



U.S. Customs and
Border Protection

HQ H354023

March 6, 2026

OT:RR:BSTC:EOE H354023 WMW

CATEGORY: 19 U.S.C. § 1337; Unfair Competition

K. Kevin Chu
Quinn Emanuel
1300 I Street NW, Suite 900
Washington, DC 20005

VIA EMAIL: kevinchu@quinnemanuel.com

RE: Ruling Request; U.S. International Trade Commission; Limited Exclusion Order; Investigation No. 337-TA-1398; Certain Smart Wearable Devices, Systems, and Components Thereof

Dear Mr. Chu:

Pursuant to 19 C.F.R. Part 177, the Exclusion Order Enforcement Branch (“EOE Branch”), Regulations and Rulings, U.S. Customs and Border Protection (“CBP”) issues this ruling in response to the request from Ultrahuman Healthcare Pvt. Ltd., Ultrahuman Healthcare Ltd., and Ultrahuman Healthcare SP LLC (“Ultrahuman”) for an administrative ruling, dated August 22, 2025, which included Exhibits 1-4 (collectively, “Ruling Request”). We find that Ultrahuman has met its burden to show that the Ring Pro (“redesigned ring” or “the articles at issue”), as described below, is not subject to exclusion from entry based on the limited exclusion order (“LEO”) that the U.S. International Trade Commission (“Commission” or “ITC”) issued in Investigation No. 337-TA-1398 (“the underlying investigation” or “the 1398 investigation”) on August 21, 2025, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”).¹ Entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption of the articles at issue, however, is conditioned on certain terms, including the drafting and approval of a certification, as discussed in this ruling. Ultrahuman must provide notice to the EOE Branch and Ouraring, Inc. and Oura Health Oy (“Oura”), as the other interested party in this inter partes proceeding, no later than 10 business days

¹ The 1398 LEO, inter alia, prohibits the unlicensed entry for consumption of smart wearable devices, systems, and components that infringe one or more of claims 1, 2, and 12-14 of U.S. Patent No. 11,868,178 (“the ’178 patent”) Certain Smart Wearable Devices, Systems, and Components Thereof, Inv. No. 337-TA-1398, EDIS Doc. ID 860139, Limited Exclusion Order (August 21, 2025) at 2 (“1398 LEO”).

after the issuance of this ruling, confirming that it accepts the terms as set forth in this ruling. See p. 13 infra.

We further note that determinations of the Commission resulting from the underlying investigation or a related proceeding under 19 C.F.R. Part 210 are binding authority on CBP and, in the case of conflict, will modify or revoke any contrary CBP ruling or decision pertaining to Section 337 exclusion orders by operation of law.

This ruling is the result of a request for an administrative ruling from CBP under 19 C.F.R. Part 177, which was conducted on an inter partes basis. The process involved the two parties with a direct and demonstrable interest in the question presented by the ruling request: (1) your client, Ultrahuman, the ruling requester and importer of the articles at issue; and (2) Ouraring, Inc. and Oura Health Oy (“Oura”), the Complainant and patent owner in the 1398 investigation. See, e.g., 19 C.F.R. § 177.1(c).

I. BACKGROUND

A. ITC Investigation No. 337-TA-1389

1. Procedural History at the ITC

The Commission instituted Investigation No. 337-TA-1389 on April 17, 2024, based on a complaint filed by Oura. Certain Smart Wearable Devices, Systems, and Components Thereof, Inv. No. 337-TA-1398, EDIS Doc. ID 861286, Public Commission Opinion (September 5, 2020) (“Comm’n Op.”) at 1 (citing 89 Fed. Reg. 27452-53 (Apr. 17, 2024)). The complaint, as amended, alleged a violation of Section 337 by reason of infringement of claims 1, 2, and 12-14 of the ’178 patent. Id. The notice of investigation named Ultrahuman Healthcare Pvt. Ltd., Ultrahuman Healthcare SP LLC, Ultrahuman Healthcare Ltd., Guangdong Jiu Zhi Technology, Co. Ltd., RingConn LLC, and Circular SAS as respondents. Certain Smart Wearable Devices, Systems, and Components Thereof, Inv. No. 337-TA-1398, EDIS Doc. ID 849708, Public Final Initial Determination (Apr. 18, 2025) (“FID”) at 1 (citation omitted). The Office of Unfair Import Investigations (“OUII”) was also a party in the investigation. Id.

On April 18, 2025, the ALJ issued the final initial determination finding a violation of Section 337. Comm’n Op. at 1. Specifically, the ALJ determined that a violation of Section 337 occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of the accused products due to infringement of claims 1, 2, and 12-14 of the ’178 patent. Id. at 2.

On June 20, 2025, the Commission issued a notice in which it determined to review in part the FID. Comm’n Op. at 5. (citing 90 Fed. Reg. 27054-57 (June 25, 2025)). The Commission, in its review of the FID, adopted the FID’s finding of a violation of Section 337 as to the asserted patent claims. Id. at 29. On September 5, 2025, the Commission found a violation of Section 337 with regard to infringement of the asserted claims of the ’178 patent and determined that the appropriate remedy was a limited exclusion order and cease and desist orders directed to Respondents. Id.

In the LEO, the Commission ordered that “[s]mart wearable devices, systems, and components thereof that infringe one or more of claims 1, 2, and 12-14 of the ’178 patent and that are manufactured abroad by, or on behalf of, or imported by or on behalf of Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the ’178 patent, except under license from, or with the permission of, the patent owner or as provided by law, and except for smart wearable devices imported for replacement, under warranty terms, of covered articles sold to end users prior to the expiration of the period of Presidential review[.]” Certain Smart Wearable Devices, Systems, and Components Thereof, Inv. No. 337-TA-1398, EDIS Doc. ID 2423293, Limited Exclusion Order (August 21, 2025) at 2 (“1398 LEO”). The LEO defines, “[t]he smart wearable devices, systems, and components thereof subject to this Order (*i.e.*, ‘covered articles’) are as follows: smart ring wearable devices, systems, and components thereof.” Id.

2. The Patent and Claims in the 1398 LEO

As noted above, the 1398 LEO prohibits the unlicensed entry for consumption of smart wearable devices, systems, and components thereof that infringe one or more of claims 1, 2, and 12-14 of the ’178 patent. The ’178 patent is directed to a smart ring with a curved housing that contains a curved battery, a semi-flexible printed circuit control board along with a window to facilitate either data transmission, battery recharge or status indication. Claim 1 is the sole independent claim.

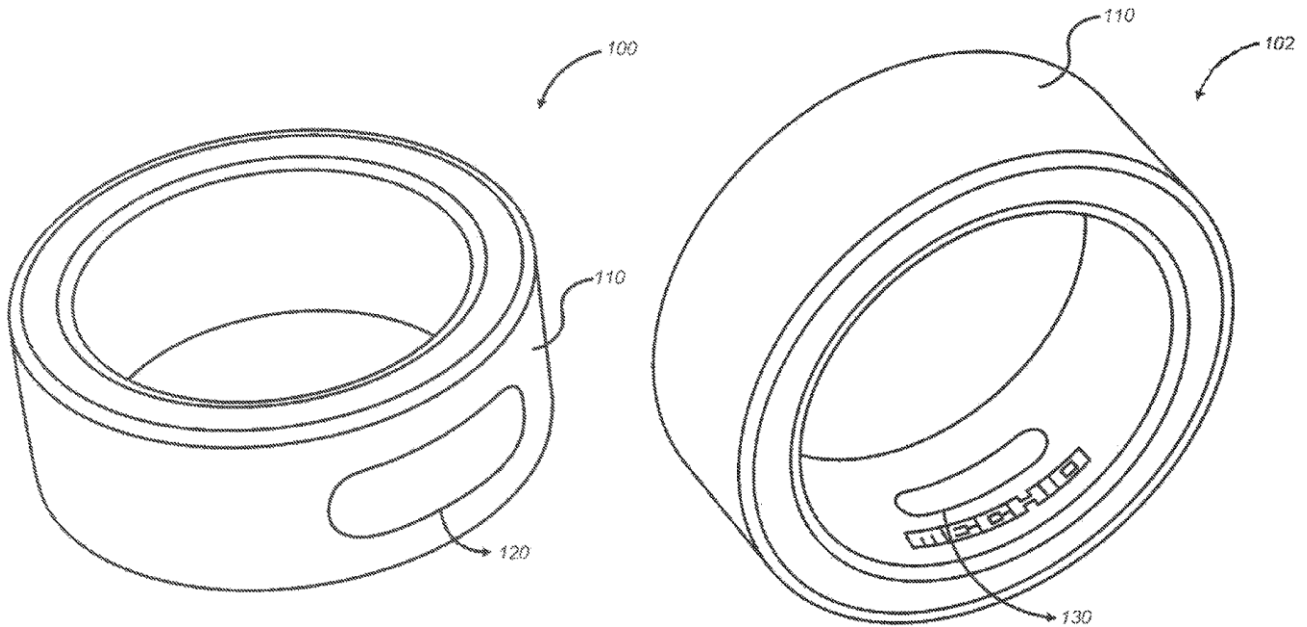
a. Claim 1 of the ’178 Patent

The ’178 patent is titled “Wearable Computing Device.” FID at 6 (internal citation omitted). Claim 1 of the ’178 patent is reproduced below:

- 1 [Preamble]. A finger-worn device, comprising:
- [1.a] an **external housing** component defining an outer circumferential surface of the finger-worn wearable ring device;
 - [1.b] an **internal housing** component defining an inner circumferential surface of the finger-worn wearable ring device, the internal housing component coupled with the external housing component,
 - [1.c] wherein at least a portion of the inner circumferential surface of the internal housing component is configured to contact a tissue of a user when the finger-worn wearable ring device is being worn by the user;
 - [1.d] a **battery positioned within a cavity formed between the internal housing component and the external housing component**,
 - [1.e] wherein the battery comprises a shape and size **configured to fit within** the cavity between the outer circumferential surface of the external housing component and the inner circumferential surface of the internal housing component, and
 - [1.f] wherein the battery extends through at least a first portion of the cavity of the finger-worn wearable ring device;

[1.g] a printed circuit board disposed between the internal housing component and the external housing component,
[1.h] wherein the printed circuit board extends through at least a second portion of the cavity of the finger-worn wearable ring device different from the first portion;
and
[1.i] one or more sensors electrically coupled with the printed circuit board and the battery and
[1.j] configured to acquire data from the user through the internal housing component

(emphasis added)²



'178 patent at Fig. 1A, Fig. 1B.

3. The Ultrahuman Legacy Product Found to Infringe in the Underlying Investigation

In the underlying investigation, Ultrahuman's accused product was its Ultrahuman Ring AIR and its associated application. FID at 7. "The Ultrahuman Ring AIR pairs with the Ultrahuman app so users can access collected data." *Id.* at 8. This legacy product was found to meet all the claim limitations of claim 1. *Id.* at 66. For example, the Ultrahuman legacy product possessed a metal outer structure defining an outer circumferential surface which was found to meet the claim limitation 1[a] of "an external housing component defining an outer circumferential surface". FID at 29-30. Additionally, the Ultrahuman legacy product was found to "include[] an internal housing component in the form of potting material" and thus met the claim limitation in

² The bolded claim limitations are the limitations at issue in the Ruling Request. *See e.g.*, Ruling Request at 3. The numbering of the claim limitations corresponds with the numbering used in the Ruling Request. *See id.* at 4.

1[b] of “an internal housing component³ defining an inner circumferential surface.” See e.g., *id.* at 32-9.

B. 19 C.F.R. Part 177 Ruling Request Procedural History

1. Ultrahuman’s Ruling Request

On August 22, 2025, Ultrahuman submitted the Ruling Request to the EOE Branch. Ultrahuman Email to EOE Branch (dated August 22, 2025). Ultrahuman requested “a ruling that Ultrahuman’s Ring Pro (“redesigned ring”), does not infringe claims 1, 2, and 12-14 of the ‘178 patent [and therefore] are outside the scope of and not subject to the Limited Exclusion Order (‘LEO’) issued on August 21, 2025, by the U.S. International Trade Commission (ITC) in Certain Smart Wearable Devices, Systems, and Components Thereof, Inv. No. 337-TA-1398 (the ‘1398 Investigation’).” Ruling Request at 1. On August 26, 2025, Ultrahuman also confirmed that it had transmitted a redacted version of the ruling request to Oura’s counsel. Ultrahuman Email to EOE Branch (dated August 26, 2025).

On September 2, 2025, the EOE Branch had an initial conference call with Ultrahuman and Oura, on which both parties agreed to conduct this proceeding on an inter partes basis as administered by the EOE Branch. During this initial call, the EOE Branch and the parties discussed the ground rules and scheduling for the inter partes proceeding. On September 4, 2025, the EOE Branch distributed the procedural schedule for the inter partes proceeding. EOE Branch Email to parties (dated September 4, 2025).

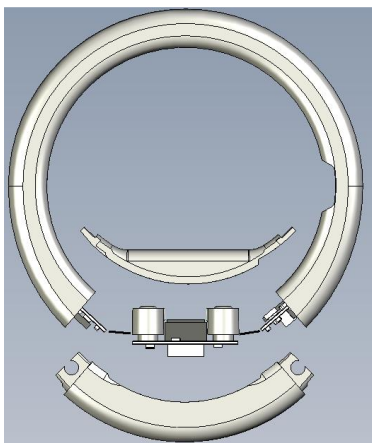
On September 26, 2025, Oura submitted their substantive response to the ruling request. Oura email to parties (dated September 26, 2025). On October 3, 2025, Ultrahuman submitted their reply. Ultrahuman email to parties (dated October 3, 2025). On October 10, 2025, Oura submitted their sur-reply. Oura email to parties (dated October 10, 2025). On October 22, 2025, the EOE Branch conducted its oral discussion with both Ultrahuman and Oura. Also on October 22, 2025, both Ultrahuman and Oura submitted copies of the presentations used during the oral discussion. Ultrahuman email to parties (dated October 22, 2025) and Oura email to parties (dated October 22, 2025). On October 29, 2025, both parties submitted their final post oral-discussion brief. Ultrahuman email to parties (dated October 29, 2025) and Oura email to parties (dated October 29, 2025).

2. The Articles at Issue

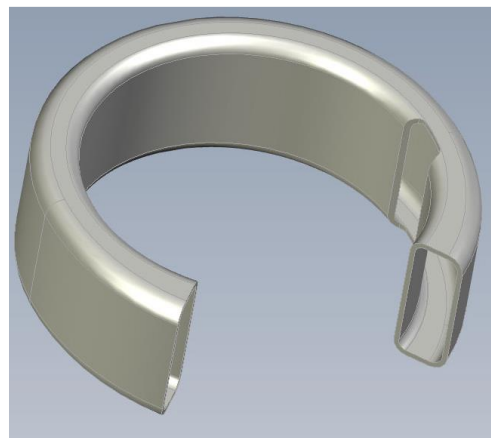
Ultrahuman requests a ruling that “Ultrahuman’s Ring Pro” (“the articles at issue” or “redesigned ring”) do not infringe the asserted claims of the ‘178 patent. Ruling Request at 1. The redesigned ring differs from the original ring in that the exterior titanium ring found to be the “exterior housing component” in the underlying investigation and the “internal housing component” user--contacting epoxy layer have been replaced by a housing tube. *Id.* at 8. The housing tube is a single, continuous, and integrally formed open-ended titanium tube. *Id.* The

³ “The term ‘internal housing component’ was construed as ‘an internal structure that encloses space and which does not necessarily exclude potting material.’” FID at 30 (citation omitted).

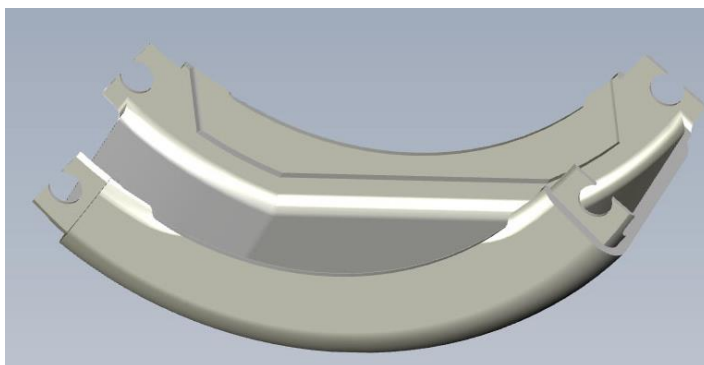
redesigned ring also has a bottom cap which is a single piece of titanium that snaps into the housing tube. Id. at 10.



Ruling Request at 8.



Ruling Request at 9.



Ruling Request at 10.

II. ISSUE

Whether Ultrahuman has met its burden to show that the articles at issue do not infringe claims 1, 2, and 12-14 of the '178 patent and thus are not subject to the LEO issued in the 1398 investigation.

III. LEGAL FRAMEWORK

A. Section 337 Exclusion Order Administration

The Commission shall investigate any alleged violation of Section 337 to determine, with respect to each investigation conducted by it under this section, whether there is a violation of this section. See 19 U.S.C. § 1337(b)(1) and (c). If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by

any person violating the provision of this section, be excluded from entry into the United States unless the Commission finds based on consideration of the public interest that such articles should not be excluded from entry. See 19 U.S.C. § 1337(d)(1).

When the Commission determines that there is a violation of Section 337, it generally issues one of two types of exclusion orders: (1) a limited exclusion order or (2) a general exclusion order. See Fuji Photo Film Co., Ltd. v. ITC, 474 F.3d 1281, 1286 (Fed. Cir. 2007). Both types of orders direct CBP to bar infringing products from entering the country. See Yingbin-Nature (Guangdong) Wood Indus. Co. v. ITC, 535 F.3d 1322, 1330 (Fed. Cir. 2008). “A limited exclusion order is ‘limited’ in that it only applies to the specific parties before the Commission in the investigation. In contrast, a general exclusion order bars the importation of infringing products by everyone, regardless of whether they were respondents in the Commission's investigation.” Id. A general exclusion order is appropriate only if two exceptional circumstances apply: if (1) “necessary to prevent circumvention of a limited exclusion order,” or (2) “there is a pattern of violation of this section and it is difficult to identify the source of infringing products.” See Kyocera Wireless Corp. v. ITC, 545 F.3d 1340, 1356 (Fed. Cir. 2008) (“If a complainant wishes to obtain an exclusion order operative against articles of non-respondents, it must seek a GEO [general exclusion order] by satisfying the heightened burdens of §§ 1337(d)(2)(A) and (B).”); 19 U.S.C. § 1337(d)(2).

In addition to the action taken above, the Commission may issue an order under 19 U.S.C. § 1337(i) directing CBP to seize and forfeit articles attempting entry in violation of an exclusion order if their owner, importer, or consignee previously had articles denied entry on the basis of that exclusion order and received notice that seizure and forfeiture would result from any future attempt to enter articles subject to the same. An exclusion order under § 1337(d)—either limited or general—and a seizure and forfeiture order under § 1337(i) apply at the border only and are operative against articles presented for customs examination or articles conditionally released from customs custody but still subject to a timely demand for redelivery. See 19 U.S.C. §§ 1337(d)(1) (“The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry.”); id. at (i)(3) (“Upon the attempted entry of *articles* subject to an order issued under this subsection, the Secretary of the Treasury shall immediately notify all ports of entry of the attempted importation and shall identify the persons notified under paragraph (1)(C).”) (emphasis added).

Significantly, unlike district court injunctions, the Commission can issue a general exclusion order that broadly prohibits entry of articles that violate Section 337 of the Tariff Act of 1930 without regard to whether the persons importing such articles were parties to, or were related to parties to, the investigation that led to issuance of the general exclusion order. See Vastfame Camera, Ltd. v. ITC, 386 F.3d 1108, 1114 (Fed. Cir. 2004). The Commission also has recognized that even limited exclusion orders have broader applicability beyond just the parties found to infringe during an investigation. See Certain GPS Devices and Products Containing Same, Inv. No. 337-TA-602, Comm’n Op. at 17, n.6, Doc ID 317981 (Jan. 2009) (“We do not view the Court’s opinion in Kyocera as affecting the issuance of LEOs [limited exclusion orders] that exclude infringing products made by respondents found to be violating Section 337, but imported by

another entity. The exclusionary language in this regard that is traditionally included in LEOs is consistent with 19 U.S.C. § 1337(a)(1)(B)-(D) and 19 U.S.C. § 1337(d)(1).”).

Moreover, “[t]he Commission has consistently issued exclusion orders *coextensive with the violation* of Section 337 found to exist.” See Certain Erasable Programmable Read Only Memories, Inv. No. 337-TA-276, Enforcement Proceeding, Comm’n Op. at 11, Doc ID 43536 (Aug. 1991) (emphasis added). “[W]hile individual models may be evaluated to determine importation and [violation], the Commission’s jurisdiction extends to all models of [violative] products that are imported at the time of the Commission’s determination and to all such products that will be imported during the life of the remedial orders.” See Certain Optical Disk Controller Chips and Chipsets, Inv. No. 337-TA-506, Comm’n Op. at 56-57, USITC Pub. 3935, Doc ID 287263 (July 2007).

Lastly, despite the well-established principle that “the burden of proving infringement generally rests upon the patentee [or plaintiff],” Medtronic, Inc. v. Mirowski Family Ventures, LLC, 571 U.S. 191 (2014), the Commission has held that Medtronic is not controlling precedent and does not overturn its longstanding practice of placing the burden of proof on the party who, in light of the issued exclusion order, is seeking to have an article entered for consumption. See Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof, Inv. No. 337-TA-879, Advisory Opinion at 6-11. In particular, the Commission has noted that the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) “has upheld a Commission remedy which effectively shifted the burden of proof on infringement issues to require a company seeking to import goods to prove that its product does *not* infringe, despite the fact that, in general, the burden of proof is on the patentee to prove, by a preponderance of the evidence, that a given article *does* infringe[.]” Certain Integrated Circuit Telecommunication Chips, Inv. No. 337-TA-337, Comm’n Op. at 21, n.14, USITC Pub. 2670, Doc ID 217024 (Aug. 1993) (emphasis in original) (citing Sealed Air Corp. v. ITC, 645 F.2d 976, 988-89 (C.C.P.A. 1981)).

This approach is supported by Federal Circuit precedent. See Hyundai Elecs. Indus. Co. v. ITC, 899 F.2d 1204, 1210 (Fed. Cir. 1990) (“Indeed, we have recognized, and Hyundai does not dispute, that in an appropriate case the Commission can impose a general exclusion order that binds parties and non-parties alike and *effectively shifts to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement*. The rationale underlying the issuance of general exclusion orders—placing the risk of unfairness associated with a prophylactic order upon potential importers rather than American manufacturers that, vis-a-vis at least some foreign manufacturers and importers, have demonstrated their entitlement to protection from unfair trade practices—applies here [in regard to a limited exclusion order] with increased force.”) (emphasis added) (internal citation omitted).

B. Patent Infringement

Determining patent infringement requires two steps. Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1316 (2015). The first is to construe the limitations of the asserted claims and the second is to compare the properly construed claims to the accused product. Id. To establish literal infringement, every limitation recited in a claim must be found in the accused product whereas, under the doctrine of equivalents, infringement occurs when there is

equivalence between the elements of the accused product and the claimed elements of the patented invention. Microsoft Corp. v. GeoTag, Inc., 817 F.3d 1305, 1313 (Fed. Cir. 2016). One way to establish equivalence is by showing, on an element-by-element basis, that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented invention, which is often referred to as the function-way-result test. See Intendis GmbH v. Glenmark Pharms., Inc., 822 F.3d 1355, 1361 (Fed. Cir. 2016).

As for the first step above, “claim construction is a matter of law.” SIMO Holdings, Inc. v. H.K. uCloudlink Network Tech., Ltd., 983 F.3d 1367, 1374 (Fed. Cir. 2021). Moreover, the ultimate construction of a claim limitation is a legal conclusion, as are interpretations of the patent’s intrinsic evidence (the patent claims, specifications, and prosecution history). UltimatePointer, L.L.C. v. Nintendo Co., 816 F.3d 816, 822 (Fed. Cir. 2016) (citing Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841, 190 L. Ed. 2d 719 (2015)).⁴ “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges.” Id. at 1314. In others, courts look to public sources such as “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” Id.

“To begin with, the context in which a term is used in the asserted claim can be highly instructive.” Phillips, 415 F.3d at 1314 (“To take a simple example, the claim in this case refers to ‘steel baffles,’ which strongly implies that the term ‘baffles’ does not inherently mean objects made of steel.”). The context in which a claim term is used also includes the full chain of dependence as well as the remaining suite of claims and the written description. See Inline Plastics Corp. v. EasyPak, LLC, 799 F.3d 1364, 1371 (Fed. Cir. 2015) (“Since the specification explicitly mentions the ‘alternative’ . . . there can be no debate concerning the application of the doctrine of claim differentiation.”).

The second step to establish infringement involves a comparison of the claims, as properly construed, to the accused product, which is a question of fact. Apple Inc. v. Samsung Elecs. Co., Ltd., 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc). We apply this two-step analysis below.

IV. ANALYSIS

Ultrahuman argues that the redesigned ring does not infringe independent claim 1 of the ‘178 patent for at least two reasons:

- (1) The redesigned ring is formed with a single, continuous, and integrally formed titanium Housing Tube and has no distinct internal and external housing component[s] that satisfy claim limitations [1.a] and [1.b]; and

⁴ Although claim construction is a question of law, the consideration of extrinsic evidence may constitute a subsidiary finding of fact. Teva, 135 S. Ct. at 841, 190 L. Ed. 2d at 733.

- (2) The battery in the redesigned ring is neither positioned within nor configured to fit within the claimed cavity because it is located entirely within the bore of the Housing Tube as opposed to being positioned within a cavity formed between the internal and external housing components and as such does not satisfy claim limitations [1.d] and [1.e].

Ruling Request at 3, 13.

In response, Oura argues that the redesigned ring is no more than a “concept outlined in a Computer-Aided Drawing (CAD)” as none of the prototypes were working samples nor assembled rings. Response at 1. Oura states this concerns them, because if the redesigned ring is not a final product ready for importation, Ultrahuman may release “variations of this unfinished design later.” Id. Nonetheless, Oura argues that even if the redesigned ring were not merely conceptual, Ultrahuman has failed to meet its burden to show that it does not infringe claims 1, 2, and 12-14 of the ’178 patent. Id. at 8.

We address these arguments in the context of the three main issues in dispute: (1) whether the redesigned ring practices independent claim 1; (2) whether the ruling requestor Ultrahuman has met their burden of proof in showing non-infringement; and (3) whether the redesigned ring is hypothetical such that a ruling should not issue.

These arguments are discussed separately, below.

1. Redesigned Ring and Claim 1 of the ‘178 Patent

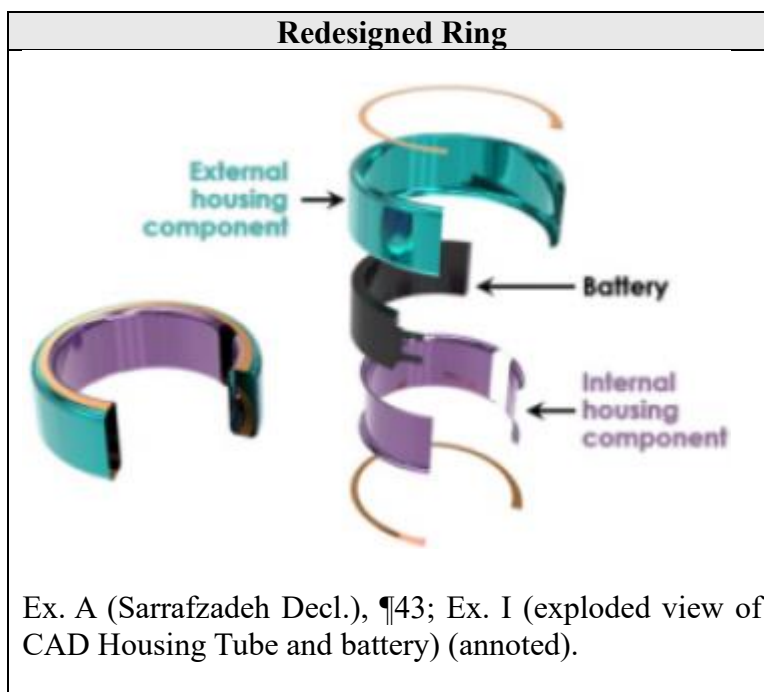
In its ruling request, Ultrahuman states that the original exterior titanium ring that was found to be the exterior housing component, and the user-contacting epoxy layer found to be the interior housing component, have been replaced with a housing tube. Ruling Request at 8. This housing tube is alleged to be a single, continuous, and integrally formed open-ended titanium tube. Id. Ultrahuman then states the epoxy layer that was found to define an inner circumferential surface has been removed. Id. at 10. Next, Ultrahuman claims that without an exterior and interior housing component, there no longer exists a single cavity which can hold the battery. Id. at 11.

By using a housing tube as opposed to an interior and exterior housing component, Ultrahuman argues that neither claim limitation 1.a nor 1.b can be practiced, nor can a cavity be formed for a battery to fit between as required by claim limitation 1.d or 1.e. Id. at 13. Ultrahuman cites to the FID in the underlying investigation to state that the internal housing component and external housing component must be distinct from each other. Id. at 14. Ultrahuman states that the battery in the redesigned ring is located in a space formed entirely by the housing tube and is not located within a cavity between the external and internal housing components as taught by the 1.d and 1.e limitations. Id. at 16.

In its Response, Oura does not address whether a housing tube as described by Ultrahuman’s Ruling Request would practice claim 1 of the ‘178 patent but instead addresses whether the redesigned ring is actually what it claims to be. Oura argues that a close inspection of

the physical samples provided by Ultrahuman reveals that the housing tube is composed of two housing components coupled together with traces of welding and polishing, rather than consisting of a single and continuous housing tube, as Ultrahuman alleges. Response at 15. Based on this observation, Oura argues that the redesigned ring is merely a copy of the design of the Oura Ring Gen. 4, which the ALJ found to be covered by the asserted claims of the '178 patent. Id. at 11. When framed in context of the ALJ's and Commissions' determinations concerning the housing components and epoxy, Oura argues, Ultrahuman has not met its burden of showing that the redesigned ring is non-infringing. Id.

In its Reply, Ultrahuman states that Oura has not contested that an integrally formed housing tube cannot be both the internal and external housing component. Reply at 4. Rather, Ultrahuman claims the arguments raised by Oura regarding infringement are predicated on ignoring, rejecting, misunderstanding, or even misrepresenting the design and structure of the housing tube as defined by the CAD files and designs specification files submitted at Attachments to the Request and as described by Ultrahuman's fact witnesses. Id. Addressing the argument that Ultrahuman is copying the design of the Oura Ring Gen. 4, Ultrahuman points out that the Oura Ring Gen. 4 is constructed of two separate metal structures, an inner and outer housing component combined by epoxy, and is not of a unibody, integrally formed housing tube, as in the redesigned ring. Id. at 5-6. This argument is not addressed by Oura in their remaining submissions nor touched upon during the oral discussion. Ultrahuman contends that Oura's Response ignores the design file and relies instead on doctored figures and conjecture. Id. at 6. Ultrahuman states that the doctored figure is the following:



Ultrahuman states that the above image is not the exploded view of the CAD file but has had coloring added that was not originally present and separates components that are not in fact separate components. Reply at 7. Ultrahuman claims that when the “exploded” view of their redesigned ring is selected the housing tube does not decompose into any sub-components but rather remains unitary and indivisible. Id. Ultrahuman then states that the photographs used by Oura to show “seams” or “physical damage” suggesting two separate components “welded together” is speculation, as Oura’s expert, Dr. Sarrafzadeh, never conducted an in-person inspection of the samples. Id. at 9. Ultrahuman next states that welding is not inconsistent with at least one method manufacturing a unibody housing tube – a rectangular strip, rolled together with one edge welded to the opposite edge. Id.

In its Sur-Reply, Oura acknowledges that the term “exploded view” is a term of art used to refer to an image where individual parts are separated from each other. Sur-Reply at 15. Oura presented the above image in its Response, Sur-Reply and at the oral discussion, falsely labeling it as an exploded view of the CAD provided by Ultrahuman. Response at 14, Sur-Reply at 15, Oura Presentation at 33. At the oral discussion, when asked about this image, Oura conceded that as opposed to an exploded view as labeled, this image was produced by separating faces of the proposed housing tube and coloring the faces accordingly.

At the oral discussion, Oura conceded that an integrally formed housing tube, such as the one proposed by Ultrahuman, would not practice all of the limitations of the ‘178 patent. Ultrahuman addresses this concession in its Post-Oral discussion brief. Ultrahuman Post Oral Discussion Submission at 1.

The EOE Branch concludes, as acknowledged by the Complainant, that an integrally formed housing tube does not practice all of the limitations from claim 1 of the ‘178 patent, such that a redesigned ring that incorporates such a tube does not infringe the asserted claims of the ‘178 patent and would not be subject to the LEO. See e.g., Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989) (“One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.”) (internal citation omitted).

2. Whether Ultrahuman has Met its Burden to Show Non-Infringement

In its substantive response, Oura states that Ultrahuman has failed to show that the redesigned ring actually includes the claimed housing tube that is a single, continuous, and integrally formed open-ended titanium tube. Response at 13. Oura points to the previously addressed falsely labeled “exploded view” image to show that the CAD file itself identifies multiple housing components that are to be coupled to form the overall housing structure. Id. at 14. Oura then points to various pictures of the samples provided that might indicate a seam which would imply multiple housing components that were coupled together. Id. at 16-18.

In its Reply, Ultrahuman states that the purported seam referenced by Oura is merely speculation provided by an expert who did not conduct an in-person inspection of the samples.

Reply at 9. Ultrahuman then states that welding is not inconsistent with at least one of the methods of manufacturing a unibody and integrally formed housing tube. Id.

In its Sur-Reply, Oura repeats that Ultrahuman has not provided sufficient evidence that the housing tube is a single, unitary component. Sur-Reply at 14. Oura states that Ultrahuman has not specified the manufacturing method to be used to create the housing tube. Id.

Throughout this proceeding Oura has misunderstood the burden borne by party previously found to infringe by the ITC. As established above, the burden is one of showing that the product being offered for entry does not infringe the patents at issue. This was noted by the Commission Federal Circuit “has upheld a Commission remedy which effectively shifted the burden of proof on infringement issues to require a company seeking to import goods to prove that its product does *not* infringe, despite the fact that, in general, the burden of proof is on the patentee to prove, by a preponderance of the evidence, that a given article *does* infringe[.]” Certain Integrated Circuit Telecommunication Chips, Inv. No. 337-TA-337, Comm’n Op. at 21, n.14, USITC Pub. 2670, Doc ID 217024 (Aug. 1993) (emphasis in original) (citing Sealed Air Corp. v. ITC, 645 F.2d 976, 988-89 (C.C.P.A. 1981)). As affirmed by the Federal Circuit in Hyundai Elecs. Indus. Co. v. ITC, 899 F.2d 1204, 1210 (Fed. Cir. 1990) (“Indeed, we have recognized, and Hyundai does not dispute, that in an appropriate case the Commission can impose a general exclusion order that binds parties and non-parties alike and *effectively shifts to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement.*”) Instead, the arguments made by Oura are directed to the manufacturing method used to make the redesigned ring. Oura did not cite any law, regulation, or administrative precedent supporting their position that Ultrahuman’s failure to specify a manufacturing method for the redesigned ring renders their burden of showing non-infringement unmet.

As stated above, Oura has conceded that the redesigned ring using an integrally formed housing tube does not practice the asserted claims of the ‘178 patent. Thus, Ultrahuman has met the burden as established by the ITC. If Ultrahuman later presents a redesigned ring that does not use an integrally formed tube, the holding of this ruling would not apply and Ultrahuman would not have met their burden.

3. Whether the Redesigned Ring is Hypothetical in Nature

In its ruling request, Ultrahuman states that the ruling it seeks is prospective and not hypothetical in nature. Ruling Request at 2. In support, Ultrahuman cites to the Computer-Aided Design (“CAD”) files submitted with the ruling request, as well as having fabricated prototypes made available for inspection during this inter partes proceeding. Id. In its response, Oura states that none of the samples that Ultrahuman made available for inspection were fully assembled rings, much less “working” prototypes. Response at 3. Oura points to the fact that what was provided for inspection was missing components needed for a final version of the redesigned ring, namely a battery, a printed circuit board (“PCB”), and even epoxy, in support of their position that redesigned ring is merely hypothetical. Id. Because none of the prototypes function, Oura claims that Ultrahuman cannot credibly claim that it will not modify the design to accommodate the placement of the battery, PCB, and other components such that the design is hypothetical in nature.

Id. at 5. Oura then points to differences in the CAD files compared to the proffered prototypes as further evidence that the redesigned ring is hypothetical in nature. Id. at 6.

Ultrahuman replied that the redesigned ring is clearly defined in the CAD files and specifications provided in the attachments to the Ruling Request. Reply at 2. Ultrahuman states that Oura cites no authority that CAD files are insufficiently fixed for a ruling to be issued. Id. Ultrahuman cites a previous ruling, CBP HQ Ruling H314355 (dated May 19, 2021), which found that a pictorial representation of the articles at issue was sufficient for the sake of the ruling, and states that the CAD files submitted in the present request are more precise than the photographs which were acceptable in H314355. Id. Ultrahuman then states that it did make available for inspection a fully assembled ring, but Oura's expert declined to inspect the samples in person. Id. at 3. Ultrahuman further argues that there is no requirement under Part 177 to provide a "functioning" or "working" prototype and Oura offers no authority for its contention. Id. Ultrahuman then cites to two previous rulings, CBP HQ Rulings H329187 (dated July 18, 2023) and H324813 (dated June 3, 2022), in which similar arguments to the ones being made by Oura were raised and rejected. Lastly, Ultrahuman states that arguments regarding differences between the samples themselves, or the provided CAD files, are irrelevant because they "do not in any way affect or alter the basic single-tube housing architecture" at the heart of the proposed redesign, and that the adjustments have nothing to do with the non-infringement analysis of the redesigned ring. Id. at 4.

In its Sur-Reply, Oura contests the assertion that a fully assembled prototype was made available for inspection. Sur-Reply at 5. Oura states that the prototypes present in the initial and subsequent inspection were lacking components, namely a PCB or a Bluetooth antenna. Id. Oura suggests that Ultrahuman should have provided CT scans of the functional redesigned ring, as were used by Oura's expert in the underlying ITC Investigation. Id. at 8. Oura then states, *ipse dixit*, that CAD files alone are insufficient to find that the redesigned ring is not hypothetical. Id. at 9.

At the oral discussion, Ultrahuman reiterated its argument that detailed pictorial representation are sufficient for a ruling to be issued and cited again to CBP HQ Ruling H314355. Ultrahuman Oral Discussion Presentation at 17. Ultrahuman then pointed out that the scope of a ruling is limited to the redesign presented, and that if any future product deviated from the single-tube housing design of the housing tube at the heart of the redesigned ring, the ruling would not cover that future product. Id. at 23. For its part in the oral discussion, Oura stated that the manufacturing method to be used to assemble the housing tube was not identified definitively by Ultrahuman. Oura Oral Discussion Presentation at 19-21.

In its post oral discussion submission, Ultrahuman cites various cases in support of its assertion that CAD drawings are sufficient to show that a design is not hypothetical. Ultrahuman post oral discussion submission at 2. Ultrahuman cites to Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc., where the Federal Circuit found that CAD drawings, and descriptions of the goods presented to a supplier were "more than enough to enable a person of ordinary skill in the art to practice the claimed invention." Id. at 3 citing Hamilton Beach, 726 F.3d 1370, 1378 (Fed. Cir. 2013). Ultrahuman then cited various ITC investigations in which CAD files were used in structural apparatus patent cases. Ultrahuman post oral discussion submission at 4. Ultrahuman

then turns to various District court cases which use CAD drawings as reliable technical evidence for structural apparatus claims. Id. at 5.

Oura, in its post-oral discussion submission, points to the various types of evidence used by the ALJ in the underlying investigation to establish infringement and argues that Ultrahuman has failed to provide four out of the five types of evidence throughout this inter partes proceeding. Oura post-oral discussion submission at 2.

Currently, there is no established test for CBP to determine whether a redesigned product is ripe for review, that is, sufficiently developed, to allow CBP to issue a ruling on whether the redesigned product is subject to exclusion. Prior EOE Branch rulings have analyzed whether a ruling request complies with the provisions of 19 C.F.R. Part 177, which included an analysis of whether the transaction is merely hypothetical in nature, e.g., CBP HQ Rulings H329187 (dated July 18, 2023), H324813 (dated June 3, 2022), and H314355 (dated May 19, 2021), but none of these ruling extensively discussed what renders a redesigned product sufficiently fixed in design to make it appropriate for adjudication. 19 C.F.R. Part 177(a).

We are persuaded by Ultrahuman's appeal to Hamilton Beach, SRAM, LLC v. Princeton Carbon Works Inc., (S.D. Fla. Aug. 20, 2025) and Wirtgen Am., Inc. v. Caterpillar, Inc., (D. Del. 2024) as well as ITC Investigations 337-TA-1331, 337-TA-1394, and 337-TA-1213, as support for their argument that CAD files are acceptable technical evidence for structural apparatus claims. As for fixedness, we look to the Commission's opinion in Certain Human Milk Oligosaccharides and Methods of Producing the Same for guidance, as it articulates a four-factor test for determining whether a redesigned product is ripe for adjudication. Inv. No. 337-TA-1120, Comm'n Op. at 18 (June 8, 2020) at 18. The four factors are: (1) whether the product is within the scope of the investigation; (2) whether it has been imported; (3) whether it is sufficiently fixed in design; and (4) whether it has been sufficiently disclosed by respondent during discovery. Id. Concerning Factor 3, we find two cases particularly informative for purposes of determining whether a redesigned product introduced in a 19 C.F.R. Part 177 ruling request is ripe for review. In Certain Mobile Devices with Multifunction Emulators, redesigns were found to be "sufficiently fixed in design" although the design did "not seem to be commercially feasible" and respondent had not completed "testing necessary to be released to the market." Inv. No. 337-TA-1170, Final Initial Determination at 10-16, EDIS Doc. ID 738549 (Mar. 16, 2021). The Administrative Law Judge relied on sample products and documentation that made it "clear what the final product will be." Id. at 13-14. Similarly, in Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof, redesigned products were found to be sufficiently fixed in design where respondents produced physical samples in discovery, although the documentation for the redesign products had not been updated and the products were not ready for mass production. Inv. 337-TA-1200, Final Initial Determination at 90-91, EDIS Doc. ID 747669 (July 9, 2021).

Based on the Federal Circuit, district court and ITC cases cited by Ultrahuman as well as the two Commission opinions discussed above, we conclude that Ultrahuman's CAD drawings and prototypes adequately show what the final redesigned ring will be, and thus, are sufficiently fixed in design and not merely hypothetical.

V. VERIFICATION

Whenever CBP issues a ruling letter finding that the redesigned article at issue does not fall within the scope of the Exclusion Order, imported articles are nevertheless “subject to the verification of the facts incorporated in the ruling letter, a comparison of the transaction described therein to the actual transaction, and the satisfaction of any conditions on which the ruling was based.” See 19 C.F.R. § 177.9(b)(1) (“The application of a ruling letter by a Customs Service field office to the transaction to which it is purported to relate is subject to the verification of the facts incorporated in the ruling letter, a comparison of the transaction described therein to the actual transaction, and the satisfaction of any conditions on which the ruling was based.”). Thus, while framed as alleging the articles at issue are “hypothetical”, see e.g., Oura Post Oral Discussion Brief at 2 to 6, we find that Oura’s arguments really concern how CBP can verify that the facts incorporated in a ruling letter, and the conditions on which a ruling are based, are consistent with an imported product, i.e., whether Ultrahuman’s redesigned ring will indeed include a housing tube that is a single, continuous, and integrally formed open-ended titanium tube.

Thus, in accordance with paragraph 4 of the 1398 LEO, CBP will require certification, as approved by CBP, from persons importing the articles at issue. CBP will require these persons to furnish, upon request, such records or analyses necessary to substantiate the certification. This may include the type of evidence identified by Oura, such as CT scans for an imported article to show whether the housing is composed of one component, manufacturing and assembly documents, product illustrations, or videos to confirm whether the housing tube is a unitary structure, and any other evidence CBP deems relevant.

Accordingly, entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption of the articles at issue, will be conditioned upon a certification containing the provisions discussed above and the approval of records or analyses CBP deems necessary to substantiate the certification.

VI. HOLDING

We find that Ultrahuman has met its burden to establish that the articles at issue do not infringe the asserted claims of the ’178 patent. However, as noted, CBP will require certification, as approved by CBP, from persons importing the articles at issue as well as any records or analyses necessary to substantiate the certification that it requests.

The parties were asked to clearly identify confidential information, including information subject to the administrative protective order in the underlying investigation, with [[red brackets]] in all of their submissions to CBP. See 19 C.F.R. §§ 177.2, 177.8. If there is additional information in this ruling letter not currently bracketed in red [[]] that either party believes constitutes confidential information, and should be redacted from the published ruling, then the parties are asked to contact CBP within ten (10) working days of the date of this ruling letter. See, e.g., 19 C.F.R. § 177.8(a)(3).

The decision above is limited to the specific facts set forth herein. If articles differ in any material way from the articles at issue described above, or if future importations vary from the facts stipulated to herein, this decision shall not be binding on CBP as provided for in 19 C.F.R. §§ 177.2(b)(1), (2), (4), and 177.9(b)(1) and (2).

Sincerely,

Alaina Van Horn
Chief, Intellectual Property Enforcement Branch /
Exclusion Order Enforcement Branch

CC: Mr. Bryan Nese
Mayer Brown LLP
1999 K Street, N.W.
Washington, DC 20006
bnese@mayerbrown.com