaint was different from the purported article ("the Masimo Watch"), it was close enough to be "representative" of that article. Masimo Br.31-32; ITC Br.26 n.14. But the agency never articulated this rationale (or made any finding of "representativeness"), and it therefore cannot support affirmance. *DHS*,

[2] As the Commission acknowledges (at 5, 27) (and Masimo ignores (at 31 n.6)), the agency took no position on "whether Masimo had shown a domestic industry in the process of being established." The agency thus cannot be affirmed on that ground. Apple Br.24-25 & n.12.

[3] Masimo incorrectly implies (at 31-32) that the ALJ found the CAD drawings reflected one of the RevE devices in its entirety. The cited passage finds the drawings depicted ***one aspect*** of that item, corresponding with an element of a claim not at issue on appeal. Appx70.

591 U.S. at 23 (discussing *Chenery* principle).[4] Regardless, Masimo did not raise the representativeness point below, and Apple was not given a fair opportunity to develop rebuttal evidence to this new theory. In fact, Apple is unaware of (and Masimo and the Commission do not cite) a legal test for determining whether the item identified in a complaint is similar enough to a later produced "article" to be representative. And if Masimo truly had a patent-practicing article at the time of the Complaint, why not include its photos instead of those of a CAD drawing of an item that has never existed? Masimo and the Commission have no real answer.

Instead, Masimo and the Commission erroneously argue that Masimo was not required to identify the patent-practicing article in the Complaint. Masimo Br.30-31; ITC Br.25-26. But the handful of cited regulations merely define the scope of the agency record and ignore the key question—whether a complainant can shift its legal theory regarding the relevant "article" after filing the complaint. Even if the regulations were on point, they could not override statutory text. Section 337 only authorizes the Commission to "investigate an[] ***alleged violation***" of the statute (including its domestic industry article requirement) "***on complaint***

[4] The Commission wrongly contends it was not required to "'address every argument raised by a party.'" ITC Br.18 (quoting *Synopsys, Inc. v. Mentor Graphics Corp.,* 814 F.3d 1309, 1322 (Fed. Cir. 2016)). *Synopsys* dealt with the narrowest of omissions—failure to reference a specific patent figure. 814 F.3d at 1322. It does not give the Commission license to dodge inconvenient arguments through silence.

under oath or upon its initiative," and an injunction cannot be ordered without such an investigation. 19 U.S.C. §1337(b), (c); Apple Br.25. The agency accordingly lacks the power to issue an injunction in cases like this one, where the investigation was started via complaint, Appx6, and the "article" ultimately relied upon was nowhere in that complaint, Apple Br. 13-14.

Masimo is also wrong (at 30-31) that the statutory "violation" contemplated by 19 U.S.C. §1337(b) is the purported infringement of Masimo's patents via sale/import and does not require a domestic industry to exist. Not only does Section 337(b) refer to "any violation ***of this section***" (which naturally includes the technical and economic prongs), but Section 337 is explicit that its prohibition on patent infringement "appl[ies] ***only if***" the domestic industry requirement is satisfied. *See* 19 U.S.C. §1337(a)(2).

Finally, Masimo errs by accusing Apple of "ignor[ing]" the Commission's conclusions that the RevA, RevD, and RevE items were made before Masimo's Complaint was filed and were part of an "iterative design process." Masimo Br.29-30. Apple's opening brief directly addressed both points. Apple Br.31-37, 39-40. But neither is relevant to whether the Complaint identified the purported article because the Complaint did not allege that RevA, RevD, and RevE were the "article[s]," *see* Appx3732-3735, and again, Section 337 requires a finished "article," not a nascent development project.

2. The Commission committed legal error by holding Section 337's technical prong satisfied by speculation that unproduced patent-practicing items *might* have existed

Masimo and the Commission attempt (but fail) to justify the ALJ's reliance on speculation by pointing to two inapposite cases. Masimo Br.33 (citing *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986)); ITC Br.26 (citing *Moleculon* and *Bio-Rad Labs. Inc. v. ITC*, 996 F.3d 1302 (Fed. Cir. 2021)). *Bio-Rad* does not use the word "circumstantial," and merely dealt with narrow factual questions about whether documentary evidence "accurately represented the operation" of the purported article. 996 F.3d at 1313-1315. *Moleculon* involved the test for direct and induced infringement, 792 F.3d at 1272—i.e., matters where (unlike here) any relevant direct evidence would likely be with the purported infringer.

Masimo and the Commission also wrongly suggest the agency could rely on items beyond the specific RevA sensor, the RevD sensor, and the three RevE sensors Masimo produced in finding the "exist" requirement satisfied. ITC Br.25-26; Masimo Br.33. This post-hoc switch cannot be squared with the decision under review, which found Masimo's domestic industry argument was based solely on six physical items. Appx60 (discussing RevA sensor (CPX-0052C), RevD sensor (CPX-0058C), RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C), and Masimo W1 (CPX-0146C))); Appx373 (similar in Commission decision);

Appx21848 (similar in Masimo's briefing); *see also infra* pp.10-11.[5] In short, the newly-minted theory that the Commission could rely on the general RevA, RevD, and RevE designs is an improper "post hoc rationalization[]" for why the agency ruled in Masimo's favor. *DHS*, 591 U.S. at 22-23.

Masimo also erroneously contends this Court can affirm without relying on speculative evidence because Masimo "***presented***" "direct evidence." Masimo Br. 33. But the agency did not affirmatively rely on anything that can be described as "direct evidence" and thus cannot be affirmed on that basis. *DHS*, 591 U.S. at 23; *see also DSS Tech. Mgmt., Inc. v. Apple Inc.*, 885 F.3d 1367, 1376 n.4 (Fed. Cir. 2018) ("declin[ing]," due to "the *Chenery* doctrine," "to consider evidence that the [agency] did not cite in its decisions"); Apple Br. 29-31.

Finally, Masimo wrongly argues the Commission "relied on internal documents, technical drawings, and circuit diagrams underlying the ***designs*** in its analysis." Masimo Br.33-34. However, none of Masimo's ten (unexplained) record cites clearly relate to the five physical prototypes at issue; they are another example of Masimo's improper reliance on general "designs" to satisfy the article requirement. *See supra* p.8; *infra* pp.10-11.

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[5] Even the Commission's opposition to Apple's motion to stay treated the individual prototypes as the purported articles. *See* C.A. Dkt. 24 at 6-7 (discussing "***the*** RevA sensor," "***the*** RevD sensor," and "the RevE sensors (***for which there were three separate devices***)").

3. The Commission's finding that an "article" existed at the time of the complaint is not supported by substantial evidence

First, Masimo and the Commission (again) press the flawed argument that the "articles" at issue were the broader RevA, RevD, and RevE "design[s]" rather than the five specific prototypes that Masimo produced. *E.g.*, ITC Br.3-4, 19-22; Masimo Br.26-27 (similar). The agency did not identify the RevA, RevD, and RevE ***designs*** as the domestic industry "articles"; it relied on five specific prototypes. *See supra* pp.8-9.

The distinction between the physical prototypes and the broader "designs" matters to the substantial evidence calculus because—unlike items in a commercial product line—each prototype that Masimo identified was distinct. To take two uncontested examples, (1) several of Masimo's RevA devices were *inoperable* at the time of the Complaint and (2) Masimo relied on three separate RevE devices to prove its case, which would have been unnecessary if all RevE items were identical. *See* Apple Br.35, 37; *see also* Masimo Br.26 (pictures of the three distinct RevE devices). More broadly, Masimo's own engineer testified that Masimo went through different iterations of the sensor design even within a "Rev." Appx40359-40362 (noting that CPX-056 (a RevA device) "Masimo CBI"

from RevA device Masimo relied upon in front of the ALJ (CPX-052)).[6] The CPX-056 and CPX-052 sensors are pictured below:

Appx65024; Appx60528.

In sum, Masimo's and the Commission's reliance on general designs to provide substantial evidence should be rejected, as nothing in the record suggests the performance or design of a device that falls into the broader categories of RevA, RevD, and RevE sensors says anything definitive about the performance or design of the specific prototypes at issue.

Second, Masimo wrongly argues substantial evidence established the five prototypes measured blood oxygen. Masimo Br.34-36. But Masimo's citations to evidence and reasoning largely go to points that the ALJ did not adopt, and Masimo concedes the key basis for the ALJ's ruling was her belief that "'designs ***consistent with***'" (i.e., different from) the specific physical prototypes had

[6] This distinction (Masimo CBI" CPX-056 vs. Masimo CBI CPX-052) meant CPX-056 did not practice the asserted claims, which require a "convex protrusion."

demonstrated blood oxygen functionality in pre-Complaint testing. Masimo Br.35 (citing Appx66-67).

Masimo (at 27, 28) also tries to argue that blood oxygen testing conducted months after filing the Complaint provides the requisite substantial evidence, but the only record evidence suggesting those tests established blood oxygen functionality was Masimo's expert's bald assertion that he found functionality based on "on Mr. Scruggs' demonstrations … [regarding] Rev. A, D, E, and W1 Masimo Watches." Appx40811. "'Conclusory statements and unspecific expert testimony'" are not substantial evidence. *DSS Technology*, 885 F.3d at 1376-1377.

Third, Masimo and the Commission are incorrect to argue substantial evidence established RevA and RevD satisfied the "user-worn" claim element. Masimo Br.35; ITC Br.20-21. The two specific prototypes produced had no strap and vague testimony that both items had a strap "at one point in time," Apple Br.34; Appx40499; Appx40501, says nothing about whether RevA or RevD had a strap at the ***required*** time—i.e., before the Complaint.

Finally, Masimo and the Commission wrongly contend that substantial evidence established that the RevD and the three RevE items were created before the Complaint. Masimo Br.34-35; ITC Br.23-24. But it is undisputed that (1) the RevD item (CPX-058C) had no software and thus was nonfunctional before July 30, 2021, Appx40553-40554(459:4-460:7) and (2) one of the RevE items (CPX-

020C) was "created in September of 2021," Appx40552-40553(458:1-459:3). While the Commission (at 24) and Masimo (at 27) assert one of the two remaining RevE items was created before the Complaint, the same witness who offered the testimony the ALJ relied upon (in a deposition) could not be any more specific at the hearing than that the remaining two RevE devices were created sometime "between May and September of 2021." *Compare* Appx89 n.23 *with* Appx40492.

Regardless, the ALJ found that the software on all four of these physical items was altered after the Complaint was filed. *See* Appx88-89 & n.23.[7] The new argument that the modified software did not meaningly affect the functionality of the items, Masimo Br.34; ITC Br.24, appears nowhere in the ALJ's opinion and thus cannot provide a ground for affirmance, *DHS*, 591 U.S. at 23.

B. There Was No Evidence Of Investment In The Patent-Practicing Articles Themselves, As The Economic Prong Requires

1. The Commission committed legal error by holding the economic prong satisfied by investment that was spent in unspecified part on non-patent-practicing items

Section 337's language and precedent require a complainant to demonstrate "significant" investment "in the United States, with respect to the articles protected by the patent." 19 U.S.C. §1337(a)(3); *see* Apple Br.37-38. Masimo cannot have

[7] The ALJ's sanctions ruling Masimo references (at 12-13) declined to resolve whether the physical prototypes "existed at the relevant time" for purposes of Section 337. Appx14139 & n.9.

satisfied that requirement, as (1) the only "article" in the Complaint never existed and, regardless, (2) Masimo's proof of investment concededly did not differentiate between the expenditures spent on patent-practicing and non-patent-practicing items. Apple Br.38-40.[8]

***First*,** the Commission and Masimo wrongly argue the agency's interpretation of Section 337(a)(3) is a question of fact. ITC Br.29; Masimo Br.22-23. But as *Laerdal* and *PS Chez* explain, whether the Commission's determination correctly applied a statute is a question of law. *See supra* p.2. While the Commission and Masimo quibble over the words Apple used to describe the parties' disagreement, there is no apparent dispute this issue turns on whether a party can satisfy the statute relying on investments spent in unspecified part on non-patent practicing items (i.e., Wings and Circle). *See, e.g.*, ITC Br.31. All that remains is to apply the legal standard in the statute to those "established facts"—a quintessential "'question[] of law.'" *See Wilkinson v. Garland*, 601 U.S. 209, 221-222 (2024).

The Commission's cases are inapposite. In *Motiva, LLC v. ITC*, there was no apparent disagreement over the relevant legal standard—the question was whether the complainant had made out its factual case, 716 F.3d 596, 600-601

[8] The first issue rises and falls with the arguments in Part I.A.

(Fed. Cir. 2013). And in *Motorola Mobility v. ITC*, this Court applied the substantial evidence standard only in a short paragraph evaluating the agency's factual findings—not in the prior paragraph discussing the scope of Section 337, 737 F.3d 1345, 1351 (Fed. Cir. 2013).

Second, the Commission (at 31-32) and Masimo (at 38) try to walk away from *Stud Finders*' holding that Section 337 bars "aggregating investments" on the ground that Apple "ignore[d]" the ALJ's reasoning for distinguishing *Stud Finders*. Not so. As explained, the ALJ's legal reasoning (that Wings and Circle were part of a broader "single product design") makes little sense, given the ALJ's subsequent acknowledgment that Wings and Circle are sufficiently distinct that they do not practice the asserted patents. Apple Br.39-40. The Commission and Masimo have no clear response.[9]

Finally, the Commission and Masimo erroneously contend Section 337 does not require domestic investment in a patent-practicing item itself so long as the investment has some connection to the later development of the patent-practicing item. ITC Br.31-32; Masimo Br.38-39. But this reading renders the economic prong toothless. Under the Commission and Masimo's logic, an investment in a

[9] If the Commission and Masimo are attempting to distinguish between commercial ***products*** that practice and ***prototypes*** that practice, they do not explain why that matters—the statute uses the general word "article," not product.

1909 Model-T could be cited a century later as an investment in a patent-practicing Ford Explorer because the Explorer is a many-iterations-later improvement of the Model-T.

This Court rejected this kind of lax approach as recently as May, acknowledging the economic prong "ties the domestic industry [showing] to products ***protected by a particular patent***." *Zircon*, 101 F.4th at 823; *see also id.* at 824 (investment must "pertain to products that are covered by the [asserted] patent"). As the Commission's own authority establishes, the statute requires a showing that the investment is "***directed to*** … the article." *Motorola*, 737 F.3d at 1351; *accord Microsoft Corp. v. ITC*, 731 F.3d 1354, 1361-1362 (Fed. Cir. 2013) ("A company seeking section 337 protection must … provide evidence that its substantial domestic investment … relates to an actual article that practices the patent.").[10]

While there is no absolute requirement that the complainant "break[] out investments on a per-patent basis," the complainant must offer ***some*** way to determine "the domestic industry requirement is met for each patent." *Zircon*, 101

[10] Masimo's accusation (at 37-38) that Apple "distorts" *Microsoft* is meritless. The relevant passage cites the economic prong and explains why Microsoft's "substantial investments" in a non-patent-practicing item (Microsoft's operating system) were "unmistakably" "not enough under the statute." 731 F.3d at 1361-1362.

F.4th at 824. Masimo failed to provide such a basis here, as the ALJ found that absent aggregation of all expenditures, "there is no reasonable way to delineate between work on separate prototypes"—some of which practiced the patents and some of which did not. Appx308. At minimum, *Zircon* requires a remand for the ALJ to address whether Masimo met its burden to satisfy the economic prong based solely on the items that practice the patent. *Compare* Appx308-309 (ALJ noting "the most relevant timeframe" for expenditures is "the time period leading up to" July 2021 and that expenses as late as November 2020 were "likely to involve … improvements to the Wings sensor") *with* ITC Br.30 (economic prong analysis relied on Masimo's "2019-2021 aggregated labor investments").

2. The agency's finding of "significant" employment is unsupported by substantial evidence

The three spreadsheets that formed the basis for the finding that Masimo's investments were "significant" cannot be substantial evidence, as they are uncorroborated and lack any clear, reliable methodology. Apple Br.40-42.

The Commission and Masimo do not identify concrete evidence corroborating the spreadsheet information. They cite high-level testimony from Masimo's CFO and expert indicating the two participated in (and oversaw the collection of) the data. Masimo Br.41; ITC Br.33-34. But neither individual explained (1) *how* Masimo developed individualized time estimates for dozens of

employees or (2) why a purportedly conservative estimate was anything more than a post-hoc guess. Apple Br. 41-42.

The Commission and Masimo also wrongly argue this Court should affirm on a purported "independent basis" for finding significance—i.e., that most of Masimo's research and development work was done in the U.S. ITC Br.32-33; Masimo Br.36-37. That alone cannot be enough. Masimo was required to show a "'significant' ***increase***" in—or a significant magnitude of—employment "by virtue of [Masimo's] commercial activity in the United States." *Lelo Inc. v. ITC*, 786 F.3d 879, 883-884 (Fed. Cir. 2015); *see also* Apple Br.40. Because Masimo was unable to reliably quantify its labor expenditures, there is no reliable evidence as to how long each employee worked on the various prototypes at issue—any individual employee could have spent just minutes on the project.

II. THE ASSERTED CLAIMS ARE INVALID

A. The Asserted Claims Are Obvious

1. The Commission erred by requiring Lumidigm to enable more than the asserted patents disclose

The Commission erred by holding Lumidigm did not satisfy the "user-worn" limitation as a party challenging validity cannot be required to show a prior art reference discloses ***more*** than the patent-at-issue. Apple Br.45-49.

First, the Commission and Masimo erroneously contend Apple waived this argument by first raising it in front of the Commission (rather than the ALJ). ITC

Br.39-49; Masimo Br.44-45. But a party is not required to preemptively guess an agency's reasoning to preserve an issue for appeal. "A party may raise on appeal any issue that was … actually decided below," *Apple Inc. v. MPH Techs. Oy*, 2022 WL 4103286, at *4-5 (Fed. Cir. Sept. 8, 2022) (alteration in original), and Apple promptly raised the ALJ's error in front of the Commission. Regardless, *Chenery* precludes this Court from "affirm[ing] on the ground of waiver" where "the Commission [decision] did not hold or suggest that the issue had been waived." *Vizio, Inc. v. ITC*, 605 F.3d 1330, 1343 n.11 (Fed. Cir. 2010) (this Court "cannot properly substitute our decision on a discretionary issue for that of the Commission").[11] Even the Commission's later ruling on Apple's motion to stay addressed the issue on the merits without mentioning waiver. Appx27238-27239.

Second, the Commission is wrong that the decision below can be affirmed on the purportedly independent basis that Apple failed to establish a reasonable likelihood of success of measuring blood oxygen at the wrist. ITC Br.37-38, 40. The reasonable likelihood ruling cannot be disentangled from the ALJ's ruling on enablement. Had the ALJ applied the proper legal standard, Apple would have only been required to show a reasonable expectation of success at measuring blood

[11] The Commission argues (at 17 n.8) this Court implicitly reached a different conclusion in *Broadcom Corp. v. ITC*, 542 F.3d 894, 901 (Fed. Cir. 2008). But unlike *Vizio*, *Broadcom* did not address *Chenery*.

oxygen somewhere on the body—not on the wrist specifically. Apple Br.45, 48; *see also* Appx123 n.44 (ALJ citing "the difficulty in achieving blood oxygen measurements ***at the wrist***" as the reason for lack of reasonable expectation of success).[12]

Third, Masimo (at 45) and the Commission (at 41) argue it was legally permissible to require Lumidigm to enable more than the asserted claims, but provide no clear reason why that is so. Their position appears to rest on the general point that the standards for assessing obviousness and enablement are different. That high-level observation is irrelevant to the specific legal question at hand and certainly provides no reason to distinguish the authorities cited by Apple (at 45-47). In particular, the Commission and Masimo do not provide any specific reason for why *Epstein* and *Paulsen* are inapplicable here beyond simply repeating the procedural objections dispatched above (e.g., waiver and a purported alternative ground for affirmance).

Fourth, Masimo and the Commission wrongly contend the agency's error was Apple's fault because Apple's obviousness theory centered on the wrist. ITC Br.40; Masimo Br.43-44. This reasoning appears nowhere in the decision under

[12] Masimo is wrong (at 42) that a challenge to the ***legal standard*** applied is a question of fact, *see Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (de novo review of tribunal's "failure to apply the correct legal standards").

review and thus cannot be a basis for affirmance. *DHS*, 591 U.S. at 23. While Masimo here (at 43-44) and elsewhere, *infra* pp.30-31, directs this Court to the agency's subsequent ruling on Apple's motion to stay pending appeal, that "post hoc rationalization[]" was not provided until nearly two months after the decision under review and cannot be relied upon on appeal. *DHS*, 591 U.S. at 23 (declining to consider new rationales provided in formal memo from agency head months after original agency action). Regardless, while Apple ***cited*** the wristwatch embodiment in Lumidigm, Apple's ***argument*** was that the embodiment rendered obvious utilizing the claimed user-worn device to measure blood oxygen at any location—not just at the wrist. *See* Appx22703-22704; Appx22712-22713; *see also* Appx122 (ALJ noting Apple presented evidence "blood oxygen measurements … at other locations on the body" beyond the wrist were well-known in the art).

The Commission relatedly (and incorrectly) argues the wristwatch embodiment does not disclose measurement of blood oxygen elsewhere on the body. ITC Br.41-42; *see also* Masimo Br.49. This reasoning appears nowhere in the agency's decision and cannot be a basis for affirmance. *DHS*, 591 U.S. at 23. And the Commission and Masimo do not provide any concrete explanation why a resizable wristwatch cannot be worn elsewhere, such as a slightly broader part of the body (e.g., upper arm or ankle). The ALJ herself found Lumidigm generally

discloses the use of a blood oxygen sensor in a wearable "'portable electronic device,'" Appx119-120, of which a watch is just one implementation, *see* Appx70402, 70417-70418(18:1-2, 19:18-28) (Lumidigm).

Finally, Masimo alone argues (at 46-47) the Commission found Lumidigm "does not disclose measuring oxygen saturation at all." Masimo is wrong. *See* Appx119-120 ("Lumidigm describes 'extended functionality' including measurements of 'oxygenation and/or hemoglobin levels in the blood'" and "contemplates blood oxygen measurement in a wristwatch as one implementation of its 'extended functionality'"); *see also* Appx95 (similar).[13]

2. Lumidigm renders obvious the "extending" and "within" limitations

a. "Extending Across." The Commission's ruling cannot be squared with the *KSR* "finite" solutions doctrine. Apple Br.52-53.

On the merits, it is undisputed Apple's expert identified only two possible configurations for this limitation—either a single window to cover all openings, or a separate window for each opening—and Masimo's expert provided no contrary testimony. *See* Masimo Br.52-53; ITC Br.46. While the Commission (at 46) speculates about a third solution (a hybrid of the two identified by Apple's expert),

[13] Appx95 cites the column and line numbers of Lumidigm's disclosure of blood oxygen measurement (i.e., Appx70418 (Lumidigm at 19:18-28)). *See also* Appx119 (cross-referencing discussion of Lumidigm's "extended functionality" that appears on Appx95).

the Commission cites no record evidence supporting its argument. *See Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020) (applying *KSR* where "[t]he record reflects only two possible methods of achieving" a desired outcome). In any event, three configurations would still be a finite number.[14]

Contrary to Masimo's assertion, the Commission did not implicitly reject Apple's *KSR* argument in noting obviousness requires a showing a skilled artisan "would" (rather than "could") do something. *See* Masimo Br.52 (citing Appx395). That only a finite number of predictable options exist in the art to solve a particular design problem itself provides a motivation to combine. *See Uber*, 957 F.3d at 1339-1340.

The Commission (at 45-46) and Masimo (at 53) also wrongly contend Apple's *KSR* argument was waived because it was "untimely." But the Commission's decision made no such finding and thus cannot be affirmed on that ground. *Vizio*, 605 F.3d at 1343 n.11. Regardless, the Commission and Masimo do not identify any authority barring a party from raising an alternative ground for affirmance in front of the Commission in response to an argument made in a petition for review. While the Commission (at 46) generally refers this Court to Part II of its own brief, three of the four cases that section cites for the waiver

[14] The Commission's argument (at 44) that having multiple windows "seems likely to worsen contact and ergonomics" is also pure speculation.

standard involve a factual scenario absent here: An appellant that failed to bring an error in the ***ALJ's*** ruling to the Commission's attention in any way. *See* ITC Br.15-18; *see also Finnegan Corp. v. ITC*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) (challenge to ALJ ruling not "specifically assert[ed]" in petition for review to Commission); *Broadcom*, 542 F.3d at 901-902 (same); *Philip Morris Prods. S.A. v. ITC*, 63 F.4th 1328, 1337 (Fed. Cir. 2023) (appellant's suggestion in petition for review that Commission "'may find it enlightening'" to confer with FDA failed to preserve argument that "FDA's lack of participation was erroneous").[15] The fourth is a straightforward application of the (inapposite) rule that a tribunal cannot invent an argument not advanced by the parties. *See In re Magnum Oil Tools International*, 829 F.3d 1364, 1380-1391 (Fed. Cir. 2016).

Here, in contrast, (1) *KSR* was raised by Apple in front of the agency, *see* Appx24099-24100 (Apple's response to Masimo's petition for review), and (2) the Commission's procedures only require a party to file a petition for review on issues "***decided adversely***" to that party, *see* 19 C.F.R. §210.43(b)(3)-(4); *accord id.* §210.43(b)(2) (petition for review must raise issues where Commission's review "is necessary or appropriate ***to resolve*** an important issue of fact, law or policy");

[15] *Broadcom* also involved a finding of waiver at the ALJ-level, but "[b]ased on a statement in [appellant's] post-trial reply brief" that the ALJ had ***not*** erred on the issue that the appellant later challenged on appeal. 542 F.3d at 901. Here, Apple is not challenging the ALJ's reasoning on this issue.

cf. Fuji Photo Film Co. v. ITC, 386 F.3d 1095, 1104 (Fed. Cir. 2004) (appellant did not waive right to appeal issue under Section 210.43(b)(4) where "there was no adverse judgment" against appellant with respect to the contested limitation in the ALJ's first initial determination). Put slightly differently, Apple had no reason to press the *KSR* issue as an argument in its own right until Masimo's petition challenged—and the Commission (wrongly) overruled—the ALJ's transmissive windows finding. *Cf. O'Keefe v. United States Postal Serv.*, 318 F.3d 1310, 1317 (Fed. Cir. 2002) (argument raised for first time on appeal not barred where appellant "had no reason to raise this issue until after the Board reversed the administrative judge").

b. "Within Each." Uncontradicted testimony established the benefits of windows within openings was known in the prior art; that testimony went unaddressed by the agency. Apple Br.54. Masimo's contrary assertion (at 53) relies on a page providing a thumbnail sketch of Apple's position—not ruling on it, Appx392. And the Commission is wrong (at 44-45) to argue Dr. Warren's testimony was ignored because (1) Apple did not identify the "within" limitation in Lumidigm and (2) Dr. Warren's testimony relied entirely on Lumidigm. Dr. Warren testified about what a skilled artisan would know about transmissive material and coverings in July 2008 based on the state of the art, including other prior art references and a skilled artisan's general knowledge. *See* Appx41318-

41319(1221:19-1222:25); *see also* Appx41290-41291(1193:24-1194:14). The ALJ itself acknowledged that—even beyond Lumidigm—Apple identified two examples of transparent material within openings. *See* Appx129 & n.49.

B. The Asserted Claims Lack An Adequate Written Description

1. The Commission and Masimo fail to justify the ALJ's mixing-and-matching of disparate features from specification Figures 3C and 7B. *See* Apple Br.55-57. Masimo and the Commission do not appear to dispute that only one high-level sentence in the specification directly connects 3C and 7B: "The features of the sensors 701 [Figure 7B] can be implemented with any of the sensors 101, 201, 301 [Figure 3C] described above." *See* Appx584(26:25-26) *see also* Appx163 (ALJ relying on this sentence to find written description). That line cannot be enough under this Court's precedent, which requires the specification to "present each claim as an 'integrated whole.'" *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at *3 (Fed. Cir. July 14, 2021). The cited line does not identify ***any*** of the numerous features from 7B that can be advantageously substituted for certain features from 3C (or vice versa). Apple Br.57.[16]

The Commission's attempt to prop up the agency's ruling with never-considered evidence and reasoning violates *Chenery*. *See DSS Tech.*, 885 F.3d at

[16] Masimo again wrongly argues (at 55) that failure to apply the proper legal standard is a question of fact subject to substantial evidence review. *But see supra* n.12 (citing *Axonics*).

1376 n.4. Most notably, the ALJ ***did not*** find "Figure 3C alone includes the claim elements," nor that it included "multiple LEDs," "opaque surfaces" lining openings, or "separate windows" made of "conductive glass." *Compare* ITC Br.50-51, *with* Appx163 (finding only Figure 3C "shows four photodetectors in four separate openings").

Masimo's assertion (at 55) that Apple's expert testimony was too conclusory fares no better. Dr. Warren stated the result of his review: he could not "find a single embodiment" in the shared specification containing each claimed feature. Appx41343-Appx41344. Regardless, "no expert testimony is necessary to show a failure to comply with the written description requirement." Appx424-425 n.43 (Commissioner Johanson, dissenting).

Finally, Masimo and the Commission (again) wrongly retreat to accusations of waiver. ITC Br.47-48; Masimo Br.55. But the decision under review (again) made no such finding and cannot be affirmed on this ground. *See Vizio*, 605 F.3d at 1343 n.11. Moreover, Apple preserved the issue by presenting the substance of the ALJ's error to the Commission: "While the ID identified various limitations dispersed throughout the specification, it erroneously found that they belong to the same embodiment by citing to generic language providing that one embodiment

can mix-and-match between different sensors." Appx23712.[17] Because Apple's petition specifically raised the issue, the Commission's waiver cases are not on point. *See supra* pp.23-24.

2. Claim 28 of the '502 patent and claim 12 of the '648 patent lack written description support because there is no disclosure of emitters (or sets of LEDs) having matching sets of wavelengths. Apple Br.58-59. The ALJ and Chairman Johanson rightly concluded Apple met its written-description burden by pointing to the lack of a disclosure in the specification. Appx168-169; Appx424-425 n.43. There is "no teaching that the emitters" in Figures 7A and 7B "are the same," Appx424-425 n.43 (Chairman Johanson, dissenting), and thus no basis for the assumption each emitter "***must*** emit the same visible and near-infrared optical radiation," Appx422.

The Commission and Masimo fail to address Chairman Johanson's compelling dissent or identify anything contrary in the specification. ***First***, that emitters 104 share a numerical label (ITC Br.54) does not indicate they are the same; LEDs 104 (in Figure 7A) also share a label but have two different wavelengths, *see* Appx522-523. ***Second***, the specification's description of optical sources "capable of emitting visible and near-infrared optical radiation" (ITC

[17] Tellingly, Masimo responded on the merits, pressing the same basic arguments it does here. Appx23871-23872.

Br.55) does not suggest emitters must have the same visible and near-infrared wavelengths—there are many wavelengths along the visible light and near-infrared spectrum. *See, e.g.*, Appx70065-70066. ***Third***, the specification does not say "***each*** emitter 104" emits light "at or about 1610 nm, about 1640 nm, and about 1665nm," (ITC Br.55), but merely that "***the*** emitter 104" can use those three wavelengths, Appx577(12:35-44)—it does not state there are two, identical such emitters in a given device. ***Finally***, that the prior art knew of sets of LEDs with matching wavelengths (Masimo Br.59) does not show ***Masimo*** combined that feature with the other claimed elements.

III. APPLE WATCH DOES NOT INFRINGE

The ALJ's findings of infringement should be reversed because they depend on flawed claim constructions of "over," "above," and "through." Apple Br.60-62.

As to "over," there is no dispute the ALJ's analogies to a bandage and a mask—and the specification's reference to conductive material spread "over" a surface—use "over" to refer to ***physical*** features covering one another. *See* ITC Br.57-59; Masimo Br.60-62. There is also no evidence of "over" being used synonymously with "cover" under the circumstances identified in the patent—i.e., when the thing that is ostensibly "over" an object is the absence of material. And while Masimo (at 60-61) points to supposed "findings" beyond the ALJ's analogies, the cited passages merely ***summarize*** Masimo's arguments to the

agency—they do not adopt them. *See* Appx32-35; *see also DHS*, 591 U.S. at 23 (*Chenery* bars affirmance based on rationale not adopted by agency). Finally, as to "above," Masimo and the Commission do not even attempt to explain how the ALJ's construction (a "position relative the device") would mean anything at all to a skilled artisan without more context (such as in relation to the ordinary reference frame of the Earth). *See Board of Regents v. BENQ*, 533 F.3d 1362, 1370 (Fed. Cir. 2008) (rejecting construction that would "effect [a] nonsensical result").[18]

As to the "through" limitations, the Commission and Masimo fail to identify any examples in the specification or claims—much less common English usage—where "openings … ***through***" a surface or "***through*** holes" can exist if such openings or holes are plugged with an uninterrupted barrier to the outside (as is the case with the accused products). The intrinsic evidence the Commission and Masimo do cite refers almost entirely to openings and holes—not "openings through" or "through holes." The sole exception—claim 20 of the '648 patent ("each through hole including a window")—does not in-and-of-itself require the use of any internal material at all.

[18] The Commission newly—and wrongly—asserts (at 58-59) that specification figures 2B-2D support the ALJ's construction. Those figures depict the sensor with the protrusion above the photodiodes in the bottom half of the sensor. Appx509-511.

IV. PROSECUTION LACHES APPLIES

Laches barred Masimo from enforcing the '648 and '502 patents. Apple Br.63-67. While the Commission (at 61-62) and Masimo (63-65) retreat to waiver, affirmance on this ground is improper because the Commission's decision under review did not find waiver. *Vizio*, 605 F.3d at 1343 n.11. The waiver "holding" cited is a post-hoc rationale from the stay ruling issued nearly two months after the agency's original decision. *See supra* p.21; *see also* Masimo Br.65 (describing stay ruling as a "later waiver explanation"). Regardless, Apple explicitly raised laches in its petition for review and did so in the "concise" manner required by the Commission's regulations. *See* 19 C.F.R. §210.43(b)(2); *see also* Appx23713-23714; Appx23692-23693. The Commission and Masimo do not identify a case finding waiver where the appellant's petition was crystal clear as to the issue being challenged. *See supra* pp.23-24 (discussing *Broadcom, Finnegan, Philip Morris,* and *Magnum*); *see also Guangdong v. ITC*, 936 F.3d 1353, 1362 (Fed. Cir. 2019) (appellant failed to make "specific [indefiniteness] argument" in petition).

On the merits, the Commission and Masimo largely parrot the ALJ's reasoning without directly responding to Apple's arguments, such as (1) Masimo and its witnesses failed to explain why Masimo's patent applications that coincided with releases of Apple Watch were not filed earlier and (2) Masimo's prosecution counsel admitted he viewed "nonpublic teardowns of the Apple Watch Series 6

during prosecution" of the two patents at issue. *See* Apple Br.64. And while the Commission (at 65 n.32) and Masimo (at 68-69) attempt to distinguish Apple's laches cases on their facts, it is undisputed that (1) there are similarities (such as Masimo's substantial delay and pattern of tracking product releases with new applications) and (2) there is no one set of facts required for laches to apply.

To be sure, Masimo and the Commission emphasize there was "continuous prosecution" of applications within the family of related patents. Masimo Br.66-67, ITC Br.64. But that Masimo "diligently prosecuted [***other***] patent applications" makes its delay as to the asserted patents "all the more unreasonable and inexcusable." *Sonos, Inc. v. Google LLC*, 2023 WL 6542320, at *17 (N.D. Cal. Oct. 6, 2023).

CONCLUSION

The Commission's decision should be reversed or—at minimum—vacated and remanded.

Respectfully submitted,

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July 19, 2024

CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of July, 2024, I filed the Non-Confidential Reply Brief for Appellant Apple Inc. with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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