No. 24-1285

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLE INC.,
Appellant,

v.

INTERNATIONAL TRADE COMMISSION,
Appellee,

MASIMO CORPORATION, CERACOR LABORATORIES, INC.,
Intervenors.

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

RESPONSE OF APPELLEE INTERNATIONAL TRADE COMMISSION TO APPELLANT'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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Dated: June 17, 2026

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I. INTRODUCTION

Apple's petition, supported by Amici, should be denied because it fails to show any of the narrow circumstances that would justify panel rehearing or rehearing en banc. The Commission found that Complainants below, Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo"), designed, developed, and manufactured in California, a series of prototypes, each improving upon the other that ultimately resulted in the Masimo Watch. The Commission further found that the "employment of labor"[1] in those prototypes, three of which practice the asserted patents and two of which led to them (*i.e.*, were precursors), established a domestic industry as required under 19 U.S.C. § 1337(a)(3)(B). The Commission made these and other factual determinations after carefully considering and weighing the record evidence.

A panel of this Court affirmed the Commission's determinations under substantial evidence review. This straightforward and unremarkable affirmance of the Commission's factual findings warrants neither panel rehearing nor rehearing en banc. The Court's affirmance simply recognizes that research, development, and engineering builds on the labor, time, and energy spent developing the early prototypes, not just the final patented articles. Yet, Apple vaguely disputes factual

[1] "Employment of labor" is often measured by investments or expenditures, so these terms are used interchangeably.

findings, concocts hollow *Chenery* arguments, and makes incorrect (and waived) arguments about the interpretation of the Commission's domestic industry statute.

II. BACKGROUND

A. The Patents at Issue

There are two patents at issue, both of which are drawn to user-worn devices configured to non-invasively measure oxygen saturation of the user: U.S. Patent Nos. 10,912,502 ("'502 patent") and 10,945,648 ("'648 patent"). Appx597; Appx707.

B. Technical Prong Determination

The domestic industry requirement is often broken into two prongs: (1) the technical prong, which requires that at least one domestic product practice each element of a claim in the asserted patent, and (2) the economic prong, which requires domestic investments "with respect to" the patented product. To satisfy the technical prong, Masimo relied on its "Masimo Watch" product, which included the series of prototypes.[2] Appx10; Appx60; Appx306. Each prototype was part of an iterative design process that led to the subsequent design, and each was an improvement of the prior one, a common practice in R&D. Appx308–309. From earliest to latest, the prototypes are: (1) the Circle sensor (built in October

[2] The pre-complaint versions of this product served as the basis of the Commission's final determination, and a consumer-ready version (the "W1 Watch") was produced after the complaint was filed.

2019), (2) the Wings sensor (built in January 2020), (3) the RevA version (built in November 2020), (4) the RevD version (built in April 2021), and (5) the RevE version (first built in May 2021).[3] Appx308.

The panel affirmed the Commission's findings that the RevA, RevD, and RevE versions practice the '648 patent and the RevD and RevE versions practice the '502 patent. Op. at 17 (holding that the Commission "reasonably viewed the RevA, RevD, and RevE versions of [the Masimo] watch – … – as physical articles practicing the asserted claims, thereby satisfying the technical prong's requirement that a material patent-practicing article exist at the time of the complaint"); Appx425–426; Appx60–65; Appx73–90; *see also* Appx65–73. At this point, Apple does not dispute the findings that these Rev versions practice the respective patent claims.[4] The Circle and Wings sensors, while not satisfying every limitation

[3] Apple inaccurately suggests that each version was produced with multiple distinct designs. *See, e.g.*, Pet. at 7. The evidence showed that Masimo manufactured each prototype of each generation in accordance with its respective schematic. Appx40355; Appx40363–40364; Appx40368–40371; Appx40407–40408; Appx40439; Appx40488–40492; Appx40496; Appx40514–40517; Appx40520; Appx21154–21156; Appx21154–21156. Thus, as the Commission and panel properly found, the CAD drawings and schematics for each version *represent* the physical devices for that version, *and* vice-versa. While *a single* version was modified *post-production*, Masimo did *not* introduce them as *representative* for that version. *See* Appx40358–40362; Appx40369–40371.

[4] The panel correctly held that the Commission agreed with the ALJ that numerous "Masimo Watch products" satisfied the article requirement. Op. 10-11, 13-14. Specifically, the Commission did not review the ALJ's finding in Order No. 31

[*Footnote continued on next page*]

of the asserted claims, were precursors to the other prototypes, and included at least the claimed arrangement of LEDs and photodiodes.[5] *See, e.g.*, Appx306–307; Appx40488–40489; Op. at 22.

C. Economic Prong Determination

For the economic prong, the Commission credited Masimo's employment of labor directed to developing the Masimo Watch prototypes, including investments in developing the RevA, RevD, and RevE versions, and in developing the Circle and Wings sensors, because those sensors were merely early iterations of the Rev versions, all of which resulted in the same product, the Masimo Watch. Appx308. The panel affirmed, noting that whether a complainant's investments are "with respect to" the patent protected articles is a question of fact, not law. Op. at 20. Specifically as to the Circle and Wings sensors, the panel concluded that "substantial evidence supports the Commission's finding that Masimo's investments in [them] were made as part of the same iterative design process Masimo undertook [in] its development of a single patent-practicing commercial product," and that "those *investments* led to specifically tailored, significant

(Appx14128-14140) and hence adopted that finding. *See* 19 C.F.R. 210.38(a), (d); 210.42(a)(1)(i), (h)(2). Apple's argument to the contrary is incorrect. Pet. at 9 n.3.

[5] The Circle and Wings sensors sensed blood oxygen but relied on an external device to calculate oxygen saturation; the RevA version added onboard processing; the RevD version added a display; and the RevE version improved the optical components. Appx306–307.

technical features of patent-practicing articles, including the RevA and RevD variants of the Masimo Watch" and thus can be considered according to section 337(a)(2)–(3). Op. at 23–24 (emphasis added); *see also id.* at 22 (recognizing that the "Circle and Wings sensors … contributed to [the] arrangement of [structural] elements in the RevA and RevD models," referring to the arrangement of, *inter alia*, the claimed LEDs and emitters); *see also* Appx40489–40491.[6]

III. PANEL REHEARING AND REHEARING EN BANC SHOULD BE DENIED

A. Apple Has Failed to Raise Any Issues that Warrant Panel Rehearing or Rehearing En Banc

Apple's petition should be denied because "[p]etitions for rehearing should not be used to reargue issues previously presented that were not accepted by the merits panel during initial consideration of the appeal."[7] Apple has also failed to identify any of the limited circumstances for en banc review. *See* Fed. R. App. P. 40(b)(2); Fed. Cir. R. 40(c); Fed. Cir. IOP #13; Fed. R. App. P. 40(c) ("Rehearing en banc is not favored and ordinarily will be allowed only if one of the criteria in Rule 40(b)(2)(A)-(D) is met.").

[6] The panel did *not*, as Apple alleges, make a finding that the Circle and Wings sensors are *components* of the later Masimo Watch versions, nor did it or the Commission need to. *Contra* Pet. at 15–16, *with* Op. at 21–24.

[7] U.S. Court of Appeals for the Federal Circuit, Petitions for Rehearing & Rehearing En Banc, Petitions for Rehearing.

B. The Domestic Industry Requirement Broadly Includes Employment of Labor "With Respect To" the Domestic Industry Product

Apple attempts to limit the domestic industry investments in labor permitted under subsection (B) to only those that are "in" the specific domestic industry product alleged in the complaint. 19 U.S.C. § 1337(a)(3)(B); Pet. at 14-16. Subsection (B), however, is not so limited; rather, it extends to labor investments "with respect to" domestic industry products, which is broader. *See also* 19 U.S.C. § 1337(a)(2) (broadly stating that the domestic industry must "relat[e] to the articles protected by the patent"). Here, the Commission and the panel recognized that Masimo had a pipeline of prototypes from the Circle sensors to the Rev versions, each building on the progress of the prior, such that there is no reasonable way to delineate between work on the separate designs and prototypes. Op. at 10-11, 14 (finding that the "Masimo Watch" "did not refer to a singular product, but instead [to] 'multiple physical … items'" (the Circle, Wings, RevA, RevD, and RevE) that "were developed as part of an iterative design process that resulted in the W1 Watch," and thus were "successive embodiments of that same article") (quoting Appx141135, Appx373). The Commission further found that the employment of labor in the domestic industry products that practice the patents, *i.e.*, the RevA, RevD, and RevE versions, were part of the domestic industry. Regarding the Circle and Wings sensors, which do not practice every limitation of

the claims, the Commission found and the panel agreed that the related investments were "with respect to" the domestic industry products because they led up to, and were directed to significant aspects of, the domestic industry products. Appx308; Op. at 23–24; 19 U.S.C. § 1337(a)(3)(B).

1. Technical Prong: The Rev Prototypes Are the Domestic Industry Products

The technical prong of domestic industry only requires the existence of a single article protected by the patent. 19 U.S.C. § 1337(a)(2). In this investigation, the Commission found that the prototypes—the RevA, RevD, and RevE versions—are articles protected by the patents. The panel affirmed under substantial evidence review. Op. at 15. Specifically, the panel pointed to the ALJ's findings (at Appx88-90) and evidence demonstrating that Masimo proved by a preponderance of the evidence that the RevA, RevD, and RevE versions practice the respective patents.

Apple's sole technical prong argument is that the panel erred by holding that the identified five physical prototypes were "representative" of an undisclosed patent-practicing article. Pet. at 16-19 (citing Op. 5, 14-15, 17). The Commission finding that the panel affirmed, however, was that the prototypes were *representative* of other devices made according to the same design. That is, the prototype designs were part of a continuous design process where the disclosed prototypes improved upon each other and three of them – RevA, RevD, and/or

RevE – actually practiced the relevant patents. Op. at 15 (referring to the ALJ's findings at Appx88–90 (citing evidence)); *see also, e.g.*, Appx40496; Appx40354–40356; Appx40357–40364; Appx40368–40371; Appx40407–40408; Appx40488–40492; Appx40514–40520. Thus, Apple's "representative" argument, and "open questions" based thereon, are wholly unfounded. Nor is there a *Chenery* issue simply because the panel used different wording than the Commission. *SEC v. Chenery Corp.*, 332 U.S. 194 (1947).

2. Economic Prong: There Was a Significant Employment of Labor with Respect to the Domestic Industry Products (Including Labor for their Precursors)

Apple argues that the Commission found a domestic industry based on products that do not practice the patents, but that is devoid of context. Rather, the Commission credited labor investments in the RevA, RevD, and RevE versions, because they practice the patents, and also credited labor investments in the Circle and Wings sensors, because they were precursors to the Rev versions. In other words, the labor that went into the Circle and Wings sensors led to the Rev versions and therefore was "with respect to" those patent-practicing products. 19 U.S.C. § 1337(a)(3)(B).

Regarding expenditures in the Circle and Wings sensors that Apple asserts should not have counted, as the panel noted the evidence credited by the Commission showed that they were made as part of the same iterative design

process that "led to specifically tailored, significant technical features of patent-practicing articles, including the RevA and RevD variants of the Masimo Watch." Op. at 22, 23–24 (citing Appx308). The panel found that the evidence supports the Commission counting such expenditures. Thus, whether they are called "significant components" of the Rev versions, a "substantial part" of the Rev versions, or "specifically tailored" for use in the Rev versions (and ultimately, the Masimo Watch), the investments made in the Circle and Wings sensors were made "with respect to" the products protected by the patent, *i.e.*, the Rev versions.

At bottom, Apple's arguments are an invitation for the Court to reweigh the evidentiary record; an invitation the Court has consistently declined. *See, e.g.*, *Norgren Inc. v. ITC*, 699 F.3d 1317, 1326 (Fed. Cir. 2012).

C. Apple's Statutory and *Chenery* Arguments Are Likewise Unavailing

1. Apple's Proposed Interpretation of Subsection (B) Is Waived and Has Already Been Rejected by this Court

Apple proposes an interpretation of subsection (B) that would exclude all domestic investments in labor and capital directed to research and development ("R&D"). Apple, however, did not present this argument to the Commission or the panel, and has waived it. *See, e.g.*, *Pentax Corp. v. Robison*, 135 F.3d 760, 762 (Fed. Cir. 1998) ("Just as this court will not address issues raised for the first time

on appeal or issues not presented on appeal, we decline to address the government's new theory raised for the first time in its petition for rehearing.").

Moreover, this Court has rejected such an interpretation of subsection (B). In *Lashify*, the Court broadly held that subsection (B) "covers significant use of 'labor' and 'capital' *without any limitation* on the use within an enterprise to which those items are put, *i.e.*, the enterprise function they serve." *Lashify, Inc. v. ITC*, 130 F.4th 948, 958 (Fed. Cir. 2025) (emphasis added). The Court in *Lashify* used this language to address other activities, stating that "there is no carveout of employment of labor or capital for sales, marketing, warehousing, quality control, or distribution. Nor is there a suggestion that such uses, to count, must be accompanied by significant employment for other functions, such as manufacturing." *Id.* at 958-59. However, the Court noted without objection that Lashify "conducts its research, design, and development work in the United States" but "manufactures its products abroad before shipping them to customers, including U.S. customers, who purchase them through its website." *Lashify*, 130 F.4th at 951. Thus, the Court interpreted subsection (B) to include domestic expenditures in capital and labor directed to R&D.

Apple's suggestion that the Court did not decide the issue is plainly wrong. *Lashify*, 130 F.4th at 958 (subsection (B) "covers significant use of 'labor' and 'capital' without any limitation on the use within an enterprise to which those

items are put…"); *see also*, *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1362 (Fed. Cir. 2019) (affirming the Commission's finding of domestic industry under both subsections (B) and (C) as domestic R&D investments were a prerequisite to the ongoing field service and assembly of the domestic industry products). There is no reason for the Court to revisit this issue as to R&D.

2. The Commission's Longstanding Inclusion of Domestic R&D Labor and Capital Investments Under Subsection (B) Is Consistent with the Statutory Text and Legislative History

Apple's reliance on the Commission's petition for rehearing in *Lashify*, where the Commission sought to exclude sales and marketing expenditures under subsection (B), is misplaced.[8] Pet. at 11. Indeed, since enactment of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (1988) ("1988 Act"), the Commission has permitted expenditures on labor and capital employed in engineering and R&D activities to support a domestic industry under subsection (B). *See, e.g.*, *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 14, 2018 WL 4300500, at *9 (June 29, 2018) ("[T]he text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude non-manufacturing activities, such as investments in engineering and research and development."). The Commission

[8] The Court denied the Commission's petition.

has long recognized that the text of section 337 does not limit subsection (B) to investments related to manufacturing.[9] It only requires that the investments in employment of labor or capital be domestic and be "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3).

Also, contrary to Apple's assertion, even though subsection (C) expressly identifies "engineering" and "research and development" as exemplary investments in the "exploitation" of the patent, that language does not unambiguously narrow subsection (B) (or (A)) to exclude those same types of investments. 19 U.S.C. § 1337(a)(3)(C); *Lashify*, 130 F.4th at 958.

The legislative history further undermines Apple's argument. Subsections (A)–(C) were added to the statute as part of the 1988 Act. The accompanying

[9] *Certain Electronic Imaging Devices*, Inv. No. 337-TA-850, Comm'n Op. at 92 (Apr. 21, 2014), 2018 WL 11201935, at *55 (Nov. 1, 2018) (rejecting respondents' argument that "research and development investments should be considered under subsection 337(a)(3)(C) and not under subsection 337(a)(3)(B)."); *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 58-59, 64, 2016 WL 10987364, at *39-42 (Jan. 6, 2016) (finding that complainant's investment in labor and capital, of which a majority of expenditures pertained to research and development and engineering, satisfied the economic prong of the domestic industry requirement under subsection (B)); *Certain Ground Fault Circuit Interrupters and Products Containing Same*, Inv. No. 337-TA-739, Comm'n Op. at 80-81, 2012 WL 2394435 at *51-52 (Jun. 8, 2012) (finding that complainant had satisfied the economic prong of the domestic industry requirement under subsections (A) and (B) based on the complainant's investments in plant and equipment and employment of labor and capital associated with its engineering and research and development activities concerning the domestic industry products).

legislative history, like the statutory text, shows no intent to narrow subsections (A) and (B) to manufacturing activities, but rather shows an intent to read subsections (A)–(C) broadly. *See* H. Rep. No. 100-40, at 22 (1987) (The "domestic industry requirement is retained with an *expanded* definition.") (emphasis added). The 1987 House Committee Report that accompanied the 1988 Act explains that the three prongs of the statutory text, together, provide a "definition" to "clarify the [domestic] industry standard." *Id.* at 157. The Committee Report makes clear that "[t]his definition does not require actual production of the article in the United States if it can be demonstrated that significant investment and activities of the type enumerated are taking place in the United States." *Id.*; *see also InterDigital Commc'ns, LLC v. ITC*, 707 F.3d 1295, 1303–04 (Fed. Cir. 2013) (analyzing legislative history). That is, when clarifying that the "definition does not require actual production" in the United States, the Report referred to the overall "definition" and not the third factor in isolation. *See id.* This indicates that Congress did not intend to limit subsections (A) or (B) to manufacturing activities in the United States. *See also* S. Rep. No. 100–71, at 127-129 (1987); H. Rep. No. 99–581, at 112 (1986).

3. The "Cannon Against Surplusage" Does Not Apply to the Commission's Application of Subsections (B) and (C)

Contrary to Apple's assertion, while there may be overlap between subsections (B) and (C), crediting domestic expenditures in R&D under subsection

(B) does not render subsection (C) superfluous. *See Lashify*, 130 F.4th at 954 (recognizing that "section 337(a)(3) identifies three potentially overlapping but independently sufficient bases" for finding the economic prong satisfied). As an example, subsection (C) is available to entities, such as universities, who may not have significant labor and/or capital investments (including in R&D, engineering, etc.) in the articles protected by the patent, but who have substantial investments in the exploitation of the intellectual property that generates articles protected by the intellectual property. *See InterDigital Commc'ns, LLC v. ITC*, 690 F.3d 1318, 1329–30 (Fed. Cir. 2012); *see also InterDigital*, 707 F.3d at 1303–04. As another example, subsection (C) may allow a university to satisfy the domestic industry requirement when its investments in either plant and equipment alone (subsection (A)) or labor and capital alone (subsection (B)) would not meet the "significant" threshold, but whose R&D-related plant, equipment, labor, and capital investments *combined* are substantial. Thus, Congress, through subsection (C), "provided for the [Commission] to offer a remedy to those industries upon proof that imported goods infringed valid patent rights, and the Commission has consistently interpreted the statute to authorize it to do so." *Id.*

Accordingly, the "cannon against surplusage" (Pet. at 13) does not apply to the Commission's interpretation of subsections (B) and (C). The two subsections may overlap, but subsection (B) does not subsume subsection (C).

4. There Is No *Chenery* Violation Because the Panel Relied on the Same Rationale the Commission Applied and the Same Evidence the Commission Credited

Apple's *Chenery* arguments are unavailing because the panel affirmed the Commission based on the same rationale and evidence that the Commission relied on. *Compare* Op. 22-23 *with* Appx308-309 (both relying on "with respect to" and record evidence). Indeed, Apple's *Chenery* arguments are a blatant invitation for the Court to ignore its own precedent and reweigh the evidence on domestic industry and invalidity in this case.

Apple asserts that the panel relied on subsection (C) instead of subsection (B). Pet. at 12. But this is simply not true. Nowhere does the panel invoke subsection (C). The panel merely held that the Commission's crediting the investments made in the various prototypes that resulted in the Masimo Watch under subsection (B) was not error. Op. at 21–23. Apple makes much of the panel's citation to *Motorola Mobility, LLC v. ITC*, 737 F.3d 1345, 1351 (Fed. Cir. 2013), and *Microsoft Corp. v. ITC*, 731 F.3d 1354, 1358 (Fed. Cir. 2013).[10] Pet. at 15. The panel, however, cited *Motorola* and *Microsoft* for the unremarkable and well-settled proposition that "[a]n investment directed to a specifically tailored, significant aspect of the article is still directed to the article." Op. at 22

[10] Apple's argument that the Commission did not rely on *Motorola* until oral argument is plainly wrong. Red Brief at 29.

(recognizing that this Court's precedent permits counting investments in the prototypes that led to the Masimo Watch).

Apple also argues that the panel brushed aside decisions like *Zircon* in affirming the Commission's finding that the Wings and Circle sensors can be counted. Pet. at 15. Apple misunderstands *Zircon*, the panel's ruling, and the Commission's findings. *Zircon* stands for the proposition that if a complainant presents different groups of products purportedly practicing different patents, "the complainant would need to establish separate domestic industries for each of those different groups of products." *Zircon Corp. v. ITC*, 101 F.4th 817, 824 (Fed. Cir. 2024). That is not the case here. Rather, the Commission found, and the panel affirmed, that each prototype design was part of an iterative design process, each led to the subsequent design, and each was an improvement of the prior one, ultimately leading to the Rev versions and the Masimo Watch. Appx308–309. "Various products purportedly practicing different patents," as in *Zircon*, is not an issue here.

Regarding obviousness, the panel affirmed the Commission's finding that "Lumidigm merely 'describes functionality for measuring several different physiological parameters,' but not blood oxygen saturation" for the reasons expressed by the Commission. Op. at 33; Appx97-98. Moreover, Apple does not challenge the Commission's other grounds for finding that Lumidigm does not

render the asserted claims obvious. Pet. at 19, *see* Op. at 32-33 (discussing two "independently adequate basis for rejecting Apple's obviousness case").

With respect to written description, Apple's contention that the panel relied on Masimo's arguments that it "found persuasive in the first instance—not on the rationale the agency actually provided" is baseless. Pet. at 20. But even a cursory review of the panel's decision shows an in-depth discussion of the Commission's findings. Op. at 28–32.

As such, there is no *Chenery* issue here.

IV. CONCLUSION

For the foregoing reasons, the Commission respectfully requests that the Court deny Apple's combined petition.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE, AND TYPE STYLE REQUIREMENTS

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(b)(3), I hereby certify that the attached response complies with the type-volume limitation and typeface requirements of Federal Rules of Appellate Procedure 32(a), 32(c), 32(f), and 35(e) and Federal Circuit Rules 32(b)(2) and 35(e)(2). The response has been prepared in a proportionally-spaced typeface using Microsoft Office 365, in Times New Roman 14-point font. The response contains a total of 3900 words, obtained from the word-count function of the word-processing system, including all footnotes and annotations.

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