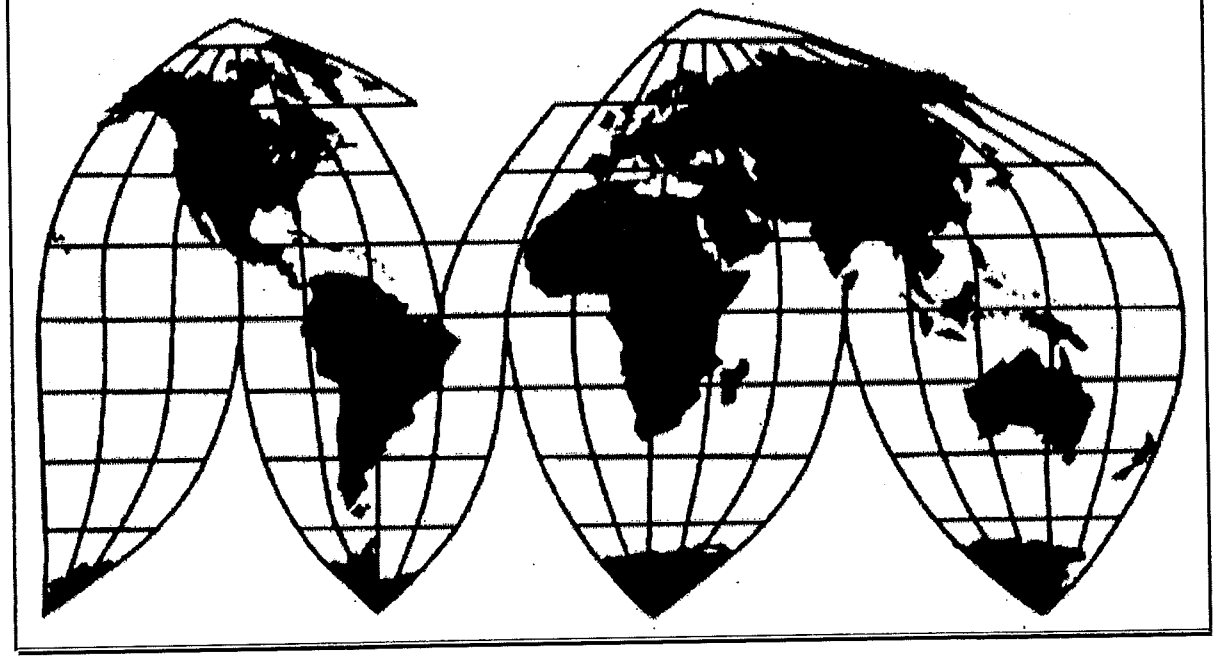
In the Matter of

CERTAIN KINESIOTHERAPY DEVICES AND COMPONENTS THEREOF

337-TA-823

Publication 4551 **August 2015**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

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Shara Aranoff, Commissioner,
Dean Pinkert, Commissioner
David Johanson, Commissioner
Meredith Broadbent, Commissioner

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U.S. International Trade Commission

Washington, DC 20436
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In the Matter of

CERTAIN KINESIOTHERAPY DEVICES AND COMPONENTS THEREOF

337-TA-823

Publication 4551

August 2015

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

NOTICE OF COMMISSION DECISION TO RESCIND A GENERAL EXCLUSION ORDER AND CEASE AND DESIST ORDERS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has rescinded the general exclusion order and cease and desist orders issued at the conclusion of the above-captioned investigation. The general exclusion order was directed against infringing kinesiotherapy devices and components thereof, and the cease and desist orders were directed against certain respondents.

FOR FURTHER INFORMATION CONTACT: Michael K. Haldenstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3041. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 10, 2012, based on a complaint filed by Standard Innovation Corporation of Ottawa, ON, Canada and Standard Innovation (US) Corp. of Wilmington, Delaware (collectively, "Standard Innovation"). 77 *Fed. Reg.* 1504-05 (Jan. 10, 2012). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by reason of infringement of certain claims of United States Patent Nos. 7,931,605 ("the '605 patent") and D605,779 ("the D'779 patent"). The complaint named twenty-one business entities as respondents, several of which have since been terminated from the investigation based upon

consent orders or withdrawal of the complaint. On July 25, 2012, the Commission determined not to review an ID (Order No. 25) granting Standard Innovation's motion to withdraw the D'779 patent from the investigation. An evidentiary hearing was held from August 21, 2012, to August 24, 2012.

On January 8, 2013, the ALJ issued a final ID finding no violation of Section 337. The ALJ also issued a recommended determination on remedy and bonding on January 22, 2013. Specifically, the ALJ found that Standard Innovation had not satisfied the economic prong of the domestic industry requirement. The ALJ found, however, that the accused products infringe the asserted claims, that the asserted claims were not shown to be invalid, and that the technical prong of the domestic industry requirement was shown to be satisfied.

On January 22, 2013, Standard Innovation and the Commission investigative attorney filed petitions for review of the final ID, and the remaining respondents in the investigation filed a contingent petition for review. On January 30, 2013, each party filed a response.

On March 25, 2013, the Commission determined to review the ID in its entirety and posed questions to the parties concerning the satisfaction of the economic prong of the domestic industry and remedy, the public interest, and bonding. The parties and the IA submitted briefs on April 8, 2013, and briefs in reply on April 15, 2013. The target date for completion of the investigation was also extended until June 17, 2013.

On June 17, 2013, the Commission issued its final determination finding that Standard Innovation had satisfied the economic prong of the domestic industry requirement and that Standard Innovation had proven a violation of Section 337 by reason of infringement of the '605 patent. Based on evidence of a pattern of violation and difficulty ascertaining the source of the infringing products, the Commission issued a general exclusion order against certain kinesiotherapy devices that infringe the '605 patent. The Commission also issued cease and desist orders against the following respondents: LELO Inc. of San Jose, California; PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina; Nalpac Enterprises, Ltd. of Ferndale, Michigan; E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado; Williams Trading Co., Inc. of Pennsauken, New Jersey; Honey's Place Inc. of San Fernando, California; and Lover's Lane & Co. of Plymouth, Michigan. The Commission's remedial orders allowed entry under bond during the Presidential review period.

On August 20, 2013, respondents LELO, Inc. and Leloi AB filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit seeking review of the Commission's final determination. Standard Innovation intervened in the appeal and the parties filed briefs with the Court. On May 11, 2015, the Federal Circuit issued its opinion in *Lelo Inc. v. International Trade Commission*, 786 F.3d 879 (Fed. Cir. 2015). The Court indicated that the Commission had erred in relying solely upon qualitative factors to find "significant investment in plant and equipment" and "significant employment of labor or capital" under prongs (A) and (B) of the domestic industry requirement. Accordingly, the Court reversed the Commission's finding of a violation of 19 U.S.C. § 1337. The Court issued its mandate on July 2, 2015.

As the U.S. Court of Appeals for the Federal Circuit has reversed the Commission's finding of violation, the Commission has determined that there is no longer a basis for the general exclusion order or the cease and desist orders previously issued in this investigation. The Commission has therefore rescinded the orders.

This action is taken under the authority of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337(k) and Commission rule 210.76, 19 C.F.R. § 210.76.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: July 21, 2015

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, **July 23, 2015**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

COMPLAINANTS STANDARD INNOVATION CORPORATION AND STANDARD INNOVATION (US) CORP.::

Robert P. Lord
OSHA LIANG LLP
909 Fannin Street, Suite 3500
Houston, TX 77010

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

ON BEHALF OF RESPONDENT MILE INC. D/B/A/ LION'S DEN ADULT:

Michael H. Selter, Esq.
MANELLI SELTER PLLC
2000 M Street, NW
Suite 700
Washington, DC 2003

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

ON BEHALF OF RESPONDENTS LELO INC., LELOI AB, PHE, INC., LELO, NATURAL CONTOURS EUROPE , MOMENTUM MANAGEMENT, LLC, EVOLVED NOVELTIES INC., PHE, INC., NALPAC ENTERPRISES, LTD., E.T.C., INC., WILLIAMS TRADING CO., INC., AND HONEY'S PLACE, INC.:

Michael H. Selter, Esq.
MANELLI SELTER PLLC
2000 M Street, NW
Suite 700
Washington, DC 20036

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

Respondents:

LOVER'S LANE & CO.
46750 Port St.
Plymouth, MI 48170

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

CASTLE MEGASTORE GROUP, INC.
1045 S. Edward Drive
Tempe, AZ 85281

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☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

SHAMROCK 51 MANAGEMENT COMPANY, INC.
(D/B/A FAIRVILLA.COM)
105 Candace Drive, Unit 109
Maitland, FL 32751

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

PARIS INTIMATES, LLC
4244 MacQueen Dr.
West Bloomfield, MI 48323

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☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

DRUGSTORE.COM, LLC
411 108th Avenue NE,
Suite 1400
Bellevue, WA 98804

☐ Via Hand Delivery
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PEEKAY INC.
901 W. Main Street, Suite A
Auburn, WA 98001

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☒ Via First Class Mail
☐ Other:_____

MARSONER, INC.
(D/B/A FASCINATION)
315 South Bracken Lane
Chandler, AZ 85224

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LOVE BOUTIQUE-VISTA, LLC
(D/B/A DÉJÀ VU)
2130 Industrial Court
Vista, CA 92081

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TOYS IN BABELAND LLC
707 East Pike Street
Seattle, WA 98122

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☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

ORDER OF RESCISSION

The Commission instituted this investigation on January 10, 2012, based on a complaint filed by Standard Innovation Corporation of Ottawa, ON, Canada and Standard Innovation (US) Corp. of Wilmington, Delaware (collectively, "Standard Innovation"). 77 *Fed. Reg.* 1504-05 (Jan. 10, 2012). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by reason of infringement of certain claims of United States Patent Nos. 7,931,605 ("the '605 patent") and D605,779 ("the D'779 patent"). The complaint named twenty-one business entities as respondents, several of which have since been terminated from the investigation based upon consent orders or withdrawal of the complaint. On July 25, 2012, the Commission determined not to review an ID (Order No. 25) granting Standard Innovation's motion to withdraw the D'779 patent from the investigation. An evidentiary hearing was held from August 21, 2012, to August 24, 2012.

On January 8, 2013, the ALJ issued a final ID finding no violation of Section 337. The ALJ also issued a recommended determination on remedy and bonding on January 22, 2013. Specifically, the ALJ found that Standard Innovation had not satisfied the economic prong of the domestic industry requirement. The ALJ found, however, that the accused products infringe the

asserted claims, that the asserted claims were not shown to be invalid, and that the technical prong of the domestic industry requirement was shown to be satisfied.

On January 22, 2013, Standard Innovation and the Commission investigative attorney filed petitions for review of the final ID, and the remaining respondents in the investigation filed a contingent petition for review. On January 30, 2013, each party filed a response.

On March 25, 2013, the Commission determined to review the ID in its entirety and posed questions to the parties concerning the satisfaction of the economic prong of the domestic industry and remedy, the public interest, and bonding. The parties and the IA submitted briefs on April 8, 2013, and briefs in reply on April 15, 2013. The target date for completion of the investigation was also extended until June 17, 2013.

On June 17, 2013, the Commission issued its final determination finding that Standard Innovation had satisfied the economic prong of the domestic industry requirement and that Standard Innovation had proven a violation of Section 337 by reason of infringement of the '605 patent. Based on evidence of a pattern of violation and difficulty ascertaining the source of the infringing products, the Commission issued a general exclusion order against certain kinesiotherapy devices that infringe the '605 patent. The Commission also issued cease and desist orders against the following respondents: LELO Inc. of San Jose, California; PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina; Nalpac Enterprises, Ltd. of Ferndale, Michigan; E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado; Williams Trading Co., Inc. of Pennsauken, New Jersey; Honey's Place Inc. of San Fernando, California; and Lover's Lane & Co. of Plymouth, Michigan. The Commission's remedial orders allowed entry under bond during the Presidential review period.

On August 20, 2013, respondents LELO, Inc. and Leloi AB filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit seeking review of the Commission's final determination. Standard Innovation intervened in the appeal and the parties filed briefs with the Court. On May 11, 2015, the Federal Circuit issued its opinion in *Lelo Inc. v. International Trade Commission*, 786 F.3d 879 (Fed. Cir. 2015). The Court indicated that the Commission had erred in relying solely upon qualitative factors to find "significant investment in plant and equipment" and "significant employment of labor or capital" under prongs (A) and (B) of the domestic industry requirement. Accordingly, the Court reversed the Commission's finding of a violation of 19 U.S.C. § 1337. The Court issued its mandate on July 2, 2015.

As the U.S. Court of Appeals for the Federal Circuit has reversed the Commission's finding of violation, the Commission has determined that there is no longer a basis for the general exclusion order or the cease and desist orders previously issued in this investigation.

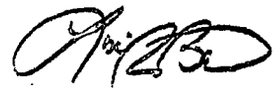
Accordingly, it is hereby ORDERED THAT:

1. The general exclusion order in this investigation is rescinded.

2. The cease and desist orders in this investigation are rescinded.

3. The Secretary shall serve a copy of this order on all parties of record and publish notice thereof in the *Federal Register*.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: July 21, 2015

CERTAIN KINESIOTHERAPY DEVICES **Inv. No. 337-TA-823**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION ORDER** has been served upon the following parties as indicated, **July 23, 2015.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

COMPLAINANTS STANDARD INNOVATION CORPORATION AND STANDARD INNOVATION (US) CORP.::

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

FINAL COMMISSION DETERMINATION OF VIOLATION; ISSUANCE OF A GENERAL EXCLUSION ORDER AND CEASE AND DESIST ORDERS; AND TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has terminated the above-captioned investigation with a finding of violation of section 337, and has issued a general exclusion order directed against infringing kinesiotherapy devices and components thereof, and cease and desist orders directed against respondents LELO Inc. of San Jose, California; PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina; Nalpac Enterprises, Ltd. of Ferndale, Michigan; E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado; Williams Trading Co., Inc. of Pennsauken, New Jersey; Honey's Place Inc. of San Fernando, California; and Lover's Lane & Co. of Plymouth, Michigan. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michael K. Haldenstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3041. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 10, 2012, based on a complaint filed by Standard Innovation Corporation of Ottawa, ON, Canada and Standard Innovation (US) Corp. of Wilmington, Delaware (collectively, "Standard Innovation"). 77 *Fed. Reg.* 1504 (Jan. 10, 2012). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by reason of infringement of certain claims of United States Patent Nos. 7,931,605 ("the '605 patent") and D605,779 ("the

D'779 patent"). The complaint named twenty-one business entities as respondents, several of which have since been terminated from the investigation based upon consent orders or withdrawal of the complaint. On July 25, 2012, the Commission determined not to review an ID (Order No. 25) granting Standard Innovation's motion to withdraw the D'779 patent from the investigation.

An evidentiary hearing was held from August 21, 2012, to August 24, 2012.

On January 8, 2013, the ALJ issued a final initial determination ("ID") finding no violation of section 337. The ALJ also issued a recommended determination on remedy and bonding on January 22, 2013. Specifically, the ALJ found that Standard Innovation had not satisfied the economic prong of the domestic industry requirement of section 337. The ALJ found, however, that the accused products infringe the asserted claims, that the asserted claims were not shown to be invalid, and that the technical prong of the domestic industry requirement was shown to be satisfied.

On January 22, 2013, Standard Innovation and the Commission investigative attorney ("IA") filed petitions for review of the final ID. Also on January 22, 2013, the respondents remaining in the investigation filed a joint contingent petition for review. On January 30, 2013, the parties filed responses to the petitions.

On March 25, 2013, the Commission determined to review the ID in its entirety and posed four questions to the parties concerning the economic prong of the domestic industry requirement of section 337. The parties and the IA submitted briefs on April 8, 2013, and briefs in reply on April 15, 2013 concerning the Commission's questions and remedy, the public interest, and bonding. The Commission extended the target date to June 7, 2013 and then to June 17, 2013.

Having examined the record in this investigation, including the ID, the petitions for review, and the submissions on review and responses thereto, the Commission has determined that Standard Innovation has satisfied the domestic industry requirement and that there is a violation of section 337 with respect to 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 Commission has also made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is both: (1) a general exclusion order prohibiting the unlicensed entry of kinesiotherapy devices and components thereof that infringe claims 1-7, 9-21,23, 24, 33-40, 42-54, 56, 57, 66-73, 75-87, 89, or 90 of the '605 patent; and (2) cease and desist orders prohibiting LELO Inc. of San Jose, California; PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina; Nalpac Enterprises, Ltd. of Ferndale, Michigan; E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado; Williams Trading Co., Inc. of Pennsauken, New Jersey; Honey's Place Inc. of San Fernando, California; and Lover's Lane & Co. of Plymouth, Michigan from conducting any of the following activities in the United States: importing, selling, marketing, advertising,

distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, kinesiotherapy devices and components with respect to the same claims.

The Commission further determined that the public interest factors enumerated in section 337(d)(1) and (f)(1) (19 U.S.C. §§ 1337(d)(1), (f)(1)) do not preclude issuance of the general exclusion order or the cease and desist orders. Finally, the Commission determined that there shall be a bond in the amount of zero percent of entered value to permit temporary importation during the period of Presidential review (19 U.S.C. § 1337(j)). The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The Commission has terminated this investigation. The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.50).

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

GENERAL EXCLUSION ORDER

The Commission has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation and sale of certain kinesiotherapy devices and components thereof infringe claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-87, 89, and 90 of U.S. Patent No. 7,931,605 ("the '605 patent").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that a general exclusion from entry for consumption is necessary because there is a pattern of violation of section 337 and it is difficult to identify the source of the infringing products. Accordingly, the Commission has determined to issue a general exclusion order prohibiting the unlicensed importation of infringing kinesiotherapy devices and components thereof ("covered products").

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the general exclusion order, and that the bond be shall be in the amount of zero percent of the entered value for all covered products during the Presidential review period.

Accordingly, the Commission hereby **ORDERS** that:

1. Kinesiotherapy devices and components thereof are infringed by one or more of claims 1-7, 9-21, 23, 24, 26, 33-40, 42-54, 56, 57, 59, 66-73, 75-87, 89, and 90 of

the '605 patent ("covered products") are excluded from entry into the United States for consumption, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the patent, except under license of the patent owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the aforesaid kinesiotherapy devices and components thereof are entitled to entry into the United States for consumption, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption under bond in the amount of zero percent of the entered value for the covered products, pursuant to subsection (j) of Section 337 (19 U.S.C. § 1337(j)) and the Presidential memorandum for the United States Trade Representative of July 21, 2005 (70 *Fed. Reg.* 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty days after the date of receipt of this Order.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to procedures that it establishes, persons seeking to import kinesiotherapy devices and components thereof that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the

certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

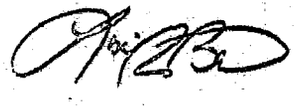
4. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to kinesiotherapy devices and components thereof imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

6. The Commission Secretary shall serve copies of this Order upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and U.S. Customs and Border Protection.

7. Notice of this Order shall be published in the *Federal Register*.

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT LELO Inc. of San Jose, California cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means LELO Inc. of San Jose, California.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the

original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount of zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of

temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

[2] See Footnote 1.

By Order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means PHE, Inc. d/b/a Adam & Eve of Hillsborough, North Carolina.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount of zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

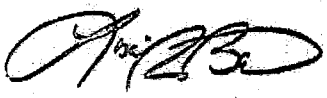
The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

[2] See Footnote 1.

By Order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Nalpac Enterprises, Ltd. of Ferndale, Michigan cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means Nalpac Enterprises, Ltd. of Ferndale, Michigan.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount of zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

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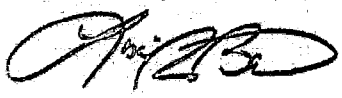
[2] See Footnote 1.

By Order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means E.T.C. Inc. (d/b/a Eldorado Trading Company, Inc.) of Broomfield, Colorado.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

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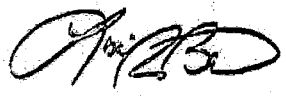
[2] See Footnote 1.

By Order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Williams Trading Co., Inc. of Pennsauken, New Jersey cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means Williams Trading Co., Inc. of Pennsauken, New Jersey.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount of zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

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[2] See Footnote 1.

By Order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Honey's Place Inc. of San Fernando, California cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means Honey's Place Inc. of San Fernando, California.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount of zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

[2] See Footnote 1.

By Order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

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

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Lover's Lane & Co. of Plymouth, Michigan cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for, 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, 75-87, 89 and 90 of U.S. Patent No. 7,931,605 ("the '605 patent") in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

I.

Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean Standard Innovation (US) Corp. and Standard Innovation Corporation.

(C) "Respondent" means Lover's Lane & Co. of Plymouth, Michigan.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the Respondent or its majority owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean 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, and 75-87, 89, and 90 of the '605 patent.

II.

Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by Section III, *infra,* for, with, or otherwise on behalf of a Respondent.

III.

Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the '605 patent, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, offer for sale, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV.

Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '605 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

V.

Reporting

The reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2013. The reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of each reporting period, Respondent shall report to the Commission (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in

inventory in the United States at the end of the reporting period. Respondents filing written submissions must file the original document and two copies with the Office of the Secretary. Any Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.

Record-keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by the federal courts of the United States, duly authorized representatives of the Commission, upon reasonable written notice by the Commission or its staff, shall be permitted access and the right to inspect and copy in the Respondent's principal offices during office hours, and in the presence of counsel or other representatives if the Respondent so chooses, all books, ledgers, accounts, correspondence,

[1] Complainant must file a letter with the Secretary identifying the attorney to receive the reports or bond information. The designated attorney must be on the protective order entered in the investigation.

memoranda, and other records and documents, both in detail and in summary form as are required to be retained by subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this Order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the date of expiration of the '605 patent.

VIII.

Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.

Enforcement

Violation of this Order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.75, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, 19 U.S.C. § 1337(f), and any other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information.

X.

Modification

The Commission may amend this Order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

XI.

Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), subject to Respondent posting a bond in the amount zero percent of the entered value for the covered products. This bond provision does not apply to conduct that is otherwise permitted by Section IV of this Order. Covered products imported on or after the date of issuance of this order are subject to the entry bond as set forth in the general exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary, (a) the Secretary will serve an acceptance letter on all parties and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to a Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

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[2] See Footnote 1.

By Order of the Commission.

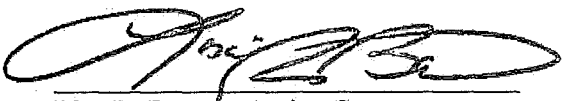
Lisa R. Barton
Acting Secretary to the Commission

Issued: June 17, 2013

CERTAIN KINESIOTHERAPY DEVICES **337-TA-823**

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION NOTICE** has been served by hand upon the Commission Investigative Attorney, **Monisha Deka, Esq.**, and the following parties as indicated, on **June 17, 2013.**



Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANTS STANDARD INNOVATION CORPORATION AND STANDARD INNOVATION (US) CORP.:

Robert P. Lord
OSHA LIANG LLP
909 Fannin Street, Suite 3500
Houston, TX 77010

( ) Via Hand Delivery
(x) Via Overnight Mail
( ) Via First Class Mail
( ) Other: _____

ON BEHALF OF RESPONDENTS LELO INC., LELOI AB, PHE, INC., NALPAC ENTERPRISES, LTD., E.T.C., INC., WILLIAMS TRADING CO., INC., AND HONEY'S PLACE, INC.:

Michael H. Selter, Esq.
MANELLI SELTER PLLC
2000 M Street, NW
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( ) Via Hand Delivery
(x) Via Overnight Mail
( ) Via First Class Mail
( ) Other: _____

PUBLIC VERSION

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

COMMISSION OPINION

I. INTRODUCTION

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

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

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

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

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

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

II. BACKGROUND

A. Procedural History

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

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

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

B. Patent and Technology at Issue

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

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

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

C. Products at Issue

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

III. DISCUSSION

A. Claim Construction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

wherein, the elongate inner arm and the elongate outer arm are enlarged relative to the connecting portion and at least one of the arms tapers down toward said connecting portion; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Infringement

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

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

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

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

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

1. Standard Innovation Did Not Waive Its Arguments Regarding Infringement

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

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

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

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

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

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

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

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

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

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

2. Infringement of the Asserted Claims

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

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

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

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

C. Validity

1. Anticipation

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

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

2. Obviousness

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

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

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

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

D. Domestic Industry

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

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

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

Section 337(a)(3) provides:

> (3) [A]n industry in the United States shall be considered to exist if there is in the United States, with respect to articles protected by the patent . . . concerned –
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

statute indicates that the domestic industry has to exist "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). Requiring that the components be developed for the patented article would go well beyond the statutory language, which requires only that investment relate to the articles protected by the patent. Here, complainant has established that the components were critical for the We-Vibe, which the ALJ found to be protected by the patent. This is sufficient for us to consider the component expenses in our economic prong analysis. Moreover, complainant's investments in these components are indicative of the investments of its U.S. subcontractors in their plants and equipment, and labor and capital that are necessary to produce these components in the United States.

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

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

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

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

amounts spent to purchase the domestic components can reasonably be considered as evidence of a relevant investment by U.S. subcontractors in plant and equipment under prong A and labor and capital under prong B because the components were manufactured in the United States for incorporation into articles protected by the patent, even if the purchase price arguably includes other costs incurred by the subcontractors.[9]

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

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

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

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

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

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

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

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

2013 WL 1943205 at *5 n.6 (Fed. Cir. May 13, 2013).

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

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

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

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

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

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

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

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[13] These expenditures included $[ ] on microcontroller parts, $[ ] for pigments. ID at 71-73.

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

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

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

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

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

] while leaving an even finish. CX-0280C at Q/A170. The microcontroller products from [ ] are also crucial components; they

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

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

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

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

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

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

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

IV. REMEDY, THE PUBLIC INTEREST, AND BONDING

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

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

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

> The authority of the Commission to issue an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that--
>
> (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
>
> (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

19 U.S.C. § 1337(d)(2).

We agree with the ALJ that the appropriate statutory relief is a general exclusion order. Standard Innovation has shown that there is a pattern of violation of section 337 and that it is difficult to identify the source of the infringing imports.[15] 19 U.S.C. § 1337(d)(2)(B). The ALJ found evidence of counterfeiting of the We-Vibe products and extensive sales of those counterfeits in the record. RD at 4 (citing CX_278C at Q/A 271; CX-0072; CX-282 at Q/A 92; CX-282C at Q/A 95). The market conditions for these products encourage counterfeiters to sell infringing products in the U.S. market. Specifically, the ALJ found that U.S. consumers purchase over one billion dollars of kinesiotherapy devices imported from overseas each year, that profit margins are often in excess of 400%, and that foreign entities wishing to enter the market have ready access to fully established distribution networks. RD at 4-5 (citing CX-280C at Q/A 287-288, 292; CX-218; CX-282C at Q/A 93-94). The counterfeiting coupled with the Commission's findings regarding the infringing products at issue in this investigation and the current market conditions are evidence of a pattern of the sale of goods infringing the '605 patent.[16]

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

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

[16] We do not rely upon the consent orders issued in this case as evidence of a pattern of infringement.

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

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

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

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

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

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

B. The Public Interest

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

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

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

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

C. Bond

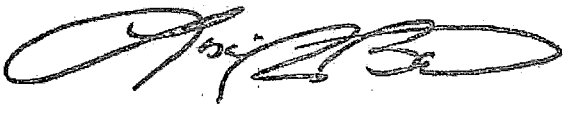
The ALJ noted that when reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. He found that Standard Innovation's calculation was flawed because it included LELO's Noa, a new product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

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

V. CONCLUSION

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

By order of the Commission.



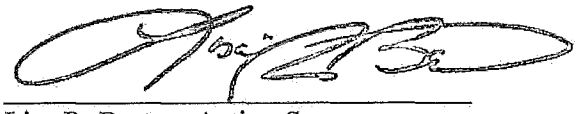
Lisa R. Barton
Acting Secretary to the Commission

Issued: July 12, 2013

CERTAIN KINESIOTHERAPY DEVICES **337-TA-823**

CERTIFICATE OF SERVICE

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



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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

NOTICE OF COMMISSION DETERMINATION TO REVIEW THE FINAL INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE AND TO EXTEND THE TARGET DATE FOR COMPLETION OF THE INVESTIGATION BY TWO WEEKS TO JUNE 7, 2013

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination ("final ID" or "ID") of the presiding administrative law judge ("ALJ") in its entirety in the above-captioned investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"). The ALJ found no violation of section 337. The Commission has further determined to extend the target date for completion of the investigation by two weeks to June 7, 2013.

FOR FURTHER INFORMATION CONTACT: Michael K. Haldenstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3041. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 10, 2012, based on a complaint filed by Standard Innovation Corporation of Ottawa, ON, Canada and Standard Innovation (US) Corp. of Wilmington, Delaware (collectively, "Standard Innovation"). 77 *Fed. Reg.* 1504 (Jan. 10, 2012). The complaint alleged violations of

section 337 of the Tariff Act of 1930, as amended 19 U.S.C. § 1337, by reason of infringement of certain claims of United States Patent Nos. 7,931,605 ("the '605 patent") and D605,779 ("the '779 patent"). The complaint named twenty one business entities as respondents, several of which have since been terminated from the investigation based upon consent order stipulations. On July 25, 2012, the Commission determined not to review an ID (Order No. 25) granting Standard Innovation's motion to withdraw the '779 patent from the investigation.

An evidentiary hearing was held from August 21, 2012, to August 24, 2012.

On January 8, 2013, the ALJ issued a final ID finding no violation of section 337. The ALJ also issued a recommended determination on remedy and bonding on January 22, 2013. Specifically, the ALJ found that Standard Innovation had not satisfied the economic prong of the domestic industry requirement. The ALJ found, however, that the accused products infringe the asserted claims, that the asserted claims were not shown to be invalid, and that the technical prong of the domestic industry requirement was shown to be satisfied.

On January 22, 2013, Standard Innovation and the Commission investigative attorney filed petitions for review of the final ID. Also on January 22, 2013, the respondents remaining in the investigation (Lelo Inc., Leloi AB, PHE, Inc. d/b/a Adam & Eve, Nalpac Enterprises, Ltd. d/b/a/ Nalpac, Ltd., E.TC. Inc. d/b/a Eldorado Trading Company, Inc., Williams Trading Co. Inc., Honey's Place Inc. and Lover's Lane & Co.) filed a joint contingent petition for review. On January 30, 2013, the parties filed responses to the petitions.

Having examined the final ID, the petitions for review, the responses thereto, and the relevant portions of the record in this investigation, the Commission has determined to review the final ID in its entirety. The Commission has further determined to extend the target date for completion of the investigation by two weeks to June 7, 2013.

The parties are requested to brief their positions on only the following questions, with reference to the applicable law and the evidentiary record:

1. Please provide evidentiary support in the record showing U.S. investments relating to the components that are relied on by complainant to meet the domestic industry requirement, including as appropriate information relating to component providers, contractors, and subcontractors.
2. Please comment on the significance of the relative contribution of domestic inputs as compared to total production (domestic and foreign) of complainant's products alleged to practice the '605 patent.
3. Please provide evidentiary support in the record regarding whether the U.S. investments alleged by complainant are significant or substantial in the context of the complainant's business, the relevant industry, and market realities.
4. Please explain how component purchasing expenditures for U.S. components not made specifically for the domestic industry products constitute an investment in plant and

equipment, employment of labor or capital, or an investment in exploitation under 19 U.S.C. § 1337(a)(3).

In connection with the final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background information, see the Commission Opinion, *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

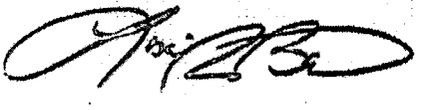
If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation, including references to exhibits and testimony. Additionally, the parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the ALJ's recommended determination on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is requested to supply the expiration date of the patent at issue and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than the close of business on April 8, 2013, and should be no more than 25 pages. Reply submissions must be filed no later than the close of business on April 15, 2013, and should be no more than 15 pages. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must do so in accordance with Commission rule 210.4(f), 19 C.F.R. § 210.4(f), which requires electronic filing. The original document and eight true copies thereof must also be filed on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 C.F.R § 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and under sections 210.42 - .46, .51(a) of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42 - .46, .51(a)).

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: March 25, 2013

CERTAIN KINESIOTHERAPY DEVICES **337-TA-823**

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Monisha Deka, Esq.**, and the following parties as indicated, on **March 25, 2013.**

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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:

For Complainants Standard Innovation Corporation and Standard Innovation (US) Corp.:

Brian K. Wunder, Esq., Robert P. Lord, Esq., Lisa Erin Margonis, Esq., Tammy Terry, Esq., and Carlyn A. Burton, Esq. of Osha Liang LLP, Houston, TX

Gary M. Hnath, Esq. of Mayer Brown LLP, Washington, DC

For Respondents LELO Inc., Leloi AB, PHE, Inc. d/b/a Adam & Eve, Nalpac Enterprises, Ltd. d/b/a/ Nalpac, Ltd., E.T.C. Inc. d/b/a Eldorado Trading Company, Inc., Williams Trading Co., Inc., Honey's Place Inc. and Lover's Lane & Co.:

Michael H. Selter, Esq. and Jeffrey S. Melcher of Manelli Selter PLLC, Washington, DC

For the Commission Investigative Staff:

David Lloyd, Esq., Supervisory Attorney, and Maressa Frederick, Esq., Investigative Attorney of the Office of Unfair Import Investigations, U.S. International Trade Commission, Washington, DC

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

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)

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.*) [

]

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.*)

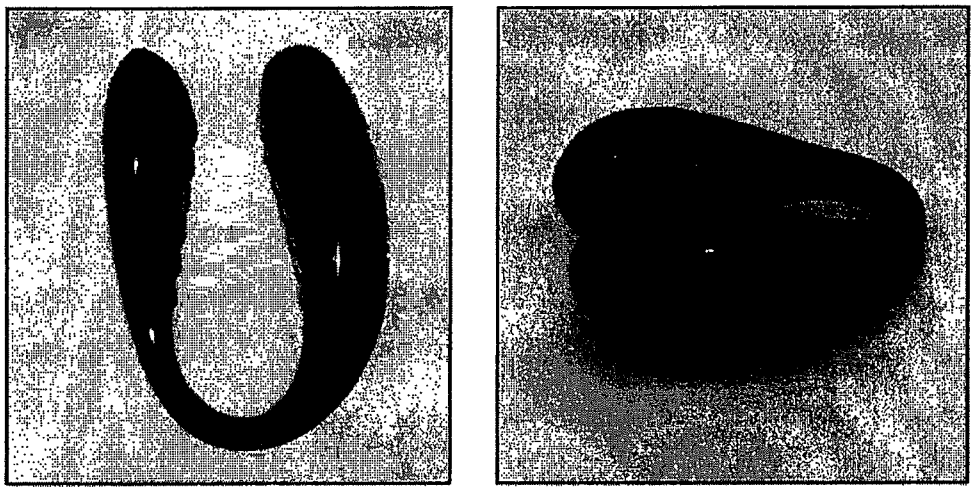
D. Products at Issue

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

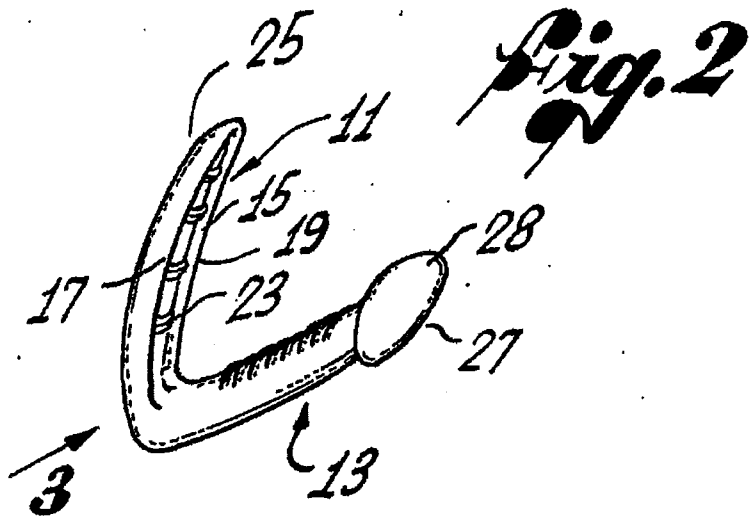
inconsistent with the plain and ordinary meaning. Respondents criticize Standard Innovation and Staff's definition as being circular, but notably Respondents definition suffers the same flaw. While Respondents are correct that a circular definition is not useful in construing the term, here, a circular 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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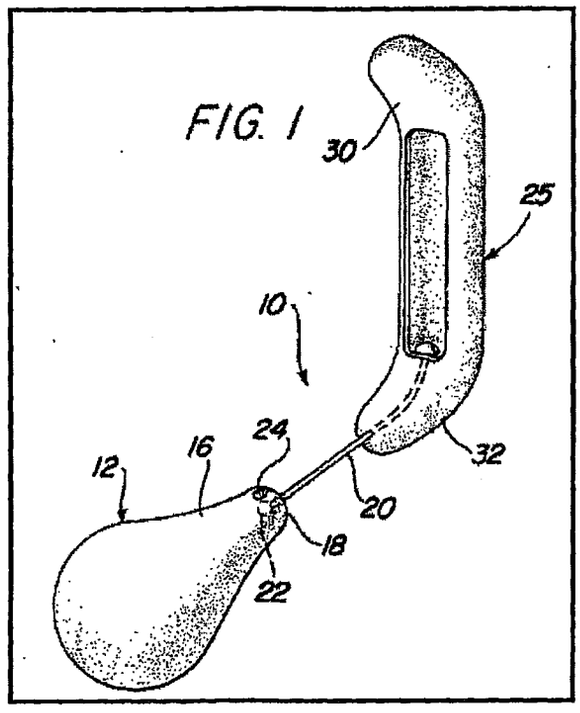
be a concurrence by Staff. Standard Innovation's abuse of the Staff's participation is not condoned.

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 2013.

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

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