PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	
CERTAIN KINESIOTHERAPY DEVICES AND COMPONENTS THEREOF	**Investigation No. 337-TA-823**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge Thomas B. Pender

(January 08, 2013)

Appearances:

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List of Abbreviations

CDX	Complainant's Demonstrative Exhibit
CIB	Complainant's Initial Post-Hearing Brief
CRB	Complainant's Reply Post-Hearing Brief
CPHB	Complainant's Pre-Hearing Brief
CX	Complainant's Exhibit
Depo.	Deposition
JX	Joint Exhibit
RDX	Respondent's Demonstrative Exhibit
RIB	Respondent's Initial Post-Hearing Brief
RRB	Respondent's Reply Post-Hearing Brief
RX	Respondent's Exhibit
Tr.	Hearing Transcript
DWS	Direct Witness Statement (Including Revised Direct Witness Statements)
RWS	Rebuttal Witness Statement
SIB	Staff's Initial Post-Hearing Brief
SRB	Staff's Reply Post-Hearing Brief

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Pursuant to the Notice of Investigation and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, this is the Initial Determination in the matter of *Certain Kinesiotherapy Devices and Components Thereof*, United States International Trade Commission Investigation No. 337-TA-823.

It is held that a violation of Section 337 of the Tariff Act of 1930, as amended, has not been found in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain kinesiotherapy devices and components thereof with respect to claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-90, and 92 of U.S. Patent No. 7,931,605. Furthermore, it is held that a domestic industry in the United States does not exist that practices or exploits U.S. Patent No. 7,931,605.

I. INTRODUCTION

A. Procedural History

On December 2, 2011, complainants Standard Innovation (US) Corp. and Standard Innovation Corporation (collectively, "Standard Innovation") filed a Complaint with the Commission pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. In its Complaint, Standard Innovation alleged violations of Section 337 by respondents LELO Inc., LELOi AB, and LELO[1] (collectively "Lelo Respondents"); Natural Contours Europe; Momentum Management, LLC a.k.a. Bushman Products; Evolved Novelties, Inc.; Nalpac Enterprises, Ltd. d/b/a Nalpac, Ltd.; E. T.C., Inc. d/b/a Eldorado Trading Company, Inc. ("ETC"); Williams Trading Co., Inc.; Honey's Place, Inc.; Lover's Lane & Co. ("Lover's Lane"); PHE, Inc. d/b/a Adam & Eve ("PHE"); Castle Megastore Group, Inc.; Shamrock 51 Management Company, Inc.; Paris Intimates, LLC; Drugstore.com, Inc.; Peekay Inc.; Mile Inc. d/b/a Lion's Den Adult; Marsoner, Inc. d/b/a Fascinations; Love Boutique-Vista, LLC d/b/a Déjà vu; and Toys in Babeland LLC, based upon the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain kinesiotherapy devices and components thereof that allegedly infringe claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-90, and 92 of U.S. Patent No. 7,931,605 ("the '605 patent") and the design claimed in U.S. Patent No. D605,779 ("the '779 patent").

This Investigation was instituted by the Commission on January 4, 2012, to determine whether there is a violation of subsection (a)(1)(B) of Section 337 in the importation into the

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[1] On April 17, 2012, Chief Judge Bullock issued an Initial Determination granting Standard Innovation's motion for leave to amend the Complaint and Notice of Investigation to correct the entity name as Lelo Shanghai Trading Ltd. (Order. No. 21 (unreviewed by Comm'n May 18, 2012).)

United States, the sale for importation, or the sale within the United States after importation of certain kinesiotherapy devices and components thereof that infringe one or more of claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-90, and 92 of the '605 patent and the claim of the '779 patent, and whether an industry in the United States exists as required by subsection (a)(2) of Section 337. *See* 77 Fed. Reg. 1504 (Jan. 10, 2012).

This investigation was originally assigned to Chief Administrative Law Judge Bullock. (*See* Jan. 4, 2012, Notice to the Parties.) On May 7, 2012, this investigation was reassigned to me. (*See* May 7, 2012, Notice to the Parties.)

Respondent Drugstore.com, Inc. was terminated from this Investigation based on a consent order issued April 11, 2012. (*See* Consent Order; Comm'n Notice (Apr. 11, 2012); Order No. 9 (Mar. 9, 2012).)

Respondent Mile Inc. d/b/a Lion's Den Adult was terminated from this Investigation based on a consent order issued on May 8, 2012. (*See* Consent Order; Comm'n Notice (May 8, 2012); Order No. 19 (Apr. 6, 2012).)

Respondent Paris Intimates, LLC was terminated from this investigation based on a consent order issued on May 15, 2012. (*See* Consent Order; Comm'n Notice (May 15, 2012); Order No. 20 (Apr. 12, 2012).)

On June 28, 2012, I issued an Initial Determination Granting Standard Innovation's Motion for Termination of the Investigation with Respect to the '799 Patent. (Order. No. 25.) The Commission determined not to review Order No. 25. (Comm'n Notice (Jul. 25, 2012).)

On July 24, 2012, I struck respondent Lover's Lane inequitable conduct defense and denied respondents Lelo, Nalpac Enterprises, Ltd., ETC, Williams Trading Co., and Honey's Place, Inc.'s motion to amend their responses to the complaint to add the defense of inequitable

conduct. (Order Nos. 29-30.) Thus, inequitable conduct is no longer at issue in this Investigation.

Respondent Castle Megastore Group, Inc. was terminated from this investigation based on a consent order issued on August 9, 2012. (*See* Consent Order; Comm'n Notice (Aug. 9, 2012); Order No. 26 (Jul. 10, 2012).)

Respondents Love Boutique-Vista, LLC d/b/a Déjà vu, Peekay, Inc., and Shamrock 51 Management Company, Inc. were terminated from this Investigation based on respective consent orders issued on August 20, 2012. (*See* Consent Orders; Comm'n Notice (Aug. 20, 2012); Order Nos. 31-33 (Jul. 26, 2012).)

Respondent Marsoner, Inc. d/b/a Fascinations was terminated from this Investigation based on consent order issued on August 29, 2012. (*See* Consent Order; Comm'n Notice (Aug. 29, 2012); Order No. 34 (Aug. 1, 2012).)

Respondent Toys in Babeland LLC was terminated from this Investigation based on consent order issued on September, 2012. (*See* Consent Order; Comm'n Notice (Sept. 20, 2012); Order No. 39 (Aug. 21, 2012).)

On October 1, 2012, I issued an Initial Determination granting an unopposed motion to terminate the Investigation with respect to Natural Contours Europe and Lelo Shanghai Trading Ltd. based on partial withdrawal of the complaint. (Order. No. 40 (unreviewed by Comm'n Oct. 31, 2012).)

Respondents Momentum Management, LLC a.k.a. Bushman Products and Evolved Novelties, Inc. were terminated from this Investigation based on respective consent orders issued on November 5, 2012. (*See* Consent Orders; Comm'n Notice (Nov. 5, 2012); Comm'n Notice (Sept. 10, 2012); Order Nos. 36-37 (Aug. 9, 2012).)

An evidentiary hearing was held in this Investigation from August 21 – 24, 2012.

On October 26, 2012, the private parties filed a joint motion to correct two errors in the record. First, the private parties state that Order No. 38 struck RPX-0007. Complainants request that RPX-0007 be removed from the record. Respondents and the Staff do not oppose this request. RPX-0007 was not admitted. Accordingly, there is nothing to strike from the record.

Second, the private parties state that the wrong version of the "Feeldoe" was marked as Respondents' Physical Exhibit RPX-0008, and that the correct version of the device was not marked. Specifically, the private parties state the "Feeldoe Classic," which is purple in color and has packaging that includes a checkmark by the word "Classic," was erroneously marked as RPX-0008. The private parties further state the "Feeldoe Slim," which is blue in color, should have been marked as RPX-0008. To clarify the record, the parties have marked the correct blue "Feeldoe Slim" device as RPX-0008 and request that the blue "Feeldoe Slim" device replace the purple "Feeldoe Classic." The parties request that the purple "Feeldoe Classic" device be removed from the final record before the Commission. The Staff does not oppose this request. The parties request is granted.

On September 4, 2012, Standard Innovation requested a ruling on RX-0128C(2), an email from Melody Murison (spouse of the named inventor of the '605 patent), to an unidentified person and included as a copy of the original RX-128C, a two-page document with the label "SIC PKG 003.001" in the top left corner of the first page. Standard Innovation objects that the exhibit lacks proper foundation under Fed. R. Evid. 104 and lacks a proper sponsoring witness under Ground Rule 12.5. Standard Innovation argues that Respondents have failed to establish any foundation for how this exhibit is probative of any issue in this Investigation and Dr. Locker is not the proper sponsoring witness for this exhibit.

Respondents argue that the exhibit shows that at least Melody Murison thought that the Feeldoe could be used by a couple during sex and that Dr. Locker understood the reference to sex in the chart as meaning intercourse. Respondents further argue that Dr. Locker relied on the exhibit in part for her opinion that Kain teaches the limitation in the preamble. The Staff does not support admission of this exhibit and asserts the Respondents have failed to establish a proper foundation for the document. The Staff notes there is nothing in the record to indicate who drafted the document or under what circumstances the document was prepared. The Staff further notes that there is no evidence of what, if anything, Ms. Murison thought about the substance of the document because simply forwarding a document to another person does not mean that she believes that anything in the document was true.

Here, I find the Staff and Standard Innovation's arguments go to the weight I should give the document rather than its admissibility. Accordingly, RX-0128C(2) is admitted. However, as the Staff notes, there is no evidence that Ms. Murison agreed with the statements in the attachment to the email. Further, Dr. Locker offers no explanation for her interpretation of "sex" in the document as "intercourse." Finally, while the document indicates that the Feeldoe can be used by a couple during sex, the document also indicates that the Feeldoe does not "allow[] access to vagina for penis or dildo." RX-0128C(2). Accordingly, to the extent I give any weight to this document, I find it supports Standard Innovation's position that the Feeldoe does not anticipate the '605 patent because, as discussed below, I find the preamble limiting. And the document indicates that the Feeldoe is not dimensioned to be worn on the body of a female during coitus.

B. Parties

1. Complainants

Standard Innovation Corporation is a corporation organized under the laws of Canada and has its headquarters in Ontario, Canada. (Complaint at ¶ 5.) Standard Corporation has been involved in the design and manufacturing of sexual wellness products since 2004 and the company has grown rapidly since its inception. (*Id.*; CX-0278C (Webster WS) at Q/A 31.)

Standard Innovation (US) Corporation is the U.S. subsidiary of Standard Innovation Corporation and distributes and sells Standard Innovation Corporation's products in the United States. (CX-0280C (Finlayson WS) at Q/A 24-25.)

2. Respondents

Lelo Inc. is a California corporation having its principal place of business in San Jose, California. (Complaint at ¶ 22.)

Lelo AB is a corporation having its principal place of business in Stockholm, Sweden. (*Id.*) [

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PHE, Inc. d/b/a Adam &Eve is a corporation organized under the laws of New Jersey and has its principal place of business in Hillsborough, NC. (Complaint at ¶ 92.) PHE Inc., d/b/a Adam & Eve, has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani. (JX-0012 at ¶ 5.)

Nalpac Enterprises, Ltd. is a corporation organized under the laws of Michigan and maintains its principal place of business in Ferndale, Michigan. (Complaint at ¶ 92.) Nalpac Enterprises has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani and Lelo's PicoBong Mahana. (JX-0012 at ¶ 11.)

E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) is a corporation organized under the laws of Colorado and maintains its principal place of business in Bloomfield, CO. (Complaint at ¶ 61.) E.T.C. has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani and Lelo's PicoBong Mahana. (JX-0012 at ¶ 7.)

Williams Trading Co., Inc. is a corporation organized under the laws of New Jersey and maintains its principal place of business in Pennsauken, NJ. (Complaint at ¶ 69.) Williams Trading Co., Inc. has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani. (JX-0012 at ¶ 9.)

Honey's Place Inc. is a corporation organized under the laws of California and maintains its principal place of business in San Fernando, California. (Complaint at ¶ 80.) Honey's Place has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani. (JX-0012 at ¶ 13.)

Lover's Lane & Co. is a corporation organized under the laws of Michigan and maintains its principal place of business in Plymouth, MI. (Complaint at ¶ 88.) Lover's Lane has sold after importation into the United States one or more of the Accused Products, including Lelo's Insignia Tiani and Tiani2. (JX-0012 at ¶ 15.)

C. Patent at Issue

The '605 patent is the only patent at issue in this investigation. 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-0001 at 002.) The '605 patent is assigned to Standard innovation Corporation. (*Id.*)

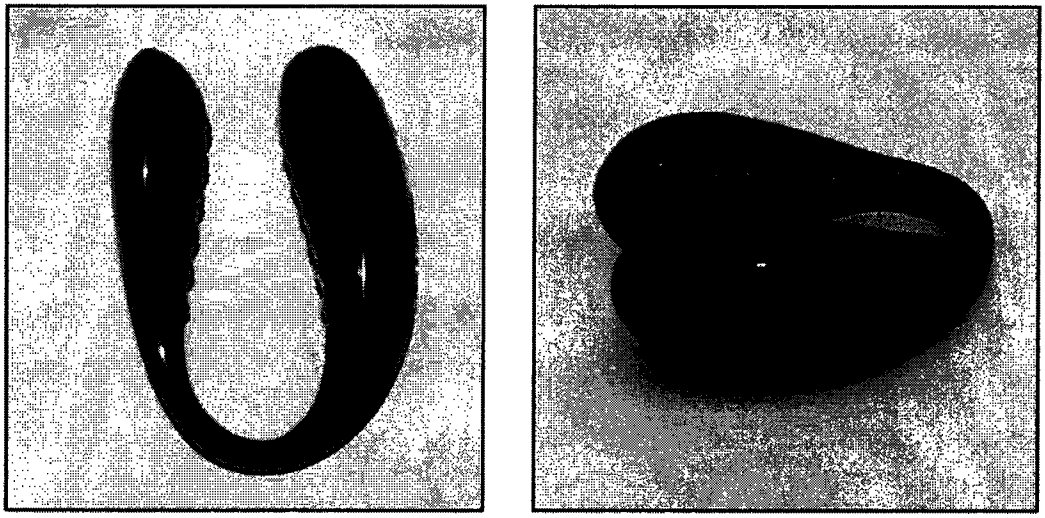
D. Products at Issue

Standard Innovation relies on the We-Vibe (original), the We-Vibe II, and the We-Vibe 3 ("Domestic Industry Products") to support its showing of the domestic industry requirement for the '605 patent. (CIB at 3-4.)

The accused products are Lelo's Insignia Tiani, Lelo's Insignia Tiani 2, and Lelo's Picobong Mahana ("Accused Products"). (CX-0282C (Oscada WS) at Q/A 25; JX-0012.)

E. Overview of the Technology

The technology at issue concerns sexual stimulation devices designed to be worn by a woman during sexual intercourse. (CX-0277C (Villaraga WS) at Q/A 61.) These devices are generally U-shaped and have inner and outer arms joined together by a connecting arm, as depicted below. (*Id.* at Q/A 62.)



CDX–0064 (original We-Vibe)

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. (*Id.* at Q/A 63.) 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. (*Id.*) Further, both the inner and outer arms may contain a vibrator to stimulate the clitoris, the G-spot, and the vagina simultaneously. (*Id.*)

II. IMPORTATION OR SALE

Each Respondent admits that it has imported or sold after importation in the United States at least one of the Accused Products in this investigation. (JX-0012.) It has long been recognized that an importation of even one accused product can satisfy the importation requirement of Section 337. *See Certain Trolley Wheel Assemblies*, Inv. No. 337-TA-161, Comm'n Op. at 7-8, USITC Pub. 1605 (Nov. 1984) (importation requirement satisfied by importation of a single product of no commercial value). Thus, I find the importation requirement is satisfied with respect to the '605 patent.

On December 2, 2011, the Commission issued its opinion in *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724. ("*Electronic Devices with Image Processing Systems*"). The Commission stated in its opinion that "the ALJ's importation analysis must include an evaluation of whether the type of infringement alleged will support a finding that there has been an importation of an article that infringes in violation of Section 337. *Electronic Devices with Image Processing Systems*, Inv. 337-TA-724, Comm'n Op. at 13, n. 8 (December 2, 2011). In particular, the Commission held that:

> [S]ection 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to "articles that – infringe." We also interpret the phrase "articles that – infringe" to reference the status of the articles at the time of importation. Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of Section 337.

Id. at 13-14. The Commission further held that "[w]e analyze a violation of Section 337(a)(1)(B)(i) based on method claim[s] [] under the statutory rubrics of indirect infringement." *Id.* at 18. In that investigation, the Commission held that the complainant failed to show importation, sale for importation, or sale after importation of articles that infringe a method claim directly or indirectly. *Id.* at 18-19.

Standard Innovation alleges that the Accused Products directly infringe the asserted apparatus claims of the '605 patent. Standard Innovation's allegations of direct infringement of the apparatus claims of the '605 patent support a finding that there has been an importation of an article that infringes in violation of Section 337.

III. JURISDICTION

In order to have the power to decide a case, a court or agency must have both subject matter jurisdiction and jurisdiction over either the parties or the property involved. 19 U.S.C. § 1337; *Certain Steel Rod Treating Apparatus and Components Thereof*, Inv. No. 337-TA-97, Commission Memorandum Opinion, 215 U.S.P.Q. 229, 231 (1981).

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the International Trade Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation, the sale for importation, or the sale after importation of articles into the United States. (*See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2).) Standard Innovation alleges in the Complaint that Respondents have violated Subsection 337(a)(1)(B) in the importation and sale of products that infringe the asserted patents. (*See* Complaint.) Each Respondent has stipulated that it either imports or sells after importation in the United States at least one Accused Product in this investigation. (JX-0012.) Accordingly, I find the Commission has jurisdiction

over this investigation under Section 337 of the Tariff Act of 1930. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

Respondents have fully participated in the Investigation by, among other things, participating in discovery, participating in the hearing, and filing pre-hearing and post-hearing briefs. Accordingly, I find that Respondents have submitted to the jurisdiction of the Commission.[2] *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, Pub. No. 1948, Initial Determination at 4, 1986 WL 379287 (U.S.I.T.C., October 15, 1986) (unreviewed by Commission in relevant part).

C. In Rem Jurisdiction

The Commission has in rem jurisdiction over the products at issue by virtue of the above finding that the Accused Products have been imported into the United States. *See Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981).

IV. STANDARDS OF LAW

A. Claim Construction

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction is a "matter of law exclusively for the court." *Id.* at

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[2] Respondents state that they "do not dispute that the Commission has jurisdiction over them with the exception of Leloi AB, which does not manufacture, sell for importation, import into the United States or sell within the United States after importation any of products at issue." (RIB at 2.) I find Leloi AB waived said argument by fully participating in the hearing.

970-71. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit in *Phillips* explained, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in art at the time of the invention. 415 F.3d at 1313. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claims terms." *Id.* at 1314; *see also Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [ ] out and distinctly claim [ ] the subject matter which the patentee regards as his invention."). The context in which a term is used in an asserted claim can be ""highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be ... the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

In addition to the claims and the specification, the prosecution history should be examined, if in evidence. *Id.* at 1317; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). The prosecution history can "often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317; *see also Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.").

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered.

Phillips, 415 F.3d at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* at 1317. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity. *Phillips*, 415 F.3d at 1327. Claims, however, cannot be judicially rewritten in order to fulfill the axiom of preserving their validity. *See Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). Thus, "if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid." *Id.*

B. Infringement

Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005). A complainant must prove either literal infringement or infringement under the doctrine of equivalents to support a finding of direct infringement.

1. Literal Infringement

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). If any claim

limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000.)

2. Doctrine of Equivalents

Where literal infringement is not found, infringement nevertheless can be found under the doctrine of equivalents. Determining infringement under the doctrine of equivalents "requires an intensely factual inquiry." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1381 (Fed. Cir. 2000). According to the Federal Circuit:

> Infringement under the doctrine of equivalents may be found when the accused device contains an "insubstantial" change from the claimed invention. Whether equivalency exists may be determined based on the "insubstantial differences" test or based on the "triple identity" test, namely, whether the element of the accused device "performs substantially the same function in substantially the same way to obtain the same result." The essential inquiry is whether "the accused product or process contain elements identical or equivalent to each claimed element of the patented invention[.]"

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376-77 (Fed. Cir. 2008) (citations omitted). Thus, if an element is missing or not satisfied, infringement cannot be found under the doctrine of equivalents as a matter of law. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991).

C. Validity

It is Respondents' burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, see 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006).

The clear and convincing evidence standard placed on the party asserting the invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not

susceptible to precise definition, "clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of a factual contention is 'highly probable.'" *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (citing *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988).)

"When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job[.]" *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Therefore, the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990).

1. Anticipation

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Company USA v. Monsanto Company,* 948 F.2d 1264, 1269 (Fed.Cir.1991). To be considered anticipatory, a prior art reference must describe the applicant's "claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000) (quoting *In re Paulsen,* 30 F.3d 1475, 1479 (Fed. Cir.

1994)). Anticipation is a question of fact. *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1177 (Fed. Cir. 1993).

2. Obviousness

Under 35 U.S.C. § 103(a), a patent is valid unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The ultimate question of obviousness is a question of law, but "it is well understood that there are factual issues underlying the ultimate obviousness decision." *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997); *Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The underlying factual determinations include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

Although the Federal Circuit has historically required that, in order to prove obviousness, the patent challenger must demonstrate, by clear and convincing evidence, that there is a "teaching, suggestion, or motivation to combine," the Supreme Court has rejected this "rigid approach." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-418 (2007). In KSR, the Supreme Court described a more flexible analysis:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue... As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account

> of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id. Since KSR was decided, the Federal Circuit has announced that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

3. Indefiniteness

The definiteness requirement of 35 U.S.C. § 112 ensures that the patent claims particularly point out and distinctly claim the subject matter that the patentee regards to be the invention. *See* 35 U.S.C. § 112, ¶ 2; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004). If a claim's legal scope is not clear enough so that a person of ordinary skill in the art could determine whether or not a particular product infringes, the claim is indefinite, and is, therefore, invalid. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).[3]

Thus, it has been found that:

> When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite.

Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

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[3] Indefiniteness is a question of law. *IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109 (Fed. Cir. 2011).

D. Domestic Industry

In a patent-based complaint, a violation of Section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this "domestic industry requirement" of Section 337 consists of an economic prong and a technical prong. *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12-14, 2009 WL 5134139 (U.S.I.T.C. Dec. 2009). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Final Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002) (unreviewed by Commission in relevant part).

1. Economic Prong

The economic prong of the domestic industry requirement is defined in Section 337(a)(3) as follows:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark or mask work 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.

19 U.S.C. § 1337(a)(3). The economic prong of the domestic industry requirement is satisfied by meeting the criteria of any one of the three factors listed above.

Section 337(a)(3)(C) provides for domestic industry based on "substantial investment" in the enumerated activities, including licensing of a patent. *See Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-

TA-559, Initial Determination at 88 (May 11, 2007) ("Certain Digital Processors"). Mere ownership of the patent is insufficient to satisfy the domestic industry requirement. *Certain Digital Processors* at 93 (citing the Senate and House Reports on the Omnibus Trade and Competitiveness Act of 1988, S.Rep. No. 71). However, entities that are actively engaged in licensing their patents in the United States can meet the domestic industry requirement. *Certain Digital Processors* at 93. In establishing a domestic industry under Section 337(a)(3)(C), the complainant does not need to show that it or one of its licensees is practicing a patent-in-suit. *See Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-432, Order No. 13, at 11, (January 24, 2001) ("Certain Semiconductor Chips").

In *Certain Multimedia Display & Navigation Devices & Systems, Components Thereof, & Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. (Aug. 8, 2011) (*"Multimedia Display"*), the Commission stated that a complainant seeking to rely on licensing activities must satisfy three requirements: (1) the investment must be "an investment in the exploitation of the asserted patent;" (2) the investment must relate to licensing; and (3) the investment "must be domestic, *i.e.*, it must occur in the United States." *Id.* at 7-8. The Commission stated that "[o]nly after determining the extent to which the complainant's investments fall within these statutory parameters can we evaluate whether complainant's qualifying investments are 'substantial,' as required by the statute." *Id.* at 8.

Under the first of the three requirements, the complainant must show a nexus between the licensing activity and the asserted patent. *Id.* at 9. When the asserted patent is part of a patent portfolio, and the licensing activities relate to the portfolio as a whole, the Commission requires that the facts be examined to determine the strength of the nexus between the asserted patent and

the licensing activities. *Id.* The Commission provided a non-exhaustive list of factors to consider, such as (1) whether the licensee's efforts relate to "an article protected by" the asserted patent under Section 337 (a)(2)-(3); (2) the number of patents in the portfolio; (3) the relative value contributed by the asserted patent to the portfolio; (4) the prominence of the asserted patent in licensing discussions, negotiations, and any resulting licensing agreement; and (5) the scope of technology covered by the portfolio compared to the scope of the asserted patent. *Id.* at 9-10. The Commission explained that the asserted patent may be shown to be particularly important or valuable within the portfolio where there is evidence that: (1) it was discussed during licensing negotiations; (2) it has been successfully litigated before by the complainant; (3) it is related to a technology industry standard; (4) it is a base patent or pioneering patent; (5) it is infringed or practiced in the United States; or (6) the market recognizes the patent's value in some other way. *Id.* at 10-11.

Once a complainant's investment in licensing the asserted patent in the United States has been assessed in the manner described above, the next inquiry is whether the investment is "substantial." 19 U.S.C. § 1337(a)(3)(C). The Commission takes "a flexible approach whereby a complainant whose showing on one or more of the three Section 337(a)(3)(C) requirements is relatively weak may nevertheless establish that its investment is 'substantial' by demonstrating that its activities and/or expenses are of a large magnitude." *Multimedia Display and Navigation Devices*, Comm'n Op. at 15. The Commission has indicated that whether an investment is "substantial" may depend on:

(1) the nature of the industry and the resources of the complainant;

(2) the existence of other types of "exploitation" activities;

(3) the existence of license-related "ancillary" activities;

(4) whether complainant's licensing activities are continuing; and

> (5) whether complainant's licensing activities are the type of activities that are referenced favorably in the legislative history of Section 337(a)(3)(C).

Id. at 15-16. The complainant's return on its licensing investment (or lack thereof) may also be circumstantial evidence of substantiality. *Id.* at 16. In addition, litigation expenses may be evidence of the complainant's investment, but "should not automatically be considered a 'substantial investment in . . . licensing,' even if the lawsuit happens to culminate in a license." *See John Mezzalingua Associates, Inc. v. U.S. Int'l Trade Comm'n*, --- F.3d ---, 2011 U.S. App. LEXIS 20128 at *13 (Fed. Cir. Oct. 4, 2011).

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based Section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. §1337 (a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (U.S.I.T.C. Jan. 16, 1996). "In order to satisfy the technical prong of the domestic industry requirement, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers*, Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C., Jan. 2004).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C., May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine

whether it falls within the scope of the claims." *Certain Doxorubicin and Preparations Containing Same*, Initial Determination at 109. To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, Initial Determination at 44, Pub. No. 2575 (U.S.I.T.C., November 1992).

V. U.S. PATENT NO. 7,931,605

The '605 patent issued on April 26, 2011. (JX-0001 at [45].) Bruce Murison is the named inventor. (*Id.* at [75].) Standard Innovation Corporation is the asignee. (*Id.* at [73].) The '605 patent relates generally to a device for use by a female for sexual stimulation comprising an inner arm dimensioned for insertion into a vagina, to contact the wall of the vagina at or near the G-spot, an outer arm dimensioned to contact the clitoris, and a resilient U-shaped member connecting the inner and outer arms. (*Id.*)

A. Asserted Claims

The '605 patent has 98 claims. Claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-90, and 92 are asserted in this Investigation. Claims 1, 33, and 66 are independent claims. The asserted claims read as follows:

> 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.

2. The device of claim 1, wherein said connecting portion resiliently urges said inner and outer arms towards each other when flexed apart.

3. The device of claim 1, wherein said elongate inner arm is dimensionally shaped to permit contact substantially along its length with the anterior wall of the vagina.

4. The device of claim 1, wherein said connecting portion maintains the inner and outer arms resiliently spaced apart in a relaxed position.

5. The device of claim 1, wherein the connecting portion permits the arms to be moved to multiple angles.

6. The device of claim 1, further including an outer, substantially continuous covering of an elastomeric material, covering at least a portion of the device.

7. The device of claim 6, wherein the elastomer material comprises a soft pliable layer selected from the group consisting of silicone, rubber, vinyl and combinations thereof.

9. The device of claim 1, further including a skeleton.

10. The device of claim 9, wherein the skeleton is selected from the group consisting of a shape memory material, a thermoplastic polymer and combinations thereof.

11. The device of claim 9, wherein the skeleton is selected from the group consisting of resilient materials, malleable materials and combinations thereof.

12. The device of claim 1, further including at least one vibrating mechanism.

13. The device of claim 12, wherein the vibrating mechanism is positioned in at least one of the inner or outer arms.

14. The device of claim 12, further including a power source.

15. The device of claim 14, wherein the power source includes at least one battery.

16. The device of claim 15, wherein the at least one battery is a rechargeable battery or a disposable battery.

17. The device of claim 14, further including a switch connecting said power source to said at least one vibrating mechanism.

18. The device of claim 17, wherein said switch includes multiple settings to include at least one of the following for said vibrator mechanism: i) one or more levels of power; ii) one or more directions of movement; iii) intermittent power.

19. The device of claim 18, wherein one or more of the settings are adjustable.

20. The device of claim 12, further including a recharging outlet.

21. The device of claim 20, further including a re-sealable access means for charging the power source.

23. The device of claim 1, wherein the inner arm is smaller than the outer arm.

24. The device of claim 1, wherein the connecting portion is generally C-shaped.

26. The device of claim 1, further including a texturing on a surface for enhanced stimulation.

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.

34. The device of claim 33, wherein the inner arm has a width which is greater than its thickness.

35. The device of claim 33, wherein said connecting portion resiliently urges said inner and outer arms towards each other when flexed apart.

36. The device of claim 33, wherein said elongate inner arm is dimensionally shaped to permit contact substantially along its length with the anterior wall of the vagina.

37. The device of claim 33, wherein said connecting portion maintains the inner and outer arms resiliently spaced apart in a relaxed position.

38. The device of claim 33, wherein the connecting portion permits the arms to be moved to multiple angles.

39. The device of claim 33, further including an outer covering of an elastomeric material, covering at least a portion of the device.

40. The device of claim 39, wherein the elastomer material comprises a soft pliable layer selected from the group consisting of silicone, rubber, vinyl and combinations thereof.

42. The device of claim 33, further including a skeleton.

43. The device of claim 42, wherein the skeleton is selected from the group consisting of a shape memory material, a thermoplastic polymer and combinations thereof.

44. The device of claim 42, wherein the skeleton is selected from the group consisting of resilient materials, malleable materials and combinations thereof.

45. The device of claim 33, further including at least one vibrating mechanism.

46. The device of claim 45, wherein the vibrating mechanism is positioned in at least one of the inner or outer arms.

47. The device of claim 45, further including a power source.

48. The device of claim 47, wherein the power source includes at least one battery.

49. The device of claim 48, wherein the at least one battery is a rechargeable battery or a disposable battery.

50. The device of claim 47, further including a recharging outlet.

51. The device of claim 50, further including a re-sealable access means for recharging a battery.

52. The device of claim 47, further including a switch connecting said power source to said at least one vibrating mechanism.

53. The device of claim 52, wherein said switch includes multiple settings to include at least one of the following for said vibrator mechanism: i) one or more levels of power; ii) one or more directions of movement; iii) intermittent power.

54. The device of claim 53, wherein one or more of the settings are adjustable.

56. The device of claim 33, wherein the inner arm is smaller than the outer arm.

57. The device of claim 33, wherein the connecting portion is generally C-shaped.

59. The device of claim 33, further including a texturing on a surface for enhanced stimulation.

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

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

67. The device of claim 66, wherein the inner arm tapers down toward the connecting portion.

68. The device of claim 66, wherein said connecting portion resiliently urges said inner and outer arms towards each other when flexed apart.

69. The device of claim 66, wherein said elongate inner arm is dimensionally shaped to permit contact substantially along its length with the anterior wall of the vagina.

70. The device of claim 66, wherein said connecting portion maintains the inner and outer arms resiliently spaced apart in a relaxed position.

71. The device of claim 66, wherein the connecting portion permits the arms to be moved to multiple angles.

72. The device of claim 66, further including an outer covering of an elastomeric material covering at least a portion of the device.

73. The device of claim 72, wherein the elastomer material comprises a soft pliable layer selected from the group consisting of silicone, rubber, vinyl and combinations thereof.

75. The device of claim 66, further including a skeleton.

76. The device of claim 75, wherein the skeleton is selected from the group consisting of a shape memory material, a thermoplastic polymer and combinations thereof.

77. The device of claim 75, wherein the skeleton is selected from the group consisting of resilient materials, malleable materials and combinations thereof.

78. The device of claim 66, further including at least one vibrating mechanism.

79. The device of claim 67, wherein the vibrating mechanism is positioned in at least one of the inner or outer arms.

80. The device of claim 78, further including a power source.

81. The device of claim 80, wherein the power source includes at least one battery.

82. The device of claim 81, wherein the at least one battery is a rechargeable battery or a disposable battery.

83. The device of claim 80, further including a recharging outlet.

84. The device of claim 83, further including a re-sealable access means for recharging.

85. The device of claim 80, further including a switch connecting said power source to said at least one vibrating mechanism.

86. The device of claim 85, wherein said switch includes multiple settings to include at least one of the following for said vibrator mechanism: i) one or more levels of power; ii) one or more directions of movement; iii) intermittent power.

87. The device of claim 86, wherein one or more of the settings are adjustable.

88. The device of claim 78, including at least two vibrator mechanisms which vibrate in harmonic wave patterns.

89. The device of claim 66, wherein the inner arm is smaller than the outer arm.

90. The device of claim 66, wherein the connecting portion is generally C-shaped.

92. The device of claim 66, further including a texturing on a surface for enhanced stimulation.

B. Level of Ordinary Skill in the Art

Complainants and the Staff assert that a person of ordinary skill in the art of the '605 patent is a sexual device designer who has a working knowledge of basic engineering principles and a working knowledge of female genital anatomy, intercourse, and human sexual behavior as proposed by Standard Innovation and the Staff. (CX-0275C (Herbenick DWS) at Q/A 54; CX-0277C (Villarraga DWS) at Q/A 43; CIB at 5-6; CRB at 4; SIB 51-53; SRB 1-2.) The Respondents contend that one of ordinary skill in the art is "a woman who uses vibrators." (RIB at 2-3; RRB at 4-6.)

The Federal Circuit looks to a number of factors to determine skill level, for example, the type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666–67 (Fed. Cir. 2000). Depending on the facts of the case, every factor may not be present, or one or more factors may predominate. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Here, at least two factors are relevant. In particular, the evidence shows that the products at issue in this Investigation involve relatively sophisticated technology as the development of these products required extensive engineering work to find the appropriate materials. For example, the evidence shows that Bruce Murison, the inventor of the '605 patent, had to experiment with "many, many different plastics, [and] resins" to find the appropriate polymer for the skeleton of the We Vibe device. (Tr. 178:12-21.) Similarly, Mr. Murison also conducted significant research when trying to find a silicone that would be compatible with the electronic devices contained in the We-Vibe. (Tr. 237:15-25.) In addition, the record shows that Standard Innovation worked with numerous engineers to develop different components for the We-Vibe. (Tr. 183:18-24; 184:11-20; 227:21-228:6; 231:7-11.)

Notably, Pavle Sedic, the president of Lelo Inc., testified that he designed the electrical components for the first products Lelo produced. (Tr. 686:15-25.) Mr. Sedic holds a degree in electrical engineering. (*Id.*) Thus, the evidence shows that at least some level of technical expertise, gained either through education or work experience, would be necessary to design a sexual stimulation device, such as those involved in the instant Investigation. However, I find Complainant and the Staff's definition too narrow because it is limited to people who have previously designed a sexual device. I find that a person who has a working knowledge of basic

engineering principles and a working knowledge of female genital anatomy, intercourse, and human sexual behavior would be a person of ordinary skill in the art.

Respondents argue that their definition is appropriate because a woman who uses vibrators would know the different definitions of intercourse and prior art in the vibrator field. (RIB at 3.) Respondents further argue that a woman who uses vibrators "would have the knowledge to compare the We-Vibe and the prior art to determine whether the We-Vibe is anticipated or made obvious by the prior art." (*Id.*; *see also* RRB at 5-6.) However, Respondents simply present no evidence that a woman who uses vibrators would have such knowledge and I do not find Respondents' unsupported attorney argument persuasive.

C. Claim Construction

1. Preamble

The claim term "dimensioned to be worn by a female during intercourse" appears in the preamble of asserted independent claims 1, 33, and 66. (JX-0001 at claims 1, 33, 66.) Standard Innovation and the Staff argue that the preamble limits the scope of the claimed invention and that it should be construed to mean "sized to be carried on the body of a female during coitus." (CIB at 10-15; SIB at 19-31.) Respondents argue that the preamble does not limit the scope of the claims, but if it does, Respondents argue intercourse should not be limited to coitus. (RIB at 4-11.)

Based on the intrinsic evidence, "dimensioned to be worn by a female during intercourse" is a limitation which is construed to mean "dimensioned to be worn by a female during coitus." Although a claim preamble is not usually construed as a claim limitation, a preamble is regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim. Here, the evidence shows that the preamble limits the claimed invention

because it recites essential structure and is "necessary to give meaning to the claim." Respondents' arguments to the contrary are not persuasive.

A preamble is limiting if any of the following circumstances exist: (1) the specification makes clear that the inventors were working on the specific problem described by the preamble; (2) the preamble provides necessary context for the claimed invention that is necessary to describe the invention; (3) the preamble adds a structural limitation to the body of the claim; or (4) the patentee uses the limitations in the preamble to distinguish the prior art during prosecution. *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 807–11 (Fed. Cir. 2002) (summarizing factors tending to show that the preamble qualifies as a claim limitation). Here, the evidence shows all four of these conditions are present.

With respect to the first factor, the specification of the '605 patent discloses that the inventor was working on the specific problem described in the preamble. The specification distinguishes the prior art by noting that, "[n]o direct vibration means effective to stimulate the vagina or G-spot during intercourse were provided." (JX-0001 at 1:59-60.) The summary of the invention states the inventor wanted to overcome this shortcoming by providing a vibrator that was a "significant advancement over known vibrators." (*Id.* at 1:64-67.) One feature that the specification credits for this advancement is the use of the claimed vibrator for use during intercourse. (*Id.* at 2:2-4.)

Turning to the second factor, the specification makes clear that "dimensioned to be worn by a female" provides a framework for the other limitations recited in the body of the claim. Indeed, the very first words of the patent illustrate the importance of the preamble to the claims as the "Title of the Invention" describes the invention as an "Electro-Mechanical Sexual Stimulation Device to be Worn During Intercourse." Thus, at the very outset, the inventor has

defined his invention as relating to devices worn during intercourse. *Poly-America, L.P. v. GSE Lining Technology, Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (term "blown-film" in preamble in referring to a type of liner covered by the patent was properly treated as a claim limitation where the intrinsic evidence, including the title, showed that the patentee relied on the term to describe a "fundamental characteristic" of the claimed invention).

The "Field of Invention" continues this theme by defining the relevant field as follows:

> The present invention relates to the field of sexual paraphernalia. In particular, the present invention provides an electro-mechanical device for sexual stimulation intended for use by women either as an auto-erotic aid or during intercourse.

(JX-0001 at 1:19-24.) Thus, the specification explicitly teaches that its devices can be used during intercourse.

This focus is carried out throughout the specification. In the "Summary of the Invention," the patentee distinguishes his claimed device from the prior art by relying on this claimed feature—"the vibrator of ***the present invention*** can *be comfortably worn during intercourse* unlike the devices of the prior art." (*Id.* at 2:1-4 (emphasis added).) The patentee goes on to further describe his entire invention as follows:

> In a broad aspect, then, the ***present invention*** relates to a device for use during intercourse by a female for sexual stimulation comprising an inner arm dimensioned for insertion into the vagina, to contact the wall of the vagina at or near the G-spot, an outer arm dimensioned to contact the clitoris, and a resilient U-shaped member connecting the inner and outer arms.

(*Id.* at 2:13-19 (emphasis added).) In both excerpts, the patentee characterized his overall "invention" as being used during intercourse, rather than describing this feature as an embodiment or an example of how his invention could be used. Such characterizations in the summary of the invention have been used to support limiting the claims. *Certain Inkjet Cartridges with Printheads and Compoents Thereof,* Inv. No. 337-TA-723, Initial Determination

at pp. 43-44 (June 10, 2011); *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) ("Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. Statements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention."). Thus, the patentee broadly described his invention by emphasizing its use during intercourse. (*See also* JX-0001 at 1:27-31, 5:11-20.) Thus, the '605 patent clearly and repeatedly describes the claimed sexual stimulation device as worn by a woman in her vagina during intercourse in a way that it is well-understood that "intercourse" is synonymous with "coitus." (*See e.g.*, JX-1, 1:20-23, 2:2-4, 3:27-31, 5:11-20, 9:65-10:6, 10:17-21.) Indeed, the preamble, read in light of the specification, sets the focus for the limitations recited in the body of the claim by providing the framework for which the claimed device is used. Without the preamble, the claim limitations have no context.

With regard to the third factor, the evidence shows that the preamble is limiting because it discloses structural elements that are necessary in the claims. In particular, the specification shows that the preamble is not merely setting the stage for the limitations recited in the body of the claim, as argued by the Respondents, but mandating that the device must be dimensioned to be worn by a female during intercourse.

The structural aspects of the preamble are detailed throughout the specification. For example, when discussing the arms of the claimed device, the specification emphasizes that the shape of these arms cannot interfere with intercourse. (*Id.* at 7:21-29, 7:58-60, 8:4-8, 10:4-6.) Thus, 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.

Finally, the evidence has shown that the inventors relied on the preamble to distinguish the prior art during the prosecution of the application leading to the '605 patent. Such reliance shows that the preamble is a positive limitation in the asserted claims. *Certain Digital Televisions and Components Thereof,* Inv. No. 337-TA-789, Order No. 32 at 44-45 (Aug. 31, 2011).

As an initial matter, the July 11, 2007 Preliminary Amendment submitted by the applicant included the following limitation in the body of the independent claims: "wherein said U-shaped member is slender enough to permit sexual intercourse when said inner arm is inserted in a vagina." (JX-0002 at 58-60.) The fact that the body of the claims required the U-shaped member to be slender enough to permit sexual intercourse when the inner arm is inserted in a vagina clearly shows, from the beginning, the applicant considered this a defining feature of his invention.

Further the March 18, 2009 Preliminary Amendment submitted by the applicant included the following limitation in the body of independent claim 19: "a middle portion connecting the inner arm to the outer arm, and being sized and shaped to permit sexual intercourse when said sexual stimulation device is emplaced on said woman." (*Id.* at 127.) Likewise, then pending independent claim 63 recited "said device being sized and shaped to be worn during sexual intercourse;" independent claim 64 recited "said admittance arm is thin enough to permit said device to be worn by a woman during sexual intercourse;" and independent claim 65 recited "said admittance arm is narrow enough to permit said device to be worn by a woman during sexual intercourse." (*Id.* at 132.) Again, the fact that the body of the claims required the device to be sized for use during sexual intercourse clearly shows, from the beginning, that the applicant considered this a defining feature of his invention.

Other statements made to the Examiner by the applicant to gain allowance of the claims confirm this understanding. In particular, in responding to the Examiner's first Office Action, the applicant made several important statements regarding the structure of his invention. Specifically, he stated that "[t]he sexual stimulation device of the instant application is primarily intended to be worn by a woman while engaging in sexual intercourse with a man." (*Id.* at 16 (Amendment dated January 7, 2009).) Moreover, in distinguishing the invention from the prior art Marshall reference, the applicant stated that Marshall failed to anticipate the then-pending claims because it did not teach or suggest the use of its device during intercourse:

> [I]t is respectfully submitted that Marshall fails to teach or even suggest the possibility of a device . . . 'to permit sexual intercourse when said sexual stimulation device is emplaced on said woman', since the shaft portion in Marshall is clearly intended as a single person masturbation device which provides penetrative stimulation of the vagina . . . .

(*Id.* at 23.) Thus, it is clear that the applicant believed that the fact that his device could be used during intercourse was one of the critical distinguishing features of his invention.

The applicant continued to characterize its invention in this way throughout the course of the prosecution of the application leading to the '605 patent. For example, in another Amendment filed with the USPTO, the applicant stated that "the Applicant's invention is intended to be worn by a woman **during intercourse** which differentiates Applicant's invention from any other cited prior art device." (*Id.* at 14 (Amendment filed April 29, 2010) (emphasis in original). The applicant then distinguished the claims from the prior art reference Sekulich by arguing that this reference was not intended for use during sexual intercourse. (*Id.* at 15.) In particular, the applicant argued the following:

> Turning now to the specific teachings of Sekulich, the first point to note is that the inner arm is essentially phallus shaped. As such, rather than complementing a man, this device is clearly intended to replace a man and thus it is quite clear that this reference teaches,

> as a matter of first impression, directly away from the Applicant's invention, **which is to be used during normal intercourse** as claimed. That Sekulich teaches the stimulator is for **pre-**intercourse stimulation, not **during** intercourse stimulation, is clearly articulated in the plain language of the Sekulich specification.

(*Id.* at 16.) Thus, the applicant repeatedly emphasized that the important aspect of its invention is the fact that it can be worn while having sexual intercourse.

Contrary to the Respondents' arguments, this emphasis did not change even after the applicant amended the claims to read as they appear in the issued patent. As discussed above, after the Examiner rejected the claims over the Sekulich reference, the applicant amended the claims to require the enlarged arms to "taper down towards the connecting portion." (*Id.* at 14 (Amendment dated October 12, 2012).) Along with this amendment, the Applicant also amended the preamble to read "a sexual stimulation device dimensioned to be worn by a female during intercourse." (*Id.*) In making these amendments, the Applicant stated the following:

> As discussed during the telephonic interview, each of the arms of the device are enlarged, i.e. larger, relative to the connection portion. Moreover, the enlarged arm(s) taper <u>down towards</u> the middle portion to provide a configuration which is dimensioned to be worn by a female during intercourse. The tapering of the enlarger arms down toward the middle connecting portion is in fact not shown by the Sekulich reference or other references in the prior art . . . . The combination of the enlarged arms relative to the connecting portion and the tapering down of at least one arm, and desirably both arms <u>toward</u> the connecting portion, clearly distinguishes the invention from the prior art and in fact permits the configuration to be dimensioned such that the female can wear it during intercourse. These claimed features are neither taught or suggested by the prior art.

(*Id.* at 15-16 (emphases in original).) Thus, it is clear, that the Applicant not only continued to believe that the preamble was a distinguishing and limiting feature, he also relied on the preamble to argue for patentablity over the Sekulich reference.

2. "dimensioned to be worn by a female during intercourse" (claims 1, 33, 66)

Standard Innovations' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"sized to be carried on the body of a female during coitus"	"of a size to be engaged with any part of the female's body during intercourse"	"sized to be carried on the body of a female during coitus"

As to the proper construction of the preamble, the evidence has shown that it should be construed to mean "sized to be worn on the body of a female during coitus." While Standard Innovation and the Staff agree as to the preamble's construction, the Respondents offer a much broader construction for this limitation. Specifically, the Respondents contend that the term "intercourse" in the preamble refers to "penile-vaginal intercourse, or penile-anal, or penile-oral, or digital-vaginal, or digital-anal, or device-vaginal, or device-anal." Respondents Pre-Hearing Brief, p. 14. Consistent with their broad interpretation of "intercourse," the Respondents also contend that "dimensioned" means "of a size to be engaged with any part of the female's body." The evidence has shown that the ordinary meaning of "intercourse" is "coitus," which is penile-vaginal intercourse occurring between one woman and one man. (CX-0275C at Q/A 151, 158; CX-0277C at Q/A 130, 138; Tr., 306:1- 307:17, 308:9-309:4, 309:15-310:14, 311:3-314:17.) The evidence does not support the Respondents overly broad construction.

Respondents offer no support for their proposed construction of "dimensioned to be worn by a female during intercourse. (RIB at 8-11.) Rather, Respondents first argue that this term should not be construed as "dimensioned to be inserted in a vagina during sexual intercourse." (*Id.* at 8-9.) However, as no party has proposed such a construction, I find Respondents argument without merit. Next, Respondents argue that "intercourse," as used in the preamble, should not be construed to mean "sexual intercourse" or "coitus."

The term "intercourse" refers to intercourse between a man and a woman, *i.e.* coitus. The specification confirms this understanding. Specifically, the specification states that "the device is sized and shaped so that emplacement of the device will not interfere with *ordinary sexual intercourse.*" (JX-0001 at 3:29-31 (emphasis added).) The evidence has shown that one of skilled in the art would consider ordinary sexual intercourse to refer to intercourse between a man and a woman. (Tr. 306:12-16; 310:6-14.)

In this respect, the specification refers to men and women when discussing how to wear the claimed device: "[w]hen worn, the inner surface is against the woman and the outer surface is against the man" (JX-0001 at 8:50-53); "[i]t should be noted also that the device conforms to the shape of the vagina even when this shape changes when a penis is inserted and also changes when the penis is at different angles relative to the woman" (*id.* at 10:3-6); and "[t]he 'outer' surface of the clitoral pad, internal arm and internal vibrating module that is against the man's skin is glass smooth to minimize friction to reduce tendency of the device to move with the man as the penis moves in and out of the vagina" (*id.* at 10:17-21). Thus, the specification clearly contemplates the use of the device during coitus. (*See e.g.*, JX-1, 1:20-23, 2:2-4, 3:27-31, 5:11-20, 9:65-10:6, 10:17-21.)

The prosecution history is consistent with this understanding. When describing the invention to the Examiner, the Applicant characterized his invention as a "sexual stimulation device . . . intended to be worn by a woman while engaging in intercourse with a man . . . ." (JX-0002 (Amendment dated January 7, 2012 at 16-17).) Further, in distinguishing the invention from the Marshall reference, the Applicant stated that "[t]here is no suggestion that Marshall may be used between a man and a woman as is Applicant's invention." (*Id.* at 20.) Additionally, in distinguishing the invention from the Sekulick reference, the Applicant states that "the

[Sekulick] device is clearly intended to replace a man and thus it is quite clear that this reference teaches, as a matter of first impression, directly away from the Applicant's invention, **which is to be used during normal intercourse** as claimed." (JX-0002 (Amendment dated April 29, 2010 at 16).) Thus, the prosecution history shows that the Applicant contemplated using his claimed device during coitus and not with the many other types of intercourse contemplated by the Respondents.

Standard Innovation's expert agreed. Her testimony from the hearing is particularly illustrative and convincing of the meaning and scope of the term "intercourse":

> Q. ***** So you would agree that intercourse is a broader term than coitus?
>
> A. Yes it is. So as we've talked about it is as Dr. Kinsey and his colleagues wrote, possible for two individuals of the same sex as well as two of the opposite sex to have intercourse, but that as he said as we've already noted, 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. What we see and certainly when I first looked at the way in a, you know, the Complainants and certainly the ITC Staff and the Respondents were proposing meanings for these terms, as one of ordinary skill in the art and certainly having read the claims in the '605 patent, the specification, it was very clear to me what intercourse in this investigation means. It has the ordinary meaning of penile/vaginal intercourse. When I saw the far broader definition that I was being presented with in the list from the Respondents, I you know, I did what I do as a scientist right. Which is say, well, let me go back.
>
> I'm going to go back to the person who started it all in the United States, systematic scientific research, which was Dr. Elder Kinsey. I reviewed his books from the '40s and '50s. I reviewed the books of other Kinsey Institute directors, including Becoming Orgasmic by Julia Heiman, yes, that is her real name, spelled differently. Dr. June Reinisch's book about the new -- from the 1990s. I also reviewed books of popular figures such as Dr. Ruth, including my own books as well and other books in the field. What I kept finding is that the term intercourse when used alone without a modifier and

> spanning, you know, seven or eight decades has an ordinary meaning throughout time of penile/vaginal intercourse. It is not that there are never any other types of intercourse. Of course there are. What we see in nearly all cases is the ordinary sense of penile/vaginal intercourse and we certainly see it in the context of the '605 patent.

(Tr. 315:10:317:5.) Thus, the record aptly establishes that the meaning of the term "intercourse" in the context of the '605 patent is coitus.

As mentioned above, the Respondents also claim that, under their construction, the term "intercourse" involves "multiple locations of insertion, such as if the intercourse is female-female or female-male intercourse with the female inserting a vibrator into the anus, while one or more objects are inserted into the vagina." (RX-0196C at Q/A 121.) Such an interpretation, however, would mean that the claimed device could be inserted in something other than the vaginal cavity or contacting something other than the clitoris. This reading is completely inconsistent with the limitations in the body of the claims which require the device to be in only two places – in the vagina and against the clitoral area. Thus, the claims themselves contradict Respondents' broad reading. (JX-0001 at Claim 1.)

In addition, the specification describes the device as worn and further describes where and how the device is worn on the body:

> In a broad aspect, then, the present invention relates to a device for use during intercourse by a female for sexual stimulation comprising an inner arm dimensioned for insertion into a vagina, to contact the wall of the vagina at or near the G-spot, an outer arm dimensioned to contact the clitoris, and a resilient U-shaped member connecting the inner and outer arms.

(JX-1 at 2:13-19.) The specification later explains that "because of this unique "U" feature, the device does not require any straps or attachments to hold it in placed. The clitoral pad will stay in place under all reasonable circumstances before, during and after intercourse." (*Id.* at 5:11-

14.) Thus, the specification, as well as the claims, has limit where on the body and how the device is to be worn during intercourse. There is nothing to suggest that the claimed device should be inserted in a different manner, as the Respondents suggest.

I generally agree with the claim construction proposed by Standard Innovation and the Staff as "sized to be worn by a female on the body during coitus." However, as there is no debate over "sized," I find this portion of the claim term need not be construed. Accordingly, the evidence has shown that the preamble should be construed to mean "dimensioned to be worn by a female on the body during coitus."

3. "generally tear drop shaped" (claims 1, 33, 66)

Standard Innovations' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"for the most part shaped like a tear-drop"	"looking like a tear drop, which is a three dimensional figure"	"for the most part shaped like a tear-drop"

Claims 1, 33, and 66 recite "at least one of the inner and outer arms are generally tear drop shaped." Standard Innovation and Staff argue this term should be construed to mean "for the most part shaped like a tear-drop." Respondents, contend, however, that Standard Innovation disclaimed "bulbous" and "hook" shapes from this limitation. Thus, the central dispute with respect to this limitation is whether the construction of "generally tear-drop shaped" should include these configurations.

The evidence shows that "generally tear-drop shaped" should be given its plain and ordinary meaning. (Tr. at 332:7-14.) The specification comports with this understanding as it refers to the shape of the end of the arm, as "generally teardrop-shaped: "a generally teardrop-shaped pad" (JX-0001 at 2:24-25) or an "inner-arm 1 that terminates in a bulbous teardrop-shaped pad 2" (*id.* at 3:11-13). Further, I find Respondents' proposed construction is not

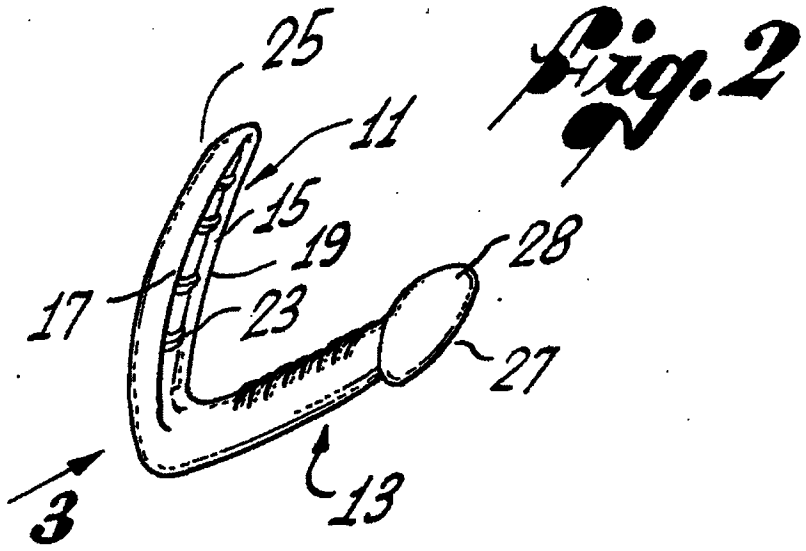
inconsistent with the plain and ordinary meaning. Respondents criticize Standard Innovation and Staff's definition as being circular, but notably Respondents definition suffers the same flaw. While Respondents are correct that a circular definition is not useful in construing the term, here, a circular definition results because the claim term has a plain and ordinary meaning and requires no construction.

Respondents have not shown that bulbous or round shapes were disclaimed. The Examiner rejected claims 19, 20, 21, and 22 under 35 U.S.C. § 102 over the Sekulick reference, stating the following:

> Sekulick teaches an inner arm 13 dimensioned to contact a wall of a vagina when inserted into said vagina of said woman, an outer arm 11 dimensioned to contact a clitoral area of said woman and a middle portion connecting the inner arm to the outer arm. The diameter of the device is approximately 5/16 inch . . . . This would appear to be a low profile that would permit sexual intercourse when the device is emplaced on the woman . . . .

(JX-0002 at 2 (Office Action dated February 5, 2012).) Respondents' prosecution history disclaimer argument rests upon the statements made by the Applicant to support patentability of the pending claims over the Sekulich reference.

In response to the rejection, the Applicant argued that Sekilick'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-0002 at 18 (Amendment dated April 29, 2012).) A depiction of the Sekulick device is shown below:



With respect to the shape of the device, the Applicant argued that:

> [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-0002 at 18-19.) 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 and out as the Sekulich device is not shaped to be retained out of the way during intercourse . . . .

(*Id.*) I find this language falls far short of disclaiming bulbous or round shapes. The Respondents also contend that hooked shaped arms were disclaimed based on arguments made with respect to two other prior art references—Marshall and Jacobs. Specifically, the Respondents ground their disclaimer argument on the following excerpt from the Marshall reference:

> As recited in Applicant's claims, and fully supported by the Specification and the drawings of the Applicant's invention, in direct contrast and opposite fashion, the present invention has a middle portion that has "a smaller cross-sectional area than either one or both of the inner arm and the outer arm". This low profile middle portion or admittance arm permits sexual intercourse when the device is emplaced on a woman. Not only does Marshall not anticipate Applicant's invention as claimed, but it is respectfully submitted that it is so different as to not render Applicant's invention obvious. *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.*
>
> 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-0002 at 20 (Response to Office Action dated January 7, 2009) (emphasis added).)

These passages reveal that the hook-shape arms in conjunction with the thicker middle portion that connects them of the Marshall device teaches away from the present invention as it would cause blockage of the vaginal passage thus preventing its use during intercourse. Indeed, when asked if a hook-shaped device such as the Rock Chick, *i.e.* the commercial embodiment as described in the Marshall patent, could be used during intercourse, Dr. Herbenick authoritatively

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. 412:20-413:6.) Accordingly, Respondents simply have not shown disclaimer of hook shapes.

Accordingly, "generally tear-drop shaped" shall be given its plain and ordinary meaning.

D. Infringement

1. Literal Infringement

Standard Innovation alleges the Tiani infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent; the Tiani 2 infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent; and the 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 of the '605 patent.

Despite alleging infringement of three independent claims and dozens of dependent claims, Standard Innovation devotes no more than **one page** of its post hearing brief in support of its allegations, to wit:

> At the hearing, Standard Innovation presented overwhelming evidence that each of the accused products—Lelo's Tiani, Tiani 2,[] and Mahana products—literally infringes the asserted claims of the '605 patent as follows:
>
> - Lelo's Tiani product infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent (JX-1; JPX-4; CX-275C Q. 398-421, 456-554; CDX-46C; CX-277C Q. 687-718, 733-1000; CDX-49C; CDX-56; CX-10C; CX-12C; CX-46; CX-220; CX-237; CX-269C; CX-272, CX-273; CDX-65);
>
> - Lelo's Tiani 2 product infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent (JX-1; JPX-5; CPX-1; CX-275C Q. 555-647; CDX-46C; CX-277C, Q. 687-694, 719-1000; CDX-49C; CDX-57;

CX-11C-13C; CX-30C; CX-235; CX-269C; CX-270, CX-272, CX-273; CX-274); and,

- Lelo's 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 of the '605 patent (JX-1; JPX-6; CX-275C Q. 648-736; CDX-47C; CDX-58; CDX-29C; CX-277C Q. 1001-1223; CDX-50C; CX-11C; CX-13C; CX-28C; CX-30C; CX-45; CX-235).

The only non-infringement position asserted by Respondents in their pre-hearing brief and at the hearing is with respect to the claim limitation "wherein, at least one of the inner and outer arms are generally tear-drop shaped." Respondents argue that the inner and outer arms of the accused products have shapes (*e.g.*, "bulbous", "hook", or "round shaft shaped") that were disclaimed during the prosecution history of the '605 patent. For the reasons discussed above, none of these shapes were disclaimed because there was no "unequivocal disavowal" of "bulbous", "hook", or "round shaft shaped" as asserted by Respondents. Moreover, even if prosecution disclaimer did apply, the evidence has shown that each of the accused devices nevertheless has at least one arm that is generally tear-drop shaped. CX-275C Q. 521-531, 613-624, 703-713; CX-277C Q. 786-796, 1072-1082; Tr., 381:18-389:3; Tr., 518:10-15, 532:19-21.

Thus, the Accused Products infringe the asserted claims.

(CIB at 21-22.)

I find Standard Innovation's non-specific string citation to the record fails to provide factual support for its allegations that the Accused Products infringe any claim of the '605 patent. For example, with respect to the Tiani, Standard Innovation cites to **419** questions and answers in witness statements without any explanation as to how those **419** questions and answers relate to any limitation of the numerous asserted claims. Further, Standard Innovation's citation to nearly two hundred pages of documentary evidence fails to provide any explanation of how those pages relate to any limitation of the numerous asserted claims. Finally, with respect to Standard Innovation's citation to demonstratives, demonstratives are not evidence and Standard innovation fails to provide any explanation as to how these demonstratives relate to any

limitation of the numerous asserted claims. My Ground Rules state that "[a]ny factual or legal issues not addressed in the post-hearing briefs shall be deemed waived." (G.R. 13.1.1.) I find Standard Innovation's string citations do not adequately address how any Accused Product meets any limitation of any asserted claim.[4] Accordingly, I find Standard Innovation effectively waived its allegations of direct infringement.

However, the Staff has identified evidence that the Accused Products meet each limitation of each asserted claim. (SIB 37-47.) The Respondents' only argument that the Accused Products do not meet each limitation of independent claims 1, 33, and 66 is that they do not meet the limitation "wherein, at least one of the inner and outer arms are generally tear-drop shaped." (RIB at 20-25.) Respondents further argue that because the Accused Products do not infringe the independent claims of the '605 patent, they also cannot infringe any dependent claims. (*Id.* at 21.)

Specifically, Respondents contend that both arms of the Tiani, Tiani 2, and Mahana are bulbous; that the inner arms of the Tiani and Tiani 2 have a hook shape; that both arms of the Mahana have a round cross-section; and that the inner arm of the Mahana has a round shaft. (*Id.* at 22-25.) Respondents argue that the Accused Products 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. However, as discussed above, Respondents have not shown that such shapes were disclaimed during prosecution of the '605 patent. Indeed, the evidence shows

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[4] I set the page limit for the post-hearing briefs to 75 pages. Inexplicably, Standard Innovation devoted only one page to infringement. Standard Innovation's string citation to its alleged evidence of infringement is an attempt at an end run around the page limit to allow a disproportionate **28** pages of briefing directed to the economic prong of domestic industry. I noted, in its pre-hearing brief, Standard Innovation devoted 39 pages to infringement and only 14 pages to the economic prong of the domestic industry. (CPHB at 38-76, 146-159.)

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." (CX-0275C (Herbenick DWS) at Q/A 521-532, 613-625, 703-714; CX-0277C (Villarraga DWS) at Q/A 786-797, 1072-1083; CDX-0046C at 007; CDX-0047C at 004.)

Accordingly, I find the evidence shows the Tiani infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent; the Tiani 2 infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent; and the Mahana infringes claims 1-7, 12-19, 24, 33, 35-40, 45-49, 52-54, 57, 66-73, 78-82, 85-87, and 90 of the '605 patent.

2. Doctrine of Equivalents

Standard Innovation's entire argument with respect to the doctrine of equivalents is:

> If the evidence, for some reason, does not support a finding of literal infringement, then the evidence easily supports a finding of infringement under the doctrine of equivalents because each of the accused products perform substantially the same function in substantially the same way to achieve substantially the same result as each of the asserted claims. CX-275C Q. 402, 456-736; CDX-46C; CDX-47C; CX-277C Q. 687-1223; CDX-49C; CDX-50C.

(CIB at 22.)

I find that Standard Innovation has failed to meet its burden of proving infringement under the doctrine of equivalents. "The determination of equivalence should be applied as an objective inquiry on an element-by element basis." *Warner-Jenkinson Co.* v. *Hilton Davis Chern. Co.,* 520 U.S. 17, 40 (1997). As an initial matter, Standard Innovation's string citation to hundreds of pages of testimony falls far short of that burden.

Rather than providing an analysis under the doctrine of equivalents, Standard Innovation criticizes Respondents for not making a "***serious attempt*** to demonstrate that the accused products did not *literally* infringe the asserted claims of the '605 patent." (CIB at 23 (emphasis

added).) Standard Innovation states the only non-infringement argument made by Respondents was that the inner arms of the accused devices were not generally tear-drop shaped. Standard Innovation contends "[t]he overwhelming evidence was to the contrary, making an analysis under the doctrine of equivalents ***superfluous***." (*Id.* (emphasis added).)

Here, Standard Innovation failed to make a "***serious attempt***" to demonstrate that the Accused Products did infringe the asserted claims under the doctrine of equivalents. A keyword search of Dr. Herbenick's testimony shows that Dr. Herbenick addressed the doctrine of equivalents in response to only ***one*** question despite Standard Innovation's citation to ***281*** questions and answers. The entirety of Dr. Herbenick's doctrine of equivalents "analysis" is cursory at best, and instead, relies upon conclusory statements:

> If, for some reason, the infringement is found not to be literal, I have determined that each of the accused products (the Tiani, the Tiani 2, and the Mahana) infringes under the doctrine of equivalents because they perform substantially the same function in substantially the same way to achieve substantially the same result of the asserted claims of the '605 patent.

(*Id.* at Q/A 402.) Likewise, despite citing to ***536*** questions and answers of Dr. Villarraga's testimony, Dr. Villarraga's testimony contains no analysis under the doctrine of equivalents. (CX-0277C (Villarraga DWS) at Q/A 687-1223.) I find Standard Innovation's argument relating to the doctrine of equivalents frivolous and its citation to evidence misleading in violation of Commission Rule 210.4(c)(3) which requires that allegations and other factual contentions have evidentiary support.

E. Technical Prong of Domestic Industry

Standard Innovation devoted **one sentence** in support of its assertion that the We-Vibe, We-Vibe II, and We-Vibe 3 products practice the asserted patent, to wit:

> Standard Innovation presented overwhelming and undisputed evidence that each of Standard Innovation's We-Vibe (original), We-

> Vibe II, and We-Vibe 3 products (the "Domestic Products") satisfies the technical prong of the domestic industry requirement because each product practices at least claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent. JX-1; JPX-1-3; CX-275C Q. 49, 65-117, 254, 289-397; CDX-45C; CDX-51-55; CDX-64; CX-210C-216C; CX-234; CX-277C Q. 38, 55-106, 341, 366-686; CDX-48C; CX-46C-49C; CX-50C-55C; CX-57C; CX-59C-67C; Tr., 390:25-391:22, 515:22-516:7.

(CIB at 19.) For the reasons discussed above, such string citations are insufficient to meet Standard Innovation's burden of proof.

Nevertheless, the Staff did identify evidence that the domestic industry products meet each limitation of claim 1 of the '605 patent. (SIB 48-51.) Respondents' only colorable argument to the contrary is that the Domestic Industry Products have a bulbous shape that was disclaimed from the claims the '605 patent.[5] (RIB at 25.) However, as discussed above, Respondents have not shown that bulbous shapes were disclaimed during prosecution of the '605 patent. Therefore, I find the evidence shows that the Domestic Industry Products practice claim 1 of the '605 patent.

The Staff contends that Standard Innovation "provided further evidence showing that the domestic products also practice the remaining asserted claims. CX-275C, Q. 442-686; CX-277C, Q. 366-391." (SIB at 51-52.) For the reasons discussed above, such string citations are insufficient to meet Standard Innovation's burden of proof.[6]

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[5] Respondents alternatively argue, "if the claim term 'generally tear drop shaped' is interpreted to mean bulbous, *see* Tr. 20:11-21:2, then the We-Vibe cannot be covered by the claims of the '605 patent based on the testimony of Dr. Villarraga, who believes that the We-Vibe's inner and outer arms are not bulbous, but they are generally tear drop shaped. Tr. 515:8-516:2." (RIB 26.) As I did not construe generally-tear drop shape to mean "bulbous," it is unnecessary to address Respondents' argument

[6] As Staff has addressed all limitations of claim 1, this is not a criticism of the Staff. If Standard Innovation had made any effort to meet its burden of proof in its post-hearing brief, this would

F. Validity

Respondents state that they set forth an invalidity analysis only for independent claims 1, 33, and 66 because during the hearing Standard Innovation agreed that the limitations of the dependent claims are obvious additions that must be looked at in the context of the independent claims. (RIB at 26.) Standard Innovation strenuously disagrees. (CRB at 9-.)

Respondents grossly mischaracterize the relevant portion of the transcript in which Standard Innovation's counsel responded, "We have to look at it in the context of the [independent] claims" (Tr. at 859:11-15) when I asked, "You're not going to make an argument that silicone and that batteries and that the flexibility and everything is brand new with this patent, '605 patent, are you, sir? I mean, except in the context of the independent claims." (*id.* at 859:5-10). Nothing in this exchange can be construed as an agreement that the limitations of the dependent claims are obvious additions of the independent claims. (*See also,* CRB at 9-10.) My Ground Rules state that "[a]ny factual or legal issues not addressed in the post-hearing briefs shall be deemed waived." (G.R. 13.1.1.) Accordingly, I find Respondents effectively waived their allegation that the dependent claims are obvious.

1. Anticipation

a. Mitchener

Respondents assert that U.S. Patent No. 4,574,791 to Mitchener (RX-0008) ("Mitchener") anticipates asserted claims 1, 33, and 66 of the '605 patent. (RIB at 30-33.) Mitchener issued on March 11, 1986 (RX-0008 at [45]) and is prior art to the '605 patent. Mitchener discloses a muscle-toning device for strengthening the female pelvic muscle. (RX-

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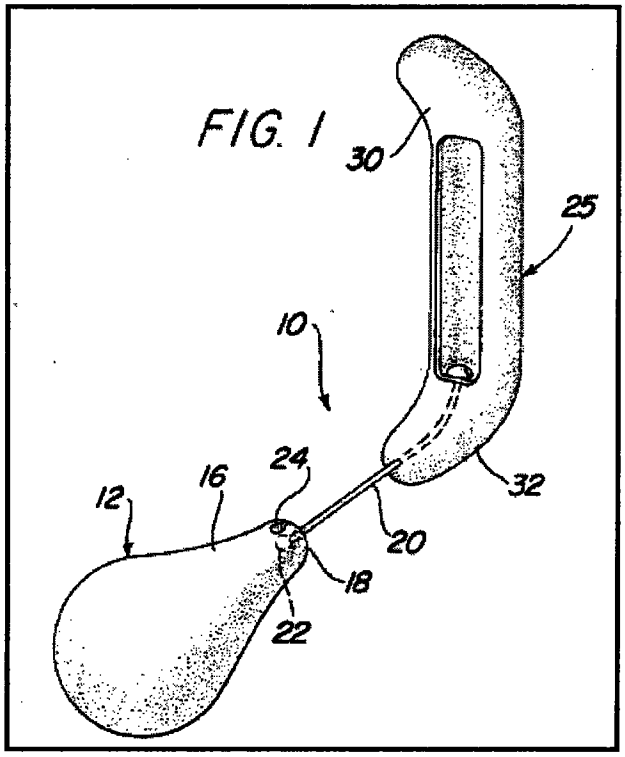
be a concurrence by Staff. Standard Innovation's abuse of the Staff's participation is not condoned.

0008 at [57].) For the reasons set forth below, Respondents have not proven that Mitchener discloses every limitation of claims 1, 33, and 66 of the '605 patent by clear and convincing evidence.

Respondents assert that Mitchener anticipates claims 1, 33, and 66. (RIB at 30-33 (citing RX-0196C (Locker DWS) at Q/A 269, 296, 283).) Despite black letter law that Respondents bear the burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity (*Scanner Techs.*, 528 F.3d at 1380), Respondents state they are limiting their arguments in their post hearing brief to the limitations disputed by Standard Innovation and Dr. Herbenick with respect to claims 1, 33, and 66. (RIB at 30-33.) Respondents' failure to address all limitations of claims 1, 33, and 66 is fatal to their argument that Mitchener anticipates claims 1, 33, and 66 of the '605 patent.

Nevertheless, *assuming arguendo*, that Respondents had addressed all limitations of claims 1, 33, and 66, Respondents have not shown that Mitchener teaches the limitation "a sexual stimulation device dimensioned to be worn by a female during intercourse" as required by the preamble of the asserted claims.[7] As an initial matter, the device disclosed in the Mitchener (shown below) is not a sexual stimulation device — it is a muscle toning device for strengthening the pubococcygeal muscle ("PC muscle") of a female. (RX-0008 at [57].)

[7] As discussed above, I find the preamble of claims 1, 33, and 66 is limiting.



RX-0008, Figure 1

Moreover, the evidence shows the device described is not dimensioned to be worn by a female during intercourse. (CX-0276C at Q/A 346-47.) The "vaginal insert member" of the device (which resembles a pear ("12" in the figure)) is designed to be inserted in the vagina such that the female can contract her PC muscle around the insert to effect toning of the muscle. (RX-0008 at 3:50-57, [57].) The neck of the pear is intended to be positioned either adjacent to or protruding out of the vaginal opening. (*Id.* at 3:10-17.)

Dr. Locker testified:

> There is no teaching in Mitchener that excludes the device from being worn by a woman during intercourse. In fact, women are often encouraged by sex therapists and sex educators to tone their pubococcygeus muscle during penile-vaginal intercourse, so the use of a device such as Mitchener during penile-vaginal intercourse would be logical. The size of the Mitchener device is such that it could be worn by a woman during intercourse including penile-vaginal intercourse since such use depends on relative size of vagina and penis."

(RX-0196C (Locker DWS) at Q/A 269 (emphasis added).)

In her testimony, Dr. Locker merely asserts that Mitchener is capable of being worn by a female during intercourse. (*Id.*) However, even if the device disclosed in Mitchener is capable of being worn during intercourse, there is no evidence that the device disclosed in Mitchener is "***dimensioned*** to be worn by a female during intercourse" as required by the asserted claims. Accordingly, for at least this reason, Mitchener does not anticipate the claims of the '605 patent.

b. Ultime

The Ultime is a personal massager marketed by Natural Contours. (RPX-0004.) The Ultime was first sold in March 2001 and is prior art to the '605 patent. (JX-0014C at 191:23-192:14.) For the reasons set forth below, Respondents have not proven that the Ultime discloses every limitation of claims 1, 33, and 66 of the '605 patent by clear and convincing evidence.

Respondents assert that Ultime anticipates claims 1, 33, and 66. (RIB at 30-33 (citing RX-0196C (Locker DWS) at Q/A 310, 322, 335).) Despite black letter law that Respondents bear the burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity (*Scanner Techs.*, 528 F.3d at 1380), Respondents state they are limiting their arguments in their post hearing brief to the limitations disputed by Standard Innovation and Dr. Herbenick with respect to claims 1, 33, and 66. (RIB at 33-36.) Respondents' failure to address all limitations of claims 1, 33, and 66 is fatal to their argument that the Ultime anticipates claims 1, 33, and 66 of the '605 patent.

Nevertheless, *assuming arguendo*, that Respondents had addressed all limitations of claims 1, 33, and 66, Respondents have not shown that the Ultime teaches the limitation "a sexual stimulation device dimensioned to be worn by a female during intercourse" as required by

the preamble of the asserted claims.[8] In fact, the evidence shows the device described is not dimensioned to be worn by a female during intercourse. (CX-0276C at Q/A 256-82; CX-0285 at Q/A 187-308.) Indeed, neither the instruction manual nor the website for the Ultime even suggest that the Ultime product is dimensioned to be worn by a female during intercourse. (*Id.*)

Dr. Locker testified:

> Ultime has a slender width of only 1 inch and the inner arm inserts up to 4 inches into the vagina. Thus, Ultime discloses a sexual stimulation device which is dimensioned to be worn by a female during intercourse. The size and shape of the Ultime is such that intercourse, including penile-vaginal intercourse, can be performed while the inner arm is inserted within the vagina since such use depends on relative size.

(Locker DWS at Q/A 310.) I am not persuaded by Dr. Locker's conclusion that the Ultime is dimensioned to be worn by a female during intercourse. (*Id.*) Dr. Locker offers no support for her conclusion. Further, I find her testimony merely supports a finding that the Ultime could be worn during intercourse as opposed to being dimensioned to be worn by a female during intercourse. Specifically, Dr. Locker's testimony concludes that intercourse "***can*** be performed" and fails to address how the Ultime is dimensioned to be worn by a female during intercourse. Accordingly, for at least this reason, the Ultime does not anticipate the claims of the '605 patent.

c. Kain

Respondents assert that U.S. Patent No. 5,690,603 to Kain (RX-0002) ("Kain") anticipates asserted claims 1, 33, and 66 of the '605 patent. (ROB at 36-39.) Kain issued on November 25, 1997 (RX-0002 at [45]) and is prior art to the '605 patent. The Kain patent describes a device designed "with a first phallic end which is used in the normal manner and a second bulbous end which is inserted within the vaginal or anal cavity of the wearing partner."

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[8] As discussed above, I find the preamble of claims 1, 33, and 66 is limiting.

(RX-0002 at [57].) For the reasons set forth below, Respondents have not proven that Kain discloses every limitation of claims 1, 33, and 66 of the '605 patent by clear and convincing evidence.

Respondents assert that Kain anticipates claims 1, 33, and 66. (RIB at 36-39 (citing RX-0196C (Locker DWS) at Q/A 142, 159).) Despite black letter law that Respondents bear the burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity (*Scanner Techs.*, 528 F.3d at 1380), Respondents state they are limiting their arguments in their post hearing brief to the limitations disputed by Standard Innovation and Dr. Herbenick with respect to claims 1, 33, and 66. (RIB at 36-39.) Respondents' failure to address all limitations of claims 1, 33, and 66 is fatal to their argument that Kain anticipates claims 1, 33, and 66 of the '605 patent.

Nevertheless, *assuming arguendo*, that Respondents had addressed all limitations of claims 1, 33, and 66, Respondents have not shown that Kain teaches the limitation "a sexual stimulation device dimensioned to be worn by a female during intercourse" as required by the preamble of the asserted claims.[9]

The evidence shows that Kain is not dimensioned to be worn by a female during intercourse. (CX-0276C at Q/A 154-238; CX-0285C at 81-120.)

Dr. Locker testified:

> Kain's device ***can*** be worn by a woman during intercourse including penile-vaginal intercourse since such use depends on relative size of vagina and penis.

(RX-0196C (Locker DWS) at Q/A 142 (emphasis added).) In her testimony, Dr. Locker merely asserts that Kain is capable of being worn by a female during intercourse. (*Id.*) However, even

[9] As discussed above, I find the preamble of claims 1, 33, and 66 is limiting.

if the device disclosed in Mitchener is capable of being worn during intercourse, there is no evidence that the device disclosed in Mitchener is "***dimensioned*** to be worn by a female during intercourse" as required by the asserted claims.

Further, Dr. Locker testified:

> In the SIC's chart in Exhibit RX-0128C, under the heading "can be used by a coupled during sex", is there a Y marked for both the We-Vibe and the Feeldoe that indicates "yes". The Feeldoe is the commercial embodiment of Kain. In my view, "sex" in this chart means intercourse.

(RX-0196C (Locker DWS) at Q/A 142.)

As discussed above, there is no testimony regarding the author of this document or the meaning of this document, accordingly I give it little weight. Dr. Locker offers no explanation for her interpretation of "sex" in the document as "intercourse." While the document indicates that the Feeldoe can be used by a couple during sex, the document also indicates that the Feeldoe does not "allow[] access to vagina for penis or dildo." RX-0128C(2). Accordingly, I find this document supports Standard Innovation's position that the Feeldoe does not anticipate the '605 patent because the Feeldoe is not dimensioned to be worn on the body of a female during coitus. Accordingly, for at least this reason, Kain does not anticipate the claims of the '605 patent.

2. Obviousness

Respondents devote a mere three pages of their post-hearing brief in support of three arguments that the independent claims of the '605 patent are obvious under 35 U.S.C. § 103(a). (RIB at 39-41.) As discussed below, Respondents' arguments fail factually and legally.

a. Generally Tear-Drop Shaped

Respondents state they will not engage in an extended obviousness analysis under 35 U.S.C. § 103 for two reasons:

> First, the Examiner allowed the claims because he had not seen the term "generally tear-drop shaped" in the prior art. SIC's Supplemental Response to Respondent's Interrogatory No. 2.] See RX-0030_0006-0007. SIC, however, does not dispute that Mitchener, the Ultime or Kain in fact disclose a generally tear-drop shaped arm. Although Mitchener and the Ultime are not prior art of record, Kain is. SIC has switched its position and after agreeing with the Examiner that Kain does not disclose a generally tear-drop shaped, RX-0034C_0089-0091, it now admits that Kain does. RX-0030_0012. In light of SIC's admissions, the claims of the '605 patent are obvious over the Examiner's prior art rejections in view of any of Mitchener, the Ultime or Kain, which disclose the allegedly missing generally tear drop shaped arm teaching.

(RIB at 39.)

Respondents assert that Standard Innovation initially agreed with the Examiner that Kain does not disclose a generally tear-drop shape. However, the cited testimony states that the witness does not recall discussing the Kain reference with the Examiner during the interview. (*Id.*) Respondents have not cited any evidence that Standard Innovation initially agreed with the Examiner that Kain does not disclose a generally tear-drop shape. Moreover, Respondents fail to explain how Standard Innovation's alleged admissions result in a finding that "the claims of the '605 patent are obvious over the Examiner's prior art rejections in view of any of Mitchener, the Ultime or Kain, which disclose the allegedly missing generally tear drop shaped." Indeed, as discussed above, I found that none of these references—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.

It is unclear why Respondents did not engage in an extended obviousness analysis under 35 U.S.C. § 103. I find that, by simply making cursory assertions and conclusory arguments, Respondents fall far short of meeting the clear and convincing standard necessary to invalidate the '605 patent as obvious. *See PharmaStem*, 491 F.3d at 1360 (a patent challenger must "show by clear and convincing evidence that a person of ordinary skill in the art would have had reason

to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so."); *see also Tech. Licensing*, 545 F.3d at 1327 ("When an alleged infringer attacks the validity of an issued patent, [the] well-established law places the burden of persuasion on the attacker to *prove invalidity by clear and convincing evidence*." (emphasis added)).

A person is not entitled to a patent if the differences between the claimed invention and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. The underlying factual inquiries relating to non-obviousness include: 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) secondary considerations of non-obviousness, such as long-felt need, commercial success, and the failure of others. *See Graham v. John Deere Co.*, 383 U.S. at 17. Respondents address none of these inquiries and, further, have failed to provide any motivation for one of ordinary skill in the art to combine the references, which is also required for a finding of obviousness. *See C.R. Bard*, 157 F.3d at 1352.

b. The Ultime in Combination with Mitchener or Kain

Respondents' entire argument that the '605 patent is obvious in light of Ultime in combination with Mitchener or Kain consists of:

> Second, the analysis in § III.E.1 shows that independent claims 1, 33 and 66 are anticipated by either of Mitchener, the Ultime or Kain. To the extent that the Administrative Law Judge disagrees, the foregoing analysis shows that the independent claims are obvious over the Ultime in light of either of Kain or Mitchener. Each of these devices (1) is dimensioned to be worn by a female during intercourse, and (2) has an elongate inner arm that is dimensioned for insertion into a vagina, an elongate outer arm that contacts a clitoral area, with both arms tapering toward a connecting portion, a connecting portion with a width that is equal to or greater than its width to minimize obstruction to the vagina,

> and at least one generally tear-drop shaped arm. It would have been obvious to combine an element from either Kain or Mitchener to whatever the Administrative Law Judge finds lacking in the Ultime.

(RIB at 39-40.)

Here, Respondents' decision to forgo an extended obviousness analysis is baffling. Respondents do not cite any evidence to support its argument that "[e]ach of these devices (1) is dimensioned to be worn by a female during intercourse, and (2) has an elongate inner arm that is dimensioned for insertion into a vagina, an elongate outer arm that contacts a clitoral area, with both arms tapering toward a connecting portion, a connecting portion with a width that is equal to or greater than its width to minimize obstruction to the vagina, and at least one generally tear-drop shaped arm." Likewise, Respondents do not cite any record evidence to support its argument that "[i]t would have been obvious to combine an element from either Kain or Mitchener to whatever the Administrative Law Judge finds lacking in the Ultime."

Respondents rely entirely on attorney argument to make its obviousness case. Attorney argument, however, is not evidence. Therefore, I find Respondents have failed as a matter of law to set forth a *prima facia* case of obviousness. *See Graham v. John Deere Co.*, 383 U.S. at 17 (stating that the underlying factual determinations include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness).

c. Ultime in Combination with Marshall

Respondents' entire argument that the '605 patent is obvious in light of Ultime in combination with Marshall consists of:

> The anticipation analysis did not discuss Marshall. However, the independent claims are also obvious over the Ultime in light of Marshall. Marshall discloses the following limitations of the independent claims. It would have been obvious to combine any

of these elements from Marshall to whatever the Administrative Law Judge finds lacking in the Ultime.

A sexual stimulation device dimensioned to be worn by a female during intercourse – Marshall teaches a sexual stimulation device. Dr. Herbenick admitted at the hearing that the inner arm of the Rock Chick, which is the embodiment of Marshall, Tr.828:13-16, could be inserted into a vagina during coitus. Tr. 411:25-412:2 This is confirmed by Exhibit RX-0051_0002, which states that the Rock Chick "can also be used during sex, provided your partners' penis or the dildo you're using together will fit alongside the insertable shaft."

- an elongate inner arm dimensioned for placement inside a vagina – It is not disputed that Marshall discloses an elongate inner arm 2 dimensioned for placement inside a vagina.

- an elongate outer arm dimensioned for placement against a clitoral area – It is not disputed that Marshall has an elongate outer arm dimensioned for placement against a clitoral area.

- a connecting portion connecting said inner and outer arms – Marshall has a connecting portion 8 connecting said inner and outer arms.

- wherein, at least one of the inner and outer arms are generally tear-drop shaped – The International Preliminary Report on Patentability ("IPRP") found that Marshall disclosed a "generally tear-drop shaped pad." *See* JX-0002_0102-0104. The Australian Examiner examining SIC's corresponding Australian application also found that Marshall disclosed a "generally tear-drop shaped pad." *See* JX-0008_039.

- wherein said connecting portion which has a width which is equal to or greater than its thickness to minimize obstruction to the vaginal opening – The connecting portion 8 of Marshall has a width equal to or greater than its thickness. RX-0004_0002.

(RIB at 40-41.)

Again, I find that, by simply making cursory assertions and conclusory arguments, Respondents have failed to meet the clear and convincing standard necessary to invalidate the

'605 patent based on obviousness. *See PharmaStem*, 491 F.3d at 1360; *see also Tech. Licensing*, 545 F.3d at 1327. Respondents have also failed to provide any motivation for one of ordinary skill in the art to combine the reference, which is also required for a finding of obviousness. *See C.R. Bard*, 157 F.3d at 1352.

d. Objective Indicia of Nonobviousness

Since I find that Respondents have failed to make a prima facie argument regarding obviousness, I find that an extensive analysis of secondary considerations to rebut the obviousness arguments is unnecessary.

3. Indefiniteness

The Respondents contend that the claim limitations "generally tear-drop shape" and "dimensioned to be worn by a female during intercourse" are indefinite. The evidence does not support this contention.

Claims of invalidity require proof by clear and convincing evidence. *Scanner Technologies Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). Where, as here, the challenge is brought under 35 U.S.C. § 112, ¶ 2, clear and convincing evidence must establish that a person of ordinary skill in the relevant art would not understand the scope of what the challenged claims when read in light of the specification. *Personalized Media Communications, L.L.C. v. ITC,* 161 F.3d 696 (Fed. Cir. 1998).

The Respondents have fallen far short of satisfying this heavy burden with respect to the "generally tear-drop shaped" limitation. As discussed above, the term generally tear-drop shaped does not require construction and is given its plain and ordinary meaning. The 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. (CX-276C at Q/A117; RX-0196C (Locker DWS) at Q/A 78.)

Similarly, the evidence does not show that the phrase "dimensioned to be worn by a female during intercourse" is indefinite. The Respondents contend that because the preamble does not specify where on the female body the sexual stimulation device should be worn, this claim term is indefinite. This contention, however, is not supported by the record.

The specification provides sufficient guidance to one skilled in the art regarding the term "intercourse." In particular, 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. (JX-0001 at 9:53-10:21 ("The 'outer' surface of the clitoral pad, internal arm and internal vibrating module that is against the man's skin is glass smooth to minimize friction to reduce any tendency of the device to move with the mas as the penis moves in and out of the vagina.").)

Further, the specification refers to men and women when discussing how to wear the claimed device: "[w]hen worn, the inner surface is against the woman and the outer surface is against the man" (*id.* at 8:50-53); "[i]t should be noted also that the device conforms to the shape of the vagina even when this shape changes when a penis is inserted and also changes when the penis is at different angles relative to the woman" (*id.* at 10:3-6). Thus, the intrinsic record of the '605 patent provides more than enough understanding of the scope and meaning of the term "intercourse." Accordingly, based on the above, evidence has not shown that the claim limitation "dimensioned to be worn by a female during intercourse" is indefinite.

VI. ECONOMIC PRONG OF DOMESTIC INDUSTRY

To satisfy the economic prong, Standard Innovation must prove, with respect to the articles it alleges are protected by the '605 patent "(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in [the '605 patent's] exploitation, including engineering, research and development, or licensing."

19 U.S.C. § 1337(a)(3) (internal formatting removed). Because the statute uses the disjunctive term "or," Standard Innovation bears the burden of establishing that the domestic industry requirement is satisfied based on any one of the three subsections (A) through (C). 19 U.S.C. § 1337(a)(3).

In its pre-hearing brief, Standard Innovation applied the "governing legal standards to Standard Innovation's activities." (CPHB at 148-159.) Standard Innovation identified specific activities that it alleged constitute significant investment in plant and equipment under prong A (*id.* at 148-152), significant employment of labor or capital under prong B (*id.* at 152-153), and substantial investment in exploitation, including engineering, research and development, or licensing under prong C (*id.* at 154-158). Specifically, Standard Innovation allocated the following expenses to prong A:

- the cost of eight components or materials purchased from U.S. companies for use in its We-Vibe products (*id.* at 148-151); and
    1. [ ]
    2. [ ]
    3. microcontrollers [ ]
    4. DC to DC converters [ ]
    5. Charger ICs[ ]
    6. transceivers [ ]
    7. crystals [ ] and
    8. pigment [ ]
- payments for warehousing services (*id.* at 152).

Standard Innovation allocated the following expenses to prong B:

- salary of U.S. employees (*id.* at 152-153); and
- administrative costs (*id.* at 153).

Standard Innovation allocated the following expenses to prong C:

- engineering work performed by [ ] (*id.* at 154-155);
- research and development work conducted with U.S. companies (*id.* at 155-156);
- sexual wellness education efforts (*id.* at 156-158);
- service and warranty fulfillment (*id.* at 158); and
- the profits earned by U.S. distributors and retailers of the We-Vibe (*id.* at 158).

Standard Innovation argues in its post-hearing brief that its expenditures "relating to exploitation of the '605 patent represent ***significant or substantial*** investments under prongs (A)-(C). (*CIB* at 68 (emphasis added).) Quite confusingly, Standard Innovation then goes on to argue that the following expenditures relating to the exploitation of the '605 patent in the U.S. are ***significant and substantial***, and satisfy the economic prong of the domestic industry test:

Expenditures	2008 – Nov. 2011	2008 – June 2012
US manufactured materials and components	[ ]	[ ]
Service / Warranty	[ ]	[ ]
Other components purchased from US companies	[ ]	[ ]
Warehousing	[ ]	[ ]
Educational Events and Trade Shows	[ ]	[ ]
Product samples	[ ]	[ ]

Other sales/marketing	[ ]	[ ]
US Employees	[ ]	[ ]
Administrative costs	[ ]	[ ]
TOTAL	[ ]	[ ]

(CIB at 69-70.)

To the extent Standard Innovation now argues in its post-hearing brief that each of its asserted expenditures are relevant under prongs (A), (B), and (C), I find Standard Innovation has far exceeded the scope of its pre-hearing brief. My Ground Rules are clear that contentions not raised in a party's pre-hearing brief are deemed abandoned or withdrawn. (Ground Rule 9.2 (May 8, 2012, Notice of Ground Rules) ("Any contentions not set forth with the level of particularity required [in the pre-hearing brief] shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not have been aware in the exercise of reasonable diligence at the time of filing the pre-hearing brief.").) Moreover, allowing Standard Innovation to raise contentions for the first time in its post-hearing brief would prejudice Respondents and the Staff who had no opportunity to address these arguments at the hearing. Thus, I find Standard Innovation has waived its arguments in its post-hearing brief that its asserted expenditures support a finding that it has satisfied the economic prong of the domestic industry requirement under prongs (A), (B), and (C). Accordingly, my analysis of Standard Innovation's expenditures set forth in its post-hearing brief as they relate to prongs (A)-(C) shall be confined to that as set forth in its pre-hearing brief.

The Staff is of the view that, while Standard Innovation's evidence of domestic industry presents a close question based on applicable Commission precedent, when taken as a whole, the evidence shows that Standard Innovation has satisfied the domestic industry requirement under

§ 1337(a)(3)(C). (SIB at 69-77.) As discussed below, the Staff asserts the evidence shows that Standard Innovation's purchases of U.S. manufactured component parts—[ ] microcontroller part and DC to DC converter from [ ] and pigments by [ ]—that are allegedly critical to the success of the We-Vibe products are sufficient to satisfy prong C of the domestic industry requirement.[10] (*Id.* at 69.)

The Staff notes that Standard Innovation also relies on a number of activities that cannot be factored into the domestic industry analysis, such as, expenditures relating to the marketing and sales of the domestic products, warehousing, customer support, and unquantified research and development/engineering costs for the We-Vibe devices. (*Id.* at 74 n.8.) The evidence does not show that these expenditures can be used to establish the domestic industry requirement as the marketing and sales activities are not production related and/or do not occur in the United States and the research and development costs are not properly quantified.

Respondents argue that Standard Innovation has not shown a significant investment in plant and equipment (RIB at 56-62); has not shown a significant employment of labor or capital (*id.* at 62-64); and has not substantially invested in the exploitation of the '605 patent (*id.* at 64-66). Respondents argue that because Standard Innovation did not allege that a domestic industry was in the process of being established in its complaint, this issue is not properly part of this Investigation. (*Id.* at 66-67.)

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[10] Standard Innovation allocates these expenditures under prong A. The parties do not discuss this difference in their briefs.

1. Activities Occurring After Filing of the Complaint Are Irrelevant

Standard Innovation acknowledges that as a general matter only those activities occurring before the filing of the complaint are relevant to the determination of the existence of a domestic industry. (CIB at 46.) However, Standard Innovation argues that in appropriate circumstances depending on the specific facts and circumstances of an investigation, post-complaint domestic industry activities may be considered. (*Id.* at 46-47 (citing *Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op. at 5-6 (Jan. 20, 2012)).) Standard Innovation argues that "given the relatively small size of the company, the fact that sales only began in 2008 in a market that Standard Innovation had to create, and the continued dramatic growth of both sales and investments in the U.S., Complainants submit that the circumstances justify consideration of post-complaint expenditures in this investigation." (*Id.* at 47.)

I am not persuaded by Standard Innovation's argument. Standard Innovation fails to identify any specific facts or circumstances that justify considering domestic industry activities that occurred after the filing of the complaint. The circumstances raised by Standard Innovation are not unique; rather they appear consistent with the challenges of any new business. However, Standard Innovation did not allege that a domestic industry was in the process of being established in its complaint.[11]

2. Expenditures Relating to the We-Vibe (Original) are Irrelevant

Section 337 is written in the present tense and requires a domestic industry that exists at the time of the filing of the complaint. 19 U.S.C. § 1337(a)(2). While not addressed by the

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[11] Even if Standard Innovation had alleged that a domestic industry was in the process of being established, "only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3)." *Coaxial Cables*, Inv. No. 337-TA-650 Comm'n. Op. at 51 n.17.

parties, the record shows Standard Innovation stopped selling the We Vibe (original) in 2009. (CX-0280C (Finlayson DWS) at Q/A 55-56; CDX-0008C.) A product that had not been sold for two years before the filing of the complaint is not persuasive evidence of Standard Innovation's existing domestic industry. Accordingly, expenditures solely relating to the We-Vibe (original) are not relevant to Standard Innovation's contention that a domestic industry exists.

3. Standard Innovation's Purchase of Components Does Not Satisfy the Domestic Industry Requirement

It is undisputed that the Domestic Industry Products are assembled overseas in China. (Tr. 71:10-16.) Standard Innovation works with two contract manufacturers who purchase and assemble the components for the domestic industry products. (Tr. at 71:10-16.) The components for the domestic industry products include, among other things, silicone, backbone, batteries, vibrators, micro-controllers, a material used to [ ] the device called [ ], motors, and the material used in the backbone of the device called [ ] (Tr. 213:9-214:20.)

Standard Innovation and the Staff assert Standard Innovation's purchase of four components manufactured in the United States that are allegedly crucial to the performance of the We-Vibe products are sufficient to establish a domestic industry under prong A and prong C, respectively.[12] (CIB at 53-58; SIB at 69-77.) First, the evidence shows that Standard Innovation requires its contract manufacturers to use [ ] which is manufactured in the U.S. by [ ] (CX-280C at Q/A 164-177.) [ ] is a silicone used to [ ] of the We-Vibe in order to create a smooth and even finish. *Id.* Standard Innovation has spent [ ] from 2008 to November 2011 for

[12] Standard Innovation allocates these expenditures to prong A. The Staff allocates these expenditures to prong C. The parties do not address this difference.

use in its We Vibe products.[13] (CDX-85C at 9; CX-0076; CX-0116C.) The evidence shows that [ ] is a critical component in the We-Vibe products. (Tr. at 180:8-15, 176:4-14.)

Second, the evidence shows that [ ] is a critical component in the We-Vibe products. (Tr. at 213:11-214:3; *see also id.* at 176:4-14; *id.* at 235:9-236:17.) Standard Innovation has spent [ ] on [ ] from 2008 to mid-2011 for use in its We-Vibe products.[14] (CDX-85C_009; CX-0076; CX-0116C.)

Additionally, Standard Innovation purchases microcontroller parts for the We-Vibe 2 and both a microcontroller part and DC to DC converter from [ ] for the We-Vibe 2 and We-Vibe III products. (CX-280 at Q/A 80-89; Tr. 180-16-181:10.) The microcontroller controls the vibrator motor and the DC to DC converter convert the voltage in order to run the processor and RF circuitry. *Id.* While these products are made in the U.S., only a portion of the manufacturing actually occurs here. (Tr. 181:11-19.) The wafers for these products are made in the United States and the assembly and testing is done offshore. *Id.* The wafer fabrication accounts for approximately 80% of the cost of production. *Id.* Standard Innovation has spent [ ] on the purchases of these components from 2009 to November 2011 for use in the We-Vibe 2 and We-Vibe III products. (CDX-85C_009; CX-0076; CX-0116C.) Hence, I can only attribute 80% of this cost to Standard Innovation's domestic industry, *i.e.* [ ]

With respect to these three components, the record shows that each directly relate to a claim in the '605 patent. Standard Innovation's expert, Dr. Villaraga, testified that [ ] relates to the dependent claims that recite [features of the outer covering of the We-Vibe device,

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[13] This amount has not been reduced by the amount spent on the original We-Vibe.

[14] This amount has not been reduced by the amount spent on the original We-Vibe.

i.e., claims 6, 7, 39, 40, 72, and 7 (Tr. at 570:5-571:5; CX-277C, at Q/A 548-561.) The [ ] component specifically relates to at dependent claims 9, 10, 11, 42, 43, 44, 75, 76, and 77 39 which recite limitations relating to the skeleton of the We-Vibe device.] (Tr. at 570:5-571:5; CX-277 at Q/A 562-592; CDX-0048C at 30-31.) Likewise, the microcontroller] relates to at least dependent claims [17, 18, 19, 52, 53, 54, 85, 86, and 87. (Tr. at 568:21-569:6; CX-277 at Q/A 618-639; CDX-0048C at 46-47.) Thus, not only are these components critical to the function of the We-Vibe devices, they also directly relate to claimed features in the '605 patent. *See Concealed Cabinet Hinges and Mounting Plates,* 337-TA-289, Comm. Op. at 23 (Jan. 9, 1990) ("The only domestic addition to the completed product is the addition of imported dowels, which is optional and, because the patent covers the completed hinge, not the dowel feature, does not bear directly on the "exploitation' of any claim of the '735 patent . . . Because of its indirect bearing on the patented features . . . we reduce the weight we otherwise would accord complainant's investment in plant and equipment."). Finally, the evidence also shows Standard Innovation purchases silicone color pigments, made in the United States, from [ ] for the We-Vibe II. (CX-280 at Q/A 111-118.) Standard Innovation has spent [ ] for the purchase of this product from [ ] (*Id.*) I find this component does not directly relate to a claim in the '605 patent and is not relevant to prong C. (*See* CX-280C at Q/A 118.)

While Standard Innovation's post-hearing brief is unclear as to how it is allocating these expenditures, Standard Innovation is bound by the argument in its pre-hearing brief that its purchase of these components supports a finding of a significant investment in plant and equipment under prong A. However, 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. (CIB at 54-58.) Accordingly, there is absolutely no basis for me to attribute these expenses to prong A.

The Staff asserts that these expenditures are sufficient to satisfy the economic prong of the domestic industry under § 1337(a)(3)(C). (SIB 69-77.) However, 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.

Section 337(a)(3)(C) states that "an industry in the United States shall be considered to exist if there is in the United States ... substantial investment in ... exploitation [of the patent], including engineering, research and development, or licensing." Notably, the provision does not specifically mention the purchase of components. With respect to [ ] and the silicone color pigments, the evidence shows that these components were selected due to their suitability for the We-Vibe products rather than developed for use in the We-Vibe.[15] As such, investments in engineering as well as in research and development cannot represent efforts to facilitate and/or hasten the practical application of the invention of the '605 patent.[16] Notably, Standard Innovation provides only the total amount it spent on such components and does not break out any engineering or research and development costs incurred by the manufacturer of

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[15] For example, the [ ] costs per unit were calculated based on the estimated grams per unit multiplied by the cost per gram.

[16] To the extent such investments may be relevant; Standard Innovation provides only the total amount spend on these components. Further, there is no evidence the color pigments from [ ] relate in any way to the exploitation of the '605 patent.

these products. Thus, I must not consider the purchase of these components as engineering or research and development activities relevant to prong C.[17]

With respect to the components from [ ] while Standard Innovation asserts the components were customized, there is no evidence regarding customization, including the alleged costs of such customization. (CIB at 58.) Again, Standard Innovation provides the total amount it spent on such components and does not break out any engineering or research and development costs. (*Id.*)

Regardless, assuming arguendo that Standard Innovation had shown that the mere purchase of [ ] color pigments, and components from [ ] were relevant to domestic industry without identifying plant and equipment or engineering or research and development costs, I find these investments are not substantial or significant. The Staff asserts that the evidence shows that Standard Innovation has spent a total of [ ][18] on components manufactured in the U.S. for use in the We-Vibe products since 2008 until the filing of the Complaint and that "these expenditures account for slightly less than 5% of the total costs of the products (taking into account that only 80% of the production for the microcontroller occurs in the United States)." (SIB at 75.) The Staff further asserts the monies spent on U.S. source components is a significant investment for a start-up company. (*Id.*) Likewise, Standard Innovation argues that an investment of $1 million may not be significant to enormous companies like Apple, IBM, HP, or Samsung, but for a company the size of Standard

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[17] While the language of the statute leaves open that something more than engineering, research and development, and licensing could be relevant to prong C, no party has argued why the mere purchase of components is relevant.

[18] This amount includes costs associated with the We-Vibe (original) that are irrelevant to domestic industry.

Innovation, [ ] is a significant and substantial amount relative to the size of its overall operations. (CRB at 27.)

Because Standard Innovation's expenditures per unit do not vary over time, I find it is more appropriate to look at Standard Innovation's per unit expenditures rather than over a multiple year period. With respect to the We-Vibe II, Standard Innovation attributes [ ] to the Microcontroller [ ] taking into account that only 80% of the production for the microcontroller occurs in the United States); [ ] (CX-0280C (Finlayson DWS) at Q/A 195; CDX-0037C.) While Standard Innovation argues this is 5% of the total value added (RRB at 26), I find this argument misleading at best. The evidence establishes that the [ ] cost of components supplied by U.S. companies is less than 5% of the **total product raw cost** of [ ] (CX-0280C (Finlayson DWS) at Q/A 195; CDX-0037C.) Dividing Standard Innovation's worldwide We-Vibe II revenue by its worldwide unit sales results in a per unit revenue of over [ ] (CX-0280C (Finlayson DWS) at Q/A 56, 62; CDX-0008C; CDX-0010C.) The [ ] cost of components supplied by U.S. companies is really only around [ ] of the total product revenue.

Standard Innovation's argument that a [ ] investment is large based on its size is not persuasive. Standard Innovation fails to offer any quantification of its size or explain how these costs are related to prong A . Notably, Standard Innovation's "investment" of [ ] resulted in [ ] in revenue. (CX-0280C (Finlayson DWS) at Q/A 62.)

While Standard Innovation has spent nearly [ ] on these components, it is because Standard Innovation has experienced tremendous sales, which cuts against its argument that it is a small startup company. Indeed, in 2010 alone, Standard Innovation sold [ ] We-Vibe II's. (CX-0280-C at Q/A 56; CDX-0008C.) Standard Innovation's expenditure of nearly

[ ] is directly proportional to its sales. If Standard Innovation had sold half as many We-Vibe's, Standard Innovation would have incurred only about [ ] in expenditures.

4. Standard Innovation Has Not Otherwise Established a Domestic Industry[19]

The Staff notes that Standard Innovation also relies on a number of activities that cannot be factored into the domestic industry analysis, such as, expenditures relating to the marketing and sales of the domestic products, warehousing, customer support, and unquantified research and development/engineering costs for the We-Vibe devices. I agree. The evidence does not show that these expenditures can be used to establish the domestic industry requirement as the marketing and sales activities are not production related and/or do not occur in the United States and the research and development costs are not properly quantified.

Standard Innovation's pre-hearing brief contends that warehouses in the U.S. support a domestic industry under prong A. (CPHB at 148-152.) The warehousing costs identified by Standard Innovation (CIB at 67) include costs incurred after the filing of the complaint. Accordingly, Standard Innovation provides no basis by which to assess its alleged warehousing costs.

Standard Innovation argues that the salaries and bonuses of its U.S. employees support a finding of domestic industry under prong B. However, the evidence cited states "marketing salaries." (CIB at 65.) In fact, Standard Innovation's brief confirms that these employees are sales and marketing type employees that are not relevant to domestic industry.[20]

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[19] Standard Innovation's contentions are limited by its pre-hearing brief. (CPHB at 152-153.)

[20] Standard Innovation acknowledges that sales and marketing alone are not cognizable under the statute. (CIB at 66.)

Standard Innovation alleges it has incurred [ ] in administrative expenses in the U.S. from 2008 to the filing of the complaint. (CIB at 68.) Standard Innovation argues, "**[i]nsofar** as these expenditures support Standard Innovation's educational, sales and marketing efforts that are directed to exploiting the '605 patent, they also may be included in the domestic industry analysis." (*Id.* (emphasis added).) Standard Innovation's use of the word "insofar" indicates that its argument relates to only a portion of its [ ] expenditure. Nor has Standard Innovation shown that these expenditures are relevant to domestic industry.

I am not persuaded by Standard Innovation's arguments (CIB at 63-65) that its sexual wellness education efforts are relevant to domestic industry. Standard Innovation asserts it spent [ ] on service and warranty fulfillment for U.S. consumers up to the date the complaint was filed. (CIB at 58-59.) However, the testimony cited by Standard Innovation does not sufficiently establish the alleged expenditure occurred in the United States. (CX-0280 at Q/A 266-269.) Further, there is no indication or explanation as to how Standard Innovation derived the [ ] amount, which is miniscule in any event.

Accordingly, for the reasons discussed above, I find Standard Innovation has not proven by a preponderance of the evidence that a Domestic Industry exists for the asserted '605 patent.

VII. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties, and subject-matter jurisdiction over the accused products.

2. The importation or sale requirement of Section 337 is satisfied.

3. Lelo's Tiani product infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent.

4. Lelo's Tiani 2 product infringes claims 1-7, 9-21, 23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, and 90 of the '605 patent.

5. Lelo's 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 of the '605 patent.

6. The Accused Products do not infringe any claims of the '605 patent under the doctrine of equivalents.

7. Claims 1, 33, and 66 of the '605 patent are not invalid as anticipated under 35 U.S.C. § 102.

8. Claims 1, 33, and 66 of the '605 patent are not invalid as obvious under 35 U.S.C. § 103.

9. The '605 patent is not indefinite under 35 U.S.C. § 112.

10. The Domestic Industry Products practice the '605 patent.

11. The domestic industry requirement is not satisfied with respect to the '605 patent.

12. There has been no violation of Section 337 with respect to the '605 patent.

VIII. INITIAL DETERMINATION[21]

Based on the foregoing, it is the Initial Determination of this Administrative Law Judge that a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, has not occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain kinesiotherapy devices and components thereof with respect to claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-90, and 92 of U.S. Patent No. 7,931,605.

The undersigned hereby CERTIFIES to the Commission this Initial Determination, together with the record of the hearing in this investigation consisting of the following: the transcripts of the evidentiary and claim construction hearings, with appropriate corrections as may hereafter be ordered; and the exhibits accepted into evidence in this investigation as listed in Appendix A hereto.[22]

The Secretary shall serve a public version of this Initial Determination upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R.

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[21] The failure to discuss any matter raised by the parties or any portion of the record herein does not indicate that said matter was not considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial, or meritless. Arguments made on brief which were otherwise unsupported by record evidence or legal precedent have been accorded no weight.

[22] The pleadings of the parties filed with the Secretary need not be certified as they are already in the Commission's possession in accordance with Commission rules.

§ 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within seven days of the date of this document, each party shall submit to the Office of the Administrative Law Judges a statement as to whether or not it seeks to have any portion of this document deleted from the public version. The parties' submissions must be made by hard copy by the aforementioned date and must include a copy of this document with red brackets indicating any portion asserted to contain confidential business information to be deleted from the public version, along with a list indicating each page on which such a bracket is to be found. The parties' submissions concerning the public version of this document need not be filed with the Commission.

SO ORDERED.

Thomas B. Pender
Administrative Law Judge

IN THE MATTER OF CERTAIN KINESIOTHERAPY DEVICES AND COMPONENTS THEREOF **337-TA-823**

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **PUBLIC INITIAL DETERMINATION** has been served by hand upon the Commission Investigative Attorney, **Monisha Deka, Esq.**, and the following parties as indicated, on FEB -8 2013 , 201.

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On Behalf of Complainants Standard Innovation Corporation and Standard Innovation (US) Corp.:

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CERTAIN KINESIOTHERAPY DVICES AND COMPONENTS THEREOF	Inv. No. 337-TA-823

PUBLIC CERTIFICATE OF SERVICE

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