

**PUBLIC VERSION**

**In the Matter of**

**CERTAIN KINESIOTHERAPY DEVICES  
AND COMPONENTS THEREOF**

**Investigation No. 337-TA-823**

**COMMISSION OPINION**

**I. INTRODUCTION**

On January 8, 2013, the presiding administrative law judge (“ALJ”) (Judge Pender) issued a final initial determination (“ID”) finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the accused products of the Lelo Respondents (LELO Inc. and Leloi AB) (“Respondents”) in connection with United States Patent No. 7,931,605 (“the ‘605 patent”). He found that the accused products infringed the asserted claims of the ‘605 patent; the claims were not invalid by reason of obviousness under 35 U.S.C. § 103, indefiniteness under 35 U.S.C. § 112, or as anticipated under 35 U.S.C. § 102; and the technical prong of the domestic industry requirement was satisfied. However, he found that the economic prong of the domestic industry requirement was not satisfied. Shortly thereafter, the ALJ issued a recommended determination (“RD”) on remedy and bonding in the event the Commission determined to find a violation. Each of the parties filed a petition or contingent petition for review of the final ID.

On March 25, 2013, the Commission determined to review the ID in its entirety and requested briefing from the parties concerning the economic prong of the domestic industry requirement as well as comments on the appropriate remedy, public interest considerations, and

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bonding. Complainant, Respondents, and the Investigative Attorney (“IA”) submitted briefs on April 8, 2013, and briefs in reply on April 15, 2013, concerning the Commission’s questions and remedy, the public interest, and bonding.

Upon review of the ID, the Commission has determined to reverse the ALJ’s conclusion that complainants Standard Innovation (US) Corp. and Standard Innovation Corporation (collectively, “Standard Innovation”) have not satisfied the economic prong of the domestic industry requirement. We further determine to affirm the majority of the ALJ’s conclusions with respect to claim construction, infringement, and validity. With respect to the construction of the claim term “tear-drop shape” in independent claims 1, 33, and 66, we find that the patentee disclaimed round shapes during prosecution of the ‘605 patent, and accordingly modify the construction of the term “tear-drop shape” to exclude a round shape. Applying this revised claim construction, we find that one of Respondents’ accused products, the Picobong Mahana, which has round arms, does not infringe the asserted claims of the ‘605 patent. We affirm the ALJ’s findings that the Respondents’ other two accused products, the Tiani and Tiani 2 products, infringe these claims. We also find that complainant did not waive its allegations concerning infringement and the technical prong of the domestic industry requirement. The Commission hereby adopts all other factual findings of the ID that are not inconsistent with its determinations. Accordingly, the Commission finds that there is a violation of section 337.

The Commission has determined that the appropriate remedy for the violation is a general exclusion order barring importation of infringing articles from all sources and cease and desist orders barring Respondents from further sales and importation of articles that infringe the ‘605 patent. The Commission finds that these remedies will not have an adverse impact on the public

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interest. The Commission has determined to set a bond in the amount of zero percent of entered value for importation of infringing articles during the Presidential review period.

### II. BACKGROUND

#### A. Procedural History

The Commission instituted this investigation on January 10, 2012, based on a complaint filed by Standard Innovation Corporation of Ottawa, ON, Canada and Standard Innovation (US) Corp. of Wilmington, Delaware *77 Fed. Reg.* 1504 (Jan. 10, 2012). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended 19 U.S.C. § 1337, by reason of infringement of certain claims of United States Patent No. D605,779 (“the D’779 Patent”) and the ‘605 patent. The complaint named twenty-one business entities as respondents, several of which have since been terminated from the investigation based upon consent orders or withdrawal of the complaint. On June 28, 2012, the ALJ issued an initial determination granting Standard Innovation’s motion for termination of the investigation with respect to the D’779 patent. The Commission determined not to review that ID.

The ALJ issued the subject final ID on January 8, 2013, and an RD on remedy and bonding on January 22, 2013. On January 22, 2013, Standard Innovation and the IA filed petitions for review of the final ID that challenge the ALJ’s finding that the domestic industry requirement is not satisfied. Respondents filed a contingent petition for review of the final ID on January 22, 2013, arguing that many of the ALJ’s findings with respect to claim construction, infringement, and validity were incorrect. Each of the parties filed a response to the petitions for review on January 30, 2013.

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On March 25, 2013, the Commission determined to review the ID in its entirety and requested briefing from the parties as to four questions concerning whether the economic prong of the domestic industry was demonstrated in this investigation. 78 *Fed. Reg.* 19309 (March 29, 2013). The parties submitted briefs on April 8, 2013, and briefs in reply on April 15, 2013 concerning the Commission's questions and remedy, the public interest, and bonding. The Commission extended the target date for completion of this investigation to June 7, 2013, and again to June 17, 2013.

### **B. Patent and Technology at Issue**

The '605 patent, titled "Electro-Mechanical Sexual Stimulation Device to be Worn During Intercourse," issued on April 26, 2011, to the named inventor Bruce Murison. JX-1 at 2. The '605 patent is assigned to Standard Innovation Corporation. Claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 are at issue in this investigation. Of these, claims 1, 33 and 66 are independent claims.

The field of invention relates to electro-mechanical sexual stimulation devices for use by women either as an auto-erotic aid or during intercourse. According to the '605 patent's Summary of the Invention, the sexual stimulation devices at issue are generally U-shaped and have inner and outer arms joined together by a connecting arm. The inner arm (*i.e.*, the smaller arm) of the device is sized to be inserted into the vagina so that it contacts the wall of the vagina at or near the G-spot during intercourse. *See* '605 Patent, 2:13-20. The outer arm is sized to contact the clitoris during intercourse. *Id.* The C-shaped member that connects the two arms is slender and resilient, which enables it to be worn during intercourse. Further, both the inner and outer arms may contain a vibrator to stimulate the clitoris, the G-spot, and the vagina



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simultaneously. ID at 9-10. The patentee asserts that the claimed device is the first to allow use during intercourse because the inner arm is dimensioned to permit a male member to enter the vagina while the device is in use. *See* '605 Patent, 2:2-20.

### C. Products at Issue

Standard Innovation accused three Lelo products: Insignia Tiani, Insignia Tiani 2, and Picobong Mahana (“accused products”). ID at 9. The We-Vibe (original), We-Vibe II, and We-Vibe 3 are Standard Innovation’s products offered to satisfy the technical prong of the domestic industry requirement.

## III. DISCUSSION

### A. Claim Construction

The parties dispute three claim construction issues in their petitions for review:

(1) whether the preamble of independent claims 1, 33, and 66 is limiting; (2) whether the claim term “generally tear-drop shaped” excludes hook, round, or bulbous shapes; and (3) the proper construction of “intercourse.” Having considered the ALJ’s findings in the ID and the arguments of the parties in the petitions for review and the responses thereto, the Commission has determined to affirm the ALJ’s findings and conclusions with respect to the issues of the preamble as a claim limitation and the claim construction of “intercourse” for the reasons stated in the ID.<sup>1</sup> With respect to the issue of the proper construction of “generally tear-drop shaped,” the Commission affirms the ID’s findings and conclusions as modified below.

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<sup>1</sup> Respondents’ argument that the preamble merely states a purpose or intended use of the invention is incorrect as the preamble provides more than mere purpose, but rather provides structure. *See Catalina Mktg. Int’l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002). Specifically, the invention must be properly sized to be used during intercourse. ‘605 Patent, 7:21-29, 58-60; 8:4-8, 10.

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Independent claims 1, 33, and 66 provide as follows (disputed terms in bold):

1. 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**.

'605 patent, col. 10, lines 24-37.

33. 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;

wherein said connecting portion which has a width which is equal to or greater than its thickness to minimize obstruction to the vaginal opening; and

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

'605 patent, col. 11, lines 44-59.

66. 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 at least one of the arms tapers down toward said connecting portion; and

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

'605 patent, col. 11, lines 44-59.

Claims 1, 33, and 66 recite “at least one of the inner and outer arms are [sic] generally tear- drop shaped.” Before the ALJ, the parties generally agreed that the “generally tear-drop shaped” limitation “has a plain and ordinary meaning and requires no construction.” ID at 43-44. Respondents contended, however, that the applicant disclaimed “bulbous,” “round,” and “hook” shapes from this limitation during prosecution. Based on his review of the relevant portions of the prosecution history, the ALJ disagreed with Respondents’ argument. He explained that the examiner rejected then pending claims 19, 20, 21, and 22 under 35 U.S.C. § 102 over the Sekulich reference. In response to the rejection, the applicant argued that Sekulich’s device did not anticipate the claims because it was “clearly the wrong shape, located in the wrong position and used in the wrong way to be worn during intercourse.” JX-2, at 349-50 (Amendment dated April 29, 2012). The applicant continued:

[The anterior shaft of Sekulich] is phallus shaped. This means that the shaft is generally round until almost the very end which is provided with a bulbous head. A lip projects between the bulbous head and the round shaft. This phallus shape is completely unsuitable for accommodating a man's member and is opposite of the Applicant's claimed shape.

JX-2, at 349-50. The applicant further distinguished the phallic shape by contending that:

[T]he rounded shaft provides no surface against which the male member can slide, because it is the wrong shape. The rounded shaft of Sekulich would tend to be displaced to one side or the other, displacing the man's member to one side or the other, making the act uncomfortable for both man and woman. Furthermore, the projecting lip would act as an irritant on the sensitive male member. Lastly, the in and out motion of the man during intercourse would cause the Sekulich device to also move in

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and out as the Sekulich device is not shaped to be retained out of the way during intercourse ....

JX-2 at 350. The ALJ found that this language falls “far short” of disclaiming bulbous or round shapes. ID 46 (citing JX-2 at 350).

The ALJ also concluded that hook shapes were not disclaimed. With respect to the Marshall reference, the ALJ noted that the ‘605 patent applicant had stated:

Marshall's teaching is exactly opposite to Applicant's invention as claimed, by teaching that the comparable middle portion of the Marshall device is thicker and provides penetrative stimulation by reason of its thicker distal end.

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As shown, Marshall teaches a re-entrant hook shape 5 ... for contacting the G-spot of the woman using the device. However, as can be understood, the hook shape, to apply pressure to the G-Spot, spaces the penetrative shaft portion outwardly away from the anterior surface of the vagina. Thus, by definition, the shaft portion will be blocking more of the vaginal passage, directly opposite to the applicant's claimed invention. Furthermore, in use, the Marshall device positions a middle portion of the device against a far side of the vaginal opening, blocking the vaginal opening.

JX-2 at 291 (Response to Office Action dated January 7, 2009) (emphasis added). The ALJ found that these passages reveal that use of hook-shape arms, in conjunction with the thicker middle portion of the Marshall device that connects them, teach away from the present invention as it would cause blockage of the vaginal passage thus preventing its use during intercourse. ID at 47. The ALJ noted that Dr. Herbenick testified that “[i]t is not the hook that's the problem. It's the hook in the context of this device as a whole with a large connecting portion that obstructs the vaginal opening with a rigidity that would function to push away ....” Tr. 412:20-

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413:6. Accordingly, he found that Respondents did not show disclaimer of hook shapes. ID at 47.

Respondents argue that the ALJ erred by using a circular definition of “generally tear-drop shaped.” They claim that the ALJ’s definition was improper because it provides no structure for understanding the shape other than using the same terms as those intended to be defined. Respondents’ Petition at 14-15. Moreover, they contend that the ALJ misunderstood Respondent’s position with respect to the term, and they did not agree with the other parties concerning the term’s definition. *Id.* at 15-16. Respondents assert that they construed “tear-drop shaped” to be “having a globular form at the bottom, tapering to a narrower portion at the top.” *Id.* at 16. Respondents further argue that the ALJ erred by not providing a definition because Standard Innovation’s experts provided several different definitions. *Id.* at 15.

Respondents further assert that the ALJ erroneously held that the prosecution history did not show a disclaimer of bulbous, round, and hook shapes. Respondents criticize the ALJ’s finding that the applicants did not disclaim bulbous shapes when addressing the Sekulich reference, noting that he provided no analysis for his conclusion that the language was “far short” of a disclaimer. *Id.* at 20. Further, Respondents maintain that the ALJ did not address the alleged disclaimer of the “bulbous” inner arm shown in Kain (RX-2) from the term “generally tear-drop shaped” as a result of the interview between applicant’s attorney and the examiner. *Id.* at 21-22. Respondents also contend that the ALJ erred in rejecting their argument that the applicant disclaimed a hook-shaped inner arm in order to overcome the Marshall reference. They assert that the ALJ’s conclusion that it was not disclaimed, and that Marshall was

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distinguished on the basis that it blocked the vaginal opening, was erroneous because it ignored the prosecution history and the background section of the '605 patent. *Id.* at 2-24.

Standard Innovation contends the ALJ correctly found that the term “generally tear-drop shaped” should be given its plain and ordinary meaning. It argues that Respondents are wrong that the ALJ avoided construing the claim term “generally tear-drop shaped” by finding that the term should be given its plain and ordinary meaning. It contends that Respondents argued below for “looking like a tear drop, which is a 3-dimensional figure,” a definition not inconsistent with that adopted by the ALJ. Standard Innovation’s Response at 11. It thus maintains that there was no real dispute over the meaning of generally tear-drop shaped. *Id.*

Standard Innovation further argues that for the doctrine of prosecution history disclaimer to attach, the patentee must have unequivocally disavowed a certain meaning to obtain his patent. *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-24 (Fed. Cir. 2003). Standard Innovation argues that no such disclaimer was shown. Standard Innovation’s Response at 13. With respect to bulbous and round shapes, it argues that Respondents ignore the full context in which “unsuitable” and “wrong shaped” were used, including the very specific shape those words modified – a *phallus-shaped* inner arm which would block intercourse. *Id.* at 13-14.

The IA agrees with the ID’s construction of “generally tear-drop shaped.” She maintains that contrary to the Respondents’ position, there is no requirement that the ALJ construe a claim beyond giving the term its plain and ordinary meaning and no construction was necessary. Hence, the plain and ordinary meaning was the appropriate definition in her view. The IA asserts that the prosecution history does not reflect a clear disclaimer, but if there was any disclaimer, the applicant disclaimed a phallus shaped shaft. When referring to “the rounded

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shaft” and a “bulbous head,” the applicant referenced a “phallus shape” which is “completely unsuitable” for the invention. IA’s Response at 10.

Having considered the parties’ arguments, and upon review of the claim language, the specification, and relevant portions of the prosecution history, we affirm the ALJ’s reliance on the plain and ordinary meaning of “tear-drop shaped” and affirm the ALJ’s finding that the patentee did not disclaim bulbous or hook shapes during prosecution of the ‘605 patent. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1316-17 (Fed. Cir. 2005) (en banc) (Claim terms are interpreted as they would be understood by a person of ordinary skill in the art in the context of the intrinsic evidence, consisting of the claims, the specification, and the prosecution history, if in evidence, and relevant extrinsic evidence of the meaning of the claim to a person of ordinary skill in the art.). However, as explained below, we find that the applicant disclaimed a round shaped arm during prosecution.

First, we find that the ALJ appropriately relied on the ordinary definition of “tear-drop shaped” because the term is within common knowledge and sufficiently clear on its face so that no further explanation for the meaning of the term was warranted. Respondents’ expert’s definition (“looking like a tear drop, which is a 3-dimensional figure”) is consistent with the ALJ’s view that no further explanation was needed. *See* RX-196C Q/A 78. As Respondents failed to show any genuine dispute as to the meaning of “generally tear-drop shaped,” we find construction of the term was unnecessary.

We also affirm the ALJ’s finding that the patentee did not disclaim “bulbous” shapes during prosecution of the ‘605 patent. The patentee did not criticize bulbous shapes in general. Rather the prosecution history shows that the applicant distinguished a phallus shape with a lip

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as an inappropriate shape for the claimed invention because it would be irritating during intercourse. *See* JX-2 at 350 (“Furthermore, the projecting lip would act as an irritant on the sensitive male member.”). The ‘605 patent’s first preferred embodiment also describes the teardrop shaped pad of the inner arm as “bulbous,” suggesting that a bulbous shape was not disclaimed during prosecution. ‘605 Patent, 3:12 (“an inner arm 1 that terminates in a bulbous teardrop-shaped pad”). Claim terms are typically not interpreted in a way that excludes embodiments disclosed in the specification. *See Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed.Cir.2007) (rejecting proposed claim interpretation that would exclude disclosed examples in the specification). We also note that the evidence relied upon by Respondents consisted of deposition testimony that was not part of the prosecution history and was not pertinent to disclaimer. Contingent Petition at 21 (quoting RX-0034C, at 0091:19-24).

With respect to the alleged disclaimer of hook-shape arms, the ALJ found that the patentee had explained during prosecution that a hook shape, along with a thicker middle portion, would block the vaginal passage and prevent the device’s use during intercourse. ID 46. We do not find that the cited portions of the specification and prosecution history (JX-2 at 291-292 and ‘605 Patent, 1:41-60) indicate the patentee disclaimed coverage of hook shapes as argued by Respondents. Rather, the patentee indicated that the Marshall device was unsuitable for use during intercourse because its shaft portion blocked the vaginal passage and it narrowed from the proximal to the distal portion of the arm, the opposite of the invention described in the ‘605 patent. JX-2 at 291-92.

On the other hand, we find that the patentee’s discussion of the problems with a round shaft do rise to the level of prosecution history disclaimer. A patentee must have unequivocally



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disavowed a certain meaning to obtain his patent. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-24 (Fed. Cir. 2003). According to the patentee, it was the roundness of the phallic shape that was most problematic about the Sekulich device even though it is “small in diameter.” JX-2, at 349. The applicant stated during prosecution that:

the rounded shaft provides no surface against which the male member can slide because it is the wrong shape. The rounded shaft of Sekulich would tend to be displaced to one side or the other displacing the man's member to one side or the other making the act uncomfortable for both man and woman.

JX-2 at 350. He went on to note that the lip would also be irritating, making a phallus shape unsuitable. Although the statements most clearly refer to the phallus shape, the patentee's explanation emphasizes the “rounded shaft” of the phallus shape that renders the Sekulich device unsuitable. We find that, with these statements, the patentee relinquished claim scope with respect to round arms, and therefore a “generally tear-drop shaped” arm does not include a round arm.

Further, we affirm the ALJ's finding that Respondents have not proven that the claim term “tear-drop shaped” is indefinite under the ALJ's construction. The ALJ found that the meaning of “generally tear-drop shaped” is clear on its face and the specification provides sufficient explanation for the meaning of generally tear-drop shaped arms (*see, e.g.*, '605 Patent, Figs. 1-5). In addition to these figures, the specification discusses the shape of the arms of the device. *See* '605 Patent, 2:25, 3:12. Thus, the term “generally tear-drop shaped” has not been shown to be indefinite.

### **B. Infringement**

The ID found that Respondents' products infringe the asserted claims of the '605 patent.

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Specifically, the ALJ found that the Tiani infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90; that the Tiani 2 infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90; and that the Picobong Mahana product infringes claims 1-7, 12-19, 24, 33, 35-40, 45-49, 52-54, 57, 66-73, 78-82, 85-87, and 90. Respondents petition for review of these findings.

Direct infringement of a patent under 35 U.S.C. § 271(a) consists of making, using, offering to sell, or selling a patented invention without consent of the patent owner or importing a patented invention into the United States without consent of the patent owner. Section 337 prohibits “the importation into the United States, the sale for importation, or the sale within the United States after importation . . . of articles that infringe a valid and enforceable United States patent . . . .” 19 U.S.C. § 1337(a)(1)(B)(i).

A determination of patent infringement encompasses a two-step analysis. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). First, the scope and meaning of the asserted patent claims are determined, and then the properly construed claims are compared to the allegedly infringing device. *Id.* Each patent claim element or limitation is considered material and essential to an infringement determination. *See London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). “Literal infringement of a claim exists when each of the claim limitations reads on, or in other words is found in, the accused device.” *Allen Eng. Corp. v. Bartell Indus.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). To prove direct infringement, the complainant must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device either literally or under the doctrine of equivalents. *Scimed*, 261 F.3d at 1336. In a section 337 investigation, the

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complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998). Applying the same analysis, complainant bears the burden of establishing that its products practice one or more claims of the asserted patents. The test for satisfying the “technical prong” of the industry requirement is essentially the same as that for infringement, *i.e.*, a comparison of the claim to the product or activity relied on to satisfy the domestic industry requirement. *See Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1367-68, 1375 (Fed. Cir. 2003).

### 1. **Standard Innovation Did Not Waive Its Arguments Regarding Infringement**

Although the ALJ found that the IA proved infringement, *see infra*, the ALJ ruled that Standard Innovation waived its infringement allegations because it had not adequately addressed infringement in its post-hearing brief in violation of his ground rules. ID at 49. The ALJ noted that Standard Innovation’s post-hearing brief contained “non-specific string citation to the record fail[ing] to provide factual support for its allegations that the accused products infringe any claim of the ‘605 patent.” *Id.* at 48. He found that Standard Innovation's citation to nearly two hundred pages of documentary evidence did not explain how those pages relate to any limitation of the numerous asserted claims. He characterized Standard Innovation's string citation as an attempted “end run” around the page limit to allow a disproportionate 28 pages of briefing directed to the economic prong of domestic industry. *Id.* at 49 n.4. With respect to Standard Innovation's citation to demonstrative exhibits, the ALJ indicated that demonstratives are not

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evidence and Standard Innovation did not explain how these demonstratives relate to any limitation of the numerous asserted claims. *Id.* at 48-49.

Standard Innovation argues that the ALJ erred in finding that it had waived its infringement arguments. It contends that because these issues were largely uncontested, it was appropriate for it to limit its discussion of infringement to those issues raised in Respondents' post-hearing brief. It notes that the Commission has recognized that, although an ALJ's Ground Rules for managing the proceedings before him are important, extensive detailed discussion is not necessary where an issue is uncontested. Standard Innovation's Petition at 52-53, 55 (citing *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, Comm'n Op. at 13-14, 15 (June 5, 2012) (reversing ALJ's finding of waiver) ("*Certain Mobile Devices*")).

Standard Innovation argues that the ALJ's criticism that Standard Innovation devoted "no more than one page" to the discussion of infringement is wrong, and ignores the previous discussion relating to the only disputed issue, prosecution history disclaimer, which pertains to both infringement and the technical prong of the domestic industry requirement. Further, it contends that its citations were not aimed at making an end run around the page limitation. By providing these citations, Standard Innovation argues that it provided factual support for its allegations of infringement and was in direct response to the ALJ's repeated requests that the parties focus their briefing on areas of real dispute and on issues of concern to the ALJ. Standard Innovation's Petition at 25-27, 56-57.

Respondents support the waiver finding but contend that OUII's ("the Office of Unfair Import Investigations") arguments cannot cure the waiver. Thus, it was error for the ALJ to find

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infringement established, according to Respondents, as the IA's brief cannot resurrect a waived argument. Respondents argue that while OUII participates as a party in a section 337 investigation, in that it engages in discovery and it takes positions on the issues, its function is merely advisory, and it does not substitute for the complainant or any other party. They argue that it does not propound claims or carry the burden of proof on issues relating the violation of section 337 and it cannot substitute for either party in meeting their respective burdens of proof. Respondents' Contingent Petition at 27-28.

The IA argues that the ID's finding that Standard Innovation had waived its affirmative case was legal error. Given that the issue of infringement was unrebutted and that the record contained ample evidence establishing infringement, the IA argues that the ID incorrectly found that Standard Innovation waived infringement. IA's Response at 25, 33-34. The IA states that in *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, USITC Pub. 4384, Comm. Op. at 13-15 (June 2012), the ID found that the complainants had waived infringement because their entire direct infringement case was no more than "three conclusory sentences." The Commission reversed the ALJ, finding that there was no waiver because the issue of infringement was uncontested and the record provided ample evidence of infringement. IA's Response at 25-26.

The IA also takes issue with Respondents' position that the IA cannot cure Standard Innovation's waiver. It argues that it is well-established that the IA is an independent third party that represents the public interest in 337 investigations. IA's Response at 13 (citing *Certain NAND Flash Memory Circuits and Products Containing Same*, 337-TA-526, Initial Determination, at 8 (Dec. 2006); 19 C.F.R. § 210.3 ("Party means each complainant, respondent,

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intervenor, or Commission investigative attorney’)). Thus, it was entirely appropriate for the ALJ to rely on the IA’s briefing in support of his infringement determinations. IA’s Response at 14.

While we recognize the importance of the ALJ’s ground rules, we do not find, under the facts of this case, that complainant waived its infringement arguments. Aside from claim construction, infringement was uncontested by the time of the post-hearing brief, and Standard Innovation had briefed satisfaction of each claim limitation with respect to the accused products in its prehearing brief. Complainant also presented its infringement allegations in its post-hearing brief, albeit briefly, to the extent it was contested, and provided sufficient citations to uncontested facts in the record to support its allegations. Under similar circumstances in *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, USITC Pub. 4384, Comm. Op. at 13-15 (June 2012), we reversed the ALJ’s finding of waiver. Compare *Certain Automated Media Library Devices*, Inv. No. 337-TA-746, Comm’n Op. at 51-56 (Nov. 19, 2012) (reversing finding of waiver when issue was uncontested) with *Certain Static Random Access Memories and Products Containing Same*, Inv. No. 337-TA-792, Comm’n Op. at 27 (June 7, 2013) (affirming ALJ’s finding of waiver when party failed to fully brief contested issue). We therefore find that the complainant did not waive its allegations concerning infringement.

### 2. Infringement of the Asserted Claims

The ALJ found that the IA provided sufficient evidence that each limitation of the asserted claims was satisfied, but he did not address the limitations separately. He rejected Respondents’ only argument that the accused products do not infringe independent claims 1, 33,

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and 66 because they do not meet the limitation “wherein, at least one of the inner and outer arms are generally tear-drop shaped” because bulbous, hook, and round shafts were disclaimed. ID at 49.

Respondents contest infringement on the basis of their proposed claim construction. They state that the Picobong Mahana is round and would be displaced during intercourse. Resp. Pet. at 32- 33. They also argue that the Tiani and Tiani 2 have hook-like arms that are bulbous, and since the patentee disclaimed these shapes during prosecution, these two accused products do not satisfy the tear-drop shape limitation. Resp. Pet. at 30-31. Complainant and the IA argue that under the proper claim construction, infringement is demonstrated.

As discussed above, infringement was uncontested with the exception of Respondents’ arguments under their alternative claim constructions. We have affirmed the ALJ’s claim construction of “generally tear-drop shaped” (with the exception of disclaimer of round-shaped arms) and therefore affirm the ALJ’s finding that the Lelo Tianai and Lelo Tiani 2 infringe the asserted claims of the ‘605 patent. As we have explained, the patentee disclaimed round-shaped arms during prosecution. As a result, the tear-drop shaped claim limitation does not read on a round-shaped arm. It was undisputed before the ALJ that Lelo’s Picobong Mahana has two round arms. Tr. at 532 (Villarraga); Tr. at 389 (Herbenick). We therefore find that the Picobong Mahana does not infringe the asserted claims of the ‘605 patent.

### **C. Validity**

#### **1. Anticipation**

Three prior art patents, Mitchener, Utime, and Kain were alleged to anticipate the asserted claims of the ‘605 patent. We affirm the ALJ’s determination that Respondents failed to

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prove by clear and convincing evidence that the asserted claims of the '605 patent are invalid for anticipation as none of the three references disclose the preamble limitation of a device "dimensioned to be worn by a woman during intercourse." In fact, the record indicates, as the ALJ found, these devices are not designed for use during intercourse and no evidence was cited that they are dimensioned for that purpose.

### 2. Obviousness

Respondents argue that the claims of the '605 Patent are obvious because the prior art references disclose "generally tear-drop shaped" arms and the examiner found all the other limitations of the independent claims present in the prior art with exception of the tear-drop shaped arm limitation.<sup>2</sup> We affirm the ALJ's determination that, regardless of the "tear-drop shape limitation," neither Mitchener, the Ultime, or Kain teach a sexual stimulation device dimensioned to be worn by a female during intercourse, as required by the asserted claims. ID at 60.

Respondents also raised a new argument in their contingent petition for review. They contend that the independent claims of the '605 patent are obvious in light of Sekulich in combination with Mitchener, Ultime or Kain. Respondents' Contingent Petition at 44-45. However, arguments not raised below may not be raised in a petition for review to the

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<sup>2</sup> We reject Respondents' argument that the ALJ abused his discretion by striking portions of Dr. Locker's direct testimony (Q/A 192-198 and 348-420) because they were not properly supported in her initial expert report, relying on a claim chart attached to Dr. Locker's expert report. Respondents have not shown that the ALJ abused his discretion because the expert report did not provide notice that she would offer opinions on obviousness in violation of the ALJ's Ground Rule. *See* Ground Rule 10.5.6 ("An expert's testimony at the trial shall be limited in accordance with the scope of his or her expert report(s)."). Respondents' assertions to the contrary do not identify specific obviousness opinions in Dr. Locker's expert report. Thus, we affirm the ALJ's decision in Order No. 38 to exclude the testimony.



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Commission. The Commission therefore finds this argument waived as it was not raised before the ALJ. See *Hazani v. United States Int'l Trade Comm'n*, 126 F.3d 1473, 1476-77 (Fed. Cir. 1997) (argument presented for first time in petition for reconsideration is waived).

### D. Domestic Industry

#### 1. The Complainant Has Established the Economic Prong of the Domestic Industry Requirement

The domestic industry requirement of section 337 is set out at section 337(a)(2) and (a)(3). 19 U.S.C. § 1337(a)(2), (a)(3). Section 337(a)(2) provides:

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) [concerning violations of section 337] apply only if an industry in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

Section 337(a)(3) provides:

(3) [A]n industry in the United States shall be considered to exist if there is in the United States, with respect to articles protected by the patent . . . concerned –

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

The Commission has divided the domestic industry requirement into an economic prong (which requires certain activities and investments) and a technical prong (which requires that these activities and investments relate to the article covered by the intellectual property being protected), such that an industry must exist or be in the process of being established. 19 U.S.C. § 1337(a)(2), (a)(3); see, e.g., *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. 3003, Comm'n Op. at 14-17 (Nov. 1996) (“*Wind Turbines*”).

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I"). Under the definitions of section 337(a), an industry exists if there is, with respect to articles protected by the patent, "significant investment in plant and equipment," "significant employment of labor or capital," or "substantial investment in [the patent's] exploitation, including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3)(A), (B)-(C).

The ALJ found the economic prong of the domestic industry requirement was not satisfied and, as a result, found no violation of section 337. ID at 65-78. As explained below, the Commission finds that the economic prong has been satisfied.

Although complainant's product, the We-Vibe, is assembled in China, Standard Innovation, in its economic prong arguments, relied upon investments in four crucial components that are manufactured in the United States and used in the production of the We-Vibe. ID at 71. The ALJ considered Standard Innovation's purchase of these U.S. manufactured components in analyzing whether such investments satisfy the domestic industry requirement.<sup>3</sup> *Id.* First, the ALJ noted that Standard Innovation spent \$[ ], manufactured by [ ], from 2008 to November 2011. This product is used to create a smooth and even finish that was found critical to the product. *Id.* at 71-72. Second, the ALJ found that [ ] and manufactured by [ ], was critical to the We-Vibe. Standard Innovation spent \$[ ] from 2008 to November 2011 on [ ]. ID at 72. Third, Standard Innovation purchased microcontroller parts for the We-Vibe 2 and both a

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<sup>3</sup> The ALJ also concluded that activities related to the original version of the We-Vibe could not be considered because, as he explained, the statute is written in the present tense, the original We-Vibe was not sold after 2009, and a product that has not been sold for two years before the filing of the complaint is not persuasive evidence of the existence of a domestic industry. The ID is unclear as to the effect, if any, of this finding as the ALJ appears to have considered the expenses related to the original We-Vibe. *See* ID 72, 75 nn.13-14, 18.

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microcontroller part and DC to DC converter from [ ] for the We-Vibe 2 and We-Vibe III products; these components run the vibrator motor. *Id.* He credited 80 percent of the manufacturing costs of these parts to account for the portion of the manufacturing that occurs in the United States. *Id.* He thus found \$[ ] of the microcontroller parts expense eligible to be attributed to Standard Innovation's domestic industry. *Id.*

The ALJ explained that these three components directly related to the claimed features of the '605 patent. He also found that the components were critical to the function of the We-Vibe.<sup>4</sup> ID at 73. Nonetheless, the ALJ stated that "Standard Innovation failed to explain how these expenditures relate, in any way, to an investment in plant or equipment by Standard Innovation, its manufacturer, or the manufacturer of the components. Accordingly, there is absolutely no basis for me to attribute these expenses to prong A." *Id.* at 73-74 (citation omitted).

The ALJ rejected the IA's argument that these component expenses can be attributed to prong C (as opposed to prong A) and found that "the Staff does not address how the purchase of U.S. manufactured component parts, even if critical to the success of the domestic industry products, is relevant to prong C."<sup>5</sup> ID at 74. He noted that Standard Innovation provided only the total amount it spent on such components and did not break out any engineering or research and development costs incurred by the manufacturer of these products. Thus, he did not consider the purchase of these components as pertinent to engineering or research and development activities

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<sup>4</sup> The ALJ also examined an expense of \$[ ] for another component, a silicone pigment purchased for the We-Vibe II, but declined to consider this expense in connection with prong C because it "does not directly relate to the '605 patent." ID at 73

<sup>5</sup> The ALJ also rejected investments in the components [ ], and the silicone color pigments because they were selected due to their suitability for the We-Vibe products rather than developed for use in the We-Vibe. ID 74.

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relevant to prong C. *Id.* at 74. Similarly, the ALJ found that, with respect to the components from [ ], Standard Innovation provided the total amount it spent on such components but did not break out any engineering or research and development costs incurred by [ ], and therefore the ALJ did not allocate the expense to prong C. *Id.* at 75.

The ALJ found that, even if it were proper to consider the identified expenses in assessing the domestic industry requirement, they were not “substantial or significant.” *Id.* He noted that Standard Innovation’s expenses for U.S. manufactured components totaled \$[ ] from 2008 until the filing of the complaint. *Id.* However, he indicated these expenses were slightly less than 5 percent of the total cost of the We-Vibe products. *Id.* Further, on a per unit basis, he found that the U.S. component expense was \$[ ] out of the total raw product cost of \$[ ]. *Id.* at 76. He found that “[t]he \$[ ] cost of components supplied by U.S. companies is really only around [ ]% of the total product revenue.” *Id.* at 75. In addition, the ALJ found unpersuasive Standard Innovation’s argument that an approximately \$[ ] investment is large based on its size and stated that Standard Innovation did not quantify its size. *Id.* at 76. He stated that Standard Innovation has experienced “tremendous sales growth,” selling [ ] We-Vibe products in 2010, which in his view suggested it is not a startup company. *Id.* In this context, he found the \$[ ] investment was not large enough to find a domestic industry.<sup>6</sup> *Id.* at 76-77.

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<sup>6</sup> The ALJ rejected Standard Innovation’s other expenses, which were related to the marketing and sales of the domestic products, warehousing, customer support, and unquantified research and development/engineering costs for the We-Vibe devices, as not appropriate to consideration of prong A or B under the facts of this case. *ID* at 77-78.

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Standard Innovation and the IA petitioned for review of the ALJ's determination that the economic prong of the domestic industry requirement was not met. Standard Innovation argues the ALJ erred in finding that it did not have a domestic industry under the statute. It contends that domestic production-related activities are not required since the 1988 amendments. Standard Innovation's Petition at 10-11. It claims that foreign production can satisfy the requirement if coupled with activities and investments in the United States. *Id.* at 11 (citing *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, USITC Pub. 2978, Unreviewed ID at 124 (July 1996)). It also contends that the analysis of the economic prong of the domestic industry should be focused on the realities of the marketplace and not be "overly rigid." *Id.* at 12. Standard Innovation also alleges several specific errors by the ALJ.

The IA likewise takes the position that the ALJ applied an overly rigid standard in assessing the domestic industry requirement and determining that expenditures relating to Standard Innovation's purchases were insufficient to satisfy the economic prong. The IA asserts the ID therefore improperly concluded that Standard Innovation did not satisfy the domestic industry requirement. IA's Petition at 6.

Respondents support the ALJ, arguing that he correctly found that Standard Innovation has not demonstrated the existence of a domestic industry under the statute. They argue that the activities of Standard Innovation are the same as are undertaken by any typical importer and the determination that there is no domestic industry in this case is correct and compelled by the record. Respondents' Response at 1. Respondents argue that Standard Innovation has failed to satisfy the domestic industry requirement because it did not quantify the amounts spent on

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research and development, plant and equipment, labor, or capital by the subcontractors who produced purchased components. Respondents' Pet. Resp. at 7-9.

In addition to Standard Innovation's and the IA's petitions for review and the Respondents' response thereto, the parties filed submissions in response to four questions posed by the Commission in its March 29, 2013 notice of review.

Two main issues are raised by the petitions: (1) the extent to which a domestic industry can be based on expenditures in components produced by a domestic subcontractor; and (2) whether the relative contribution of domestic and foreign inputs or the value-added analysis shows that Standard Innovation has made a substantial or significant investment in labor, capital, plant, or equipment. As we explain below, after considering the record in this investigation, the ALJ's factual findings in the ID, and the parties' submissions, we reverse the ALJ's determination and find that Standard Innovation has satisfied the domestic industry requirement based on its expenditures on components produced domestically that are critical to the We-Vibe.

As a threshold matter, we find that, consistent with Commission precedent, the ALJ correctly found 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. *See, e.g., Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007) (noting activities to be considered may include those of a complainant's subcontractor); *Certain Home Vacuum Packaging Products*, Inv. No. 337-TA-496, USITC Pub. 3681, ID at 143 (December 17, 2003) (unreviewed in relevant part by Notice, Jan. 22, 2004) (complainant subcontracted for engineering services). The Commission has specifically credited complainants' investments in U.S. manufactured components used in the production of articles

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protected by the patents. *See e.g., Certain Cold Cathode Fluorescent Lamp ("CCFL") Inverter Circuits and Products Containing Same*, Inv. No. 337-TA-666, unreviewed ID at 5 (Sept. 22, 2009) (subcontracted wafer production for use in inverter circuits); *Certain GPS Chips, Associated Software and Systems, and Products Containing Same*, Inv. No. 337-TA-596, unreviewed ID at 16 (Feb. 27, 2008) (subcontracted RF chips that are assembled with other components); *Certain Portable On-Car Disc Brake Lathes and Components Thereof*, Inv. No. 337-TA-361, ID at 17-18 (August 12, 1994) (unreviewed in relevant part by Notice, Oct. 5, 1994) (subcontracted component manufacture and assembly); *Certain Bag Closure Clips*, Inv. No. 337-TA-170, unreviewed ID at 39 (1984) (same). Indeed, 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.

However, the ALJ rejected reliance on such components in this investigation based on several grounds, including: (1) failure to demonstrate that the components were specifically designed or customized for the We-Vibe; (2) they were not relevant to the '605 patent; (3) there was no clear allocation of expenses under prongs A, B, and/or C; and (4) timing of the claimed investments.

As discussed above, although the ALJ found that three components – [ ], and microcontrollers and related parts -- were critical to the complainant's products and related to claimed features of the '605 patent, he declined to credit expenditures for those components because Standard Innovation had not shown these components were developed or customized for use with the We-Vibe. ID at 74-75. However, there is no requirement that the components must be developed or produced specifically for the domestic industry products. The

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statute indicates that the domestic industry has to exist “with respect to the articles protected by the patent.” 19 U.S.C. § 1337(a)(3). Requiring 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. Here, complainant has established that the components were critical for the We-Vibe, which the ALJ found to be protected by the patent. This is sufficient for us to consider the component expenses in our economic prong analysis. Moreover, 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.

The ALJ also declined to credit complainant’s investments in pigments for the We-Vibe 2 because the color of the We-Vibe 2 does not relate directly to a claimed feature of the ‘605 patent. ID at 73. In our view, the ALJ’s position is inconsistent with the precedent he relied upon, *Concealed Cabinet Hinges*, and is unduly restrictive. In *Concealed Cabinet Hinges*, the Commission took into account in its domestic industry analysis a nonpatented component, which was an optional addition to the imported finished hinges. While according them reduced weight, the Commission did not find the expenditures irrelevant. *Certain Concealed Cabinet Hinges and Mounting Plates*, 337-TA-289, Comm. Op. at 23 (Jan. 9, 1990). Here, the record indicates that, in order for the We-Vibe to be commercially marketable, complainant required the use of certain pigments that [ ], which is an important feature of the device. CX-280C Q. 118; See ‘605 patent, 10:19-20 (indicating skin must be “glass smooth to minimize friction”). Thus, we find that Standard Innovation’s expenditures on pigments were relevant to demonstration of a domestic industry in articles protected by the patent.



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With respect to qualifying component expenditures, the ALJ rejected Standard Innovation's expenditures because it did not identify what portion of total expenditures were attributable to the subcontractors' engineering or research and development costs, and as a result, he declined to consider the expenditures of approximately \$[ ] to be relevant to domestic industry. ID at 74-75. We disagree with the ALJ's conclusion on this point. Commission precedent does not require an accounting of subcontractors' expenditures by statutory category for the domestic industry analysis. The Commission has allocated the entire amount of a complainant's purchases from U.S. subcontractors to the domestic industry in past investigations. *See Certain Home Vacuum Packaging Products*, Inv. No. 337-TA-496, USITC Pub. 3681, ID (Order No. 36) at 143 (December 17, 2003) (unreviewed in relevant part by Notice, Jan. 22, 2004) (subcontracting engineering services); *Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, unreviewed portion of Initial Determination at 142 (Dec. 8, 1989). In fact, in *Carbonated Candy*, the only relevant domestic activities were those of a U.S. subcontractor, and the Commission did not require a specific allocation of the subcontractor's expenditures relating thereto.<sup>7</sup> Therefore, we consider the complainant's investments in components critical to the We-Vibe and related to the claims of the '605 patent despite Standard Innovation's lack of evidence concerning its subcontractors' expenditures for plant and equipment under prong A and labor and capital under prong B.<sup>8</sup> We further find that the

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<sup>7</sup> See also *Certain GPS Chips, Associated Software and Systems, and Products Containing Same*, Inv. No. 337-TA-596, Order No. 37 at 16 (Feb. 27, 2008) (unreviewed); *CCFL*, Inv. No. 337-TA-666, Order No. 30 at 5-6 (Sept. 22, 2009) (unreviewed); *Certain Portable On-Car Disc Brake Lathes*, Inv. No. 337-TA-361, Initial Determination at 17-18 (unreviewed in relevant part) (1994).

<sup>8</sup> Standard Innovation argues that a variety of other activities are relevant to the establishment of the domestic industry under prong C. These expenses primarily relate to sales

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amounts spent to purchase the domestic 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 because the components were manufactured in the United States for incorporation into articles protected by the patent, even if the purchase price arguably includes other costs incurred by the subcontractors.<sup>9</sup>

We also disagree with the ALJ's refusal to consider expenditures related to the original We-Vibe because they occurred more than two years prior to the filing of the complaint.<sup>10</sup> ID at 71. His rationale was that these expenditures are unrelated to the *current* existence of a domestic industry. *Id.* Taken to its logical extreme, however, this would mean that only expenditures made on the day the complaint is filed should be relied upon. The record indicates that while the product updates to the We-Vibe added new features, the fundamental product did not change in any way relevant to the patented features. As the We-Vibe is Standard Innovation's flagship product that continued to be developed and refined in the We-Vibe II and We-Vibe 3, we deem expenses relating to the original We-Vibe to be relevant to domestic industry.<sup>11</sup>

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and marketing and are not the sort of expenditures that the Commission has considered sufficiently related to the claims of the patent. The Commission and the Federal Circuit have generally treated these activities as no different from those of an importer. *See Schaper Mfg. Co. v. U.S. Int'l. Trade Comm'n* 717 F.2d 1368, 1373 (Fed. Cir. 1983).

<sup>9</sup> Commissioner Pinkert concurs with the Commission's conclusion regarding the economic prong of the domestic industry analysis, but finds that the purchase of inputs in the United States should be considered the "employment of capital" within the meaning of the statute.

<sup>10</sup> As stated earlier, the ALJ appears to have nonetheless considered these expenses. ID at 72 nn. 13-14, 75 n.18.

<sup>11</sup> The ALJ properly declined to consider Complainant's post-complaint expenditures. *See Bally/Midway Manufacturing. Co. v. Int'l Trade Comm'n*, 714 F.2d 1117, 1121 (Fed. Cir. 1983) ("Bally's Rally-X business . . . constituted a domestic industry under section 337(a) at the time the complaint was filed" and "[t]he deterioration of that business during the Commission proceedings does not undermine that conclusion."). *See also Motiva, LLC v. ITC*, \_\_\_ F.3d \_\_\_,

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With regard to the assessment of whether the claimed expenditures were significant or substantial within the meaning of section 337(a)(3), the ALJ found that, even if it were proper to attribute the component expenses to the domestic industry, Standard Innovation's expenditures for domestically produced components were slightly less than 5 percent of total product cost, and only [ ] percent of per unit revenue. *Id* at 75-76. He rejected Standard Innovation's contention that an approximately \$[ ] investment is sufficiently large to find a domestic industry in light of its small size and that it was a start-up company. Thus he found these expenditures to be neither significant nor substantial. *Id* at 76-77.

Standard Innovation contends that the ALJ erred in comparing the per unit cost of U.S. components to the per unit revenue because it results in an artificially low domestic contribution. Standard Innovation maintains that U.S. manufactured materials and components represent approximately 5 percent of value added if viewed in the context of the entire production, and [ ] percent of value added when the domestic components are compared with foreign components. Complainant's Response at 6. The IA states that U.S. manufactured components add both quantitative value to the finished product ([ ] percent of raw material costs) and that these components impart essential qualitative value to the finished products as the ALJ found these components critical to the patented features of the product. IA's Reply to Comm. at 5.

As our prior decisions recognize, "the magnitude of the investment cannot be assessed without consideration of the nature and importance of the complainant's activities to the patented products in the context of the marketplace or industry in question." *Certain Printing and Imaging Devices*, Inv. 337-TA-690, Comm. Op. at 31-32 (Feb. 17, 2011) (citing *Stringed*

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*Musical Instruments*, Inv. No. 337-TA-586, Comm. Op. at 26). Where, as here, the complainant relies on domestic manufacturing-related activities, the Commission evaluates whether the U.S. investments are significant under prongs A and B in terms of their contribution to the patented products and in relation to the company and the marketplace, taking into account the value added by foreign operations. See, e.g., *Schaper Mfg. Co. v. Int'l Trade Comm'n*, 717 F.2d 1368, 1372 (Fed. Cir. 1983) (affirming the Commission's determination of no domestic industry in *Certain Miniature, Battery-Operated, All-Terrain, Wheeled Vehicles*, Investigation No. 337-TA-122); *Cabinet Hinges*, Comm'n Op. at 33-34 (Sept. 28, 2009); *Certain Printing and Imaging Devices*, Inv. 337-TA-690, Comm. Op. at 31-32 (Feb. 17, 2011).

Consistent with Commission precedent, the ALJ correctly found that a complainant's subcontractors can be relied upon to establish the economic prong. See, e.g., *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007) (noting activities to be considered may include those of a complainant's subcontractor); *Certain Home Vacuum Packaging Products*, Inv. No. 337-TA-496, USITC Pub. 3681, ID at 143 (December 17, 2003) (unreviewed in relevant part by Notice, Jan. 22, 2004) (complainant subcontracted engineering services). Indeed, 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. Further, the purchase of domestically produced components has been the basis for satisfaction of the economic prong of the domestic industry requirement. See *Certain GPS Chips, Associated Software and Systems, and Products Containing Same*, Inv. No. 337-TA-596, Order No. 37 at 16 (Feb. 27, 2008) (noting that domestically manufactured chips used to make the patented article were manufactured in the United States by a subcontractor.) *Id.*

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Given the importance of context in the Commission's analysis, there is no threshold test for what is considered "significant" within the meaning of the statute. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op., at 39 (Aug. 1, 2007). Instead, the determination is made by "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* The term "significant" in section 337(a)(3) is not expressly defined in the statute. *Id.*

As the investments here involve U.S. manufacturing of some of the components in the United States, a value added analysis is appropriate. The Federal Circuit has endorsed a value-added analysis, explaining that the patentee must add a value greater than that of an importer. *Schaper Mfg. Co. v. U.S. Int'l Trade Comm'n* 717 F.2d 1368, 1372-73, 1370 n.5 (Fed. Cir. 1983) ("Congress did not mean to protect American importers (like Schaper) who cause the imported item to be produced for them abroad and engage in relatively small nonpromotional and non-financing activities in this country- *i.e.*, they engage in design and a small amount of inspection and packaging in this country.").<sup>12</sup> The Commission's decisions in *Stringed Instruments*, *Printing and Imaging Devices*, and *Male Prophylactics* indicate that the analysis is not limited to a strictly numerical comparison of domestic and foreign activities, but rather that the assessment is made in the context of the complainant's size and the industry as a whole. *Certain Printing and Imaging Devices*, Inv. 337-TA-690, Comm'n Op. at 31-32 (Feb. 17, 2011) *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op., at 39 (Aug. 1, 2007); *Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 26.

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<sup>12</sup> Although this case was decided before the elimination of the injury requirement (and the requirement for an efficiently operated industry) in 1988, the case is relevant to the domestic industry requirement.

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The ALJ found that Standard Innovation's expenditures on components produced in the United States by subcontractors, which totaled \$[ ],<sup>13</sup> were not significant or substantial enough to demonstrate the existence of a domestic industry. ID at 76. The ALJ found that the domestic component expense was small relative to product revenue, but raw material costs are often small relative to sales revenue for a consumer product. *Id.* We believe that the ALJ should have evaluated Standard Innovations' component expenditures of \$[ ] giving due consideration to the critical nature of the components to the patented products and in the context of the industry and the company.

In this investigation, [ ] percent of components for the We-Vibe are sourced domestically and these components account for 5 percent of the total cost of production.<sup>14</sup> ID 76 (citing CX - 87C; CX-280C at Q/A195). We recognize that [ ] percent is a relatively modest proportion of domestic content viewed in isolation. Nonetheless, as the Commission explained in *Male Prophylactics*, there is no bright-line threshold for domestic value-added to satisfy the domestic industry requirement. Although the statute does not provide a precise definition of "significant" investment, it does not indicate that the significance of investment in the United States must be evaluated relative to the significance of the foreign investment in purely mathematical terms. As the Commission indicated in *Male Prophylactics*, it also gives weight to qualitative considerations in assessing significance. In that case, the Commission analyzed the value added

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<sup>13</sup> These expenditures included \$[ ] on microcontroller parts, \$[ ] for pigments. ID at 71-73.

<sup>14</sup> Standard Innovation and the IA contend that [ ] percent of the content of the We-Vibe is accounted for by domestic components. CX -87C; CX-280C at Q/A195. Although Respondents challenge the [ ] percent, the figure is based upon the same information in complainant's exhibits as the ALJ's calculation. We consider both the [ ] percent and 5 percent figures relevant to the question of how much value is added domestically to the We-Vibe products.

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by U.S. operations from both a quantitative and qualitative standpoint. The Commission found that complainant's domestic activities were limited to lubrication and foiling (because the condoms themselves were manufactured abroad), and that these domestic operations were necessary to the commercial marketability of these products. *Id.* at 42-43. Moreover, the Commission noted that the U.S. finishing operations were directed to the practice of certain patent claims.

The contribution of the components at issue from a qualitative standpoint is indeed significant under the facts in this investigation, considering the article of commerce, and the realities of the marketplace. The record indicates that the three domestically-sourced components ([ ] and the microcontroller products) are crucial to the functionality of the We-Vibe. [ ] and is considered its "secret sauce" because it is so critical to the We-Vibe functionality. After Standard Innovation experimented with [ ]

[ ] CX-0280C at Q/A39-40. [ ] is another critical component for the We-Vibe. [ ]

[ ] Standard Innovation spent months just prior to the launch of We-Vibe trying to resolve these manufacturing issues. Standard Innovation determined that the best resolution was to [ ]

[ ] while leaving an even finish. CX-0280C at Q/A170.

The microcontroller products from [ ] are also crucial components; they

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enable the We-Vibe to function as a vibrator (particularly as a vibrator with multiple vibration modes) by controlling the vibrator motor and mode selection. CX-280C at 21.

Standard Innovation has also explained that We-Vibe is the company's flagship product and that it has created a new niche market for couples vibrators through its product innovations. CX-282C Q. 18; CX-275C at 105-106. The We-Vibe products account for more than [ ] percent of Standard Innovation's sales, and those sales have increased dramatically since the We-Vibe's launch. CX-280C Q. 204; CX-282C Q. 16, 17, 25; Tr., 146:8-147:2, 169:3-20; CX-73C. Thus, 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.

In conclusion, we note that the reality of today's marketplace is that many products are assembled overseas. In this instance, crucial components for the We-Vibe are produced domestically. We find that Standard Innovation's expenditures of over \$[ ] on components directly related to the '605 patent and critical to the We-Vibe (the company's flagship product) are significant in the context of a small start-up company developing a new market for couples vibrators. Thus, Standard Innovation (by and through its subcontractors) has shown a significant investment in domestically produced components.

### **2. Complainant Did Not Waive its Arguments that the Technical Prong of the Domestic Industry Is Met**

Although the ALJ found that the IA proved that the technical prong was satisfied, he found establishment of this requirement had been waived by Standard Innovation because its post-hearing brief only offered a string citation in support. ID 51-52. As was the case with infringement, he found that Staff identified evidence that showed the technical prong to be



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satisfied by claim 1 of the '605 patent. ID 52. Standard Innovation and the IA petitioned for review on this issue and the Respondents opposed.

We reverse the ALJ's waiver finding with respect to the technical prong for the same reasons we reverse his waiver finding with respect to infringement. The technical prong was adequately briefed by Standard Innovation and essentially uncontested (except for Respondents' prosecution disclaimer, which we have rejected). We affirm the ALJ's conclusion that the technical prong is met.

### IV. REMEDY, THE PUBLIC INTEREST, AND BONDING

In his Recommended Determination ("RD") on remedy and bonding, the ALJ recommended that, if the Commission finds a violation, it should issue a general exclusion order. RD at 2-6. He also recommended a bond amount during the Presidential review period based on the difference in average prices of the accused products and Standard Innovation's products. RD at 9-10. The ALJ did not recommend cease and desist orders ("CDOs"). *Id.*

#### A. The Appropriate Remedy is a General Exclusion Order and Cease and Desist Orders

The Commission's authority to issue a general exclusion order in this investigation is found in section 337(d)(2), which provides the following:

The authority of the Commission to issue an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that--

- (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
- (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

19 U.S.C. § 1337(d)(2).

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We agree with the ALJ that the appropriate statutory relief is a general exclusion order. Standard Innovation has shown that there is a pattern of violation of section 337 and that it is difficult to identify the source of the infringing imports.<sup>15</sup> 19 U.S.C. § 1337(d)(2)(B). The ALJ found evidence of counterfeiting of the We-Vibe products and extensive sales of those counterfeits in the record. RD at 4 (citing CX\_278C at Q/A 271; CX-0072; CX-282 at Q/A 92; CX-282C at Q/A 95). The market conditions for these products encourage counterfeiters to sell infringing products in the U.S. market. Specifically, the ALJ found that U.S. consumers purchase over one billion dollars of kinesiotherapy devices imported from overseas each year, that profit margins are often in excess of 400%, and that foreign entities wishing to enter the market have ready access to fully established distribution networks. RD at 4-5 (citing CX-280C at Q/A 287-288, 292; CX-218; CX-282C at Q/A 93-94). The counterfeiting coupled with the Commission's findings regarding the infringing products at issue in this investigation and the current market conditions are evidence of a pattern of the sale of goods infringing the '605 patent.<sup>16</sup>

We further agree with the ALJ that Standard Innovation has adequately documented the difficulty in identifying the source of the infringing goods. Online purchases of kinesiotherapy devices are commonplace in this industry. CX-288C at Q/A 68; CX-1971C at Q/A 527-528; CX-746; CX 723. The ALJ found that the actual identities of these online retailers are often hidden and that numerous entities have multiple storefronts or web addresses which make

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<sup>15</sup> We affirm the ALJ's determination that the record does not show that a general exclusion order is necessary to prevent circumvention of a limited exclusion order under 19 U.S.C. §1337(d)(2)(A). RD at 2-3.

<sup>16</sup> We do not rely upon the consent orders issued in this case as evidence of a pattern of infringement.

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identification impossible. RD at 5 (citing CX-278C Q/A 269, 277-279; CX-1089; CX-3-4C; CX-280C Q/A 298-299; CX-282C at Q/A 83-87). Furthermore, the ALJ found that Standard Innovation had shown that it is difficult to identify the source of the infringing products by providing evidence of its own failed efforts to make such determinations. RD at 6 (citing Tr. 143:6-144:3). We therefore determine to issue a general exclusion order.<sup>17</sup>

The Commission generally issues a CDO directed to a domestic respondent when there is a “commercially significant” amount of infringing, imported product in the United States that could be sold as to undercut the remedy provided by an exclusion order. *See Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm’n Op. at 26-28 (Aug. 27, 1997). The ALJ recommended that the Commission not issue CDOs here because he found that respondents did not maintain “commercially significant” amounts of infringing products in the United States. RD at 7. In particular, he stressed that a stipulation on inventory amounts entered into by the parties did not break out the inventories by accused products. *Id.* at 8.

The IA and Standard Innovation argue that CDOs are warranted by the record in this investigation. The IA notes that the inventory figures are broken out for the remaining accused products in Respondents’ confidential exhibits to their answer to the complaint, indicating that [ ] units of the Lelo Tiani were held in inventory in the United States.<sup>18</sup>

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<sup>17</sup> We note that the ALJ included claims 88 and 92 in his discussion of the asserted claims and his section entitled “Initial Determination” but he did not specifically analyze them in his infringement discussion or conclusions of law. Standard Innovation does not include the claims in its requested relief. Accordingly, we do not include claims 88 and 92 in the scope of the issued orders.

<sup>18</sup> Inventories held by Respondents are the following: LELO, Inc., [ ] units of Lelo Tiani; PHE, [ ] units of Lelo Tiani; NALPAC, [ ] units of Lelo Tiani; Eldorado, [ ] units of

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Based on these [ ] units, the Commission finds that there are commercially significant inventories in the United States, and therefore has determined to issue cease and desist orders to remaining domestic respondents: LELO Inc. of San Jose, California; PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina; Nalpac Enterprises, Ltd. of Ferndale, Michigan; E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado; Williams Trading Co., Inc. of Pennsauken, New Jersey; Honey's Place Inc. of San Fernando, California and Lover's Lane & Co. of Plymouth, Michigan.

### **B. The Public Interest**

Standard Innovation and the IA argue that entry of a general exclusion order and cease and desist orders as described above would not be contrary to the public interest. Standard Innovation Response to the Commission at 21. IA's Response to the Commission at 23. Neither Respondents nor any member of the public raised any public interest concerns in this investigation.

There is no evidence that U.S. demand for certain kinesiotherapy devices and components thereof cannot be adequately met by complainant and legitimate competitors, *i.e.*, manufacturers and retailers of certain kinesiotherapy devices and components thereof that have not been found to infringe the '605 patent. Moreover, the record contains no indication of any adverse effects of the general exclusion order and cease and desist orders on the public health and welfare, U.S. production of like or directly competitive products, competitive conditions in

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Lelo Tiani, WTC, [ ] units of Lelo Tiani; Honey Place, [ ] units of Lelo Tiani. Answer to the Complaint, Respondents' exhibits 1, 2, 5-8. We have not included inventories of the Picobong Mahana as we find that this device does not infringe.

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the United States, or U.S. consumers. Thus, we do not find any public interest considerations that would weigh against our remedies.

### C. Bond

The ALJ noted that when reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. He found that Standard Innovation's calculation was flawed because it included LELO's Noa, a new product not accused in this investigation. He recommended the bond amount be set based on the difference between average of the prices for the Tiani, Tiani2, and Picobong Mahana and the average of prices for the We-Vibe 2 and 3. RD at 9. The ALJ did not recommend a specific bond amount. RD at 9. The IA asserts that a bond in the amount of 4.6 percent is appropriate. IA Reply Briefing at 9.

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. a 24 (1995). The Commission agrees with the ALJ that it is appropriate to exclude the prices of the Noa because it is not an accused product. The Commission further excludes the price of the Picobong Mahana from the bond calculation because we have found that it does not infringe. Therefore, we set a bond based on the differential between the We-Vibe products (\$119) and the Tiani (\$159). Standard Innovation Response to the Commission at 24. Because the Tiani is sold at a higher average price, we are setting a bond in the amount of zero percent of the entered value during the presidential review period.

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**V. CONCLUSION**

Upon review of the ID, the Commission determines to: (1) reverse the ALJ's finding that the complainant's investments were insufficient to satisfy the economic prong of the domestic industry requirement, (2) reverse the ALJ's finding that round shapes were not disclaimed during prosecution, (3) reverse the ALJ's findings that the complainant waived infringement and the technical prong of the domestic industry requirement, and (4) affirm the remainder of the ID that is consistent with this opinion. We therefore determine to: (1) find a violation of section 337, (2) issue a general exclusion order and cease and desist orders, and (3) set a bond in the amount of zero percent of the entered value during the presidential review period.

By order of the Commission.



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Lisa R. Barton  
Acting Secretary to the Commission

Issued: July 12, 2013

**CERTAIN KINESIOTHERAPY DEVICES**

**337-TA-823**

**CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, **Monisha Deka, Esq.**, and the following parties as indicated, on **July 12, 2013**.



Lisa R. Barton, Acting Secretary  
U.S. International Trade Commission  
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