United States Court of Appeals for the Federal Circuit

APPLE INC.,
Appellant

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,
Intervenors

2024-1285

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

Decided: March 19, 2026

JOSEPH J. MUELLER, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for appellant. Also represented by SARAH R. FRAZIER; DEREK ANTHONY GOSMA, Los Angeles, CA; MARK D. SELWYN, THOMAS GREGORY SPRANKLING, Palo Alto, CA; DAVID P. YIN, Washington, DC.

RONALD TRAUD, Office of the General Counsel, United States International Trade Commission, Washington, DC, argued for appellee. Also represented by MICHELLE W.

KLANCNIK, MARGARET D. MACDONALD, HOUDA MORAD.

JOSEPH R. RE, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for intervenors. Also represented by BRIAN CHRISTOPHER CLAASSEN, STEPHEN C. JENSEN, SHEILA N. SWAROOP; JONATHAN EDWARD BACHAND, Washington, DC.

Before LOURIE, REYNA, and STARK, *Circuit Judges*.

STARK, *Circuit Judge*.

In September 2020, Apple Inc. ("Apple") launched the Apple Watch Series 6 ("Apple Watch"), which included a feature capable of estimating the wearer's blood oxygenation level. Nine months later, in June 2021, Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo") filed a complaint with the United States International Trade Commission ("Commission"), under § 337 of the Tariff Act of 1930 as amended ("Tariff Act"), alleging that Apple's importation and sale of the Apple Watch infringed several Masimo patents covering wearable blood oxygen measurement devices. In its complaint, Masimo charged that Apple was unlawfully engaged in unfair trade practices in violation of the Tariff Act. The Commission instituted an investigation and found that Masimo proved Apple did, in fact, violate § 337 by importing, selling, and offering for sale Apple Watch models that incorporated the blood oxygen functionality covered by Masimo's patents. Accordingly, the Commission issued a limited exclusion order ("LEO") barring importation of the infringing Apple Watches. Apple now appeals. Finding no error in the Commission's domestic industry determination, its validity rulings, or its infringement findings, we affirm.

I

A

Masimo was founded in California in 1989 with a goal of addressing persistent problems encountered by conventional noninvasive pulse oximeters used to measure blood oxygenation levels, including inaccurate and false readings, particularly under clinical conditions. In 1995, Masimo introduced its motion- and low-perfusion-tolerant Signal Extraction Technology ("Masimo SET"), which substantially reduced false alarms caused by certain conditions prevalent in clinical settings, such as patient movement or poor circulation.

Masimo has obtained multiple patents for the Masimo SET technology and is the assignee of U.S. Patent Nos. 10,912,502 (the "'502 patent") and 10,945,648 (the "'648 patent"). Because both the '502 and '648 patents name Jeroen Poeze as their first named inventor, we will refer to them collectively throughout this opinion as the "Poeze Patents." The Poeze Patents claim priority to an application filed on July 3, 2008, and they share a title, "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User." J.A. 366. Generally, the Poeze Patents cover wearable technology that measures user physiological metrics by way of optical emitters and photodetection. These devices use light-emitting diodes ("LEDs") to emit light at specific wavelengths into tissue at a measurement site, such as the fingertip. Photodetectors on the device then measure the returned intensity of these optical emissions, which is attenuated by the wearer's tissue and blood. The level of attenuation is then used to determine the desired physiological parameter of the device wearer.

On September 24, 2020, Masimo filed with the U.S. Patent and Trademark Office the applications that later became the Poeze Patents. Their claims share substantially similar limitations, including that the covered devices

must be "user-worn" and utilize transmissive windows that extend across or exist within a convex protrusion of the device. Claim 19 of the '502 patent, from which asserted claim 22 depends, is representative for purposes of the issues presented in this appeal:

> *A user-worn device* configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:
>
> a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
>
> four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
>
> *a protrusion comprising a convex surface including separate openings extending through the protrusion* and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
>
> *optically transparent material within each of the openings*; and
>
> one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

J.A. 704 at 46:22-45 (emphasis added).

Figure 3B of the '502 patent, reproduced below, depicts an illustrative embodiment of a claimed pulse oximeter:

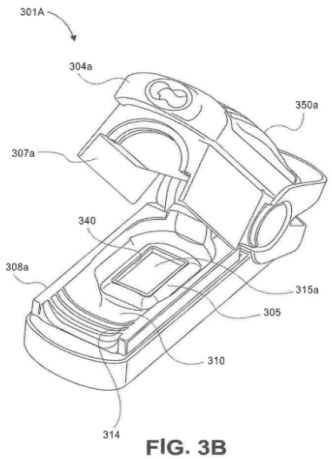

FIG. 3B

J.A. 623.

B

Apple released the accused version of the Apple Watch on September 15, 2020. It contained a feature Apple called the "Blood Oxygen sensor," which "employs LEDs, along with photodiodes" to measure the wearer's "blood oxygen levels." J.A. 70359.

On June 30, 2021, Masimo filed its complaint against Apple with the Commission, which it amended on July 7, 2021. Masimo's amended complaint alleged that the Apple Watch infringed various claims of several Masimo patents, including the Poeze Patents, and sought an exclusion order pursuant to § 337 of the Tariff Act prohibiting Apple from importing the Apple Watch. Section 337 makes it "unlawful to import articles that infringe a valid and enforceable United States patent if 'an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established.'" *Motiva LLC v. Int'l Trade Comm'n*, 716 F.3d 596,

597 (Fed. Cir. 2013) (quoting 19 U.S.C. § 1337(a)(2)). Upon finding a § 337 violation, the Commission is empowered to "declare[] certain activities related to importation to be unlawful trade acts and . . . to grant prospective relief," including prohibiting importation of infringing articles, when appropriate. *ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1289 (Fed. Cir. 2015) (internal quotation marks omitted).

The Commission instituted an investigation to determine whether Masimo was entitled to such relief. In June 2022, an administrative law judge ("ALJ") held a five-day hearing, during which she heard testimony from 22 live witnesses, and after which she issued a 342-page opinion, setting out her determinations that: (i) Masimo established the existence of a domestic industry relating to the Poeze Patent claims it was asserting against Apple; (ii) the Apple Watch infringed some of those claims; (iii) some of the infringed claims had not been proven invalid for lack of adequate written description or obviousness; and (iv) Masimo was not estopped by prosecution history laches from enforcing its patents. Ultimately, the ALJ held that Apple violated § 337 because the Apple Watch infringed claims 24 and 30 of the '648 patent, claims practiced by Masimo that Apple failed to prove were invalid.

Apple and Masimo then cross-petitioned for Commission review of the ALJ's ruling, and the Commission granted such review in part. On October 26, 2023, the Commission issued its final determination, affirming the ALJ's finding of a § 337 violation as to claims 24 and 30 of the '648 patent and reversing her determination that claim 12 of the '648 patent and claims 22 and 28 of the '502 patent were invalid for lack of adequate written description. However, the Commission also found that no domestic industry existed as to claim 22 of the '502 patent. Based on these rulings, the Commission's overall finding was that Apple violated § 337 with respect to four claims that had not been shown to be invalid: claims 12, 24, and 30 of the '648 patent

and claim 28 of the '502 patent.[1] As relief, the Commission issued a LEO barring importation of the infringing Apple Watches.

Apple timely appealed from the Commission's judgment, and we granted Masimo leave to intervene in support of the Commission. We have jurisdiction under 28 U.S.C. § 1295(a)(6).[2]

II

"Our review of the Commission's final determination of a Section 337 violation is governed by the standards of the Administrative Procedure Act" ("APA"). *Mayborn Grp., Ltd. v. Int'l Trade Comm'n*, 965 F.3d 1350, 1353 (Fed. Cir. 2020). "The Commission's factual findings are reviewed for substantial evidence, and legal determinations are reviewed *de novo*." *Broadcom Corp. v. Int'l Trade Comm'n*, 28 F.4th 240, 249 (Fed. Cir. 2022); *see also* 5 U.S.C. § 706. Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to

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[1] The Chairman of the Commission dissented from the holding that claim 28 of the '502 patent and claim 12 of the '648 patent were not proven invalid due to lack of adequate written description.

[2] On November 14, 2025, during the pendency of this appeal, the Commission instituted a combined modification and enforcement proceeding ("ancillary proceeding") to consider whether a redesigned version of the Apple Watch should also be barred from importation under the LEO at issue in this appeal. The parties agree that the LEO we are reviewing remains in effect during the pendency of that ancillary proceeding. While Apple has argued to the Commission that it lacks jurisdiction to initiate the ancillary proceeding during the pendency of this appeal, Apple has not sought any relief from us in connection with the ancillary proceeding.

support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 227 (1938). We "must affirm a Commission determination if it is reasonable and supported by the record as a whole, even if some evidence detracts from the Commission's conclusion." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1344 (Fed. Cir. 2010) (internal quotation marks omitted). Determinations by the ALJ not reviewed by the Commission become determinations of the Commission for purposes of appeal. *See Microsoft Corp. v. Int'l Trade Comm'n*, 731 F.3d 1354, 1358 (Fed. Cir. 2013). Hence, except when necessary to distinguish the ALJ's findings from the Commission's, this opinion refers to the ALJ's findings as the Commission's own findings.

III

Apple first argues that the Commission erroneously concluded that Masimo demonstrated a domestic industry as is required to establish a violation of § 337. We disagree with Apple.

A

In order to demonstrate that an unlawful trade act has occurred in violation of § 337, a complainant must show that "the respondents named in the Commission proceeding [are] importing 'articles that . . . infringe' a United States patent" *and* further show that "there [is] (already or in process of establishment) an industry in the United States that relates to [those] articles." *Lashify v. Int'l Trade Comm'n*, 130 F.4th 948, 954 (Fed. Cir. 2025). This is the Tariff Act's domestic industry requirement, and it consists of two prongs: the economic prong, which requires that there be an industry in the United States relating to the patent, and the technical prong, which requires that the industry relate to articles protected by the patent. *Id.* The domestic industry requirement is assessed based on the status of the alleged industry at the time of the filing of a complaint with the Commission. *See Philip Morris Prods. S.A. v. Int'l Trade Comm'n*,

63 F.4th 1328, 1341 n.4 (Fed. Cir. 2023) ("[T]he filing date of the complaint is the relevant date at which to determine if the domestic industry requirement' is satisfied.") (internal quotation marks omitted). "The question of whether the domestic industry requirement is satisfied presents issues of both law and fact." *Motiva*, 716 F.3d at 600.

Apple's challenge to the Commission's domestic industry determination includes attacks on its findings with respect to both the technical prong and the economic prong. We address both below.

1

a

In order to satisfy the technical prong of the domestic industry requirement, "an actual article protected by the patent is needed." *Broadcom Corp.*, 28 F.4th at 250. For purposes of § 337, "Congress's unambiguously expressed intent was for 'articles' to mean 'material things.'" *ClearCorrect*, 810 F.3d at 1294. In a § 337 proceeding, then, the complainant must show there is a domestic industry article that actually practices at least one claim of an asserted patent. *See Microsoft*, 731 F.3d at 1361; *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1359 (Fed. Cir. 2007) ("The domestic product, to meet the technical prong test, Section 337(a)(2), must be covered by the asserted claims."). Hence, "[f]or the technical prong, the question is essentially [the] same as that for infringement, i.e., a comparison of domestic products to the asserted claims." *Lashify*, 130 F.4th at 954 (internal quotation marks omitted).

In its governing amended complaint filed on July 7, 2021,[3] Masimo "identif[ied] a 'Masimo Watch' . . . as

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[3] The Commission granted Masimo a filing date of July 12, 2021, based on its filing of a "Confidential

the alleged domestic industry product" for the asserted patents at issue in this appeal. J.A. 14129. Masimo further alleged that a "confidential sample of a Masimo Watch that embodies the claims of the [asserted patents] is available upon request," attaching to its complaint exhibits showing digital renderings and a photograph of the purported Masimo Watch. *Id.* at 14129-30. The ALJ found that this identification did not refer to a singular product but, instead, that "multiple . . . physical [domestic industry] items existed at the time of the Amended Complaint." J.A. 14135; *see also* J.A. 14138. The ALJ rejected Apple's contention that the physical items produced by Masimo lacked the firmware necessary to determine oxygen saturation and pulse rate, as required by the asserted claims, crediting instead the testimony of Masimo's witness, Ammar Al-Ali – who oversees technology development at Masimo – regarding testing of blood oxygen saturation performed on a version of the Masimo Watch *before* the complaint was filed. J.A. 10, 88-89 (citing J.A. 40369-71 at 276:17-278:13). As the ALJ observed, this testing could not have occurred unless the tested device existed and contained the required firmware. From the totality of evidence, the ALJ found that Masimo had proven by a preponderance of the evidence that articles covered by the asserted claims existed at the time of the complaint, and therefore the article requirement of the technical prong of the domestic industry analysis was satisfied.

On review, the Commission agreed with the ALJ that the complaint did not specify a singular "Masimo Watch" as the pertinent domestic industry product. Rather, the Commission determined that, with respect to the Poeze Patent claims asserted here, "[Masimo] rel[ied] on [its]

Amendment to the [July 7, 2021] Public Complaint and Exhibits" on that date. J.A. 361. This determination is not at issue in this appeal.

'Masimo Watch' products" "includ[ing] certain prototypes identified as the 'Circle Sensor' (CPX-0021C), the 'Wings Sensor' (CPX-0029C), the 'RevA Sensor' (CPX-0052C), the 'RevD Sensor' (CPX-0058C), the 'RevE Sensors' (CPX-0019C, CPX-0020C, CPX-0065C) . . . and a product identified as the 'W1 Watch' (CPX-0146C)."[4] J.A. 373. The Commission observed that the Circle, Wings, RevA, RevD, and RevE sensors "were developed as part of an iterative design process that resulted in the W1 Watch, which was not completed until after the Complaint was filed." J.A. 373. Ultimately, the Commission affirmed the ALJ's determination that Masimo satisfied the technical prong of the domestic industry requirement by showing "by a preponderance of the evidence that the RevA, RevD, and RevE devices practice[d] claims 12, 24 and 30 of the '648 patent, and that the RevD and RevE devices also practiced claim 28 of the '502 patent." J.A. 87; *see also* J.A. 425-26 (citing J.A. 341).

In contesting the Commission's finding, Apple critiques the Commission for purportedly relying on a "hypothetical" Masimo Watch, rather than an actual article when evaluating the technical prong, emphasizing that a hypothetical device cannot satisfy the domestic industry requirement. Apple's contention, however, rests on three flawed premises, as we now explain.

i

First, Apple asserts that, in the course of a § 337 proceeding, the Commission must find the technical prong

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[4] Masimo only relied on the Circle Sensor and Wings Sensor for purposes of the economic prong of the domestic industry analysis as to the Poeze Patents, and the ALJ determined that the W1 Watch was produced after the time of the filing of the complaint and therefore could not be considered despite Masimo's reliance on it.

satisfied only by the exact article identified in the complaint. The law is not so rigid.

Neither the Tariff Act nor the APA supports Apple's contention. Section 337 specifies that:

> The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section . . . . Each determination shall be made on the record after notice and opportunity for a hearing . . . .

19 U.S.C. § 1337(c). The APA adds that parties to an agency adjudication must receive notice of the time, place, and nature of a hearing; the legal authority and jurisdiction under which the hearing is to be held; and the matters of fact and law asserted. *See* 5 U.S.C. § 554(b). The APA additionally provides that agencies "may . . . adopt procedures for the submission of . . . evidence" during a proceeding. 5 U.S.C. § 556(d).

Pursuant to the APA, the Commission has promulgated regulations governing what a § 337 complaint must contain. *See id.*; *see also* 19 U.S.C. § 1335 ("The [C]omission is authorized to adopt such reasonable procedures and rules as it deems necessary to carry out its functions and duties."). Most pertinent here is 19 C.F.R. § 210.12(a)(9)(ix), which requires that "[t]he complainant shall make such showing [of an article protected by the asserted patent(s)] by appropriate allegations, and when practicable, by a chart that applies an exemplary claim of each involved U.S. patent to *a representative involved domestic article*" (emphasis added). This regulation does not require a complainant to identify, in its complaint, the exact physical article upon which it may ultimately rely throughout a § 337 investigation. It is sufficient for the complaint to identify "a representative" article.

Masimo's complaint satisfies this requirement. It expressly alleges: "With respect to the . . . [Poeze Patents], . . . Masimo's activities in the United States with respect to at least its Masimo Watch . . . constitute a domestic industry for purposes of Section 337." J.A. 3732 (¶ 86); *see also, e.g.*, J.A. 3708 (¶ 18). It further states: "Drawings, photographs, or other visual representations of *representative* Masimo domestic industry products (specifically, the Masimo Watch . . .) are attached hereto . . . . Claim charts showing how a *representative* Masimo domestic industry product practices exemplary claims of the . . . [Poeze Patents] . . . are attached hereto . . . ." J.A. 3733 at ¶ 89 (emphasis added). The complaint, thus, makes clear that the Masimo Watch is Masimo's identified domestic industry article, and it includes computer aided design ("CAD") drawings, among other visual depictions, of representative embodiments of that article, in satisfaction of § 210.12(a)(9)(ix). Apple cites no authority that should have restricted the ALJ's or the Commission's domestic industry investigation to only the representative CAD drawings provided in Masimo's complaint, or physical models identical to those drawings, rather than allowing them to make findings regarding the existence of a domestic industry article based on the totality of the evidence introduced during the five-day evidentiary hearing. *See* 19 C.F.R. § 210.38 (providing that ALJ must make findings based on full record developed at hearing).

In its reply brief, Apple articulates its position as being that "a complainant can[not] shift its legal theory regarding the relevant 'article' after filing the complaint." Reply Br. at 6. But Masimo did not alter its identified domestic industry article after filing its complaint. To the contrary, the Commission affirmed the ALJ's determination that Masimo "rel[ied] on certain 'Masimo Watch' products" to satisfy the domestic industry analysis, that "[t]h[o]se Masimo Watch products include certain prototypes," and that Masimo was not limited to the complaint's CAD

drawings. J.A. 10; *see also* J.A. 373 (Commission relying on ALJ's determination); *see also* Comm'n. Br. at 29 ("[T]he complaint did not purport to identify a singular hypothetical Masimo Watch that was merely represented by CAD drawings."). Those determinations were based on substantial evidence,[5] including the testimony of multiple witnesses to the effect that Masimo "designed, built, and tested many iterations of the Masimo Watch." J.A. 92 (citing J.A. 40487 at 393:12-20); *see also* J.A. 40436-37 at 342:25-343:7 (testimony regarding "many iterations of the wrist sensors"); J.A. 40439 at 345:2-7 (witness describing "[m]any iterations on the watch through the design phases"); J.A. 40368-69 at 275:13-276:11 (testimony as to how each subsequent model "gets a little bit better"). On this record, the ALJ and the Commission appropriately treated the Masimo Watch as the domestic industry article and viewed the CAD drawings contained in the complaint and the physical prototypes Masimo produced in discovery as successive embodiments of that same article.

ii

Apple next argues that the Commission was required to confine its technical prong analysis to the specific RevA, RevD, and RevE models Masimo produced during discovery (i.e., CPX-0052C, CPX-0058C, CPX-0019C, CPX-0020C, and CPX-0065C). The ALJ, when analyzing the RevA, RevD, and RevE models to see if they practiced Masimo's asserted patent claims, referred broadly to "the RevA, RevD, and RevE devices," without suggesting that her analysis was limited to only those particular physical units that happened to be produced in discovery. J.A. 87.

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[5] The ALJ found, as a matter of fact, that "it [was] objectively reasonable to read the Amended Complaint" as not referring to a single Masimo Watch. J.A. 14136.

The APA allows parties to rely on a wide array of evidence during an administrative adjudication, *see* 5 U.S.C. § 556(d), and authorizes agencies to make rules regarding how such evidence is received, *see* 5 U.S.C. §§ 554(b), 556(d). Here, the pertinent regulations provide that the ALJ and "[t]he Commission also may make any findings or conclusions that in its judgment are proper *based on the record* in the proceeding." 19 C.F.R. § 210.45(c) (emphasis added); *see also* 19 C.F.R. § 210.38. Nothing in the Tariff Act, the APA, or the Commission's rules supports Apple's contention that the technical prong analysis must be confined to only those individual devices a complainant physically produces in discovery, as opposed to treating such devices as representative embodiments of the broader domestic industry article they are found to reflect.

Apple argues that the ALJ found only that "'prototype devices with designs that are *consistent with the asserted domestic industry products*,'" existed at the time Masimo filed its complaint, rather than finding that actual patent-practicing articles existed. Open. Br. at 30 (quoting J.A. 89 at n.22). But the ALJ's accompanying discussion explains that she found – based on testing, witness testimony, and other circumstantial evidence – that physical prototype devices sharing the patent-practicing features embodied in the RevA, RevD, and RevE units produced in discovery, were "articles protected by claims of the Poeze [P]atents existing at the time of the complaint." J.A. 88-90.

iii

Apple next suggests that a complainant may not rely on circumstantial evidence to meet its burden to prove that a patent-practicing article existed at the time it filed its complaint. *See, e.g.*, Open. Br. at 3 (faulting Commission for "allow[ing] Masimo to prevail on the theory that Masimo had provided *circumstantial* evidence that it had at one time possessed *different* pre-complaint items that practiced the patents"); *id.* at 19 (emphasizing that Masimo

"failed to provide direct evidence of a single pre-complaint item practicing the asserted patents"); *id.* at 30 ("If a patent-practicing physical article actually existed at the time of the complaint, the Commission should not have needed to resort to circumstantial evidence and speculative inferences . . . ."). In Apple's view, "the respondent, the Commission, and this Court should be able to *see* the claimed domestic industry article." Open. Br. at 31. To the extent this is a restatement of Apple's contention that the Commission is limited to analyzing only the specific, physical models produced in discovery, we have already rejected that view. If, alternatively, Apple more broadly means that circumstantial evidence is an unacceptable basis on which the Commission may find the domestic industry technical prong satisfied, Apple identifies no statutory, regulatory, or caselaw support for its position.

Indeed, the APA broadly sets out that "*[a]ny* oral or documentary evidence may be received" during an agency adjudication, and "[a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required." 5 U.S.C. § 556(d) (emphasis added). Nothing about this authorization restricts an agency's consideration solely to direct evidence. In general, "[c]ircumstantial evidence is just that – evidence [and is not] second-class to direct evidence." *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1337 (Fed. Cir. 2023). More particularly, as in *Medtronic*, "[Apple's] argument is tantamount to requiring that [the technical prong] can be proven only by direct evidence . . . rather than circumstantial evidence. . . . Our caselaw has never drawn any such distinction, nor would such a distinction be consistent with basic principles of evidence and inference." *Id.* We therefore reject Apple's contention that reliance on circumstantial evidence in § 337 proceedings is in any way improper.

iv

Accordingly, the Commission permissibly treated the Masimo Watch as Masimo's domestic industry article and reasonably viewed the RevA, RevD, and RevE versions of that watch – prototype units it found were manufactured and tested before the filing of the complaint – 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. Thus, the Commission did not rely on a "hypothetical" article as Apple wrongly asserts; instead the Commission identified as the pertinent patent-practicing article the Masimo Watch, as representatively described in Masimo's complaint, and supported by the prototypes Masimo produced in discovery, and as further proven by the testimony of multiple witnesses, product testing data, and other circumstantial evidence the ALJ credited. The ALJ and the Commission were permitted to credit all of this evidence. Therefore, we discern no error in the Commission's reliance on the Masimo Watch as the patent-practicing article for purposes of the technical prong.

b

Having determined that the Commission properly relied on the Masimo Watch – which includes certain prototypes and is not limited to the CAD drawings in Masimo's complaint or the specific units produced in discovery – we turn to Apple's contention that those prototypes do not satisfy the technical prong of the domestic industry requirement because they do not practice any asserted claim of the Poeze Patents. Apple specifically disputes Masimo's showing that, as of the complaint date, the Masimo Watch met the "user-worn" and blood oxygen measuring limitations of the asserted claims. We conclude that substantial evidence supports the Commission's finding that, at the time of the complaint, the Masimo Watch was both user-worn and capable of measuring blood oxygen.

i

Substantial evidence supports the Commission's finding that the RevA and RevD sensors were "user-worn" at the time of the complaint, even though the specific devices Masimo produced in discovery lacked a strap. The ALJ found that "each of [the produced RevA and RevD] sensors include[d] mechanisms for attaching a strap." J.A. 66. She additionally credited the testimony of a Masimo witness that the sensors "had straps at one point in time." J.A. 66 (internal quotation marks omitted). This combination of circumstantial and direct evidence constitutes substantial evidence supporting the finding that the Masimo RevA and RevD sensors were "user-worn" at the time of the complaint as required by the asserted claims.

ii

Substantial evidence also supports the finding that the RevA, RevD, and RevE sensors measured blood oxygen levels. The ALJ credited the testimony of Masimo's Mr. Al-Ali, who provided direct evidence that Masimo performed testing of the blood oxygen functionality of the RevA sensor in 2020, of the RevD sensor in early 2021, and of the RevE sensor in June 2021, all of which was before the July 12, 2021 complaint date. The ALJ additionally credited testimony from Masimo's expert, Dr. Vijay Madisetti, who stated he had observed successful blood oxygen calculation testing of each of the devices. The testimony of these witnesses, in combination with documents describing the results of these tests, is substantial evidence that "Masimo's sensors [were] configured to take oxygen saturation measurements" as of the time of the complaint. J.A. 67.

Thus, we affirm the Commission's determination that Masimo met its burden to prove that its Masimo Watch satisfies the technical prong of the domestic industry requirement of § 337.

2

We turn now to the economic prong of the domestic industry requirement. The economic prong "requires that there be in existence or in the process of being established an industry in the United States pertaining to the patent[(s)]." *Lashify*, 130 F.4th at 954 (internal quotation marks and alterations omitted). Section 337(a)(3) "identifies three potentially overlapping but independently sufficient bases" for finding the economic prong satisfied. *Id.* They are:

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

19 U.S.C. § 1337(a)(3).

In her initial determination, the ALJ found Masimo had satisfied subsection (B) above, by showing "significant employment of labor or capital" by way of Masimo's "investments in research and development for the Masimo Watch." J.A. 322. The ALJ based this finding on evidence of the number of employees working on the Masimo Watch, Masimo's monetary investments in the Masimo Watch, and the fact that "all of the research and development ('R&D') for the Masimo Watch has occurred in the United States." *Id.* While the ALJ found that Masimo demonstrated a domestic industry both "in existence" and "in the process of being established," the Commission affirmed only the finding of a domestic industry "in existence," choosing not to reach the question of whether Masimo additionally proved an industry "in the process of being established." The Commission reasoned that the qualitative significance of Masimo's R&D in the Masimo Watch, and particularly the percentage of Masimo's R&D engineers working on the article and that their work was predominantly, if not

exclusively, domestic, was sufficient grounds to find the economic prong satisfied. The Commission concluded that a domestic industry therefore "exist[ed] . . . *with respect to* the articles protected by the patent." 19 U.S.C. § 1337(a)(3) (emphasis added).

Apple does not argue that Masimo's investments in the Masimo Watch were not "significant." Apple instead alleges that the Commission credited improper evidence in assessing that significance. Specifically, Apple argues the Commission erred in two respects: by crediting investments in non-patent practicing articles that were not, in Apple's view, made "with respect to the articles protected by the patent," and by relying on purportedly improper investment accountings. Apple does not dispute that, if properly credited, Masimo's investments would be "significant." Because the Commission committed no error in crediting Masimo's evidence of its investments, Apple's arguments fail.

a

As an initial matter, notwithstanding Apple's protestations, the determination of whether a complainant's investments are "with respect to" the patent protected articles is a question of fact, not law, and thus is one we review for substantial evidence. *See, e.g.*, *Zircon Corp. v. Int'l Trade Comm'n*, 101 F.4th 817, 822 (Fed. Cir. 2024) (holding that substantial evidence supported Commission's determination that complainant "failed to satisfy the statutory requirement that it establish the existence of an industry relating to the articles 'protected by the patent,' as required by section 337").

Turning to the evidence, Apple first argues that the Commission erred in crediting investments in prototypes of the Masimo Watch – which, in Apple's view, are not the articles upon which the technical prong was satisfied – as investments in the Masimo Watch generally. Again, Apple complains that the various prototypes produced in

discovery are not commensurate with the Masimo Watch alleged in the complaint, and additionally takes issue with the fact that some of the prototypes – namely, the Circle and Wings Sensors – do not practice the asserted claims of the Poeze Patents. Thus, it argues, it was error for the Commission to rely on investments in the Masimo Watch generally (i.e., all variations preceding the post-complaint W1 model) for the economic prong while relying instead on the RevA, RevD, and RevE models for the technical prong. As we have discussed, however, the Commission did rely on the same article for both the technical and economic prongs of the domestic industry analysis; namely, the Masimo Watch, which the ALJ and Commission defined to include particular Masimo Watch prototypes, all of which were made as part of an iterative design process involving the Circle, Wings, RevA, RevD, and RevE models. And, even if the Circle and Wings sensors were considered distinct articles from the patent-practicing RevA, RevD, and RevE devices – which they are not – that would present no legal obstacle, as § 337's technical prong requires only a patent-practicing article, while the economic prong requires significant investment with respect to that article. *See Lashify*, 130 F.4th at 954.

Apple counters that even if it was proper to view the various Masimo Watch prototypes as commensurate with Masimo Watch, the ALJ erred by also including in her analysis investments in the Circle Sensor and Wings Sensor, as these were non-patent practicing precursors to the patent-practicing RevA, RevD, and RevE models. As the ALJ observed, Masimo did "not assert[] that the Circle sensor or the Wings sensor practice claims of the [Poeze] [P]atents," but she found nevertheless that "the record show[ed] that the development of these prototypes led to the development of the RevA, RevD, and RevE prototypes that [Masimo did] assert[] as domestic industry products for the [Poeze] [P]atents." J.A. 309. From this, she concluded that such investments qualified as having been

made "with respect to" the patent-practicing Masimo Watch prototypes under § 337, even though the Circle and Wings sensors themselves do not practice the patents. J.A. 308-09.

The Commission properly adopted these findings and this reasoning. The ALJ's conclusion was entirely consistent with § 337(a)(3), which allows for significant investments in aspects of production other than the patent-practicing article itself to count toward meeting the economic prong. *See* 19 U.S.C. § 1337(a)(3) (allowing complainant to prove domestic industry based on "[s]ignificant investment in plant and equipment" or "[s]ubstantial investment in . . . engineering, research and development"). "[N]othing in § 337 precludes a complainant from relying on investments or employment directed to significant components, specifically tailored for use in an article protected by the patent. The investment must only be 'with respect to the articles protected by the patent.' An investment directed to a specifically tailored, significant aspect of the article is still directed to the article." *Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1351 (Fed. Cir. 2013) (internal citation omitted); *see also Microsoft*, 731 F.3d at 1361-62 ("A company seeking section 337 protection must therefore provide evidence that its substantial domestic investment . . . *relates to* an actual article that practices the patent.") (emphasis added).

Substantial evidence, including the development timeline of the devices and witness testimony, supports the ALJ's finding that the Circle and Wings led to the development of significant features of the patent-practicing devices. *See, e.g.*, J.A. 308 (discussing development timeline); J.A. 40490-91 at 396:20-397:6 (testimony of Masimo witness discussing particular arrangements of elements within Circle and Wings sensors that contributed to later arrangement of same elements in the RevA and RevD models). As such, Masimo's investments in the development of the Circle and Wings sensors were investments "directed

to significant components, specifically tailored for use in" the Masimo Watch. *Motorola*, 737 F.3d at 1351. The investments in the Circle and Wings are, thus, investments "with respect to" or "relat[ing] to an actual article that practices the patent" and are, hence, appropriately counted toward Masimo's satisfaction of the economic prong. *Microsoft*, 731 F.3d at 1362.

To be sure, not every investment in an earlier generation prototype of a patent-practicing article can necessarily be considered part of the domestic industry analysis. Qualifying investments must be "specifically tailored" to the patent-practicing article. *Motorola*, 737 F.3d at 1351. Investments that would have been made independently of the patented article, for example, are not made "in the exploitation of the intellectual property" and, therefore, cannot be considered. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1304 (Fed. Cir. 2013) (per curiam; denying petition for rehearing en banc); *see also Motiva*, 716 F.3d at 600 (finding investments that "had no impact on [the complainant's] . . . efforts or ability . . . to invest in and adopt its patented technology" were rightly not considered by Commission for purposes of economic prong); *see also Zircon*, 101 F.4th at 822 (rejecting complainant's attempt to "rely on investment data aggregated across different products protected by different patents"). Predecessor investments qualify only when they are directed to significant components "specifically tailored" for use in the patent-practicing article; that is, when there is a sufficient nexus between the earlier investment and the protected article, such that the investment can fairly be said to have been made "with respect to" that article. *Motorola*, 737 F.3d at 1351; *see also Microsoft*, 731 F.3d at 1362.

Here, substantial evidence supports the Commission's finding that Masimo's investments in the Circle and Wings Sensors were made as part of the same iterative design process Masimo undertook as part of its development of a

single patent-practicing commercial product, and those investments led to specifically tailored, significant technical features of patent-practicing articles, including the RevA and RevD variants of the Masimo Watch.

b

Apple further argues that, even assuming the Commission did not err by aggregating Masimo's investments, its finding that Masimo satisfied the economic prong is still not supported by substantial evidence. Apple contends that Masimo failed to provide a proper accounting of its purported investments. In particular, Apple asserts that the evidence on which Masimo relied was "wholly invented" for litigation, lacked contemporaneous support, and was not verified by Masimo's expert. These arguments effectively ask us to reweigh the evidence considered by the ALJ and the Commission and to reject the ALJ's credibility determinations. This we may not do. *See Bio-Rad Labs., Inc. v. Int'l Trade Comm'n*, 998 F.3d 1320, 1335 (Fed. Cir. 2021) ("It is not within our purview to reweigh the evidence or to question the ALJ's credibility determinations.").

The ALJ and Commission, relying on testimony from Masimo's Chief Financial Officer, found that Masimo calculated its total labor investments in the Masimo Watch by multiplying each Masimo employee's salary by the percent of time he or she devoted to development of the Masimo Watch. It presented that data in detailed spreadsheets that "identified the names and salaries of each employee involved in the Masimo Watch project" alongside "monthly estimates of their time from 2019 to 2021" spent on the Masimo Watch. J.A. 316. The ALJ found those time allocations were "supported by the testimony of Masimo witnesses" and were "reasonable" based on the record evidence. J.A. 316-18. On review, the Commission adopted all of these findings and added that Masimo's investments were significant because they were almost entirely domestic.

"The substantial evidence test requires only that there be evidence that a reasonable mind might accept as adequate to support a conclusion." *Cleo Inc. v. United States*, 501 F.3d 1291, 1296 (Fed. Cir. 2007). That test is met by the evidence relied on here by the ALJ and the Commission. *See, e.g.*, *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*, 127 F.4th 1334, 1338-39 (Fed. Cir. 2025) (determining substantial evidence supported finding of significant investment where "100% of [the relevant] investments occur[ed] in the United States"). Thus, we affirm the Commission's finding that Masimo met its obligation to satisfy the domestic industry requirement.

IV

In addition to its challenges to the Commission's determination that Masimo satisfied the domestic industry requirement, Apple also appeals the Commission's findings that the Apple Watch infringes the asserted claims and that those claims were not proven invalid, either for lack of adequate written description or obviousness. On all these issues, we again affirm the Commission.

A

Apple argues the Commission based its finding that the Apple Watch infringes Masimo's asserted patent claims on incorrect constructions of the claim terms "over"/"above" and "openings"/"through holes." "We review claim construction de novo and review any subsidiary factual findings based on extrinsic evidence for substantial evidence." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022). Our review here leads us to agree with the ALJ's claim constructions.[6]

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[6] The Commission did not undertake to review the ALJ's challenged constructions but otherwise affirmed her

1

The claim terms "over" and "above" relate to certain internal components of the claimed devices and their orientation. For example, claim 28 of the '502 patent requires "a protrusion arranged *above* the interior surface" of the device. J.A. 705 at 47:31 (emphasis added). The parties dispute whether, for instance in this example, the claim requires the protrusion be "above" the interior surface such that the protrusion is higher (i.e., closer to the sky) than the interior surface when the device is in operation or whether, instead, it requires simply that the protrusion cover the interior surface, without consideration of whether during operation the protrusion happens to be higher (closer to the sky) or lower (closer to the ground) than the interior surface.

The ALJ construed "above," as used in claim 28 of the '502 patent, and "over," as used in claims 20 and 34 of the '648 patent, to mean "arrangement[s] where one feature covers another – not the relative arrangement of the[] features in a vertical direction." J.A. 34. That is, the terms "refer[] to a position relative to the device's features and not to its orientation relative to Earth." *Id.* at n.4. In arriving at those constructions, the ALJ rejected Apple's position that the terms "require a vertical arrangement of features in a particular orientation." J.A. 35; *see also* Open. Br. at 60 ("[E]ach claim requires a protrusion, openings, or holes situated over or above the photodiodes or interior surface of the device, when the device is configured to measure blood oxygen saturation") (internal emphasis and quotation marks omitted).

As the ALJ correctly determined, the plain and ordinary meaning of "over" and "above," as used in the field of

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ultimate validity determination. Therefore, we discuss the ALJ's analysis.

wearable medical equipment, relates to positions of the equipment's components relative to other components, without any further restriction on the orientation of the device. Thus, for example, a bandage is said to be "over" or "above" a wound so long as the bandage covers the wound, even if the wound is on the bottom of, for example, one's foot, leaving the bandage closer to the ground than the wound is when one is walking.

Additional support for this construction is found in Figure 7A of the Poeze Patents' shared specification. The ALJ explained that the embodiment depicted in Figure 7A (reproduced below, *see infra* Section IV.B.1) is described in the specification as containing material "over" a glass layer even though the figure itself shows such material as below that layer, in the sense that the material is closer to the ground than the glass layer. Generally, a construction that would exclude a disclosed embodiment, as Apple's construction would by excluding the embodiment of Figure 7A, is not preferred. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015). We therefore agree with the ALJ's construction.

2

Apple's challenge to the ALJ's construction of "openings"/"through holes," as used in all asserted claims, also lacks merit. The claims require that "each *through hole* [be] . . . arranged over a different one of the . . . photodiodes." J.A. 815 at 46:43-45 (emphasis added). The ALJ correctly construed these terms as encompassing "openings and holes that include material." J.A. 36. She was right to reject Apple's proposed construction, which would have required the claimed "openings" and "through holes" to be devoid of material, including even transparent material.

Nothing in the claim language precludes the "openings" and "through holes" from including material. To the contrary, certain of the claims actually *require* such material. For example, claim 19 of the '502 patent requires "an

optically transparent material *within each of the openings,*" J.A. 704 at 46:38 (emphasis added), and claim 20 of the '648 patent requires that "each through hole *includ[e] a window*," J.A. 815 at 46:43-44 (emphasis added). While these claims are not asserted by Masimo, they would suggest to a person of ordinary skill in the art that "openings" and "windows" as used in the patents are not necessarily and always devoid of material. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) ("Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.").

The shared specification provides more support for this conclusion. It expressly teaches that "[t]he openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through one or more detectors." J.A. 575 at 8:26-30; *see also* J.A. 37. Apple's proposed construction would exclude this embodiment because it would not allow the openings to be made from glass, which is of course a material. *See Pacing Techs.*, 778 F.3d at 1026 (disfavoring constructions that exclude disclosed embodiments). As such, we do not agree with Apple's proposed construction of these terms.

As Apple's sole challenges to the Commission's infringement findings require that we reverse its claim constructions, our affirmance of those constructions requires that we also affirm the Commission's finding that the Apple Watch infringes the asserted claims.

B

Apple has similarly failed to persuade us that the Commission erred in determining that the infringed claims were not proven invalid. We agree with the Commission and reject Apple's claims that the Poeze Patents lack adequate written description or would have been obvious.

1

A patent's specification must contain an adequate written description of the invention. *See* 35 U.S.C. § 112(a). "A specification adequately describes an invention when it reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (internal quotation marks omitted). "Whether a claim satisfies the written description requirement is a question of fact." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1016 (Fed. Cir. 2022) (internal quotation marks omitted).

Each of the claims at issue here requires: (i) sets of LEDs, each set having multiple LEDs; (ii) four photodiodes; and (iii) an opaque protrusion with a plurality of "openings" or "holes" positioned or arranged over the photodiodes. J.A. 704 at 46:51-54; J.A. 705 at 47:13-48:23; J.A. 815 at 46:15-16, 46:59-61; J.A. 816 at 47:6-7; *see also* J.A. 161-62. Claim 28 of the '502 patent and claim 12 of the '648 patent additionally require "separate sets of LEDs emitting at a First Wavelength and a Second Wavelength" (the "matching wavelength" limitation). J.A. 167. Apple argues that neither the required combination of specific LEDs and photodiodes, nor the matching wavelength limitations, are supported by adequate written description. However, the ALJ's contrary findings, adopted by the Commission, are supported by substantial evidence.

Apple contends that the ALJ improperly relied "on elements taken from four separate embodiments" in the specification to find the asserted claims' combination of required elements supported by adequate written description. Open. Br. at 55. Specifically, Apple claims the ALJ relied on the 301A sensor embodiment (shown in Figure 3C) to disclose the required four photodiodes over which a protrusion rests with openings arranged over the photodiodes; on the 101 sensor embodiment (shown in Figure 1) for

disclosure of an emitter with three or more LEDs; and on the 701 sensor embodiment (shown in Figure 7B) for an opaque protrusion. Apple concedes that the specification discloses all of the claimed features but insists that it fails to do so in any single embodiment.

The ALJ found that "[t]he specification of the Poeze [P]atents expressly states that Figure 3C and Figure 7B are not distinct embodiments" but, instead, that "[t]he features of the sensors 701 can be implemented with any of the sensors 101, 201, [and] 301." J.A. 164. In making that finding, the ALJ noted additional places in the specification in which the embodiments are linked. *See, e.g.*, J.A 163 (referencing specification's description of "system 100 that [is] comprised [of] four LEDs in emitter 104 and four independent detector streams from detector 106"). She further credited Masimo's expert, who testified as to how a skilled artisan would understand these disclosures to show the patentee had possession of the embodiments of the claims. All of this constitutes substantial evidence supporting the ALJ's finding that the embodiments Apple insists are distinct may, instead, be understood as disclosing a combined implementation contained in a single embodiment. Thus, the Commission did not erroneously rely on an "amalgam of disclosures plucked selectively from the [original] application." *NovozymesA/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

Substantial evidence further supports the Commission's finding that the Poeze Patents provide adequate written description for claim 28 of the '502 patent and claim 12 of the '624 patent. These claims add the matching wavelength limitation, *i.e.*, a "first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength," as well as a "second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength." J.A. 414; *see also* J.A. 419-24.

Apple argues that the patents contain no disclosure of multiple emitters having an identical set of LEDs. In rejecting this contention, the Commission found the inventors possessed the matching wavelength limitation, relying on Figures 7A and 7B, both of which show an element 104, although Figure 7A labels element 104 "LEDs" while Figure 7B labels the same element "Emitters." J.A. 522-23. Figures 7A and 7B are reproduced below:

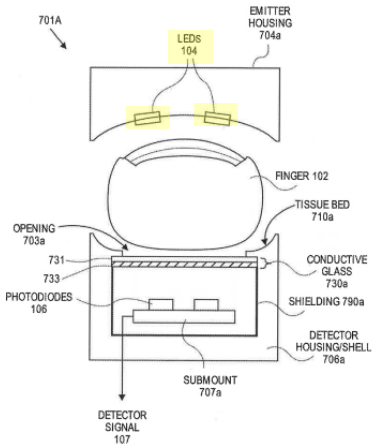

FIG. 7A

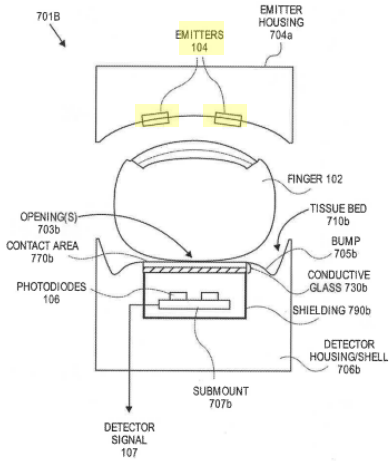

FIG. 7B

Id. (annotations added).

The Commission reasoned "the two LEDs in Figure 7A are the same, and the two emitters in Figure 7B are the same," further finding "[i]f the two sets of LEDs or the two emitters having sets of optical sources are the same, then they must emit the same visible and near-infrared optical radiation, i.e., at the same two respective wavelengths." J.A. 422. The Commission additionally found that the specification discloses a set of LEDs in each emitter 104 of Figure 7B capable of emitting light "at or about 1610 nm, at or about 1640 nm, and at or about 1665 nm." J.A. 424 (citing J.A. 577 at 12:38-40).

The Commission's findings are supported by substantial evidence. Its reading of the specification's references to element 104 is reasonable. Apple's insistence that "nothing in the specification states that the emitters 104 *must* be identical" is correct, Open. Br. at 58 (emphasis added), but is also largely irrelevant, as our review only asks whether there is substantial evidence to support reading the specification as disclosing, as the Commission found, that emitters 104 may be identical. *See Bio-Rad*, 998 F.3d at 1329 ("Under substantial evidence review, we must affirm a Commission determination if it is reasonable and supported by the record as a whole, even if some evidence detracts from the Commission's conclusion.") (internal quotation marks omitted).

Therefore, again, we affirm the Commission's finding that the asserted claims are not invalid for lack of adequate written description.

2

Apple additionally argues that the asserted claims are invalid as obvious in view of U.S. Patent No. 7,620,212 ("Lumidigm"), which generally discloses devices containing "electro-optical sensors" that, in some embodiments, can be used for "biometric identification." The Commission rejected Apple's obviousness case after finding Lumidigm does not disclose (i) measuring blood oxygen level at the wrist, or (ii) transmissive windows extending across openings and within openings. "The ultimate question of obviousness is a legal question that we review de novo with underlying factual findings that we review for substantial evidence." *Roku, Inc. v. Universal Elecs., Inc.*, 63 F.4th 1319, 1324 (Fed. Cir. 2023). Here the ALJ, whose determinations were adopted by the Commission, committed no legal error and her factual findings were supported by substantial evidence.

One premise of the ALJ's rejection of Apple's obviousness defense was her determination that Lumidigm failed

to enable a "user-worn" device capable of measuring blood oxygen saturation at the wrist. Apple faults the ALJ's analysis on this point because, in its view, the device of the asserted claims is not required to measure blood oxygen levels *at the wrist*; therefore, prior art likewise need not enable such an embodiment to be invalidating. Regardless of whether Apple's proposition is correct (an issue we need not decide), it is immaterial, for two reasons. First, Apple chose to premise its obviousness theory on Lumidigm teaching measurement of blood oxygen levels at the wrist, requiring the ALJ to assess whether Lumidigm does so, in order to determine whether Apple had proven its own theory of obviousness. Second, and an independently adequate basis for rejecting Apple's obviousness case, is that Lumidigm fails to disclose measuring blood oxygen saturation *at all, anywhere on the body*, yet that functionality is indisputably a limitation of the asserted claims.

With respect to the second point, the ALJ found in particular that "[t]here is little to no technical description of the blood oxygen functionality in Lumidigm." J.A. 120 n.40. She further determined that Lumidigm "does not include the communication of an oxygen saturation measurement . . . because no such measurement is disclosed in Lumidigm." J.A. 138. The ALJ explicitly found that Lumidigm merely "describes functionality for measuring several different physiological parameters," but not blood oxygen saturation. J.A. 97.

The ALJ's factual finding regarding what Lumidigm discloses, and does not disclose, is supported by substantial evidence. The intrinsic record supports finding Lumidigm discloses measuring "physiological state[s]" generally by way of "electro-optical sensors;" it does not describe measuring blood oxygen specifically, nor does it give any direction to a skilled artisan regarding how one might modify its disclosures in order to measure blood oxygen levels. The ALJ also relied on the testimony of Robert Rowe, an inventor of Lumidigm, who testified that "he never made a device

that calculated blood oxygen." J.A. 120. The ALJ, thus, had substantial evidence for her finding that Lumidigm does not teach the claim limitation of measuring blood oxygen levels.

This conclusion makes it unnecessary to consider Apple's additional argument that the ALJ erred in finding Lumidigm failed to render obvious the asserted claims' "separate windows" limitation. Thus, we affirm the Commission's conclusion that Apple failed to prove the asserted claims are invalid due to obviousness.

V

Finally, Apple contends that the Commission erred in concluding that prosecution laches did not render Masimo's asserted patents unenforceable. "[P]rosecution laches may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). "[A]n examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims, may trigger laches." *Id.* at 1386. We review a determination of the applicability of prosecution laches for abuse of discretion. *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1359 (Fed. Cir. 2021).

Apple argued to the Commission that Masimo engaged in an unreasonable 12-year delay when it waited from 2008, when it filed its provisional applications, to September 2020, when it finally filed the applications that led to the asserted patent claims. The ALJ considered this interlude and found it did not constitute a delay at all, crediting testimony showing "continuous prosecution activity in the [asserted] patents during th[at] time." J.A. 177. Apple countered that "the 2015 continuation application could

have been filed earlier,"[7] J.A. 178, and that Masimo's purported delays reflect Masimo's intent "to draft the claims only after reviewing Apple's products." Open. Br. at 64. To the ALJ, the fact that Masimo could have filed its continuation application earlier was "not a sufficient basis for a finding of prosecution laches, as . . . there are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches," adding that laches "should be applied only in egregious cases of misuse of the statutory patent system." J.A. 178 (internal quotation marks, alteration, and citation omitted). The ALJ further found that Apple did "not provide[] evidence showing that [the] newly asserted claim limitations were specifically drawn to the Accused products." J.A. 179 n. 65.

Assuming, without deciding, that Apple preserved its prosecution laches claim, Apple has failed to demonstrate that the ALJ abused her discretion in rejecting it. To the contrary, it was entirely reasonable for the ALJ to find, based on the evidence before her, that Apple failed to meet its burden to prove that Masimo engaged in unreasonable and unexplained delay and to credit, instead, Masimo's expert, who opined that there was a "continuous unbroken chain of patent prosecution." J.A. 41512 at 1415:6-7. There is also no record evidence that Masimo delayed any prosecution activities for the purpose of drafting the claims to cover Apple's products. *See OSI Pharms., LLC, v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019) ("Mere speculation is not substantial evidence"); *see also In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) ("An applicant's attempt

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[7] Masimo consistently filed continuations and continuations-in-part between summer 2008 and July 1, 2010. Apple contends that "Masimo then lay in wait and did not file a new application in the chain for five years . . . immediately following the release of the original Watch Series 0 in April 2015." Open. Br. at 63.

to obtain new claims directed to inventions that he or she believes are fully disclosed and supported in an earlier application [is distinct from laches]."). Therefore, we affirm the Commission's finding that prosecution laches does not bar Masimo from enforcing its asserted patents.

VI

We have considered Apple's remaining arguments and find they lack merit. For the foregoing reasons, the judgment of the Commission is affirmed.

AFFIRMED