

No. 2013-1582

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

LELO INC. & LELOI AB,

Appellants,

– v. –

INTERNATIONAL TRADE COMMISSION,

Appellee,

and

STANDARD INNOVATION (US) CORP. &
STANDARD INNOVATION CORPORATION,

Intervenors.

Appeal from the United States International Trade Commission,
Investigation No. 337-TA-823

**NON-CONFIDENTIAL BRIEF FOR INTERVENORS
STANDARD INNOVATION (US) CORP. &
STANDARD INNOVATION CORPORATION**

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Robert P. Lord, counsel for Intervenor Standard Innovation (US) Corp. & Standard Innovation Corporation, certifies the following:

1. The full name of the parties represented by me are:

Standard Innovation (US) Corp. & Standard Innovation Corporation.

2. The name of the real party-in-interest (if the party named in the caption is not the real party-in-interest) represented by me is:

Not applicable.

3. All parent corporations or any publicly held corporations that own 10% or more of the stock of Intervenor Inc.:

Standard Innovation (US) Corp. is a wholly-owned subsidiary of Standard Innovation Corporation. Standard Innovation Corporation is a privately-held company; no publicly held corporation owns 10% or more of Standard Innovation Corporation stock.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in this proceeding are:

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May 12, 2014

/s/ Robert P. Lord
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On pages 13 through 43, confidential information has been redacted pursuant to the protective order issued by the International Trade Commission. This confidential business information relates to materials, suppliers, and pricing of components used to manufacture We-Vibe devices, as well as sales figures of We-Vibe products and other expenditures of Standard Innovation.

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STATEMENT OF RELATED CASES

No appeal from this ITC proceeding was previously before this Court or any other appellate court. This case may affect a matter pending in the United States District Court for the Southern District of Texas, *Standard Innovation Corp. v. LELOi AB et al.*, No. 4:11-cv-4172. Likewise, the asserted patent claims in this proceeding are currently subject to an *ex parte* reexamination in No. 90/013,035.

ISSUES TO BE DECIDED

1. Whether the International Trade Commission (the “Commission” or “ITC”) properly exercised its discretion in concluding that the domestic industry aspect of 19 U.S.C. § 1337(a)(3) is satisfied given the facts of this case.

2. Whether the Commission properly construed the disputed claim terms—to the extent the construction of those terms has not been mooted by appellants’ abandonment of their anticipation and obviousness arguments.

3. Whether substantial evidence supports the Commission’s conclusion that appellants’ devices infringed the asserted claims of the ’605 Patent.

4. Whether substantial evidence supports the Commission’s conclusion that the asserted claims of the ’605 Patent are not invalid.

STATEMENT OF THE CASE

A. The ’605 Patent: Standard Innovation’s Creation Of The First “Couples” Vibrator.

In 2008, intervenor Standard Innovation, a small start-up company, launched a groundbreaking “couples” product in the United States that forever changed the kinesiotherapy device market. This product—the We-Vibe—was the world’s first vibrator designed to be worn by a female *dur-*

ing intercourse. It has been described by professionals in the industry as a “game changer,” “unique,” and “revolutionary;” indeed, Standard Innovation created a wholly new product the world had never before seen. A14953; A2227.

The We-Vibe has “had a profound effect” on users “in terms of improving their lives.” A2180:102. It has “promoted the concept of enhancing intimacy between couples in a way that did not previously exist.” A14953.

The We-Vibe provides simultaneous stimulation to the vagina near the G-spot and to the clitoris, while also permitting the female wearer to engage in intercourse. Add.169.¹ This is accomplished by a device that is U-shaped, with an inner arm designed to be inserted into the vagina, the outer arm sized to contact the clitoris, and the whole device dimensioned to be used during intercourse. *Id.*

As the Commission found, Standard Innovation “has created a new niche market for couples vibrators through its product innovations.” Add.201. The commercial reception of the products has been enormous; “sales have increased dramatically since the We-Vibe’s launch.” *Id.*

¹ Appellants have included the decisions below and the ’605 Patent in both the addendum to their opening brief, as well as in the appendix. We cite to the addendum as “Add.” and the appendix as “A.”

Standard Innovation's valuable intellectual property is protected by U.S. Patent No. 7,931,605 (the "605 Patent"). Add.169. As its summary explains, the patent "seeks to overcome the shortcomings of the prior art by providing ... vibratory stimulation simultaneously to the clitoris, G-spot and vagina" and to do so in a device that, "unlike the devices of the prior art," "can be comfortably worn during intercourse." Add.220. Independent claim 1 is representative of the claims at issue:

A sexual stimulation device dimensioned to be worn by a female during intercourse comprising;

- a.) an elongate inner arm dimensioned for placement inside a vagina;
- b.) an elongate outer arm dimensioned for placement against a clitoral area;
- c.) a connecting portion connecting said inner and outer arms;

wherein, the elongate inner arm and the elongate outer arm are enlarged relative to the connecting portion and each of said arms taper down toward said connecting portion; and

wherein, at least one of the inner and outer arms are generally tear-drop shaped.

Add.224.

The We-Vibe, the We-Vibe II, and the We-Vibe 3, manufactured by Standard Innovation, are each commercial embodiments of claims of the '605 Patent.

We-Vibe



We-Vibe II



We-Vibe 3



A1625.

In producing the We-Vibe products, as we will detail at length below, Standard Innovation has chosen to source high-value components and materials from domestic U.S. manufacturers.

B. The Infringing Products.

Following Standard Innovation's introduction of the We-Vibe and its tremendous commercial success, imitators flocked to copy the product. Relevant here, appellants introduced two nearly identical products into the U.S. market: the Tiani and the Tiani 2. Add.170.

The Tiani



A15385.

The Tiani 2



A15386.

C. Proceedings Below.

Following the introduction of copycat products into the U.S. market, Standard Innovation instituted this Section 337 proceeding.

ALJ Pender construed the disputed claim terms, found that the products plainly infringed the asserted claims of the '605 Patent, and held the asserted patent claims valid. Add.1-85. The ALJ, however, concluded that Standard Innovation had not satisfied the economic prong of the domestic industry requirement. *Id.*

The ITC affirmed the ALJ's findings with respect to claim construction, infringement, and patent validity in relevant part. Add.166-208. (The Commission reversed the finding of infringement with respect to appellants' PicoBong Mahana product, a holding that Standard Innovation does not challenge.) The Commission reversed the ALJ's conclusion with respect to domestic industry; it held that the significance of domestically-produced components to the We-Vibe satisfied the economic prong of that requirement. *Id.* The Commission subsequently entered a general exclusion order.

SUMMARY OF THE ARGUMENT

I. The Commission was well within its broad discretion in finding the domestic industry requirement satisfied. Following its long-standing

precedent, the Commission concluded that (1) U.S. expenditures by a complainant’s subcontractors may satisfy the domestic industry requirement and (2) Standard Innovation’s use of domestically-produced components crucial to a patented product fabricated abroad may satisfy the domestic industry requirement. Significantly, appellants do not challenge this legal framework.

Indeed, these holdings are critical to effectuate the very purpose of Section 337—to promote investment in the most valuable components and materials manufactured in the United States. As the Commission has noted, the realities of the marketplace often dictate that end-products are assembled abroad; the Commission’s interpretation of the statute is necessary to encourage domestic industries to source high-value components from the United States. The Commission’s construction of the statute—which is further necessary to ensure that the Section 337 remedy remains open to small start-up businesses—is well within its discretion.

Against this backdrop, appellants merely dispute the ITC’s application of fact to law. Here, the Commission found that the domestic production of four components that are critical to production of the We-Vibe—including one component that is indisputably the “secret sauce” of the device—was sufficient to show a domestic industry. Appellants contend that

these components are not sufficiently significant, but the Commission's finding, which turned on the intersection of qualitative and quantitative factors, is supported by substantial evidence.

Appellants alternatively argue that Standard Innovation failed to produce direct evidence that details precisely the expenditures in the statutory categories. But the Commission correctly rejected this interpretation of Section 337; indirect evidence may be used to prove the existence of a domestic industry.

II. The Commission properly construed the disputed claim terms. Appellants contest at length (1) whether the preamble is a claim limitation and (2) whether “intercourse” means “coitus.” But these disputes are now largely moot: below, these arguments were part of appellants’ anticipation and obviousness contentions. Appellants, however, have now abandoned their anticipation and obviousness challenges to the ’605 Patent.

In any event, the construction below was correct. The preamble—which claims a device “dimensioned to be worn by a female during intercourse”—is a limitation, in part, because it places a physical limitation on the structure of the device. Separately, the specification, the prosecution history, and the plain meaning of the term all confirm that “intercourse,” as used here, means “coitus.”

Appellants additionally contend that the term “generally tear-drop shaped” should have been construed below. But appellants’ argument—which now focuses on the word “generally”—is wholly new and is thus waived. It is also incorrect, as these terms have plain meaning and do not require construction.

Finally, appellants are wrong to argue that the patentee disclaimed either bulbous or hook shapes. A showing of prosecution disclaimer requires a particularly substantial showing; here, however, the prosecution record makes plain that the applicant distinguished the prior art on other grounds.

III. The Commission’s finding of infringement is supported by substantial evidence. Although appellants claim that their devices are either bulbous or hook shaped, the patentee has not disclaimed such structures. Separately, there is substantial evidence to conclude that the accused devices do in fact use “generally tear-drop shaped” arms.

IV. The Commission properly rejected appellants’ indefiniteness arguments. Appellants argue that the term “generally tear-drop shaped” is indefinite because it contains a term of degree—the word “generally.” But as this Court has previously held, degree terms, including the word “generally,” do not typically render a claim indefinite. Here, because the speci-

fication provides significant context for the claim terms, appellants' indefiniteness contention fails.

Likewise, the term "dimensioned to be worn by a female during intercourse" is sufficiently definite as it directs one skilled in the art how to size a device so that it may be used during intercourse. The fact that the vast majority of male and female parts are within a narrow range of sizes demonstrates that the term is sufficiently definite.

STANDARD OF REVIEW

Because review of the ITC's decision in a Section 337 proceeding is subject to the Administrative Procedure Act (*see* 19 U.S.C. § 1337(c)), the Court reviews the ITC's factual findings for substantial evidence, it defers to the ITC's construction of Section 337, and it reviews other questions of law *de novo*.

The ITC's factual findings are reviewed for substantial evidence. *Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1348 (Fed. Cir. 2013). In this context, "[s]ubstantial evidence is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1302 (Fed. Cir. 2010). This standard is demanding: substantial evidence review is akin to a court's review of a jury's factual findings; the inquiry is "whether on this

record it would have been possible for a reasonable jury to reach the [agency's] conclusion.” *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 366-67 (1998). For these reasons, “[t]he court should not supplant the agency’s findings merely by identifying alternative findings that could be supported by substantial evidence.” *Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992).

Because Congress has entrusted the ITC to administer Section 337, its construction of the statute is subject to deferential review pursuant to *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). That is, “[a]s the agency charged with the administration of [Section] 1337, the Commission is entitled to appropriate deference to its interpretation of the statute.” *VastFame Camera, Ltd. v. Int’l Trade Comm’n*, 386 F.3d 1108, 1111 (Fed. Cir. 2004).

If a statutory provision is unambiguous, it must be interpreted according to its terms; if a statute has some ambiguity, however, the ITC has discretion in construing it. *Suprema, Inc. v. Int’l Trade Comm’n*, 742 F.3d 1350, 1358 (Fed. Cir. 2013). In the face of ambiguity, the ITC’s construction may be set aside only if it is “arbitrary, capricious, or manifestly contrary to the statute.” *Chevron*, 467 U.S. at 844; *see also Nucor Corp. v. United States*, 601 F.3d 1291, 1295 (Fed. Cir. 2010).

Ultimately, pursuant to the APA, findings of the Commission may be overturned only if they are “arbitrary or capricious.” *Norgren Inc. v. Int’l Trade Comm’n*, 699 F.3d 1317, 1328 (Fed. Cir. 2012).²

ARGUMENT

I. The ITC Properly Concluded That The Domestic Industry Requirement Is Satisfied.

A patent-based Section 337 action requires the existence of a domestic industry that relates to the patented article. The domestic industry analysis has two prongs. The technical prong, 19 U.S.C. § 1337(a)(2), turns on a showing similar to infringement. *See Crocs*, 598 F.3d at 1306. Appellants do not contest that the technical prong has been satisfied, *i.e.*, that the We-Vibe practices the claims of the ’605 Patent.

The economic prong, 19 U.S.C. § 1337(a)(3), requires a showing that there is, “with respect to the articles protected by the patent,” a “(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including

² Although the Court considers claim construction a question of law subject to *de novo* review, we respectfully submit that this is a question of fact—or a mixed question of fact and law—subject to deferential review. The Supreme Court recently granted certiorari to address this issue. *See Teva Pharm. USA, Inc. v. Sandoz Inc.*, 124 S. Ct. 1761 (2014). For the same reason, we submit that indefiniteness is also subject to deferential review as it is “a subset of claim construction.” *In re Packard*, 2014 WL 1775996, at *2 (Fed. Cir. 2014).

engineering, research and development, or licensing.” *Motorola Mobility*, 737 F.3d at 1351. “Because these three criteria are listed in the disjunctive, a complainant need only establish one factor in order to satisfy the economic prong of the domestic industry requirement.” *Certain Printing and Imaging Devices*, Inv. No. 337-TA-690, 2011 WL 1303160, at *14 (ITC 2011).

The Omnibus Trade and Competitiveness Act of 1988 (Pub. L. No. 100-418, § 1342, 102 Stat. 1107, 1213) “liberalized the domestic industry requirement [of Section 337] by allowing that requirement to be satisfied by proof of non-manufacturing activity, such as licensing and research.” *John Mezzalingua Assocs., Inc. v. Int’l Trade Comm’n*, 660 F.3d 1322, 1327 (Fed. Cir. 2011). In so amending the statute, “Congress contemplated that the domestic industry requirement could be satisfied by foreign production under the patent at issue if coupled with activities and investments in the United States.” *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, 1996 WL 1056309, at *64 (ITC 1996).

In light of the purpose of Section 337 and its broad statutory language, the ITC has long held (1) that U.S. expenditures by a complainant’s subcontractors may satisfy the domestic industry requirement (*see, e.g., Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, 2008 WL

2952724, at *24 (ITC 2007)) and (2) that use of domestically-produced components crucial to a patented product fabricated abroad may satisfy the domestic industry requirement (*see, e.g., Certain Cold Cathode Fluorescent Lamp (“CCFL”) Inverter Circuits*, Inv. No. 337-TA-666, 2009 WL 3328064 (unreviewed ID 2009)). Here, the ITC applied these principles to conclude that “a complainant’s investments in U.S. components promote manufacturing in the United States by the subcontractor as if the complainant was itself producing the components.” Add.192.

In contending that the ITC erred in its domestic industry analysis, appellants do not challenge *any* of these points. Nor do appellants contend that the ITC misapplied any precedent of *this* Court. Instead, appellants argue that the ITC erred in its construction of the record and that it misapplied its *own* precedent.

Not only are appellants’ contentions wrong, but they also fail to satisfy the demanding burden imposed by the standard of review: they cannot demonstrate that the Commission’s decision was *unreasonable*. *Crocs*, 598 F.3d at 1302. The ITC’s authority is at its zenith when interpreting and applying the domestic industry requirement, which is a unique creature of Section 337 that Congress specifically entrusted to the Commission. *See InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 690 F.3d 1318, 1330

(Fed. Cir. 2012). Likewise, in applying the domestic industry requirement to the facts of an individual case, the Commission's authority is substantial; these determinations are "intimately wed to the particular facts of each case," which "is precisely the type of question which Congress has committed to the expertise of the Commission." *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1486 (Fed. Cir. 1986).

A. Substantial evidence supports the ITC's conclusion that prongs A and B of the "economic" domestic industry requirement are satisfied.

The ITC properly concluded that the "economic" prong of the domestic industry requirement, 19 U.S.C. § 1337(a)(3), is satisfied. The Commission evaluated "four crucial components that are manufactured in the United States and used in the production of the We-Vibe." Add.187. It further found that Standard Innovation's "investments in components critical to the We-Vibe" "can reasonably be considered evidence of a relevant investment" in "plant and equipment under prong A and labor and capital under prong B." Add.194-195. Both "the importance of the components to the We-Vibe and the importance of the We-Vibe to Standard Innovation weigh heavily in favor of finding a domestic industry." Add.201. The four relevant components are [REDACTED] specific microcontrollers, and certain pigments.

[REDACTED], the Commission explained, is the “secret sauce” of the We-Vibe “because it is so critical to the We-Vibe functionality.” Add.200. [REDACTED], manufactured in [REDACTED]. A2224:178; A14908. Standard Innovation chose [REDACTED] after significant investigation; [REDACTED].” Add.200. This component, the evidence showed, was thus crucial to the success of the patented products. *Id.* Standard Innovation spent \$[REDACTED] on [REDACTED] in the relevant period. Add.187; A14908-14; A15265-66; A15315; A13887.

[REDACTED] “is another critical component for the We-Vibe.” Add.200. This component is necessary because [REDACTED].” *Id.* After “Standard Innovation spent months ... trying to resolve these manufacturing issues,” it “determined that the best resolution was to [REDACTED] while leaving an even finish.” *Id.* Testimony before the ALJ indicated that the We-Vibe products could not be manufactured without using [REDACTED]: asked whether “you [could] make the We-Vibe

without the [REDACTED],” Anne Finlayson (Standard Innovation’s VP of Operations, A2221) replied “No.” A2225:180. Standard Innovation spent \$[REDACTED] on [REDACTED], which is manufactured in [REDACTED]. Add.187; A2225:180; A13975; A14832-39; A15268; A15315; A13890; A13896; A13902; A13926.

The “microcontroller products from [REDACTED] are also crucial components” as “they enable the We-Vibe to function as a vibrator.” Add.200-201; *see also* Add.76-77; Add.192; A14893-94. In particular, the microcontroller permits the devices to have “multiple vibration modes,” and it does so “by controlling the vibrator motor and mode selection.” Add.201. [REDACTED] is headquartered in [REDACTED] and manufactures wafers in [REDACTED]. A2225:181. The ITC credited \$[REDACTED] of these parts to the domestic industry. Add.188; A14891-94; A6989-7011.³

Finally, pigments purchased by Standard Innovation were necessary “in order for the We-Vibe to be commercially marketable,” as the pigments

³ Appellants quibble that there was no precise evidence as to the allocation of the value of the microcontrollers as manufactured in the United States compared against dicing, packaging, and testing that occurred in [REDACTED]. Lelo Br. 26. Standard Innovation’s evidence explained that approximately 85 to 90 percent of the cost was attributable to domestic production. *See* A196; A2225:181. The ITC’s use of an 80% cost ratio (Add.188) is thus supported by substantial evidence.

were specialized so as to “[REDACTED].” Add.193. The ITC therefore found “that Standard Innovation’s expenditures on pigments were relevant to demonstration of a domestic industry in articles protected by the patent.” *Id.* Standard Innovation purchased the pigments from [REDACTED]. A2225:182. A total of \$[REDACTED] was spent on pigments. Add.199 n.13; A14898-A14899; A6987-A6988; A14036.⁴

Evaluating these components together, the ITC concluded that Standard Innovation’s expenditures were sufficient to “show[] a significant investment in domestically produced components.” Add.201. The amount spent on these products was “significant in the context of a small start-up company developing a new market for couples vibrators.” *Id.*

Although these components are manufactured by subcontractors, rather than Standard Innovation itself, the ITC, citing a string of unbroken precedent, concluded that “a complainant’s investments in U.S. subcontracted components and services can be relied upon to establish the economic prong of the domestic industry requirement.” Add.191-192. Appellants did not dispute this conclusion below, and they do not dispute it

⁴ The ITC concluded that, unlike the other three components, the pigments were not directly related to a claimed feature of the ’605 patent, so the ITC accorded these purchases “reduced weight.” Add.193. It nonetheless found these expenditures “relevant to demonstration of a domestic industry in articles protected by the patent.” *Id.*

here; any contrary contention is, accordingly, waived. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006).

Appellants instead proffer two basic arguments: 1) that expenditures relating to the domestically-sourced components at issue in this case are not “significant,” and 2) that the ITC did not adequately find a connection between those components and the domestic industry statutory categories. The first argument is simply a disagreement with the ITC’s application of fact to established and undisputed law; substantial evidence, however, supports the ITC’s conclusion. The second argument turns on appellants’ implicit contention that indirect evidence cannot be used to show a domestic industry, an argument flatly inconsistent with fundamental principles of law.

1. Substantial evidence supports the ITC’s conclusion that expenditures for the domestically-sourced components are “significant.”

The ITC concluded that the expenditures on U.S.-manufactured components, evaluated “in the context of the industry and the company,” were sufficiently “significant” to satisfy the domestic industry requirement under prongs A and B. Add.199-201. The Commission considered *both* qualitative *and* quantitative value added by the domestically-sourced components.

Pointing to its own long-standing precedent, the ITC explained that “there is no threshold test for what is considered ‘significant’ within the meaning” of Section 337’s domestic industry requirement. Add.198. That is, “[t]he Commission’s determination on the economic prong is not made according to any rigid formula—there is no mathematical threshold test.” *Male Prophylactic Devices*, 2008 WL 2952724, at *24. Instead, this “determination is made by ‘an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace.’” Add.198 (quoting *Male Prophylactic Devices*, 2008 WL 2952724, at *24). This analysis “gives weight” to both “qualitative considerations in assessing significance,” as well as a quantitative analysis. Add.199.

“[F]rom a qualitative standpoint,” “[t]he contribution of the components at issue ... is indeed significant under the facts in this investigation, considering the article of commerce, and the realities of the marketplace.” Add.200. This is because the “domestically-sourced components ... are crucial to the functionality of the We-Vibe.” *Id.* With its patented products that use domestically-sourced components, Standard Innovation “has created a new niche market for couples vibrators through its product innovations.” Add.201.

The quantitative analysis bolstered this conclusion. In assessing quantitative significance, “whether the complainant’s investment and/or employment activities are ‘significant’ is not measured in the abstract or in an absolute sense, but rather is assessed with respect to the nature of the activities and how they are ‘significant’ to the articles protected by the intellectual property right.” *Certain Printing and Imaging Devices*, 2011 WL 1303160, at *15. Applying that framework, the ITC focused on the fact that “[redacted] percent of components for the We-Vibe are sourced domestically and these components account for [redacted] percent of the total cost of production.” Add.199. In “the reality of today’s marketplace,” the ITC found that “Standard Innovation’s expenditures of over \$[redacted] on components directly related to the ’605 patent and critical to the We-Vibe ... are significant in the context of a small start-up company developing a new market for couples vibrators.” Add.201.

The combination of qualitative and quantitative value, the ITC ultimately concluded, “show[ed] a significant investment in domestically produced components.” Add.201. Appellants’ hodgepodge of contrary arguments fails to demonstrate that the ITC’s conclusion was unreasonable.

a. The Commission properly considered all domestic component purchases.

Appellants assert that Standard Innovation’s purchase of domestically-sourced products should be discounted to reflect the portion of product ultimately sold in the United States. Lelo Br. 22-23. This argument fails on several levels.

To begin with, appellants never made this argument below. They did not assert the argument in the briefing to the Commission itself (A1683-1752; A2035-61), nor did appellants press this argument to the ALJ (A1364-449). Because this argument was not raised, the ITC did not address it.

This Court “will not consider” on appeal an argument that appellants “waived the right to pursue ... while at the Commission.” *Texas Instruments Inc. v. Int’l Trade Comm’n*, 988 F.2d 1165, 1176 (Fed. Cir. 1993); *see also Broadcom Corp. v. Int’l Trade Comm’n*, 542 F.3d 894, 901 (Fed. Cir. 2008). Indeed, “[t]he waiver rule serves particularly important purposes in the administrative review context” because it “accords respect to the agency decision making process by providing the agency with the ‘opportunity to address a party’s objections, ... apply its expertise, exercise its informed discretion, and create a more finely tuned record for judicial re-

view.” *Upper Blackstone Water Pollution Abatement Dist. v. EPA*, 690 F.3d 9, 30 (1st Cir. 2012).

The waiver must be enforced here for two reasons. First, appellants’ argument would be a novel construction of Section 337, but it is the ITC’s obligation to interpret that statute in the first instance. Second, if appellants’ contention were correct, that would merely alter the factual background against which the ITC would apply its discretion.

In any event, the argument is wrong. In considering whether Standard Innovation’s patented products have contributed to a domestic industry, there is no basis to divide domestic expenditures between products that are ultimately sold inside and outside the United States. The statute simply provides that there must be “an industry in the United States ... with respect to the articles protected by the patent.” 19 U.S.C. § 1337(a)(3). Appellants do not dispute that the component purchases at issue qualify for these purposes. Thus, given that the U.S.-based component purchases are, as a category, undeniably relevant, it is proper to consider the *total* volume of purchases of these components used in articles protected by the ’605 Patent, regardless of where those articles are sold.

Indeed, recent decisions of this Court and the ITC establish that the requirement of having “articles” protected by the patent under Section 337

is satisfied even if the articles are manufactured outside of the United States. See *Microsoft Corp. v. Int’l Trade Comm’n*, 731 F.3d 1354, 1362 (Fed. Cir. 2013) (the domestic industry requirements must be satisfied with respect “to an actual article that practices the patent, regardless of whether or not that article is manufactured domestically or abroad”); *Certain Computers and Computer Peripheral Devices, and Components Thereof, and Products Containing Same*, Inv. No. 337-TA-841, at *34 (ITC 2014) (“the existence of an article practicing the patent is required, but that article need not be made in the United States”). It follows that the articles can also be sold outside of the United States, as long as the relevant investments and activities that are included in the domestic industry analysis take place in the United States.

Appellants’ construction of the statute would turn the domestic industry analysis on its head: this statutory element is designed to protect U.S.-based *production*, not U.S.-based *sales*. Appellants’ proposal, however, would set aside wholesale segments of domestic production simply because the end products wind up outside the country. There is no compelling reason to interpret the statute in a manner at odds with its fundamental purpose.

Moreover, even if the domestic component purchases were discounted, the ITC's rationale would be unaffected. Appellants' argument has no relevance for the ITC's qualitative analysis whatsoever. *See, supra*, 21. And appellants' argument has no relevance to the quantitative analysis, either. The Commission's quantitative analysis focused primarily on the amount of domestically-produced components *per-unit*; it concluded that [] percent of the value of *each* device is domestic content. Add.199. That number remains fixed regardless of whether the ITC were to examine domestic or worldwide sales.

Appellants' last contention—that the Court should compare the cost of components used for *domestically*-sold devices to *worldwide* sales (Lelo Br. 23)—is nothing but sleight-of-hand. If component purchases for domestically-sold devices is the relevant factor (which it is not), that would have to be compared against *domestic* sales.⁵

⁵ Appellants also argue that Standard Innovation's U.S. sales were "*at most*" []% of worldwide sales. Lelo Br. 22. Substantial evidence in the record, however, demonstrates the precise percentage of each product that is actually sold in the United States. *See* A14884; A15315. Thus, to the extent that this would be a relevant consideration, there was abundant evidence in the record to render a finding. A15251; A15315; A13887; A13890; A13896, A13902; A13926; A13992-A14003; A14832-39; A14903-14. Appellants are thus flatly wrong to contend that "the exact amount cannot be determined." Lelo Br. 23.

b. The domestic components are quantitatively significant.

Separately, appellants argue that the purchase of domestic components was quantitatively insufficient. Lelo Br. 33-35. Appellants do not, however, challenge the ITC's construction of the statute—*i.e.*, its finding that there is no “threshold test for what is considered ‘significant’ within the meaning of the statute.” *Id.* at 33 (quoting Add.198). Nor do appellants challenge the Commission's holding that a qualitative analysis is an integral aspect of evaluating whether domestically-sourced components are sufficiently “significant.” Add.199. Thus, appellants have no disagreement with the ITC's guiding principles; they only quarrel with how the Commission applied the facts of this case to well-established law.

Appellants cannot demonstrate that the ITC's decision is unreasonable. Although appellants again attempt to compare the cost of domestically-manufactured components to worldwide sales (Lelo Br. 34), the Commission focused on the *per-unit* make-up of each product. *See, supra*, 26.

Appellants' argument that the Commission misapplied its *own* decisions is not well-founded. Lelo Br. 34-35. Appellants rely heavily on the decision of a single administrative law judge (*not* the Commission), *Certain Feathered Coats and Pelts, and Process for the Manufacture Thereof*, Inv. No. 337-TA-260, 0088 WL 1572173 (ID 1988). *See* Lelo Br. 34-35.

While appellants cited that same decision below (*see* A2047), the Commission did not find it persuasive. Indeed, *Certain Feathered Coats* was decided *before* the Omnibus Trade and Competitiveness Act of 1988 “liberalized the domestic industry requirement.” *John Mezzalingua Assocs.*, 660 F.3d at 1327.

Additionally, appellants overlook that the analysis in this case turned on a combination of qualitative *and* quantitative factors. The ITC “recognize[d] that [■] percent is a relatively modest proportion of domestic content *viewed in isolation*.” Add.199 (emphasis added). But looking only at the quantitative factors, the Commission explained, would be error because the statute does not define “significant” “in purely mathematical terms.” *Id.* In *Feathered Coats*, there was no evidence or contention that the domestic value add was *qualitatively* critical to the protected products. That decision, accordingly, says nothing at all about the circumstances here, where the domestic components (including one that is the “secret sauce”) are “crucial” to the commercial success of the products. Add.200.

Male Prophylactic Devices, which also underscores that “there is no mathematical test,” *supports* Standard Innovation. 2008 WL 2952724, at *24. There, the domestic industry requirement was found satisfied, in substantial part, because the U.S. value add to the product was *necessary* for

its successful operation. *Id.* at *25. Absent that addition, “the bulk con-
doms [were] not useable or saleable.” *Id.* The same is true here: the value
added by the domestically-sourced components is essential to the success
of the products. *See, supra*, 16-19.

The ITC’s approach below closely follows its consistent decisions
finding that qualitative value added may play an essential role in estab-
lishing that domestically-sourced components are sufficiently “significant”
to satisfy the domestic industry requirement. *See, e.g., Certain Semicon-
ductor Chips and Products Containing Same*, Inv. No. 337-TA-753,
Comm’n Op. at 47 (ITC 2012); *Certain Printing and Imaging Devices*, Inv.
2011 WL 1303160, at *15.

Because appellants do not contend that the ITC erred in its construc-
tion of Section 337, their argument is nothing more than a rudderless con-
tention that *these facts* should not suffice. Appellants offer no rule or
standard demonstrating why that is so. The ITC rejected appellants’ very
same factual arguments below, and there is no basis to find that decision
unreasonable.

c. The component purchases are qualitatively significant.

Appellants separately contest the ITC’s factual findings regarding
the qualitative importance of the domestically-sourced components. Lelo

Br. 35-38. But, similar to *Male Prophylactic Devices*, the ITC concluded that the domestically-sourced components are of a “critical nature ... to the patented products” (Add.199) and are “crucial to the functionality of the We-Vibe.” Add.200. The ITC consistently underscored these findings: “[REDACTED] is the “secret sauce’ because it is so critical to the We-Vibe functionality;” “[REDACTED] is another critical component;” and the “microcontroller products ... are also crucial components.” *Id.*

Appellants do not even attempt to dispute the ITC’s findings that [REDACTED] are essential to the patented products. *See* Lelo Br. 36-37. Nor do appellants contest that the pigments make the We-Vibe commercially viable. Add.193. This alone is a basis to conclude that the ITC’s decision is supported by substantial evidence.

Appellants instead argue that some important components are sourced from [REDACTED]. Lelo Br. 36. This argument is new and thus waived. *See, supra*, 23-24. It is also irrelevant. The fact that critical components to a product’s functionality are produced in the United States “weigh[s] heavily in favor of finding a domestic industry.” Add.201. Whether *other* important aspects derive from sources outside the United States is not a factor that weighs to the contrary.

Appellants also contest the significance of the microcontrollers, arguing that, because microcontrollers were not used in the first We-Vibe, they cannot be critical components. Lelo Br. 36-37.⁶ But the microcontroller is necessary to practice asserted, dependent claims—*i.e.*, claims relating to a vibrator that has multiple vibration modes. *See* Add.30 (*e.g.*, Claims 17 to 19); Add.77. The “[m]icrocontrollers control the vibrator motor and mode selection, which are important for the device to operate as a vibrator, particularly as a vibrator with multiple vibration modes.” A14893. The record makes clear that the circuitry components, including the microcontrollers, “enable the functionality of the device as required in Claims 17-19.” A14631; *see also* Add.77.

By including multiple vibration modes, the We-Vibe II and We-Vibe 3 devices have advanced features, which specifically practice asserted, dependent claims. Especially in the context of a small start-up, such as Standard Innovation, there is little surprise that later-generation products offer additional, advanced features. And when the domestic activity is “directed to the practice of certain patent claims,” this is particularly compelling evidence with respect to the domestic injury analysis. *Male Prophylac-*

⁶ [REDACTED] were indisputably used in the first generation We-Vibe. A14881-82; A13890-91.

tic Devices, 2008 WL 2952724, at *25. These components are thus a substantial factor weighing in favor of the ITC’s findings regarding domestic industry. Add.200-201.

The ITC’s conclusion that the domestic components are qualitatively significant to the production of the patented goods is supported by substantial evidence. And the fact that the We-Vibe is Standard Innovation’s “flagship product” further supports this determination.

2. Substantial evidence supports the ITC’s conclusion that the domestic purchases are sufficiently connected to the statutory categories.

Appellants also contend that the ITC erred in finding that the domestically-sourced products are sufficiently associated with the statutory domestic industry categories. In sum, appellants dispute the Commission’s factual holding that “complainant’s investments in these components are indicative of the investments of its U.S. subcontractors in their plants and equipment, and labor and capital that are necessary to produce these components in the United States.” Add.193.

Appellants’ argument, it seems, is that Section 337 may be satisfied only if a complainant provides *direct* evidence demonstrating how the statutory categories (*i.e.*, investment in plant and equipment, or employment of labor or capital) are satisfied. But the ITC concluded that it could

draw reasonable inferences from indirect evidence. That construction of the statute is reasonable.

Not only are appellants' arguments wrong, but they are quite dangerous. If appellants' contention were accepted, it would gut the ability of small start-up companies to receive protection from Section 337. Such companies often cannot provide, as a practical matter, the meticulous precision that appellants seek to impose. Given that "the reality of today's marketplace is that many products are assembled overseas," appellants' argument would have a devastating effect on the ability of small companies to take advantage of the remedies available at the ITC. Add.201.

Such a result, however, would be at odds with core principles underlying Section 337. "The fact that a complainant may be a small business is not preclusive" because it is fundamental that "small businesses" may "get a hearing at the ITC." *Male Prophylactic Devices*, 2008 WL 2952724, at *24. "Small businesses in this country can become large ones, and there is a public interest in protecting them against unfair theft of their property rights." *Id.* (quotation omitted).

a. "Off-the-shelf" component purchases may establish a domestic industry.

Appellants first contend that the components at issue here cannot satisfy the domestic industry requirement because they are "off-the-shelf"

products that were not designed specifically for Standard Innovation. Lelo Br. 24-26. But the ITC interpreted the statute as foreclosing that argument: “there is no requirement that the components must be developed or produced specifically” for use in the patented products and “[r]equiring that the components be developed for the patented article would go well beyond the statutory language, which requires only that investment relate to the articles protected by the patent.” Add.192-193. Appellants do not attempt to show that the ITC’s construction of the statute is “arbitrary, capricious, or manifestly contrary to the statute.” *Chevron*, 467 U.S. at 844. Nor could they: a domestic industry surely may exist for components that have multiple uses, and appellants offer no reason to think otherwise. The ITC’s decision is, accordingly, well within its broad discretion.

b. Indirect evidence may satisfy the statutory categories.

Appellants’ next argument is closely related: because these are off-the-shelf components, appellants argue, the ITC erred in finding that they relate to “investment in plant and equipment” or the “employment of labor or capital.” 19 U.S.C. § 1337(a)(3); *see* Lelo Br. 25-33. In appellants’ view, for domestically-sourced components to qualify as evidence of a domestic industry, the ITC must document with precision the exact amount subcontractors spent on plant, equipment, labor, or capital costs.

Appellants package this argument in many forms: “[l]ump-sum payments for purchases of commodity products” do not qualify (Lelo Br. 25-26); “[t]he lack of evidence prevented the ... Commission assessing how SIC’s purchases impacted [REDACTED]’s U.S. operations” (*id.* at 26); and “payments to subcontractors must be based on evidence to show the statutory categories” (*id.* at 28, 32). But each variation is ultimately the same.

The ITC, however, flatly rejected this interpretation of the statute. The Commission “does not require an accounting of subcontractors’ expenditures by statutory category for the domestic industry analysis.” Add.194. That is, “investments in components critical to the We-Vibe and related to the claims of the ’605 patent” are relevant to the domestic industry analysis despite a “lack of evidence concerning its subcontractors’ expenditures for plant and equipment under prong A and labor and capital under prong B.” *Id.*

This conclusion is correct because the costs associated with purchasing components “can reasonably be considered as evidence of a relevant investment by U.S. subcontractors in plant and equipment under prong A and labor and capital under prong B.” Add.195. Here, proof of component purchases from domestic subcontractors compels the finding that those subcontractors invested in plant and equipment and employed labor or

capital. Add.193-195. For example, the evidence demonstrates that the microcontrollers were manufactured in [REDACTED]'s facilities in [REDACTED] [REDACTED] must have made expenditures on facilities and labor with respect to these components. A14903; A14907; A2236:186. Likewise, the undisputed evidence demonstrated that [REDACTED] [REDACTED] were manufactured at facilities in the United States. A14903; A14908; A14914. In sum, in the context of this case, the ITC treated evidence of the purchase of domestically-sourced components as indirect evidence of investment in the domestic industry by the subcontractors.

Appellants' argument is necessarily that Section 337 somehow requires *direct* evidence. But appellants offer no reason to interpret the statute in this manner. They do not contend that such a rule is compelled by an unambiguous statutory command. Nor could they: while prongs A and B of Section 337(a)(3) require a showing of investment, the statutory text says nothing at all about *how* a complainant may prove that investment. There is thus no "unambiguously expressed intent of Congress" on this issue. *Chevron*, 467 U.S. at 843. And the ITC's construction of Section 337, that *indirect* evidence is relevant, is certainly not "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844.

“It is hornbook law that a patentee may prove an issue of fact by either direct or circumstantial evidence.” *Frolow v. Wilson Sporting Goods Co.*, 710 F.3d 1303, 1310 (Fed. Cir. 2013) (quotation omitted). Indeed, in some situations, “circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.” *Id.* (quotation omitted). Likewise, the ITC has broadly embraced the basic point that circumstantial evidence often may be sufficient proof of a disputed factual contention. *See, e.g., Certain Optoelectronic Devices*, Inv. No. 337-TA-669, 2011 WL 7628061, at *42 (ITC 2011); *Certain Semiconductor Chips with Minimized Chip Package Size*, Inv. No. 337-TA-605, 2009 WL 8144934, at *26 (ITC 2009). It would be bizarre to depart from such fundamental principles in this context.

And the Commission’s holding also makes good sense. For a small start-up like Standard Innovation, it is often impossible to obtain *direct* evidence of a subcontractor’s allocation of component expenses to the statutory categories. But circumstantial evidence may permit the finder of fact to conclude, as the ITC did here, that the statutory criteria are satisfied.

Appellants’ contention that the ITC misapplied its own precedent again falls flat. *See* Add.194 & n.7. Appellants point to cases—primarily ALJ decisions—in which they allege that there was a more detailed ac-

counting of expenditures by subcontractors. See Lelo Br. 27-33 (citing *Male Prophylactic Devices*, 2008 WL 2952724, at *24; *Inverter Circuits*, 2009 WL 3328064 (ALJ 2009); *Certain GPS Chips*, Inv. No. 337-TA-596, 2008 WL 838257 (ALJ 2008); *Certain Vacuum Packaging Machines*, Inv. No. 337-TA-496, 2003 WL 23210691, at *74 (ALJ 2003); *Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, 1989 WL 608787, at *64 (ALJ 1989)). Even if this contention were true, it would nonetheless be unhelpful for appellants: the fact that a domestic industry was found when allegedly more detail was shown says nothing at all about whether the ITC was correct in finding the evidence sufficient in *this* case.

Appellants' characterization of this authority is nonetheless inaccurate. In *GPS Chips*, for example, the ALJ considered "domestically manufactured component parts" as relevant to the domestic industry, without further consideration as to the economics underlying the subcontractor. 2008 WL 838257, at *2. The ALJ *separately* looked at research and development under prong C (Lelo Br. 27-28), but that had nothing to do with the consideration of domestically manufactured components. *Inverter Circuits*, which considered the complainant's servicing of the subcontractor for purposes of prong C, is wholly unlike the issues presented here. 2009 WL 3328064, at *3. And *Carbonated Candy*, which found sufficient domes-

tic activities that were performed *solely* by a subcontractor, strongly *supports* the result reached below. *See* Add.194-195.

Appellants offer no support for their assertion that the effect of the ITC decision here is to “allow a lower standard of proof where it is a subcontractor, rather than the complainant itself” whose conduct satisfies the domestic industry requirement. Lelo Br. 32-33. Far from it: as the ITC made plain, all parties must demonstrate satisfaction of the statutory categories; significant use of domestically-sourced components, however, may provide sufficient evidence to satisfy that requirement. Add.193-195. That is true regardless of whether the components are manufactured by the complainant itself or by a subcontractor.

Moreover, when a U.S. patent holder uses domestically sourced components, there *is* “contact with the United States.” *InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1302 (Fed. Cir. 2013). Restricting the ITC’s ability to find domestic industry in these circumstances would have the untoward effect of discouraging manufacturers from sourcing their critical components from the United States. Appellants’ argument, accordingly, would defeat a critical goal of the statute—the encouragement of investment in critical, high value components manufactured in the United States.

In short, appellants' argument requires the Court to eliminate wholly the ability of the ITC to rely on indirect and circumstantial evidence in concluding that the domestic industry requirements are satisfied. The statute does not compel such an illogical result, and the ITC's contrary reading of the statute is reasonable.

B. Independent grounds support affirmance of the Commission's domestic industry finding.

For the foregoing reasons, the Commission's conclusion in this case is correct and should be affirmed on its own terms. Two additional grounds, however, each independently justify the result reached below.

The Court may "affirm" an agency's holding "on grounds other than those relied upon in rendering its decision, when upholding the agency's decision does not depend upon making a determination of fact not previously made by the agency." *Flo Healthcare Solutions, LLC v. Kappos*, 697 F.3d 1367, 1375 n.7 (Fed. Cir. 2012) (quotation omitted). Two such grounds are present here; at the very least, these arguments would be available to the Commission should the Court remand. (And because these are merely alternative grounds supporting the result reached below, a cross-petition was neither necessary nor appropriate. *See Amkor Tech., Inc. v. Int'l Trade Comm'n*, 692 F.3d 1250, 1259 (Fed. Cir. 2012)).

1. As Commissioner Pinkert indicated, the Commission’s conclusion is separately appropriate on the ground the Standard Innovation’s purchase of domestically-manufactured components *directly* establishes a domestic industry under prong B; “the purchase of inputs in the United States should be considered the ‘employment of capital’ within the meaning of the statute.” Add.195 n.9. This result accords with the plain terms of the statute: the funds that Standard Innovation expended on purchases of domestic components qualify as “capital,” and Standard Innovation “employ[ed]” that capital in the United States.

2. Additionally, in order to create a market for its novel patented articles, Standard Innovation made significant domestic expenditures that qualify as “substantial investment” in the “exploitation” of U.S. intellectual property rights under prong C. 19 U.S.C. § 1337(a)(3)(C).

Although the statute lists “engineering, research and development, or licensing” as ways in which a party may “exploit[]” via “investment” its intellectual property (19 U.S.C. § 1337(a)(3)(C)), the Commission has concluded that, “by using the term ‘including’ and the conjunction ‘or’ in section 337(a)(3)(C), Congress indicated that” these “are examples of exploitation and they do not form an exhaustive list of what can constitute ‘exploitation.’” *Certain Coaxial Connectors*, Inv. No. 337-TA-650, 2011 WL

7463395, at *36 (ITC 2011). Thus, activities like customer training and support may, under certain circumstances, support a domestic industry under prong C. See *Printing and Imaging Devices*, 2011 WL 7628059, at *19 n.9; *Certain Connecting Devices (“Quick-Clamps”) for Use with Modular Compressed Air Conditioning Units*, Inv. No. 337-TA-587, 2008 WL 618218, at *33, unreviewed Initial Determination (2008).

Here, because the Commission found prongs A and B satisfied, it had no need to rely upon prong C. It nonetheless noted in passing that Standard Innovation’s “expenses primarily relate to sales and marketing” and were activities similar to “those of an importer.” Add.194-195 n.8.⁷ The Commission did not therefore consider an additional category of expenses unrelated to acts of an importer: Standard Innovation’s significant expenditures in the United States necessary to create a market (and thus demand) for its patented products.

Unrefuted evidence demonstrates that because no prior product like the We-Vibe existed, Standard Innovation was required to expend substantial sums to educate the public as to the purpose, benefits, and use of

⁷ In support of the view that activities similar to an importer do not qualify under prong C, the Commission cited a case decided *before* prong C was created, *Schaper Mfg. Co. v. Int’l Trade Comm’n*, 717 F.2d 1368, 1373 (Fed. Cir. 1983).

the product. Standard Innovation spent more than \$[REDACTED] on educational outreach activities (A14937-14939; A7014; A14040; A14041-71), and it further provided more than \$[REDACTED] in sample product in order to create a new marketplace for its products. A14940-14941. Standard Innovation spent an additional \$[REDACTED] on trade shows and other events to educate customers as to the use of its new product. A14490; A7014. And Standard Innovation hired three U.S.-based employees to further these market-building efforts and to provide customer support; prior to the filing of the complaint, about \$[REDACTED] in U.S. employee salaries was allocable to such activities. A14928; A7014.

These costs—totaling more than \$[REDACTED]—were necessary to establish a brand new marketplace for a product of a type that had never existed previously. Unlike typical importation or marketing efforts, these expenditures were necessary for Standard Innovation’s successful “exploitation” of its intellectual property and support a finding of domestic industry.

II. The ITC Properly Affirmed The ALJ’s Claim Construction.

Appellants’ arguments that the ITC erred in adopting the ALJ’s claim construction are each without merit. But a substantial portion of appellants’ argument on claim construction fails for a more fundamental

reason: appellants have flatly abandoned their anticipation and obviousness defenses on appeal.

A. Appellants have abandoned their anticipation and obviousness arguments.

The majority of appellants' claim construction argument challenges the conclusion below relating to whether the preamble in the independent claims is a limitation and the construction of the term "intercourse" contained in the preamble. Lelo Br. 38-48. The dispute regarding these claim terms, however, has been rendered moot by appellants' failure to appeal the Commission's separate decisions regarding anticipation and obviousness.

Below, appellants claimed that the asserted claims were anticipated or rendered obvious by prior art. Add.57-68. To make this argument, appellants contended, in part, that (1) the preamble was not limiting and (2) the term "intercourse" did not mean "coitus." *See, e.g.*, Add.58-59.

The ALJ rejected appellants' anticipation and obviousness grounds for multiple reasons. Add.57-68. The ALJ rejected appellants' arguments based on each of the three anticipation references because appellants' "failure to address all limitations" of the asserted claims was "fatal." Add.58; Add.60; Add.62. The ALJ *then* explained, "*assuming arguendo*, that [appellants] had addressed all limitations" of the asserted claims,

they “have not shown” that the prior art references taught the limitation contained within the preamble—“a sexual stimulation device dimensioned to be worn by a female during intercourse.” *See id.* The Commission agreed with the ALJ’s rejection of the anticipation argument. Add.184-185.

With respect to obviousness, the ALJ found that appellants’ argument failed, in part, because they “simply” made “cursory assertions and conclusory arguments.” Add.64. Appellants “address[ed] none” of the inquiries relevant to an obviousness finding. Add.65. And appellants “rel[ied] entirely on attorney argument to make its obviousness case,” which “is not evidence.” Add.66. Because of the complete failure “to make a prima facie argument regarding obviousness,” the ALJ found that “an extensive analysis of secondary considerations to rebut the obviousness arguments is unnecessary.” Add.68. Again, the ITC affirmed the ALJ’s conclusion, and it denied as waived new arguments that appellants submitted. Add.185-186.

On appeal, appellants fail to challenge the holdings below with respect to either anticipation or obviousness in their opening brief; they have therefore waived those arguments and cannot raise them in their reply brief. *See, supra*, 19-20. If appellants had raised these issues, Standard Innovation would, for example, point the Court to the extraordinary vol-

ume of evidence relating to secondary considerations supporting the conclusion of non-obviousness rendered below. *See, e.g.*, A1234-36.

Once anticipation and obviousness are set aside, these claim construction disputes become irrelevant⁸ and need not be resolved by the court. *See, e.g., Paradox Sec. Sys., Ltd. v. ADT Sec. Servs., Inc.*, 388 F. App'x 976, 983 (Fed. Cir. 2010).

B. The ITC's claim construction is correct.

1. The preambles are claim limitations.

In any event, the ITC properly concluded that the preamble contained in each of independent claims 1, 33, and 66 of the '605 Patent—describing “[a] sexual stimulation device dimensioned to be worn by a female during intercourse”—is a claim limitation. In fact, the Commission found the issue so plain that it merely adopted the ALJ's analysis. Add.170 n.1.

While recognizing that “no litmus test defines when a preamble limits claim scope,” the Court has identified several “guideposts” that demonstrate a preamble serves as a limitation. *Catalina Mktg. Int'l v.*

⁸ Oddly, while these arguments can no longer benefit appellants, success on these points would negate their separate assertion that the preamble term “dimensioned to be worn by a female during intercourse” is indefinite. Lelo Br. 61-63.

Coolsavings.com, Inc., 289 F.3d 801, 807-11 (Fed. Cir. 2002). These include that (1) the preamble “recites essential structure or steps;” (2) the preamble “recit[es] additional structure ... underscored as important by the specification,” including aspects designed to solve “the prior art problem;” (3) “the preamble is essential to understand limitations or terms in the claim body;” or (4) the patentee relied “on the preamble during prosecution to distinguish the claimed invention from the prior art.” *Id.* While any one of these factors may be sufficient to show that a preamble is limiting, the ALJ found that *all four* of these conditions are present. Add.36-42.

Structural limitation. In describing “[a] sexual stimulation device dimensioned to be worn by a female during intercourse,” the preamble necessarily “mandate[es] that the device must be *dimensioned* to be worn by a female during intercourse.” Add.39 (emphasis added). This places a physical limitation on other claim elements, such as the arms and the connecting portion; if those components are not properly sized, the device cannot be used during intercourse. For this reason, “how the claimed device is used is a key feature that necessarily limits the structure of the invention described in the body of the claims.” *Id.* As the Commission concluded, “the invention must be properly sized to be used during intercourse,” which is a “structur[al]” limitation on the device. Add.170 n.1.

Appellants argue that the preamble states an intended purpose for the device and nothing more. Lelo Br. 38-40. This cannot be correct. Indeed, in their brief, appellants truncate an essential aspect of the preamble—“a sexual stimulation device dimensioned”—in arguing that the incomplete phrase “to be worn by a female during intercourse” merely describes an intended use. *Id.* at 38. And whether the device can be used for purposes other than intercourse (*e.g.*, as an auto-erotic aid, *id.* at 39) says nothing about whether the preamble establishes physical limitations.

Later, appellants argue that “the preamble does not provide an antecedent basis for any terms in the body of the claim” because “[n]one of the elements of the body of the claim refer back to the term ‘dimensioned to be worn by a female during intercourse’ as antecedent basis.” Lelo Br. 44. But this contention just assumes Lelo’s conclusion. If the preamble *is* a limitation, then the subsequent terms in the body of the claim are controlled by the preamble.

Indeed, while appellants call the preamble “abstract” (which is wrong, *see, infra*, 68-72), they nonetheless admit that it provides an “overall dimensional feature.” Lelo Br. 44. A dimensional feature *is* a structural limitation, as it controls the physical size of the elements used in the device.

Problem in the prior art. Additionally, as the ALJ concluded, “the specification of the ’605 patent discloses that the inventor was working on the specific problem described in the preamble.” Add.37. “No direct vibration means effective to stimulate the vagina or G-spot during intercourse were provided” in the prior art. *Id.* (quoting Add.220 1:59-60). The inventor sought to overcome this problem, which the very title of the Patent—”Electro-Mechanical Sexual Stimulation Device to be Worn During Intercourse” (Add.220)—makes clear. The “Field of the Invention” and the “Summary of the Invention” confirm this point. Add.38; *see Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (title and summary relevant to considering whether the preamble functions as a limitation). Indeed, appellants do not challenge this conclusion.

Understanding of other claim terms. Moreover, the preamble provides the “framework for the other limitations recited in the body of the claim.” Add.37. “Without the preamble, the claim limitations have no context.” Add.39. In light of the preamble, the other limitations must be understood as contributing to a device that may be used during intercourse.

The foregoing points alone compel the conclusion that, in this case, the preamble functions as a limitation. In *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1358 (Fed. Cir. 2012), the Court found that a preamble was

a limitation where it “inform[ed] one of skill in the art as to the structure required by the claim” and the specification (including the patent’s title and summary) supported this conclusion. In fact, the applicant in *Deere* did *not* disclaim prior art on the basis of the preamble. *Id.* at 1358-59. Under *Deere*, accordingly, the foregoing factors show that the preamble is a limitation *regardless* of the prosecution history. *See also, e.g., Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1373 (Fed. Cir. 2014); *Poly-Am.*, 383 F.3d at 1310. The vast majority of appellants’ argument—that the prosecution history does not demonstrate that the preamble is a limitation (Lelo Br. 40-44)—is thus beside the point.

Prosecution history. In any event, the prosecution history strongly supports the conclusion that the preamble is a limitation. In amending the claims to include the phrase “dimensioned to be worn by a female during intercourse” in the preamble, the applicant clearly stated that “each independent claim *requires* that the device be dimensioned to be worn by a female during intercourse.” A2892 (emphasis added). During prosecution of the ’605 Patent, the applicant relied on the preamble to distinguish over the prior art; the ALJ held so explicitly and meticulously documented the evidence. Add.40-42.

Appellants’ argument to the contrary appears to be as follows. Appellants acknowledge that, in earlier amendments, the applicant used limitations referencing “intercourse” in the *body* of the claim and further that applicant asserted that this limitation was relevant in assessing the claims against prior art. Lelo Br. 40-42. But in the claims that were granted, the “intercourse” limitation was moved from the body of the claim to the preamble. *Id.* at 42-43. On this basis, appellants somehow contend that the prosecution history supports their view that the preamble is not limiting. This contention defies law and logic.⁹

This prosecution history strongly *supports* the conclusion that the preamble is a limitation. It demonstrates that the applicant *always* viewed “intercourse” as a claim limitation—a conclusion bolstered by several other *Catalina* factors—and it continuously relied on this limitation to distinguish prior art. The genesis of the limitation as earlier appearing in the

⁹ Appellants also point to one cancelled application claim—claim 67—that contained the intercourse limitation in both the preamble and the body of the claim. Lelo Br. 41. Invoking the canon of surplusage, appellants argue this proves the preamble has no meaning. This argument is new on appeal and thus waived. *See, supra*, 23-24. Moreover, it proves too much; it shows that “intercourse” is in fact an integral limitation of the claim, and that the applicant simply solved any alleged surplusage issue by placing the limitation in just one place in the issued claim.

claim body therefore supports this result. This case thus fits squarely within *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1295 (Fed. Cir. 2004).

Appellant's reliance (Lelo Br. 44) on *United States v. Telectronics, Inc.*, 857 F.2d 778, 782-84 (Fed. Cir. 1988), is also misplaced. There, the applicant deleted a claim limitation *entirely* from the claim; here, the applicant simply moved the limitation from the body to the preamble. *Id.*

2. The term “intercourse” means “coitus.”

Appellants next contest the construction of the term “intercourse” as used in the preambles. Standard Innovation and the ITC staff attorney contended that “intercourse” would be understood by a person of ordinary skill in the art in question as meaning “coitus” (*i.e.*, penile-vaginal intercourse); appellants, however, contend that the term is broader, encompassing acts like digital-vaginal penetration. Add.43.

The Commission again adopted (Add.170 & n.1) the ALJ's construction of the term, that “intercourse” means “coitus” (Add.43-47). The ALJ's conclusion drew from the specification, which “clearly contemplates the use of the device during coitus” (Add.44); the prosecution history, which “shows that the Applicant contemplated using his claimed device during coitus” (Add.44-45); and testimony from Standard Innovation's expert, Dr. Herbenick (Add.45-46).

Appellants take a small snippet of Dr. Herbenick’s testimony out of context. Lelo Br. 45-46. As the ALJ found, she plainly concluded that, as used here, “intercourse” means “coitus.” Add.45-46. She explained that “the term coitus as used in the present volume refers to a union of female and male genitals. And the term intercourse when used without a modifier is often intended as an exact synonym of coitus.” A2259:315. In her view, “it was very clear” that “intercourse in this investigation” “has the ordinary meaning of penile/vaginal intercourse.” A2259:316. Against this, appellants offer no evidence, expert or otherwise, that “intercourse” has a different meaning.

Appellants next contend that a fleeting use of the term “sexual intercourse” in an earlier amendment bars construing “intercourse” as “coitus.” Lelo Br. 46. Appellants, however, provide no basis to suggest that the word “sexual” actually limits the term “intercourse”—making this situation entirely unlike *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005), where “steel” plainly limited the term “baffles.” Moreover, although appellants suggest that the preamble does not specifically reference a vagina, they ignore that the body of the claim *does* specifically discuss “an elongate inner arm dimensioned for placement inside a vagina.” Add.224 (claim 1). And, as the ALJ correctly concluded, the ’605 Patent clearly and repeated-

ly describes the claimed sexual stimulation device as worn by a woman in her vagina during intercourse in a manner that makes it clear that “intercourse” is synonymous with “coitus.” Add.44; *see also* Add.220-224: 1:20-23, 2:2-4, 3:27-31, 5:11-20, 9:65-10:6, 10:17-21. The prosecution history, too, confirms this point. Add.44-45. Standard Innovation’s use of the term “intercourse” in its correspondence with the patent examiner during the prosecution of the ’605 Patent consistently referred to penile penetration of a vagina, *i.e.* coitus. *See, e.g.*, A2794-95; A2848; A2852.

Finally, while it is true that preferred embodiments should not be read into the claims, it is equally true that claim terms must be read in light of a patent’s intrinsic record. *See Fuji Photo Film Co. v. Int’l Trade Comm’n*, 386 F.3d 1095, 1098 (Fed. Cir. 2004). Appellants’ overly broad interpretation of the term “intercourse” is inconsistent with the claims and the specification of the ’605 Patent. Add.46. In claims 1, 33, and 66, it is clear that the device being claimed is a device that is dimensioned for placement against a clitoral area, dimensioned for placement inside a vagina, and dimensioned to be worn by a female during intercourse, *i.e.*, coitus. *Id.*

3. The term “generally tear-drop shaped” should be given its plain and ordinary meaning.

The ITC properly found that construction of the claim term “generally tear-drop shaped” is unnecessary because the term is within common knowledge and sufficiently clear on its face. Add.176. There is no legal requirement for a court to construe every limitation of a claim. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). Claim construction is appropriate when it is required to give meaning to claim terms other than their plain and ordinary meaning, not to unnecessarily redefine claim recitations or read limitations into the claims. *See Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1331 (Fed. Cir. 2011). The term “tear-drop” is not a term of art; it is a commonly used term in the English language that does not require a detailed definition.

The Commission correctly concluded that the ordinary meaning of “tear-drop shaped” is “within common knowledge and sufficiently clear on its face so that no further explanation for the meaning of the term was warranted.” Add.176. As the Commission held, appellants “failed to show any genuine dispute as to the meaning of ‘generally tear-drop shaped.’” *Id.* Even the definition of appellants’ expert (“looking like a tear drop, which

is a 3-dimensional figure”) is consistent with the finding that no further explanation was needed. *Id.*

On appeal, after effectively conceding that “the term ‘tear-drop shape’ may be sufficiently within common knowledge,” appellants mint a wholly new argument: that the word “generally” requires construction. Lelo Br. 48-51. But appellants never made this argument below; instead, their quarrel was entirely the failure to define “tear-drop shaped.” Add.47-48; A1701-05; A1384-87. Having deprived both the ALJ and the ITC the opportunity to consider their newfound focus on “generally,” appellants’ argument is waived. *See, supra*, 23-24. The waiver doctrine bars exactly this kind of sandbagging; “a party may not introduce new claim construction arguments on appeal or alter the scope of the claim construction positions it took below.” *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1358-59 (Fed. Cir. 2006).

And appellants try yet another new argument: that the Tiani 2 product has an inner arm “shaped almost like a phallus, with a protruding head,” and that from one angle looks “more like a paddle than a tear-drop.” Lelo Br. 49. But this is a non-infringement argument—not a claim construction dispute—and it is certainly not a contention raised below. *See, e.g.*, A1717-20; A1393-98. Thus, even if appellants were right that the

claim term should have been construed, and construed narrowly, this would merely be in service of a hypothetical non-infringement contention that appellants never raised. Appellants cannot smuggle through the backdoor of claim construction a wholly new non-infringement argument.

In any event, appellants' argument is also wrong. Appellants get it backwards by pointing to the infringing device as a basis for needing to define a term; "[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, *not* in light of the accused device." *Sri Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985). And appellants have offered no evidence to believe that the whole phrase "generally tear-drop shaped" is outside of ordinary, common understanding. There was thus no obligation to specifically construe it.

Appellants cite *Baush & Lomb Inc. v. Mario S.A.*, 222 F. Supp. 2d 616 (E.D. Pa. 2002), relating to the construction of the term "tear drop" in a different case. Lelo Br. 50. The ALJ quickly dispatched this argument as "misleading" because it is "extrinsic evidence" that "relates to an unrelated patent, unrelated parties, and unrelated technology." A15318. It is no different now.

4. **Bulbous and hook shapes were not disclaimed.**

The Commission correctly affirmed (Add.176-178) the ALJ's conclusion that Standard Innovation did not disclaim bulbous or hook shapes during prosecution of the '605 Patent. Add.48-51. For the doctrine of prosecution history disclaimer to apply, the patentee must "unequivocally disavow[] a certain meaning;" the record must be "so clear as to show reasonable clarity and deliberateness" and "so unmistakable as to be an unambiguous evidence of disclaimer." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324-25 (Fed. Cir. 2003).

Bulbous shapes. Appellants first point to the applicant's method of distinguishing Sekulich—art that taught the use of a V-shaped device with a *phallus-shaped* bulbous head and a "lip." Lelo Br. 51. As the Commission found, the applicant distinguished this art for reasons *other* than the bulbous shape. Add.176-177. The "lip" in the art "would be irritating during intercourse." *Id.* (citing A2846-54). Additionally, a number of characteristics of this device, taken together as a whole, demonstrate that the Sekulich device is not dimensioned to be worn by a female during intercourse. Add.49; *see also* A14201; A14515; A2846-54. Finally, because "[t]he '605 patent's first preferred embodiment also describes the tear-drop shaped pad of the inner arm as 'bulbous,'" this strongly "suggest[s] that a bulbous

shape was not disclaimed during prosecution.” Add.177. Indeed, “a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.” *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007).

Appellants now attempt to rely on an Interview Summary of an interview with the Examiner on October 7, 2010. Lelo Br. 51. The summary, drafted by the Examiner, merely notes that “[i]t was agreed that adding the language from depending claims where at least one of the inner and outer arms are generally tear-drop shaped into all independent claims would be allowable.” A2931. The rationale behind the agreement is not provided, but the term “bulbous” is not mentioned. There is certainly no “unambiguous evidence” of an “unequivocal[] disavow[al]” of bulbous shapes.

Hook shapes. The ITC also correctly found that Standard Innovation did not disclaim hook shapes. Add.177. As the Commission concluded, the applicant distinguished “the Marshall device” because it “was unsuitable for use during intercourse because its shaft portion blocked the vaginal passage” in a way that is “the opposite of the invention described in the ’605 patent.” *Id.* (citing A2793-94). Indeed, as the ALJ noted, “Dr. Herbenick authoritatively testified that ‘[i]t is not the hook that’s the problem.’” Add.50-51 (quoting A2283:412-13). And the Jacobs patent was never

admitted into evidence and never discussed in the prosecution history. Again, there is certainly no “unequivocal[] disavow[al]” of a hook shape.

III. The ITC Properly Concluded That Lelo’s Products Infringe The ’605 Patent.

Because the ITC’s infringement findings are questions of fact reviewed under the substantial evidence standard (*Linear Tech. Corp. v. Int’l Trade Comm’n*, 566 F.3d 1049, 1060 (Fed. Cir. 2009)), review is akin to that of a jury verdict. *See, supra*, 11-12.

Appellants argue that the Tiani and Tiani 2 do not infringe the ’605 Patent because the arms “are bulbous and the inner arms have a hook shape” and the ALJ and ITC erred in finding no disclaimer of bulbous or hook shaped arms. Lelo Br. 53. But, as we demonstrated above, there was no disclaimer of bulbous or hook shapes.

Separately, substantial evidence supports the ITC’s factual determination of infringement since the Tiani and Tiani 2 are neither bulbous nor hook shaped. As the ALJ concluded, “the evidence shows that the inner and outer arm of each Accused Product are ‘generally tear-drop shaped’ which clearly satisfies the limitation ‘wherein, at least one of the inner and outer arms are generally tear-drop shaped.’” Add.53-54 (citing (A14261-62; A14282-85; A14302-04:703-714; A14659-64; A14750; A14753-54; A15328)). By contrast, appellants offer nothing other than unsupported

assertions that the Tiani and Tiani 2 inner or outer arms are bulbous or hook shaped. Thus, even if bulbous and hook shapes *were* disclaimed, the infringement decision below would still be rational.

IV. The ITC Properly Concluded That The Claim Terms Are Not Indefinite.

As this Court has explained, “[a]lthough indefiniteness is a question of law, we review a trial court’s factual findings in support of its legal conclusion for clear error.” *HTC Corp. v. ICom GmbH & Co., KG*, 667 F.3d 1270, 1279 (Fed. Cir. 2012).

“[P]roof of indefiniteness must meet ‘an exacting standard.’” *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010). “A claim is not indefinite merely because parties disagree concerning its construction.” *Id.* “Only claims ‘not amenable to construction’ or ‘insolubly ambiguous’ are indefinite.” *Id.* An accused infringer must demonstrate by “clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art.” *Id.*

A. “Generally tear-drop shaped” is not indefinite.

The Commission properly affirmed (Add.178) the ALJ’s conclusion (Add.68) that the term “generally tear-drop shaped” is not indefinite. As

the ALJ concluded, appellants' indefiniteness challenge "fall[s] far short of satisfying" the "heavy burden" of showing a claim indefinite. *Id.* Instead, "[t]he evidence shows that one skilled in the art would have a sufficient understanding of the term 'generally tear-drop shape' and the shapes that meet this limitation." *Id.* (citing A14334; A3514-15). And the Commission explained that "the specification provides sufficient explanation for the meaning of generally tear-drop shaped arms," citing the '605 Patent, Figures 1 through 5. Add.178.

Appellants' contention to the contrary is simply that the claim term is indefinite because it provides no objective measurement for "how 'tear-drop shaped' an arm must be in order to be '*generally* tear-drop shaped.'" Lelo Br. 55 (emphasis added). This is appellants' repeated contention—that there must be an "objective standard" (*id.* at 54) and that the claim term is too "malleable" (*id.* at 56).

This argument is unavailing. Indeed, the Court has previously held that "the use of modifiers in the claim, like '*generally*' and 'substantial,' does not by itself render the claims indefinite." *Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc.*, 119 F.3d 16, 1997 WL 368379 (Fed. Cir. 1997) (table) (emphasis added).

That is to say, a claim term is not indefinite simply because it uses a non-objective measurement of degree; “[n]ot all terms of degree are indefinite.” *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1367 (Fed. Cir. 2010). Rather, “a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” *Id.* A term of degree is not indefinite where the specification provides some basis for “measuring the scope of the phrase.” *Id.*

Here, the Commission found that the specification does precisely that. Add.178. The figures (identified by the Commission) make apparent the general kind of shape described by the claims:

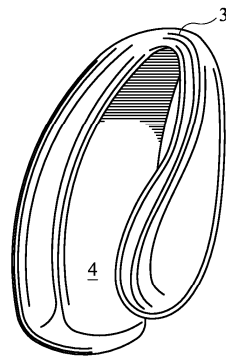


FIG. 1

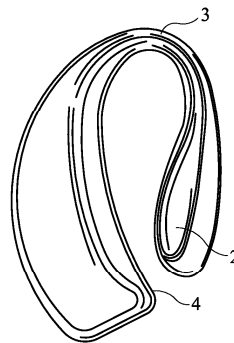


FIG. 2

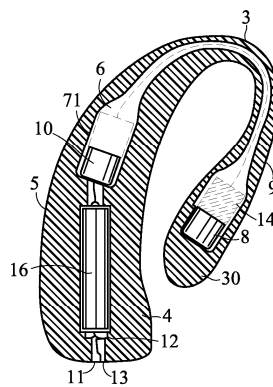


FIG. 3

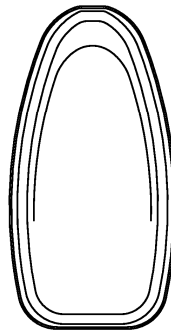


FIG. 4

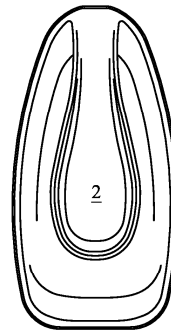


FIG. 5

Add.212. And the specification, which the Commission also expressly referenced, provides significant additional detail: the “inner arm 1 that terminates in the bulbous teardrop-shaped pad 2.” Add.221:3:11-13. *See also* Add.220:2:25.

Hearing Components is instructive. There, the Court rejected an indefiniteness challenge against the claim term “readily installed” because, in part, “the specification is clear in its examples.” 600 F.3d at 1368. While the concept of “readily” is not subject to an objective standard, it nonethe-

less was sufficiently definite in the context of the patent. So too here; the examples and figures in the specification provide significant context for the concept of “generally tear-drop shaped.”

Moreover, the expert evidence was clear that one would readily understand the meaning of the claim term. As Standard Innovation’s expert, Dr. Herbenick, stated, “[a] teardrop shape is easily recognizable to those of ordinary skill in the art and laypersons.” A14334. The understanding was plain: “things that are generally teardrop shaped often start out smaller and get a little bigger in some way, in a more gradual capacity or way.” *Id.*¹⁰ In fact, appellants’ own expert, Dr. Locker, stated that “tear-drop shaped’ means looking like a tear drop, which is a 3-dimensional figure.” A3515.

When, like here, one would understand the meaning of a term of degree, the Court routinely finds a claim term sufficiently definite. Thus, for example, the term “‘substantially’ serves reasonably to describe the subject matter so that its scope would be understood by persons in the field of the invention.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir.

¹⁰ Below, appellants pointed to Dr. Herbenick’s testimony that “generally tear-drop shaped” has no special meaning in the field, as well as her observation of this shape in different contexts. That is precisely the point: the term “is clear on its face.” Add.178.

2002). In fact, terms like “‘approach each other,’ ‘close to,’ ‘substantially equal,’ and ‘closely approximate’ are ubiquitously used in patent claims and ... such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts.” *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001). The term “generally” is just the same.

Appellants’ criticism of the definition of “generally tear-drop shaped” as being “circular” also lacks merit. As noted by the ALJ, whatever circularity may exist results simply because the claim term has a plain and ordinary meaning. Add.48. Appellants’ own expert’s testimony (which the ALJ recognized as being similarly circular (*id.*)) also supports the ALJ’s finding. Add.68.

Appellants’ only purported evidence of why “such circular definitions are ‘improper’”—Dr. Villarraga’s testimony regarding the horizontal oval shape of a hand drawn picture during the ITC hearing, Lelo Br. 56—does not establish that the term “generally tear-drop shaped” is indefinite. In fact, at the hearing, when Standard Innovation’s counsel rotated the image 90-degrees, Dr. Villarraga then acknowledged that the hand-drawn

figure did indeed appear to be tear-drop shaped. A2468. All this shows is that a hand-drawn two-dimensional figure, the basis of Dr. Villarraga's testimony, has nothing to do with either a real-world sexual simulation device or the definiteness of the term at issue. The ALJ and the Commission were correct in disregarding this testimony—particularly in light of appellants' burden to prove indefiniteness by clear and convincing evidence, and the exceptional standard necessary to show a claim indefinite.

Appellants' effort to reargue the facts is particularly misplaced because, as the evidence at the hearing showed, one skilled in the art may discern whether an arm on a three-dimensional device is, or is not, "tear-drop shaped." A14334. Dr. Hebernick explained that, "[a]s one of ordinary skill in the art, it is my opinion that the claim term 'generally tear-drop shaped' is definite." *Id.* Thus, "[a] teardrop shape is easily recognizable to those of ordinary skill in the art and laypersons." *Id.*; *see also* A2333-38; A2342-46.

Finally, appellants point to a host of other devices not at issue here. Lelo Br. 56-61. Although appellants' argument is not entirely clear, it seems that they are trying to show that some accused vibrator products may not have "generally tear-drop shaped" arms. That argument, which is presented in cursory, selective fashion without full description or illustra-

tion of the accused devices, is simply not before the Court in this case and contradicts the evidence in the underlying investigation that these devices did, in fact, have generally tear-drop shaped arms. Even if appellants were correct in asserting that those devices do not have “generally tear-drop shaped” arms,¹¹ that would simply be a non-infringement argument. It says nothing at all about indefiniteness. And, to the extent it suggests that “[a] construction of ‘generally tear-drop shaped’ was necessary” (*id.* at 56), appellants waived that argument below. *See, supra*, 56.

B. “Dimensioned to be worn by a female during intercourse” is not indefinite.

The Commission adopted (Add.170) the ALJ’s conclusion that “the evidence does not show that the phrase ‘dimensioned to be worn by a female during intercourse’ is indefinite” (Add.69). As the ALJ explained, “the specification discloses that the claimed device is sized and shaped so that a penis can move in and out of the vagina and thus contact the outer surface of the internal arm.” *Id.* And the specification continuously refers to intercourse between a man and a woman in describing how the device is to be structured. *Id.*

¹¹ To be sure, appellants’ suggestion is wrong. Other accused devices, not at issue here, do have “generally tear-drop shaped” arms. But that is not an issue before the Court.

Appellants make two contradictory contentions: they first contend that because the size of human vaginas and penises vary, the dimensions of a device are indefinite (Lelo Br. 61-62), but they then turn around and (for the first time on appeal) assert that the patentee “could have easily provided” a “narrow range” of sizes “in the specification” (*id.* at 62).

Appellants are wrong to argue that the term is indefinite. As the Court has long held, “there is nothing wrong with defining the dimensions of a device in terms of the environment in which it is to be used.” *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1111 (Fed. Cir. 2000). That is precisely what the claims do here.

As appellants recognize, Dr. Herbenick explained that there is a standard range of circumferences for erect penises and a range of vaginal sizes. Lelo Br. 61 (citing A14320; A2253). Indeed, the testimony in this case established that “95 percent of women fall, again, within 0.7 inches of one another The erect male penis only varies in diameter 0.8 inches for 95 percent of men.” A2254:297:4-13. One skilled in the art, accordingly, can readily size the device so that it is “dimensioned” for use in intercourse.¹²

¹² In stating that there is no “standard” for sizing devices to be used for intercourse, Dr. Herbenick simply meant that no industry-wide standard

Ex parte Brummer does not aid appellants. The claim there was directed to a bicycle with a wheelbase “between 58 percent and 75 percent of the height of *the rider* that the bicycle was *designed for*.” *Ex parte Brummer*, 12 U.S.P.Q. 2d 1653, *1 (B.P.A.I. 1989) (emphasis added). The problem with such a claim is that “whether the bicycle was covered by the claim would be determined not on the basis of the structural elements and their interrelationships, as set forth in the claim, but by means of a label placed upon the bicycle at the discretion of the manufacturer.” *Id.* at *2.

Unlike the claims in the *Ex parte Brummer* patent, the claims in the '605 Patent are not restricted to a device that is expressly designed for a user of a certain size. The evidence presented at trial before the ITC established that those of ordinary skill in the art can discern the meaning of “dimensioned to be worn by a female during intercourse” as “sized and shaped to be carried on the body of a female during coitus.” A14191-92; A14319-27; A14503-06; A2256-58:306:1-307:17; 308:9-309:4, 309:15-310:14, 311:3-314:17.

has been created given that “this is such a new invention.” A2457. She explained that “a person who is familiar with penile and vaginal dimensions and sexual intercourse would have some sense of devices that can be used during intercourse and devices that can’t.” A2456.

This case is similar to *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1575 (Fed. Cir. 1986), in which a claim limitation specifying that a certain part of a pediatric wheelchair be “so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats” was held sufficiently definite. The Court explained that the phrase “so dimensioned” is as accurate as the subject matter permits and noted that a patentee need not include all possible lengths corresponding to the spaces in the hundreds of different automobiles. *Id.* at 1576. Given Dr. Herbenick’s undisputed testimony with respect to the known and relatively narrow anatomical size ranges applicable for 95% of all men and 95% of all women, the claim language here is also sufficiently definite.

Rather than respond to this point, appellants now argue that, assuming we are right, the patentee could have provided a “narrow range” of sizes in the specification. Lelo Br. 62. But this is not a basis to hold the term indefinite. If the claim term is unambiguous as written, as this claim term certainly is, it is sufficiently definite, regardless of any additional detail the patentee could have hypothetically included. *Every* patent claim *could* be claimed with ever-increased amounts of detail, but such an approach would render a patent worthless.

Finally, appellants point to ways in which the applicant distinguished prior art in the prosecution history. Lelo Br. 62-63. Appellants then attempt to tether that to the preamble term, in an apparent effort to show some latent ambiguity. Not only is this argument new (and thus waived), but it is also unsupported by authority or logic. The question here is whether the phrase “dimensioned to be worn by a female during intercourse” is sufficiently definite; as we show, it undoubtedly is. If a subset of structures that would fit that term were disclaimed in the course of prosecution, that would merely add an additional, implicit limitation, relevant for purposes of infringement. It would not show that *this* limitation is indefinite.

CONCLUSION

The Court should affirm the ITC’s findings and issuance of an exclusion and cease and desist orders against the appellants.

Respectfully submitted,

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Dated: May 12, 2014

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2014, I served the foregoing Non-Confidential Brief for Intervenors on each party separately represented via the Court's electronic Pacer/ECF system.

Dated: May 12, 2014

/s/ Robert P. Lord
Robert P. Lord

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 13,968 words, including footnotes and excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2007 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: May 12, 2014

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