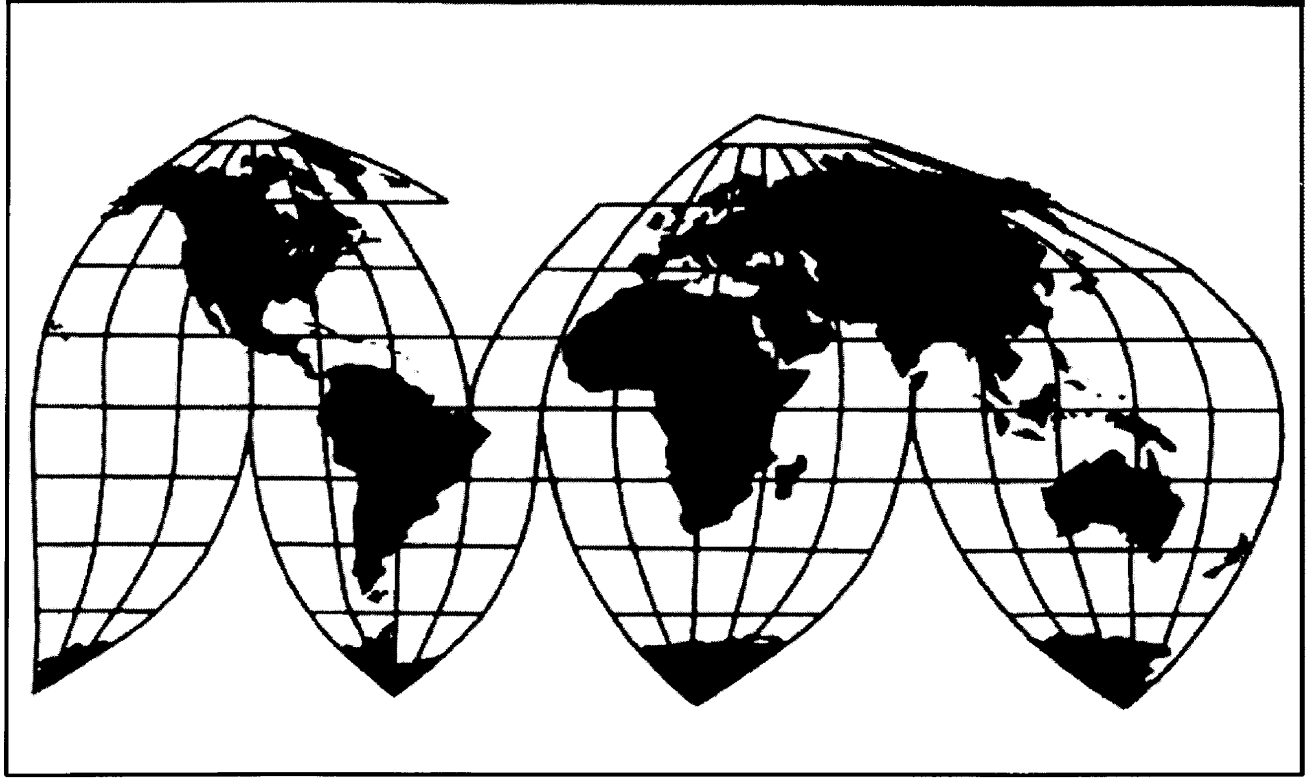
In the Matter of

Certain Male Prophylactic Devices

Investigation No. 337-TA-546

Publication 4005 **May 2008**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

Daniel R. Pearson, Chairman
Shara L. Aranoff, Vice Chairman*
Deanna Tanner Okun
Charlotte R. Lane
Irving A. Williamson*
Dean A. Pinkert*

---

*Commissioner Marcia E. Miller, whose term ended on September 6, 2005, participated in the decision to institute the investigation. Commissioner Shara L. Aranoff, whose term commenced on September 6, 2005, participated in all subsequent phases of the investigation. Commissioner Stephen Koplan, whose term ended on February 6, 2007, and Commissioner Jennifer A. Hillman, whose term ended on February 23, 2007, participated in this investigation through the decision to remand the investigation to the Administrative Law Judge for further proceedings. Commissioner Irving A. Williamson, whose term commenced on February 7, 2007, and Commissioner Dean A. Pinkert, whose term commenced on February 26, 2007, participated in the decision to reverse the determination of the Administrative Law Judge and in the finding of no violation.

Address all communications to
Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

U.S. International Trade Commission

Washington, DC 20436
www.usitc.gov

In the Matter of

Certain Male Prophylactic Devices

Investigation No. 337-TA-546

Publication 4005

May 2008

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN MALE PROPHYLACTIC DEVICES	)	Inv. No. 337-TA-~~546~~

NOTICE OF COMMISSION DETERMINATION TO REVERSE AN INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE THAT SECTION 337 HAS BEEN VIOLATED; TERMINATION OF INVESTIGATION WITH A FINDING OF NO VIOLATION OF SECTION 337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to reverse the presiding administrative law judge's finding of violation of section 337 of the Tariff Act, as amended, and has terminated the investigation with a finding of no violation of section 337.

FOR FURTHER INFORMATION CONTACT: Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3116. The public version of all nonconfidential 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-ON-LINE) 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: This investigation was instituted on August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004. The respondents named in the investigation are Church & Dwight Co., Inc., of

Princeton, New Jersey; Reddy Medtech, Ltd., of Tamil Nadu, India; and Intellx, Inc., of Petoskey, Michigan.

On June 30, 2006, the presiding administrative law judge ("ALJ") issued a final initial determination ("ID") in which he ruled that there is no violation of section 337 of the Tariff Act of 1930, as amended. He found that certain valid claims were infringed, but concluded that there was no domestic industry under the economic prong of the domestic industry requirement. All parties petitioned for review of various parts of the final ID.

On September 29, 2006, the Commission determined to review the issues of claim construction, infringement, invalidity due to anticipation, and domestic industry, and requested briefing on these issues and certain subissues. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). On December 5, 2006, the Commission determined to affirm in part, reverse in part, and remand in part the final ID. Among other things, the Commission reversed the ALJ's finding of no domestic industry under the economic prong. The Commission also determined to extend the target date for completion of the investigation until June 5, 2007. The date was subsequently moved to June 21, 2007, by an unreviewed ID.

On March 19, 2007, the ALJ issued his remand ID, in which he ruled that there is a violation of section 337 based on the infringement of certain valid claims and found that there is a domestic industry. In further briefing before the Commission, all parties claimed error.

Upon consideration of the parties' submissions and the record in this proceeding, the Commission has determined to reverse the ALJ's finding of violation of section 337 and has terminated the investigation with a finding of no violation. In reaching this conclusion, the Commission has reversed the ALJ's finding that the accused products infringe certain claims of U.S. Patent No. 5,082,004, as well as his finding that certain claims of that patent are invalid as anticipated by the prior art.

The authority for this notice is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and in section 210.45(c) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.45(c)).

By order of the Commission.

William R. Bishop

William R. Bishop
Acting Secretary to the Commission

Issued: June 21, 2007

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN MALE PROPHYLACTIC DEVICES	Inv. No. 337-TA-546

ORDER

This investigation was instituted on August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004. The respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey ("C&D"); Reddy Medtech, Ltd., of Tamil Nadu, India; and Intellx, Inc., of Petoskey, Michigan.

On June 30, 2006, the presiding administrative law judge ("ALJ") issued a final initial determination ("ID") in which he ruled that there is no violation of section 337 of the Tariff Act of 1930, as amended. He found that certain valid claims were infringed, but concluded that there was no domestic industry under the economic prong of the domestic industry requirement. All parties petitioned for review of various parts of the final ID.

On September 29, 2006, the Commission determined to review the issues of claim construction, infringement, invalidity due to anticipation, and domestic industry, and requested briefing on these issues and certain subissues. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). On December

5, 2006, the Commission determined to affirm in part, reverse in part, and remand in part the final ID. Among other things, the Commission reversed the ALJ's finding of no domestic industry under the economic prong. The Commission also determined to extend the target date for completion of the investigation until June 5, 2007. The date was subsequently moved to June 21, 2007, by an unreviewed ID.

On March 19, 2007, the ALJ issued his remand ID ("IDR"), in which he ruled that there is a violation of section 337 based on the infringement of certain valid claims and the finding that there is a domestic industry. In further briefing before the Commission, all parties claimed error.

Having examined the parties' submissions and the record in this proceeding, it is hereby ORDERED that –

(1) The ALJ's finding of violation of section 337 is reversed;

(2) the ALJ's finding that the accused products infringe certain claims of U.S. Patent No. 5,082,004 is reversed;

(3) the ALJ's finding that the Twisted Pleasure product fails to meet the thickness limitation of claims 22 and 25 of the asserted patent is reversed;

(4) the ALJ's finding that C&D waived its argument that claim 31 of the asserted patent is invalid as anticipated by the prior art is reversed;

(5) the ALJ's finding that claims 1, 6, and 9 of the asserted patent are invalid in view of the prior art are reversed;

(6) the IDR is vacated except where consistent with the determination of the Commission;

(7) the motion of the Office of Unfair Import Investigations to file its reply out of time is granted;

(8) the investigation is terminated with a finding of no violation of section 337;

(9) the Secretary shall serve a copy of this Order and the Commission Opinion in support thereof, as soon as it is issued, upon each party to the

investigation; and

(10) the Secretary shall publish notice of this order and termination of the investigation in the *Federal Register.*

By order of the Commission.

William R. Bishop
Acting Secretary to the Commission

Issued: June 21, 2007

CERTAIN MALE PROPHYLATIC DEVICES COMPONENTS 337-TA-546

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE TO REVERSE ID** has been served by hand upon the Commission Investigative Attorney, Rett Snotherly, Esq., and the following parties as indicated, on June 22, 2007

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

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

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

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

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

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

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor

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

New York, NY 10281

ON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

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

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

James H. Shalek, Esq
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299
P - 212-969-3000
F- 212-969-2900

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

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

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

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MALE PROPHYLACTIC DEVICES**	**Investigation No. 337-TA-546**

COMMISSION OPINION

On June 21, 2007, the Commission issued notice of its final determination to terminate the captioned investigation with a finding of no violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337) ("section 337"), reversing an initial determination ("ID") of the presiding administrative law judge ("ALJ"). An order accompanied the notice. This opinion sets forth the reasons for the Commission's determination, including the basis for its earlier reversal of the ALJ's original finding of no domestic industry. As discussed below, we find that there is a domestic industry within the meaning of section 337; however, there is no patent infringement. Therefore, we have terminated the investigation with a finding of no violation of section 337.

I. BACKGROUND

The Commission instituted this investigation on August 5, 2005, based on the complaint of Portfolio Technologies, Inc., of Chicago, Illinois ("PTI"). 70 *Fed. Reg.* 45422 (Aug. 5, 2005). The complaint, as amended and supplemented, alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27,

31-33, and 36 of U.S. Patent No. 5,082,004 ("'004" patent). Respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey ("C&D"), which imports, markets, and distributes the first of two accused products, the Trojan Twisted Pleasure prophylactic ("Twisted Pleasure"); Intellx, Inc., of Petoskey, Michigan ("Intellx"), which imports, markets, and distributes the second accused product, the Inspiral prophylactic ("Inspiral"); and Reddy Medtech, Ltd., of Tamil Nadu, India ("Medtech"),[1] which manufactures both accused products.[2]

On June 30, 2006, the ALJ issued his final ID, in which he ruled that the Twisted Pleasure infringes claims 1, 13, 18, and 31 of the '004 patent, but does not infringe claims 2-4, 15, 16, 22, 25, 32, and 36. He found that the Inspiral infringes claims 1, 6, 9, 22, 25, and 31 of the '004 patent, but does not infringe claims 2-4 and 8. He also ruled that claims 1, 6, and 9 of the '004 patent are invalid as anticipated by U.K. Patent No. 1,252,255 ("UK" or "'255" patent). The ALJ thus found infringement of certain valid claims of the '004 patent (13, 18, and 31 by Twisted Pleasure, and 22, 25, and 31 by Inspiral). The ALJ further found that PTI practices the patent with its product the "Pleasure Plus," thereby satisfying the technical prong of the statute's domestic industry requirement, but failed to demonstrate the economic criteria required to prove the existence of a domestic industry. He therefore found no domestic industry and, accordingly,

---

[1] Medtech and Intellx have the same representation in this proceeding and their filings are joint. We reference their arguments as those of "Medtech."

[2] The inventor of the '004 patent is Dr. Reddy, who founded Medtech and is its chairman and managing director. One of Dr. Reddy's former companies, Reddy Laboratories International, Ltd. ("RLIL"), owned the '004 patent. The '004 patent and other property of RLIL were purchased in 1998 by Complainant in RLIL's involuntary bankruptcy proceeding.

no violation of section 337. Final ID at 129-30.

All parties, including the investigative attorney ("IA"), petitioned for review. On September 29, 2006, the Commission determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). On December 5, 2006, the Commission affirmed in part, reversed in part, and remanded in part. The Commission found that PTI engaged in sufficient domestic activities under the statute to satisfy the economic criteria of the domestic industry requirement, reversing the ALJ's finding to the contrary. Commission Opinion ("Comm'n Op.") at 20.[3] The Commission also reversed the ALJ's claim interpretations that relied on "theoretical" constructs and "crux of the invention" references and set forth its own constructions. Specifically, the Commission interpreted "elongated tubular portion" to mean "the remaining portions of the condom that are not identified as one or more second pouches and are tubular in shape," Comm'n Op. at 8-9; "circumference" to mean "the external surface of the tubular portion of the condom," *id.* at 10; "generally constant diameter from the open end to the closed end" as requiring "the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant," *id.* at 11; and "longitudinally directed chamber" to mean the enclosed space or compartment into which the penis is inserted," with the notation that "where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom." *Id.* at 15.

---

[3] The confidential version issued on December 5, 2006. The confidential and public versions of the opinion are the same – ultimately, no material was redacted.

In addition, the Commission held that, contrary to the ALJ's finding in the final ID, functional language in the patent was not without effect. Comm'n Op. at 5-7. The Commission thus remanded for the ALJ's interpretation of the functional limitations and his reconsideration of the issues of infringement, validity, and the technical prong of the domestic industry requirement in light of the new claim constructions. Comm'n Op. at 5-7, 17-20. The Commission also remanded for reconsideration of the findings on infringement with respect to claims 22 and 25 because it found that the ALJ had not taken into consideration all of the record evidence. Comm'n Op. at 18-19. The Commission expressed no opinion on the merits of the issues of infringement, validity, or the technical prong of the domestic industry. Comm'n Op. at 20-21.

The ALJ issued his initial determination on remand ("IDR") on March 19, 2007. He interpreted the functional limitations, IDR at 6-11, and, applying the new claim constructions, reached the same conclusions on infringement, validity, and the technical prong of the domestic industry requirement that he reached in the final ID. That is, he found that the Twisted Pleasure and Inspiral infringed the following claims that he found were not anticipated by prior art: 13, 18, and 31 (Twisted Pleasure); 22, 25, and 31 (Inspiral). He found that the Twisted Pleasure also infringed claim 1, and that the Inspiral infringed claims 1, 6, and 9. IDR at 12-56 (infringement analysis for Twisted Pleasure and Inspiral). He found, however, that claims 1, 6, and 9 were invalid as anticipated. IDR at 56-66. He also found that, under the new claim constructions, the technical prong of the domestic industry requirement was satisfied. IDR at 66-71. Given the Commission's finding on review that the economic prong of the domestic industry requirement

was met, the ALJ found that there is a domestic industry within the meaning of the statute and, accordingly, he concluded that there is a violation of section 337. IDR at 71.

On March 29, 2007, all parties filed comments on the IDR. Respondents and Complainant filed responses on April 5, 2007. Due to an electronic filing error, the IA's response was not timely received. The IA refiled the response upon learning of the error, accompanied by a motion for leave for the Commission to accept it late. No party opposed the motion, which we granted in our order on final disposition.

II. ANALYSIS

When, as here, the Commission determines to review an initial determination, its review is conducted *de novo*. *Certain Polyethylene Terephthalate Yarn and Prods. Containing Same*, Inv. No. 337-TA-457, Comm'n Op. at 9 (June 18, 2002). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits and Prods. Containing Same,* Inv. No. 337-TA-382, USITC Pub. 3046 (July 1997), Comm'n Op. at 9-10 (quoting *Certain Acid-Washed Denim Garments and Accessories,* Inv. No. 337-TA-324, USITC Pub. 2576 (Nov. 1992), Comm'n Op. at 5). Commission practice in this regard is consistent with the Administrative Procedure Act. *Certain EPROM, EEPROM, Flash Memory, and Flash Microcontroller Semiconductor Devices and Prods. Containing Same,* Inv. No. 337-TA-395, Comm'n Op. at 6 (Dec. 11, 2000) (*EPROM*); *see also* 5 U.S.C. § 557(b).

Upon review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge. The Commission also may make any findings or conclusions that in its judgment are proper

based on the record in the proceeding." 19 C.F.R. § 210.45(c). This rule reflects the fact that the Commission is not an appellate court, but is the body responsible for making the final agency decision. On appeal, it is the Commission's final decision that is under review. *See EPROM* at 6, *citing Fischer & Porter Co. v. Int'l Trade Comm'n*, 831 F.2d 1574, 1576-77 (Fed. Cir. 1987).

A. Claim Construction

As the Commission indicated in its remand opinion, functional limitations are as pertinent as structural limitations in determining infringement of an apparatus claim. In the '004 patent, the functional limitations are identified as differentiating the invention from the prior art. The Meldahl design patent, for example, is distinguished as failing to arrange bulges so as to stimulate the surface of the glans penis during coitus. JX-1 at 1:36-40. A stated advantage of the '004 patent is to enhance the sensation of the male user. Thus, the claimed invention is described as including "a pouch or pouches on the tubular pouch in the thin membrane material of the condom that will move back and forth on the underside region of the glans penis or in areas adjacent to and encircling the glans penis during coitus to provide enhanced stimulation and sensitivity to the male user of the condom." JX-1 at 2:12-18.

On remand, the ALJ found that one of ordinary skill in the art at the time of the invention would construe the functional limitation in claim 1, "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto," as requiring "the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate the glans penis." IDR at 8. He found that one of ordinary skill in the art at

the time of the invention would construe the functional limitation in claim 9, "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis," as requiring that the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis. IDR at 9. Finally, he found that one of ordinary skill in the art at the time of the invention would construe the functional limitation in claim 18, "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches," as requiring the portions of the tubular portion located between the second pouches to maintain a generally constant diameter throughout the length of the tubular portion, resist stretching of the tubular portion, and maintain the shape of the second pouches. IDR at 11.

Respondents dispute the ALJ's interpretations of the first and third limitations. PTI and the IA support the claim constructions. With respect to the first functional limitation, the ALJ specifically states that the limitation requires the inner surface of the second pouch to be capable of moving inwardly through the boundary between the first and second pouch of the condom "as well as" capable of back and forth movement against the glans penis. IDR at 8. The IDR thus does not ignore the "back and forth" movement prescribed by this functional limitation, as Respondents suggest. Language in the IDR to the effect that the in-and-out movement of the interior of the second pouch may produce the desired rubbing action during coitus does not detract from the ultimate conclusion reached by the ALJ – that both in-and-out and back-and-forth movement are contemplated.

The ALJ's interpretation of the second functional limitation regarding hydrodynamic

rubbing is unchallenged. His construction of the language to require that the inner surface of the second pouch be coated with lubricant to facilitate the rubbing of the inner surface of the second pouch is well supported. IDR at 9. Respondents argue that the functional language in claim 19 requires that, throughout the length of the first pouch, there be a diameter on the interspersed first pouch portions having the same generally constant diameter as the open end of the tubular pouch, and further that these portions serve to keep the tubular pouch from stretching so as to keep the shape of the second pouches intact. The ALJ's interpretation of the third limitation to require that the portions of the tubular portion located between the second pouches (1) maintain a generally constant diameter throughout the length of the tubular portion and (2) resist stretching of the tubular portion and (3) maintain the shape of the second pouches, reflects a straightforward reading of the claim. We find no basis for disturbing it and, accordingly, adopt the claim constructions made in the IDR.

B. Infringement

Once the claims at issue have been properly construed, they are compared to the allegedly infringing device in order to determine infringement. *Deering Precision Instrument, L.L.C. v. Vector Distribution Systems, Inc.*, 347 F.3d 1314, 1322 (Fed. Cir. 2003). Literal infringement, the only type of infringement claimed here, is found when "every limitation of a claim is met in the accused structure." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). Under the "all elements rule," there can be no infringement if even one limitation is not present in the accused device. *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003).

In the final ID, the ALJ applied certain incorrectly construed claim terms to the accused

products (he incorrectly read theoretical structure into limitations), and did not apply other claim terms at all (he incorrectly found that functional limitations were without effect). The Commission remanded the entire infringement analysis to the ALJ without opining on the merits of whether the accused products were or were not infringing. On remand, the ALJ applied the new claim constructions and reached the same conclusions respecting the merits, finding that the Twisted Pleasure infringes claims 1, 13, 18, and 31, and that the Inspiral infringes claims 1, 6, 9, 22, 25, and 31. C&D and Medtech challenge all findings of infringement, with C&D focusing on the Twisted Pleasure and Medtech joining in those arguments and arguing separately with respect to the Inspiral. PTI and the IA argue that the IDR only erred in finding non-infringement of claims 22 and 25. In its petition for review of the final ID, PTI also preserved arguments that the ALJ's findings of non-infringement of claims 15, 16, 32, and 36 in the final ID were erroneous.

Upon consideration of the parties' arguments and the record in this case, we find the IDR in error. Properly applying the new claim constructions warrants the conclusion that the "all elements" rule is not met with respect to any claim of the '004 patent and, therefore, findings of non-infringement are warranted for both the Twisted Pleasure and the Inspiral. We address the products and the claims they were found to infringe seriatim. We then turn to the ALJ's findings from his final ID that certain other asserted claims were not infringed and as to which PTI preserved challenges.

Twisted Pleasure

Claims Found Infringed By ALJ

Claim 1

Claim 1 reads as follows:

1. A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:

said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and

a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

Structural Limitation Issues

In the final ID, the ALJ found that the "elongated tubular portion" of the claimed condom consists of "both the physical tube-like structure and the theoretical tube-like structure beneath the pouch or pouches . . . ." ID at 23-24. On this theory, the tubular portion of the condom continued beneath the spiral region of the Twisted Pleasure to the closed end of the condom. The problem with this construction, the Commission held in remanding the investigation, is that the claims require "said tubular portion being formed of thin membrane material," which means that the tubular portion consists of actual physical material and does not include the theoretical continuance of the tubular shape in areas underlying the secondary pouches. Comm'n Op. at 8. The Commission construed "elongated tubular portion" to mean "the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular

in shape." *Id.* at 8-9. This construction, the Commission noted, is consistent with the phrase "elongated tubular portion" being used synonymously with the claim term "first pouch." The Commission further noted that the elongated tubular portion includes the tapered portion of the condom closest to the reservoir tip. *Id.* at 9.

On remand, the ALJ has determined that said tubular portion of the Twisted Pleasure consists of one length of "contiguous" thin membrane material that extends from the open end of the condom through the valleys in the spiral region, to the closed end of the condom. IDR at 20. Under this application of the claim language, illustrated in the IDR at 16, theoretical structure of the tubular portion has been replaced by thin strings of material in the spiral region, referred to as "the valleys," that wind around and connect the shaft of the condom to the reservoir tip. The elongated tubular portion of the condom, as IDR at 16 demonstrates, is reduced to a tip, helical strings, and a shaft. We agree with C&D and Medtech that this is a misapplication of the construction of elongated tubular portion adopted by the Commission. The valleys of the Twisted Pleasure are not part of the tubular portion of the condom. There is nothing in the valleys of the spiral region that is tubular in shape under an ordinary reading of the claim terms. There is nothing like a circumference in the valleys of the spiral region. Complainant's own expert could not identify a circumference in the spiral region. Tr. 460-61. Nor is there a diameter to the valleys. The evidence showed that with their particular spring-like shape, the valleys are offset such that the distance between them is not a "diameter" at all, but rather a chord. *See, e.g.*, Tr. at 970, 974, 978; RX-110, Q. 91. The evidence also showed that the distance of the chord between the valleys exceeds the diameter of the shaft of the Twisted Pleasure. *See, e.g.*, Tr. at 891-93, 978; RX-110, Q. 95.

PTI and the IA argue that, under the claim constructions adopted by the Commission on review, there is no requirement of a *continuous* cylindrical tube to meet the definition of elongated tubular portion. PTI Reply at 3-6; OUII Reply at 3-6. For example, the IA points to the "star" embodiment of the '004 patent (Figs. 11-13), in which sections of the first pouch that are located between the second pouches do not meet a solid-cylinder definition for the tubular portion and yet are clearly referred to in the patent as part of the tubular portion. *See* Fig. 11 (item 82). Respondents acknowledge that under the Commission's claim interpretation the closed end can be part of the tube, the tube can have interruptions, and the tube may be comprised of one or more pieces. C&D Brief at 15-16. They contend that the absence of any real material in virtually the entirety of the spiral region, however, exceeds any reasonable concept that permits some lack of continuity in the traverse of the tubular portion along a '004 patent condom. Medtech Brief at 10-11. We agree.

Under the definition of the elongated tubular portion applied in the IDR, the nature of the structure is irrelevant, so long as there is some measurable piece of "thin membrane" to be found. Indeed, the strings could be even wispier than they are and satisfy the definition. This strikes us as, at best, one insignificant remove from the imaginary lines that the ALJ originally drew in the final ID. The Commission's claim construction expressly rejected such creative license. Every independent claim of the '004 patent requires that the tubular portion be formed of thin membrane material, and the specification provides that the tubular portion be of "sufficient strength to prevent rupture of the condom during use and of a sufficient close fit to prevent dislodging of the condom during use." Comm'n Op. at 9, *citing* JX-1 at 1:17-20, 3:63-66. Thus, in addition to referring back to the tubular-in-shape requirement, the Commission's definition

was premised on the requirement that the tubular portion consist of real and substantial material, not that which barely exceeds the imaginary. The Commission's interpretation on review of the terms "circumference" and "generally constant diameter from the open end to the closed end" does not alter this conclusion. "Circumference" was defined by the Commission to mean "the external surface of the tubular portion of the condom," not simply "an external surface," as applied by the ALJ. Comm'n Op. at 10; *cf.* IDR at 22. "Generally constant diameter from open end to closed end" was defined to require the "diameter of the tubular portion from the open end to the closed end to be, for the most part, constant." Comm'n Op. at 11-12.

Figures 4-6 and 10 in the '004 patent, cited in the IDR, and Figures 11-13 referenced above, also support this conclusion. Those illustrations depict embodiments of the '004 patent with the secondary pouches located between gaps in the tubular portion overlying the glans penis, but the material on either side of the gap is real and substantial. None demonstrates mere wisps between gaps, and none of the embodiments is lacking in a tapered portion of the condom, which the Commission has defined to be part of the tubular portion of a '004 condom. Comm'n Op. at 9. The spiral region of the Twisted Pleasure, on the other hand, has no tapered portion or anything else that fairly constitutes the tubular portion of the condom. The strings of material that constitute the valleys are not tubular in shape, do not have any structure like a diameter or circumference, and are wider than the shaft portion of the Twisted Pleasure. Their structure is insubstantial, much less of a sort to prevent accidental dislodgement of the condom. We therefore find that the valleys of the spiral region of the Twisted Pleasure do not meet the definition of elongated tubular portion.

This conclusion, in and of itself, does not require a finding of non-infringement. Even

without the spiral region being characterized as a tubular portion, the Twisted Pleasure arguably meets the limitation of an elongated tubular portion "having a generally constant diameter from the open end to the closed end" absent the spiral region, given the structure of the condom from its open end to the reservoir tip at its closed end. As the IA points out, Figure 10, in particular, of the '004 patent shows that a condom can have considerable lengths in which no portion of any cross-section of the second pouch tracks that of a traditional straight-walled condom and yet the elongated tubular portion has a "generally constant diameter." OUII Reply at 7. But the reason this is so is not the product of straining to characterize the baggy end of a condom as a tubular portion but rather of considering the material that actually constitutes tubular portion, as a whole, from the open end to the closed end of the condom. We therefore do not rely for our finding of non-infringement on any failure to meet the limitations of elongated tubular portion, generally constant diameter, or a first pouch having a circumference.

However, having found that the valleys of the spiral region of the Twisted Pleasure do not meet the definition of elongated tubular portion, we find that as a result the limitation of an "entrance," or movement through it, is not met. Specifically, claim 1 requires a second pouch "having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto."[4] The final ID construed the term "entrance," which the Commission left unchanged on review, to mean the boundary between the first pouch and any of the second pouches. Final ID at 35 (interpreting

---

[4] All the independent claims have the same or similar language. As discussed further below, this language was added to the claims to induce issuance of the patent in an amendment in which it was explained that the inner surface of the second pouch penetrates through an entrance so as to enter into the longitudinal chamber to stroke the glans penis. JX-4 at 139-40.

"entrance with an open area").

On remand, the ALJ found that the boundary between the Twisted Pleasure spirals and the valleys forms an "entrance." IDR at 25-26. He cites CX-82, reproduced in the final ID at 48, in which the entrance is identified as the outline of the boundary between the spirals (shown removed in the left pane) and the valleys. He also cites Dr. Wool's accompanying testimony regarding this delimited entrance (Tr. at 343:18-22). The ALJ thus adopted PTI's theory of the case on this particular point. However, this theory is premised on the assumption that the valleys in the spiral region of the Twisted Pleasure are part of the elongated tubular portion forming the first pouch of the condom. As discussed above, we determine that proper application of "elongated tubular portion" does not cover the valleys in the spiral region of the Twisted Pleasure, depicted in RDX-1, IDR at 16. Thus, there is no structure in the Twisted Pleasure to create or perform the function of the entrance, which is to provide the targeted stimulation patented by the '004 patent. Because the entrance can be present only where the first pouch intersects the second pouch, and the valleys are not part of the elongated tubular portion or first pouch, there is no entrance within the meaning of the claim limitation. Neither PTI nor the IA has identified other structure in the Twisted Pleasure as forming an entrance, or offered evidence to prove movement through it. As movement of the spirals through the valleys is not movement through an entrance, we conclude that the ALJ erred in finding infringement.

Functional Limitation Issues

Claim 1 requires a second pouch "having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." As the ALJ correctly determined, the movement is two-fold:

radial inversion through the entrance, and back and forth motion. The enhanced stimulatory effect provided by the claimed condom comes about due to the radial inversion of the second pouch through the entrance, within the confines of which the inner surface of the second pouch moves back and forth. It does not arise from the more generalized sliding motion of any pouch over the entire head and distal shaft of the penis. *See, e.g.*, JX-1 at 4:12-13, 4:44-46, 5:39-40, 6:42-44, 7:1-3. This latter type of movement is how the prior-art, baggy-end condoms function. *See, e.g.*, RX-11, RX-12, RX-13, RX-16 (examples of the class of baggy-end condoms, including the UK patent that is the subject of the ALJ's validity findings). In those condoms, the inner wall of the baggy portion of the condom slides up and down over the head (the glans penis) and distal shaft of the penis to stimulate the male. *See, e.g.*, RX-110, Q. 17, 23.

The evidence shows that the Twisted Pleasure functions like the prior art, in that the entire spiral region moves longitudinally to stimulate the penis. The condom is essentially a baggy-end condom, with the baggy end twisted. RX-120, Q. 147. There is no movement through an entrance; in fact, there is no entrance. Under the forces that operate during coitus, the material of the condom wrinkles, folds, and freely moves over the entire surface of the glans penis, as is generally true of baggy-end condoms. *See, e.g.*, RX-110, Q. 78, 81, 87; RX-120, Q. 144-53, 165-66; RDX-6-RDX-13. The two-step movement required by the functional limitation, inversion of the inner surface of the second pouch through an entrance, and back-and-forth movement within that entrance, is not present. *See, e.g.*, RX-108C, Q. 56; RX-120, Q. 178. Complainant and the IA claim the issue is simply one of dueling experts, and, point in particular to the testimony of PTI's expert, Dr. Wool:

Q: Does each second pouch have an inner surface moveable through the

> entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation thereto?
>
> A: Yes, it does.

Tr. at 343:18-22. Dr. Wool further testified that "[v]ery light pressure allows the interior surface and the interior space to communicate through the entrance region." Tr. at 349:24-350:1. The problem with the testimony is that it is premised on movement through an entrance that is not an entrance at all under the Commission's claim construction, as discussed above. *See also* Tr. at 351:13-16 (Dr. Wool: "The secondary pouches are separated by the so-called valleys, which is basically part of the primary pouch. And movement will depend on the level of forces that are exerted during coitus."). The valleys in the spiral region of the Twisted Pleasure do not constitute tubular portion of the condom forming the first pouch. They are not part of the first pouch, and thus do not form the claimed entrance. Dr. Wool's testimony also does not indicate how the accused condoms actually function in operation other than to suggest that the spirals would move through the valleys if a light force were applied. IDR at 24-25.

In sum, the record fails to demonstrate that the Twisted Pleasure meets the functional limitation of claim 1. The Twisted Pleasure is designed to slide. It does not contain an entrance through which the inner surface of the second pouch can or does invert in the manner claimed, much less move back and forth within an entrance during coitus to provide stimulation. It operates and moves in similar fashion to the baggy-end prior art.[5] The limitations in claim 1

[5] The IA points out that the entire spiral region of the Twisted Pleasure does not slide identically to prior-art, baggy-end condoms, noting that while baggy-end condoms have a constant "bloated" diameter in their distal region, the accused products have variation, *i.e.*, the valleys extend a lesser distance from the axis. OUII Reply at 13. However, the record indicates that the entire spiral region does actually slide, which is not the targeted movement claimed by

respecting an entrance and respecting movement are not met by the Twisted Pleasure.

Accordingly, we find that the Twisted Pleasure does not infringe claim 1.

Claim 13

Independent claim 13 reads as follows:

> 13. A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
>
> a plurality of second pouches arranged around the circumference; each of said second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending

---

the '004 patent, including the movement shown in Figure 10 of the '004 patent, which perhaps comes the closest to appearing like prior-art, baggy-end condoms. The movement in that figure is demonstrated by the dotted lines, 74c. Dr. Wool distinguished Figure 10 from the prior art by stating:

> Q: And in what respect do you consider figure 10 of the '004 patent to be different from the figures shown in this patent that you believe is material to whether or not the claims cover them?
>
> . . .
>
> Q: Do we have the pending question?
>
> A: Yes. And the answer is, if the figure 10 design behaves in a way as outlined by Dr. Reddy, in that the pouch acts as a secondary pouch on the primary pouch and is able to collapse under the pressures of coitus and it acts in the vicinity of the glans penis, then they would presumably – this design would probably work in the manner that Dr. Reddy had outlined. The problem with the other two designs is that they're designed for sliding, the looseness, and they're designed to provide nontight comfort to the glans penis.

Tr. at 425:15-426:19.

> lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis to produce movement thereof against the surface of the glans penis.

Claim 13 thus differs from claim 1 insofar as it requires a plurality of second pouches. For the same reasons discussed above in connection with claim 1, we find that the ALJ erred in finding infringement of claim 13. Based on the proper application of the claim constructions, the valleys in the spiral region of the Twisted Pleasure do not constitute an elongated tubular portion forming the first pouch, and the entrance and movement limitations are therefore not met. In addition, there is no "plurality" of second pouches in the spiral region, and thus there is an additional basis upon which to find no infringement. The ALJ's finding that this limitation was met is based upon his erroneous understanding that the material between the spirals constitutes elongated tubular portion of the condom separating the spirals and demarcating them as more than one pouch. However, as discussed above, there is no elongated tubular portion in the spiral region of the Twisted Pleasure. We therefore find that claim 13 is not infringed by the Twisted Pleasure.

Claim 18

Independent claim 18 reads as follows:

> 18. A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
>
> a plurality of second pouches arranged around the circumference;

> each of said second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; each of said pouches having an inner surface moveable through said entrance and against the glans penis;
>
> portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches; said second pouches providing looseness at the outer surface of the glans penis to increase its sensitivity to the rubbing action.

In addition to the limitations of claim 1, claim 18, like claim 13, requires a "plurality of second pouches." For the same reasons discussed above in connection with claims 1 and 13, we find that the ALJ erred in finding infringement of claim 18. Claim 18 also contains an additional structural limitation specifying that there are "portions of said tubular portion located between each of said second pouches." The IDR found infringement of this limitation by the valleys of the Twisted Pleasure. IDR at 30. As analyzed above, however, the valleys are not part of the elongated tubular portion. Therefore, there is no part of the first pouch that separates the spirals. The additional structural limitation of claim 18 is, accordingly, not met.

Claim 18 also contains additional functional language that the Commission instructed the ALJ to consider on remand. This language, as the ALJ found on remand and we have adopted, specifies that there are portions of the tubular portion located between each of the second pouches (1) "maintaining said constant diameter throughout the length of the tubular portion;" (2) "to resist stretching of said tubular portion;" (3) "to thereby maintain the shape of the second pouches." The ALJ determined that the valleys in the spiral region of the Twisted Pleasure

perform these functions. We disagree. Fundamentally, there is no tubular portion in the spiral region to perform these functional limitations. In addition, the evidence shows that even the thin valley regions do not perform these functions. The valleys do not resist stretching of the condom, they are too thin and narrow to provide any sort of structural support to the condom. *See, e.g.*, RX-110, Q. 114. Nor do they function to maintain the shape of the bulging spirals. They move and change shape along with the spirals. *See, e.g.*, RX-110, Q. 115; RX-120, Q. 129, 132, 135, 138. Dr. Potter, throughout his testimony, emphasized that the spirals do not maintain their shape. *See* RX-120, Q. 125-28, 130-31, 133-34, 136-37, 139, 165-66. *See also* Tr. at 1015:11-15 ("I was attempting to show that the valley portions are basically very insubstantial, do not really have any structural integrity, and could certainly not hold the spiral end of the condom in the position as described in the '004 patent."). Dr. Reddy, the inventor of the '004 patent and designer of the Twisted Pleasure, testified to the same effect. "[T]his entire distal end is constantly in motion and changing shape during intercourse." RX-108C, Q. 56.

Dr. Reddy also testified to the spring action of the Twisted Pleasure, which the ALJ cited in support of the Twisted Pleasure meeting the additional functional limitations of claim 18. Dr. Reddy's testimony, however, appears to support precisely the opposite proposition. The spring-like action of these condoms is not taught in the '004 patent. Dr. Reddy (not his son Ravi Reddy as identified by the ALJ) testified that the lay-flat widths of the condoms, which go all the way to the reservoir tip, are much greater than in the shaft region, and that this greater lay-flat width actually starts before the spirals. RX-108C, Q. 55; *see* JX-7 (Dr. Reddy's 1999 patent for the "Spring Action Male Condom," U.S. Patent No. 6,000,398 ("'398 patent")). According to the '398 patent, the helical, spring-like shape imposes a spring-bias action on a condom that when

stretched axially will cause the condom to spring back to its normally, unbiased shape. JX-7 at 3:52-63. The lay-flat width, from just below the spirals to the tip of the condom is bigger than the average male penis, so this entire region, including the spirals and material between them, moves. "This is the whole point of these condoms. They are designed to be loose at the entire distal end during intercourse." RX-108C, Q. 56. Dr. Reddy's testimony therefore supports the dynamic sliding effect of the entire spiral region, not the maintenance of shape of spirals by the valleys.

The valleys in the spiral region thus do not help to maintain the generally constant diameter of the tubular portion (they contribute nothing to the diameter of the tubular portion), resist stretching, or maintain the shape of the second pouches. Dr. Wool's testimony, which is the most favorable for Complainant, does little to support the contrary proposition. In addition to incorrectly assuming that the valleys are part of the tubular portion, his opinion is that "for light forces . . . they [the valleys] stay in place." IDR at 32. He also testified that whether the valleys actually maintain the shape of the second pouches, "depends on the magnitude of the forces that are placed upon the second pouches." IDR at 32. The '004 patent's limitations are not so qualified, and Dr. Wool's circumspection offers, at best, a weak rebuttal to the evidence on the other side of whether the additional functional limitations are met. We therefore find that the Twisted Pleasure does not infringe claim 18.

Claim 31

Independent claim 31 reads as follows:

> 31. A prophylactic pouch for use by a male, having an elongated tubular portion forming a first pouch including a circumference, an open end and a closed end, said tubular portion having a generally constant diameter from

end to end, characterized by:

a second pouch integrally formed on the circumference of said tubular portion as an outward bulge on the closed end in overlying spaced relationship to a glans penis and operable to move thereon to provide stimulation during coitus; said second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement.

Claim 31 recites structural limitations that the second pouch be integrally formed on the circumference of the closed end of the tubular portion and with an entrance that extends lengthwise of the glans penis at least 1 cm. However, Claim 31 otherwise contains the same limitations discussed in connection with claim 1 above, and is therefore not infringed for the same reasons.

ALJ's Findings of Non-Infringement As To Which PTI Has Preserved Challenges

Claims 15-16

Dependent claims 15 and 16 read as follows:

15. The prophylactic pouch of claim 9[6] characterized by the second pouches comprising a plurality of longitudinally spaced open pouches to produce rubbing movement along the length of the surface of the glans penis and to provide clitoral stimulation during coitus.

---

[6] Claim 9 provides:

9. The prophylactic pouch of claim 1 characterized by the second pouch having its inner surface coated with a lubricant to provide a hydrodynamic rubbing of the glans penis.

16. The prophylactic pouch of claim 15 characterized by the second pouches being coated with a lubricant to provide a hydrodynamic rubbing of the glans penis.

The final ID found that the Twisted Pleasure did not infringe dependent claims 15 and 16 because the condom did not meet the requirement in claim 15 that the second pouches be longitudinally spaced from one another. Final ID at 57. The ALJ determined that, as shown in Figures 8 and 9, "longitudinally spaced" requires that a cross-sectional cut fall fully between the two second pouches. Applying this construction, he found that any cross section of the spiral region intersects both secondary pouches, and therefore the longitudinally spaced limitation is not met in the Twisted Pleasure. The Commission did not review this construction, and the ALJ's application for the infringement analysis, so far as it goes, appears well supported. *Compare* JPX-6 *with* JX-1 at Figures 8, 9. The specification indicates that the embodiment describing longitudinally spaced pouches has pouches that do not overlap along the longitudinal access and, to the contrary, have considerable space between them. JX-1 at 5:64-7:15. Accordingly, in addition to the analysis above supporting a finding of non-infringement of claim 1 and the analysis above regarding the lack of a "plurality" of secondary pouches in the Twisted Pleasure, we find non-infringement of claims 15 and 16 because the "longitudinally spaced" requirement does not read on the Twisted Pleasure.

Claims 22 and 25

Claims 22 and 25 read as follows:

22. A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:

said tubular portion being formed of thin membrane material and having a

generally constant diameter from the open end to the closed end;

a second pouch integrally formed on the circumference of the closed end for forming a loose pocket overlying in spaced relationship to the glans penis and having an inner surface moveable back and forth thereon during coitus for providing stimulation thereto;

said tubular portion and said second pouch having a wall thickness of 0.11 mm ± 0.04 mm; and

said second pouch having its inner surface spaced radially outwardly of said tubular portion to provide looseness between said tubular portion and the outer surface of the glans penis to prevent binding of the glans penis with consequent reduction in sensitivity.

. . .

25. The prophylactic pouch of claim 22 characterized by the second pouch being coated with a lubricant to provide a hydrodynamic rubbing of the glans penis.

In the final ID, the ALJ found that, while stated in slightly different terms, the limitations in claim 22 are the same as those recited in claim 1, except that claim 22 explicitly requires that both the tubular portion and second pouch have a wall thickness of 0.11 mm ± 0.04 mm, and that the second pouch be integrally formed on the circumference of the closed end of the tubular portion. Final ID at 61. We agree with this construction of claim 22.

Claim 22 uses somewhat different language to recite the same targeted rubbing action through an entrance envisioned by the '004 patent. Claim 22 recites a "second pouch . . . forming a loose pocket overlying in spaced relationship to the glans penis." The claim also recites that the "second pouch" has an "inner surface spaced radially outwardly of said tubular portion" and that this "inner surface" is "moveable back and forth" on the glans penis. The limitation of an entrance at the boundary of the first and second pouches, and movement through

such an entrance, are necessary to perform this method of stimulation. Indeed, every independent claim issued as a result of the distinction made during the prosecution history between, on the one hand, inversion of the inner surface of a second pouch causing it to penetrate through an entrance and, on the other, the back and forth sliding movement characteristic of baggy-end prior art condoms. Every independent claim has language directed to such movement.

The new language concerning movement was added to the claims to induce issuance of the patent in an amendment in which it was explained that the inner surface of the second pouch penetrates through an entrance so as to enter into the longitudinal chamber to stroke the glans penis. JX-4 at 139-40 ("Haines '903 does not teach a pouch having an inner wall that will penetrate through an entrance to stroke a glans penis"). The remarks in the prosecution history directed to all claims leave no doubt as to the type of movement to which each of the claims, including claim 22, is directed. *Cf. Chimie v. PPG Indus.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("claims are not construed one way in order to obtain their allowance and in a different way against accused infringers."). Accordingly, while the language is not identical, no other method of stimulation is disclosed, and the ALJ properly did not differentiate one claim from the other claims on this basis. *Cf. Alloc v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("the specification read as a whole suggests that the very characteristic of the invention requires the limitation be a part of every embodiment").

The ALJ found that PTI failed to prove that the tubular portion and the second pouch of the Twisted Pleasure have a wall thickness of 0.11 mm ± 0.04 mm and, therefore, he found non-infringement of claim 22 and dependent claim 25 for failure to meet the thickness limitation. Final ID at 63. In addition to directing the reconsideration of all infringement findings based on

the new claim constructions, the Commission directed the ALJ to reconsider this thickness finding with respect to claim 22 because it appeared that he had not considered all of the record evidence. On remand, the ALJ revisited the thickness limitation issue as regards claim 22, and he reached the same conclusion – that the record does not demonstrate that the Twisted Pleasure has a wall thickness of 0.11 mm ± 0.04 mm. He thus found no infringement of claims 22 or 25. IDR at 36-37.

We determine that the Twisted Pleasure does not infringe claims 22 and 25, but not for the reasons relied on by the ALJ. Rather, a finding of non-infringement is warranted for all of the reasons discussed with respect to claim 1. That is, as set forth above, a proper application of the claim construction, including "elongated tubular portion," to the Twisted Pleasure shows that neither the entrance nor the functional limitations are met in the accused condom. On the other hand, we find that the record supports the finding that the Twisted Pleasure meets the thickness limitation.

The ALJ was satisfied that the Double Springer condom as depicted in exhibit JX-34C has the requisite wall thickness. IDR at 35. JX-34C includes thickness measurements for design input, design output, and "norms finalised," as well for "Finished Product Testing." JX-34C at 56, 118-19. Where the ALJ perceived an evidentiary gap was on the question whether the design of the Double-Springer, in its final measurements in JX-34C, became the Twisted Pleasure. He did not find an adequate connection between certain hand drawings, CX-228, and the Twisted Pleasure, and we do not disagree. *See* IDR at 35-36 (citing testimony distinguishing design in CX-228 with final product that became Twisted Pleasure). However, we do disagree with his analysis of the record in terms of the connection between the measurements in JX-34C and the

Twisted Pleasure. JX-34C, according to Respondents' own witness, Ravi Reddy, is the entire design and development book, kept in the ordinary course of Medtech's business, "for the Twisted Pleasure." RX-109C, Q. 29 & 32. It contains, in addition to the historical record of the development of the condom, "*the technical and other data that we use to make the molds and formers, and the condoms themselves.*" RX-109C, Q. 29 (emphasis supplied). PTI thus met its burden of proof through Respondents' own witness.

While Respondents claim that PTI and the IA failed to include proper pinpoint record citations below, the Commission's remand instructed the ALJ to take into account the entire record on this issue. Similarly, their claim that the final thickness measurement set forth in JX-34C actually shows non-infringement, because it states ".013 mm ± .02 mm" rather than ".13 mm ± .02 mm," is unpersuasive. Clearly, the movement of the decimal point is a typographical error.

We are mindful that PTI's expert, Dr. Wool, had no credibility on this issue because he testified that he was simply relying on what counsel told him. However, consistent with the Commission's remand instruction for the ALJ to take into consideration all of the record evidence on this issue, it is apparent that the ALJ erred in finding a lack of proof that measurements he otherwise credited as meeting the thickness limitation were not applicable to the Twisted Pleasure. We thus find no infringement of claim 22 or independent claim 25, but for reasons different than those articulated by the ALJ.

Claims 32 and 36

Claims 32 and 36 read as follows:

32. The prophylactic pouch of claim 31[7], further characterized by:

A third pouch formed as an outward bulge intermediate the open and closed end for engaging and stimulating the clitoris of a female partner during coitus.

. . .

36. The prophylactic pouch of claim 32, further characterized by:

At least those pouches overlying the glans penis containing a coating of a lubricant to provide hydrodynamic rubbing of the glans penis during pouch movement.

The final ID found that the Twisted Pleasure did not infringe claims 32 and 36 because both pouches of the Twisted Pleasure were formed on the closed end rather than "intermediate the open and closed end," as the claims require for placement of the "third pouch" for stimulating the clitoris. Final ID at 65-66. PTI petitioned for review of the final ID on the ground that the spirals should be viewed, for purposes of these claims, as simultaneously formed at the closed

---

[7] Claim 31 provides as follows:

31. A prophylactic pouch for use by a male, having an elongated tubular portion forming a first pouch including a circumference, an open end and a closed end, said tubular portion having a generally constant diameter from end to end, characterized by:

a second pouch integrally formed on the circumference of said tubular portion as an outward bulge on the closed end in overlying spaced relationship to a glans penis and operable to move thereon to provide stimulation during coitus; said second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement.

end and between the open and closed ends.

We find no infringement of these claims for all of the reasons discussed with respect to claims 1 and 13. In addition, we agree with the ALJ's analysis as to the lack of the specified third pouch. Claims 32 and 34 provide that the bulges intermediate to the open and closed ends stimulate the clitoris. The corresponding portion of the specification describes an embodiment of the claims in which pairs of diametrically-opposed pouches (items 64b-d) are said to stimulate the clitoris. JX-1 at 6:16-6:26. Significantly, the specification omits reference to item 64a – the pair closest to the closed end – as intermediate pouches. The distinction drawn in the specification suggests that a pouch should not be considered, as PTI claims, both intermediate to the ends and formed at the closed end. Accordingly, we adopt the ALJ's finding of non-infringement.

Inspiral

The IDR found that the Inspiral infringes claims 1, 6, 9, 22, 25, and 31. The ALJ's infringement findings overlap with the Twisted Pleasure as to claims 1 and 31, and depart from the analysis under claims 22 and 25 only insofar as the ALJ found that PTI demonstrated that the Inspiral met the thickness limitation. In the final ID, the ALJ also found that the Inspiral does not infringe claims 2-4 or 8 of the '004 patent, but PTI did not petition for review of these findings.

For the same reasons discussed with respect to the Twisted Pleasure above, we find that the Inspiral does not infringe claims 1, 22, 25, or 31. In addition, because claims 6 and 9 depend from claim 1, we find that the Inspiral does not infringe these claims for reasons including those discussed with respect to claim 1.

Claims 1, 22, 25, and 31

Applying the Commission's construction of "elongated tubular portion" to the Inspiral, the ALJ found on remand that the tubular portion of this condom consists of one contiguous piece of thin membrane material that reaches from the shaft of the condom to the reservoir tip through a "tendril" depicted in RDX-2, which is reproduced in the IDR at 42. The ALJ's analysis otherwise tracks that of the Twisted Pleasure, thus replacing the helical strips described in the spiral region of the latter with the singular filamentary tendril in the spiral region of the former. Under this theory of the case, the "entrance" through which the inner surface of the spiral moves is depicted as running along the edge of the tendril as it twists through the spiral region, as depicted in CX-78, reproduced in the final ID at 70 (left side) and 71 (right side).

The IA argues that the tendril depicted in RDX-2, adopted by the ALJ, actually understates the amount of material in the valley of the Inspiral's spiral region, and expresses a preference for the depictions of the tendril in CX-76, 78-79, and JPX-5. We concur with Respondents, however, that regardless of the demonstrative exhibit to which this theory resorts (and we think the ALJ reasonably relied upon RDX-2), the tendril of the Inspiral, like the helical threads of the Twisted Pleasure, is not a tubular portion of the condom.

Replacing the theoretical continuation of the tubular portion applied in the final ID with a wispy, insubstantial thread, as the ALJ did on remand, does not satisfy the structural limitation to which the Commission's claim construction gives effect. There is nothing remotely tubular in shape in the tendril. The material at this junction in the spiral portion of the Inspiral is insubstantial; it is too narrow to have structural integrity or stability. *See, e.g.*, Tr. at 970. Indeed, the entire baggy end of the Inspiral has a lay-flat width of 68-70 mm, which is substantially larger than the straight-walled portion of the condom, and is also larger than the

girth of the average erect male penis. *See, e.g.*, RX-110, Q. 74, 78.

We have determined that the proper interpretation of "elongated tubular portion" does not cover the valley in the spiral region of the Inspiral. Thus, there is no structure in the Inspiral to create or perform the function of the "entrance" to provide the targeted stimulation patented by the '004 patent. Because the entrance can only be present where the first pouch intersects the second pouch, and the valley is not part of the elongated tubular portion or first pouch, we find no entrance within the meaning of the claim limitation. Neither PTI nor the IA has identified other structure in the Inspiral as forming an entrance, or offered evidence to prove movement through it. Movement of the spiral through the edge of the tendril is not movement through an entrance within the meaning of the patent.

The Inspiral is essentially nothing more than a baggy-end condom with the baggy end twisted. Its design bears none of the hallmark "entrance" and "second pouch having an inner surface moveable through said entrance" elements that appear as limitations in the '004 patent. Nor does it perform the functional limitation of claim 1. The entire distal end of the Inspiral condom moves along the distal end of the penis during coitus. The narrow strip of material of the tendril – the only portion PTI contends constitutes a first pouch in the spiral region of the Inspiral – moves freely in use, as does the spiral itself. *See, e.g.*, RX-108C, Q. 56; RX-120, Q. 143-53, 165-67. The structure thus does not form an entrance through which the inner surface can or does invert in the manner claimed, much less move back and forth within an entrance during coitus to provide stimulation. Accordingly, we find that the limitations common to all independent claims respecting an entrance and respecting movement are not met by the Inspiral. *See, e.g.*, Tr. at 895-98; RX-110, Q. 74, 78-80; RX-120, Q. 178-79. Our analysis respecting the

Twisted Pleasure and these limitations applies equally to the Inspiral. For all of these reasons, we find that the Inspiral does not infringe claims 1, 22, 25, or 31.

Claims 6 and 9

Dependent claims 6 and 9 read as follows:

> 6. The prophylactic pouch of claim 1 characterized by the second pouch being formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis.
>
> . . .
>
> 9. The prophylactic pouch of claim 1 characterized by the second pouch having its inner surface coated with a lubricant to provide a hydrodynamic rubbing of the glans penis.

Claims 6 and 9 depend from claim 1, and the Inspiral therefore does not infringe either claim for the same reasons it does not infringe claim 1. Claim 6 also adds the limitation of the "second pouch being formed completely around the circumference to produce an annular pocket . . ." In the final ID, the ALJ construed annular pocket to mean "a bag-like structure forming a ring-like shape." Unlike the ring-shape in the embodiment in Figure 4 of the '004 patent, the twisting structure in the spiral region of the Inspiral appears to push the limits of the claim terms. However, we cannot say that they are not broad enough to read on the Inspiral. Accordingly, we do not find non-infringement on this basis. We also do not find non-infringement of claim 9 on the alternative basis proposed by Medtech, that is, that the lubricant in the Inspiral does not contribute to "rubbing" action. Medtech's complaint appears to be with the artfulness of the claim's drafting – suggesting that having a lubricant and providing rubbing are scientifically at odds. There is no dispute that the Inspiral is generally sold in a lubricated state; the ALJ's finding that the limitation is met by the Inspiral is reasonable.

C. Validity

A determination that a patent is invalid as being anticipated under 35 U.S.C. § 102 requires a finding that each and every limitation is found either expressly or inherently in a single prior art reference. *See Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). An element need not be expressly disclosed in the reference so long as the missing element is inherently disclosed by the reference. *See Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). A claim limitation is inherently disclosed if a person of ordinary skill in the art would recognize that the limitation is necessarily satisfied by the reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) ("Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Anticipation must be established by clear and convincing evidence. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995).

We conclude that the ALJ erred in finding claims 1, 6, and 9 of the '004 patent invalid as anticipated, and further that he erred in finding that C&D waived any argument that claim 31 is also invalid.[8] Even considering the merits of the latter argument, however, we similarly conclude that claim 31 is not invalid as anticipated. We thus reverse the ALJ's findings to the contrary.

Dr. Reddy was clearly not the first to invent a condom in which the inner surface of a

---

[8] Medtech did not independently advocate finding invalidity (Medtech was formed by the inventor of the '004 patent). The ALJ reasonably determined, however, that a finding of invalidity, if made, should apply to the Inspiral if it applied to the Twisted Pleasure. Prehearing Conf. Tr. at 94.

loose pouch of material on a condom comes into contact with the glans penis. Many such condoms were present in the prior art, including the entire class of baggy-end condoms identified in exhibits RX-11, RX-12, RX-13, and RX-16. RX-12, U.K. Patent No. 1,252,255 ("UK" or "'255" patent) is the reference identified in the IDR as anticipating several claims. This UK patent, filed on November 10, 1967, provides for a condom with "a head section and a main body section, both of generally cylindrical shape." RX-12 at 1:34:37. The diameter of the head section is "substantially larger than that of the main body section, and its length does not exceed that of the main body section." RX-12 at 1:37-41. The specification of the '255 patent also states that the "employment of [the] two distinct sections" avoids the gripping of the swollen head of the penis," which the patent notes is beneficial because the head (glans) is "primarily sensitive to friction and heat." RX-12 at 2:49-52, 55-58. Other prior patents similarly altered the shape of the condom. The Meldahl design patent (filed on December 20, 1977), for example, which was before the examiner and mentioned in the '004 specification, discloses a condom "in which the pouch of a male condom has outwardly directed bulges." JX-1 at 1:36-38. The larger bulge of that patent is over the glans penis. JX-17 at Figures 1-2. The '004 specification states, however, that "the bulges [of Meldahl] are not arranged so as to stimulate the surface of the glans penis." JX-1 at 1:39-40.

The ALJ based his conclusion in the IDR that claims 1, 6, and 9 of the '004 patent are invalid upon the '255 patent. IDR at 56. The final ID noted that "the '255 patent does not disclose the exact nature of how the 'head section' stimulates the glans," but found that the functional limitation in claim 1 was not a patentable distinction. Final ID at 87. On review, the Commission reversed the finding that the functional limitations of the '004 patent were without

effect and vacated the findings that claims 1, 6, and 9 were invalid. On remand, the ALJ found that the functional limitation of claim 1 of the '004 patent is met because the '255 patent inherently performs the function. IDR at 63. He recognizes in the IDR, as he did in the final ID, that the UK patent recites no functional limitation. However, he finds there must "necessarily be some type of movement back and forth along the glans penis" in the invention of the '255 patent, and therefore the patent discloses a "second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." IDR at 63.

The ALJ properly declined to accept the non-disclosed dimensions for the '255 patent argued by C&D and the inference C&D sought to draw about the length of the condom (importing current ASTM standards into the '255 patent and assuming a certain class length was referred to). IDR at 62. The ALJ's finding about the function of the "head section," however, is unsupported, particularly against a clear and convincing evidence standard. As the ALJ acknowledged, there is no express functional limitation disclosed in the '255 patent. Moreover, as its specification makes clear, the '255 patent is not about creating an additional stimulant for the "swollen head of the penis, when in erect state," so much as removing an obstacle to sexual stimulation by avoiding "gripping" in that area of the penis. The patent states that it enables "gripping of the swollen head . . . *to be avoided.*" RX-12 at 2:56-58 (emphasis supplied). The '255 patent thus contains no movement limitation. Nor is the movement limitation of the '004 patent inherent in the '255 patent's limitations. A second pouch of a condom cannot be of virtually any size and still practice the '004 patent. The evidence shows that the design in Figure 10, which is the '004 patent embodiment that the '255 patent most closely resembles, contrasts

with the prior-art, baggy-end condoms in its prescribed manner of movement – moving through and within an entrance as depicted by dotted lines 74c in Figure 10 to stroke the glans penis. If a condom designer modified the second pouch of Figure 10 by gradually increasing its width and length, at some point the second pouch would collapse backwards or simply slide during use and no longer practice the targeted stimulation of the '004 patent. This sort of collapse would greatly reduce or altogether eliminate the ability of the second pouch's inner surface to produce the desired rubbing. *See* Tr. at 417, 425-26. The '255 patent does not contain this limitation, and there is no clear and convincing evidence that this targeted stimulation inheres in that condom.[9] Accordingly, we conclude that there is no inherency in the '255 patent appreciable by one of ordinary skill in the art that renders claim 1 or dependent claims 6 and 9 invalid.

We also find that claim 31 of the '004 patent is not invalid as anticipated, but not for the reasons cited by the ALJ. The ALJ found that C&D had waived any challenge to the validity of claim 31 based on the failure to brief it in response to his Order No. 33. However, C&D did indeed raise the issue in its brief in response to that order. *See* Brief of Respondent Church & Dwight Co., Inc., In Response to Order Nos. 33 and 35, at 41. C&D also raised the issue in its petition for review of the final ID and, under our order, the Commission reserved entertaining the merits of challenges to the validity finding pending the ALJ's application of the new claim constructions. On the merits, however, claim 31 depends from claim 1. Thus, the same reasons

---

[9] There is no law of nature that prescribes the function (or dimensions) of second pouches of male prophylactic devices. *Cf. EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001) (finding that the reference "inherently discloses the law of nature by which such fuses rupture under the heat of a laser"). If there were, the movement limitation would inhere in every single prior-art, baggy-end condom, not simply the UK patent.

apply for finding that claim 31 is not anticipated by the '255 patent.[10]

For all of these reasons, we do not find any claims of the '004 patent to be invalid.

D. Domestic Industry

As a prerequisite to a finding of violation of section 337, Complainant must establish that "an industry in the United States, relating to the articles protected by the [intellectual property right] ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Typically, the domestic industry requirement of section 337 is viewed as consisting of two prongs: the technical prong and the economic prong. *See, e.g., Certain Variable Speed Wind Turbines and Components Thereof,* Inv. No. 337-TA-376, USITC Pub. 3003 (Nov. 1996), Comm'n Op. at 14-17. The technical prong, which is not at issue here, concerns whether Complainant (or its licensee) practices at least one claim of the asserted patents (the claim practiced need not be one asserted in the investigation).[11] The economic prong concerns domestic activities with respect to the patent or patented article. To satisfy the economic prong, these activities must involve:

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

---

[10] We do agree with the ALJ in rejecting C&D's argument that the 1 cm limitation in claim 31 reads on the '255 patent. IDR at 66, *citing* Staff's reply memorandum at 14.

[11] That PTI practices the '004 patent with its Pleasure Plus condom is not disputed on this record. The ALJ found the technical prong met in the final ID and Respondents did not petition for review on that basis. Based on the new claim constructions, we preserved the issue and directed its reconsideration on remand. On remand, Respondents did not argue that the technical prong was not met, and the ALJ again found the requirement satisfied. Respondents do not claim error. We adopt the ALJ's uncontested conclusion that there is a domestic industry under the technical prong.

(C) substantial investment in exploitation of the patent, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

The economic prong requirement exists to assure that domestic production-related activities, as opposed to those of a mere importer, are protected by the statute. *Certain Products with Gremlin Character Depictions*, Inv. No. 337-TA-201, USITC Pub. 1815 (Mar. 1986), Comm'n Op. at 6. The 1988 Omnibus Trade and Competitiveness Act codified existing Commission practice by adding the first two subparagraphs under 19 U.S.C. § 1337(a)(3). It also added the third subparagraph. The legislative history states that:

> The first two factors in this definition have been relied on in some Commission decisions finding that an industry does exist in the United States. The third factor, however, goes beyond ITC's recent decisions in this area. This definition does not require actual production of the article in the United States if it can be demonstrated that significant investment and activities of the type enumerated are taking place in the United States.

H.R. Rep. No. 40, 100th Cong., 1st Sess., pt. 1 at 157 (1987).

The Commission's determination on the economic prong is not made according to any rigid formula – there is no mathematical threshold test. Instead, the determination is made by "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Certain Double-Sided Floppy Disk Drives and Components Thereof (TEO)*, Inv. No. 337-TA-215, USITC Pub. 1860 (May 1986), Comm'n Op. at 17. The relevant domestic activities to be considered may include those of a complainant's subcontractor. *See, e.g.*, *Certain Home Vacuum Packaging Products*, Inv. No. 337-TA-496, USITC Pub. 3681 (May 2004), Order No. 36 at 143. The fact that a complainant may be a small business is not preclusive as "[t]he Commission in the past has allowed very small businesses to get a hearing [at the ITC]. Small

businesses in this country can become large ones, and there is a public interest in protecting them against unfair theft of their property rights." *Certain Static Random Access Memories and Integrated Circuit Devices Containing Same, Processes for Making Same, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-325, Order No. 9 at 4 (May 14, 1991).

The ALJ found that Complainant failed to demonstrate a domestic industry under the economic prong of the domestic industry requirement. Complainant and the IA petitioned for review of this finding and the Commission determined to review this issue. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). On review, the Commission determined that the ALJ's finding against Complainant was not supported by proper application of the statute or Commission precedent, or the record in this case. The Commission reversed the ALJ's determination, finding that the economic criteria for a domestic industry had been met. Comm'n Op. at 20.

Our reversal is based on our finding that the facts that are not genuinely disputed in this investigation, including certain facts found by the ALJ, are sufficient in their own right to demonstrate the level of significance required by subparagraphs (A)-(B) of § 1337(a)(3).[12] These facts include the following. PTI is a United States corporation with its headquarters in Chicago, Illinois. Joint Statement of Undisputed Facts ("JSUF") ¶4. The Pleasure Plus is the only product that PTI sells or has ever sold. CX-242, Q. 128. PTI purchased the rights to the '004 patent, which covers the Pleasure Plus, from the bankruptcy estate of Reddy Laboratories International, Ltd. ("RLIL"). JX-71. PTI paid [ ] for intangible assets owned by RLIL, including the '004 patent. JSUF ¶31.

[12] Subparagraph (C) is not at issue in this investigation.

PTI operates its business in the United States by way of a management agreement with Global Protection Corp. ("GPC"), a shareholder of PTI. JSUF ¶¶ 5, 30. GPC leases approximately 14,900 square feet of space for production, shipping, and office work related to Pleasure Plus and other GPC products. The facility is located in Boston, Massachusetts. JSUF ¶32. GPC bills PTI for its use of space in its facility. JSUF ¶32.

GPC has nineteen production and office employees who perform work related to the Pleasure Plus and other GPC products. JSUF ¶33. The time spent on PTI matters is billed by GPC to PTI. JSUF ¶33. In the 14-month period ending February 2005, GPC charged PTI for approximately [ ] hours of work on PTI matters. JSUF ¶34. The ALJ determined that this time was equivalent to [ ] employees working 40-hour weeks. Final ID at 117-18.

PTI, through GPC, lubricates, foils, tests, and packages Pleasure Plus prophylactics at GPC's facility in Boston. The unfinished condoms, also referred to as latex balloons, are shipped from China. Final ID at 123-24. These balloons are lubricated and foiled on a machine in GPC's FDA-compliant clean room. Foiling of a prophylactic is the process whereby the rolled balloon is enclosed in an air-tight, two-sided square of foil. Tr. at 785. Lubrication is injected in the prophylactic just prior to the sealing of the foil. Tr. at 948. The testing performed at GPC includes water-leak and package integrity tests. CX-244, Q. 79.[13] Pleasure Plus condoms are packaged in 3-pack or 12-pack boxes. *Id.* Some of the finished condoms are also sold by PTI in bulk to health organizations without further packaging. Final ID at 126. In 2005 alone, PTI sold [ ] Pleasure Plus prophylactics that GPC lubricated, foiled, tested, and packaged. JSUF

[13] Foiling, lubricating, and quality testing are referred to as "second staging."

¶35.

The unfinished condoms imported from China are not saleable to the consumer as imported. Final ID at 126. Exposure to light and air would cause the latex to oxidize and become brittle. Tr. at 936. It is not until the prophylactics are sealed in foil and tested according to FDA standards that they are merchantable in the United States, an important fact that the ALJ improperly declined to accord any weight. Final ID at 120-22. Prior investigations instruct that if the product is not saleable without the domestic activities, this factor supports finding a domestic industry. For example, in *Certain Diltiazem Hydrochloride and Diltiazem Preparations*, the economic prong was held to be satisfied even though the entire patented process for the drug in question was practiced overseas by one co-complainant. Inv. No. 337-TA-349, USITC Pub. 2902 (June 1995), Initial Determination at 133-45 (unreviewed in relevant part). The determination was based in part on the fact that the drug as imported in bulk form was not usable until it was converted into dosage form at domestic facilities (owned by the second co-complainant). *Id.* at 141-45.

Not only are the bulk condoms not useable or saleable as imported, the lubrication added in the United States is directed to the practice of certain patent claims, an additional factor relevant to domestic industry analysis that the ALJ did not consider. *See Certain Plastic Encapsulated Integrated Circuits,* Inv. No. 337-TA-315, USITC Pub. 2574 (Nov. 1992), Initial Determination at 90 (nature and significance inquiry included whether domestic activities relate to something covered by the patent); *Certain Concealed Cabinet Hinges and Mounting Plates,* Inv. No. 337-TA-289, Comm'n Op. at 23 (Jan. 8 1990) ("Because of its indirect bearing on the patented features of the [product], we reduce the weight we otherwise would accord

complainant's investment."). Claims 9 and 25 of the '004 patent require application of lubrication to the inner surface of the second pouch.

There is also no genuine dispute that, measured on a comparative basis, the domestic activities in which PTI invested create "value added" to the bulk product imported from China. The ALJ declined to consider this alternative factor, which under the circumstances tends to support the finding of a domestic industry, because he determined that Complainant's value-added calculation was unreliable. Relying on the figures that the ALJ did credit (the per-unit cost of the imported bulk condoms is [ ] and the per-unit cost of lubricating, foiling, and testing the condoms is [ ]), we find a value added of 34 percent. Under Respondents' own calculation, the value added by PTI ranged from 27 percent to 35 percent.[14] Final ID at 124.[15]

The ALJ also rejected the total amount of labor expenses that PTI allegedly incurred in the production of the Pleasure Plus, [ ], because PTI's accountant, Mr. Chabon, testified that the numbers were "off" for a six-month period in 2003. Final ID at 115. The ALJ stated he would have considered total labor expenses if the IA "had broken the number down by month

---

[14] We agree with the ALJ that adding in the cost of fancier packaging, which is not necesssary for the production of the Pleasure Plus, is inappropriate. Final ID at 125-26.

[15] Respondents wrongly assert that PTI was under an "obligation" to present evidence necessary to perform a comparative analysis of foreign and domestic assets in order to prevail on the economic prong, citing *Certain Microlithographic Machines and Components Thereof*, Inv. No. 337-TA-468, Initial Determination (Jan. 29, 2003). However, the Commission declined to adopt this portion of the cited ID, and as a result it has no binding effect. Notice of Commission Decision Not To Review An Initial Final Determination at 2 (Mar. 17, 2003). There is no Commission precedent supporting the proposition that a comparison of domestic and foreign producers' assets must be performed. Nor was the evidence to make such a comparison available on this record, despite PTI's attempts to obtain it. In short, the inability to perform a comparison of PTI's assets to the assets of the Chinese producer of bulk condoms does not undermine the finding of a domestic industry in this investigation under 19 U.S.C. § 1337(a)(2).

and/or year so that I could discount the unreliable numbers for 2003." Final ID at 116. We find, however, that the labor numbers in the record were broken down by year, so arriving at a conservative "corrected" figure, discounting for the *entire* year 2003, merely required subtraction. On this basis, the record demonstrated [ ] in labor expenses. CX-243, Q. 10, 12; JX-10 at Exh. 12; CFF 562 (1999-2004 aggregate labor expenses of [ ] minus 2003 labor expenses of [ ] equals [ ]).

The ALJ further rejected PTI's purported investment of $256,407 in tangible assets, including in the foiling-lubricating machine, the air-burst machine, and the packaging machine used in the production of the Pleasure Plus. In support of this figure for investments in tangible assets, PTI submitted its balance sheet, which was approved by its accountants and submitted under penalty of law to the Internal Revenue Service for tax purposes. CX-36; Tr. at 606-07. PTI's president, Mr. Rogers, corroborated the amount of investment. CX-242, Q. 120-21; Tr. at 180, 182-83. The ALJ declined to consider investments in tangible assets because Mr. Chabon stated that certain balance sheet figures were unreliable. The ALJ ignored that Mr. Chabon testified that he deemed figures for only a six-month period in 2003 to be unreliable and that the amounts assessed for equipment were calculated well before then. Tr. at 592-93. Mr. Chabon's testimony thus did not call into question the period for which the equipment was assessed. More fundamentally, the ALJ proceeded to ignore these investments altogether, even though there was no serious contest that PTI purchased the equipment, that these physical assets still exist, and that they are used in the production of the Pleasure Plus. Even if PTI's tangible assets have a lesser value than PTI represented at trial, it is undisputed that PTI's business invested in industrial equipment to produce the Pleasure Plus.

Ultimately, the ALJ seems to have been more influenced by the Customs marking "Manufactured in China" on the Pleasure Plus 12-pack box than the complete record before him. Final ID at 107 (noting that Customs marking was "quite damaging") & 127 (finding that on this record Complainant "has only proven" that it employs [ ] persons). However, Customs marking standards, and an individual corporate entity's marking as it applies those standards, do not answer the question whether the "significant" investment in plant and equipment or employment of labor or capital required to demonstrate a domestic industry under 19 U.S.C. § 1337(a)(3) are met. *Cf. Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Products*, Inv. No. 337-TA-148-169, Comm'n Op. at 6-8 (Sept. 9, 1994) (rejecting the argument that Customs regulations concerning "entry" into the United States were controlling on the meaning of "entry" under section 337). Indeed, under the statutory domestic industry test, as set forth in the 1988 amendments, actual production is not necessarily required to give a company standing to claim relief under section 337. His ID demonstrated that the ALJ improperly treated the Pleasure Plus Customs marking as an indication that PTI was not "an industry in the United States" within the meaning of 19 U.S.C. § 1337(a)(2). Thus, he conflated different provisions in unrelated statutory schemes administered by separate administrative entities to find no domestic industry under the economic prong.

We determine that the nature and significance of the domestic activities of PTI in its employment of labor and capital and its investments in the production of the Pleasure Plus condom are sufficient to satisfy the economic prong of the domestic industry requirement. Based on the undisputed facts, PTI is engaged not in mere importation, but domestic production, precisely the activity that section 337 is designed to cover. The realities of the U.S. marketplace

are such that three companies, C&D among them, account for 98 percent of all domestic sales; that brand recognition is crucial in the prophylactic business; and that C&D's Trojan brand is 90 years old. RX-105, Q. 15-16; Tr. at 810. PTI is only a small player in this market, but its size relative to the dominant firms does not operate to preclude requested relief under section 337 as a domestic industry. We therefore reversed the ALJ's erroneous determination that PTI did not demonstrate a domestic industry within the meaning of 19 U.S.C. § 1337(a)(2).

III. CONCLUSION

For the above-stated reasons, the Commission determines that there is a domestic industry within the meaning of the statute. Nonetheless, the investigation is terminated with a finding of no violation because we find that the accused products do not infringe any claim of the '004 patent.

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: August 1, 2007

CERTAIN MALE PROPHYLATIC DEVICES COMPONENTS 337-TA-546

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Rett Snotherly, Esq., and the following parties as indicated, on August 1, 2007 .

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

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

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

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

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

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

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor
New York, NY 10281

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

ON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

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

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

James H. Shalek, Esq
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299
P - 212-969-3000
F- 212-969-2900

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

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

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

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before the Honorable Robert L. Barton, Jr.
Administrative Law Judge

In the Matter of	Inv. No. 337-TA-546 (REMAND)
CERTAIN MALE PROPHYLACTIC DEVICES	

INITIAL DETERMINATION ON REMAND ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BONDING

(March 19, 2007)

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CDX	Complainant's demonstrative exhibit
CIB	Complainant's initial post-hearing brief
CIBR	Complainant's initial post-hearing brief on remand
CPX	Complainant's physical exhibit
CRB	Complainant's post-hearing reply brief
CRBR	Complainant's reply post-hearing brief on remand
CX	Complainant's exhibit
JPX	Joint Physical Exhibit
JX	Joint Exhibit
RDX	Respondents' demonstrative exhibit
RCDIB	Respondent Church & Dwight's initial post-hearing brief
RCDIBR	Respondent Church & Dwight's initial brief on remand
RMIIB	Respondent Medtech/Intellx's initial post-hearing brief
RMIIBR	Respondent Medtech/Intellx's initial brief on remand
RCDRB	Respondent Church & Dwight's post-hearing reply brief
RCDRBR	Respondent Church & Dwight's reply brief on remand
RMIRB	Respondent Medtech/Intellx's post-hearing reply brief
RMIRBR	Respondent Medtech/Intellx's reply brief on remand
RX	Respondents' exhibit
SIB	Staff's initial post-hearing brief
SIBR	Staff's initial brief on remand
SRB	Staff's post-hearing reply brief
SRBR	Staff's reply brief on remand
SX	Staff's exhibit
Tr.	Hearing Transcript

I. SUMMARY

Pursuant to the Notice of Investigation, 70 Fed. Reg. 45422-23 (August 5, 2005), and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, 19 C.F.R. § 210.42(a), this is the Administrative Law Judge's Initial and Recommended Determination on Remand in the matter of Certain Male Prophylactic Devices, Investigation No. 337-TA-546 ("IDR").

Respondent Church & Dwight Co.'s accused Twisted Pleasure prophylactic infringes claims 1, 13, 18 and 31 of U.S. Patent No. 5,082,004. Respondent Church & Dwight Co.'s Twisted Pleasure prophylactic does not infringe claims 2-4, 15, 16, 22, 25, 32 and 36 of U.S. Patent No. 5,082,004. Respondents Medtech Products, Ltd. and Intellx, Inc.'s accused Inspiral prophylactic infringes claims 1, 6, 9, 22, 25 and 31 of U.S. Patent No. 5,082,004. Respondents Medtech Products, Ltd. and Intellx, Inc.'s Inspiral prophylactic does not infringe claims 2-4 and 8 of U.S. Patent No. 5,082,004. I have determined that claims 1, 6, and 9 of U.S. Patent No. 5,082,004 are invalid as anticipated by U.K. Patent No. 1,252,255. Claims 2-4, 8, 13, 15-16, 18, 22, 25, 31-32, and 36 of U.S. Patent No. 5,082,004 are not invalid.

I conclude that a domestic industry exists in the United States that practices U.S. Patent No. 5,082,004. After full consideration of the evidentiary record and the briefs, I conclude on remand that a violation of Section 337 of the Tariff Act of 1930, as amended, has been found in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain male prophylactic devices in connection with claims 13, 18, 22, 25 and 31 of U.S. Patent No. 5,082,004. Because I have found a violation of Section 337, I recommend that the Commission issue a limited exclusion order prohibiting the importation of all products manufactured

by or for Respondents that infringe claims 13, 18, 22, 25 or 31 of U.S. Patent No. 5,082,004. I also recommend that the Commission include in an exclusion order that may issue, a reporting requirement for Complainant Portfolio Technologies, Inc. Additionally, I recommend that the Commission issue a cease and desist order against Respondents Church & Dwight Co. and Intellx, Inc. Should the Commission issue an exclusion order or cease and desist order, I recommend an appropriate bond for the Twisted Pleasure in the amount of [ ] per unit and an appropriate bond for the Inspiral in the amount of [ ] per unit.

II. BACKGROUND

On August 5, 2005, this investigation was instituted on behalf of Complainant Portfolio Technologies, Inc. ("PTI"). The complaint, as amended and supplemented, alleges that Respondents Church & Dwight Co, Inc. ("C&D"), Reddy Medtech, Ltd. ("Medtech"), and Intellx, Inc. ("Intellx"), are in violation of 19. U.S.C. § 1337 for importing into the United States, selling for importation, and selling within the United States after importation certain male prophylactic devices that infringe claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004 ("the '004 patent"). Specifically, PTI alleges that the Trojan Twisted Pleasure prophylactic ("Twisted Pleasure") and the Inspiral prophylactic ("Inspiral") infringe the '004 patent. The Twisted Pleasure is manufactured by Medtech, and imported, marketed and distributed by C&D. The Inspiral is manufactured by Medtech, and imported, marketed and distributed by Intellx.

I issued the Initial Determination ("ID") on June 30, 2006. The ID found that the Twisted Pleasure infringes claims 1, 13, 18 and 31 of the '004 patent and that the Inspiral infringes claims 1, 6, 9, 22, 25 and 31 of the '004 patent. The ID also found that claims 1, 6 and 9 of the '004 patent were invalid as anticipated by U.K. Patent No. 1,252,255 ("the '255 patent"). Additionally, the ID

found PTI satisfied the technical prong of the domestic industry requirement. However, because PTI failed to satisfy the economic prong of the domestic industry, the ID ultimately found no violation of Section 337.

On September 29, 2006, the Commission noticed its decision to review the ID. See 71 Fed. Reg. 58875 (Oct. 5, 2006). On December 5, 2006, the Commission issued an opinion (Commission Opinion) affirming in part, reversing in part, and remanding in part the ID. On review, the Commission determined not to adopt the ID's construction of the limitations "elongated tubular portion," "circumference," "generally constant diameter from the open end to the closed end," and "longitudinally directed chamber." Instead, the Commission opted to set forth its own constructions for these claim limitations. Also on review, the Commission determined that the ID failed to properly consider the functional language in claims 1, 9 and 18 of the '004 patent. The Commission ordered that the functional limitations should be construed and applied to the infringement, invalidity and technical prong analysis on remand. The Commission adopted all of the ID's other claim constructions. Lastly, the Commission determined on review that the ID erred in finding that PTI failed to satisfy the economic prong of the domestic industry requirement. The Commission reversed the ID's determination on that issue, holding that PTI did in fact satisfy the economic prong.

On December 30, 2006, I issued Order No. 33, directing the parties to brief certain issues raised by the Commission's opinion. Order No. 33 also granted the parties an opportunity to brief additional relevant issues provided the parties first sought leave to do so. No party sought leave to brief any additional issues. On January 5, 2007, I issued Order No. 35, amending the briefing schedule set forth in Order No. 33. On January 23, 2007, the parties filed initial remand briefs. On January 30, 2007, the parties filed reply remand briefs. On February 28, 2007, I issued Order No.

36, extending the date for the IDR from March 5, 2007, to March 21, 2007, and the target date from June 5, 2007, to June 21, 2007.

III. CLAIM CONSTRUCTION

As discussed above, the Commission opted on review to set forth its own claim constructions for several disputed claim limitations, remand for proper construction several functional limitations, and affirm the ID's other claim constructions. Those claim constructions specifically set forth by the Commission as well as those that the Commission affirmed are summarized below for ease of reference. Those limitations that the Commission remanded for proper claim construction are addressed thereafter.

Claim Limitation	Claim Construction
pouch	something resembling a bag in shape ID at 21.
elongated tubular portion	the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular in shape Commission Opinion at 8.
circumference	the external surface of the tubular portion of the condom Commission Opinion at 10.
generally constant diameter from the open end to the closed end	requires the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant ID at 28-29; Commission Opinion at 11.
longitudinally directed chamber	the enclosed space or compartment into which the penis is inserted, with the notation that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom Commission Opinion at 15.

extending outwardly spaced radially outwardly	requires the second pouch(es) to extend radially away from the central axis of the first pouch ID at 33.
entrance with an open area	the boundary between the first pouch and a second pouch ID at 34-35.
said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis	requires the entrance to the second pouch to overlie a portion of the glans penis ID at 39-40.
overlying in spaced relationship to the glans penis	requires the entrance to the second pouch to overlie a portion of the glans penis ID at 39-40.
inner surface moveable through said entrance	requires the surface of the second pouch facing the penis to be capable of moving inwardly through the boundary between the first pouch and a second pouch ID at 41-42.
annular pocket hollow ring	a bag-like structure forming a ring-like shape ID at 44.

A. "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" (claim 1)

PTI argues on remand that the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" is properly construed as requiring that the interior surface of the second pouch facing the penis be capable of moving inwardly through the boundary between the first and second pouches for the purpose of movement; back and forth on the glans penis during coitus for providing stimulation thereto. CIBR at 2. C&D argues on remand that the disputed limitation refers to both the radially inward motion of the second pouch through an entrance followed by the back and forth motion within that entrance during coitus to provide stimulation.

RCDIBR at 13. Medtech/Intellx do not put forth a claim construction for this limitation, but rather "concur and join in the arguments" presented by C&D. RMIIBR at 1. The Staff argues that the limitation is properly construed as requiring that the second pouch be sufficiently loose-fitting on the surface of the penis and of such dimensions that it rubs back and forth on the penis to such an extent that it provides heightened pleasure during coitus. SIBR at 5.

Looking at the parties' proposed constructions, it appears that they are in general agreement regarding the proper construction of the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." Both PTI and Respondents acknowledge that the disputed claim limitation requires that the inner surface of the second pouch be capable of moving inwardly through the entrance and also back and forth against the glans penis. See CIBR at 2; RCDIBR at 13.

The Federal Circuit has noted that "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." See Phillips, 415 F.3d at 1314. This is such a case. The plain and ordinary meaning of the disputed claim language requires the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate the glans penis. This construction is consistent with the widely accepted meaning of the commonly understood words of the disputed claim limitation and is fully supported by the specification of the '004 patent. See JX-1 at 2:12-19 ("[T]he condom includes a pouch or pouches on the tubular pouch

. . . that will move back and forth on the underside region of the glans penis . . . during coitus to provide enhanced stimulation."), 7:1-3 ("the pouch on pouch array 84 has a star pattern which will move in and out of the interior of the tubular portion 82 to produce the desired rubbing action."), Figure 3; see also id. at 2:55-57, 4:63-5:4. Nothing in the prosecution history suggests that a different interpretation of the disputed claim limitation is warranted.

C&D contrasts the inward movement of the inner surface of the second pouch through the entrance with the back and forth movement of the inner surface of the second pouch against the glans penis. RCDIBR at 13-14. In so doing, C&D argues that the second pouch must perform both "inward movement through an entrance and then back and forth stroking within that entrance to stimulate the glans penis." Id. at 14 (emphasis added). However, neither the plain and ordinary meaning of the disputed claim limitation nor the portion of the prosecution history to which C&D cites requires such a restrictive reading. Contrary to C&D's argument, the disputed limitation is not so narrow as to require the inward movement to be distinct from the back and forth movement. In fact, the specification makes clear that the stimulation of the glans penis by the inner surface of the second pouch during coitus may occur by the in and out movement of the inner surface of the second pouch through the interior of the tubular portion. See JX-1 at 6:68-7:4 ("As seen in FIG. 11, the pouch on pouch array 84 has a star pattern which will move in and out of the interior of the tubular portion 82 to produce the desired rubbing action and hydrodynamic action (if lubricated) as described above."); see also 5:9-12 ("The lubricant in the hollow interior of the pouch or pouches on pouch facilitates the in and out rubbing action of the pouch or pouches on pouch against the outer surface of the glans penis."), 5:37-40 ("The portions 58a, 58b can be lubricated as set forth above to provde a hydrodynamic rubbing action as the pouch on pouch portions move in and out of the tubular pouch

52 during coitus."). Accordingly, I find C&D's argument unpersuasive.

For the reasons discussed hereinabove, I find that one of ordinary skill in the art at the time of the invention would construe the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" as requiring the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate to the glans penis.

B. "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" (claim 9)

PTI argues that the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" should be construed as requiring the back and forth movement of the inner surface of the second pouch on the glans penis to be facilitated by a lubricant. CIBR at 3. C&D does not provide a construction for this limitation. See RCDIB at 14. Neither does Medtech/Intellx. RMIIBR at 1. The Staff also does not provide a claim construction. However, the Staff notes that the presence of lubricant applied to the inner surface of the second pouch will *ipso facto* provide the hydrodynamic rubbing referred to in the disputed claim limitation. SIBR at 5.

The plain and ordinary meaning of the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" is clear from the claim language itself. In this instance, proper claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." See Phillips, 415 F.3d at 1314.

As plainly written, the disputed claim limitation requires the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis. This interpretation is also supported by the specification, which states that "[t]he lubricant in the hollow interior of the pouch or pouches on pouch facilitates the in and out rubbing action of the pouch or pouches on pouch against the outer surface of the glans penis and produce a hydrodynamic flushing of the outer surface of the glans penis to enhance stimulation thereof during coitus." See JX-1 at 5:5-14; see also id. at 5:37-40 ("[t]he portions 58a, 58b can be lubricated as set forth above to provide a hydrodynamic rubbing action as the pouch on pouch portions move in and out of the tubular pouch during coitus."), 6:12-15, 7:1-5. Nothing in the prosecution history would demand a different interpretation.

Accordingly, for the reasons discussed hereinabove, I find that one of ordinary skill in the art at the time of the invention would construe the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" as requiring that the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis.

C. "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches" (claim 18)

PTI argues that the limitation "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches" is properly construed as requiring the portions of the tubular portion located between each second

pouch to: (1) maintain the constant diameter throughout the length of the tubular portion; (2) resist stretching of the tubular portion; and (3) maintain the shape of the second pouches. CIBR at 3-4. C&D argues that the disputed limitation should be construed to require that, throughout its length, there be a diameter on the interspersed first pouch portions having the same generally constant diameter as the open end of the tubular pouch and that the first pouch portions serve to keep the tubular pouch from stretching so as to keep the shape of the second pouches in tact. RCDIBR at 16. Medtech/Intellx do not put forth a claim construction for this limitation, but rather "concur and join in the arguments" presented by C&D. RMIIBR at 1. The Staff argues that the limitation should be construed as requiring the portions of the first pouch located between the second pouches to resist stretching of the tubular portion and thereby maintain the shape of the second pouches. SIBR at 6.

The plain and ordinary meaning of this disputed claim limitation is clear from the claim language itself. No party suggests otherwise. Looking to the language of claim 18 for guidance, it is noted that the term "said constant diameter" finds antecedent basis with the limitation "generally constant diameter." As plainly written, the disputed claim limitation requires the portions of the tubular portion located between the second pouches to: (1) maintain a generally constant diameter throughout the length of the tubular portion; (2) resist stretching of the tubular portion; and (3) maintain the shape of the second pouches. See Phillips, 415 F.3d at 1314 (In some instances, proper claim construction "involves little more than the application of the widely accepted meaning of commonly understood words."). This interpretation is consistent with the specification that states, in describing the embodiment of the invention illustrated in Figures 11-13, that "[e]ach of the wall segments combine to maintain the shape of the tubular portion with the bulges to maintain a looseness of the glans penis, by resisting undue stretching of the condom on the penis." JX-1 at

6:63-65.

Accordingly, for the reasons discussed hereinabove, I find that one of ordinary skill in the art at the time of the invention would construe the limitation "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches" as requiring the portions of the tubular portion located between the second pouches to maintain a generally constant diameter throughout the length of the tubular portion, resist stretching of the tubular portion, and maintain the shape of the second pouches.

IV. INFRINGEMENT

As previously discussed, on review the Commission construed the limitations "elongated tubular portion," "circumference," "generally constant diameter from the open end to the closed end," and "longitudinally directed chamber" and also remanded for consideration the construction of the functional language in claims 1, 9 and 18 of the '004 patent. In light of the Commission's claim constructions and the constructions of the functional limitations, the Commission directed that I revisit the issue of infringement on remand. In so doing, the Commission specifically directed that I also revisit the issue of infringement with regard to claims 22 and 25 to determine whether PTI has demonstrated as a matter of fact that the Twisted Pleasure meets the thickness limitations of those claims. Commission Opinion at 18. Except as just noted with regard to claims 22 and 25, because the Commission affirmed the remaining claim constructions in the ID, to determine infringement on remand I need only analyze whether the accused products satisfy the limitations construed by the Commission on review and the functional limitations construed herein.

A. C&D's Twisted Pleasure

The ID found C&D's Twisted Pleasure infringes claims 1, 13, 18 and 31 of the '004 patent. See ID at 129. On remand, PTI and the Staff argue that I should reaffirm those findings. CIBR at 6; SIBR at 27. PTI and the Staff also argue on remand that the Twisted Pleasure infringes claims 22 and 25. CIBR at 16; SIBR at 27. C&D argues on remand that the claim constructions the Commission adopted on review and the newly construed functional language of claims 1, 9 and 18 require a finding of non-infringement. RCDIBR at 26. C&D also argues that claims 22 and 25 are not infringed. RCDRBR at 15. Because PTI and the Staff do not argue that any additional claims of the '004 patent should be found infringed on remand, the infringement analysis on remand will be confined to those claims found infringed in the ID and those claims which the Commission asked that I revisit on remand.

1. Claim 1

Independent Claim 1 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> >
> > a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

PTI and the Staff argue on remand that the Twisted Pleasure infringes claim 1 of the '004 patent. CIBR at 6; SIBR at 1. C&D argues to the contrary. RCDIB at 33. For the reasons discussed in detail below, I find on remand that the Twisted Pleasure meets those limitations construed by the Commission on review as well as the applicable functional limitations construed herein. Accordingly, I find on remand that the Twisted Pleasure literally infringes claim 1 of the '004 patent.

a. "tubular portion . . . having a generally constant diameter"

PTI argues on remand that the Commission's constructions of "elongated tubular portion" and "generally constant diameter" do not effect the ID's previous finding that the Twisted Pleasure has an elongated tubular portion formed of a thin membrane material with a generally constant diameter from the open end to the closed end. See CIBR at 7, 8. PTI relies on much of the same evidence that was cited in the ID in support of its infringement argument on remand. Id. Specifically, PTI relies on the testimony of Dr. Wool, who discussed and demonstrated at the hearing that the Twisted Pleasure has a tubular portion formed of a thin membrane material with a generally constant diameter from the open end to the closed end. Tr. at 342:16-24. PTI also relies on Dr. Wool's testimony that the constant diameter continues up through the spirals of the Twisted Pleasure. Tr. at 355:1-3. Additionally, PTI cites to Exhibit CX-80, which is a marked-up photograph of the Twisted Pleasure illustrating Dr. Wool's infringement opinions and Exhibit JPX-6, which is the glass former of the Twisted Pleasure. See CX-80; JPX-6.

C&D argues on remand that the Twisted Pleasure does not infringe claim 1, because it does not meet the limitation of claim 1 requiring "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." RCDIBR at 26. C&D reaches this conclusion by arguing that

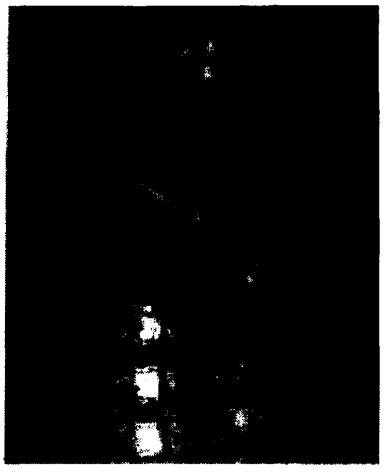
the valleys between the second pouches in the Twisted Pleasure are not part of the elongated tubular portion or first pouch and thus cannot define the entrance required by claim 1 and relied upon by PTI at the hearing to show infringement. RCDRBR at 4-7. C&D argues that the valleys are not part of the tubular portion or first pouch because the "structure that remains after the second pouches are removed is not cylindrical." RCRIBR at 23. C&D also argues that the valleys are not part of the tubular portion or first pouch because "[i]n the valleys of the Twisted Pleasure spirals, there is no diameter at all, much less a generally constant diameter." Id. at 24.

The Staff argues on remand that the "first pouch" regions identified in Exhibits CX-81 and CX-82 satisfy the Commission's claim construction of an elongated tubular portion. See SIBR at 8. In support of its argument, the Staff relies on Exhibits CX-81 and CX-82, the glass former of the Twisted Pleasure, and the testimony of Dr. Wool. Id. (citing Tr. at 342-43, and JPX-6). With respect to the limitation "generally constant diameter," the Staff argues that "the infringement analysis differs only slightly from that undertaken in the ID." Id. According the Staff, measurements of the glass former show that the diameter of the valleys in the spiral region of the Twisted Pleasure is close to the diameter of the shaft region. Id. at 8-9. Specifically, the Staff asserts that "measurements taken with a ruler or calipers at a location approximately half way up the spiral regions (where the two valley regions are diametrically opposed) indicates a distance of 36 mm, which is only a slight deviation from the 35 mm measurement of the shaft region." Id. at 9. The Staff only cites to the glass former of the Twisted Pleasure in support of its assertion, so the origins of the measurements relied upon by the Staff are unclear from the Staff's brief. In addition to arguing that the measured diameter of the valleys in the spiral region of the Twisted Pleasure is close to the measured diameter of the shaft region of the Twisted Pleasure, the Staff argues that the

"regions of the accused products that constitute the 'tubular portion' should be analyzed with respect to whether they are flush with the surface of the penis rather than applying a rigid and absolute diameter test." Id.

Claim 1 requires an elongated tubular portion with a generally constant diameter. The Commission has construed the term "elongated tubular portion" as the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular in shape. Commission Opinion at 8. The Commission has construed the term "generally constant diameter" as requiring the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant. Id. at 11. Thus, to infringe claim 1 on remand, the evidence must show that the remaining portions of the Twisted Pleasure that are not identified as the second pouches and are tubular in shape have a diameter from the open end to the closed end that is, for the most part, constant.

Exhibit RDX-1, which is reproduced below, shows the remaining portions of the Twisted Pleasure that are not identified as second pouches from the spiral region to the tip of the condom. Although not shown in RDX-1, it is beyond question that the portion of the condom below the spiral region to the open end of the condom is also included among the remaining portions not identified as second pouches. See CX-234; JPX-6.



RDX-1

According to the Commission's claim construction, the elongated tubular portion is not merely the remaining portions of the condom that are not identified as second pouches, but the "remaining portions of the condom that . . . are tubular in shape." As previously discussed, C&D argues that the valleys in the spiral region of the Twisted Pleasure are not tubular in shape and therefore not part of the elongated tubular portion. I find C&D's argument unpersuasive because it incorrectly assumes that the Commission's claim construction requires the elongated tubular portion to be tubular in shape at each of its cross sections. Neither the Commission's construction nor the specification of the '004 patent support such an interpretation. Had the Commission intended the "elongated tubular portion" to be tubular in shape at each of its cross sections, the Commission could have simply so stated. The term "cross section" has an easily identifiable and specific meaning, and I see no reason why the Commission would not simply have used such a term if it so intended.

Contrary to C&D's argument, the Commission's use of the phrase "remaining portions of the condom" in its claim construction of the limitation "elongated tubular portion" does not conflate to mean that the tubular portion must be tubular in shape at each of its cross sections. The '004

patent discloses a variety of embodiments. Some of these embodiments, such as those illustrated in Figures 1-3, 7-8 and 11-12, have secondary pouch(es) that are interspersed around the circumference of the first pouch, but are not formed completely around the circumference. See JX-1 at Figures 1-3, 7-8, 11-12. In these embodiments, what remains that is not a second pouch is a single piece of thin membrane material that runs contiguously from the open end of the condom through the closed end of the condom. Other embodiments, such as those illustrated in Figures 4-6 and 10, have a single secondary pouch that is formed completely around the circumference of the first pouch. See JX-1 at Figures 4-6, 10. In these embodiments, what remains that is not a second pouch is two separate and distinct sections of thin membrane material. One section runs approximately the length of the shaft of the penis, while the other section consists of the tapered end section of the condom. In these embodiments there is a complete disconnect between the sections at the place where the second pouch lies. Confronted with these various incarnations of the invention, I find the Commission's use of the phrase "remaining portions" in construing the limitation "tubular portion" to be quite natural. By using the plural "remaining portions" the Commission is able to capture the embodiments illustrated in Figures 1-3, 7-8 and 11-12 where there is but one remaining portion and the embodiments illustrated in Figures 4-6, and 10, where there are two distinct portions.

I find further support for this interpretation in the Commission's Opinion. The Commission notes in its Opinion that the "tapered portion of the condom closest to the reservoir tip should be considered part of the tubular portion." Commission Opinion at 9 (emphasis added). In support of this conclusion, the Commission cites to Figure 6 of the '004. Id. Figure 6 of the '004 patent illustrates an embodiment of the invention where there are two separate and distinct portions of condom. See JX-1 at Figure 6. As previously discussed, one portion runs approximately the length

of the shaft of the penis, while the other portion consists of the tapered end section of the condom. The fact that the Commission refers to the tapered end section as the "tapered portion" supports my interpretation that the Commission used the plural "remaining portions" as a vehicle to capture those embodiments, such as the embodiment of Figure 6, where there remains two separate and distinct portions that are not a second pouch. However, that is not to say that the Commission's construction excludes those embodiments with only a single remaining portion that is not a second pouch. As discussed above, I find the Commission's use of the phrase "remaining portions" naturally incorporates those embodiments with more than one remaining portion and those embodiments with only one remaining portion.

Applying the Commission's construction of "elongated tubular portion" to the Twisted Pleasure reveals a single remaining portion of the condom that is formed of a contiguous piece of thin membrane material. Exhibit RDX-1 clearly shows the one contiguous piece of thin membrane material that goes from the open end of the condom up through the valleys to the tapered end of the condom. See RDX-1. Contrary to C&D's argument, this portion need not be absolutely cylindrical in order to be tubular in shape. For example, the patent indicates that the closed end of the condom is part of the tubular portion; however, the closed end is not "cylindrical" in shape. See, e.g., JX-1 at 7:12-14. All the '004 patent and the Commission's construction require is that the remaining portion follow a generally tube-like shape. Based on the evidence of record, there is no question that the remaining portion of the Twisted Pleasure that is not identified as the second pouches is tubular in shape. See Tr. at 342:16-24, 355:1-3; CX-80; JPX-6. .

Not only does claim 1 require that the remaining portions of the Twisted Pleasure that are not identified as the second pouches be tubular in shape, but claim 1 also requires that the remaining

portions have a generally constant diameter from the open end to the closed end. As previously discussed, C&D argues that the valleys in the spiral region of the Twisted Pleasure have "no diameter at all, much less a generally constant diameter." RCDIBR at 24. According to C&D, because the valleys do not form a diameter, "they cannot define a part of the 'elongated tubular portion' as a matter of law." RCDRBR at 6. In reaching this conclusion, C&D relies on the Commission's statement that "[t]he claim language . . . merely requires a generally constant diameter in those lengths in which the tubular portion is present." See Commission Opinion at 11; see also RCDRBR at 5-6. Because C&D incorrectly assumes that the Commission's statement requires the tubular portion to have a generally constant diameter in each of its cross sections, I find C&D's argument unpersuasive. There is nothing in the Commission's claim construction or the specification of the '004 patent that necessitates such an interpretation. Again, had the Commission intended the tubular portion to have a generally constant diameter in each of its cross sections, the Commission could have simply so stated.

Contrary to C&D's argument, the Commission's reference to "in those lengths" does not conflate to mean that the tubular portion must have a generally constant diameter at each of its cross sections. Consistent with my interpretation of the Commission's use of the phrase "remaining portions" in the construction of the limitation "elongated tubular portion," I find that the phrase "in those lengths" is used by the Commission to account for the various embodiments of the '004 patent. Specifically, by using the term "lengths" the Commission's construction captures those embodiments of the '004 patent, such as those illustrated in Figures 4-6, and 10, where the tubular portion consists of two or more separate and distinct portions, or lengths, and those embodiments, such as those illustrated in Figures 1-3, 7-8 and 11-12, where the tubular portion consists of a single portion, or

length. See Merriam-Webster Online Dictionary (length - 5.b. "a piece constituting . . . part of the whole"). As the evidence of record clearly shows, the tubular portion of the Twisted Pleasure consists of one length of contiguous thin membrane material that extends from the open end of the condom through the valleys in the spiral region to the closed end of the condom. See RDX-1; JPX-6. Under the correct interpretation of the Commission's construction of the limitation "generally constant diameter," the evidence shows that as a whole, from the open end of the condom to the closed end of the condom, the tubular portion of the Twisted Pleasure has a generally constant diameter. Id.

b. "circumference"

PTI argues on remand that the Commission's claim construction of the limitation "circumference" does not affect the finding made in the ID that the Twisted Pleasure has a first pouch with a circumference. CIBR at 7. PTI relies on the same evidence cited in the ID in support of its argument on remand. Specifically, PTI cites to the testimony of Dr. Wool and exhibits CX-80 and CX-81, which are marked-up photographs of the Twisted Pleasure illustrating Dr. Wool's infringement opinions. See Tr. at 342:7-9; CX-80; CX-81.

As previously discussed, C&D argues on remand that the Twisted Pleasure does not infringe claim 1, because it does not meet the limitation of claim 1 requiring "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." RCDIBR at 26. C&D reaches this conclusion by arguing that the valleys between the second pouches in the Twisted Pleasure are not part of the elongated tubular portion or first pouch and thus cannot define the entrance required by claim 1 and relied upon by PTI at the hearing to show infringement. RCDRBR at 4-7. C&D argues

that the valleys are not part of the first pouch, because they do not define a circumference. RCDIBR at 25. Specifically, C&D argues that there is no physical material in the spiral region of the Twisted Pleasure that defines "any sort of perimeter" in that region. Id. According to C&D, "the absence of a circumference indicates the absence of a 'first pouch' in the spiral region, and the absence of infringement." Id.

The Staff argues on remand that the Commission's claim construction of the limitation "circumference" does not alter the conclusion found in the ID that the Twisted Pleasure infringes claim 1 of the '004 patent. SIBR at 7. Specifically, the Staff argues that the Twisted Pleasure meets the revised construction of the limitation "circumference" "given that the first pouch has a physical external surface that is tubular in shape. Id. at 8. In support of its argument, the Staff cites to exhibits CX-81 and CX-82. Id.

Claim 1 requires "a first pouch having a circumference." According to the Commission, the first pouch is used to distinguish those portions of the condom that are not secondary pouches. Commission Opinion at 9. Also according to the Commission, the "circumference" is properly construed as the external surface of an object. Id. at 10. Thus, to infringe claim 1 on remand the evidence must show that the remaining portions of the Twisted Pleasure that are not secondary pouches have an external surface.

As previously discussed, C&D argues that the valleys in the spiral region of the Twisted Pleasure are not part of the first pouch because the valleys do not define a perimeter in the spiral region. RCDIBR at 25. Contrary to C&D's argument, the Commission's construction of the limitation "circumference" does not necessitate that the valleys define a perimeter in the spiral region of the Twisted Pleasure in order to be considered part of the first pouch. In fact, the Commission

explicitly acknowledges in its Opinion that the specification of the '004 patent teaches that there can be interruptions in the circumference of the first pouch. See Commission Opinion at 10; see, e.g., JX-1 at Figure 11.

As stated above, to prove infringement on remand, the evidence must show that the remaining portions of the Twisted Pleasure that are not secondary pouches have an external surface. Exhibit RDX-1 shows the remaining portion of the Twisted Pleasure that is not identified as the secondary pouches. See RDX-1. The evidence of record shows that this portion is made of a thin membrane material that goes contiguously from the open end of the condom up through the valleys to the tapered end of the condom. See CX-81; CX-82. Because the evidence shows that the tubular portion, and thus the first pouch, has an external surface, I find that the evidence shows that the Twisted Pleasure meets the limitation of claim 1 requiring a first pouch having a circumference.

c. "longitudinally directed chamber"

PTI argues on remand that the Commission's construction of the limitation "longitudinally directed chamber" has no effect on the ID's finding that the Twisted Pleasure has a longitudinally directed chamber. CIBR at 8-9. PTI relies on the same evidence cited in the ID in support of its argument on remand. Specifically, PTI cites to the testimony of Dr. Wool and exhibit CX-80, which is a marked-up photograph of the Twisted Pleasure illustrating the basis for Dr. Wool's infringement opinions. Id. at 9 (citing Tr. at 342:16-24; CX-80).

C&D summarizes on remand the Commission's claim construction of the limitation "longitudinally directed chamber, " but does not argue that the Twisted Pleasure fails to satisfy this limitation. See RCDIBR at 8. Having chosen not to argue that the Twisted Pleasure fails to satisfy the limitation of claim 1 of the '004 patent requiring a longitudinally directed chamber, Respondent

has waived any such argument.

The Staff argues on remand that there is little practical difference between the ID's construction of the limitation "longitudinally directed chamber" and the construction adopted by the Commission on review. SIBR at 9. Accordingly, the Staff argues that the finding in the ID that the Twisted Pleasure has a longitudinally directed chamber should be reaffirmed on remand. Id. Specifically, the Staff argues that the tubular portion of the Twisted Pleasure defines a longitudinally directed chamber that is defined by the surface of the penis. Id. at 9-10. In support of its argument, the Staff cites to Dr. Wool's testimony, as well as, exhibit CX-82. Id. at 10.

Claim 1 of the '004 patent includes a limitation requiring the tubular portion to define a longitudinally directed chamber for the male penis. The Commission construed the limitation "longitudinally directed chamber" on review as

> the enclosed space or compartment into which the penis is inserted, and note that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom.

Commission Opinion at 15. As previously discussed, the elongated tubular portion of the Twisted Pleasure is formed of a thin membrane material that extends from the open end of the condom through the valleys in the spiral region to the closed end of the condom. As is plainly seen in exhibit CX-82, the tubular portion follows the surface of the penis thereby defining, as shown in CX-80, a longitudinally directed chamber. See CX-80; CX-82; see also Tr. at 342:16-24; JPX-6; CPX-6.

d. "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto"

C&D argues on remand that the Twisted Pleasure fails to satisfy this claim limitation because the valleys in the spiral region of the Twisted Pleasure are not part of the tubular portion and thus cannot form an entrance though which the inner surface of the second pouch may move through as required by the claims. C&D's conclusion that the valleys in the spiral region of the Twisted Pleasure are not part of the tubular portion is based on its assumption that the valleys do not meet the following claim limitations: elongated tubular portion; generally constant diameter; and circumference. As discussed in detail, supra, I have found on remand that the valleys in the spiral region of the Twisted Pleasure are part of the tubular portion, that the tubular portion has a generally constant diameter, and that the first pouch has a circumference. As my findings on remand completely undercut the foundation of C&D's argument, I find C&D's argument unpersuasive.

C&D also arguea on remand that the Twisted Pleasure does not satisfy this limitation because the first and second pouches of the Twisted Pleasure do not intersect over the glans penis to form an entrance through which the inner surface of the second pouches may move to contact the glans penis. See RCDIBR at 19, 27-28. C&D bases its argument on the fact that the Twisted Pleasure is 185 mm in length and the condom shown in Figure 10 of the '004 patent is approximately 160 mm in length. Id. at 28. According to C&D, the difference in lengths means that the Twisted Pleasure has an additional 2+ cm more space between the latex at the closed end and the glans penis than that illustrated in Figure 10 of the '004 patent. Id. at 28. Thus, C&D argues, the first and second pouches will not intersect over the glans penis.

I find this argument unpersuasive because C&D fails to convincingly explain why the 2+ cm differential would lie beyond the glans penis. Moreover, C&D's argument is completely belied by the instructions for use printed on the inside of the Twisted Pleasure box, which clearly describes and illustrates only the reservoir tip extending beyond the end of the penis. JPX-2. Additionally, C&D's argument fails to recognize the way in which a rolled condom is placed on the penis. When a rolled condom is placed on the penis, any excess length remains unrolled at the base of the penis, not dangling off the end of the penis as Respondents suggest. See id. Furthermore, C&D's argument is in stark contrast to statements C&D has previously made in this investigation. For example, in its memorandum in response to Order No. 10, C&D wrote that the "the spirals of the Twisted Pleasure completely wrap around and cover the entire glans penis." See C&D Memo. to Order No. 10 at 28; see also C&D Prehearing Brief at 11 ("About the last one-quarter to one-third of the Twisted Pleasure is twisted into a double spiral continuing from the far end of the straight walled portion to the tip of the condom. This part of the condom will cover the glans penis as well as part of the shaft.").

The limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" has been construed herein as requiring the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as capable of back and forth movement against the glans penis during coitus in order to stimulate the glans penis. At the hearing in this investigation, PTI's expert, Dr. Wool, testified that each second pouch of the Twisted Pleasure has an inner surface which is moveable through the entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation

thereto. Tr. at 343:18-22; see CX-82. Dr. Wool also testified and demonstrated that "[v]ery light pressure allows the interior surface [of the Twisted Pleasure] and the interior space to communicate through the entrance region." Tr. at 349:24-350:1. Further, C&D's expert, Dr. Potter, testified that "[t]he intention is that [the Twisted Pleasure and the Inspiral] will remain relatively stationary to the vaginal wall and primarily move against the glans penis to produce the stimulation." Tr. at 965:13-16. Based on this record evidence, I find on remand that the Twisted Pleasure has a "second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto."

2. Claim 13

Independent Claim 13 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> >
> > a plurality of second pouches arranged around the circumference; each of said second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis to produce movement thereof against the surface of the glans penis.

Claim 13 contains many of the same limitations found in claim1. However, claim 13 differs from claim 1 in that claim 13 requires a plurality of second pouches that are arranged around the

circumference of the first pouch. Both PTI and the Staff argue on remand that the Twisted Pleasure infringes claim13. CIBR at 6; SIBR at 18. C&D argues on remand that the Twisted Pleasure does not infringe claim 13. RCDIBR at 34-35. Specifically, C&D argues that the Twisted Pleasure does not have a plurality of second pouches because "without the valleys to serve as an extension of the first pouch into the spiral region separating the spirals from one another, the spirals are not separated from one another and are not arranged around the circumference." Id. As I have already rejected in my analysis of claim 1 on remand C&D's argument that the valleys in the spiral region of the Twisted Pleasure are not part of the tubular portion, I find C&D's argument unpersuasive. Contrary to C&D's argument, the record evidence clearly shows that Twisted Pleasure has a plurality of second pouches arranged around the circumference. See Tr. at 349:2-11; CX-80; CX-81; CX-82; CX-83; JPX-6. Accordingly, for this reason as well as those discussed with regard to claim 1, supra, I find on remand that the Twisted Pleasure literally infringes claim 13 of the '004 patent.

3. Claim 18

Independent Claim 18 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end having a tip characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end;
> >
> > a plurality of second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; each of said second pouches having an inner surface moveable through said

entrance and against the glans penis;

portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches;

said second pouches providing looseness at the outer surface of the glans penis to increase its sensitivity to the rubbing action.

Although many of the limitations of claim 18 are materially the same as those found in claim 1, there are some additional limitations in claim 18 that are not found in claim 1. Specifically, claim 18 requires that: (1) the second pouches extend lengthwise of the glans penis at least 1 cm; (2) portions of said tubular portion located between each of said second pouches maintain the constant diameter throughout the length of the tubular portion to resist stretching of the tubular portion to thereby maintain the shape of the second pouches; and (3) the second pouches provide looseness at the outer surface of the glans penis to increase sensitivity to rubbing. PTI and the Staff argue on remand that the Twisted Pleasure infringes claim 18 of the '004 patent. CIBR at 11-12; SIBR at 19-21. C&D argue on remand that there is no infringement. RCDIBR at 34-36. For the reasons discussed in detail below, I find on remand that PTI has proved by a preponderance of the evidence that the Twisted Pleasure satisfies the additional limitations of claim 18 not found in claim 1. Thus, for the reasons discussed hereinbelow and for the reasons espoused with regard to claim 1, I find on remand that the Twisted Pleasure infringes claim 18 of the '004 patent.

a. "second pouches . . . extending lengthwise of the glans penis at least 1 cm"

Claim 18 requires that the second pouches extend lengthwise of the glans penis at least 1 cm. The ID found this limitation satisfied. ID at 58-59. The Commission's opinion did not disturb this

finding and Respondents do not directly dispute this finding on remand. Accordingly, I reaffirm on remand that the Twisted Pleasure has second pouches that extend lengthwise of the glans penis at least 1 cm.

b. "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches"

The limitation "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches" has been construed herein as requiring the portions of the tubular portion located between the second pouches to maintain a generally constant diameter throughout the length of the tubular portion, resist stretching of the tubular portion, and maintain the shape of the second pouches.

PTI asserts on remand that the ID found that the Twisted Pleasure satisfies this claim limitation and therefore asks that I reaffirm the finding on remand. CIBR at 11-12. PTI bases its assertion on the fact that I cited Dr. Wool's testimony covering this limitation in the ID. Id. While the ID did cite to the testimony from Dr. Wool, the ID made no specific findings with regard to this limitation. See ID at 60; see also Commission Opinion at 5-7 (remanding the ID for consideration of functional language not considered in the ID). PTI makes no other argument on remand. I will assume for purposes of this IDR that PTI is arguing that Dr. Wool's testimony supports a finding that this claim limitation is satisfied.

C&D argues on remand that the Twisted Pleasure lacks both the structural and functional aspects of this limitation. Specifically, C&D argues that the valleys in the spiral section of the

Twisted Pleasure cannot be the "portions of said tubular portion" and that even if the valleys were the "portions of said tubular portion" referred to in the claim, the valleys do not "maintain a generally constant diameter," do not "resist stretching," and do not "maintain the shape of the second pouches." See RCDIBR at 34-40. C&D primarily relies on the testimony of its expert, Dr. Potter, in support of its non-infringement argument.

The Staff argues on remand that the Twisted Pleasure meets the functional language of this limitation. SIBR at 19-21. Specifically, the Staff argues that the valleys in the spiral section of the Twisted Pleasure help maintain the tubular portion's generally constant diameter, resist stretching and maintain the shape of the second pouches. Id. In support of its argument, the Staff relies on the testimony of Dr. Wool as well as the testimony of Ravi Reddy. Id. at 20. The Staff also cites to U.S. Patent No. 6,000,398 (the '398 patent) for support. Id.

As discussed above, C&D argues on remand that the Twisted Pleasure lacks both the structural and functional aspects of this limitation. With regard to the structural aspects, C&D argues that the Twisted Pleasure does not have "portions of said tubular portion located between each of the second pouches," because the valleys in the spiral section of the Twisted Pleasure are not part of the tubular portion. RCDIBR at 34. Thus, according to C&D, the valleys cannot be the "portions" of the tubular portion located between the second pouches. Because I have already determined in my analysis of claim 1, supra, that the valleys are part of the tubular portion, I find C&D's argument unpersuasive.

With regard to the functional aspects, C&D argues that the valleys in the spiral section of the Twisted Pleasure do not "maintain a generally constant diameter," do not "resist stretching," and do not "maintain the shape of the second pouches." RCDIBR at 35-36. In support, C&D relies on the

testimony of its expert, Dr. Potter. On direct, Dr. Potter testified that the valleys in the spiral section of the Twisted Pleasure are "too thin and narrow to provide any sort of structural support to the condom." RX-110 at Q.114. Specifically, Dr. Potter testified that "the valley portions are basically very insubstantial, do not really have any structural integrity, and could certainly not hold the spiral end of the condom in position as described in the '004 patent." Tr. at 1015:11-15. Dr. Potter also testified that the valleys "move and change shape right along with the spirals." RX-110 at Q.115. According to Dr. Potter, the valleys "wrinkle, flex and move." RX-120 at Q.129, Q.132.

Dr. Potter attempted to explain his opinion at the hearing through a demonstration allegedly showing the movement of the Twisted Pleasure condom during coitus. See RDX-6 - RDX-9. For the reasons discussed in the Staff's Post-Hearing Reply Brief, I find Dr. Potter' demonstration to be unavailing and his opinion unpersuasive. See SRB at 10-13. In fact, as can be readily seen in exhibit RDX-6, the condom is incorrectly positioned on the demonstrator with more of the condom than just the reservoir tip dangling off the end. See RDX-6; see also, JPX-2 (Twisted Pleasure box showing proper placement of condom on penis).

As previously discussed, both PTI and the Staff argue that the valleys in the Twisted Pleasure perform the functions required by this limitation. In so arguing, both parties rely on the testimony of Dr. Wool. At the hearing, Dr. Wool testified as follows:

> A. The valleys -- that's correct. The valleys are left over when the two secondary pouches are made as an integral part of the primary pouch. And so they're twisted around. And you see the valleys twisting up around the primary pouch. And to an excellent -- that is basically the constant diameter, continuing on up through the spirals.
>
> Q. All right. Thank you. That may cover my next

question, but just to be complete: Do those portions between the second pouches maintain the constant diameter throughout the length of the tubular portion?
A. Yes, they do. I think it's clearly obvious when you examine the condom on this demonstrator where the secondary pouches are and where the material of the primary pouch is carrying on up through. And you can see that those valleys are not in a puffed-up state; they're in contact with the penis up around the material.

Q. Do those portions resist stretching of the tubular portion?
A. Yes, I would think so.

Q. Do those portions between the second pouches, do they help to maintain the shape of the second pouches?
A. Yes, they do.

Q. And do they actually maintain the shape of the second pouches?
A. It depends on the magnitude of the forces that are placed upon the secondary pouches. For light forces like so, which provides the stimulation, we can see that they stay in place. If I apply a lot of force, then clearly I would reach a threshold level where the whole tip will start to move -- not in unison necessarily, because you have a stress field among the elastomers at the top. But there will be some threshold level of force, shear force. In terms of this type of force, they will stay in place. But in terms of longitudinal shear force, one way or the other I would think eventually you will reach a level where some movement can occur.

Tr 354:22-356:11. In addition to the testimony of Dr. Wool, the Staff relies on the testimony of Ravi Reddy who noted that the Twisted Pleasure provides "spring action." RX-108 at Q.55. According to Ravi Reddy, the "spring action" approach is described in the '398 patent of which he is an inventor. Id. According to the '398 patent, the helical spring-like shape imposes a spring bias action

on a condom that when stretched axially will cause the condom to spring back to its normally, unbiased state. See JX-7 at 3:52-63.

Having reviewed the evidence and having judged the credibility of both witnesses, I find on remand that a preponderance of the evidence shows that the Twisted Pleasure satisfies the functional limitations of claim 18. The combined testimony and demonstration of Dr. Wool coupled with the testimony of Ravi Reddy regarding the "spring action" of the Twisted Pleasure leads me to conclude that the valleys in the spiral section of the Twisted Pleasure: (1) help to maintain the generally constant diameter of the tubular portion; (2) resist stretching; and (3) maintain the shape of the second pouches. Accordingly, I find on remand that the Twisted Pleasure satisfies the limitation of claim 18 requiring "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches."

c. "said second pouches providing looseness at the outer surface of the glans penis to increase its sensitivity to the rubbing action"

There appears to be no dispute that the second pouches of the Twisted Pleasure provide looseness at the outer surface of the glans penis to provide increased sensitivity to the rubbing action. PTI's expert, Dr. Wool, testified that each second pouch has an inner surface movable through the entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation thereto. Tr. at 343:18-21. Respondents' expert, Dr. Potter, testified that the Twisted Pleasure "primarily move[s] against the glans penis to produce stimulation." Tr. at 965:13-16. Additionally, Dr. Potter testified that "any portion of this loose-fitting part of the condom will be free to move over the glans during coitus." Tr. at 968:15-17. Based on this record evidence, I find on

remand that the second pouches of the Twisted Pleasure provide "looseness at the outer surface of the glans penis to increase its sensitivity to the rubbing action."

4. Claim 22

Independent Claim 22 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end;
> >
> > a second pouch integrally formed on the circumference of the closed end for forming a loose pocket overlying in spaced relationship to the glans penis and having an inner surface movable back and forth thereon during coitus for providing stimulation thereto;
> >
> > said tubular portion and said second pouch having a wall thickness of 0.11 mm ± 0.04 mm; and
> >
> > said second pouch having its inner surface spaced radially outwardly of said tubular portion to provide looseness between said tubular portion and the outer surface of the glans penis to prevent binding of the glans penis with consequent reduction in sensitivity.

While stated in slightly different terms, for the most part, the limitations in claim 22 are the same as those recited in claim 1. However, claim 22 differs from claim 1 in one regard that is of import on remand. That is, claim 22 includes a limitation that explicitly requires that both the tubular portion and second pouch have a wall thickness of 0.11 mm ± 0.04 mm. In remanding the ID in this investigation, the Commission specifically requested that I revisit the evidence of record to determine whether the tubular portion and second pouches of the Twisted Pleasure are of the requisite thickness. Commission Opinion at 18. Complainant and the Staff argue on remand that

the Twisted Pleasure infringes claim 22 of the '004 patent. CIBR at 14-16; SIBR at 22-23. Respondents disagree. RCDRBR at 9-15.

On remand, both PTI and the Staff provide additional pinpoint citations to record evidence allegedly showing that the wall thickness of the tubular portion and second pouches of the Double Springer condom are within the range proscribed in claim 22 of the '004 patent. CIBR at 14-16; SIBR at 22-23. For the record, I find that Exhibit JX-34 does disclose that the Double Springer has a wall thickness in both the tubular portion and the second pouches that is 0.11 mm ± 0.04 mm. See JX-34 at 57, 118, 119. The problem is that neither PTI nor the Staff have provided any convincing evidence that the Double Springer condom disclosed in JX-34 is the Twisted Pleasure condom sold by C&D. It is the Twisted Pleasure, not the Double Springer, that is accused of infringement in this case. Therefore, to prove claim 22 infringed, there must be evidence that links the Double Springer disclosed in JX-34 to the Twisted Pleasure accused in this investigation.

The only direct evidence that the Twisted Pleasure has the requisite wall thickness is the conclusory testimony of PTI's expert, Dr. Wool. As discussed in detail in the ID, and reaffirmed herein, I give Dr. Wool's testimony as to the wall thickness of the Twisted Pleasure no weight. See ID at 62. Among other things, Dr. Wool admitted on cross examination that he never actually measured the Twisted Pleasure and was given the information "by the attorneys." Id.

In the ID I stated that the "Double Springer condom was later referred to as the Twisted Pleasure." See ID at 62. My statement was drawn from Dr. Reddy's testimony that the "Double Springer . . . is what eventually became the Trojan Twisted Pleasure." See Tr. at 88:4-19. This is the same testimony relied on by PTI on remand. CIBR at 15 ("the Double Springer (subsequently renamed Twisted Pleasure, see Dr. Reddy testimony at Tr. 88:1-19)"). On remand, the Staff merely

relies on my statement in the ID. See SIBR at 22 ("As the ID found, the "Double Springers condom was later referred to as the Twisted Pleasure."). Neither my statement in the ID, nor Dr. Reddy's testimony on which it is based, sufficiently establishes that the Double Springer disclosed in JX-34 is the same as the Twisted Pleasure accused of infringement in this investigation. Dr. Reddy's testimony only establishes that at some point in time what was known as the Double Springer became known as the Twisted Pleasure.

The fact is the evidence strongly suggests that the accused Twisted Pleasure condom may not be the same as the Double Springer. At the hearing, Ravi Reddy, President of Medtech, testified as follows:

> Q. Mr. Reddy, the Double Springer, that's the second to the last there, that design became the Twisted Pleasure; correct?
>
> A. Not the shape. I mean, it's obviously a lot different than what -- the final product is obviously a lot different than what it shows on this picture.

Tr. at 724:7-25. Additionally, when asked "[w]hat relationship does this reference to this Double Springer diagram bear to the final design of what was called the Twisted Pleasure," Ravi Reddy answered "[n]ot much." Tr. 735:20-23. Ravi Reddy's testimony establishes that there were design changes between the product known as the Double Springer and the product later referred to as the Twisted Pleasure. Ravi Reddy's testimony severely undercuts the less specific testimony of Dr. Reddy relied on by PTI and the Staff.

Taking into consideration the evidence as presented by the parties, for the reasons discussed hereinabove, I find on remand that PTI has failed to establish by a preponderance of the evidence that the thickness of the tubular portion and second pouches of the Twisted Pleasure is within the range of 0.11 mm ± 0.04 mm as required by claim 22. As PTI has the burden of proving infringement and

has rested its case on the insufficient testimony of Dr. Reddy, I find on remand that the Twisted Pleasure does not infringe claim 22.

5. Claim 25

Claim 25 depends from claim 22. Because I have found that the Twisted Pleasure does not infringe claim 22, the Twisted Pleasure does not infringe dependant claim 25 as a matter of law.

6. Claim 31

Independent claim 31 reads as follows:

> A prophylactic pouch for use by a male, having an elongated tubular portion forming a first pouch including a circumference, an open end and a closed end, said tubular portion having a generally constant diameter from end to end, characterized by:
>
> > a second pouch integrally formed on the circumference of said tubular portion as an outward bulge on the closed end in overlying spaced relationship to a glans penis and operable to move thereon to provide stimulation during coitus; said second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement.

Claim 31 contains many of the same limitations found in claim 1. For all intents and purposes, there are only two differences between claim 31 and claim 1. The first is that claim 31 requires a second pouch integrally formed on the circumference of the closed end of the tubular portion. The second is that claim 31 requires a second pouch with an entrance that extends lengthwise of the glans penis at least 1 cm. The ID found that the Twisted Pleasure satisfies these additional limitations and nothing in the Commission's opinion on review affects those findings. Complainant and the Staff argue on remand that the Twisted Pleasure infringes claim 31. CIBR at

6; SIBR at 24-25. C&D argues on remand that the Twisted Pleasure does not infringe claim 31. RCDIBR at 31.

C&D's noninfringement arguments on remand are the same as those proffered with regard to claim 1. Accordingly, for the same reasons espoused with regard to claim 1, supra, I find on remand that the Twisted Pleasure satisfies those limitations construed by the Commission on review as well as those applicable functional limitations construed herein. Thus, I find on remand that the Twisted Pleasure infringes claim 31 of the '004 patent.

B. Medtech/Intellx's Inspiral

The ID found Medtech/Intellx's Inspiral infringes claims 1, 6, 9, 22, 25 and 31 of the '004 patent. See ID at 130. On remand, PTI and the Staff argue that I should reaffirm those findings. CIBR at 6; SIBR at 7-25. Because PTI and the Staff do not argue that any additional claims of the '004 patent should be found infringed on remand, the infringement analysis on remand will be confined to those claims found infringed in the ID. Medtech/Intellx note on remand that they "concur and join in the [noninfringement] analysis and arguments set forth in [C&D's] brief." RMIIBR at 5-6. According to Medtech/Intellx, "[f]ollowing the same reasoning as set forth in C&D's brief, the Inspiral . . . does not infringe any valid claim of the '004 patent." Id. at 6. Because Medtech/Intellx join in the analysis and arguments set forth in C&D's brief, many of the citations below are to C&D's remand briefs.

1. Claim 1

Independent Claim 1 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:

> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
>
> a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

Complainant and the Staff argue on remand that the Inspiral infringes claim 1 of the '004 patent. CIBR at 6; SIBR at 1. Medtech/Intellx argue to the contrary. RCMIIBR at 6. For the reasons discussed in detail below, I find on remand that the Inspiral meets those limitations construed by the Commission on review as well as the applicable functional limitations construed herein. Accordingly, I find on remand that the Inspiral literally infringes claim 1 of the '004 patent.

a. "tubular portion . . . having a generally constant diameter"

PTI argues on remand that the Commission's constructions of "elongated tubular portion" and "generally constant diameter" do not affect the ID's previous finding that the Inspiral has an elongated tubular portion formed of a thin membrane material with a generally constant diameter from the open end to the closed end. See CIBR at 6-8. PTI relies on much of the same evidence that was cited in the ID in support of its infringement argument on remand. Id. Specifically, PTI relies on the testimony of Dr. Wool, who discussed and demonstrated at the hearing that the Inspiral has a tubular portion formed of a thin membrane material with a generally constant diameter from the open end to the closed end. Tr. at 325:10-12. PTI also relies on Dr. Wool's testimony that the generally constant diameter continues from the open end of the condom up through the spiral to the

closed end of the Inspiral. Tr. at 325:18-20, 331:3-6. Additionally, PTI cites to Exhibit CX-76, which is a marked-up photograph of the Inspiral illustrating Dr. Wool's infringement opinions. See CX-76.

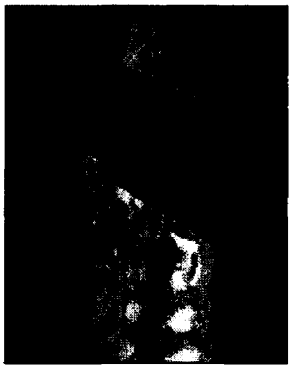
Medtech/Intellx argue on remand that the Inspiral does not infringe claim 1, because it does not meet the limitation of claim 1 requiring "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." RMIIBR at 8. Medtech/Intellx reach this conclusion by arguing that the tendril that runs along the second pouch in the Inspiral is not part of the elongated tubular portion or first pouch and thus cannot define the entrance required by claim 1 and relied upon by PTI at the hearing to show infringement. RMIIBR at 6-9. Medtech/Intellx argue that the tendril is not part of the tubular portion or first pouch because it is not cylindrical. RMIIBR at 8-9. Medtech/Intellx also argue that the tendril is not part of the tubular portion or first pouch because "there is nothing like a . . . diameter in the spiral region of the Inspiral, let alone one that could be considered constant." Id. at 9.

The Staff argues on remand that the "first pouch" region identified in Exhibits CX-76 and CX-77 satisfies the Commission's claim construction of an elongated tubular portion. See SIBR at 8. In support of its argument, the Staff relies on Exhibits CX-76 and CX-77, the glass former of the Inspiral, and the testimony of Dr. Wool. Id. (citing Tr. at 324-26, 334-35 and JPX-5). With respect to the limitation "generally constant diameter," the Staff argues that "the infringement analysis differs only slightly from that undertaken in the ID." Id. According to the Staff, measurements of the glass former show that the diameter of the valleys in the spiral region of the Inspiral is close to the diameter of the shaft region. Id. at 8-9. Specifically, the Staff asserts that measurements taken

with a ruler or calipers at a location approximately half way up the spiral region indicates a distance which is only a slight deviation from the measurement of the shaft region. Id. at 9. In addition to arguing that the measured diameter of the tendril in the spiral region of the Inspiral is close to the measured diameter of the shaft region of the Inspiral, the Staff argues that the "regions of the accused products that constitute the 'tubular portion' should be analyzed with respect to whether they are flush with the surface of the penis rather than applying a rigid and absolute diameter test." Id. The Staff provides no explanation as to why such an analysis is proper.

Claim 1 requires an elongated tubular portion with a generally constant diameter. The Commission has construed the term "elongated tubular portion" as the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular in shape. Commission Opinion at 8. The Commission has construed the term "generally constant diameter" as requiring the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant. Id. at 11. Thus, to infringe claim 1 on remand, the evidence must show that the remaining portions of the Twisted Pleasure that are not identified as the second pouches and are tubular in shape have a diameter from the open end to the closed end that is for the most part constant.

Exhibit RDX-2, which is reproduced below, shows the remaining portions of the Inspiral that are not identified as the second pouch from partially up the shaft to the tip of the condom. Although not shown in RDX-2, it is beyond question that the entire shaft portion of the condom below the spiral region to the open end of the condom is also included among the remaining portions not identified as the second pouch. See JPX-5.



RDX-2

According to the Commission's claim construction, the elongated tubular portion is not merely the remaining portions of the condom that are not identified as second pouches, but the "remaining portions of the condom that . . . are tubular in shape." As previously discussed, Medtech/Intellx argue that the tendril in the spiral region of the Inspiral is not tubular in shape and therefore not part of the elongated tubular portion. I find Medtech/Intellx's argument unpersuasive because it incorrectly assumes that the Commission's claim construction requires the elongated tubular portion to be tubular in shape at each of its cross sections. Neither the Commission's construction nor the specification of the '004 patent supports such an interpretation. Had the Commission intended the "elongated tubular portion" to be tubular in shape at each of its cross sections, the Commission could have simply so stated. The term "cross section" has an easily identifiable and specific meaning, and I see no reason why the Commission would not simply have used such a term if it so intended.

Contrary to Medtech/Intellx's argument, the Commission's use of the phrase "remaining portions of the condom" in its claim construction of the limitation "elongated tubular portion" does not conflate to mean that the tubular portion must be tubular in shape at each of its cross sections. The '004 patent discloses a variety of embodiments. Some of the embodiments, such as those

illustrated in Figures 1-3, 7-8 and 11-12, have secondary pouch(es) that are interspersed around the circumference of the first pouch, but are not formed completely around the circumference. See JX-1 at Figures 1-3, 7-8, 11-12. In these embodiments, what remains that is not a second pouch is a single piece of thin membrane material that runs contiguously from the open end of the condom through the closed end of the condom. Other embodiments, such as those illustrated in Figures 4-6 and 10, have a single secondary pouch that is formed completely around the circumference of the first pouch. See JX-1 at Figures 4-6, 10. In these embodiments, what remains that is not a second pouch is two separate and distinct sections of thin membrane material. One section runs approximately the length of the shaft of the penis, while the other section consists of the tapered end section of the condom. In these embodiments there is a complete disconnect between the sections at the place where the second pouch lies. Confronted with these various incarnations of the invention, I find the Commission's use of the phrase "remaining portions" in construing the limitation "tubular portion" to be quite natural. By using the plural "remaining portions" the Commission is able to capture the embodiments illustrated in Figures 1-3, 7-8 and 11-12 where there is but one remaining portion and the embodiments illustrated in Figures 4-6, and 10, where there are two distinct portions.

I find further support for this interpretation in the Commission's Opinion. The Commission notes in its Opinion that the "tapered portion of the condom closest to the reservoir tip should be considered part of the tubular portion." Commission Opinion at 9 (emphasis added). In support of this conclusion, the Commission cites to Figure 6 of the '004. Id. Figure 6 of the '004 patent illustrates an embodiment of the invention where there are two separate and distinct portions of condom. See JX-1 at Figure 6. As previously discussed, one portion runs approximately the length of the shaft of the penis, while the other portion consists of the tapered end section of the condom.

The fact that the Commission refers to the tapered end section as the "tapered portion" supports my interpretation that the Commission used the plural "remaining portions" as a vehicle to capture those embodiments, such as the embodiment of Figure 6, where there remains two separate and distinct portions that are not a second pouch. However, that is not to say that the Commission's construction excludes those embodiments with only a single remaining portion that is not a second pouch. As discussed above, I find the Commission's use of the phrase "remaining portions" naturally incorporates those embodiments with more than one remaining portion and those embodiments with only one remaining portion.

Applying the Commission's construction of "elongated tubular portion" to the Inspiral reveals a single remaining portion of the condom that is formed of a contiguous piece of thin membrane material. Exhibit RDX-2 clearly shows the one contiguous piece of thin membrane material that goes from the open end of the condom up through the tendril to the tapered end of the condom. See RDX-2. Contrary to Medtech/Intellx's argument, the portion need not be absolutely cylindrical in order to be tubular in shape. For example, the patent indicates that the closed end of the condom is part of the tubular portion; however, the closed end is not "cylindrical" in shape. See, e.g., JX-1 at 7:12-14. All the '004 patent and the Commission's construction require is that the remaining portion follow a generally tube-like shape. Based on the evidence of record, there is no question that the remaining portion of the Inspiral that is not identified as the second pouch is tubular in shape. See Tr. at 325:18-20, 331:3-6, CX-76; JPX-5.

Claim 1 not only requires that the remaining portions of the Twisted Pleasure not identified as the second pouch be tubular in shape, but also that the remaining portions have a generally constant diameter from the open end to the closed end. As previously discussed, Medtech/Intellx

argue that the tendril in the spiral region of the Inspiral has "nothing like a . . . diameter . . . let alone one that could be considered constant." RMIIBR at 9. According to Medtech/Intellx, because the tendril does not form a diameter, it "cannot define a part of the 'elongated tubular portion' as a matter of law." RCDRBR at 6. In reaching this conclusion, Medtech/Intellx rely on the Commission's statement that "[t]he claim language . . . merely requires a generally constant diameter in those lengths in which the tubular portion is present." See Commission Opinion at 11; see also RCDRBR at 5-6. Because Medtech/Intellx incorrectly assume that the Commission's statement requires the tubular portion to have a generally constant diameter in each of its cross sections, I find Medtech/Intellx's argument unpersuasive. There is nothing in the Commission's claim construction or the specification of the '004 patent that necessitates such an interpretation. Again, had the Commission intended the tubular portion to have a generally constant diameter in each of its cross sections, the Commission could have simply so stated.

Contrary to Medtech/Intellx's argument, the Commission's reference to "in those lengths" does not conflate to mean that the tubular portion must have a generally constant diameter at each of its cross sections. Consistent with my interpretation of the Commission's use of the phrase "remaining portions" in the construction of the limitation "elongated tubular portion," I find that the phrase "in those lengths" is used by the Commission to account for the various embodiments of the '004 patent. Specifically, by using the term "lengths" the Commission's construction captures those embodiments of the '004 patent, such as those illustrated in Figures 4-6 and 10, where the tubular portion consists of two or more distinct portions, or lengths, and those embodiments, such as those illustrated in Figures 1-3, 7-8 and 11-12, where the tubular portion consists of a single portion, or length. See Merriam-Webster Online Dictionary (length - 5.b. "a piece constituting . . . part of the

whole"). As the evidence of record clearly shows, the tubular portion of the Inspiral consists of one length of contiguous thin membrane material that extends from the open end of the condom through the valleys in the spiral region to the closed end of the condom. See RDX-2; JPX-5. Under the correct interpretation of the Commission's construction of the limitation "generally constant diameter," the evidence shows that as a whole, from the open end of the condom to the closed end of the condom, the tubular portion of the Inspiral has a generally constant diameter. Id.

b. "circumference"

PTI argues on remand that the Commission's claim construction of the limitation "circumference" does not affect the finding made in the ID that the Inspiral has a first pouch with a circumference. CIBR at 7. PTI relies on the same evidence cited in the ID in support of its argument on remand. Specifically, PTI cites to the testimony of Dr. Wool and Exhibit CX-76, which is a marked-up photograph of the Inspiral illustrating Dr. Wool's infringement opinions. See Tr. at 325:10-12; CX-76.

As previously discussed, Medtech/Intellx argue on remand that the Inspiral does not infringe claim 1, because it does not meet the limitation of claim 1 requiring "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." RCDIBR at 26; RMIIBR at 8. Medtech/Intellx reach this conclusion by arguing that the tendril that runs along the second pouch in the spiral region of the Inspiral is not part of the elongated tubular portion or first pouch and thus cannot define the entrance required by claim 1 and relied upon by PTI at the hearing to show infringement. RCDRBR at 4-7; RMIIBR at 8. Medtech/Intellx argue that the tendril is not part of the first pouch, because it does not define a circumference. RMIIBR at 9; RCDIBR at 25.

Specifically, Medtech/Intellx argue that there is no physical material in the spiral region of the Inspiral that defines "any sort of perimeter" in that region. RCDIBR at 25. According to Medtech/Intellx, "the absence of a circumference indicates the absence of a 'first pouch' in the spiral region, and the absence of infringement." Id.

The Staff argues on remand that the Commission's claim construction of the limitation "circumference" does not alter the conclusion found in the ID that the Inspiral infringes claim 1 of the '004 patent. SIBR at 7. Specifically, the Staff argues that the Inspiral meets the revised construction of the limitation "circumference" "given that the first pouch has a physical external surface that is tubular in shape." Id. at 8. In support of its argument, the Staff cites to Exhibit CX-76. Id.

Claim 1 requires "a first pouch having a circumference." According to the Commission, the first pouch is used to distinguish those portions of the condom that are not secondary pouches. Commission Opinion at 9. Also according to the Commission, the "circumference" is properly construed as the external surface of an object. Commission Opinion at 10. Thus, to infringe claim 1 on remand the evidence must show that the remaining portions of the Inspiral that are not secondary pouches have an external surface.

As previously discussed, Medtech/Intellx argue that the tendril in the spiral region of the Inspiral is not part of the first pouch because the tendril does not define a perimeter in the spiral region. RCDIBR at 25. Contrary to Medtech/Intellx's argument, the Commission's construction of the limitation "circumference" does not necessitate that the tendril define a perimeter in the spiral region of the Inspiral in order to be considered part of the first pouch. In fact, the Commission explicitly acknowledges in its Opinion that the specification of the '004 patent teaches that there can

be interruptions in the circumference of the first pouch. See Commission Opinion at 10; see, e.g., JX-1 at Figure 11.

As stated above, to prove infringement on remand, the evidence must show that the remaining portions of the Inspiral that are not secondary pouches have an external surface. Exhibit RDX-2 shows the remaining portion of the Inspiral that is not identified as the secondary pouch. See RDX-2. The evidence of record shows that this portion is made of a thin membrane material that goes contiguously from the open end of the condom up through the valleys to the tapered end of the condom. See CX-76. Because the evidence shows that the tubular portion, and thus the first pouch, has an external surface, I find that the evidence shows that the Inspiral meets the limitation of claim 1 requiring a first pouch having a circumference.

c. "longitudinally directed chamber"

PTI argues on remand that the Commission's construction of the limitation "longitudinally directed chamber" has no effect on the ID's finding that the Inspiral has a longitudinally directed chamber. CIBR at 8-9. PTI relies on the same evidence cited in the ID in support of its argument on remand. Specifically, PTI cites to the testimony of Dr. Wool and exhibit CX-76, which is a marked-up photograph of the Inspiral illustrating the basis for Dr. Wool's infringement opinions. Id. at 9 (citing Tr. at 325:21-23; CX-76).

Medtech/Intellx summarize on remand the Commission's claim construction of the limitation "longitudinally directed chamber," but do not argue that the Inspiral fails to satisfy this limitation. See RCDIBR at 8. Having chosen not to argue that the Inspiral fails to satisfy the limitation of claim 1 of the '004 patent requiring a longitudinally directed chamber, Respondents have waived any such argument.

The Staff argues on remand that there is little practical difference between the ID's construction of the limitation "longitudinally directed chamber" and the construction adopted by the Commission on review. SIBR at 9. Accordingly, the Staff argues that the finding in the ID that the Inspiral has a longitudinally directed chamber should be reaffirmed on remand. Id. Specifically, the Staff argues that the tubular portion of the Inspiral defines a longitudinally directed chamber that is defined by the surface of the penis. Id. at 9-10. In support of its argument, the Staff cites to Dr. Wool's testimony, as well as, Exhibits CX-78 and CX-79. Id. at 10.

Claim 1 of the '004 patent includes a limitation requiring the tubular portion to define a longitudinally directed chamber for the male penis. The Commission construed the limitation "longitudinally directed chamber" on review as

> the enclosed space or compartment into which the penis is inserted, and note that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom.

Commission Opinion at 15. As previously discussed, the elongated tubular portion of the Inspiral is formed of a thin membrane material that extends from the open end of the condom through the tendril in the spiral region to the closed end of the condom. As is plainly seen in exhibits CX-76, CX-78 and CX-79, the tubular portion follows the surface of the penis thereby defining a longitudinally directed chamber. See Tr. at 324:16-23; CX-76; CX-78; CX-79; JPX-5.

d. "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto"

Medtech/Intellx argue on remand that the Inspiral fails to satisfy this claim limitation because

the tendril in the spiral region of the Inspiral is not part of the tubular portion and thus cannot form an entrance though which the inner surface of the second pouch may move through as required by the claims. RMIIBR at 8. Medtech/Intellx's conclusion that the tendril in the spiral region of the Inspiral is not part of the tubular portion is based on its assumption that the tendril does not meet the following claim limitations: elongated tubular portion; generally constant diameter; and circumference. As discussed in detail, supra, I have found on remand that the tendril in the spiral region of the Twisted Pleasure is part of the tubular portion, that the tubular portion has a generally constant diameter, and that the first pouch has a circumference. As my findings on remand completely undercut the foundation of Respondents' argument, I find Medtech/Intellx's argument unpersuasive.

Medtech/Intellx also argue on remand that the Inspiral does not satisfy this limitation because the first and second pouches of the Inspiral does not intersect over the glans penis to form an entrance through which the inner surface of the second pouches may move to contact the glans penis. See RCDIBR at 19, 27-28; RMIIBR at 11. Medtech/Intellx base its argument on the fact that the Inspiral is 180 mm in length and the condom shown in Figure 10 of the '004 patent is approximately 160 mm in length. RMIIBR at 11. According to Medtech/Intellx, the difference in lengths means that the Inspiral is "a full 30% larger" than the condom illustrated in Figure 10 of the '004 patent with the distal end of the Inspiral extending well beyond the end of the glans penis. Id. Thus, Respondents argue, the first and second pouches will not intersect over the glans penis. Id.

I find this argument unpersuasive because Medtech/Intellx fail to convincingly explain why the 30% differential would lie beyond the glans penis. Moreover, Medtech/Intellx's argument is completely belied by the instructions for use provided in the Inspiral box, which clearly describes

and illustrates only the reservoir tip extending beyond the end of the penis. See JPX-1. Additionally, Medtech/Intellx's argument fails to recognize the way in which a rolled condom is placed on the penis. When a rolled condom is placed on the penis, any excess length remains unrolled at the base of the penis, not dangling off the end of the penis as Medtech/Intellx suggest. See id. Furthermore, Medtech/Intellx's argument is in stark contrast to statements Respondents have previously made in this investigation. For example, in its memorandum in response to Order No. 10, Respondents wrote that the "the Inspiral condom design . . . continue[es] as a single spiral around and along the shaft of the penis to the reservoir tip." See Medtech Memo. to Order No. 10 at 17-18.

The limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" has been construed herein as requiring the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate the glans penis. At the hearing in this investigation, PTI's expert, Dr. Wool, testified that the second pouch of the Inspiral has an inner surface which is moveable through the entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation thereto. Tr. at 326:19-25; see CX-78. Further, Medtech/Intellx's expert, Dr. Potter, testified that "[t]he intention is that [the Twisted Pleasure and the Inspiral] will remain relatively stationary to the vaginal wall and primarily move against the glans penis to produce the stimulation." Tr. at 965:13-16. Based on this record evidence, I find on remand that the Inspiral has a "second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto."

2. Claim 6

Claim 6 depends from claim 1 of the '004 patent and adds a limitation requiring the "second pouch being formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis." Although the construction of the limitation "circumference" that was applied in the ID was changed by the Commission on review, the resulting change to the claim construction does not alter the finding made in the ID that the second pouch of the Inspiral is formed completely around the circumference of the first pouch to produce an annular pocket. See ID at 73; see also JPX-5. The Commission construed the limitation "circumference" on review as the external surface of an object. Commission Opinion at 10. In addition, the Commission noted with regard to claim 6 that "[t]he term is used to describe where the second pouch is formed ('around the circumference'), but does not conflate to mean, at this location, the circumference of the condom including the second pouch." Id. at 11. As can be plainly seen in Exhibits CX-76 and CX-79 and the Inspiral glass former, the second pouch of the Inspiral is formed completely around the circumference of the first pouch to produce an annular pocket for movement on all of the surface of the glans penis. See CX-76; cx-79; JPX-5; see also ID at 73 (finding the Inspiral satisfies the limitation "for movement on all of the surface of the glans penis"). Accordingly, I find on remand that the Inspiral satisfies the limitation of claim 6 of the '004 patent. Because the Inspiral meets all of the limitations of claim 6 and all of the limitations of claim 1, from which claim 6 depends, I find on remand that the Inspiral infringes claim 6 of the '004 patent.

3. Claim 9

Claim 9 of the '004 patent depends from claim 1 and adds a limitation requiring the second pouch to have "its inner surface coated with lubricant to provide a hydrodynamic rubbing of the

glans penis." The ID found that the inner surface of the second pouch of the Inspiral is coated with lubricant, but did not address the functional limitation requiring the hydrodynamic rubbing of the glans penis. See ID at 73. As construed herein, the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" requires that the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis. PTI and the Staff both argue on remand that the Inspiral meets this claim limitation. CIBR at 11; SIBR at 16. Medtech/Intellx argue that this limitation is not satisfied. RMIIBR at 12.

Medtech/Intellx admits on remand "that the Inspiral is generally sold in a lubricated state." RMIIBR at 12. However, Medtech/Intellx argue that I should find on remand that claim 9 not infringed because PTI has failed to demonstrate that the lubrication "contributes to any 'rubbing' action." Id. According to Medtech/Intellx, "the very purpose of lubrication is the antithesis of such friction." Id.

As the Staff correctly points out in its reply brief, Medtech/Intellx's characterization of the "rubbing" with "friction" is not supported by the evidence. See SRBR at 12. In fact, the '004 patent equates the "rubbing" with "movement." See JX-1 at 6:39-49. The evidence of record clearly shows that the lubrication in the Inspiral will facilitate the rubbing of the glans penis. See Tr. at 326:19-25, 330:9-12. Accordingly, I find on remand that the Inspiral meets the additional claim limitation of claim 9. Thus, because I have found that the Inspiral meets all of the limitations of claim 9 and all of the limitations of claim 1, from which claim 9 depends, I find on remand that the Inspiral infringes claim 9 of the '004 patent.

4. Claim 22

Independent Claim 22 reads as follows:

A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:

> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end;
>
> a second pouch integrally formed on the circumference of the closed end for forming a loose pocket overlying in spaced relationship to the glans penis and having an inner surface movable back and forth thereon during coitus for providing stimulation thereto;
>
> said tubular portion and said second pouch having a wall thickness of 0.11 mm ± 0.04 mm; and
>
> said second pouch having its inner surface spaced radially outwardly of said tubular portion to provide looseness between said tubular portion and the outer surface of the glans penis to prevent binding of the glans penis with consequent reduction in sensitivity.

While stated in slightly different terms, for the most part, the limitations in claim 22 are the same as those recited in claim 1. Claim 22 differs from claim 1 in three ways: (1) the second pouch must be "integrally formed;" (2) the tubular portion and second pouch must have a wall thickness of 0.11 mm ± 0.04 mm; and (3) the inner surface of the second pouch must be spaced radially outwardly of the tubular portion. The ID found that the Inspiral satisfies these additional claim limitations and nothing in the Commission's Opinion on review disturbed those findings. See ID at 74-75. Complainant and the Staff argue on remand that the Inspiral infringes claim 22. CIBR at 6; SIBR at 22. Medtech/Intellx argue on remand that the Inspiral does not infringe claim 22. RMIIBR at 8.

Medtech/Intellx's noninfringement arguments on remand are the same as those proffered with regard to claim 1. Accordingly, for the same reasons espoused with regard to claim 1, supra, I find on remand that the Inspiral satisfies those limitations construed by the Commission on review as well as those applicable functional limitations construed herein. Thus, I find on remand that the Inspiral literally infringes claim 22 of the '004 patent.

5. Claim 25

Claim 25 depends from claim 22 and adds a limitation requiring "the second pouch being coated with a lubricant to provide a hydrodynamic rubbing of the glans penis." This is the same limitation found in claim 9. Accordingly, for the same reasons discussed with regard to claim 9, supra, I find on remand that the Inspiral meets this claim limitation. Because the Inspiral meets all of the limitations of claim 25 and all of the limitations of claim 22, from which claim 25 depends, I find on remand that the Inspiral literally infringes claim 25 of the '004 patent.

6. Claim 31

Independent claim 31 reads as follows:

> A prophylactic pouch for use by a male, having an elongated tubular portion forming a first pouch including a circumference, an open end and a closed end, said tubular portion having a generally constant diameter from end to end, characterized by:
>
> > a second pouch integrally formed on the circumference of said tubular portion as an outward bulge on the closed end in overlying spaced relationship to a glans penis and operable to move thereon to provide stimulation during coitus; said second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement.

Claim 31 contains many of the same limitations found in claim 1. There are two differences between claim 31 and claim 1 that are of import on remand. The first is that claim 31 requires the second pouch to be "integrally formed " and the second is that claim 31 requires a second pouch with an entrance that extends lengthwise of the glans penis at least 1 cm. The ID found that the Inspiral satisfies these additional limitations and nothing in the Commission's opinion on review affects those findings. Complainant and the Staff argue on remand that the Inspiral infringes claim 31. CIBR at 6; SIBR at 24-25. Medtech/Intellx argue on remand that the Inspiral does not infringe claim 31. RMIIBR at 8.

Medtech/Intellx's noninfringement arguments on remand are the same as those proffered with regard to claim 1. Accordingly, for the same reasons espoused with regard to claim 1, supra, I find on remand that the Inspiral satisfies those limitations construed by the Commission on review as well as those applicable functional limitations construed herein. Thus, I find on remand that the Inspiral infringes claim 31 of the '004 patent.

V. VALIDITY - ANTICIPATION

On review, the Commission set forth its own claim constructions for four claim terms and ordered the construction, in the first instance, of several functional limitations not evaluated in the ID. In light of the Commission's claim constructions and the constructions of the functional limitations, the Commission directed that I revisit the issue of anticipation on remand. Commission Opinion at 19.

The ID found claims 1, 6 and 9 of the '004 patent invalid as anticipated by U.K. Patent No. 1,252,255. Of these claims, C&D only argues on remand that independent claim 1 is anticipated by the '255 patent. RCDIBR at 37-40. C&D does not address on remand the anticipation of dependent

claims 6 and 9. Medtech/Intellx note on remand that they "concur and join in the arguments set for [in C&D's brief]." RMIIBR at 13. The Staff asserts that claims 6 and 9 are anticipated on remand. SIBR at 15, 17. Accordingly, I will address claims 6 and 9. In addition to arguing on remand that claim 1 is anticipated, C&D also argues that claim 31 is anticipated by the '255 patent. Id. at 41.

A. Claim 1

With the exception of the four claim terms the Commission construed and the functional limitations construed herein, the Commission affirmed the remaining claim constructions in the ID. Commission Opinion at 17. Accordingly, I need only analyze whether the '255 patent discloses those limitations construed by the Commission and the functional limitations construed herein to establish whether the '255 patent anticipates claim 1 of the '004 patent on remand.

1. "elongated tubular portion"

On review, the Commission construed the limitation "elongated tubular portion" as the remaining portions of the condom not identified as one or more second pouches (or a third pouch) and are tubular in shape. Commission Opinion at 8. C&D argues on remand that the '255 patent discloses an "elongated tubular portion." RCDIBR at 37. On remand, neither PTI nor the Staff dispute that the '255 patent discloses this limitation.

The '255 patent discloses a single "second pouch" that is formed completely around the circumference of the first pouch. See RX-12 at Figure 1. The "second pouch" consists of the frusco-conical connecting section (labeled "3" in Figure 1), the head section (labeled "4" in Figure 1), and the part of the end closing section (labeled "5" in Figure 1) from the head section to the tapered end of the end closing section. Id. According to the Commission's claim construction, the "elongated tubular portion" is that part of the condom illustrated in Figure 1 of the '255 patent not identified

above as the second pouch and that is tubular in shape. Applying this construction, I find on remand that the elongated tubular portion in Figure 1 of the '255 patent consists of two portions, the "tubular stem section" (labeled "2" in Figure 1) and the tapered end of the "end closing section" (labeled "5" in Figure 1). See RX-12 at Figure 1; see also RCDIBR at 37. As may be clearly seen in Figure 1, both of these portions are tubular in shape. See RX-12 at 1:33-37 ("a head section and a main body section, both of generally cylindrical shape and circular cross section").

2. "tubular portion . . having a generally constant diameter"

On review, the Commission construed the limitation "tubular portion . . . having a generally constant diameter" as requiring the diameter of the tubular portion to be, for the most part, constant. Commission Opinion at 11. In construing this limitation, the Commission stated that "[t]he claim language, we note, merely requires a generally constant diameter in those lengths in which the tubular portion is present." Id. C&D argues on remand that the '255 patent discloses a "generally constant diameter." RCDIBR at 37. On remand, neither PTI nor the Staff dispute that the '255 patent discloses this limitation.

As discussed above, the elongated tubular portion in Figure 1 of the '255 patent consists of two portions, or lengths. As illustrated in Figure 1, I find on remand that these portions clearly have a generally constant diameter. See RX-12 at Figure 1. In fact, the specification of the '255 patent explicitly states that the tubular stem section has a diameter of 30 mms. RX-12 at 1:72-73.

3. "longitudinally directed chamber"

The Commission construed the limitation "longitudinally directed chamber" on review as the enclosed space or compartment into which the penis is inserted, and noted that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with

the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom. Commission Opinion at 15. C&D argues on remand that the finding in the ID that the '255 patent discloses this limitation is still valid under the Commission's claim construction. RCDIBR at 37. On remand, neither PTI nor the Staff dispute that the '255 patent discloses this limitation.

As is plainly seen in Figure 1 of the '255 patent, I find on remand that the tubular portion of the condom disclosed in the '255 patent follows the contour of the penis from the open end of the condom to the closed end of the condom to define a longitudinally directed chamber. See RX-12 at Figure 1; see also id. at 1:59-65 ("the gripping of the stem section around substantially the whole length of the shaft of the penis provides a degree of sealing against the escape of seminal fluid").

4. "circumference"

The Commission construed the limitation "circumference" on review as the external surface of an object. Commission Opinion at 10. Claim 1 of the '004 patent requires "a first pouch having a circumference." JX-1 at 7:13-14. C&D argues on remand that the '255 patent discloses a "circumference" under the Commission claim construction. RIBR at 37. On remand, neither PTI nor the Staff dispute that the '255 patent discloses this limitation.

According to the Commission, the first pouch is used to distinguish those portions of the condom that are not secondary pouches. Commission Opinion at 9. As I discussed in my analysis of the limitation "elongated tubular portion," the remaining portions of the condom illustrated in Figure 1 not identified as the second pouch are the tubular stem section (labeled "2" in Figure 1) and the tapered end of the end closing section (labeled "5" in Figure 1). See RX-12 at Figure 1. As illustrated in Figure 1 of the '255 patent, those portions clearly have an external surface. See id.

Accordingly, I find on remand that Figure 1 of the '255 patent discloses a first pouch having a circumference.

5. "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto"

PTI argues that claim 1 should be held on remand not anticipated by the '255 patent because the ID already found that the '255 patent does not disclose the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." CIBR at 5. In support of its argument on remand, PTI relies on a statement in the ID that reads, "the '255 patent does not disclose the exact nature of how the 'head section' stimulates the glans." CIBR at 5 (citing ID at 87).

Contrary to PTI's argument, this statement is not a finding that the '255 patent does not disclose "an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto." This statement is merely dicta. The ID specifically found that the '255 patent does disclose "a second pouch having an inner surface moveable through said entrance and against the glans penis." ID at 87 ("Thus, the '255 patent discloses that the inner surface of the "head section" inverts through the entrance to abut against the glans penis."). With regard to the remainder of the claim limitation "for movement; back and forth thereon during coitus for providing stimulation thereto" the ID made no specific finding one way or the other. See id.

The Staff contends on remand that the '255 patent does not disclose the limitation "for movement; back and forth thereon during coitus for providing stimulation thereto." SIBR at 12-13. However, the Staff does not argue the point on remand because the Staff notes that all of its non-

anticipation arguments were previous rejected in the ID. Id. at 12. Nevertheless, the Staff states that "it expects to assert these grounds to the Commission on review." Id. at 13. Specifically, the Staff notes that the ID rejected its arguments that: (1) the dimensions of the second pouch must be of such proportions so that the pouch does not collapse backward such that it fails to move back and forth and provide enhanced stimulation to the glans penis; and (2) although the '255 patent discloses a wide range of proportions for the second pouch (in relation to the shaft portion) and the dimensions described in Figure 10 of the '004 patent condom fall within that range, the '255 patent does not anticipate claim 1 given the criticality of the sub-range dimensions in providing the functional element of claim 1. Id. at 12. For the same reasons set forth in detail in the ID, I reaffirm my previous decision not to adopt the Staff's non-anticipation arguments. See ID at 78-82.

C&D argues on remand that the '255 patent discloses the limitation of claim 1 of the '004 patent requiring "movement; back and forth thereon during coitus for proving stimulation thereto," because the same language in the '255 patent that the ID relied on to support a finding that the "head section" inverts through the entrance to abut against the glans penis, supports a finding on remand that the "head section" also moves back and forth. RCDIBR at 38. Specifically, C&D argues that the mere inversion of the "head section" to abut the glans penis would be insufficient to create the disclosed friction to stimulate the penis. Id. at 38-39. Thus, according to the C&D, "there would have to be some movement back and forth." Id.

Additionally, C&D argues that claim 1 of the '004 patent is anticipated by the '255 patent because the condom disclosed in Figure 10 of the '004 patent is of the same dimensions as the condom disclosed in Figure 1 of the '255 patent. Id. at 39. Respondents argument is based on the Commission's finding on review that claim 1 reads on the embodiment of the invention illustrated

in Figure 10 of the '004 patent. See Commission Opinion at 15-17. C&D admits that the '255 patent does not disclose the dimensions for the "end closing section 5" of the condom illustrated in Figure 1 of the '255 patent. RCDIBR at 39. Nevertheless, C&D argues that the condom illustrated in Figure 10 of the '004 patent and the condom illustrated in Figure 1 of the '255 patent have similar dimensions. Id. To reach this conclusion, C&D relies on the ASTM specifications for contraceptives described in Exhibit RX-8 at 2, Table 1, discussions in another prior art reference admitted as RX-11, and a "fair inference that the widened 'head section' configuration is being applied to a Class B, 160 mm condom. See RCDIBR at 39-40.

C&D's reliance on evidence outside of the '255 patent to support its anticipation finding is improper. Similarly, C&D's reliance on what it terms a "fair inference" is also improper. A claim is anticipated when "the four corners of a single prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000). C&D seemingly confuse obviousness under 35 U.S.C. 103, with anticipation under 35 U.S.C. 102. Because only the anticipation of claim 1 of the '004 patent is at issue on remand, I hereby reject C&D's arguments that rely on outside evidence as well as its "fair inference."

As construed herein, the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" requires the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate to the glans

penis. According to the specification of the '255 patent, the purpose of the invention is to provide a condom with improved sensation that takes advantage of the fact that different portions of the penis are sensitive to different types of stimulation. RX-12 at 1:27-30, 1:42-46. The '255 patent discloses that the head of the penis from just behind the coronal sulcus to the meatus (i.e., the glans penis) is sensitive to friction. Id. at 1:49-51. According to the '255 patent, "[t]he employment of two distinct sections enables on the one hand gripping of the swollen head of the penis, when in erect state, to be avoided whilst simultaneously providing a tight grip around the root of the penis." Id. at 1:55-57, Figure 1.

The ID found, and I reaffirm herein, that a fair reading of the specification discloses that the wider "head section" allows friction on the head of the penis to improve stimulation. ID at 86. To accomplish this, the ID found, and I reaffirm herein, that the walls of the "head section" must invert from the outward position that is depicted in Figure 1 through the "entrance" at the boundary of the first pouch and the second pouch to make contact with the glans penis. Id. at 86-87. Although the ID did not address the issue, on remand I note that the mere inversion of the head section to make contact with the glans penis would be insufficient to create the friction discussed in the specification of the '255 patent. See RX-12 at 1:49-50. To create the desired friction, there necessarily must be some type of movement back and forth along the glans penis. Accordingly, I find on remand that the '255 patent discloses a "second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto."

As discussed above, the '255 patent discloses those claim limitations construed by the Commission on review and those applicable limitations construed in the first instance herein.

Coupled with the findings made in the ID that were not disturbed by the Commission, I find on remand clear and convincing evidence that the '255 patent discloses each and every claim limitation of claim 1 of the '004 patent. Accordingly, I find that the '255 patent anticipates claim 1 of the '004 patent.

B. Claim 6

Claim 6 depends from claim 1 of the '004 patent and adds a limitation requiring the "second pouch being formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis." Although the construction of the limitation "circumference" that was applied in the ID was changed by the Commission on review, the resulting change to the claim construction does not alter the finding made in the ID that the second pouch of the condom illustrated in Figure 1 of the '255 patent is formed completely around the circumference of the first pouch to produce an annular pocket. See RX-12 at Figure 1. The Commission construed the limitation "circumference" on review as the external surface of an object. Commission Opinion at 10. In addition, the Commission noted with regard to claim 6 that "[t]he term is used to describe where the second pouch is formed ('around the circumference'), but does not conflate to mean, at this location, the circumference of the condom including the second pouch." Id. at 11.

As illustrated in Figure 1 of the '255 patent, it is clear that under the Commission's construction of the limitation "circumference" that the second pouch is formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis. See RX-12 at Figure 1; see also ID at 88 (finding the '255 patent discloses "for movement on all of the surface of the glans penis"). Accordingly, I find on remand clear and convincing evidence that the '255 patent discloses each and every limitation of claim 6 of the '004 patent.

Because the '255 patent discloses all of the limitations of claim 6 and all of the limitations of claim 1, from which claim 6 depends, I find on remand that the '255 patent anticipates claim 6 of the '004 patent.

C. Claim 9

Claim 9 of the '004 patent depends from claim 1 and adds a limitation requiring the second pouch to have "its inner surface coated with lubricant to provide a hydrodynamic rubbing of the glans penis." The ID found that the '255 patent teaches coating the inner surface of the second pouch with lubricant, but did not address the functional limitation requiring the hydrodynamic rubbing of the glans penis. See ID at 89. As construed herein, the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis" requires that the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis. The '255 patent teaches that the inside surface of a condom may be coated with a lubricant to improve sensation. RX-12 at 1:22-25.

As discussed with regard to claim 1 above, the '255 patent also discloses that the second pouch has an inner surface moveable through the entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto. Because the addition of lubricant to the inside of the second pouch will necessarily facilitate the rubbing of the inner surface of the second pouch against the glans penis that occurs during the movement back and forth during coitus, I find on remand that the '255 patent discloses a "second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis." Accordingly, I find on remand clear and convincing evidence that the '255 patent discloses each and every limitation of claim 9 of the '004 patent. Because the '255 patent discloses all of the limitations of claim 9 and

all of the limitations of claim 1, from which claim 9 depends, I find on remand that the '255 patent anticipates claim 9 of the '004 patent.

D. Claim 31

The ID found claim 31 not anticipated by the '255 patent, because the '255 patent failed to disclose a second pouch with "an entrance with an open area extending lengthwise of the glans penis at least 1 cm." This finding was not disturbed by the Commission's Opinion on review. Nevertheless, C&D argues on remand that claim 31 does in fact disclose an open area extending lengthwise of the glans penis by at least 1 cm.

In response to the Commission's opinion remanding this investigation for further consideration and to facilitate the proper resolution of this investigation on remand, I issued Order No. 33, which set forth several issues that I wished the parties to brief. I specifically noted in Order No. 33 that any party wishing to brief an issue not listed therein must first move for leave to do so. The limitation of claim 31 requiring "an open area extending lengthwise of the glans penis at least 1 cm" was not included among the issues I ordered the parties to brief and C&D failed to move for leave to brief the issue. Accordingly, I find C&D has violated Order No. 33 and have waived any right on remand to argue that claim 31 is anticipated by the '255 patent. Moreover, for the reasons stated in the Staff's reply memoranda on remand I would find that C&D has failed to prove by clear and convincing evidence that claim 31 of the '004 patent is anticipated by the '255 patent. See SRBR at 14.

VI. DOMESTIC INDUSTRY

A. Technical Prong

On review, the Commission set forth its own claim constructions for four disputed claim

terms and ordered the construction, in the first instance, of several functional limitations not evaluated in the ID. The Commission affirmed the remaining claim constructions in the ID. Because the Commission affirmed the remaining claim constructions in the ID, I need only evaluate whether the Pleasure Plus satisfies the four disputed claim limitations that the Commission chose to construe on review and the functional limitations construed herein, to determine on remand whether the Pleasure Plus satisfies the technical prong of the Section 337 domestic industry requirement.

PTI asserts on remand that its Pleasure Plus condom practices claims 1-4, 9, 22, 25 and 31 of the '004 patent thereby satisfying the technical prong of the Section 337 domestic industry requirement. CIBR at 12. C&D and Medtech/ Intellx do not address technical prong in their remand briefs and have thereby waived the issue on remand. See Order No. 33. The Staff argues on remand that the Pleasure Plus satisfies the technical prong of the domestic industry requirement. SIBR at 10.

1. "elongated tubular portion"

On review, the Commission construed the limitation "elongated tubular portion" as the remaining portions of the condom not identified as one or more second pouches (or a third pouch) and are tubular in shape. Commission Opinion at 8. Exhibit CX-91 shows the Pleasure Plus with its single second pouch shaded in blue. CX-91. Exhibit CX-90 shows the upper section of the Pleasure Plus with the second pouch removed. CX-90. As is plainly seen in Exhibits CX-88, CX-90 and CX-91, the remaining portion of the Pleasure Plus not identified as the second pouch is formed of a contiguous thin membrane material that extends from the open end of the condom to the closed end of the condom. See CX-88; CX-90; CX-91. There can be no question that the remaining

portion of the Pleasure Plus not identified as the second pouch is also tubular in shape. Id.

2. "tubular portion . . having a generally constant diameter"

On review, the Commission construed the limitation "tubular portion . . . having a generally constant diameter" as requiring the diameter of the tubular portion to be, for the most part, constant. Commission Opinion at 11. As discussed above, the remaining portion of the Pleasure Plus not identified as the second pouch is formed of a contiguous thin membrane material that extends from the open end of the condom to the closed end of the condom. Examining this remaining portion of the Pleasure Plus as a whole, from the open end to the closed end, the evidence supports a finding that the Pleasure Plus has a tubular portion with a generally constant diameter from the open end to the closed end. See CX-88; CX-91.

3. "longitudinally directed chamber"

The Commission construed the limitation "longitudinally directed chamber" on review as the enclosed space or compartment into which the penis is inserted, and note that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom. Commission Opinion at 15. There can be no dispute that the Pleasure Plus has a longitudinally directed chamber under the Commission's construction of the term. As is plainly seen in Exhibits CX-88 and CX-90, the tubular portion of the Pleasure Plus follows the contour of the penis from the open end of the condom to the closed end of the condom to define a longitudinally directed chamber. See CX-88; CX-90; CPX-2; CPX-4.

4. "circumference"

The Commission construed the limitation "circumference" on review as the external surface of an object. Commission Opinion at 10. According to the Commission, the first pouch is used to distinguish those portions of the condom that are not secondary pouches. Commission Opinion at 9. Based on this interpretation of "first pouch" there can be no dispute that the Pleasure Plus has a first pouch with a circumference. Exhibit CX-88 plainly shows the external surface of the first pouch with the circumference labeled accordingly. See CX-88.

5. "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto"

As construed herein, the limitation "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto" requires the inner surface of the second pouch to be capable of moving inwardly through the boundary between the second and first pouch, as well as, capable of back and forth movement against the glans penis during coitus in order to stimulate to the glans penis. At the hearing, Dr. Wool demonstrated and testified that the inner surface of the second pouch moved through the entrance and back and forth against the glans penis. Specifically, Dr. Wool testified as follows:

> Q. Does the second pouch have an inner surface movable through the entrance?
> A. Yes, it does. The inner surface is the interior surface of the secondary pouch, and it is movable, by very light pressure, either normal or shearing back and forth.
>
> Q. And I think that you may have already confirmed this, but does that inner surface move against the glans penis back and forth during coitus?
> A. Yes, it does. This very light membrane takes very little force to move it. It takes minimal forces that would allow it to move back and forth, with the lightest of pressure.

> Q. Dr. Wool, is the purpose of the elements that you have just described, is that for providing stimulation to the glans penis?
> A. Yes, it is. I think this is the great part of this invention.

Tr. at 313-314; see CPX-4. Exhibit CX-90 also illustrates the inner surface movable through the entrance and against the glans penis. See CX-90; see also CPX-4. Notably, the package insert for the Pleasure Plus specifically states that "[d]uring sex, the pouch moves back and forth, gently stimulating both partners." CPX-2. Based on the evidence discussed above, I find that the Pleasure Plus has an inner surface of the second pouch capable of moving inwardly through the boundary between the second and first pouch, as well as capable of back and forth movement against the glans penis during coitus in order to stimulate to the glans penis.

6. "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis"

Claims 9 and 25 of the '004 patent include the limitation "the second pouch having its inner surface coated with a lubricant to provide hydrodynamic rubbing of the glans penis," which has been construed herein as requiring that the inner surface of the second pouch be coated with a lubricant to facilitate the rubbing of the inner surface of the second pouch against the glans penis. At the hearing, Dr. Wool testified that the inner surface of the second pouch in the Pleasure Plus is lubricated and demonstrated how the lubrication provides the hydrodynamic rubbing of the glans penis. See Tr. at 316:23-25; see also CPX-2; CPX-4. Based on this evidence, I find that the Pleasure Plus satisfies the additional limitation of claims 9 and 25 requiring lubrication on the inner surface of the second pouch to provide hydrodynamic rubbing of the glans penis.

7. **"portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches"**

This additional limitation, which has been construed in the first instance herein at the direction of the Commission, is specific to claim 18 of the '004 patent. PTI has not asserted that its Pleasure Plus practices claim 18. Consequently, there is no need to analyze whether the Pleasure Plus satisfies this claim limitation on remand.

As discussed hereinabove, the evidence of record shows that the Pleasure Plus satisfies the four claim limitations construed by the Commission on review and the two applicable functional limitations construed, in the first instance, herein. Thus, I find PTI has proven by a preponderance of the evidence that its Pleasure Plus practices claims 1-4, 9, 22, 25 and 31 of the '004 patent. Because PTI has proven that its domestic industry practices at least one claim of the patent at issue, I find that PTI has satisfied the technical prong of the Section 337 domestic industry requirement.

B. Economic Prong

The Commission found on review that PTI has "a domestic industry under the economic prong of the requirement." Commission Opinion at 20.

C. Conclusion

I have found herein that PTI has satisfied the technical prong of the domestic industry requirement. As discussed above, the Commission found on review that PTI has satisfied the economic prong of the domestic industry requirement. Because PTI has satisfied both the economic and technical prongs of the domestic industry requirement, I find on remand that a domestic industry exists in the United States that practices U.S. Patent No. 5,082,004.

VII. REMEDY AND BONDING

A. Limited Exclusion Order

Under section 337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue, without regard to source. PTI requests that a limited exclusion order issue that prohibits the importation of all products manufactured by or for Respondents that infringe one or more claims of the '004 patent. CIB at 46. The Staff agrees that, if a violation of Section 337 is found, a limited exclusion order directed at the infringing products is warranted. SIB at 66. Additionally, the Staff recommends that any exclusion order issued should include a "complainant's reporting requirement" requiring PTI to report to the Commission concerning the status of its domestic industry. Id. C&D argues that "in the unlikely event that a violation of section 337 is found, the public interest renders . . . an exclusion order inappropriate." RCDIB at 72. Medtech/Intellx "concur and join in the arguments with respect to remedy and bonding set forth in C&D's Post-Hearing Brief." RMIIB at 19.

C&D argues that the Commission should decline to impose a remedy in this investigation, because the public interest outweighs PTI's rights to enforce its patent monopoly. RCDIB at 73. Specifically, C&D argues that the Twisted Pleasure "fills an important unmet public health need." Id. According to C&D, the "pleasure-oriented focus [of the Twisted Pleasure] encourages condom usage in segments of the population that otherwise might not use condoms regularly." Id. As a result, C&D argues that if the Twisted Pleasure is removed from the market, the "public health is

very likely to suffer in the form of greater incidence of AIDS, other sexually transmitted diseases and unwanted pregnancies." Id.

I find this argument unpersuasive. C&D's argument that the "pleasure-oriented focus" of the Twisted Pleasure entices some people to purchase condoms that would otherwise refrain from doing so is belied by the fact that C&D itself notes that it has other Trojan brand condoms in the "enhanced pleasure category." RX-122 (Daniels Reb. Wit. Stat.) at Q.22. Additionally, the evidence of record suggests that there are a variety of factors that influence people to purchase condoms. See RX-122 (Daniels Reb. Wit. Stat.) at Q.3 ("The association with the Trojan brand, the name "Twisted Pleasure," the fact that the condoms are packaged in a bright, lime green box, and the unique twist all draw customers to purchase the Twisted Pleasure who otherwise might not use condoms."). Moreover, the evidence presented by C&D is conclusory and lacks the type of evidentiary support necessary to sustain a finding that the removal of the Twisted Pleasure would result in greater incidence of AIDS or other sexually transmitted diseases.

C&D also argues that it is within the public interest not to impose a remedy, because "it is unlikely that PTI could fill the product demand" that would allegedly result from the removal of the Twisted Pleasure from the market. RCDIB at 73. According to C&D, "[s]hould the Twisted Pleasure and Inspiral be removed from the market, it is very unlikely that there will be an unmet public health need for pleasure condoms." Id. at 74. I also find this argument unpersuasive. As discussed above, C&D admits that it sells other pleasure condoms, so C&D's assumption that the demand for the Twisted Pleasure would transfer to the Pleasure Plus if the Twisted Pleasure is taken off the market is unfounded. Additionally, there is some evidence that PTI could meet an increase in demand if the Twisted Pleasure and Inspiral were excluded. CX-244C (Wedel Wit. Stat.) at

Q.138-Q.141. Moreover, any question about the continued solvency and production capability of PTI can be adequately mitigated by including a reporting requirement with an exclusion order.

Having found a violation of Section 337, it is my Recommended Determination on Remand that the Commission issue a limited exclusion order that prohibits the importation of all products manufactured by or for Respondents that infringe one or more claims of the '004 patent. Additionally, because there is some question about the continued solvency of PTI, I recommend that any exclusion order contain a reporting requirement that requires PTI to report to the Commission concerning the status of its domestic industry. See Tr. at 594:19-595:7; Tr. at 527:23-25. Such a reporting requirement has been imposed in other investigations which involved questions as to whether Complainant would continue its domestic activities going forward. See, e.g., Certain Variable Speed Wind Turbines and Components Thereof, Inv. No. 337-TA-376, Commission Opinion at 18, USITC Pub. 3003 (Nov. 1996) (imposing reporting requirement on a bankrupt domestic industry).

B. Cease and Desist Order

Under Section 337(f)(1), the Commission may issue a cease and desist order in addition to, or instead of, an exclusion order. Cease and desist orders are warranted primarily when the respondent maintains a commercially significant inventory of the accused products in the United States. Certain Crystalline Cefadroxil Monohydrate, Inv. No. 337-TA-293, Commission Opinion (March 15, 1990), 15 U.S.P.Q.2d 1263, 1277-79. PTI requests that a cease and desist order issue prohibiting Respondents from marketing, demonstrating, distributing, offering for sale, selling or otherwise transferring, including the movement of inventory, in the United States any male prophylactic devices that infringe the '004 patent. CIB at 46-47. The Staff agrees that a cease and

desist order should issue. SIB at 66. Respondents argue that a cease and desist order should not issue even if a violation is found. RCDIB at 72; RMIIB at 19. In support, Respondents rely on the same public interest arguments it makes in arguing against the imposition of an exclusion order. Id. at 72-73. Pursuant to Commission Rule 210.42(a)(1)(i), I will not address Respondents' public interest concerns in this ID. See 19 C.F.R. § 210.50(b)(1).

The record evidence shows that Respondents C&D and Intellx maintain commercially significant inventories of accused products in the United States. CX-132 (C&D Interrogatory Response No. 5); CX-146 (Intellx Interrogatory Response No. 5). Accordingly, it is my Recommended Determination on Remand that a cease and desist order issue against Respondents C&D and Intellx.

C. Bond During Presidential Review Period

If the Commission enters an exclusion order or cease and desist order, parties may continue to import and sell their products during the pendency of the Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the Complainants from any injury." 19 U.S.C. § 1337(e); 19 C.F.R. § 210.50(a)(3). On the issue of bonding, Complainant asserts that Respondents should "be required to post a bond of 80% of the entered value of their products during the Presidential review period." CIB at 47. Respondents assert that a nominal bond of $1000 would be appropriate because Complainant has not produced evidence relevant to the issue of bonding. RCDIB at 75. Staff correctly notes that "the Commission typically has considered the differential in sales price between the patented product made by domestic industry and the lower price of the infringing product." SIB at 67 (quoting Certain Microsphere Adhesives, Process for Making Same and Products Containing Same, Including Self-Stick Repositionable Notes, Inv. No.

337-TA-366, Commission Opinion at 24, 1996 WL 1056298 (U.S.I.T.C. January, 1996)).

Neither C&D nor Medtech/Intellx provide a basis for the bonding levels that they propose. The evidence, correctly summarized by Staff, shows that the prophylactics at issue are sold to retailers as a specific price per unit: 1) Complainant's Pleasure Plus at [ ] 2) Respondent Church & Dwight's Twisted Pleasure at ; and 3) Respondents Medtech/Intellx's Inspiral at [ ] CX-132 at 10; CX-146 at 9; CX-245 at 3; SIB at 67-68. Respondents agree with this assessment of the appropriate price differentials in their Post Hearing Reply Briefs. RCDRB at 49; RMIRB at 33. Thus, should the Commission issue an exclusion order or cease and desist order, I recommend an appropriate bond for the Twisted Pleasure in the amount of [ ] per unit and an appropriate bond for the Inspiral in the amount of [ ] per unit.

VIII. CONCLUSIONS OF LAW ON REMAND

1. PTI has a domestic industry in the United States, as required by subsection (a)(2) of section 337, that exploits the male prophylactic devices that are covered by the U.S. Patent No. 5,082,004.

2. Complainant PTI's Pleasure Plus prophylactic practices claims 1-4, 9, 22, 25, and 31 of the '004 patent.

3. Respondent C&D's accused product infringes claims 1, 13, 18 and 31 of U.S. Patent No. 5,082,004. Respondent C&D's accused product does not infringe claims 2-4, 15, 16, 22, 25, 32 and 36 of U.S. Patent No. 5,082,004.

4. Respondents Medtech/Intellx's accused product infringes claims 1, 6, 9, 22, 25, and 31 of U.S. Patent No. 5,082,004. Respondents Medtech/Intellx's accused product does not infringe claims 2-4 and 8 of U.S. Patent No. 5,082,004.

5. Claims 1, 6, and 9 of U.S. Patent No. 5,082,004 are invalid as anticipated by U.K. Patent No. 1,252,255.

6. Claims 2-4, 8, 13, 15-16, 18, 22, 25, 31-32, and 36 of U.S. Patent No. 5,082,004 are not invalid.

7. There is a violation of 19 U.S.C. § 1337.

8. A violation having been found, the record supports issuance of a limited exclusion order, a cease and desist order, and a bond during Presidential review.

IX. ORDER

Based on the foregoing, and the record as a whole, it is my Initial Determination on Remand that there is a violation of section 337 in the importation into the United States, sale for importation, and the sale within the United States after importation of certain male prophylactic devices. Because a violation of section 337 has been found, it is also my recommendation that limited exclusion orders and cease and desist orders should issue.

I hereby CERTIFY to the Commission my Initial and Recommended Determinations on Remand together with the record consisting of the exhibits admitted into evidence. The pleadings of the parties filed with the Secretary and the transcript of the pre-hearing conference and the hearing, including closing arguments, are not certified since they are already in the Commission's possession in accordance with Commission rules.

Further it is ORDERED that:

1. In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the Administrative Law Judge under 19 C.F.R. § 210.5 is to be given in camera treatment.

2. The Secretary shall serve a public version of this Initial Determination on Remand upon

all parties of record and the confidential version upon counsel who are signatories to the protective order issued by the Administrative Law Judge in this investigation, and upon the Commission Investigative Staff Attorney. To expedite service of the public version, counsel are hereby ordered to serve on the Administrative Law Judge by no later than April 04, 2007 a copy of this Initial Determination on Remand with those sections considered by the party to be confidential bracketed in red.

3. This Initial Determination on Remand shall become the determination of the Commission 45 days after its date of service unless the Commission within those 45 days shall have ordered review of this Initial Determination on Remand, or certain issues herein, pursuant to 19 C.F.R. § 210.43(d) or § 210.44

Robert L. Barton, Jr.
Administrative Law Judge

Issued: March 19, 2007

CERTAIN MALE PROPHYLACTIC DEVICES **Inv. No. 337-TA-546**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **ORDER** was served upon Rett Snotherly, Esq., Commission Investigative Attorney, and the following parties via first class mail and air mail where necessary on April 19, 2007.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112A
Washington, DC 20436

FOR COMPLAINANT PORTFOLIO TECHNOLOGIES, INC.:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
Jeffrey S. Becker, Esq.
Christopher M. Saternus, Esq.
John M. Sheldon, Esq.
KOZACKY & WEITZEL, P.C.
One North LaSalle Street, Suite 3150
Chicago, IL 60602

Richard P. Beem, Esq.
Michael T. Griggs, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, IL 60604

Kent R. Stevens, Esq.
Eric G. Wright, Esq.
MORGAN & FINNEGAN, LLP
1775 Eye Street, NW, Suite 400
Washington, DC 20006

CERTAIN MALE PROPHYLACTIC DEVICES **Inv. No. 337-TA-546**

FOR RESPONDENT CHURCH & DWIGHT CO., INC.:

Lewis E. Leibowitz, Esq.
Steven P. Hollman, Esq.
Susan M. Cook, Esq.
Jonathan T. Stoel, Esq.
HOGAN & HARTSON LLP
555 Thirteenth Street, NW
Washington, DC 20004-1109

James H. Shalek, Esq.
Alan Federbush, Esq.
Baldassare Vinti, Esq.
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299

FOR RESPONDENTS MEDTECH PRODUCTS LTD., AND INTELLX, INC.:

Lizbeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW, 5th Floor
Washington, DC 20007-3501

PUBLIC MAILING LIST

Sherry Robinson
LEXIS - NEXIS
8891 Gander Creek Drive
Miamisburg, OH 45342

Ronnita Green
Thomson West
1100 Thirteenth Street NW, Suite 200
Washington, DC 20005

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	
CERTAIN MALE PROPHYLACTIC DEVICES	Investigation No. 337-TA-546

NOTICE OF CLARIFICATION THAT ADMINISTRATIVE LAW JUDGE'S INITIAL DETERMINATION ON REMAND WILL NOT BECOME COMMISSION'S FINAL DETERMINATION IF NO REVIEW IS ORDERED WITHIN FORTY-FIVE DAYS OF ITS ISSUANCE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the initial determination on remand of the presiding administrative law judge ("ALJ") will not become the final determination of the U.S. International Trade Commission if no review is ordered within forty-five (45) days of issuance. Final agency action in the above-captioned investigation will take place on or before the target date, June 21, 2007.

FOR FURTHER INFORMATION CONTACT: Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3116. 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 at *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 August 5, 2005, based on a complaint filed by Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. patent 5,082,004. The respondents named in the investigation are Church & Dwight Co., Inc., of

Princeton, New Jersey; Reddy Medtech, Ltd., of Tamil Nadu, India; and Intellx, Inc., of Petoskey, Michigan.

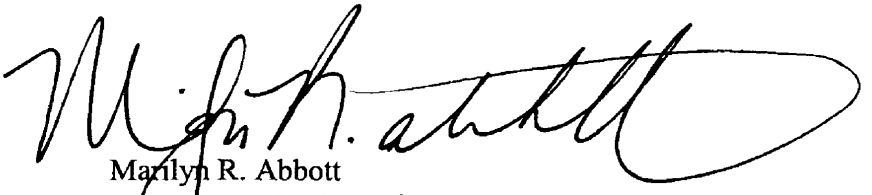
On June 30, 2006, the ALJ issued a final initial determination in which he ruled that there is no violation of section 337. On September 29, 2006, the Commission determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). On December 5, 2006, the Commission determined to affirm in part, reverse in part, and remand in part. The Commission also determined to extend the target date for completion of the investigation until June 5, 2007, and requested issuance of the ALJ's initial determination on remand ("IDR") by March 5, 2007.

On February 28, 2007, the ALJ issued an initial determination extending the deadline for issuance of the IDR to March 21, 2007, and extending the target date to June 21, 2007. The Commission determined not to review this initial determination.

On March 19, 2007, the ALJ issued the IDR, in which he indicated that the IDR will become the determination of the Commission unless the Commission orders review within 45 days. IDR at 78, citing Commission rules 210.43-.44. The Commission, however, has set no deadline, by notice or rule, by which the IDR will become the Commission's determination absent action prior to the target date of June 21, 2007. This notice is issued to clarify that the IDR will not become the Commission's determination unless so acted upon by the Commission, and that final agency action will take place on or before June 21, 2007.

The authority for this notice is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

By order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

Issued: April 16, 2007

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF CLARIFICATION THAT ADMINISTRATIVE LAW JUDGE'S INITIAL DETERMINATION ON REMAND WILL NOT BECOME COMMISSION'S FINAL DETERMINATION IF NO REVIEW IS ORDERED WITHING FORTY-FIVE DAYS OF ITS ISSUANCE** has been served upon all parties and Commission Investigative Attorney, Rett Snotherly, Esq. via first class mail and air mail where necessary on April 17, 2007.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor
New York, NY 10281

ON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

James H. Shalek, Esq
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299
P - 212-969-3000
F- 212-969-2900

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of CERTAIN MALE PROPHYLACTIC DEVICES	Investigation No. 337-TA-546

COMMISSION OPINION

On December 5, 2006, the Commission issued its notice of determination to affirm in part, reverse in part, and remand in part the final initial determination ("ID") of the presiding administrative law judge ("ALJ") that found no violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337) in the above-captioned investigation. The Commission also issued an accompanying order that, *inter alia*, extended the target date for completion of the investigation until June 5, 2007. This opinion sets forth the scope of the remand proceeding. The Commission affirms the findings of the ID on any issues under review that the Commission does not reverse, vacate, or remand.

I. BACKGROUND

This investigation was instituted on August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois ("PTI"). 70 *Fed. Reg.* 45422 (Aug. 5, 2005). The complaint, as amended and supplemented, alleged violations of section 337, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004 ("the '004 patent").

The respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey ("C&D"), which imports, markets, and distributes the first of two accused products, the Trojan Twisted Pleasure prophylactic ("Twisted Pleasure"); Reddy Medtech, Ltd., of Tamil Nadu, India ("Medtech"), which manufactures both accused products; and Intellx, Inc., of Petoskey, Michigan ("Intellx"), which imports, markets, and distributes the second accused product, the Inspiral prophylactic ("Inspiral").[1] Complainant sells its patented prophylactics under the name "Pleasure Plus."

On June 30, 2006, the ALJ issued his final ID, in which he ruled that the Twisted Pleasure infringes claims 1, 13, 18, and 31 of the '004 patent, and that the Inspiral infringes claims 1, 6, 9, 22, 25, and 31 of the '004 patent. He further ruled that claims 1, 6, and 9 of the '004 patent are invalid as anticipated by U.K. Patent No. 1,252,255. He also found that PTI practiced the '004 patent and therefore met the technical prong of the domestic industry requirement. However, because he determined that PTI failed to meet its burden of proving the existence of a domestic industry under the so-called economic prong of the domestic industry requirement, he concluded that, notwithstanding the infringement of certain valid claims of the '004 patent, there is no violation of section 337 because there is no domestic industry practicing the '004 patent.

All parties, including the Commission investigative attorney ("IA"), filed petitions for

---

[1] The inventor of the '004 patent is Dr. Reddy, the founder of Respondent Medtech and its current chairman and managing director. One of Dr. Reddy's former companies, Reddy Laboratories International, Ltd. ("RLIL"), owned the '004 patent. The '004 patent and other property of RLIL were purchased in 1998 by Complainant in RLIL's involuntary bankruptcy proceeding.

review, and responses to each other's petitions.

On September 29, 2006, the Commission determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry, and requested briefing on these issues. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). The Commission noted that it was particularly interested in briefing on the following five sub-issues: (1) the proper treatment of functional limitations in the asserted claims of the '004 patent; (2) whether the use of "theoretical constructs" to construe claim terms is appropriate, including whether the use of theoretical constructs to interpret claims would raise any issues under 35 U.S.C. § 112, second paragraph; (3) the effect that the parties' proposed claim constructions may have on the resolution of issues concerning anticipation, infringement, and the technical prong of the domestic industry; (4) whether the ID properly applied Commission precedent to determine that complainant had not met the economic prong of the domestic industry requirement; and (5) whether the ID gave appropriate weight to the evidence complainant proffered to prove that a domestic industry exists under the economic prong. The Commission also requested that the parties include responses to the following four question in their submissions:

1. Whether the ID's construction of "elongated tubular portion" to consist of both a physical tube-like structure and a theoretical tube-like structure improperly reads out of the claims the limitation that the "tubular portion" be "formed of thin membrane."

2. Whether a finding that the preferred embodiment depicted in Figure 10 of the '004 patent is not covered by any of the patent claims, as argued by Respondents, is permissible given the Federal Circuit's statement that a claim interpretation that altogether excludes a preferred embodiment from practicing any claims of the patent is "rarely, if ever, correct." *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364, 1374 (Fed. Cir. 2005) (internal quotes omitted).

3. Whether the ID, in finding no infringement of claims 22 or 25, took into consideration all the undisputed evidence in the record regarding the thickness of the Twisted Pleasure.

4. Whether the undisputed evidence in the record (whether or not credited by the ALJ), in addition to the facts found by the ALJ that go to the existence of a domestic industry, are sufficient to support a finding that Complainant satisfied the economic prong of the domestic industry requirement.

Complainant, Respondents, and the IA filed their initial submissions on October 16, 2006, and reply submissions on October 23, 2006.[2]

II. DISCUSSION

A. Claim Construction

Claim construction involves consideration of the claims themselves, the specification, and, if in evidence, the prosecution history of the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1317 (Fed. Cir. 2005) (*en banc*); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 2004) (*en banc*); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The claim language selected by the patentee defines the scope of the claim. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*en banc*). In addition to carefully considering the language of the claims, the written description must be considered to inform the proper construction of the claims, and to determine if the inventor acted as his own lexicographer and ascribed a special definition to particular terms. *Phillips*, 415 F.3d at 1316; *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d

---

[2] Medtech and Intellx joined in C&D's submissions in response to the notice to review and filed a separate memorandum only to address the question of infringement by the Inspiral product. When addressing the main arguments advanced in C&D's submissions in response to the notice to review, we therefore refer to "Respondents'" arguments.

1335, 1344 (Fed. Cir. 1998). If he did not, the ordinary meaning of the claim language to one skilled in the art controls. *Digital*, 149 F.3d at 1344; *Elekta Instrument S.A. v. O.U.R. Scientific Int'l*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take their ordinary meaning."). The prosecution history may aid claim construction, including by shedding light on the inventor's understanding of the language and whether he limited the invention during prosecution. *Phillips*, 415 F.3d at 1317. Extrinsic evidence, such as dictionaries, treatises, and inventor and expert testimony, may also inform claim construction, although it is "less significant" than the intrinsic record in determining the meaning of claim language. *Id.* (internal quotes omitted).

1. Functional Limitations

The ALJ held that the proper construction of apparatus claims requires reading functional language out of the claim language. *See, e.g.*, ID at 40-41. Therefore, he did not construe, much less apply to his analysis of the merits of the complaint, certain language appearing in independent claim 1, dependent claim 9, and independent claim 18. In his construction of claim 1, he found that the statement providing a second pouch "for movement; back and forth thereon during coitus for providing stimulation thereto" was functional and therefore not a limitation of the claim. ID at 40-41, 87. With respect to claim 9, he found that the statement "to provide hydrodynamic rubbing of the glans penis" was functional and therefore not a limitation of claim. ID at 89. Finally, with respect to claim 18, he did not consider the language "maintaining said constant diameter throughout the length of the tubular portion," "to resist stretching of said tubular portion," and "thereby maintain the shape of said second pouches," because the language

was functional and therefore, according to the ALJ, "immaterial." ID at 60.

Complainant, Respondents, and the IA are united in contending that the ALJ engaged in legal error in disregarding functionally-oriented limitations of claims 1, 9, and 18 of the '004 patent. The ALJ's approach is at odds with the law on claim construction. "A patent applicant is free to recite features of an apparatus either structurally or functionally. *See In re Swinehart*, 58 C.C.P.A. 1027, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) ('[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.')." *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997).

These and other authorities establish that, at least since 1971, there is no *per se* rule of claim construction prohibiting the use of functional language in claims, including in apparatus claims. *See, e.g., Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1374 (Fed. Cir. 2003) (noting that "every use of the term in the asserted claims includes additional adjectival qualifications further identifying sufficient structure to perform the claimed functions to one of ordinary skill in the art"); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1997) (functional language following a structural limitation did not define the structural limitation but, rather, was "an additional limitation in the claim. *See, e.g., Wright Medical Technology, Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443-44, 43 USPQ2d 1837, 1840 (Fed. Cir. 1997) (functional language analyzed as a claim limitation)."); *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1581 (Fed. Cir. 1988) ("the reduction of pain through the transmission of a low current density to the skin is intended to be a functional limitation on the nonmetallic members"). We do not read the cases cited by the ALJ to the contrary. Moreover, neither the ALJ nor the parties

suggest that the functional language used in the '004 patent is unduly broad or vague.

We determine that the ALJ erroneously declined to construe the functional claim limitations in claims 1, 9, and 18. As a result, the ID ran afoul of the "all elements" rule that "every limitation of the patent claim must be found in the accused device." *ZMI Corp.*, 844 F.2d at 1578. Respondents contend that proper consideration of these limitations should result in findings of non-infringement, while Complainant and the IA contend that such consideration should result in finding that no claims are anticipated by prior art. We do not reach these questions here. The investigation warrants a remand to the ALJ in the first instance to construe the claims in light of these limitations and to apply these constructions in his analyses of infringement, patent validity, and the technical prong of the domestic industry requirement.

2. "Theoretical" Constructs

The ALJ employed "theoretical" constructs in four of his claim interpretations. First, he construed "elongated tubular portion" (all asserted claims) to mean "the portion of the prophylactic pouch that is tubular in shape and generally resembles a traditional prophylactic and which does not include any of the pouch or pouches that are the crux of the invention (*i.e.*, the second pouch(es))." He added that "the tubular portion consists of both the physical tube-like structure and the theoretical tube-like structure beneath the pouch or pouches that are the crux of the invention (*i.e.*, the second pouch(es))." ID at 23-24.

Second, he construed "circumference" (all asserted claims) to mean the "external surface of an object" with the clarification that the surface "includes both the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or

pouches that are the crux of the invention (*i.e.*, the second pouch(es))." ID at 26.

Third, he construed "generally constant diameter from the open end to the closed end" (all asserted claims) to require "the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant." He added that the diameter includes the "physical diameter of the tubular portion and the theoretical diameter of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (*i.e.*, the second pouch(es))." ID at 28-29.

Finally, he construed "longitudinally directed chamber" (claims 1-4, 8-9, 13, 15-16, 18, 31-32, and 36) to mean the "enclosed space or compartment formed by the tubular portion into which the penis inserted." He added that the "closed space or chamber includes the area formed by the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention." ID at 31.

The parties are in accord on one aspect of the ID's use of theoretical constructs, that is, that defining "elongated tubular portion" to include theoretical structure is incorrect. We agree. The problem with the ID's construction is that the claims otherwise require "said tubular portion being formed of a thin membrane material," *see, e.g.*, '004 Patent (JX-1) at 7:16-17, which indicates that the tubular portion consists of actual physical material and thus does not include the theoretical continuance of the tubular shape in areas underlying the secondary pouches.

Elongated Tubular Portion

We construe "elongated tubular portion" to mean "the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular in shape,"

a construction that is similar to that proposed by the IA and Complainant. This interpretation gives meaning to the limitation that the tubular portion be formed of thin membrane, and eliminates the "theoretical" construct. Courts have not resorted to "theoretical" constructs as a method of claim construction; we decline to do so here, hewing to basic principles that claims are to be construed based on the claim language, specification, and file history (if in evidence). *See Vitronics Corp.*, 90 F.3d at 1582.

Reading the phrase in this manner is consistent with the fact that "elongated tubular portion" is tied to the description of "first pouch," and the "first pouch" is used to distinguish those portions of the condom that are not secondary pouches. *See, e.g.*, JX-1 at 7:13 & 7:21 (distinguishing the first and second pouches). This interpretation is also consistent with the provisions of the specification that the "tubular portion" be of sufficient strength to prevent rupture of the condom during use and of a sufficient close fit to prevent accidental dislodging of the condom during use. JX-1 at 1:17-20, 3:63-66. The specification also suggests that the tapered portion of the condom closest to the reservoir tip should be considered part of the tubular portion, JX-1 at 4:21-23 & Figure 6, which is consistent with this construction.[3] We find nothing in the prosecution history that suggests that a different interpretation of "elongated tubular portion" is warranted.

---

[3] Moreover, the ALJ found this approach reasonable, but declined to adopt it because the specific construct proposed below referred to "the remaining portions of a condom that are not identified as second pouches and are tubular in shape," and the ALJ was concerned that "second pouches" did not adequately cover "third" or "plural" pouches. ID at 22-23. The construction we adopt eliminates any such concern.

This construction also eliminates reference to the second pouches as constituting the "crux of the invention." "Crux of the invention" is similar to the phraseology "heart of the invention," which patent law generally looks upon with disfavor. *See, e.g., Aro Mfg. Co., Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336, 345 (1961) ("[it] is well settled that there is no legally recognizable or protected 'essential' element, gist or 'heart' of the invention in a combination patent."); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir.1991) (Rather, "'[t]he invention' is defined by the claims."). Use of the expression here does not contribute to the understanding of the claims.

Circumference

The ID construes "circumference" to mean "the external surface of an object" with the clarification that the surface "includes both the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es))." ID at 24-26. Consistent with the construction of elongated tubular portion above, we do not adopt the ALJ's "clarification," but otherwise affirm the definition, which refers to the external surface of the tubular portion of the condom. The term circumference is generally used in the context of the "first pouch," which, as noted above, is distinct from the second pouch.[4] The ALJ properly found that various provisions in the specification teach that there can be interruptions in the circumference of the first pouch, at which points there is no material forming a "circumference." For example, claim 6, which

[4] The ID notes that in independent claim 20, circumference refers to the "elongated tubular portion," but finds that "elongated tubular portion" and "first pouch" are synonymous. ID at 24.

depends from claim 1, describes a "second pouch being formed completely around the circumference to produce an annular pocket. . . ." JX-1 at 7:49-50. The term is thus used to describe where the second pouch is formed ("around the circumference"), but does not conflate to mean, at this location, the circumference of the condom including the second pouch.

Respondents concede that the circumference may be interrupted by material forming the second pouch, provided that enough of the physical structure of the tubular portion exists to maintain the shape of the tube and the shape of the second pouches all the way to the closed end. The ID properly found nothing in the language of the claims or specification that requires this construction of circumference.

Generally Constant Diameter From The Open End To The Closed End

The ALJ construed "generally constant diameter from the open end to the closed end" as "requiring the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant." ID at 28-29. We find no error in this quoted language and, as discussed further below, believe that the ALJ properly relied upon Figure 10 in his claim construction. Consistent with the construction of elongated tubular portion above, we do not adopt the ALJ's "clarification" that the diameter "includes both the physical diameter of the tubular portion and the theoretical diameter of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es))," but otherwise affirm the definition. The claim language, we note, merely requires a generally constant diameter in those lengths in which the tubular portion is present.

The ALJ correctly noted that this construction of "generally constant diameter from the

open end to the closed end" comports with embodiments that plainly show that the tubular portion need not continue uninterrupted from open end to closed end, *see, e.g.*, Figures 4 and 10, and further that the tubular portion need not necessarily be present at the closed end to provide, as Respondents proposed, sufficient physical structure to grip the penis to retain the physical shape of the second pouches. *See, e.g.*, Figure 10. The ID also recognizes that, per the specification, the circumference of the tubular portion, and thus its diameter, can vary. ID at 26-27.

Respondents argue that the prosecution history supports its proposed construction that there must exist sufficient material to grip the penis at the closed end of the condom so as to retain the shape of the second pouches. They note that in rejecting the claims as originally written as unpatentable over two prior art Haines Patents (U.S. Patent No. 4,852,586 in view of U.S. Patent No. 4,977,903), the Examiner did not cite Figure 9 of the Haines '586 patent, the only figure that shows a so-called baggy-end type condom. They claim that this omission establishes that no part of an elongated tubular portion having a generally constant diameter from open end to the closed end can have, as the baggy-end type condom does, a variance in diameter sufficient to allow it to slide along the surface of the penis.

Respondents' argument about drawing inferences from the Examiner's omission of a reference to Figure 9 in the Haines '586 patent is unpersuasive. This is the first time in the investigation that Respondents make this particular argument, and it requires assuming that the omission was intentional and for the reasons Respondents state. Respondents' argument appears speculative at best, and places undue emphasis on the Examiner's intent in analyzing claim scope

and prosecution history. *Cf.* Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1124 (Fed. Cir. 2004) ("It is well settled, however, that it is the applicant, not the examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims"). Respondents' claim construction is not consistent with the claims or specification, and improperly excludes the embodiment depicted in Figure 10 of the '004 patent.

Longitudinally Directed Chamber

The ID construed "longitudinally directed chamber" as "the enclosed space or compartment formed by the tubular portion into which the penis is inserted," with the clarification that the enclosed space or compartment includes "both the area formed by the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention." ID at 31.

The terms "longitudinally directed chamber" describe structural and nonstructural aspects of the patented condom. For example, claim 1 provides that the "second pouch having an interior space . . . [is] communicating . . . directly with said longitudinally directed chamber." The interior space of the second pouch thus is not part of the space defined by the longitudinally directed chamber, but rather separate space that "communicates" with the space of the longitudinally directed chamber. The ID relied upon a portion of the specification providing that "the pouch 20 has an entrance opening 20a through which the chamber 17 is communicated with an interior space 20b of the pouch 20." ID at 30, *citing* JX-1 at 4:2-5, Figures 1-3. The ID correctly notes that it "can be readily seen from Figures 1-3 that there is no physical surface or boundary in the area that lies directly beneath the entrance opening 20a and yet the patentee still

refers to this area as the chamber 17." ID at 30. Chamber 17 in Figure 1 corresponds with the surface of the penis. In describing Figures 1 and 2, the specification further provides that "the pouch 12 has a diameter which will closely fit *on the outer surface of a penis* whose glans penis will be located within the pouch in spaced relationship to the closed end 16 to define a longitudinally directed chamber." JX-1 at 3:55-60 (emphasis supplied).

The claims and specification therefore indicate that the longitudinally directed chamber corresponds with the surface of the penis, not necessarily the surface of the patented condom. It is the interior space of the condom defined by the penis; where there is a second pouch, the outermost limits of this chamber do not coincide with the latex walls but rather the chamber continues its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom.

We find that construing "longitudinally directed chamber" to include structural and nonstructural aspects of the patented condom does not run afoul of the definiteness requirement. The requirement is derived from 35 U.S.C. § 112, ¶ 2, which provides: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." In practice, definiteness requires consideration of whether "one skilled in the art would understand the bounds of the claim when read in light of the specification . . . ." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In *Exxon*, the Court further stated that, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid

invalidity on indefiniteness grounds." *Id.*

The phrase "longitudinally directed chamber" is clearly defined because it is tied to the elongated tubular portion of the condom and simply extends this cylinder shape in regions below where the second pouch is present. The specification, as noted above, also provides clear examples of where the longitudinally directed chamber is located.

In sum, we construe the terms "longitudinally directed chamber" as the enclosed space or compartment into which the penis is inserted, and note that, where there are second pouches, the outermost limits of the longitudinally directed chamber will not coincide with the latex walls but rather the chamber will continue its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom.

3. Figure 10 Of The '004 Patent

Figure 10 was relied upon by the ALJ and the parties in understanding the use of certain disputed claim terms, including the generally constant diameter limitation of claim 1. The ID expressly rejected Respondents' proposed claim construction regarding "generally constant diameter" because it impermissibly read out a preferred embodiment of the invention. ID at 28, *citing Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F. 3d 1364 (Fed. Cir. 2005). *Pfizer* provides that a claim interpretation that altogether excludes a preferred embodiment from practicing any claims of the patent is "rarely, if ever, correct." *Id.* at 1374 (internal quotes omitted).

Respondents point out that embodiments disclosed in the patent specification that are not actually claimed are not covered. *See, e.g., Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1359

(Fed. Cir. 2006); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F. 3d 1316, 1326 (Fed. Cir. 2001); *Oak Tech, Inc. v. Int'l Trade Comm'n*, 248 F.3d 1316, 1329 (Fed. Cir. 2001). Indeed, the Federal Circuit has recognized that where the intrinsic evidence illustrates that the claim does not cover the embodiment, the claim need not be arbitrarily construed to do so. *See Elekta Instrument S.A. v. O.U.R. Scientific Int'l*, 214 F.3d 1302, 1308 (Fed. Cir. 2000). The problem for Respondents in this case is that it takes a strained reading of the claims to conclude that Figure 10 is properly excluded from the scope of the claims, precisely the opposite of the heightened level of persuasion for exclusion that the canon of claim construction referred to in *Pfizer* requires. Thus, even if this canon of construction did not apply – and we think it does because Figure 10's placement under the subheading "preferred embodiments" suggests that it is, indeed, a "preferred" embodiment – Respondents' interpretation is without support.

The specification states that Figure 10 is a "single pouch embodiment of the present invention." JX-1 at 3:42-43. The specification describes Figure 10 to include "a condom 70 having a tubular portion 72 with a single pouch 74 formed on the end thereof with a length to overlie and provide looseness at the outer surface of a glans penis." JX-1 at 6:28-31. The specification therefore does not use terminology such as "pouch on pouch" or "pouches" in referring to Figure 10 as it does in the descriptions of other embodiments. The independent claims of the patents all refer to a second pouch. However, a reasonable reading of the specification is that the referenced tubular portion equates to the first pouch and the referenced "single pouch" equates to a single second pouch on the closed end. This interpretation is supported by the claims. For example, claim 8, which depends from claim 1, adds the following

limitations to claim 1: "The prophylactic pouch of claim 1 characterized by said second pouch being formed as a *single pouch on the closed end* to overlie the glans penis and providing looseness between the prophylactic pouch and a penis only at the glans portion thereof." JX-1 at 7:54-58 (emphasis supplied). This language, as Complainant points out, closely parallels the description of Figure 10. Nor is there any evidence in the prosecution history to suggest that this embodiment was disclaimed by the inventor during prosecution.

Figure 10, which was submitted twice during prosecution (before and after amendments to claim and specification language, JX-4 at 46, 51 & 125), is a two-pouch embodiment comprised of the tubular portion as the first pouch and the single pouch formed at the distal end as the second. Respondents' interpretation to exclude it altogether from coverage by any claim of the '004 patent was properly rejected by the ALJ.

4. Other Claim Construction

Except as discussed above, we adopt the claim constructions set forth in the ID.

B. Infringement

Once the claims at issue have been properly construed, they are compared to the allegedly infringing device in order to determine infringement. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (*en banc*). Comparison of a claim to an accused device is a question of fact that requires that the patent holder establish that the accused device includes every claim limitation or its equivalent. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., Inc.*, 520 U.S. 17, 29 (1997).

This investigation warrants a remand on the issue of infringement to determine whether

the accused products read on all limitations of the asserted claims, including the functional limitations that the ALJ did not construe or apply in his original analysis and the revised constructions of claim terms that the Commission provides above.

In connection with the remand on infringement, the ALJ should also consider whether, based on all of the record evidence, Complainant has demonstrated as a matter of fact that the thickness of the Twisted Pleasure is 0.11 mm ± 0.04 mm, thus reading on the thickness limitation of claims 22 and 25. Complainant and the IA sought review of the ALJ's finding that the thickness limitation was not met, claiming clear error. They have demonstrated to our satisfaction that the ALJ did not take into account all of the evidence that was introduced on this point, including measurements in JX-34 and additional trial testimony and exhibits that they claim were undisputed. Respondents concede that the ALJ did not take into consideration all of the evidence, but claim the failure was of the Complainant's making, due to citation failures in its post-hearing brief. The IA and Complainant counter that C&D raised the issue in a prejudicial manner, not including it in the Joint Narrative Statement of the Issues filed by the parties, or in its pre- or post-hearing briefs, instead waiting to argue a lack of proof as to this element in the post-hearing reply brief, to which they had no right of rebuttal.

While the burden of proving its infringement case rested on the Complainant at all times, fairness warrants a remand for further consideration under the unique circumstances presented, particularly insofar as the parties are agreed that record evidence regarding the thickness limitation was not taken into consideration below, and it appears that it did not receive attention because the Complainant and IA were not properly put on notice that this was a contested issue

and never had the opportunity to proffer a rebuttal with evidence that was properly in the record.

C. Anticipation

The ALJ determined that claims 1, 6, and 9 of the '004 patent are invalid as anticipated by U.K. Patent No. 1,252,255 ("the '255 patent"), and that claims 2-4, 8, 15-16, 18, 22, 25, 31-32, and 36 of the '004 patent are not invalid. Similar to our finding respecting infringement, the ALJ is directed to revisit the issue of anticipation in light of his new claim constructions in light of the functional limitations and the revised claim constructions set forth above.

D. Domestic Industry Requirement

As a prerequisite to finding a violation of section 337, Complainant must establish that "an industry in the United States, relating to the articles protected by the [intellectual property right] ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Typically, the domestic industry requirement of section 337 is viewed as consisting of two prongs: the technical prong and the economic prong. *See, e.g., Certain Variable Speed Wind Turbines and Components Thereof,* Inv. No. 337-TA-376, Comm'n Op. at 14-17 (1996). The technical prong concerns whether the complainant (or its licensee) practices at least one claim of the asserted patents (the claim practiced need not be one asserted in the investigation). The economic prong concerns domestic activities with respect to the patent or patented article. To satisfy the economic prong, these activities must involve:

> (1) significant investment in plant and equipment;
>
> (2) significant employment of labor or capital; or
>
> (3) substantial investment in exploitation of the patent, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

1. Technical Prong

The ALJ found that Complainant's Pleasure Plus practices claims 1-4, 9, 22, 25, and 31 of the '004 patent. He therefore found that the Complainant met its burden of proof with respect to the technical prong of the domestic industry requirement. ID at 93-101. Similar to our findings respecting infringement and anticipation, the ALJ is directed to revisit the issue of the technical prong of the domestic industry requirement in light of his new claim constructions in light of the functional limitations and the revised claim constructions set forth above.

2. Economic Prong

The ALJ found that Complainant failed to demonstrate that it was a domestic industry under the economic prong of the domestic industry requirement. Complainant and the IA petitioned for review on this issue and, as noted above, the Commission determined to review the ID on this basis. The parties have fully briefed the issue in connection with this review proceeding. We determine that the ALJ's finding against Complainant is not supported by proper application of the statute or Commission precedent, or the record in this case, and reverse his finding. Complainant has demonstrated that it is a domestic industry under the economic prong of the requirement. The final Commission opinion in this investigation will, regardless of the outcome on the merits, set forth the reasoning supporting our determination to reverse the ALJ on the issue of the economic prong of the domestic industry requirement.

* * *

In remanding this investigation to the ALJ, we render no opinion on the merits of the

issues of infringement, anticipation, or the technical prong of the domestic industry requirement. We defer making final judgment on any aspect of those issues, or on any potential issues relating to remedy, public interest, and bonding, until after the ALJ issues his initial determination on remand.

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: April 3, 2007

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **COMMISSION OPINION** has been served upon the Commission Investigative Attorney, Rett Snotherly, Esq. and all parites via first class mail and air mail where necessary on April 4, 2007.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor
New York, NY 10281

ON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

James H. Shalek, Esq
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299
P - 212-969-3000
F- 212-969-2900

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN MALE PROPHYLACTIC DEVICES	)	Inv. No. 337-TA-546

NOTICE OF COMMISSION DETERMINATION TO AFFIRM IN PART, REVERSE IN PART, AND REMAND IN PART THE INITIAL DETERMINATION FINDING NO VIOLATION OF SECTION 337, AND TO EXTEND THE TARGET DATE FOR COMPLETION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm in part, reverse in part, and remand in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on June 30, 2006, in the above-captioned investigation. The Commission has also determined to extend the target date for completion of the investigation until June 5, 2007.

FOR FURTHER INFORMATION CONTACT: Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3116. The public version of the ALJ's final ID and all other nonconfidential 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-ON-LINE) 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 August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004 ("the '004 patent"). The respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey; Reddy Medtech, Ltd., of Tamil Nadu, India; and Intellx, Inc., of Petoskey, Michigan.

On June 30, 2006, the ALJ issued a final ID in which he ruled that there is no violation of section 337 of the Tariff Act of 1930, as amended. All parties petitioned for review of various parts of the final ID.

On September 29, 2006, the Commission determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry, and requested briefing on these issues. 71 *Fed. Reg.* 58875 (Oct. 5, 2006). The Commission noted that it was particularly interested in briefing on the following five sub-issues: (1) the proper treatment of functional limitations in the asserted claims of the '004 patent; (2) whether the use of "theoretical constructs" to construe claim terms is appropriate, including whether the use of

theoretical constructs to interpret claims would raise any issues under 35 U.S.C. § 112, second paragraph; (3) the effect that the parties' proposed claim constructions may have on the resolution of issues concerning anticipation, infringement, and the technical prong of the domestic industry; (4) whether the ID properly applied Commission precedent to determine that complainant had not met the economic prong of the domestic industry requirement; and (5) whether the ID gave appropriate weight to the evidence complainant proffered to prove that a domestic industry exists under the economic prong. In order to assist the Commission in its review, the Commission also requested that the parties include responses to several briefing questions in their submissions. Id.

Complainant, Respondents, and the investigative attorney filed their initial submissions on October 16, 2006. They filed their reply submissions on October 23, 2006.

Having examined the record in this investigation, including the ALJ's final ID and the submissions of the parties, the Commission has determined that (1) the ALJ's finding that the functional limitations in claims 1, 9, and 18 are not actual claim limitations is reversed and the matter is remanded to the ALJ to construe the claims in light of these limitations; (2) the ALJ's construction of the claim phrase "elongated tubular portion" is reversed and the construction to be applied is "the remaining portions of the condom that are not identified as one or more second pouches (or a third pouch) and are tubular in shape;" (3) the ALJ's construction of "generally constant diameter from the open end to the closed end" is amended by deleting the ALJ's clarification that the diameter "includes both a physical diameter of the tubular portion and the theoretical diameter of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es));" (4) the ALJ's construction of "circumference" is

amended by deleting the ALJ's clarification that the circumference "includes both a physical diameter of the tubular portion and the theoretical diameter of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es));" (5) the ALJ's construction of "longitudinally directed chamber" is reversed and the construction to be applied is "the enclosed space or compartment into which the penis is inserted. In regions where a second pouch exists, the outermost limits of the longitudinally directed chamber do not coincide with the latex walls but rather the chamber continues its generally straight tube shape until the chamber sharply tapers and closes at the closed end of the condom;" (6) the ALJ's finding that Figure 10 of the '004 patent is covered by the patent is affirmed; (7) the issues of anticipation, infringement, and the technical prong of the domestic industry requirement are vacated and remanded to the ALJ for reconsideration in light of his new claim constructions for the subject functional limitations and the revised claim constructions set forth above; (8) the ALJ is to reconsider the finding of non-infringement as to claims 22 and 25 taking into consideration all of the record evidence regarding the thickness limitation; (9) the ALJ's finding that Complainant has not demonstrated the economic prong of the domestic industry requirement is reversed; (10) the investigation is remanded to the ALJ to conduct further proceedings in accordance with this Order and the Commission's opinion, and to issue an initial determination on remand ("IDR") by March 5, 2007; (11) any findings of the ALJ that are not reversed, vacated, or remanded by this Order are affirmed; (12) the parties may file petitions for review of the ALJ's IDR within five business days after service of the IDR and to file responses to any petitions within five business days after service of the petitions; and (13) the target date for termination of the investigation is hereby extended to June 5, 2007.

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 sections 210.45 and 210.51 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.45, 210.51).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: December 5, 2006

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION TO AFFIRM IN PART, REVERSE IN PART, AND REMAND IN PART THE INITIAL DETERMINATION FINDING NO VIOLATION OF SECTION 337, AND TO EXTEND THE TARGET DATE FRO COMPLETION OF THE INVESTIGATION** has been served on upon all parties and Commission Investigative Attorney, Rett Snotherly, Esq. via first class mail and air mail where necessary on December 7, 2006.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor
New York, NY 10281

ON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

James H. Shalek, Esq
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299
P - 212-969-3000
F- 212-969-2900

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN MALE PROPHYLACTIC DEVICES	)	Inv. No. 337-TA-546

NOTICE OF COMMISSION DETERMINATION TO REVIEW A FINAL INITIAL DETERMINATION IN PART; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on June 30, 2006, in the above-captioned investigation. The Commission has also determined to extend the target date for completion of the investigation until December 5, 2006.

FOR FURTHER INFORMATION CONTACT: Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3116. The public version of the ALJ's final ID and all other nonconfidential 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-ON-LINE) 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: This investigation was instituted on August 5, 2005, based on a complaint filed on behalf of Portfolio Technologies, Inc., of Chicago, Illinois. 70 *Fed. Reg.* 45422. The complaint, as amended and supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain male prophylactic devices by reason of infringement of claims 1-27, 31-33, and 36 of U.S. Patent No. 5,082,004 ("the '004 patent"). The respondents named in the investigation are Church & Dwight Co., Inc., of Princeton, New Jersey; Reddy Medtech, Ltd., of Tamil Nadu, India; and

Intellx, Inc., of Petoskey, Michigan.

On June 30, 2006, the ALJ issued a final ID in which he ruled that there is no violation of section 337 of the Tariff Act of 1930, as amended. All parties have petitioned for review of various parts of the final ID.

Having examined the record in this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the issues of claim construction, invalidity due to anticipation, infringement, and domestic industry.

On review, the Commission requests briefing on these issues based on the evidentiary record. The Commission is particularly interested in briefing on the following subissues: (1) the proper treatment of functional limitations in the asserted claims of the '004 patent, (2) whether the use of "theoretical constructs" to construe claim terms is appropriate, including whether the use of theoretical constructs to interpret claims would raise any issues under 35 U.S.C. § 112, second paragraph; (3) the effect that the parties' proposed claim constructions may have on the resolution of issues concerning anticipation, infringement, and the technical prong of the domestic industry; (4) whether the ID properly applied Commission precedent to determine that complainant had not met the economic prong of the domestic industry requirement; and (5) whether the ID gave appropriate weight to the evidence complainant proffered to prove that a domestic industry exists under the economic prong. The Commission also requests that the parties include responses to the following question in their submissions:

1. Whether the ID's construction of "elongated tubular portion" to consist of both a physical tube-like structure and a theoretical tube-like structure improperly reads out of the claims the limitation that the "tubular portion" be "formed of thin membrane."

2. Whether a finding that the preferred embodiment depicted in Figure 10 of the '004 patent is not covered by any of the patent claims, as argued by Respondents, is permissible given the Federal Circuit's statement that a claim interpretation that altogether excludes a preferred embodiment from practicing any claims of the patent is "rarely, if ever, correct." Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F. 3d 1364, 1374 (Fed. Cir. 2005) (internal quotes omitted).

3. Whether the ID, in finding no infringement of claims 22 or 25, took into consideration all the undisputed evidence in the record regarding the thickness of the Twisted Pleasure.

4. Whether the undisputed evidence in the record (whether or not credited by the ALJ), in addition to the facts found by the ALJ that go to the existence of a domestic industry, are sufficient to support a finding that Complainant satisfied the economic prong of the domestic industry requirement.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more 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 likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

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 President has 60 days to approve or disapprove the Commission's action. 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.

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. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the June 30, 2006, recommended determination by the ALJ 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 further requested to provide the expiration date of the '004 patent and state the HTSUS number under which the accused articles are imported. The written submissions and proposed remedial orders must be filed no later than close of business on October 16, 2006. Reply submissions must be filed no later than the close of business on October 23, 2006. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof 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* section 201.6 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

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 sections 210.42-.46 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42-.46).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: September 29, 2006

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION TO REVIEW A FINAL INITIAL DETERMINATION IN PART; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF TARGET DATE** has been served on upon all parties and Commission Investigative Attorney, Rett Snotherly, Esq. via first class mail and air mail where necessary on October 2, 2006.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

ON BEHALF OF COMPLAINANT PORTFOLIO TECHNOLOGIES:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
John M. Sheldon, Esq.
KOZACKY WEITZEL PC
One North LaSalle Street, Suite 3150
Chicago, Illinois 60602
P- 312-696-0900
F-312-696-0905

Richard P. Beem, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604
P-312-201-0011
F-312-201-0022

Kent R. Stevens, Esq.
MORGAN & FINNEGAN LLP
1775 Eye Street, NW – Suite 400
Washington, DC 20006
P-202-857-7887
F-202-857-7929

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN LLP
3 World Financial Center – 20th & 21st Floor
New York, NY 10281

JON BEHALF OF RESPONDENT CHURCH & DWIGHT CO., INC.:

Lewis E. Leibowitz, Esq.
HOGAN & HARTSON LLP
555 -15th Street, NW
Washington, DC 20004-1109
P- 202-637-5600
F- 202-637-5910

ON BEHALF OF RESPONDENT MEDTECH PRODUCTS LTD.:

Lizabeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, NW
5th Floor
Washington, DC 20007-7880
P-202-965-7880
F- 202 965-1729

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before the Honorable Robert L. Barton, Jr.
Administrative Law Judge

In the Matter of **CERTAIN MALE PROPHYLACTIC DEVICES**	**Inv. No. 337-TA-546**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BONDING

(June 30, 2006)

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CDX	Complainant's demonstrative exhibit
CFF	Complainant's proposed finding of fact
CIB	Complainant's initial post-hearing brief
CPX	Complainant's physical exhibit
CRB	Complainant's post-hearing reply brief
CX	Complainant's exhibit
DWS	Direct Witness Statement
JNSI	Joint Narrative Statement of Issues
JPX	Joint Physical Exhibit
JSUMF	Joint Statement of Undisputed Material Facts
JX	Joint Exhibit
PHC Tr.	Pre-Hearing Conference Transcript
RDX	Respondents' demonstrative exhibit
RCDIB	Respondent Church & Dwight's initial post-hearing brief
RMIIB	Respondent Medtech/Intellx's initial post-hearing brief
RCDRB	Respondent Church & Dwight's post-hearing reply brief
RMIRB	Respondent Medtech/Intellx's post-hearing reply brief
RX	Respondents' exhibit
SIB	Staff's initial post-hearing brief
SRB	Staff's post-hearing reply brief
SX	Staff's exhibit
Tr.	Hearing Transcript

I. SUMMARY

Pursuant to the Notice of Investigation, 70 Fed. Reg. 45422-23 (August 5, 2005), and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, 19 C.F.R. § 210.42(a), this is the Administrative Law Judge's Initial and Recommended Determination in the matter of Certain Male Prophylactic Devices, Investigation No. 337-TA-546 ("ID").

Respondent C&D's accused product infringes claims 1, 13, 18 and 31 of U.S. Patent No. 5,082,004. Respondent C&D's accused product does not infringe claims 2-4, 15, 16, 22, 25, 32 and 36 of U.S. Patent No. 5,082,004. Respondents Medtech/Intellx's accused product infringes claims 1, 6, 9, 22, 25, and 31 of U.S. Patent No. 5,082,004. Respondents Medtech/Intellx's accused product does not infringe claims 2-4 and 8 of U.S. Patent No. 5,082,004. I have determined that claims 1, 6, and 9 of U.S. Patent No. 5,082,004 are invalid as anticipated by U.K. Patent No. 1,252,255. Claims 2-4, 8, 13, 15-16, 18, 22, 25, 31-32, and 36 of U.S. Patent No. 5,082,004 are not invalid.

I conclude that no domestic industry exists in the United States that practices U.S. Patent No. 5,082,004. After full consideration of the evidentiary record and the briefs, I conclude that no violation of Section 337 of the Tariff Act of 1930, as amended, has been found in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain male prophylactic devices in connection with claims 1-4, 6, 8-9, 13, 15-16, 22, 25, 31-32, and 36 of United States Patent No. 5,082,004 ("the '004 patent"). Consequently, no remedy or bond is recommended.

II. INTRODUCTION

A. Procedural History

On June 29, 2005, Complainant Portfolio Technology, Inc. ("Complainant" or "PTI") filed its complaint alleging that Respondents Church & Dwight Co., Inc. ("C&D") and Medtech Products, Ltd. ("Medtech") and Intellx, Inc. ("Intellx") (collectively "Medtech/Intellx") products infringed certain claims of the '004 patent. A letter amending and supplementing the Complaint was filed on July 27, 2005. The investigation was instituted on August 5, 2005, by publication of the Notice of Investigation in the Federal Register. 70 Fed. Reg. 45422-23. On August 30, 2005, I issued Order No. 6 setting a 14-month target date with the initial determination on violation due on July 5, 2006.

On November 23, 2005, Complainant filed a motion to amend the Complaint, in which it disclosed for the first time that in 2005 a significant percentage of its Pleasure Plus prophylactics were "second staged" (i.e., lubricated and foiled) in a factory in China owned by a company identified as Guilin Latex Factory ("Guilin"). The Complaint, as instituted, alleged that Guilin only manufactured the latex balloons (a.k.a, "bulk" or "raw" product) for the Pleasure Plus prophylactics. While the original allegations of the Complaint stated that the second stage manufacturing was performed exclusively by Complainant's subcontractor, Global Protection Corporation ("GPC') at its facility in Massachusetts, the motion to amend stated that a significant percentage of the prophylactics received by GPC in 2005 had already been second staged by Guilin in China. On December 7, 2005, I denied Complainant's first motion to amend. On February 10, 2006, Complainant filed a second motion to amend the complaint. I granted the motion to amend on March 1, 2006 in Order No. 19.

On December 9, 2005, I ordered Complainant and Respondents to file pleadings with respect to claim construction. See Order No. 10. Specifically, Complainant was ordered to file a pleading, not later than December 19, 2005, stating, with respect to each claim asserted against a Respondent in the Complaint, Complainant's claim construction of the terms in the claims that are applicable. Id. I stated that the claim construction would be binding on Complainant unless, upon motion and a showing of good cause, it was permitted to modify its claim construction. I also ordered Complainant to identify any support for the claim construction that depended on either intrinsic or extrinsic evidence, and if Complainant relied exclusively on the language of the claims, it should so state. I also ordered Complainant to identify specifically the claims of the '004 patent that Respondents' accused products infringe and how Respondents' products infringe those claims literally and/or under the doctrine of equivalents.

On January 10, 2006, during a pre-hearing conference, I ruled that Complainant had deliberately disobeyed Order No. 10 by failing to construe the claims at issue. PHC Tr. at 62. Because of Complainant's deliberate failure to comply with Order No. 10, I barred Complainant from promulgating any further discovery and precluded Complainant from offering any additional evidence on claim construction that would contradict the construction of the claims Complainant provided in its memorandum response to Order No. 10. Id. On January 25, 2006, Complainant filed a motion to vacate my ruling of January 10, 2006, sanctioning Complainant for deliberately disobeying Order No. 10. I denied Complainant's motion to vacate on February 28, 2006 in Order No. 17. In addition to denying Complainant's motion to vacate, Order No. 17 clarified that the sanctions ruling did not bar "Complainant from making statements or arguments contradicting

Respondents' claim construction if those statements or arguments are consistent with Complainant's claim construction set forth in its response to Order No. 10." Order No. 17 at 4.

On February 21, 2006, Respondent C&D filed a motion for summary determination on the issues of infringement and domestic industry. Also on February 21, 2006, Respondents Medtech/Intellx filed a motion for summary determination on the issues of infringement and domestic industry. On March 15, 2006, I issued Order No. 22 denying Respondents' motions for summary determination of non-infringement and failure to meet the domestic industry requirement because genuine issues of material fact existed. In that order I clarified how to analyze a domestic industry and what evidence was required to prove a domestic industry.

Complainant and Respondents filed their pre-hearing briefs on March 13, 2006. The Commission Investigative Staff ("Staff") filed its pre-hearing brief on March 21, 2006. The final pre-hearing conference was held on March 31, 2006. The evidentiary hearing was held in this investigation from April 3-7, 2006. The parties filed initial post-hearing briefs, proposed findings of fact and conclusions of law, and final exhibit lists on April 27, 2006. The parties filed reply post-hearing briefs, as well as objections and rebuttals to proposed findings of fact on May 5, 2006.

Appearances of the counsel for the parties is set forth in Appendix A. The parties have stipulated as to certain material facts. See Appendix B. Particular stipulated facts that are relevant to this initial determination are cited accordingly.

B. The Parties

Complainant is an Illinois corporation with its headquarters at 55 East Monroe Street, Suite 4200, in Chicago, Illinois. JSUMF ¶ 4. Complainant has a contractual arrangement with one of its shareholders, Global Protection Corp. ("GPC") of Boston, Massachusetts, whereby GPC is

responsible for overseeing the manufacture, sale and distribution of Complainant's Pleasure Plus prophylactics. See id. ¶¶ 36, 43.

Respondent C&D is a Delaware corporation with its principal place of business at 469 North Harrison Street, Princeton, New Jersey. JSUMF ¶ 10. C&D imports, markets and distributes the Trojan Twisted Pleasure prophylactic ("Twisted Pleasure"). Id. ¶ 11.

Respondent Medtech is a corporation organized under the laws of India and has its principal place of business at S-59, 20th Street, Anna Nagar West, Chennai 600 040, Tamil Nadu, India. JSUMF ¶ 6. Medtech's principal is A.V. K. Reddy, the inventor of the patent at issue. Id. ¶ 7. Medtech manufactures both of the accused products, the Inspiral and the Trojan Twisted Pleasure prophylactics in India. Id.

Respondent Intellx is a Michigan corporation with its principal place of business at 5696 U.S. 131 S., P.O. Box 42, Petoskey, Michigan 49770. JSUMF ¶ 8. Intellx imports, markets and distributes the Inspiral prophylactic. Id. ¶ 9.

There are several co-pending actions related to this investigation. In 1999, Complainant filed a patent infringement suit against Medtech, Case No. 99-0889 in the District of New Jersey. JSUMF ¶ 1. In 2004, Complainant filed a patent infringement suit against C&D in the Northern District of Illinois. Id. ¶ 2. That case was transferred to the District of New Jersey, case No. 04-6340. C&D filed a motion for summary judgment of non-infringement which was denied by the district court on February 6, 2006. Id. The district court has stayed the discovery schedule in both cases until after the post-trial briefing of this investigation. Id. ¶ 1-2. In 2005, Complainant filed a patent infringement case against Intellx in the U.S. District Court for the Western District of Michigan, case

No. 05 CV 0159. The Michigan case has been stayed pending the outcome of the New Jersey cases. Id. ¶ 3.

C. Jurisdiction and Importation

Section 337 confers subject matter jurisdiction on the United States International Trade Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation of articles into the United States. 19 U.S.C. § 1337; see Certain Steel Rod Treating Apparatus and Components Thereof, Inv. No. 337-TA-97, Commission Memorandum Opinion, 215 U.S.P.Q. 229, 231 (1981). 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. Id.

1. Subject Matter Jurisdiction

Only importation, and not an unfair act, must be proven to establish subject matter jurisdiction. Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532, 1536 (Fed. Cir. 1990) ("The fact that Amgen was later unable to sustain these allegations is not material to the issue of *jurisdiction.*") (emphasis in original). Respondent C&D admits that its accused product, the Twisted Pleasure prophylactic, is imported for sale into the United States. RCDIB at 12. Respondents Medtech/Intellx concur in the positions set forth by C&D. RMIIB at 4. Because the Respondents have admitted the accused products are imported for sale into the United States, subject matter jurisdiction is established.

2. Personal Jurisdiction

Each Respondent has responded to the complaint and notice of investigation, and fully participated in the investigation. Therefore, Respondents submitted to the personal jurisdiction of

the Commission. See Certain Miniature Hacksaws, Inv. No. 337-TA-237, U.S.I.T.C. Pub. No. 1948, Initial Determination at 4, 1986 WL 379287 (U.S.I.T.C. October 15, 1986) (unreviewed by Commission in relevant part).

3. In Rem Jurisdiction

Respondent C&D contends that because its accused product, the Twisted Pleasure, does not infringe the patent at issue, the Commission lacks in rem jurisdiction to issue an exclusion order or a cease and desist order. RCDIB at 13. Respondents Medtech/Intellx concur in the positions of C&D. RMIIB at 4. Respondents misconstrue what is required for in rem jurisdiction. All that is required for in rem jurisdiction to be established is the presence of the imported property in the United States. Certain Steel Rod Treating Apparatus and Components Thereof, Inv. No. 337-TA-97, Commission Opinion at 4, 11 (presence of res establishes in rem jurisdiction in Section 337 actions). Because the Respondents admit that the accused products are imported for sale into the United States, they acknowledge the presence of the accused products in the United States and, thus, in rem jurisdiction has been established. See RCDIB at 12; RMIIB at 4.

D. The Patent at Issue

The patent at issue in this investigation is U.S. Patent 5,082,004 ("the '004 patent"). The '004 patent was issued from United States application Serial No. 545,905, filed on June 29, 1990, which is a continuation-in-part of United States application Serial No. 526,843, filed on May 22, 1990, which issued as United States Patent No. 5,027,831 on July 2, 1991. JSUMF ¶ 13. The inventor of the '004 patent, Alla V. K. Reddy, assigned all rights, title and interest in the '004 patent (except with respect to right, title and interest in the patent in India) to Reddy Laboratories International, Ltd. ("RLIL") on November 29, 1991. Id. ¶ 14.

E. The Products at Issue

The accused products in this investigation are the Inspiral prophylactic and the Trojan Twisted Pleasure prophylactic. Complaint ¶ 2-3. The Inspiral prophylactic is manufactured by Medtech in India and distributed in the United States by Intellx. JSUMF ¶ 16. The Trojan Twisted Pleasure is manufactured by Medtech in India and distributed in the United States by C&D. Id. ¶ 17. Complainant asserts that the Inspiral prophylactic infringes claims 1-4, 6, 8-9, 22, 25, and 31 of the '004 patent and that the Twisted Pleasure prophylactic infringes claims 1-4, 13, 15-16, 22, 25, 31-32, and 36 of the '004 patent. CIB at 15.

III. STANDARDS OF LAW

A. Claim Construction

Claim construction is a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976-77 (Fed.Cir. 1995), aff'd, 517 U.S. 370 (1996) ("Markman"). In construing claims, "[t]he 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." Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (internal quotations omitted); Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("Phillips"). Typically, claim terms are given their ordinary and customary meaning as understood by one of ordinary skill in the art at the time of the invention. Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed. Cir. 2004). Sometimes, the ordinary meaning of claim terms is readily apparent to laymen and claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. In such cases, "general purpose dictionaries may

be helpful." Id. More often than not, however, disputed claim terms will have a particular meaning in the art. In these cases, the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history, "usually provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of the invention." V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1310 (Fed. Cir. 2004); Phillips, 415 F.3d at 1313.

In analyzing the intrinsic evidence, one starts with an examination of the claim language itself. The claim language can provide "substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. This guidance can come from the context in which a term is used in a claim or, because claim terms are normally used consistently throughout a patent, the usage of a term in one claim versus its usage in other claims. Id. at 1314-15.

Regardless of what information or meaning can be derived from the claims themselves, the claims do not stand alone and "must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 978. A review of the specification may evince a special definition that the patentee has given a claim term that differs from the meaning it would otherwise possess. In such cases, when the patentee acts as his or her own lexicographer, it is the special definition given to the claim term that governs claim construction. Phillips, 415 F.3d at 1316 (citing CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Additionally, a review of the specification may reveal that the patentee has indicated an intention to limit the scope of a claim. In such cases of disclaimer, it is the patentee's intention that governs claim construction. Id. (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and

> intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

While the specification "is the single best guide to the meaning of a disputed term," the prosecution history, if in evidence, should also be considered in determining the proper scope of a claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("Vitronics"); Markman, 52 F.3d at 980. The prosecution history, which is part of the intrinsic record, includes the complete record of the proceedings before the PTO and any prior art cited during the examination of the patent application. Phillips, 415 F.3d at 1317. Typically, the prosecution history is less useful for claim construction purposes than the specification, because it lacks the clarity of the specification. Id.

> Nevertheless, 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.

Id. (citing Vitronics, 90 F.3d at 1582-83). Any interpretation of a claim or claim term that was disclaimed during prosecution of the patent application is excluded during claim construction. Id.

In addition to the intrinsic evidence of record, extrinsic evidence can also aid in claim construction. Phillips, 415 F.3d at 1317. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. (quoting Markman, 52 F.3d at 980). While extrinsic evidence may be useful in claim construction, as a general rule, extrinsic evidence is less significant than the intrinsic record. Id. To

obtain a reliable interpretation of a patent claim, extrinsic evidence should be considered in the context of the intrinsic evidence. Id. at 1319. Overall, extrinsic evidence is most useful in educating the court regarding the field of the invention and helping the court determine what a person of ordinary skill in the art would understand claim terms to mean. Id.

B. Infringement

Determination of patent infringement is a two-step analysis: first, the claims must be properly construed, and second, the properly construed claims must be compared to the infringing device. W.E. Hall Co. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1350 (Fed. Cir. 2004) ("W.E. Hall Co."); Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1367 (Fed. Cir. 2004). The first step, claim construction, is a matter of law, but the second step, comparison of the properly construed claims to the accused product, is a question of fact. W.E. Hall Co., 370 F.3d at 1350. The complainant has the burden of demonstrating infringement by a preponderance of the evidence. See, e.g., Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co., 204 F.3d 1360, 1364 (Fed. Cir. 2000) ("[I]t is axiomatic that the *patentee* bears the burden of proving infringement." (emphasis in original)).

Section 271(a) of title 35 sets forth the requirements for a claim of direct infringement of a patent. "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2000). In order to prove direct infringement, "the patentee must show that the accused device meets each claim limitation, either literally or under the doctrine of equivalents." Liquid Dynamics Corp., 355 F.3d at 1367. An accused device literally infringes a patent claim if it meets every limitation recited in the claim. See Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998)

("any deviation from the claim precludes a finding of literal infringement"), see also Tex. Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1563 (Fed. Cir. 1996) ("To literally infringe, the accused device or process must contain every limitation of the asserted claim."). Where literal infringement is not found, infringement nevertheless can be found under the doctrine of equivalents. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., Inc., 62 F.3d 1512, 1518-1519 (Fed. Cir. 1995), rev'd, 520 U.S. 17 (1997). An accused device is equivalent to the claim element if the differences between the two are insubstantial, or, put another way, if the accused device performs substantially the same function, in substantially the same way, with substantially the same result as the claim element. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997).

C. Validity - Anticipation

A patent is presumed valid. 35 U.S.C. § 282. The party challenging a patent's validity has the burden of overcoming this presumption by clear and convincing evidence. Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1480 (Fed. Cir. 1997) (quoting Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991)). Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001). The invalidity analysis involves two steps: the claim scope is first determined and then the properly construed claim is compared with the prior art to determine whether the claimed invention is anticipated and/or rendered obvious. Id.

A patent may be found invalid as anticipated if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b).

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

A claim is anticipated and therefore invalid when "the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000). To be considered anticipatory, the prior art reference must be enabling and 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)). Further, "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 Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003).

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). This "domestic industry requirement" has an "economic" prong and a "technical" prong. "The scope of the domestic industry in patent-based investigations has been determined on a case by case basis in light of the realities of the marketplace and encompasses not only the manufacturing operations but may include, in addition, distribution, research and development and sales." Certain Dynamic Random Access Memories, Components

Thereof and Products Containing Same, Inv. No. 337-TA-242, Commission Opinion at 62, 1987 WL 450856 (U.S.I.T.C. September 21, 1987) ("DRAMs").

1. Technical Prong

A complainant in a patent-based Section 337 investigation must demonstrate that it is practicing or exploiting the patents at issue. 19 U.S.C. § 1337(a)(2) and (3); see also Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes, Inv. No. 337-TA-366, Commission Opinion at 8, 1996 WL 1056095 (U.S.I.T.C. January 16, 1996) ("Microsphere Adhesives"), aff'd sub nom. Minnesota Mining & Mfg. Co. v. U.S. Int'l Trade Comm'n, 91 F.3d 171 (Fed. Cir. 1996) (Table). In order to find the existence of a domestic industry exploiting a patent at issue, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent. Microsphere Adhesives, supra at 7-16. Fulfillment of this "technical prong" of the domestic industry requirement is not determined by a rigid formula, but rather by the articles of commerce and the realities of the marketplace. Certain Diltiazem Hydrochloride and Diltiazem Preparations, Inv. No. 337-TA-349, Initial Determination at 138, 1995 WL 945191 (U.S.I.T.C. February 1, 1995) (unreviewed in relevant part) ("Diltiazem").

"The test for satisfying the 'technical prong' of the [domestic] industry requirement is essentially [the] same as that for infringement, i.e., a comparison of [complainant's] domestic products to the asserted claims." Alloc, Inc. v. U.S. Int'l Trade Comm'n, 342 F.3d 1361, 1375 (Fed. Cir. 2003); 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) ("Doxorubicin"), aff'd, Views of the Commission at 22 (October 31, 1990). "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." Id. As with infringement, the first step of claim construction is a question of law, whereas the second step of comparing the article to the claims is a factual determination. Markman, 52 F.3d at 976. To prevail, the complainant must establish by a preponderance of the evidence that its domestic product practices one or more claims of the patent either literally or under the doctrine of equivalents. Cf. Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. Economic Prong

Section 1337(a)(3) sets forth the requirements for the economic prong of the domestic industry:

> [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.

19 U.S.C. § 1337(a)(3). The economic prong requirement was developed to assure that domestic production related activities - as opposed to those of a mere importer - are protected by the statute. Certain Products with Gremlin Character Depictions, Inv. No. 337-TA-201, Commission Op. at 6, USITC Pub. No. 1815 (U.S.I.T.C. 1986). The domestic industry determination is not made according to any rigid formula but by "an examination of the facts in each investigation, the articles of commerce, and the realities of the marketplace." Certain Double-Sided Floppy Disk Drives and Components Thereof, Inc. No. 337-TA-215; 227 U.S.P.Q. 982, 989 (U.S.I.T.C. 1986) (Commission Op.).

A complainant need only prove the existence of one of these factors to establish a domestic industry. Certain Plastic Encapsulated Integrated Circuits, Inv. No. 337-TA-315, Initial Determination at 83, 1992 WL 813952 (U.S.I.T.C. October 16, 1991) (unreviewed in relevant part) ("Encapsulated Circuits"). The complainant bears the burden of showing that the domestic industry requirement is satisfied. Certain Set-top Boxes and Components Thereof, Inv. No. 337-TA-454, Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002). The existence of the domestic industry can be assessed as of the discovery cutoff date prior to the evidentiary hearing. Certain Concealed Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289, Commission Opinion at 21, 1990 WL 710375 (U.S.I.T.C. January 8, 1990) ("Hinges") (adopting all of the ALJ's factual findings).

Typically, the complainant in investigations before the Commission is itself engaged in activities that would fall under subsections (A)-(C), but the Commission has long recognized that the work performed by contractors and subcontractors hired by the complainant can be considered as part of an investment in the domestic industry. See, e.g., Certain Portable On-Car Disc Brake Lathes and Components Thereof, Inv. No. 337-TA-361, Initial Determination at 15-22, (U.S.I.T.C. August 12, 1994) ("Brakes") (finding that expenditures by complainant for contractor's work was part of the investment in the domestic industry). In most cases, the contractor's activities have not been the sole basis on which the complainant sought to base its domestic industry. See, e.g., id. at 17-20 (complainant invested in research and development projects, office and administrative space, equipment and materials used by the contractor, and itself produced products covered by the patent-in-suit); see also, Certain Feathered Fur Coats and Pelts, and Process for the Manufacture Thereof, Inv. No. 337-TA-260, Initial Determination at 16, 19-20, 1988 WL 583015 (U.S.I.T.C. September

24, 1987), unreviewed by Commission, Commission Notice (November 10, 1987) (complainant invested in its own domestic facilities, but also used domestic and foreign subcontractors to make products covered by the patent-in-suit). However, the Commission has found the existence of a domestic industry where the complainant based its claim exclusively on the activities of a contractor/licensee. See Certain Methods of Making Carbonated Candy Products, Inv. No. 337-TA-292, Initial Determination at 142, (U.S.I.T.C. December 8, 1989) ("Carbonated Candy") (unreviewed in relevant part) (finding existence of a domestic industry based on long-term, completely domestic production of candy by a contractor/licensee utilizing the patented process).

In some cases, such as this one, where the alleged domestic article has been produced partially abroad and partially in the United States, the Commission has assessed the relative importance of the domestic activities to the non-domestic activities in connection with the product protected by the patent under subsections (A) or (B) of Section 337(a)(3). See, e.g., Encapsulated Circuits, supra at 88; see also Certain Microlithographic Machines and Components Thereof, Inv. No. 337-TA-468, Initial Determination at 347-52, 2003 WL 183891 (U.S.I.T.C. January 29, 2003), Notice of Commision Non-Review, 68 Fed. Reg. 13951 (March 21, 2003) (ID adopted in entirety, but Commission takes no position on the "findings on criteria (A) or (B) of the economic prong of the domestic industry requirement under section 337(a)(3) when a domestic product is made partially or wholly abroad"), appeal dismissed sub nom. Nikon Corp. v. U.S. Int'l Trade Comm'n, 117 Fed. Appx. 737 (Fed. Cir. 2004) ("Microlithographic"). One method used to determine the relative importance of domestic activities is the "value added" analysis. Value added analysis involves a comparison of the cost of foreign manufacture to the cost of domestic manufacture to determine the percentage of additional value added to the final product by domestic activities. See, e.g., Certain

Cube Puzzles, Inv. No. 337-TA-112, 219 U.S.P.Q. 335 (U.S.I.T.C., December, 30, 1982) (finding significant domestic activity where domestic services added $0.92 value to products valued at $1.00 on import).

The Commission has determined that a value added analysis is only one factor in the decision of whether a domestic industry exists and that it is not dispositive in determining the significance of domestic activities. See, e.g., DRAMs, supra at 68 (holding value added analysis is a non-dispositive factor in determining whether domestic activities are sufficiently significant to find the existence of a domestic industry). Additionally, the Commission has foregone exhaustive analysis of the domestic industry issue in situations where: 1) the entire industry is located in the United States, (Certain Audible Alarm Devices for Divers, Inv. No. 337-TA-365, Initial Determination at 50, 1995 WL 1049663 (U.S.I.T.C. February 2, 1995)); and 2) the sheer size and value of the domestic industry is clearly significant ("absolute analysis"). Certain Agricultural Vehicles and Components Thereof, Inv. No. 337-TA-487, Initial Determination at 76-77, 173-79, 2004 WL 723330 (U.S.I.T.C. January 13, 2004).

Despite downplaying, in some cases, the role of comparative and value added analyses as a factor in determining whether a violation of Section 337 has occurred, the Commission has never eliminated their applicability. See, e.g., Certain In-Line Roller Skates, Inv. No. 337-TA-348, Initial Determination (Order No. 21) at 6, 1993 WL 852393 (U.S.I.T.C. July 30, 1993), reversed and remanded by Commission, Commission Notice (August 31, 1993) ("Skates") (reversing the grant of summary determination finding domestic industry based solely on the employment of five persons who tested the quality of the skates at issue). The Commission has stated "'significance' as used in the statute denotes an assessment of the relative importance of the domestic activities. We also agree

that the 1988 Act does not necessarily preclude the use of domestic value added [analysis]." Hinges, supra at 22 (emphasis in original). Additionally, the Commission has previously found that a complainant who relied solely on the "absolute" significance of its domestic activities failed to demonstrate sufficient "significance" to require a finding that a domestic industry existed. Id.; see also Microlithographic, supra at 360-61 (holding that complainant's sole reliance on "absolute analysis" to establish the significance of domestic industry is insufficient when respondent demonstrated that domestic investments were well below "significant" levels).

Prior investigations have involved complainants relying on the "absolute" significance of their investments to satisfy the economic prong of the domestic industry requirement. See generally Certain Concealed Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289, Commission Opinion, 1990 WL 710375 (U.S.I.T.C. January 8, 1990) ("Hinges"); see generally Agricultural Vehicles, supra; see generally Microlithographic, supra. The complainants in Hinges and Microlithographic, whose products were manufactured abroad, failed to establish that their domestic investments were absolutely significant, and the domestic industry issue turned on analysis of the relative importance of domestic activities compared to foreign activities. Hinges, supra, at 23; Microlithographic, supra, at 361. In Agricultural Vehicles, in contrast, the complainant was able to establish "absolute" significance of its investment, despite the foreign construction of some of complainant's products. Agricultural Vehicles at 76-77, 173-79. Thus, a complainant who relies on the "absolute" significance of its domestic investments can establish the economic prong of the domestic industry requirement without providing extensive evidence relating to a "comparative analysis." However, such a complainant bears the risk that its domestic investments will be found not to be "significant," and will be unable to meet its burden of proof under a comparative analysis.

IV. THE '004 PATENT

A. Claim Construction

With respect to all claim terms at issue, in its post-hearing briefs Complainant has proposed that the terms be given their ordinary meaning. Throughout the course of this investigation, Complainant has advanced the same position. However, Complainant has never elucidated what it considers to be the plain or ordinary meaning of any term of any claim. Instead, Complainant would ask me to sift through their arguments on infringement and validity to glean any proposed definitions from those arguments. Respondents and Staff, on the other hand, have consistently provided the assistance Complainant failed to offer. While I have not always agreed with their claim constructions, both Respondents and Staff have acted in a responsible manner. One purpose of proposing claim constructions is to allow a judge to properly frame the legal issues. Another important function of the parties' proposed constructions is to assist the judge in reaching a proper legal conclusion. In this investigation, Complainant's counsel abrogated its responsibility to propose claim constructions. In the following discussion, Complainant's position that a plain meaning should be adopted is mentioned for each claim term. However, because Complainant has proposed no specific definition for any of the contested terms, I address only Staff's and Respondents' arguments on the proper construction of these terms.

1. "Pouch" (All Claims at Issue)

Complainant argues that the term "pouch" should be construed in a manner consistent with its ordinary meaning in the field of male prophylactic devices. CIB at 9. C&D, who Medtech/Intellx join, does not construe the term "pouch" in its post-hearing briefs. RCDIB at 17-25. The Staff, noting that it does not believe there is a dispute regarding this term, argues that should the term

"pouch" need to be construed, it is properly construed as "a bag-like structure that can hold something." SIB at 18.

The term "pouch" is used in a variety of contexts in the claims, including "prophylactic pouch," "first pouch," "second pouch," "second pouches," "plural pouches" and "third pouch." See JX-1 at 7:12-12:19. An examination of the claims, however, does not inform the proper construction of the term "pouch." The written description of the invention is also of little assistance, although the figures in the specification support the view that the term "pouch" should be given its plain and ordinary meaning. See JX-1 at Figures 1-9. Certainly, there is nothing in the specification to indicate that the patentee wished to impart a special meaning to the term "pouch." The prosecution history also does not aid in the construction of this limitation. Having considered the language of the claims, specification and prosecution history, I conclude that construction of the term "pouch" involves "little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415, F.3d at 1314. As stated above, Respondents and the Staff propose that "pouch" be construed as "a bag-like structure that can hold something." Although this construction comports with the ordinary meaning of the term "pouch," I do not think it is the best fit for the patent-at-issue, as the inclusion of the language "that can hold something" may be viewed as reading additional limitations into the claims. Accordingly, I hold that one of ordinary skill in the art at the time of the invention would construe the limitation "pouch" as "something resembling a bag in shape." SX-3 at CDITC009433; available at www.bartleby.com ("pouch" - 5. Something resembling a bag in shape.).

2. "elongated tubular portion" (All Claims at Issue)

Complainant argues that the term "elongated tubular portion" should be construed in accordance with its plain and ordinary meaning. CIB at 9. C&D, who Medtech/Intellx join, construe the limitation "elongated tubular portion" as "the part of the prophylactic that generally resembles standard condoms." RCDIB at 17. The Staff argues that the proper construction of "elongated tubular portion" means "the remaining portions of a condom that are not identified as second pouches and are tubular in shape." SIB at 18.

I note at the outset that there does not appear to be any significant difference in the parties' proposed constructions. The limitation "elongated tubular portion" appears in each of the independent claims of the '004 patent. In each instance, the "elongated tubular portion" is described as having "a circumference," "an open end" and "a closed end." In several of the independent claims the "elongated tubular portion" is also described as including "a tip." Additionally, in many of the independent claims, the "elongated tubular portion" is said to form "a first pouch." As the Staff correctly points out in its post-hearing brief, the claims clearly distinguish the elongated tubular portion / first pouch from the additional pouch(es) described in the claims. For example, independent claim 1, which states that the "elongated tubular portion" forms a first pouch, includes "a second pouch . . . extending outwardly of said first pouch." JX-1 at 7:12-32. Independent claim 22 is another good example as the claim clearly distinguishes between the "elongated tubular portion" and the second pouch, stating that "said tubular portion **and** said second pouch hav[e] a wall thickness of 0.11 ± 0.04mm." JX-1 at 9:54-10:6 (emphasis added). However, not all claims include a "second pouch" limitation. For example, claim 20 refers to "plural pouches" and claim 32 refers to a "third pouch." See JX-1 at 9:29-51 (referring to "plural pouches"), 10:67-11:5

(referring to a "third pouch"). Thus, although the Staff presents a reasonable approach to construing this limitation, I do not adopt the Staff's proposed claim construction wholesale because the Staff's construction would include a "third pouch" or "plural pouches" as part of the "elongated tubular portion."

The specification of the '004 patent does not add much to the analysis, although it does support what is clear from the language of claims as described above. In describing an embodiment of the invention illustrated in Figures 11-13, the patent applicant states that "the tubular portion 82 is a tubular pouch on which is formed a circumferentially spaced multiple pouch on pouch array." JX-1 at 6:52-54, Figures 11-13. This supports both the Respondents' assertion that the "elongated tubular portion" is the part of the invention that generally resembles a traditional prophylactic (i.e., the "tubular pouch") and the Staff's assertion that the "elongated tubular portion" does not include any of the additional pouch or pouches that are the crux of the invention (i.e., "on which is formed a pouch on pouch array"). Figures 1 and 4 of the '004 patent also support these conclusions. JX-1 at Figures 1, 4. Because the pouch or pouches that are the crux of the invention are not part of the structure that defines the tubular portion, it is clear that there will be an interruption in the surface of the tubular portion beneath where the additional pouch or pouches are formed. And yet, as described above, the applicant still refers to this area of interruption as part of the tubular portion. Thus, the inescapable conclusion is that the applicant intended the tubular portion to be more of a theoretical construct than an actual physical construct that must have a physical surface along its entire length.

Having reviewed the intrinsic evidence of record, I find that one of ordinary skill in the art at the time of the invention would construe the term "elongated tubular portion" as the portion of the

prophylactic pouch that is tubular in shape and generally resembles a traditional prophylactic and which does not include any of the pouch or pouches that are the crux of the invention (i.e., the second pouch(es)). I further clarify that the tubular portion consists of both the physical tube-like structure and the theoretical tube-like structure beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es)).

3. "circumference" (All Claims at Issue)

Complainant argues that the term "circumference" should be construed in accordance with its plain and ordinary meaning in the context of the '004 patent. CIB at 10. C&D, who Medtech/Intellx join, argue that the proper construction of the limitation "circumference" is "the perimeter of the condom at any cross-sectional slice through the condom." RCDIB at 20. The Staff does not propose a construction for the term "circumference." However, the Staff does argue that the "circumference" of the first pouch does not have to be uniform and that the first pouch need not have a completely uninterrupted circumference at every cross-section. SIB at 19.

With the exception of independent claim 20 (which is not at issue in this proceeding), the remaining independent claims of the '004 patent use the term "circumference" in the context of the "first pouch." See, e.g., JX-1 at 7:12-15 ("a first pouch having a circumference"). Independent claim 20, however, refers to the "circumference" of the elongated tubular portion. Although independent claim 20 refers to the "circumference" of the elongated tubular portion, and not the "circumference" of first pouch, it is of no practical import as, for all intents and purposes, the elongated tubular portion and the first pouch are synonymous.

Claim construction of the term "circumference" involves "little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. The

ordinary and plain meaning of the term circumference is "the external boundary or surface of a figure or object." See Merriam-Webster Online Dictionary (available at www.m-w.com). Although typically one thinks of the external boundary or surface of an object as an actual physical boundary or physical surface, it is clear from the '004 patent that the patentee intended a broader definition. In light of the specification and claims of the patent it is clear that the term "circumference" is more of a theoretical construct than an actual physical construct that could be measured in all instances. The idea that the patentee used the term "circumference" in a more theoretical sense supports the Staff's argument that the "circumference" does not have to be uninterrupted at every cross-section of the first pouch. For example, dependent claim 3 states that "the second pouch [is] integrally formed with said first pouch as a side bulge in the circumference." JX-1 at 7:37-40. If the second pouch is integral to the first pouch then it is clear that absent the second pouch there would be a disconnect in the surface of the first pouch. And yet the patentee in claim 3 still refers to this area of disconnect as the circumference. Other claims also support this position. See, e.g., JX-1 at claims 2, 6, 14, 23. Likewise, Figures 1-13 of the '004 patent support this position.

Although Respondents concede that the circumference of the first pouch can be interrupted by the material forming the second pouch, Respondents argue that those interruptions must combine to maintain the shape of the tubular portion. RCDIB at 20. In support of this argument, Respondents rely on a single sentence in the specification that is clearly linked to a single embodiment of the invention. See JX-1 at 6:50-67. Respondents' argument is clearly improper as it reads a limitation from a preferred embodiment of the specification into the claims. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.1988). There is nothing in the language of the claims that requires the circumference of the first pouch to be constant. In fact, such a

construction flies directly in the face of the claims and specification of the '004 patent. The claims specifically state that the diameter of the tubular portion need only be "generally constant" and the specification clearly states that the circumference of the tubular portion "could vary if desired." See JX-1 at 7:17, 4:39. Based on the claims and the specification, therefore, it is clear that the term "circumference" must have a broader meaning than that proposed by Respondents.

Having reviewed the intrinsic evidence of record, I find that one of ordinary skill in the art at the time of the invention would construe the term "circumference" as "the external surface of an object" with the clarification that the surface includes both the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es)).

4. "generally constant diameter from the open end to the closed end" (All Claims at Issue)

Complainant argues that the limitation "generally constant diameter from the open end to the closed end" should be construed in light of its plain and ordinary meaning in the context of the '004 patent. CIB at 10. Respondents do not propose a construction for this limitation, but assert that this claim requires that "there is some circumferential band of material between or beyond the second pouches which extends the generally constant diameter to the closed end to hold the first pouch firmly against the penis and create an entrance." RCDIB at 19-20. The Staff also does not propose a claim construction. SIB at 20. However, the Staff does argue that this claim term allows for a variance in the diameter of the first pouch. Id.

The specification teaches that "[a]lthough the circumference of the pouch is generally uniform, it could vary if desired." Id. at 4:37-39. Mathematically, diameter is related to circumference by the formula, $C=\pi*d$, where "C" is the circumference and "d" is the diameter.

Because the diameter of the tubular portion and its circumference are directly related, any variation in circumference will necessarily result in a proportional variation in the diameter. Thus, the teaching in the specification that the circumference of the tubular portion "could vary if desired" necessarily is a teaching that the diameter of the tubular portion may vary. This interpretation is also consistent with the plain meaning of "generally constant." See Merriam-Webster Online Dictionary (available at www.m-w.com)(generally - "a : in disregard of specific instances and with regard to an overall picture . . .b: as a rule: USUALLY."). Accordingly, the proper construction of the limitation "generally constant diameter" must allow for some variation in the diameter.

As previously discussed with regard to the construction of the term "circumference," the specification teaches that there can be interruptions in the circumference of the first pouch. At these points of interruption, it is beyond question that there will be no physically measurable diameter of the tubular portion. Indeed, the '004 patent teaches that the diameter of the tubular portion can be completely interrupted by the placement of a second pouch. For example, Figures 4-6 show a second pouch completely around the circumference of the depicted prophylactic. JX-1, Figures 4-6. Accordingly, while it is clear from the language of the claims that the tubular portion must have a "generally constant diameter from the open end to the closed end," it is equally clear from the specification that the generally constant diameter of the tubular portion need not be continuous from the open end to the closed end.

Respondents argue that there must be "some circumferential band of material between or beyond the second pouches which extends the generally constant diameter to the closed end to hold the first pouch firmly against the penis and create an entrance." RCDIB at 19-20. The parties agree that the purpose of the "generally constant diameter" of the tubular portion is to grip the penis so as

to prevent dislodging during coitus. CIB at 10; RCDIB at 18; SIB at 20. However, Respondents' reliance on this fact to support its argument that there must be some circumferential band of material between or beyond the second pouches which extends the generally constant diameter to the closed end is misplaced. Respondents' argument is misplaced because it relies entirely on extrinsic evidence in the form of expert testimony that, if adopted, would contradict the teachings in the specification and read out a preferred embodiment of the invention. Phillips, 415 F.3d at 1318 (A court should discount any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history."); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)(A claim interpretation that reads out a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support."). Specifically, Figure 10 of the '004 patent shows an embodiment of the invention wherein the second pouch (as it is referred to in the claims) is formed on the end of the tubular portion with a length to overlie and provide looseness at the outer surface of the glans penis. JX-1 at 6:27-49, Figure 10. In this embodiment, contrary to Respondents' proposed construction, there is no "circumferential band of material between or beyond the second pouches which extends the generally constant diameter to the closed end." Id. Respondents' argument, therefore, impermissibly reads out a preferred embodiment of the invention. Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1374 (Fed. Cir. 2005).

Like the previous construction of the term "circumference," proper claim construction of the limitation "generally constant diameter from the open end to the closed end" involves "little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415, F.3d at 1314. Based on the intrinsic evidence of record, I find that one of ordinary skill in the art at

the time of the invention would construe this limitation as requiring the diameter of the tubular portion from the open end to the closed end to be, for the most part, constant. Additionally, I add the clarification that the diameter includes both the physical diameter of the tubular portion and the theoretical diameter of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention (i.e., the second pouch(es)).

5. "longitudinally directed chamber" (Claims 1-4, 6, 8-9, 13, 15-16, 18, 31-32, 36)

Complainant argues that this term should be given its ordinary meaning in the context of the '004 patent. CIB at 11. Respondents argue that the term "chamber" should be construed as an "enclosed space or compartment," and that the proper construction of "longitudinally directed chamber" requires the penis "be located within and generally enclosed by a chamber defined by the first pouch, not the second." RCDIB at 20-21. Respondents also contend that, as used in claims 18 and 31, the term lacks "proper antecedent definition." Id. at 20. Because Respondents' arguments regarding proper antecedent basis are addressed in the section of this ID dealing with validity, they will not be addressed here. Staff argues that "the longitudinally directed chamber will essentially be the interior space defined by and including the penis." SIB at 21. Staff also asserts that in areas containing a second pouch, "the outermost limits of the chamber will not coincide with the latex walls but rather the chamber will continue its generally straight-tube shape until the chamber sharply tapers and closes." Id.

The term "longitudinally directed chamber" is used in multiple claims of the '004 patent. As exemplar of this usage, claim 1 states "said tubular portion . . . having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis." A plain reading of this claim language demonstrates that the longitudinally directed chamber

is nothing more than the chamber defined by the tubular portion of the prophylactic. Such an interpretation is consistent with the specification. JX-1 at 3:56-60 ("The pouch 12 has a diameter which will closely fit on the outer surface of a penis whose glans penis will be located within the pouch in spaced relationship to the closed end 16 to define a longitudinally directed chamber 17."). Basically, as described in the specification and claims, the "longitudinally directed chamber" is the interior area of the tubular portion.

Respondents' argument that the limitation "longitudinally directed chamber" requires the penis to be within and generally enclosed in a chamber defined by the first pouch and not the second, appears to be that the chamber cannot be physically interrupted at any point along the length of the tubular portion. CRB at 10-11. Respondents' argument is not well received as it directly contradicts the teachings of the specification, which clearly show interruptions in the physical surface of the chamber at the points beneath the pouch or pouches that are the crux of the invention. JX-1, Figures 1-13. Although typically one thinks of a chamber as having a physical external boundary or surface, it is clear from the '004 patent that the patentee intended a broader definition. In light of the specification and claims of the patent it is clear that the term "longitudinally directed chamber" is more of a theoretical construct than an actual physical construct that could be measured at all instances. The idea that the patentee used the term "longitudinally directed chamber" in a more theoretical sense is supported by the specification which states that "[t]he pouch 20 has an entrance opening 20a through which the chamber 17 is communicated with an interior space 20b of the pouch 20." JX-1 at 4:2-5, Figures 1-3. It can be readily seen from Figures 1-3 that there is no physical surface or boundary in the area that lies directly beneath the entrance opening 20a, and yet the patentee still refers to this area as the chamber 17. Moreover, this proposition is supported by the

language of the claims themselves, which state "said entrance communicating said interior space directly with said longitudinally directed chamber." Id. at 7:25-27.

Based on the intrinsic evidence of record, I conclude that one of ordinary skill in the art at the time of invention would construe "longitudinally directed chamber" as the enclosed space or compartment formed by the tubular portion into which the penis is inserted. As with both the construction of "circumference" and "generally constant diameter," discussed above, I add the clarification that the enclosed space or compartment formed by the tubular portion includes both the area formed by the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath the pouch or pouches that are the crux of the invention.

6. "second (or plural) pouch(es)" (All Claims at Issue)

Complainant contends that the term "second pouch" should be given its ordinary meaning in the context of the '004 patent. CIB at 11. Respondents argue that "second pouch" refers to the only mobile part of the prophylactic, and that "if it's moving to stimulate the penis, it's part of the second pouch and can't be part of the first." RCDIB at 21. The Staff argues that "second pouch" should be construed as "those regions of the condom that are loose fitting on the surface of the penis such that they rub back and forth on the penis . . . to such an extent that they provide heightened pleasure during coitus." SIB at 21. The Staff also argues that the "second pouch" need not be limited to pouch(es) that are situated over the closed end of the prophylactic. Id.

Although the parties allege a dispute regarding the proper construction of the term "second pouch(es)," the arguments proffered by the parties indicate otherwise. A close examination of the parties' arguments reveal that the dispute is not over the proper construction of the term "second pouch(es)," but over the characteristics and structures that define the "second pouch(es)." These

characteristics and structures are expressed as additional limitations in the claims at issue and are construed individually, infra. Thus, I see no need to provide an extraneous construction of "second pouch" outside of the definitions of the terms provided below.

7. "extending outwardly" and "spaced radially outwardly" (All Claims at issue)

Complainant asserts that the two terms should be given their ordinary meaning in the context of the '004 patent. CIB at 12. In their reply brief, Complainant contends that "extending outwardly" does not preclude extensions of the second pouch "along the longitudinal axis" of the prophylactic. CRB at 7. Respondents argue that these two terms should be construed as having essentially the same meaning, i.e., "projecting in a direction radially away from the outer surface of the tubular portion . . . rather than extending along the longitudinal axis of the condom." RCDIB at 21. The Staff essentially agrees with Respondents' interpretation of the two claim terms, but also asserts that the term "does not preclude a second pouch from also extending along the longitudinal axis." SIB at 22; SRB at 5.

I agree with the Staff and Respondents that these two terms are essentially identical and should be construed to have the same meaning. The parties appear only to dispute whether these terms limit second pouch(es) to those pouch(es) that only extend radially from the first pouch. While it is clear from the plain language of the claims at issue that in order to satisfy these claim limitations the second pouch(es) must extend outwardly from the first pouch, there is nothing in the claims or specification that would indicate that the patentee intended to preclude the second pouch(es) from also extending longitudinally. In fact, Respondents' argument directly contradicts the specification which teaches that the second pouch(es) can have a longitudinal component. For example, with regard to the embodiment of the invention shown in Figures 11-13 of the '004 patent, the

specification states that "[e]ach of the pouch on pouch formations in the array 84 are formed as slightly elongated bulges in the tubular portion." JX-1 at 6:57-59, Figures 11-13. As can be readily seen in Figures 11-13, the second pouches not only extend radially outward, but also longitudinally. Moreover, every second pouch disclosed in the '004 patent has some width and therefore from a practical standpoint every second pouch disclosed has some longitudinal component. To adopt Respondents' argument that the second pouch(es) cannot extend in the longitudinal direction in addition to extending radially outward would be to impermissibly limit the claims of the invention to read out preferred embodiments. A claim construction which excludes a preferred embodiment, is "rarely, if ever, correct." Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1378 (Fed. Cir. 2001) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)).

Accordingly, I find that one of ordinary skill in the art at the time of the invention would construe the terms "extending outwardly" and "spaced radially outwardly" as requiring the second pouch(es) to extend radially away from the central axis of the first pouch.

8. "entrance with an open area" (Claims 1-4, 6, 8-9, 13, 15-16, 18, 31-32, 36)

Complainant asserts that the term "entrance with an open area" should be given its ordinary meaning in the context of the '004 patent. CIB at 12. Respondents assert that the term "entrance" should be defined as "the boundary where the second pouch meets the chamber formed by the first pouch." RCDIB at 22. Respondents also assert that this term should be construed such that the "entrance" is fixed in place. Id. The Staff agrees that "entrance" should be considered as "a boundary between the first pouch and second pouch," but does not agree that the term should be construed as requiring that the entrance be fixed in place. SIB at 23-25.

The definition of the term "entrance" as being the boundary where the first pouch and the second pouch meet is consistent with the plain language of the claim and the teachings of the specification. In describing Figure 2, the specification states "[t]he pouch 20 has an entrance opening 20a through which the chamber 17 is communicated with an interior space 20b of the pouch 20." JX-1 at 4:2-5, Figure 2. It can be readily seen from Figure 2 that the boundary between the first pouch and the second pouch is labeled as the "opening 20a." Id. Figure 3 also supports the interpretation that the entrance is the boundary between the first pouch and the second pouch(es) as it clearly shows inversion of the second pouch through the "entrance" to stimulate the glans penis. Id. at 4:11-12, Figure 3.

In contending that the "entrance" must be fixed in place relative to the surface of the penis, Respondents cite only to extrinsic evidence. RCDIB at 22-23 (citing Dr. Wool, Dr. Potter, Dr. Reddy and John Rogers). While extrinsic evidence may be useful in construing claim language, such is not the case where the extrinsic evidence contradicts the intrinsic evidence of record. Phillips, 415, F.3d at 1318 (A court should discount any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history."). Here, the term "entrance with an open area" has no other meaning in the context of the claim language and specification, than to describe the boundary between the primary and a secondary pouches; a boundary that has been referred to in various claim constrictions, supra, as the theoretical surface of the tubular portion or first pouch that lies beneath the pouch or pouches that are the crux of the invention. There is nothing in the claims or specification that indicates that any positional requirement of the secondary pouch(es) was intended by the patentee. Thus, Respondents' attempts to read in a limitation based on extrinsic evidence is inappropriate. Phillips, 415 F.3d at 1318.

Based on the plain language of the claims and the specification, I conclude that a person of ordinary skill in the art at the time of invention would construe the term "entrance with an open area" as the boundary between the first pouch and any of the secondary pouch(es).

9. "said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis" (Claims 1-4, 6, 8-9, 13, 15-16, 18, 31-32, 36); "overlying in spaced relationship to the glans penis" (Claim 22)

As an initial matter, I note that the parties group these two terms together, suggesting that they should be interpreted as having the same meaning. Additionally, the parties have not proposed separate meanings for these terms. Further, it is clear from the post-hearing briefs that the Staff and Respondents only disagree about the proper construction of the phrase "at a point overlying the glans penis." RCDIB at 23; SIB at 26. After reviewing the intrinsic evidence of record, I agree with the parties that these terms should be construed to have the same meaning. Because the parties only present argument concerning the construction of the phrase "at a point overlying the glans penis," I will confine my claim construction analysis accordingly.

Complainant asserts that the term should be given its ordinary meaning in the context of the '004 patent. CIB at 13. Respondents argue that properly construed the phrase "at a point overlying the glans penis" means that "the second pouch and its entrance to the chamber is restricted to fall only 'at a point overlying' the most sensitive region of the glans penis." RCDIB at 24. The Staff argues that the phrase "at a point overlying the glans penis" should be construed in accordance with its plain meaning such that the entrance to the second pouch need only "overlie some point of location of the glans penis." SIB at 25. The Staff affirmatively disputes Respondents' construction, asserting that "[t]he term does not require that the second pouch only overlie the glans penis." Id.

Respondents argue that language from the specification demonstrates that this term should be construed to limit the placement of the "entrance" only over the most sensitive portion of the glans penis. RCDIB at 23. In support, Respondents first quote from the abstract of the patent which states that "the pouch or pouches on the tubular pouch are configured to be moveable back and forth in the area of the glans penis from approximately 1/2 cm below the urethra orifice to a point approximately 2 cm from the orifice." JX-1 at Title Page (Item No. 57). Second, Respondents cite the background section of the '004 patent which states that "[n]one of the aforesaid condoms include a condom with a pouch or pouches on a tubular pouch arranged to produce a rubbing action on the most sensitive region of the glans penis." JX-1 at 1:53-56. Finally, Respondents quote a description of Figure 1 that "[t]he wall bulge 22 is located in one side of the pouch 12 at a point overlying and in spaced relationship to the most sensitive surface 24 of the glans penis, starting approximately 1/2 cm from the outlet 25 from the urethra and ending at a point 2 cm from the outlet 25." Id. at 4:5-10, Figure 1. "To the extent the'004 patent demonstrates the use of pouches that do not overlie the most sensitive region of the glans penis, [Respondents argue that] these embodiments were excluded from coverage" based on an amendment to the claims during the prosecution of the patent before the PTO. RCDIB at 24. Before addressing Respondents' argument based on the above cited passages from the specification, I will first address Respondents' argument that the prosecution history limits the interpretation of this claim term.

Respondents assert that the prosecution history limits the claim scope, because the entire claim term was added during prosecution in response to the examiner's rejection of the claims over two prior art patents. See RCDIB at 24. Specifically, Respondents argue that the prosecution history makes clear that the patentee limited this term such that "the second pouch and its entrance

to the chamber is restricted to fall only 'at a point overlying' the most sensitive region of the glans penis." Id. Respondents further argue that if the patentee did not intend to so limit the claim, then "he simply could have eliminated the phrase 'at a point overlying the glans penis'." CDRB at 16. The Staff disputes this reading of the prosecution history. SIB at 24.

I find Respondents' argument unpersuasive. While it is true that the patentee amended certain claims that were rejected over prior art patents, the point of distinction made was that "Haines '903 does not teach a pouch having an inner wall that will penetrate through an entrance to stroke a glans penis." JX-4 at 139-140. There is no indication from the amendments or the arguments made for allowability that the patentee intended to limit the claims such that the entrance to a second pouch must fall only at a point overlying the most sensitive portion of the glans penis. Respondents' reading of the prosecution history is overly strained. The more straightforward interpretation is that the phrase was used to further clarify that the second pouch must overlie some portion of the glans penis.

Respondents' reliance on the few passages from the specification discussed above as support for its argument is misplaced. None of those statements are so definitive as to be considered a disclaimer of claim scope on the part of the patentee. Neither are the statements a clear indication that the patentee wished to impart a special definition to the term "at a point overlying the glans penis." Furthermore, the statements on which Respondents rely contradict a plain reading of the claims and completely disregard the remainder of the specification.

With regard to the claims of the '004 patent, I note first that none of the claims use the words "over the most sensitive portion of the glans penis." The claims merely state "overlying the glans penis." Second, Respondents ignore the language of several dependent claims, including claims 2

and 8, which enlighten the proper construction of this claim term. Claim 2, for example, specifically limits the area of movement to only "part of the underside surface of the glans penis," JX-1 at 7:36, while claims 8 limits the location of the second pouch to the area "only at the glans penis portion thereof." Id. at 56-58. Both dependent claims 2 and 8 limit the placement of the second pouch to two specific regions of the penis. Thus, the language of the dependent claims strongly suggests that the proper construction of the phrase "at a point overlying the glans penis" in the independent claims must be broad enough to encompass both of these limitations. Cf. Phillips v. AWH Corp., 415 F.3d 1303, 1324.

With regard to the specification, it is clear the patentee did not intend to limit the location of the entrance of the second pouch, as Respondents' argue, only to the most sensitive area on the glans penis. For example, the specification states that a feature of one embodiment of the invention is to provide a pouch on pouch means to produce movement on the underside of the glans penis or in areas adjacent to and encircling the glans penis. JX-1 at 2:26-31. In addition, the specification describes the features of several of the embodiments of the invention, stating that "[w]hile the greatest sensitivity is on the underside of the glans penis, the other parts of the glans penis are also sensitive to rubbing action of the pouch or pouches on pouch portions of the invention." JX-1 at 4:68-5:4. Furthermore, the embodiments of the invention shown in Figures 10-13, clearly show the entrance to the second pouch overlying an area greater than that of the glans penis. JX-1 at Figures 10-13.

As additional support of the fact that Respondents' argument is misplaced, I note that the Court of Appeals for the Federal Circuit specifically addressed this claim term in affirming a district court decision not to grant a preliminary injunction. Portfolio Techs., Inc. v. Reddy Medtech, Ltd.,

2000 WL 426147 (Fed. Cir. 2000). Although the Federal Circuit did not construe this term, the Court stated that it did not endorse the district court's claim construction that "limited the stimulation of the second pouch 'to the area of the glans penis.'" Id. The Federal Circuit acknowledged that it did not have a complete record before it, but stated that "the patent's written description and drawings show the second pouch extending beyond the glans penis." Portfolio Techs., 2000 WL 426147 (Fed. Cir. 2000). Although this was a non-precedential decision and is not binding on the district court or the Commission, the stated views of the Federal Circuit on the scope of any patent claim at issue are highly persuasive.

Respondents view of the limitation "at a point overlying the glans penis" is extremely narrow. As argued, Respondents would have me construe "at a pont overlying the glans penis" as "only at a point overlying the most sensitive region of the glans penis." Because such a construction is contrary to a plain reading of the claim language and the teachings of the specification, it would be improper to adopt Respondents' proposed claim construction. It is clear from the intrinsic evidence of record that the proper construction of the term "at a point overlying the glans penis" is not limited to: 1) an entrance overlying a specific point on the glans penis; 2) an entrance that must remain fixed over that point; or 3) an entrance that must overlie that point and no others. The fact that this term was added as an amendment during prosecution does not alter its plain and ordinary meaning.

Based on the claim language, the teachings of the specification, and the prosecution history, I conclude that one of ordinary skill in the art at the time of the invention would construe the terms "said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis" and "overlying in spaced relationship to the glans penis"

as requiring the entrance to the second pouch to overlie a portion of the glans penis.

10. "inner surface moveable through said entrance" (Claims 1-4, 6, 8-9, 13, 15-16, 18, 31-32, 36)

Complainant contends that this term should be given its ordinary meaning in the context of the '004 patent. CIB at 14. Respondents assert that this term refers to the "radial in-and-out movement wherein the second pouch reverses inward," but does not include back and forth movement against the glans penis. RCDIB at 25. The Staff argues that the term "inner surface" should be construed as "the surface of the second pouch that is facing the penis" and that the term "moveable through said entrance" should be construed to mean that the inner surface "can invert from its outwardly extended position such that it touches the skin of the penis and allows for the back and forth stroking that causes the enhanced sensation in those areas." SIB at 26.

The term "inner surface" is addressed only by the Staff. Regarding this term, I agree with the Staff's conclusion that "inner surface" refers to the interior surface of the second pouch facing the penis. Regarding the proper construction of the phrase "moveable through said entrance," it appears that both the Staff and Respondents agree that this particular term refers to the inversion of an outwardly protruding second pouch towards the penis. The Staff, however, argues that the proper construction of the phrase "moveable through said entrance" must also allow for the back and forth movement of the second pouch to stimulate the penis. SIB at 26. This portion of the Staff's argument is unpersuasive. Claim 1, in pertinent part, states "said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus from providing stimulation thereto." JX-1 at 7:28-32. The phrase "for movement; back and forth thereon during coitus for providing stimulation thereto" is a functional statement and, thus, is not a limitation of apparatus Claim 1. Cross Medical Prods., Inc. v.

Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1311-12 (Fed. Cir. 2005)("To infringe an apparatus claim, the device must meet all of the structural limitations.")(emphasis added); Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990)(stating "apparatus claims cover what a device *is*, not what a device *does*")(emphasis in original); In re Michlin, 256 F.2d 317, 320 (C.C.P.A. 1958)("It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function."). Therefore, it would be improper to construe the phrase "moveable through said entrance" to require that the second pouch allow for movement back and forth during coitus. Accordingly, only the inversion motion is properly construed as part of this term.

That the second pouch can move through the entrance is demonstrated in Figures 3 and 6 of the '004 patent. JX-1 at Figures 3, 6. Additionally, this movement is described in the specification as motion towards the penis from an outwardly extending position. JX-1 at 4:11-12 ("the wall bulge 22 has a conoidal surface 26 which will be pushed inwardly during coitus"); Id. at 4:42-45 ("the glans penis pouch on pouch is dimensioned to provide a space prior to insertion and a reversal of the pouch on pouch inwardly during coitus"); Id. at 5:39-40 ("the pouch on pouch portions move in an out of the tubular pouch during coitus"). Additionally, all figures of the patent show second pouches extending away from the interior of the first pouch. As a physical reality, to move through an entrance, the inner surface of a second pouch must move towards the penis in order to move through that entrance.

Based on the language of the claims and the specification, I conclude that one of ordinary skill in the art at the time of the invention would construe the limitation "inner surface moveable

through said entrance" as requiring that the surface of the second pouch facing the penis be capable of moving inwardly through the boundary between the first and second pouches.

11. "annular pocket" and "hollow ring" (Claims 5-6)

Complainant does not address these terms at all. CIB at 5-13. Complainant states that if it inadvertently failed to address a claim term, the term should be given its ordinary meaning in view of the patent as a whole. Id. at 14. Respondents Medtech/Intellx contend that these two terms are interchangeable and that the term "annular pocket" "takes its ordinary meaning, which is the area contained between two concentric circles around the circumference of the condom." RMIIB at 5. The Staff contends that claim 5 (hollow ring) was intended to depend upon claim 6 (annular pocket) rather than claim 3. SIB at 14. Thus, the Staff asserts that the two terms are not coextensive and that the term "annular pocket" is in fact broader than the term "hollow ring." Id. at 14-15. The Staff does not propose a specific interpretation of "annular pocket." Id. at 16-26.

The Staff's argument that the term "annular pocket" should be construed in light of an error made during the prosecution of the '004 patent, is not persuasive for several reasons. First, the Staff improperly relies on a Federal Circuit case dealing with a single statement made during prosecution that was contrary to the claims at issue in that case. See Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc., 249 F.3d 1341, 1348 (Fed. Cir. 2001) ("Biotec Biologische"). In Biotec Biologische, the Federal Circuit held that the erroneous statement made during prosecution could not be reasonably relied upon because, in part, it contradicted "the plain language of the claims and the specification." Id. The instant investigation does not involve a statement made during prosecution, but an alleged error in an issued claim. Thus, Biotec Biologische is readily distinguishable from the current scenario.

Second, the Federal Circuit has clearly held that an error in an issued patent can be corrected by a district court "only if the error is evident from the face of the patent." Group One, Ltd. v. Hallmark Cards, Inc., 407 F.3d 1297, 1303 (Fed. Cir. 2005), see also Arlington Indus., Inc. v. Bridgeport Fittings, Inc., 345 F.3d 1318, 1331 n. 1 (Fed. Cir. 2003) (refusing to correct PTO error not apparent from the face of the patent), Cf. Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1203 & n. 3 (Fed. Cir. 1992)(allowing correction where patent was clearly directed to a toy trackway rather than an actual trackway). In the case of the '004 patent, determining the nature of the error, if any, requires examination of the prosecution history. Without such examination, a determination of what claim properly depends from claim 5 is not possible. Thus, it would be inappropriate to construe "annular pocket" in contradiction to the express language of the issued claims.

Finally, there is potentially more than one difference in the scope of claims 5 and 6. Claim 5 also contains the limitation that the second pouch, in the form of a "hollow ring," is formed "around the closed end of" the first pouch. JX-1 at 7:46-47. Claim 6 requires that the second pouch, in the form of an "annular pocket," be "formed completely around the circumference." This suggests a spatial difference in the placement of the pouch, and not the pouch's characterization as a "hollow ring" or "annular pocket," distinguishes the two claims from each other. Thus, assuming *arguendo* that Staff's assertion that the terms of claim 6 should be construed as if claim 5 depended from claim 6, it is not clear that "annular pocket" should be construed as encompassing more than a "hollow ring" simply because of claim differentiation.

The term "annular" is not used in the '004 patent other than in claim 6. Thus, no clear definition of this term can be discerned from the intrinsic evidence of record and reference to extrinsic evidence is proper to determine the meaning of this claim term. Phillips, 415 F.3d at 1323

(noting that dictionaries can be used as proper tools for claim construction "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents")(quoting Vitronics, 90 F.3d at 1584 n.6). The plain and ordinary meaning of "annular" is "of, relating to, or forming a ring." See Merriam-Webster Online Dictionary (available at www.m-w.com). This definition is consistent with the additional language of claim 5 requiring the second pouch be "formed completely around the circumference." JX-1 at 7:49-50. The term "pocket" is used only once in the specification and appears to be a synonymous with the term second pouch. Id. at 2:23.

Based on the plain and ordinary meaning of "annular" and the language of the specification indicating that the term "pocket" refers to a second pouch, I conclude that one of ordinary skill in the art would construe the term "annular pocket" as a bag-like structure forming a ring-like shape.

B. Infringement

1. Respondent C&D's Twisted Pleasure

Originally, Complainant alleged that Respondent C&D's Trojan Twisted Pleasure condom infringed claims 1-7, 9-27, 31-33 and 36, of the '004 patent. Second Amended Complaint at ¶ 35. Later, Complainant's withdrew claims 10-12, 17, 21 and 26. CIB at 7 ("At Dr. Reddy's deposition, PTI withdrew claims pertaining to a water soluble lubricant . . . for the Twisted Pleasure (claims 10, 11, 12, 17, 21 and 26)"). By the time of the pre-hearing conference, Complainant was asserting claims 1-7, 13-16, 18, 22-25, 27, 31, 32 and 36. Pre-hearing Conference Tr. at ¶ 8-13. During the hearing in this investigation, Complainant also withdrew claims 5-7. Tr. at 346:23-347-2. Additionally, in their post-hearing brief, Complainant expressly withdrew claims 14, 24 and 27. CIB at the 7. Though not expressly withdrawn, Complainant did not address claim 23 in its post-hearing

brief and therefore, it is considered waived. See Order No. 2 at ¶ 11.1 (All issues not set forth in the initial post-hearing brief are deemed waived.) Accordingly, the following claims remain asserted against Respondent C&D's Twisted Pleasure condom: 1-4, 13, 15-16, 18, 22, 25, 31-32 and 36.

Respondent C&D insinuates that Complainant failed to make out its prima facie case of infringement with regard to all claims at issue. RCDIB at 19. Specifically, Respondent C&D argues that "PTI makes out its entire infringement case for claim 1 (and all other asserted claims) on the conclusory testimony of its expert Dr. Wool." Id. According to Respondent C&D, Dr. Wool "offered absolutely no support for his opinions or for what claim constructions he applied in his analysis so there is no basis to determine whether his analysis is correct or credible." Id. Contrary to Respondent C&D's assertion, expert testimony on the ultimate issue of infringement is permissible. Symbol Tech., Inc. v. Opticon, Inc., 935 F.2d 1569, 1575 (Fed. Cir. 1991). Pursuant to Federal Rule of Evidence 705, an "expert may testify in terms of opinion or inference and give reasons thereof without prior disclosure of the underlying facts or data." Fed.R.Evid. 705. The responsibility for challenging the factual underpinnings of such expert testimony falls squarely on Respondent C&D during cross-examination. Symbol Tech., 935 F.2d at 1575. Accordingly, I find nothing improper with Complainant's decision to rest its prima facie case of infringement on the testimony of Dr. Wool. However, as the ultimate fact finder in this investigation, I may decide what weight, if any, to give such testimony. Id.

That being said, I note that although Complainant cites only to the conclusory testimony of Dr. Wool in support of its infringement arguments, there is other evidence of record that enlightens Dr. Wool's opinions. This evidence comes in the form of several demonstrative exhibits. See CDX -23, CDX -24, CX-80, CX-81, CX-82, CX-83, CX-84, CX-85, CX-86 (note, while CX-80 through

CX-86 were admitted as direct exhibits, they would more properly be characterized as demonstrative exhibits). The demonstrative exhibits include marked-up diagrams of the Twisted Pleasure condom that show, in Dr. Wool's opinion, how the limitations of the asserted claims are satisfied. See CX-80, CX-81, CX-82, CX-83, CX-84, CX-85, CX-86. Additionally, it is important to note that during the course of his testimony at the hearing, Dr. Wool physically demonstrated on an actual Twisted Pleasure condom where many of the limitations of the '004 patent could be located. Unfortunately, some of the markings Dr. Wool made on the Twisted Pleasure condom he used for demonstration purposes during the hearing rubbed off when Complainant packaged the exhibit for submission into evidence. While the fact that some of the markings rubbed off may present some minor difficulties in reviewing the record, it does not in any way diminish the value of those demonstrations in informing me of the underlying basis of some of Dr. Wool's infringement opinions.

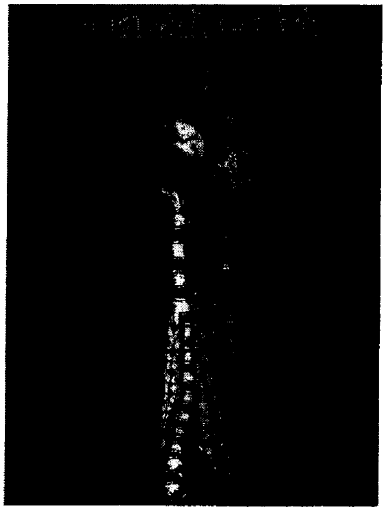
a. Claim 1

Independent Claim 1 reads as follows:

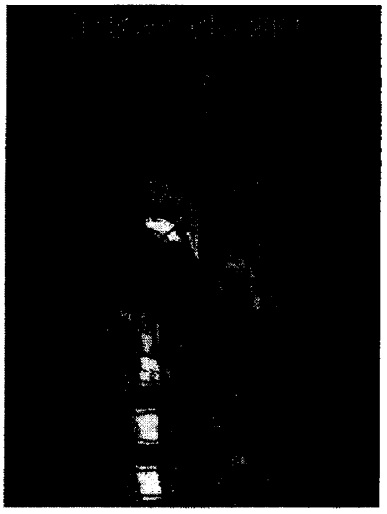
> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> >
> > a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

Complainant and the Staff argue that the Twisted Pleasure infringes claim 1 of the '004 patent. CIB at 22; SIB at 27. Respondent C&D disagrees. RCDIB at 30.

At the hearing, Dr. Wool testified that the Twisted Pleasure is a prophylactic pouch for use by a male that has an elongated tubular portion that forms a first pouch. Tr. at 342:1-9; see CX-80 (reproduced below), CX-81 (reproduced below). According to Dr. Wool's testimony, the first pouch of the Twisted Pleasure has a circumference, an open end and a closed end. Tr. at 342:7-9; see CX-80, CX-81. Dr. Wool testified that the tubular portion of the Twisted Pleasure is formed of a thin membrane material and has a generally constant diameter from the open end to the closed end. Tr. at 342:16-24; see CX-80, CX-81; see also CX-82, CX-83, CX-84. He also testified that the tubular portion defines a longitudinally directed chamber for a male penis. Tr. at 342:16-24; see CX-80.



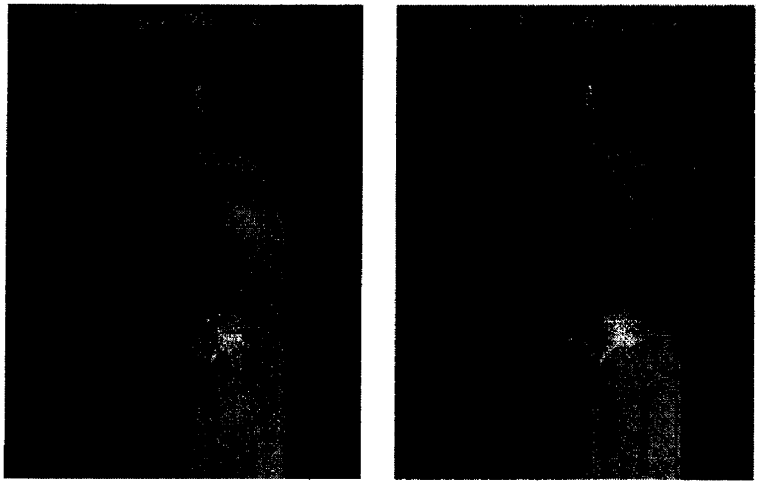
CX-80



CX-81

In addition, Dr. Wool testified that the Twisted Pleasure has two second pouches formed of a thin membrane material that extend outwardly of the first pouch. Tr. at 342:25-343:6; see CX-81.

With regard to the two second pouches, Dr. Wool testified that both pouches have an interior space, including an entrance with an open area extending lengthwise of the glans penis. Tr. at 343:7-12; see CX-82 (reproduced below). During the hearing, Dr. Wool demonstrated what he considered to be the entrance of each of the second pouches by marking dotted lines on an actual Twisted Pleasure. Tr. at 343:7-12; CPX-6. Dr. Wool further testified that the entrance of each of the second pouches on the Twisted Pleasure communicates the interior space directly with the longitudinally directed chamber at a point overlying the glans penis. Tr. at 343:13-17; see CX-81. According to Dr. Wool's testimony, each second pouch has an inner surface which is moveable though the entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation thereto. Tr. at 343:18-22; see CX-82.



CX-82

Respondent C&D attacks Complainant's prima facie case of infringement in six major respects, arguing that the Twisted Pleasure condom does not possess, or Complainant has not proven that the Twisted Pleasure possesses: (1) a tubular portion with a "generally constant diameter;" (2) "a first pouch having a circumference;" (3) a "longitudinally directed chamber for a male penis;" (4)

a second pouch "extending outwardly" of the first pouch; (5) a second pouch with "an entrance with an open area . . . communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis;" and (6) a tubular portion and second pouch formed of a thin membrane material. RCDIB at 26-34; RCDRB at 20.

Respondent C&D's argument that the Twisted Pleasure condom does not infringe claim 1 of the '004 patent because it lacks a tubular portion with a "generally constant diameter" is based on a claim construction of the limitation "generally constant diameter" that was not adopted in this ID. Respondent C&D continues to incorrectly assert that claim 1 does not permit any variation in the diameter of the tubular portion. In addition, Respondent C&D fails to recognize that as properly construed, the tubular portion and first pouch include not only the physical portion of the condom in the shaft area, but also the theoretical portion of the condom beneath the second pouch. Thus, as properly construed, the tubular portion of the Twisted Pleasure condom has a generally constant diameter from the open end to the closed end. Tr. at 342:1-24; see CX-80, CX-81, CX-82; see also JPX-6.

Respondent C&D's argument that the Twisted Pleasure condom lacks a first pouch having a circumference also stems from an incorrect claim construction that was not adopted in this ID. Again, Respondent C&D fails to recognize that the patentee used the term circumference to describe more of a theoretical construct than an actual physical construct that can be measured in all instances. Respondent C&D rejects the notion that the circumference of the first pouch can include the theoretical surface of the first pouch that extends beneath the second pouches of the Twisted Pleasure condom, arguing that the "Federal Circuit has repeatedly rejected attempts to satisfy claimed limitations directed to the structure of a claimed device with arguments that accused devices lacking

those limitations were somehow the same or should be viewed as having some meta-physical equivalent." RCDIB at 31. Respondent C&D cites to two Federal Circuit cases in support of its argument, however, none of the cited cases stand for the proposition Respondent C&D asserts. See CAE Screenplates v. Heinrich Fiedler GMBH & CO. KG, 224 F.3d 1308 (Fed. Cir. 2000); Young Dental Manufacturing Co., Inc. v. Q3 Special Products, Inc., 112 F.3d 1137 (Fed. Cir. 1997). In neither case did the Federal Circuit hold, or make any resemblance of a statement, that a theoretical construct of a structural element in an apparatus claim was improper as a matter of law. In each instance, the Federal Circuit merely applied the basic rules of claim construction in coming to its conclusions. Those same rules of claim construction are what guided the claim construction in this ID. Accordingly, the claim construction in this ID holds that the term "circumference" includes the circumference of the theoretical surface of the first pouch that extends beneath a second pouch. Thus, as properly construed, the first pouch of the Twisted Pleasure condom has a circumference. Tr. at 342:7-9; see CX-80, CX-81; see also JPX-6.

Respondent C&D's argument that the Twisted Pleasure condom lacks a "longitudinally directed chamber for a male penis," is based on Respondent C&D's notion that the longitudinally directed chamber must be a physically enclosed space for a penis. RCDIB at 32. Specifically, Respondent C&D argues that there is no longitudinally directed chamber in the spiral region of the Twisted Pleasure condom. Id. However, as properly construed herein, the longitudinally directed chamber is the enclosed space formed by the tubular portion that includes both the area formed by the physical surface of the tubular portion and the theoretical surface of the tubular portion that lies beneath a second pouch. Accordingly, based on the proper claim construction of the limitation "longitudinally directed chamber," Respondent C&D's argument must fail. Contrary to Respondent

C&D's argument, the Twisted Pleasure condom has a longitudinally directed chamber for a male penis. Tr. at 342:16-24, 348:23-25; see CX-80.

Respondent C&D argues that the Twisted Pleasure condom does not meet the limitation in claim 1 requiring that the second pouch "extend outwardly" from the first pouch. RCDIB 33. Rather, Respondent C&D argues that the spirals of the Twisted Pleasure condom extend longitudinally from the first pouch. Id. Respondent C&D's argument that the second pouch extends longitudinally, and not outwardly, is based on Respondent C&D's misconception that the end of the first pouch coincides with the end of the straight walled portion of the Twisted Pleasure condom. Id. However, as properly construed herein, the tubular portion (a.k.a. the first pouch), includes both a physical component and a theoretical component that extends beneath a second pouch. Thus, in contrast to Respondent C&D's argument, the first pouch of the Twisted Pleasure condom extends beyond the end of the straight walled portion of the condom, beneath the spiral pouches to the end of the condom. See CX-80, CX-81. With this construction in mind, the evidence shows that the spirals of the Twisted Pleasure condom extend radially away from the central axis of the first pouch, thereby satisfying the limitation of claim 1 that requires a second pouch to extend outwardly from the first pouch. Tr. at 342:25-343:6; see CX-81; see also JPX-6.

Respondent C&D argues that the Twisted Pleasure condom fails to satisfy the limitation of claim 1 of the '004 patent requiring a second pouch with "an entrance with an open area . . . communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis." RCDIB at 34. Specifically, Respondent C&D argues that the Twisted Pleasure condom does not infringe, because the action of the spirals of the Twisted Pleasure to stimulate the glans penis are not limited to a fixed point overlying the most sensitive spot on the

glans penis. Id. In fact, according to Respondent C&D, the spirals of the Twisted Pleasure slide over the entire surface of the glans penis as well as a part of the shaft. Id. As construed, however, the entrance of the second pouch need only overly a portion of the glans penis; there is no requirement that the entrance remain fixed over the most sensitive spot on the glans penis. Accordingly, Respondent C&D's argument must fail. Properly construed, the evidence shows that the Twisted Pleasure condom has a second pouch with an "entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis. Tr. at 343:7-17; see CX-81; see also CPX-6; see also JPX-6.

Respondent C&D argues that the Twisted Pleasure condom does not infringe claim 1 of the '004 patent, because Complainant failed to prove that the a tubular portion and second pouch are formed of a thin membrane material. RCDRB at 20. Specifically, Respondent C&D argues that the Twisted Pleasure has a wall thickness with a minimum dimension of .03 mm, which, as alleged by Respondent C&D, is not "thin" within the meaning of the '004 patent. Id. at 21. According to Respondent C&D, a condom with a wall thickness of .03 mm is defined as an "ultra-thin" condom, not a "thin" condom. Id. Respondent C&D never disputed the claim limitation "thin" in its pre-hearing brief, the JNSI or its initial post-hearing brief, thus depriving Complainant and the Staff of a fair opportunity to address the argument and a chance to put on additional evidence at the hearing. Furthermore, Respondent C&D raises this argument for the first time in its reply post-hearing brief in direct contravention of Ground Rule 11.1. See Order No.2 at ¶11.1. Thus, pursuant to Ground Rule 11.1, I hold that Respondent C&D has waived its argument that Complainant failed to prove that the tubular portion and second pouch are formed of a thin membrane material.

Even if Respondent C&D had timely asserted this point, I note that there is nothing in the intrinsic evidence of record that would lead me to believe that one of ordinary skill in the art at the time of the invention would construe the term "thin" to exclude thicknesses of .03 mm or less. Certainly, there is no definitive statement in the specification that would indicate that the patentee intended to give a special meaning to the term "thin." Thus, even if Respondent C&D had not waived the argument, I would find that Complainant has proven by a preponderance of the evidence that the Twisted Pleasure condom has a tubular portion and a second pouch formed of a thin membrane material. Tr. at 342:16-343:6; see CX-80, CX-81; see also CPX-6, JX-35C (stating that the technical specification for the wall thickness of a Twisted Pleasure condom is at a minimum 0.03 mm).

Having judged and properly credited the testimony of the witnesses who appeared at the hearing, having thoroughly examined the evidence of record , having analyzed the parties post-hearing briefs, and for the reasons stated hereinabove, I find that Complainant has proven by a preponderance of the evidence that Respondent C&D's Twisted Pleasure condom literally infringes claim 1 of the '004 patent.

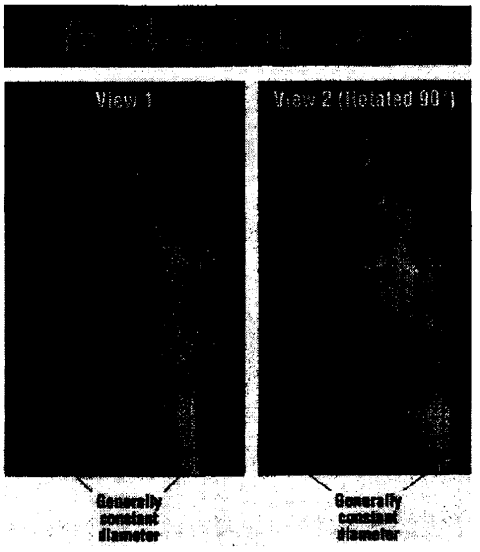
b. Claim 2

Claim 2 depends on claim 1 and adds the following limitation:

> the second pouch being formed through only a part of the circumference to produce movement only on part of the underside surface of the glans penis.

Complainant argues that the Twisted Pleasure condom infringes claim 2 of the '004 patent. CIB at 22-23. Respondent C&D and the Staff argue against such a finding. RCDIB at 35; SIB at 31.

To support its infringement argument with regard to dependant claim 2, Complainant relies on the conclusory testimony of Dr. Wool that each of the two secondary spiral pouches of the Twisted Pleasure are formed only through part of the circumference to produce movement only on part of the underside surface of the glans penis. Tr. at 344:19-345:2. Although Dr. Wool testified that each of the spirals of the Twisted Pleasure produce movement on only part of the underside of the glans penis, the weight of the evidence suggests otherwise. Specifically, Dr. Wool's testimony is contradicted by his own demonstrative exhibits that show one of the secondary spiral pouches overlying the entire underside of the glans penis, not just a portion as required by claim 2. See CX-82, CX-83 (reproduced below). A visual inspection of the glass former used to create the Twisted Pleasure reinforces this point. See JPX-6. Moreover, Respondent C&D's expert, Dr. Potter, testified that the spirals of the Twisted Pleasure completely cover the glans penis and that the Twisted Pleasure operates by sliding over the entire surface of the glans penis and a part of the shaft. RX-110, Qs. 70, 78. Accordingly, I find that Complainant has failed to prove by a preponderance of the evidence that the Twisted Pleasure infringes claim 2 of the '004 patent.



CX-83

c. Claims 3 and 4

Claims 3 and 4 each depend from claim 2. Because the Twisted Pleasure was found not to infringe claim 2, the Twisted Pleasure cannot, as a matter of law, infringe either claim 3 or 4.

d. Claim 13

Independent claim 13 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> >
> > a plurality of second pouches arranged around the circumference; each of said second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans

> penis to produce movement thereof against the surface of the glans penis.

Claim 13 contains many of the same limitations found in claim1. However, claim 13 differs from claim 1 in that claim 13 requires a plurality of second pouches that are arranged around the circumference of the first pouch. Both Complainant and the Staff argue that the Twisted Pleasure infringes claim13. CIB at 23-25; SIB at 33. Respondent C&D argues that the Twisted Pleasure does not infringe claim 13 for the same reasons Respondent C&D argues against infringement of claim 1. RCDIB at 36.

At the hearing, Dr. Wool testified that the Twisted Pleasure has a plurality of second pouches arranged around the circumference. Tr. at 349:2-6. Dr. Wool further testified that each of the second pouches is formed of a thin membrane material and that each of the second pouches extends outwardly of the first pouch. Tr. at 349:7-11. Demonstrative exhibits CX-80, CX-81, CX-82 and CX-83 support Dr. Wool's testimony and a visual inspection of the glass former used to create the Twisted Pleasure condom confirms the existence of two secondary spiral pouches that are arranged around the circumference of the first pouch. See CX-80, CX-81, CX-82, CX-83; see also JPX-6. Accordingly, for the reasons stated above along with those set forth with regard to claim 1, I find that Complainant has proven by a preponderance of the evidence that the Twisted Pleasure infringes claim 13 of the '004 patent.

e. Claim 15

Claim 15 depends on claim 9, which depends on claim 1. Claim 9 adds the following limitation: "the second pouch having an inner surface coated with a lubricant to provide a hydrodynamic rubbing of the glans penis." Claim 15 adds the following limitation:

the second pouches comprising a plurality of longitudinally spaced open pouches to produce rubbing movement along the length of the surface of the glans penis and to provide clitoral stimulation during coitus.

Complainant alleges that the Twisted Pleasure infringes claim 15. CIB at 25. Respondent C&D and the Staff argue that the Twisted Pleasure does not infringe claim 15, because, *inter alia*, the Twisted Pleasure does not have a plurality of longitudinally spaced open pouches. RCDIB at 36-37; SIB 34-35.

To support its infringement argument, Complainant relies on the testimony of Dr. Wool. At the hearing, Dr. Wool testified that the Twisted Pleasure has two secondary pouches that are longitudinally spaced from each other. Tr. at 352:17-24. Specifically, Dr. Wool testified that the secondary pouches are longitudinally spaced from each other, because "they spiral down the axis in parallel with each other." Id. at 352:23-24. While Dr. Wool is correct that the secondary pouches spiral down the longitudinal axis of the first pouch in parallel with each other, that fact does not show that the secondary pouches are longitudinally spaced from each other. In fact, it is quite clear that if one were to take a cross section of the Twisted Pleasure condom anywhere along the spiral portion, the cross section would always bisect both secondary pouches. Compare CPX-6, JPX-6, CX-80, CX-81, CX-83 with JX-1 at Figures 8, 9 (showing two good examples of configurations where the secondary pouches are longitudinally spaced). Because the cross section would always bisect both secondary pouches, the secondary pouches cannot be longitudinally spaced within the meaning of the '004 patent. Accordingly, I find Complainant has failed to prove by a preponderance of the evidence that the Twisted Pleasure infringes claim 15 of the '004 patent.

f. Claim 16

Claim 16 depends from claim 15. Because I have found that the Twisted Pleasure does not infringe claim15, the Twisted Pleasure cannot infringe claim 16 as a matter of law.

g. Claim 18

Independent Claim 18 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end having a tip characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end;
> >
> > a plurality of second pouches formed of thin membrane material extending outwardly of said first pouch; each of said second pouches having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; each of said second pouches having an inner surface moveable through said entrance and against the glans penis;
> >
> > portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches;
> >
> > said second pouches providing looseness at the outer surface of the glans penis to increase its sensitivity to the rubbing action.

Although many of the limitations of claim 18 are materially the same as those found in claim 1, there are some additional limitations in claim 18 that are not found in claim 1. First, claim 18 requires a plurality of second pouches each with an entrance extending lengthwise of the glans penis at least 1 cm. Second, claim 18 states that portions of the tubular portion located between each of the second pouches must maintain the constant diameter of the tubular portion throughout the length

of the tubular portion. Third, claim 18 states that the portions of the tubular portion located between each of the second pouches must also resist stretching the tubular portion to maintain the shape of the second pouches. Complainant and the Staff argue that the Twisted Pleasure infringes claim 18 of the '004 patent. CIB at 26-27; SIB at 35-36. Respondent C&D argues that there is no infringement. RCDIB at 37-38.

Complainant relies on the testimony of Dr. Wool in support of its infringement contention. With regard to the first additional element of claim 18, Dr. Wool testified at the hearing that the Twisted Pleasure has two secondary pouches and that each of the pouches has an entrance that extends lengthwise of the glans penis by at least 1 cm. Tr. at 353:20-23, 354:2-5. In addition, during the hearing, Dr. Wool demonstrated on a Twisted Pleasure condom that the entrance of the second pouch did, indeed, extend lengthwise of the glans penis at least 1 cm. Tr. at 354:2-5; see CPX-6. Additionally, the record contains the testimony of Respondent C&D's expert, Dr. Potter, who opined that the Twisted Pleasure operates by sliding over the entire surface of the glans penis and a part of the shaft. RX-110, Q. 105. Dr. Potter further testified that the entire spiral end changes shape and moves freely over the glans penis, as well as over a portion of the penis below it. Although Dr. Potter's testimony does not discuss the "1 cm" limitation, *per se*, it does support Dr. Wool's testimony that the second pouches of the Twisted Pleasure condom extend below the glans penis.

With regard to the second and third additional elements, Dr. Wool testified that the Twisted Pleasure condom has portions of the tubular portion located between each of the second pouches. Tr. at 354:14-17; see RDX-1. Dr. Wool demonstrated at the hearing where the portions of the tubular portion were located on a Twisted Pleasure condom. Tr. at 354:22-355:3; see CPX-6. According to Dr. Wool, the portions of the tubular portion in the Twisted Pleasure are the valleys

that run between the secondary spiral pouches. Id.; see RDX-1. Dr. Wool also testified and demonstrated that the portions between the second pouches of the Twisted Pleasure maintain the constant diameter of the tubular portion throughout the length of the tubular portion. Tr. at 354:22-355:14. Dr. Wool further testified that the portions between the second pouches of the Twisted Pleasure resist stretching of the tubular portion and help maintain the shape of the second pouches. Tr. at 355:15-21.

Claim 18 is clearly an apparatus claim, because the claim is drawn to "[a] prophylactic pouch." Although claim 18 states that the portions of the tubular portion located between each of the second pouches must: 1) maintain the constant diameter of the tubular portion throughout the length of the tubular portion; 2) resist stretching of the tubular portion; and 3) maintain the shape of the second pouches, those elements of claim 18 are merely statements of function, devoid of any structure. According to the Federal Circuit, "To infringe an apparatus claim, the [alleged infringing] device must meet all of the structural limitations." Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293 (Fed. Cir. 2005)(citing Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F2d 1464, 1468 (Fed. Cir. 1990) and In re Michlin, 256 F.2d 317, 320 (1958)); Hewlett-Packard Co., 909 F2d at 1468 ("[A]pparatus claims cover what a device *is*, not what a device *does*."); In re Michlin, 256 F.2d at 320 ("It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function."). Because those elements of claim 18 are functional limitations they are immaterial to the infringement analysis of claim 18.

Accordingly, based on the evidence of record, I find that the entrance of the second pouch in the Twisted Pleasure extends lengthwise of the glans penis at least 1 cm and that the Twisted

Pleasure has portions of the tubular portion located between each of the second pouches. Consequently, for the reasons stated hereinabove with regard to Claim 18 and for those reasons stated herein with regard to claim 1, Complainant has proven by a preponderance of the evidence that the Twisted Pleasure infringes claim 18.

h. Claim 22

Independent Claim 22 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
>
> > said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end;
> >
> > a second pouch integrally formed on the circumference of the closed end for forming a loose pocket overlying in spaced relationship to the glans penis and having an inner surface movable back and forth thereon during coitus for providing stimulation thereto;
> >
> > Said tubular portion and said second pouch having a wall thickness of 0.11 mm ± 0.04 mm; and
> >
> > Said second pouch having its inner surface spaced radially outwardly of said tubular portion to provide looseness between said tubular portion and the outer surface of the glans penis to prevent binding of the glans penis with consequent reduction in sensitivity.

While stated in slightly different terms, for the most part, the limitations in claim 22 are the same as those recited in claim 1. However, claim 22 differs from claim 1 in two regards. First, claim 22 explicitly requires that both the tubular portion and second pouch have a wall thickness of 0.11 mm ± 0.04 mm. Second, claim 22 explicitly requires that the second pouch be integrally formed on the circumference of the closed end of the tubular portion. Complainant and the Staff

argue that the Twisted Pleasure infringes claim 22 of the '004 patent. CIB at 27-28; SIB at 36. Respondent C&D disagrees. RCDIB at 38-39.

Complainant relies entirely on Dr. Wool in support of its infringement contentions. At the hearing, Dr. Wool testified that the Twisted Pleasure had a tubular portion and second pouch with a wall thickness of .11 mm ± .04 mm. Tr. at 357:19-22. Specifically, in response to Complainant's counsel's question, "In the Twisted Pleasure is the tubular portion and the second pouch, do they have a wall thickness of .11 millimeters plus or minus .04 millimeters?" Dr. Wool testified, "Yes, they do." Id. No further explanation was given.

On cross examination, Dr. Wool admitted that he never measured the wall thickness of the tubular portion of the Twisted Pleasure. Tr. at 447:2-12. In fact, Dr. Wool admitted that he did not personally determine the wall thickness of the tubular portion, but rather was given that information "by the attorneys." Id. Dr. Wool also admitted that he never made an independent determination of the thickness of the second pouch. Id. at 447:22-25. Consequently, Dr. Wool admitted that he did not know for certain whether the thickness of the spiral portion of the Twisted Pleasure condom was the same thickness as that of the tubular portion of the condom. Id. at 448:1-4. Based on Dr. Wool's responses during Respondent C&D's cross examination, I find that Dr. Wool's testimony with regard to the wall thickness of the tubular portion and second pouch is entitled to no weight.

The Staff, however, does not rely on Dr. Wool's testimony to show infringement of claim 22, but rather on what can be characterized as a rough design drawing of Respondent C&D's Double Springers condom. See CX-228. The Double Springers condom was later referred to as the Twisted Pleasure. The drawing appears to show the thickness of the secondary spiral pouches of the Double Springers to be .131 mm and .130 mm. CX-228 at 2. According to the Staff, this evidence proves

that the Twisted Pleasure infringes claim 22 of the '004 patent. SIB at 36. I disagree. For one thing, the drawing, if it is to be believed, only shows the wall thickness of the second pouches. The diagram has no indication of the wall thickness for the tubular portion and claim 22 explicitly requires that the wall thickness of the tubular portion also be within the range of .11 mm ± .04 mm. Additionally, there is testimony on the record from Ravi Reddy, President of Medtech, with regard to CX-228, that although the Twisted Pleasure may have been previously referred to as the Double Springers, the "final product is obviously a lot different than what it shows on this picture." See Tr. at 724:7-725:4; see also Tr. at 735:20-23 (Q. "What relationship does this reference to this Double Springer diagram bear to the final design of what was called the Twisted Pleasure?" A. "Not much.").

For the reasons stated hereinabove, I find that Complainant has failed to prove that the tubular portion and second pouch of the Twisted Pleasure have a wall thickness of .11 mm ± .04 mm. Consequently, the Twisted Pleasure does not infringe claim 22 of the '004 patent.

i. Claim 25

Claim 25 depends from claim 22. Because I have found that the Twisted Pleasure does not infringe claim 22, the Twisted Pleasure does not infringe claim 25 as a matter of law.

j. Claim 31

Independent claim 31 reads as follows:

> A prophylactic pouch for use by a male, having an elongated tubular portion forming a first pouch including a circumference, an open end and a closed end, said tubular portion having a generally constant diameter from end to end, characterized by:
>
> > a second pouch integrally formed on the circumference of said tubular portion as an outward bulge on the closed end in overlying spaced relationship to a glans penis and operable to move thereon to provide stimulation during coitus; said second pouch formed of thin

> membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement.

Claim 31 contains many of the same limitations found in claim 1. For all intents and purposes, there are only two differences between claim 31 and claim 1. The first is that claim 31 requires a second pouch integrally formed on the circumference of the closed end of the tubular portion. The second is that claim 31 requires a second pouch with an entrance that extends lengthwise of the glans penis at least 1 cm. Complainant and the Staff argue that the Twisted Pleasure infringes claim 31. CIB at 29-30; SIB at 37-38. Respondent C&D argues that the Twisted Pleasure does not infringe claim 31 for the same reasons Respondent C&D argues against infringement of claim 1. RCDIB at 40.

Complainant bases its infringement argument on the testimony of its expert, Dr. Wool. At the hearing, Dr. Wool testified that the Twisted Pleasure has a second pouch that is integrally formed on the circumference of the tubular portion as an outward bulge on the closed end in overlying spaced relationship to the glans penis. Tr. at 360:8-12. Dr. Wool also testified that the entrance of the second pouch extends lengthwise of the glans penis at least 1 cm. Tr. at 354:2-5, 360:19-22. In addition, during the hearing, Dr. Wool demonstrated on a Twisted Pleasure condom that the entrance of the second pouch did, indeed, extend lengthwise of the glans penis at least 1 cm. Tr. at 354:2-5; see CPX-6. Additionally, the record contains the testimony of Respondent C&D's expert, Dr. Potter, who opined that the Twisted Pleasure operates by sliding over the entire surface of the glans penis and a part of the shaft. RX-110, Q. 105. Dr. Potter further testified that the entire spiral end changes

shape and moves freely over the glans penis, as well as over a portion of the penis below it. Although Dr. Potter's testimony does not discuss the "1cm" limitation, *per se*, it does support Dr. Wool's testimony that the second pouches of the Twisted Pleasure condom extend below the glans penis.

Based on the evidence of record, the reasons stated herein above, and the reasons set forth with regard to claim 1, I find that Complainant has proven by a preponderance of the evidence that the Twisted Pleasure condom infringes claim 31 of the '004 patent.

k. Claim 32

Claim 32 depends from claim 31 and includes the following additional limitation:

> a third pouch formed as an outward bulge intermediate the open and closed end for engaging and stimulating the clitoris of a female partner during coitus.

Complainant and the Staff argue that the Twisted Pleasure infringes claim 32. CIB at 30; SIB at 39. Respondent C&D argues against a finding of infringement. RCDIB at 40-41.

At the hearing, Dr. Wool testified that the Twisted Pleasure had a third pouch formed as an outward bulge intermediate to the open and closed end. Tr. at 361:22-362:11. Dr. Wool also testified that the third pouch was capable of providing clitoral stimulation during coitus. Id. The product packaging for the Twisted Pleasure supports Dr. Wool's testimony that the Twisted Pleasure is capable of providing clitoral stimulation. JPX-2. Specifically, the product packaging states that "TROJAN® TWISTED PLEASURE™ condoms are designed with a special 'TWIST' at the closed end, to help stimulate both partners in their most sensitive areas." Id.

Complainant's only evidence that the Twisted Pleasure has a third pouch formed as an outward bulge intermediate to the open and closed end is the conclusory testimony of Dr. Wool. Tr. at 361:22-362:11. Having carefully considered Dr. Wool's testimony, I find Dr Wool's opinion on

this matter to be unreliable. In fact, I not only find it unreliable, I find it incorrect. Consequently, I give Dr. Wool's testimony no weight. Dr. Wool's testimony that the third pouch is intermediate to the open and closed end contradicts previous testimony given by Dr. Wool that the secondary pouch(es) of the Twisted Pleasure are formed on the closed end. See Tr. at 357:10-13 (testifying that the Twisted Pleasure has two secondary pouches integrally formed on the circumference of the closed end), 360:8-12 (testifying that the Twisted Pleasure has a second pouch integrally formed on the circumference of the tubular portion as an outward bulge on the closed end). It is irreconcilable for Dr. Wool to assert that the spiral pouches of the Twisted pleasure can both be formed at the closed end when discussing claims 22 and 31 and intermediate to the open and closed end when discussing claim 32. Moreover, a visual examination of the glass former used to create the Twisted Pleasure clearly shows that the third pouch is formed on the closed end, not intermediate to the open and closed end. See JPX-6. Accordingly, I find Complainant has failed to prove by a preponderance of the evidence that the Twisted Pleasure infringes claim 32 of the '004 patent.

l. Claim 36.

Claim 36 depends from claim 32. Because I have found the Twisted Pleasure does not infringe clam 32, as a matter of law, the Twisted Pleasure cannot infringe claim 36.

2. Respondents Medtech/Intellx's Inspiral

In its post-hearing brief, Complainant asserts that the Inspiral infringes claims 1-4, 6, 8-9, 22, 25, and 31 of the '004 patent, although in its post-hearing reply brief filed on May 5, 2006, Complainant accuses the Inspiral of also infringing claim 18. CIB at 15; CRB at 9. Because Complainant did not include a discussion of how the Inspiral infringes claim 18 in its initial post-hearing brief, this claim is deemed waived. See Ground Rule 11.1.

The infringement portion of Complainant's initial post hearing brief only addresses infringement in a conclusory fashion. Complainant's only cited support for its arguments is the conclusory testimony of Dr. Wool. See CIB at 15-21. Much of Complainant's post-hearing reply brief suffers from the same problem as its initial post-hearing brief. When I find that Complainant has made an argument in other than a conclusory manner, I will discuss that argument where appropriate.

Staff contends in its initial post-hearing brief that the Inspiral infringes claims 1, 9, 22, 25, and 31 of the '004 patent. SIB at 39. Staff attempts to include an infringement analysis for claim 6 in its post-hearing reply brief. SRB at 20-21. Because Staff did not include this analysis in its initial post-hearing brief, the argument is deemed waived. See Ground Rule 11.1. However, I will consider the issue because Complainant did raise it.

Furthermore, in its initial post-hearing brief discussing the alleged infringement of claim 1, Staff confuses the burden of proof on the issue of infringement. See SIB at 27-31. Staff discusses all of the points brought up by the Respondents but does not discuss how Complainant proved that each and every limitation from claim 1 is present in the Inspiral prophylactic. Id. Therefore, I will discuss some of the points that Staff brings up but will not rely heavily on Staff's briefing.

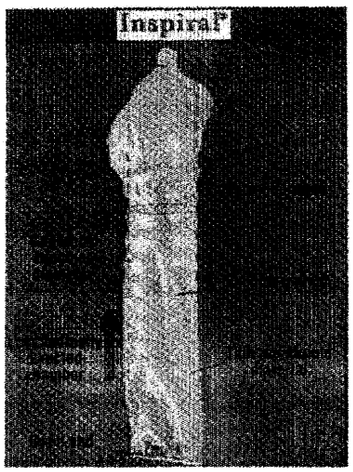
Respondents Medtech/Intellx contend that Complainant has not proven that the Inspiral prophylactic infringes any of the asserted claims of the '004 patent. RMIIB at 6-18. All of Respondents Medtech/Intellx's arguments regarding the Inspiral's alleged infringement are based on Respondents' erroneous claim constructions of the terms "pouch," "generally constant diameter," and "extending outwardly." See RMIIB at 6-15. Therefore, I will not discuss these arguments because Respondents' constructions of these terms have been rejected supra. See supra at IV.A.

a. Claim 1

Claim 1 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

The Inspiral is a prophylactic pouch for use by a male and has an elongated tubular portion which forms a first pouch which has a circumference. See CX-76 (reproduced below). The first pouch of the Inspiral also has an open end and a closed end. Id.



CX-76

The tubular portion of the Inspiral is formed of thin membrane material and has a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis. Id.

The Inspiral has a second pouch formed of thin membrane material extending outwardly of said first pouch and the second pouch has an interior space. See CX-77 (reproduced below).

CX-77

The second pouch of the Inspiral includes an entrance with an open area extending lengthwise of the glans penis. The entrance of the second pouch communicates its interior space directly with the longitudinally directed chamber at a point overlying the glans penis. The second pouch has an inner surface moveable through the entrance and against the glans penis for movement.

Complainant claims that this entrance is a single point at the beginning of the second pouch. See figure from CX-78 (reproduced below).

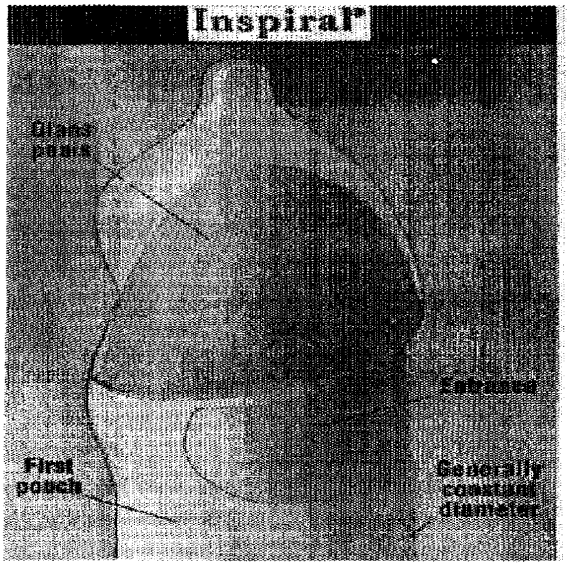


Figure on left side of CX-78

As discussed supra, the entrance is the boundary where the first pouch and the second pouch meet. See supra at IV.A.8. Therefore, as construed, the entrance is much larger than the Complainant contends. The entrance is more easily seen on the figure below from CX-78.

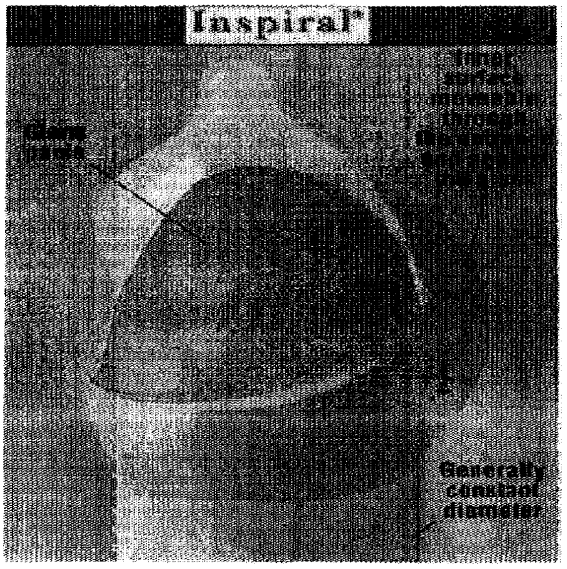


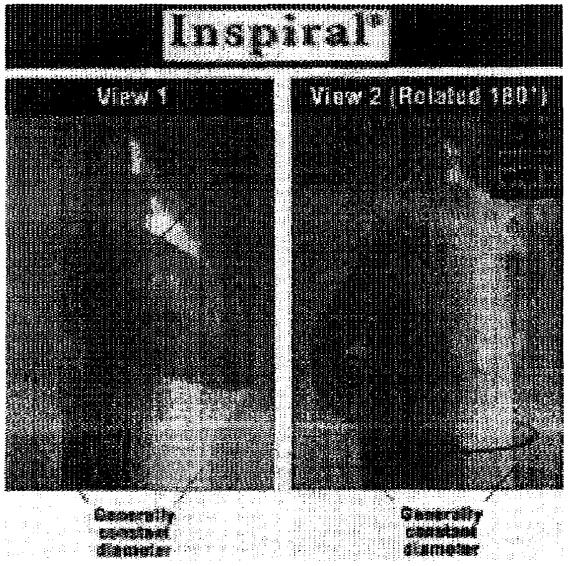
Figure on right side of CX-78

It is not possible to show the entrance clearly on these two dimensional pictures. It is the area located inside the second pouch, which is shown in pink on the demonstrative exhibit, CX-78 (reproduced above). The entrance is extending lengthwise of the glans penis. See id. Therefore, I agree with Complainant and Staff that the Inspiral prophylactic literally infringes claim 1 of the '004 patent.

b. Claim 2

Claim 2 depends from claim 1 and adds the limitation that the second pouch is formed through only a part of the circumference to produce movement only on part of the underside surface of the glans penis.

It is clear from CX-79, the demonstrative exhibit reproduced below, that the Inspiral does not infringe claim 2 of the '004 patent.



CX-79

The second pouch is formed through much more of the circumference than the portion of the circumference surrounding the glans penis. Therefore, the second pouch will not produce movement only on part of the underside surface of the glans penis. The second pouch of the Inspiral will produce movement on the entirety of the glans penis because of its shape. Therefore, because the Inspiral does not meet all the limitations of claim 2, I agree with Medtech/Intellx and Staff that the Inspiral does not infringe claim 2 of the '004 patent.

c. Claims 3 and 4

Claim 3 depends from claim 2, and claim 4 depends from claim 3. Because the Inspiral does not infringe claim 2, it cannot infringe claims 3 and 4. Cf. Wolverine World Wide v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994) (once it has been established that an independent claim is not infringed, there can be no infringement of the dependent claims). Although claim 2 is not an independent claim, because claims 3 and 4 depend from claim 2 and the Inspiral does not infringe claim 2, the Inspiral cannot infringe claims 3 and 4.

d. Claim 6

Claim 6 depends from claim 1 and adds the limitation that the second pouch must be formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis. It is clear from an inspection of JPX-5, the glass former used to produce the Inspiral prophylactic, that the second pouch is formed completely around the circumference of the first pouch. See JPX-5. The second pouch also forms an annular pocket, because the second pouch of the Inspiral is a bag-like structure forming a ring-like shape. See JPX-5. Also, the annular pocket overlies all of the glans penis and therefore would produce movement on all of the glans penis during coitus. I agree with Complainant that the Inspiral literally infringes claim 6 of the '004 patent.

e. Claim 8

Claim 8 depends from claim 1 and adds the limitation that the second pouch is formed as a single pouch on the closed end to overlie the glans penis and provides looseness between the prophylactic pouch and a penis only at the glans penis portion thereof. As discussed in reference to claim 6, the second pouch of the Inspiral is formed around the entire circumference of the first pouch and therefore would be unable to provide looseness between the prophylactic pouch and a penis only at the glans penis portion thereof. Therefore, I agree with Respondents and Staff that the Inspiral does not infringe claim 8 of the '004 patent.

f. Claim 9

Claim 9 depends from claim 1 and adds the limitation that the second pouch having its inner surface coated with a lubricant to provide a hydrodynamic rubbing of the glans penis. An inspection of the Inspiral shows that the second pouch's inner surface is coated with a lubricant. See JPX-1.

I agree with Complainant and Staff that the Inspiral prophylactic literally infringes claim 9 of the '004 patent.

g. Claim 22

Claim 22 is an independent claim. While stated in slightly different terms, for the most part, the limitations in claim 22 are the same as those recited in claim 1. However, claim 22 differs from claim 1 in two regards. First, claim 22 explicitly requires that both the tubular portion and second pouch have a wall thickness of 0.11 mm ± 0.04 mm. Second, claim 22 explicitly requires that the second pouch be integrally formed on the circumference of the closed end of the tubular portion.

Staff relies upon JX-40, a design and development document for the Inspiral, to show that the Inspiral meets this claim limitation. SIB at 36. JX-40 shows one hundred twenty-five measurements of the thickness of Inspiral prophylactics. See JX-40 at 13. It appears that JX-40 is showing measurements of five different points on each of twenty-five sample prophylactics.

JX-40 is more convincing than the evidence presented by Complainant to show infringement of the Twisted Pleasure. The evidence presented to show infringement of the Inspiral shows measurement of the actual accused product and shows measurements on different portions of the Inspiral, as opposed to the evidence for the Twisted Pleasure which only showed measurement of the thickness of the second pouch.

Of the one hundred twenty-five measurements shown in JX-40, only two measurements fall outside the scope of this claim. The measurements for the elevated pouch side 1 of the S. No. 10 and S. No. 11 Inspiral prophylactics are .152mm and .168mm, respectively. Id. The other one hundred and twenty-three measurements all fall within the range specified by claim 22 of the '004 patent. This shows that, at a minimum, twenty-three of the twenty-five prophylactics measured

infringe claim 22. Therefore, I agree with Complainant and Staff that the Inspiral literally infringes claim 22 of the '004 patent. Cf. Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed. Cir. 2001) ("in determining whether a product claim is infringed, we have held that an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation.") (citing Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832, 20 USPQ2d 1161, 1171 (Fed. Cir. 1991)).

h. Claim 25

Claim 25 depends from claim 22 and adds the limitation that the second pouch is coated with a lubricant to provide a hydrodynamic rubbing of the glans penis. I have already found in regard to claim 9 that the second pouch of the Inspiral prophylactic is coated with a lubricant. Therefore, I agree with Complainant and Staff that the Inspiral prophylactic literally infringes claim 25 of the '004 patent.

i. Claim 31

Claim 31 is an independent claim. Claim 31 contains many of the same limitations found in claim 1. For all intents and purposes, there are only two differences between claim 31 and claim 1. The first is that claim 31 requires a second pouch integrally formed on the circumference of the closed end of the tubular portion. The second is that claim 31 requires a second pouch with an entrance that extends lengthwise of the glans penis at least 1 cm. Complainant and Staff rely on Dr. Wool's testimony that the second pouch extends lengthwise of the glans penis by at least 1 cm and Dr. Wool's demonstration at the hearing. CIB at 21; SIB at 38; Wool, Tr. 333:25-334:3. Based upon Dr. Wool's testimony and his demonstration, I agree with Complainant and Staff that the Inspiral literally infringes claim 31 of the '004 patent.

3. Doctrine of Equivalents

Complainant did not address the issue of infringement under the doctrine of equivalents in its Post Hearing Brief. CIB at 15-31. Thus, Complainant has waived this argument. See Ground Rule 11.1.

C. Validity

1. Anticipation

a. The Parties' Positions

C&D argues that if the claims of the '004 patent are construed broadly enough to encompass figure 10 of the patent, that "the claims are necessarily invalid" in view of prior art. RCDIB at 71. Although C&D lists several prior art references, the main thrust of the invalidity argument focuses on UK Patent No. 1,252,255 (the '255 patent). Id. at 70-71; RX-12. C&D asserts that this prior art patent "discloses that the ratio of the shaft length to head length can be in the range from 1:1 . . . to 12:1. Id. at 71. C&D argues that, based on the disclosures of the '004 patent, figure 10 would have a ratio of shaft to head portions of 2.2. Id. Thus, based on this proportion, C&D asserts that the '255 patent discloses a prophylactic with the dimensions of figure 10. Id. Respondent Medtech/Intellx does not itself assert validity as a defense. However, Medtech/Intellx notes that "if C&D's position with respect to invalidity is accepted, then Medtech/Intellx also assert (for the same reasons) that the'004 patent is not enforceable against them." RMIIB at 19.

Complainant asserts that Respondent C&D "did not submit a claim chart or any testimony establishing" that every element of any claim of the '004 patent is disclosed by any prior art reference. CIB at 42-43. Complainant argues that this failure precludes Respondent from establishing anticipation by any prior art reference. Id.

Staff asserts that Respondent has failed to demonstrate by clear and convincing evidence that any prior art reference anticipates the claims of the '004 patent. SIB at 60-63. Staff argues that the "baggy-end" prophylactics, as described in RX-11 (WO 89/02256), teach pouches which would collapse backwards during use and, thus, would not practice a "crucial distinction of the '004 patent." Id. at 60. Staff also asserts that the '255 patent, does not disclose precise dimensions for the "baggy-end" of the patented prophylactics. Id. at 61. Staff argues that because the dimensions are not detailed in the specification of the '255 patent, it is impossible to determine whether or not it would "collapse backward during use and invalidate certain of the asserted claims." Id. at 62. Staff notes that the '255 patent discloses a range of "shaft/head length ratios" which encompasses the dimensions described for figure 10 of the '004 patent. Id. at 63. However, Staff asserts that this does not make the prior art anticipatory because the smaller sub-range described by the '004 patent has the "criticality" of "prevent[ing] the collapse of the second pouch." Id.

b. Applicability of the Prior Art

Because Respondent C&D focuses all of its invalidity arguments on the '255 patent I will consider only this reference for determining the teachings of the prior art. As a preliminary matter, I reject Complainant's contention that C&D's failure to submit a claim chart or testimony from their own expert regarding the teachings of the prior art means that C&D has failed to meet their evidentiary burden to prove invalidity. The Federal Circuit has stated that "[i]t is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991)("Scripps")(emphasis added). However, such evidence is "necessarily of limited scope and probative value," because the role of extrinsic evidence relating to prior art references "is to educate the decision-maker to what

the reference meant to persons of ordinary skill in the field of the invention." Id. In investigations such as this one where the language of the prior art references is simple and straightforward, expert testimony is of little value to educate a decision-maker. Indeed, the Federal Circuit has upheld a grant of summary judgment of invalidity without discussing any expert testimony, relying solely on the teachings of the prior art to reach its conclusion. Ohio Cellular Prods. Corp. v. Adams USA, Inc., 1996 WL 732296 (Fed. Cir. 1996)(unpublished opinion).

As another preliminary matter, the evidence of record shows that the '255 patent is indeed prior art to the '004 patent. The '255 patent was filed on November 10, 1967 and printed on November 3, 1971. RX-12 at 1. The '004 patent was filed in 1990. JX-1 at 1. Based on the filing and publication dates, I find that the '255 patent clearly qualifies as an "invention . . . patented or described in a printed publication in this or a foreign country." 35 U.S.C. § 102(a). It is also worth noting that the '255 patent was not before the examiner during prosecution. JX-1; JX-4; RX-57. Although proving anticipation normally requires that a respondent meet a clear and convincing standard, this burden is even higher in situations where a particular prior art reference was considered by the examiner during prosecution. Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323 (Fed. Cir. 1999). Because the '255 patent was not considered by the examiner during prosecution, C&D need only prove invalidity by the normal clear and convincing standard.

Staff asserts two main arguments as to why the prior art "baggy-end" prophylactics do not anticipate the claims of the '004 patent, both of which are based on analysis of the dimensions of Figure 10 of the '004 patent. For purposes of this anticipation analysis, a "baggy-end" prophylactic, in the terms of the '004 patent, is a prophylactic in which a single second pouch is formed entirely around the "closed end" of the prophylactic. See, e.g., JX-1 at Figure 10; RX-12 at Figures 1 and

2. First, Staff argues that the dimensions of the embodiment depicted in Figure 10 are considerably different than the dimensions of the prior art "baggy end" prophylactics. SIB at 60. Second, Staff asserts that if a second pouch is large enough to "collapse backward during use" that it would not practice the patent. Id. For the reasons discussed below, I find that neither of these arguments are persuasive.

None of the claims of the '004 patent recite specific size limitations on a second pouch. JX-1. In essence, Staff asks me to import limitations from the specification into the claims which potentially cover the embodiment depicted in Figure 10. This would be improper. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.1988). Instead, the claims are broadly drawn to cover second pouches of varying sizes, not just second pouches of the dimensions given for the Figure 10 embodiment. Staff compares the dimensions of the preferred embodiments of the '255 patent and the dimensions of preferred embodiment depicted in Figure 10 of the '004 patent. However, to determine whether a given claim is invalid under 35 U.S.C. §102, I must compare the claims of the '004 patent, not a single preferred embodiment, to the disclosures of the prior art. Scripps, 927 F.2d at 1567 ("Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference."(emphasis added)).

Similarly, Staff states that "the evidence shows that if a designer modified the second pouch of Figure 10 by gradually increasing its width and length, at some point the second pouch would collapse backwards during use and no longer practice the patent." SIB at 60. In support of this position, Staff points to the following portion of the specification:

> Yet another feature of the present invention is to provide a condom wherein the pouch or pouches cannot be eliminated if the user stretches the condom too tightly along the length of the penis as the condom is placed on the penis. Areas of material between the pouches are of the same diameter as the proximal shaft of the condom (open end of condom) and restrict longitudinal stretching which might tend to reduce or eliminate the pouch or pouches.

JX-1 at 3:6-14. I do not find support for Staff's position in this statement. The first sentence does not support Staff's argument because, if "the user stretches [a "baggy-end"] condom too tightly along the length of the penis," the glans of the penis would be directly in contact with the closed end of the prophylactic. This physical contact would prevent the pouch from collapsing backwards during use.

The second sentence refers to an embodiment of the '004 invention with second pouches separated by strands of material, e.g., the "star" embodiment depicted in Figures 11-13. See also JX-1 at 6:64-68 (reciting similar functions for the embodiment depicted in Figures 11-13). The embodiment depicted in Figure 10 shows a single second pouch encompassing the closed end of the prophylactic and which has no "material between the pouches." Of the asserted claims, only independent claim 18 contains the language "portions of said tubular portion located between each of said second pouches maintaining said constant diameter throughout the length of the tubular portion to resist stretching of said tubular portion to thereby maintain the shape of said second pouches." JX-1 at 8:59-63, see also Claims 19 and 20 (containing same language, but not asserted against Respondents). As the Federal Circuit stated in Phillips, "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." Phillips, 415 F.3d at 1327 (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed. Cir. 2004)). Thus, I find that

the specification does not support Staff's contention that every claim must be interpreted as being limited to this objective of the patented invention.

Staff also cites a prior art reference which shows that the single pouch on the closed end collapses. RX-16 at Figures 1 and 2. However, as mentioned above, none of the claims of the '004 patent contain limitations on the maximum size of a second pouch or a limitation requiring that pouches are incapable of collapsing backwards during use. The fact that a prior art reference discloses a pouch that can collapse backwards during use does not prevent the claims of the '004 patent from being broad enough to encompass such a prophylactic. Finally, Staff also cites to Dr. Wool's testimony. Wool, Tr. at 417:8-11 ("And would you agree that if the pouch that's shown in figure 10 became long enough, that the claims of the patent would no longer cover it? . . . That's correct."). At most, this testimony establishes that if a single pouch on the closed end of a prophylactic were of sufficient length, it would not practice the claims otherwise drawn to such an embodiment. This testimony does not support Staff's contention that any pouch which would collapse backwards during use would cease to practice the patent.

As an alternate argument that the '255 patent does not anticipate the '004 patent, Staff notes that the '004 specification describes a particular set of dimensions for the prophylactic depicted in Figure 10. SIB at 60-62. Although Staff asserts that the '255 patent does not fully disclose the precise dimensions of the distal end portion, it does disclose a range of sizes for the distal end portion that potentially encompasses the dimensions disclosed by the '004 patent specification for figure 10. Id. at 62-63. Staff argues, however, that "when a prior art reference provides a wide range of values and the patent at issue claims a much smaller sub-range due to a criticality that exists

within the sub-range, the prior art is not anticipatory." SIB at 63. Staff cites Woodruff for this proposition. In re Woodruff, 919 F.2d 1575 (Fed. Cir. 1990).

However, I do not read Woodruff as supporting this position. First, one of the claims at issue in Woodruff was drawn to a wider range of values than the range disclosed by the prior art reference. Id. at 1576. Second, the Federal Circuit found that the claims were properly rejected as obvious in light of the prior art, in part, because the applicant did not "show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range." Id. at 1578 (emphasis in original); See also Gardner v. TEC Systems, Inc., 725 F.2d 1338, 1349 (Fed. Cir. 1984)(en banc)(affirming a finding of invalidity under § 103 where the claims at issue did not specify performance and operation different than the prior art). The claims of the '004 patent recite neither a range of values for size limitations of second pouches or a limitation that a pouch must not collapse backward. Thus, nothing in the claims of the '004 patent suggest that either of these differences are critical distinctions of the invention claimed by the '004 patent.

For all of the above reasons, I find that the '255 patent is properly considered as a potentially invalidating prior art reference.

c. Analysis of the Prior Art

The '255 patent discloses a "thin-walled" prophylactic. RX-12 at Claim 1. It also discloses a prophylactic with an open and closed end. Id. at Figures 1 and 2. The prophylactics claimed by the '255 patent have at least two portions of different diameters, but both are of "generally cylindrical shape." Id. at 1:35-36, 1:55, claim 3. The first portion, "the stem section," allows for "gripping . . . around substantially the whole length of the shaft of the penis." Id. at 1:60-62. The second section allows for "gripping of the swollen head of the penis, when in erect state, to be

avoided." Id. at 1:56-58. The specification describes the preferred embodiments as having four sections (from open end to closed end): a "tubular stem section;" a "frusto-conical connecting section;" a "tubular head section," and; a "teat-type end closing section." Id. at 1:69-92. With reference to the preferred embodiments, specific dimensions are given for each of these sections, except for the "teat-type end closing section." Id. However, the specification states that the ratio of the head section diameter to stem section diameter can be between 1.8:1 to 1.1:1 and the ratio of the stem section length to head section length can be between 12:1 to 1:1. Id. at 2:7-11.

d. The Claims At Issue

1. Claim 1

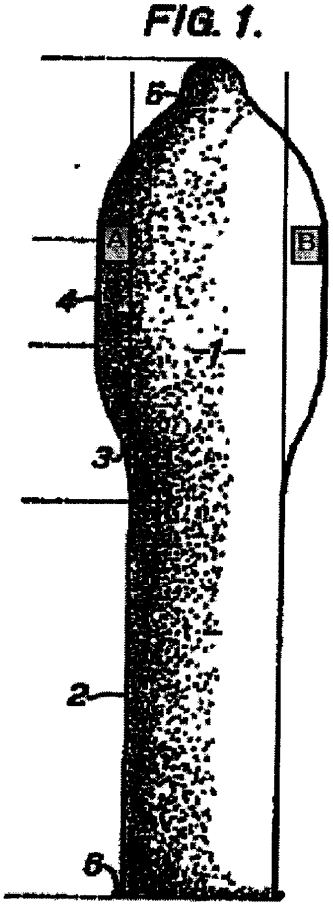
Claim 1 of the '004 patent reads:

> 1. A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

To anticipate this claim, the '255 reference must disclose each of the limitations. C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1349 (Fed. Cir. 1998). As such, I will analyze claim 1, limitation by limitation. For the purpose of clarity, I have included a modified version of Figure 1 from the '255 patent below.

The '255 patent discloses a "contraceptive sheath," which provides a "tight grip around the root of the penis" to prevent semen from escaping its confines. RX-12 at 1:28, 1:55-65, Figure 1. Although the '255 patent uses different terminology than the '004 patent, the '255 patent discloses a "prophylactic pouch." The '255 patent also discloses that the claimed prophylactic is thin-walled. Id. at 1:34, Claim 1.

I have construed the term "elongated tubular portion" as being "the portion of the prophylactic pouch that is tubular in shape and generally resembles a traditional condom and which does not include any of the . . . second pouch(es)." See, supra, IV.A.2. Additionally, I noted that this claim term includes "a theoretical tube-like structure that lies beneath the . . . second pouch(es)." Id. The '255 patent discloses a prophylactic with a main body section with a generally cylindrical shape, an open end, and a closed end. RX-12 at 1:35-36, Figures 1 (reproduced below) and 2. Thus, a prophylactic with a generally tubular shape is disclosed. The '255 patent also discloses a head section which is of greater diameter than the main body section. Id. at 1:35-39. The '255 patent teaches that this prophylactic is hollow, because it is made by using a former with a complementary configuration to the prophylactic. Id. at 2:13-17. The embodiment depicted in Figure 1 of the '255 patent shows a prophylactic generally resembling a traditional prophylactic, but with a widened section at the closed end. Id. As this embodiment would be hollow, it would have a continuation



of the "theoretical tube-like structure" continuing beneath the widened portion, as demonstrated by lines A and B in Figure 1. Thus, the '255 patent discloses an "elongated tubular portion."

Similarly, I have also construed "circumference" and "generally constant diameter," in the context of the '004 patent, to encompass the external surface of both the physical and theoretical surfaces of the tubular portion. See, supra, IV.A.3 and IV.A.4. Because the '255 patent discloses an "elongated tubular portion" it discloses the circumference and diameter of that feature. The '255 patent discloses that the diameter of the "stem section" of the claimed prophylactic is such that it will provide "a tight grip around the root of the penis." RX-12 at 1:58-59. This is the same function which all the parties to this investigation agree is the purpose of the "generally constant diameter" of the '004 patent. CIB at 10; RCDIB at 18; SIB at 20.

I have construed "longitudinally directed chamber" as "the enclosed space or compartment formed by the tubular portion into which the penis is inserted" and have included within this definition that "the tubular portion includes both the area formed by the physical surface . . . and the theoretical surface." See, supra, IV.A.5. As discussed above, the '255 patent discloses the tubular portion and can be seen as the space between lines A and B in Figure 1. The '255 patent also discloses that this portion forms an enclosed space or compartment into which a penis can be inserted. RX-12 at 55-65, Figures 1 and 2. Given that I have found that the '255 patent discloses all of these features, which are the features defining a "first pouch" in claim 1, I also find that the '255 patent discloses a prophylactic with a "first pouch."

Figure 1 of the '255 patent shows a widened area at the distal end, "the head section," of the depicted embodiments. RX-12, see also Id. at Claims 1-4. Additionally, the specification of the '255 patent states that the head section has a diameter larger than the diameter of the main body

section (i.e., the "first pouch"). Id. at 37-39. Figure 1 and the specification demonstrate that the '255 patent discloses a head section that extends radially away from the central axis of the "first pouch." This head section has an "interior space" because it is hollow. Id. at 2:13-17.

I have construed "entrance with an open area" as "the boundary between the first pouch and any of the secondary pouch(es)." See, supra, IV.A.8. As discussed above, the '255 patent discloses a first pouch which continues from the open end to the closed end. The diameter of the "head section" as depicted in Figure 1 of the '255 patent is wider than the diameter of the first pouch. See also RX-12 at claims 1-4. Thus, a boundary is created in the area of the head section between the "first pouch" and those parts of the head section lying outside the circumference of the "first pouch." This boundary is shown above as lines A and B in Figure 1. This boundary, or "entrance" in the terms used by the '004 patent, directly connects the interior space of the wider "head section," the spaces labeled A and B in Figure 1, with the underlying "longitudinally directed chamber." Thus, the '255 patent discloses that the interior space of the "head section" communicates directly with the "longitudinally directed chamber."

The '255 patent also discloses that the "head section" overlies the glans penis. RX-12 at 1:55-58 ("The employment of two distinct sections enables on the one hand gripping of the swollen head of the penis, when in erect state, to be avoided."). Furthermore, the '255 patent discloses that the altered shape of the prophylactic, relative to straight-walled prophylactics, leads to "improved sensation." Id. at 1:27-32. The '255 patent further states that the "head of the penis from just behind the coronal sulcus to the meatus is primarily sensitive to friction and temperature." Thus, the '255 patent discloses that the wider "head section" allows friction on the head of the penis to improve stimulation. In order to accomplish this, the walls of the "head section" must invert from the

outward position as depicted in Figure 1 and through the "entrance" at the boundary of the "longitudinally directed chamber" (lines A and B). Thus, the '255 patent discloses that the inner surface of the "head section" inverts through the entrance to abut against the glans penis. Given that the '255 patent discloses all the structures which define the "second pouch" of Claim 1, the '255 patent also discloses a "second pouch."

The final phrase of Claim 1, an apparatus claim, "for movement; back and forth thereon during coitus for providing stimulation thereto" is a functional statement and, thus, is not a limitation. Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1311-12 (Fed. Cir. 2005)("To infringe an apparatus claim, the device must meet all of the structural limitations.")(emphasis added); Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990)(stating "apparatus claims cover what a device *is*, not what a device *does*")(emphasis in original); In re Michlin, 256 F.2d 317, 320 (C.C.P.A. 1958)("It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function."). Thus, although the '255 patent does not disclose the exact nature of how the "head section" stimulates the glans, this function is not a patentably distinct limitation on the claim.

In conclusion, I find clear and convincing evidence that the '255 patent discloses all limitations of Claim 1. Thus, the '255 patent anticipates Claim 1.

2. Claims 2-4

The '255 patent does not disclose a prophylactic in which the second pouch is "formed through only a part of the circumference." JX-1 at 7:34-35. This limitation is present in claim 2 of the '004 patent and, therefore, is present in claims 3 and 4 which depend from claim 2. Thus, claims 2-4 are not anticipated by the '255 patent.

3. Claim 6

Claim 6 depends from claim 1 and adds the limitation "the second pouch being formed completely around the circumference to produce an annular pocket for movement on all of the surface of the glans penis." JX-1 at 7:49-51. The '255 patent discloses a second pouch formed completely around the circumference of the prophylactic. RX-12 at Figures 1 and 2. This pouch forms a ring-like pocket. Id. at 1:34-41 (noting the claimed invention contains a "head section and a main body section, both of generally cylindrical shape and circular cross section"). Additionally, the "head section" of the '255 prophylactic which encompasses the entire distal end of the prophylactic, is loose so as to prevent "gripping of the swollen head of the penis." Id. at 1:56-57, Figures 1 and 2. The '255 patent discloses that "the head of the penis from just behind the coronal sulcus to the meatus is primarily sensitive to friction and temperature." Id. at 1:49-51. Furthermore, the head section can be as large as one-half the total length of the prophylactic. Id. at Claim 4. To summarize, the '255 patent discloses that the second pouch formed by the head section is: 1) loose; 2) formed around the circumference in a circular (ring) shape; 3) covers the entire glans of the penis; and 4) can provide friction to stimulate the glans penis on all of the surface of the glans. Because the '255 patent discloses all the limitations of claim 1 and claim 6, it anticipates claim 6.

4. Claim 8

Claim 8 depends from claim 1 and adds the limitation "said second pouch being formed as a single pouch on the closed end to overlie the glans penis and providing looseness between the prophylactic pouch and a penis only at the glans penis portion thereof." JX-1 at 7:55-58. The '255 patent discloses that the stem section of the claimed prophylactic can extend "around substantially the whole length of the shaft of the penis." RX-12 at 1:60-62. Additionally, the '255 patent

discloses that the head section of the prophylactic can vary in length compared to the stem section in a ratio of between 1:1 to 1:12 (stem:head). Id. at claim 4. However, nowhere in the specification or claims is this ratio compared to the anatomy of the penis. It is possible that a prophylactic with a head portion at some lengths within this range would stimulate only the glans penis; however, no evidence of this has been provided and the '255 patent is silent on the issue. Therefore, C&D has failed to prove by clear and convincing evidence that the '255 patent anticipates this claim.

5. Claim 9

Claim 9 depends from claim 1 and adds the limitation that the second pouch has "its inner surface coated with lubricant to provide a hydrodynamic rubbing of the glans penis." JX-1 at 7:60-62. The prophylactic claimed by the '255 patent is described by the specification as an alternative to using lubricants to increase stimulation. RX-12 at 1:22-26. However, the patent does state that lubricants can be used "in order to improve sensation." Id. at 1:22-25. Although the specification does not teach using both altered shape of the prophylactic and lubricants, it does teach that both achieve the same purpose, i.e., improving sensation. Even though it could be argued that this patent "teaches away" from using lubricants, such teaching away is irrelevant to the anticipation analysis. Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998). The phrase "to provide hydrodynamic rubbing of the glans penis" is functional language and is not a limitation of this claim. Cross Medical, 424 F.3d at 1311-12. As discussed above, the '255 patent discloses all other limitations of claim 1. Thus, Claim 9 is anticipated by the '255 patent.

6. Claims 13 and 18

Both independent claims 13 and 18 claim a prophylactic with "a plurality of second pouches." JX-1. The '255 patent does not disclose a prophylactic with more than one second pouch; therefore, it does not anticipate claims 13 and 18.

7. Claims 22 and 25

Claim 22 contains the limitation "said tubular portion and said second pouch having a wall thickness of 0.11 mm ± 0.04 mm." This limitation is also present in claim 25, which depends from claim 22. The '255 patent does not disclose a specific thickness of the material of the prophylactic, only stating that the claimed invention is "thin-walled." RX-12 at 1:34, claim 1. Because the '255 patent does not specifically disclose the claimed wall thickness, it does not anticipate claims 22 and 25.

8. Claim 31

Claim 31 is an independent claim and contains the limitation "said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis at least 1 cm." JX-1 at 7:55-58. The '255 patent discloses that the stem section of the claimed prophylactic can extend "around substantially the whole length of the shaft of the penis." RX-12 at 1:60-62. Additionally, the '255 patent discloses that the head section of the prophylactic can vary in length compared to the stem section in a ratio of between 1:1 to 1:12 (stem:head). Id. at claim 4. However, nowhere in the specification or claims is the extent of coverage of the shaft of the penis by the expanded "head section" clearly defined. It is possible that a prophylactic with a 1:1 ratio would contain an "open area extending lengthwise of the glans penis at least 1 cm." However, no

evidence of this has been provided and the '255 patent is silent on the issue. Therefore, C&D has failed to prove by clear and convincing evidence that the '255 patent anticipates this claim.

9. Claims 32 and 36

Claim 32, which depends from claim 31, adds other limitations, including "a third pouch." JX-1 at 11:1. Claim 36, which depends from claim 32, also has this limitation. The '255 patent does not disclose a prophylactic with more than one second pouch. Therefore, it does not anticipate claims 32 and 36.

2. Obviousness

Respondents make no assertions in their post-hearing briefs that any combination of prior art renders any of the asserted claims of the '004 patent invalid as obvious under 35 U.S.C. § 103. RCDIB 70-72; RMIIB at 19. Thus, Respondents have waived any defense of obviousness. See Ground Rule 11.1.

3. Definiteness

Respondent C&D asserts that claims 18 and 31 are indefinite and are invalid under 35 U.S.C. § 112 for lack of antecedent basis. RCDIB at 72. Both claims use the term "said longitudinally directed chamber." Normally, use of the word "said" refers to a prior recitation of the referenced structure. Respondent C&D argues that because neither claim follows this convention, claims 18 and 31 are indefinite. Id. Complainant "contends that those skilled in the art would understand what is claimed, or the scope or bounds of the claims, when they are read in light of the specification and drawings." CIB at 45. Staff asserts that Respondents have not met their necessary burden for establishing indefiniteness and that "in the context of the intrinsic evidence, the connection of the

challenged phrase to the phrase that precedes it, 'elongated tubular portion,' is sufficiently clear." SIB at 64.

Claim definiteness is analyzed by focusing on "whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001). "When the meaning of the claim would reasonably be understood by persons of skill when read in light of the specification, the claim is not subject to invalidity upon departure from the protocol of 'antecedent basis.'" Energizer Holdings, Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 1370 (Fed. Cir. 2006). Additionally, antecedent basis can be present by implication. Slimfold Mfg. Co. v. Kinkead Indus., Inc., 810 F.2d 1113, 1116 (Fed. Cir. 1987).

The '004 specification provides clear descriptions of a "longitudinally directed chamber." JX-1 at 3:56-60 ("The pouch 12 has a diameter which will closely fit on the outer surface of a penis whose glans penis will be located within the pouch in spaced relationship to the closed end 16 to define a longitudinally directed chamber 17."); See also, supra, IV.A.5. Additionally, use of the phrase "said longitudinally directed chamber" in claims 1 and 13, provides a basis for implying the same use in claims 18 and 31. Given the teachings of the specification and the use of the same phrase in other claims, I find that one of skill in the art would understand the meaning of "said longitudinally directed chamber." Thus, claims 18 and 31 are not indefinite under 35 U.S.C. § 112.

V. DOMESTIC INDUSTRY

A. Technical Prong

1. The Parties' Positions

Complainant contends that the Pleasure Plus practices claims 1-4, 8, 9, 22, 25, and 31 of the '004 patent, and Staff agrees as to all these claims except claim 8. CIB at 31-37; SIB at 52-56. Respondent C&D contends that the whole distal portion of the Pleasure Plus is freer to move than the '004 patent permits. RCDIB at 41-42. Respondents Medtech/Intellx concur in C&D's positions. RMIIB at 18. Respondents' argument fails because it is based upon a faulty claim construction. I have previously discussed the problems with Respondents' contentions that the entrance from the first pouch to the second pouch or portions of the pouches must be fixed. See supra at IV.A.8. Respondents' other argument appears only directed at claim 8 and therefore I will discuss it when discussing claim 8. See RCDIB at 41.

2. Technical Prong Analysis

I have already construed the claims at issue. Therefore, my analysis of the technical prong will proceed to compare the properly construed claims with the Complainant's product, the Pleasure Plus prophylactic. Initially I note that Complainant and Staff repeatedly refer to JPX-8. JPX-8 was not included in the physical exhibits that were submitted by the parties. There were a number of physical exhibits that were submitted but were not labeled. It is possible that JPX-8 could have been one of those exhibits. In any event, CPX-2 is a container containing Pleasure Plus prophylactics. Therefore, I have examined one of those Pleasure Plus prophylactics in order to perform a technical prong analysis.

a. Claim 1

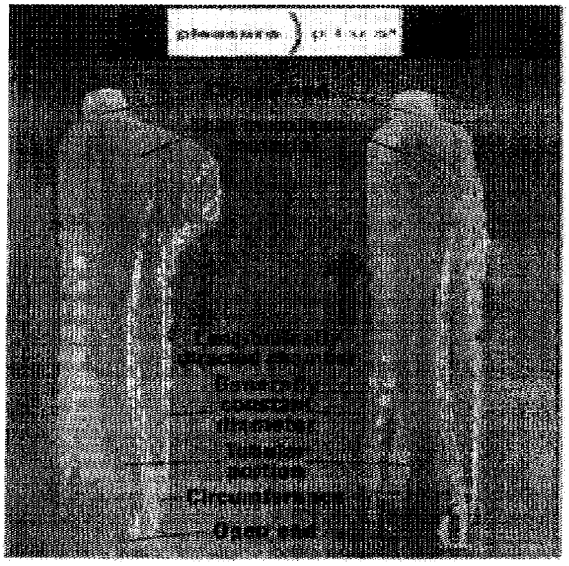
Claim 1 reads as follows:

> A prophylactic pouch for use by a male having an elongated tubular portion forming a first pouch having a circumference and having an open end and a closed end characterized by:
> said tubular portion being formed of thin membrane material and having a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis; and
> a second pouch formed of thin membrane material extending outwardly of said first pouch; said second pouch having an interior space and including an entrance with an open area extending lengthwise of the glans penis; said entrance communicating said interior space directly with said longitudinally directed chamber at a point overlying the glans penis; said second pouch having an inner surface moveable through said entrance and against the glans penis for movement; back and forth thereon during coitus for providing stimulation thereto.

Complainant relies upon Dr. Wool's testimony to satisfy its burden of proving that the Pleasure Plus practices claim 1 of the '004 patent. CIB at 31-33; Wool, Tr. 311-313. Staff agrees that the Pleasure Plus practices claim 1 of the '004 patent. SIB at 52-53. Staff contends that the underside bulge of the Pleasure Plus satisfies the "second pouch" requirement of claim 1 and that the rest of the prophylactic constitutes the first pouch. Id. at 52. Staff states that although the regions of the first pouch in the distal end may move a small amount during coitus this does not prevent the prophylactic from practicing claim 1. Id. Also, Staff asserts that the Pleasure Plus has a generally constant diameter. Id.

The parties have agreed that the Pleasure Plus is a male prophylactic, has an open end and a closed end, and is made of latex. JSUMF ¶¶ 26 - 29. Therefore, it does not appear that there is any

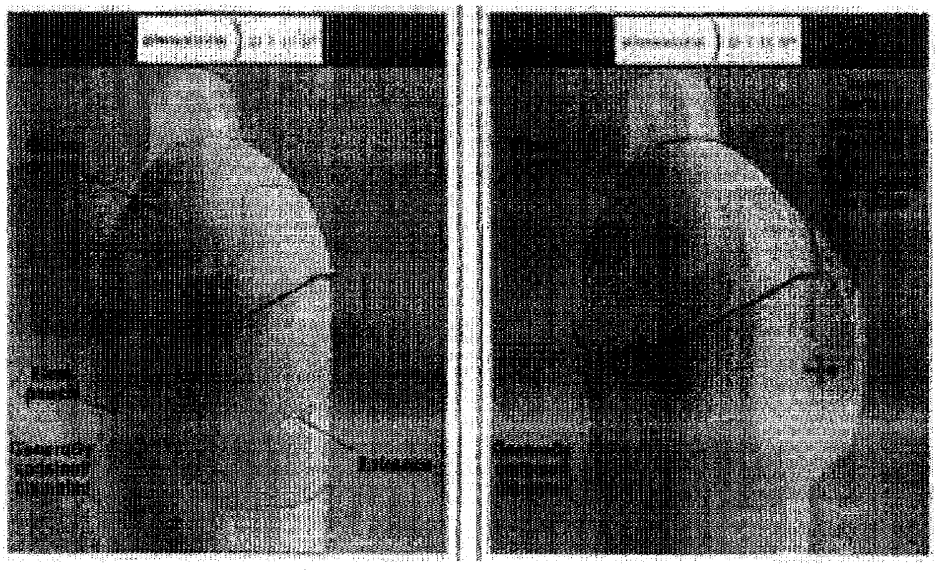
dispute that the Pleasure Plus is a prophylactic pouch for use by a male and that the Pleasure Plus has an elongated tubular portion. I find that the Pleasure Plus's elongated tubular portion forms a first pouch which has a circumference. See CPX-2. This is most easily seen in Complainant's demonstrative exhibit CX-88 (reproduced below).



CX-88

Upon examination of the Pleasure Plus, it is clear that the tubular portion is formed of thin membrane material. Id. The Pleasure Plus has a generally constant diameter from the open end to the closed end to define a longitudinally directed chamber for a male penis. Id. This generally constant diameter is interrupted by the second pouch as taught by the patent and discussed supra.

An examination of the Pleasure Plus shows that it has a second pouch formed of thin membrane material extending outwardly of said first pouch. See CPX-2. The second pouch has an interior space which includes an entrance with an open area extending lengthwise of the glans penis. This is most clearly shown in CX-90, a graphical depiction of the Pleasure Plus on a penis.



CX-90

The entrance to the second pouch communicates the interior space directly with the longitudinally directed chamber at a point overlying the glans penis. See CPX-2 and CX-90. The second pouch also has an inner surface moveable through said entrance and against the glans penis for movement back and forth thereon during coitus for providing stimulation thereto. Id. Therefore, I find that the Pleasure Plus practices claim 1 of the '004 patent.

b. Claim 2

Claim 2 depends from claim 1 and adds the limitation that the second pouch is formed through only a part of the circumference to produce movement only on part of the underside surface of the glans penis. Complainant contends that the second pouch of the Pleasure Plus produces movement only on part of the underside surface of the glans penis. CIB at 33; Wool Tr. 315:3-7. Staff contends that the evidence shows that the second pouch does not provide movement on a portion of the underside of the glans penis closest to the urethra and therefore practices claim 2 of

the '004 patent. SIB at 53; CX-90; CX-246 (Wool DWS Q&A 57). I find that the Pleasure Plus practices claim 2 of the '004 patent.

c. Claim 3

Claim 3 depends from claim 2 and adds the limitation that the first pouch must be formed of fine rubber or plastic material and the second pouch must be integrally formed with the first pouch as a side bulge in the circumference at the closed end. Complainant contends that the Pleasure Plus's first pouch is formed of fine rubber or plastic material. CIB at 33; Wool, Tr. 315:8-11. Complainant also contends that the second pouch is integrally formed with the first pouch as a side bulge in the circumference at the closed end. CIB at 33; Wool, Tr. 315:12-18. Staff contends that the Pleasure Plus practices claim 3. SIB at 53-54.

The testimony that Complainant relies upon to establish that the second pouch of the Pleasure Plus is integrally formed with the first pouch as a side bulge in the circumference at the closed end is less than clear. This is the testimony that Complainant relies upon: "Q. Is the second pouch a side bulge in the circumference at the closed end? A. This is the closed end, and this is the side bulge." Wool, Tr. 315:15-18. It is impossible from that testimony to tell where Complainant is contending that the side bulge at the closed end is. However, it appears from demonstrative exhibit CX-89 (reproduced below) that the Pleasure Plus in fact does have a second pouch that is integrally formed with the first pouch as a side bulge in the circumference at the closed end.

CX-89

Upon examination of the Pleasure Plus and CX-89, I conclude that the Pleasure Plus practices claim 3 of the '004 patent.

d. Claim 4

Claim 4 depends from claim 3 and adds the limitation that the side bulge is formed as a hollow baggy bulge having a length in excess of 1 cm. Complainant relies upon Dr. Wool's testimony to show that the Pleasure Plus meets this claim limitation. CIB at 33; CX-246 (Wool DWS) Q&A 59. Staff agrees that the Pleasure Plus practices claim 4 of the '004 patent. SIB at 54; Wool, Tr. 315:19-25.

From an examination of CX-89 (reproduced above), it is clear that the side bulge is a hollow baggy bulge. Also, Dr. Wool testified that the bulge has a length in excess of 1 cm. I find that the Pleasure Plus practices claim 4 of the '004 patent.

e. Claim 8

Claim 8 depends from claim 1 and adds the limitation that the second pouch is formed as a single pouch on the closed end to overlie the glans penis and provides looseness between the prophylactic pouch and a penis only at the glans penis portion thereof. Complainant contends that the second pouch of the Pleasure Plus meets this limitation. CIB at 34; Wool, Tr. 316:7-13. Staff contends that the second pouch of the Pleasure Plus extends beyond the glans penis and does not meet this limitation of claim 8. SIB at 54. Respondent C&D contends that the second pouch of the Pleasure Plus is larger than any of the pouches disclosed in the '004 patent. RCDIB at 41. Respondent's argument only appears relevant to the analysis of claim 8.

I agree with Staff and Respondents that the second pouch of the Pleasure Plus does appear to extend beyond the glans penis and therefore cannot provide looseness only at the glans penis. See CX-90 (showing the second pouch extending well below the glans penis), reproduced supra at V.A.2.a. I therefore find that the Pleasure Plus does not practice claim 8 of the '004 patent.

f. Claim 9

Claim 9 depends from claim 1 and adds the limitation that the second pouch having its inner surface coated with a lubricant to provide a hydrodynamic rubbing of the glans penis. Complainant and Staff contend that the Pleasure Plus is coated with a lubricant. CIB at 34; SIB at 54. An inspection of the Pleasure Plus reveals that it is coated with a lubricant. See CPX-2. I find that the Pleasure Plus practices claim 9 of the '004 patent.

g. Claim 22

Claim 22 is an independent claim. Claim 22 includes claim limitations similar to claim 1 and adds the additional requirement that the prophylactic has a thickness of .11 mm +/- 0.04 mm. Staff and Complainant contend that the Pleasure Plus meets these limitations. CIB at 34-36; SIB at 55.

Staff relies upon CX-47 to show that the thickness of the Pleasure Plus is between .07 and .08 mm. CX-47 was not listed in either the final Joint Exhibit List required by Order No. 27 or the Complainant's Final Exhibit List. See Order No. 27 (April 10, 2006). Further, my review of the transcript reveals that CX-47 was never admitted into evidence. Complainant also mistakenly included CX-47 in its final ALJ exhibit binders. Because this exhibit was not admitted into evidence, it is improper to rely upon it.

However, Staff also relies upon JX-76, which is a description of the Pleasure Plus prophylactic. JX-76 states that the thickness of the Pleasure Plus prophylactic is .12 mm. Therefore, the thickness of the Pleasure Plus falls within the range indicated by claim 22. JX-76. I find that the Pleasure Plus practices claim 22 of the '004 patent.

h. Claim 25

Claim 25 depends from claim 22 and adds the limitation that the second pouch is coated with a lubricant to provide a hydrodynamic rubbing of the glans penis. Complainant and Staff assert that the Pleasure Plus practices this additional claim limitation. CIB at 36; SIB at 55. I have previously found that the Pleasure Plus is coated with a lubricant. See supra at V.A.2.f. I find that the Pleasure Plus practices claim 25 of the '004 patent.

i. Claim 31

Claim 31 is an independent claim. Claim 31 includes claim limitations similar to claim 1 but also requires a second pouch with an entrance extending lengthwise of the glans penis at least 1 cm. Complainant asserts that the Pleasure Plus practices claim 31, and Staff agrees. CIB at 36-37; SIB at 55-56. Dr. Wool's testimony supports Complainant and Staff's assertion. See Wool, Tr. 320:23-321:2; CX-246 (Wool DWS) Q&A 64. I find that the Pleasure Plus practices claim 31 of the '004 patent.

B. Economic Prong

1. The Parties' Positions

Complainant claims that,

> [a]ny one of the following facts established at the hearing would *on its own* constitute sufficient industry for purposes of satisfying the economic prong of the domestic industry requirement: PTI's spent [sic] approximately [ ] during the past fiscal year on Pleasure Plus operational costs incurred at GPC's facilities in Boston, Massachusetts. (FF544, CX-242C, p. 19, Q. 129) PTI spent over [ ] purchasing the '004 patent assets from the RLIL bankruptcy trustee. (FF549, Wedel Tr. 546, lines 9-12.) PTI spend almost [ ] ($429,221) on American labor in Boston producing the Pleasure Plus since 1999. (FF 562, JX-10C, p. 57; CX-243C, p.4-5, Q.12.) PTI spent almost [ ] on other business expenses (excluding payroll and the cost of goods sold) producing the Pleasure Plus in Boston since 1999. (FF563, JX-10C, p. 57; CX-243C, p. 5, Q.13.)
>
> [ ] . . . adds up to a significant industry.

CIB at 37-38 (emphasis in original). This is the essence of Complainant's attempt to meet its burden to prove that it has a domestic industry. Although Complainant refers to JX-10C, there is no JX-10C in the record. In an attempt to ascertain on what Complainant was relying, I looked to an old exhibit

list and found that the complaint was at one time labeled as JX-10C. I then went to the complaint, only to find that there is no page fifty-seven to the complaint. In fact there are only nineteen pages to the complaint.

Also, it is not entirely clear under which subsection Complainant is seeking to prove its domestic industry. As already discussed, a complainant may prove that it has a domestic industry in one of three ways: (A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in the asserted patent's exploitation, including engineering, research and development, or licensing. 19 U.S.C. § 1337(a)(3). In attempting to discern what Complainant was claiming, I looked at Complainant's initial post-hearing brief and post-hearing reply briefs. There is nothing in either of these submissions to allow me to discern under which subsections Complainant is attempting to establish a domestic industry. See CIB at 37-40; CRB at 16-18. I then turned to Complainant's proposed findings of fact. Complainant only had headings for subsections (A) and (B). See CFF 541-611; more specifically the headings for sections V.B.2 and V.B.3. Then I turned to the Joint Narrative Statement of Issues. Complainant provided no detailed information in the JNSI as to which subsection on which it was relying. See JNSI pp. 45-47. However, based upon the proposed findings of fact, it appears that Complainant is seeking to prove the existence of its domestic industry under subsections (A) or (B) of 19 U.S.C. § 1337(a)(3) and has waived any argument that it has established a domestic industry under subsection (c), 19 U.S.C. § 1337(a)(3)(c).

Staff asserts that Complainant has satisfied the economic prong of the domestic industry requirement in absolute terms as well as under the value-added approach. SIB at 49. Staff also contends that GPC's operations indicate that Complainant is no mere importer of the Pleasure Plus,

given that the domestic activities performed by GPC at its Boston facilities are clearly those of a genuine domestic manufacturer. Id. Staff further asserts that significant outlays of capital have been made for the lubricating/foiling machine, testing machine, and build out of the clean room to meet FDA requirements. Id. Staff also maintains that the initial capital outlays for the acquisition of the '004 patent and royalty obligations to the bankruptcy trustee are also substantial and note that [ ] GPC employees devote a portion of their time to the manufacture and sale of the Pleasure Plus. Id.

Respondent C&D claims that if Complainant were found to have demonstrated the existence of a domestic industry under the limited facts presented at trial, the result would be to render the domestic industry requirement essentially meaningless. RCDIB at 43. Respondents Medtech/Intellx concur with the arguments of C&D. RMIIB at 18. Respondents assert that Complainant is an [ ] patent holding company that operates almost entirely through its management agreement with Global Protection Corp. Id. Respondents further assert that the company does not have its own physical office space; instead, it operates from two mailing addresses: the law firm of Seyfarth Shaw, where PTI's President John Rogers is a partner, and John Rogers' home residence. Id. Respondents further maintain that [

] Id.

Respondent C&D repeatedly relies upon the initial determination in Certain Optical Disk Controller Chips and Chipsets and Products Containing Same, Including DVD Players and PC Optical Storage Devices II. Inv. No. 337-TA-523, (U.S.I.T.C. Sept. 30, 2005); RCDIB at 42, 43, 49, 56. The Commission determined to vacate certain portions of the initial determination, including the analysis of the technical and economic prongs of the domestic industry. Inv. No. 337-TA-523,

Notice of Commission Decisions at 17138, 71 Fed. Reg. 17136-38. Because the Commission determined to vacate this part of the initial determination, it is not proper for Respondent C&D to rely upon it.

2. Burden of Proof

Complainant has the burden of proving the existence of a domestic industry. Certain Set-top Boxes and Components Thereof, Inv. No. 337-TA-454, Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002). Complainant therefore should have taken this opportunity to marshal the evidence it brought to prove its domestic industry and to show why that evidence was reliable. Instead, Complainant chose to spend only two and a half pages of its forty-seven page post-hearing brief to show how it met its burden of proof on domestic industry. Complainant did not attempt to make a well-reasoned logical argument showing the strength of its domestic industry, Complainant instead relied upon conclusory argument for its evidence. See CIB at 37-40.

Although Complainant's post-hearing brief was inadequate and unhelpful as it pertains to the issue of domestic industry, Staff has addressed this issue at length. However, in its post-hearing reply brief, Staff attempts to shift the burden of proof for domestic industry to the Respondents. See SRB at 29-34. For example, in Section E on p. 24, Staff states that "Respondents have failed to demonstrate that PTI does not satisfy the economic prong of the domestic industry requirement." SRB at 24 (emphasis added). Further, in headings five and six in Section E, Staff states respectively that "Respondents Have Offered No Substantive Evidence to Suggest that the Amount of Labor Claimed by PTI is Incorrect" and "Respondents Have Offered No Substantive Evidence to Suggest that the Amount for Capital Equipment Claimed by PTI Is Incorrect." SRB at 29 & 30 (emphasis

added). Respondents do not bear the burden of proof on domestic industry, and therefore they did not have to produce any evidence on this issue. Thus, it is not Respondents' responsibility to bring forward substantive evidence contradicting Complainant's evidence of a domestic industry; it is the Complainant's burden to prove it has a domestic industry. Certain Set-top Boxes and Components Thereof, Inv. No. 337-TA-454, Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002). Although Respondents did not have any affirmative duty to produce evidence on the issue of domestic industry, Respondents did choose to argue that certain of Complainant's evidence was not reliable, but this in no way shifted the burden of proof to Respondents.

[

] Before August 1988, Complainants were required to show that their domestic industries were "economically and efficiently" operated. See Certain Feathered Fur Coats and Pelts, and Process for the Manufacture Thereof, Inv. No. 337-TA-260, Initial Determination at 22, U.S.I.T.C. Pub. 2085 (May 1988).

[

]

4. Customs Regulations

As Respondents correctly point out, the Complainant's product, the Pleasure Plus, is labeled on the twelve-pack box as being "Manufactured in China. Packaged in USA. Distributed by Global Protection Corp." RCDIB at 43; CPX-2. Mr. Wedel testified that the labeling was done to comply

with Customs laws and regulations requiring all imported articles to be marked for the ultimate purchaser with the country of origin. Wedel, Tr. 567:18-22.

Complainant makes a passing reference to this fact in its reply brief.

> C&D makes much ado about the Pleasure Plus packaging that indicates it is 'Made in China.' (C&D Brief at 43-44.) It characterizes this as an 'admission' by PTI that it has no domestic industry. That is fanciful. The labeling - which John Rogers testified PTI would now have to reconsider in light of the regulations brought to his attention during cross examination, and for which he thanked counsel (Rogers, Tr. 207, line 7)- does not constitute an admission that PTI did not incur [ ] in operating expenses producing the Pleasure Plus in the last fiscal year. It does not constitute an admission that PTI's initial investment in capital and equipment was not [ ] It does not constitute an admission that PTI did not utilize [ ] of hours of American labor producing [ ] of Pleasure Plus condoms in Boston, Massachusetts.

CRB at 16-17.

The pertinent Customs regulation states, ". . . every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article, at the time of importation into the Customs territory of the Untied States." 19 C.F.R. § 134.11. The definition section of the regulation defines country of origin as, "the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin" within the meaning of this part." 19 C.F.R. § 134.1(b).

Staff contends that this marking on the Pleasure Plus package is irrelevant. SRB at 24-25. I disagree. In complying with the Customs regulations, Complainant decided that the Pleasure Plus prophylactic was manufactured in China and thus needed to be marked "Made in China" in accordance with Customs regulations. By this marking, Complainant has acknowledged that the Pleasure Plus, the only product that it produces (CX-242 (Rogers DWS) Q&A 128), is manufactured in China. Complainant has further conceded that the Pleasure Plus prophylactic does not undergo a substantial transformation because of the work that Global Protection Corporation does in the United States. If the prophylactic had undergone a substantial transformation, the Pleasure Plus should have been marked "Made in the U.S.A." in accordance with 19 C.F.R. § 134.1(b). Mr. Rogers' statement on cross-examination, thanking opposing counsel for pointing out the Customs regulations, and stating that he would reconsider the packing information, did nothing to undermine the tacit acknowledgment by Complainant that the Pleasure Plus product is made in China.

Although the statement on the packaging is quite damaging to Complainant's position on the domestic industry issue, it is not the end of the inquiry. The packaging does not constitute a binding admission by Complainant that there is no domestic industry for the Pleasure Plus product but the packaging does negate any contention by Complainant that the Pleasure Plus product is primarily manufactured in the United States. As detailed below, the manufacturing component in the United States is fairly minimal. In accordance with the statutory factors set forth in Section 337(a)(3), I will consider whether or not Complainant has made a significant investment in plant and equipment or significant employment of labor or capital.

5. Investment in Plant and Equipment

a. Tangible Assets

Staff asserts that [ ] was spent for tangible assets. I stated in Order No. 22 that this amount should have been reduced by the amount spent for the dipping machines which have since been sent to China. Order No. 22 at 18-19. Complainant declined my invitation to provide additional information as to how much of the [ ] should be allocated to assets still located in the United States. However, I have reconsidered the statement I made in Order No. 22 that the machines that were purchased in the United States and shipped to China cannot be included in Complainant's domestic industry. See id. at 19. A plain reading of 19 U.S.C. § 1337 shows that the investment in plant or equipment must be in the United States, but it does not say that the equipment must be located in the United States. Therefore, I will consider the amount spent for the dipping machines that have since been shipped to China as a part of Complainant's domestic industry.

The problem with the [ ] that Staff claims Complainant spent for tangible assets is that the only evidence that Staff relies upon for this number is Complainant's balance sheet and testimony of John Rogers based upon the balance sheet. SIB at 46; CX-242 (Rogers DWS) at Q&A 121; CX-36. David Chabon testified that the [ ] was capitalized on the books before he ever began working for GPC and Complainant. Chabon, Tr. 607-608. He stated that he had simply carried forward the depreciation schedule that had been laid out by the accountants before him, and because the accountants before him had signed off on the numbers he felt comfortable with the numbers. Id. However, Mr. Chabon previously had testified that the accountants who worked for

GPC and Complainant before him were incompetent. Chabon, Tr. 590:19-25. Furthermore, Mr. Chabon did not know what equipment was purchased with the money represented on this balance sheet. Chabon, Tr. 607:2-608:6. Mr. Chabon further explained what he believed to be included in the number on the balance sheet. Chabon, Tr. 607-612. Because the record contains no reliable evidence to explain what equipment was purchased with the amount reflected on the balance sheet and there is testimony casting a doubt on the accuracy of these numbers, I will not consider this amount in evaluating Complainant's domestic industry.

b. The Lubricating-Foiling Machine and Air-Burst Machine

Staff asserts that previous to the Reddy Laboratories International, Ltd. ("RLIL") bankruptcy Complainant purchased the lubrication-foiling machine that was owned by another earlier-bankrupt Reddy entity, Reddy Healthcare, that had been subsequently sold or repossessed. SIB at 46. Staff further asserts that Complainant located and purchased the air-burst machine and the packaging machines formerly owned by Reddy Healthcare. Id. Staff argues that Complainant paid to purchase and refurbish the machines, enabling Complainant to perform the manufacturing steps that take place in the United States. Id. All that Staff relies upon for these assertions is the testimony of John Rogers. See id. However, as Respondent C&D correctly points out, Davin Wedel contradicted the assertion that the equipment was purchased from an earlier Reddy entity. RCDRB at 38-39. Mr. Wedel said that the price of the lubricating and foiling machine was included in the price that Complainant paid to the bankruptcy trustee for the Reddy assets which included the patent and trademark. See Wedel Tr. 543:13-544:6. Because the testimony that Staff relies is contradicted by another of Complainant's witnesses, Davin Wedel, I find that this testimony is not reliable.

c. Clean Room Expenses

Staff asserts that Complainant incurred expenditures in building out a 'clean room,' the room where the second staging of the Pleasure Plus takes place, in order to meet FDA standards that require, *inter alia*, special exhaust systems and electrical wiring." SIB at 46. Staff asserts that, "[e]xpenditures to build-up the clean room also included installation of a water heater with pressure control, water service and flooring. CX-244C (Wedel DWS, Q&A 75)." SIB at 46. Mr. Wedel did testify about what was involved in making GPC an FDA-classified manufacturing facility. What is lacking from Mr. Wedel's testimony is evidence that Complainant paid any of these expenses or the amount of those expenses. See CX-244C (Wedel DWS) at Q&A 75-77. Therefore, I give very little weight to this factor in considering investment in plant and equipment.

6. Employment of Labor or Capital

a. Intangible Assets Purchased by Complainant

Complainant purchased the rights to the '004 patent from the bankruptcy estate of Reddy Laboratories International, Ltd, a company for which Dr. Reddy was a principal. JX-71 at 1. Staff correctly notes that the intellectual property rights to the "Bikini Condom" were excluded from the assets purchased in bankruptcy. Id. at 5; SIB at 46. Staff further asserts that Complainant's balance sheet indicates that Complainant has made capital investments in intangible assets in an amount of [ ] SIB at 45-46.

However, there are considerable problems with Staff's assertion that [ ] should be credited to Complainant's domestic industry. Complainant's balance sheet does indicate that Complainant has made capital investments in

intangible assets in an amount of [ ] But the problem is that this amount that was spent in purchasing intangible assets from the bankruptcy trustee was for more intellectual property than just the '004 patent. As I alerted Complainant in Order No. 22, "[n]o information has been provided concerning how much of this price is directly attributable to the purchase of the '004 patent." Order No. 22 at 20. Order No. 22 was issued on March 15, 2006, more than two weeks before the start of the hearing in this investigation. Rather than presenting evidence to show the amount of money spent on the '004 patent, Complainant chose to continue claiming that the entire amount is attributable to the '004 patent. See CIB at 37-38. While Staff contends that it is appropriate to credit the full amount paid to the bankruptcy trustee for the intellectual property rights of RLIL to the amount of capital invested in the domestic industry of the Pleasure Plus, Staff offers no evidentiary or legal support for this contention. See SRB at 25-26. Staff contends that this conclusion is supported by the fact that all of the intangible property is directly related to the Pleasure Plus and was purchased for the sole purpose of enabling Complainant to manufacture and sell the Pleasure Plus, including the Pleasure Plus trademark. SRB at 25. Staff offers no factual support for its assertion that all of the intangible property is directly related to the Pleasure Plus or that it was purchased for the sole purpose of enabling Complainant to manufacture and sell the Pleasure Plus.

Staff in its reply brief asserts that Complainant not only spent the [ ] that Staff argued in its initial post-hearing brief but that Complainant in fact spent [ ] to acquire the intellectual property rights related to the Pleasure Plus. SRB at 34-35. Staff suggests that the record shows that the [ ] on Complainant's balance sheet is "conservative." Id. Staff relies upon three exhibits in its reply brief to justify the [ ] it asserts. Id. Staff relies upon JX-65 (a spreadsheet of

Complainant's payments to the trustee), JX-71 (the asset purchase agreement), and CX-1 (a note from John Rogers with a voided check).

JX-65 is a spreadsheet created by Complainant showing amounts that it claims were paid to the bankruptcy trustee. I have concerns about relying upon JX-65 because Complainant has not produced any of the underlying checks or any additional documentary evidence to show that the figures contained in JX-65 are accurate, such as a statement from the bankruptcy trustee stating what has been paid to him. Staff relies upon the testimony of John Rogers and Davin Wedel. SIB at 46-47. Mr. Wedel stated that, "PTI has paid a total of [ ] to the trustee for its obligations under the Deferred Cash Payment Agreement." Id. He stated that his testimony was based upon JX-65. Id. Mr. Wedel did not state that these payments were royalty payments. Id. Therefore, Mr. Wedel's statement does not support the proposition that Complainant has made any royalty payments to the bankruptcy trustee.

Through my review of the record I found that the Deferred Cash Payment Agreement is JX-72, although neither Complainant nor Staff cited to it in their briefs. The problem with relying upon this Deferred Cash Payment Agreement is that JX-72 does not include an executed contract. JX-72 does include the signature of Paul J. Maselli, RLIL's bankruptcy trustee. But JX-72 does not include a page showing the signature of anyone signing on behalf of PTI. Therefore, it is improper to rely upon this agreement.

JX-71, the asset purchase agreement, states that the trustee is holding [ ] in escrow that was paid by NeW Way Technology Corp. JX-71 at 5. Staff asserts in its reply brief that NeW Way Technology was a Wedel group that merged into Complainant, but neither Staff nor

Complainant has cited any record evidence to support this assertion. JX-71 (the asset purchase agreement) does not provide any indication of what NeW Way Technology Corporation's relationship is to Complainant.

CX-1 is a note from John Rogers to a Joseph Markowitz, Esq., but the record does not identify Joseph Markowitz, Esq. At the bottom of the note is a copy of a check for [ ] marked "void." John Rogers could not testify as to whether the check was mailed marked "void" or whether it was marked "void" later. Rogers, Tr. 237:2-238:6. It would seem more appropriate for record keeping that someone would keep a copy of the canceled check. In any event, it is inappropriate to rely on this evidence because even the person who purportedly sent the check was not sure if it was any good when sent.

Because I find that Mr. Wedel was a credible witness, I will take his testimony as evidence that the [ ] in payments were made to the bankruptcy trustee but because nothing in his testimony supports the proposition that these were royalty payments, I will not make that finding. As discussed earlier, I cannot credit this entire amount to Complainant's domestic industry because Complainant has made no attempt to segregate the amount spent on the '004 patent as compared to the amount spent on the other intellectual property purchased from the bankruptcy trustee. See JX-71.

b. Tolling Agreement

Staff relies on a tolling agreement between the bankruptcy trustee and Complainant which states that the limitation period for the trustee to object to a failure to pay the royalties was tolled. SIB at 47. The problem with relying on this evidence is that the only contract which Complainant

has produced in this investigation is one which does not contain the signature of the bankruptcy trustee. See JX-82. The only signature contained in this agreement is the signature of Davin Wedel on behalf of Complainant. Because the evidentiary record does not contain a contract executed by both parties, it is improper to rely on this evidence. In any event, whether or not the agreement has been tolled is not of consequence; the material issue is whether Complainant has paid the bankruptcy trustee the royalty payments.

c. GPC's Testing and Payroll

1. Functions that GPC Performs

Staff discusses at length the relationship between Complainant and GPC. SIB at 47. I note that while there is testimony in the record to support the contention that GPC performs some testing and manufacturing operations for Complainant, the management agreement between Complainant and GPC says [ ] See JX-53. In fact, the management agreement states that, [

]

JX-53 at 2. Staff asserts that responsibilities to [

] SIB at 47. Staff relies on Davin Wedel's testimony for this assertion. Id. The management agreement states that,["[t]his agreement constitutes the entire agreement between the parties concerning its subject matter and supersedes in their entirety any prior or contemporaneous agreement, proposals and understandings in connection herewith. This Agreement may be amended, waived, or revoked only by a written instrument executed by both

parties." JX-53 at 9. Complainant has not produced any written amendment to this agreement where [ ]

Staff states that foiling, lubricating, and quality testing (collectively, "second staging") of the Pleasure Plus is performed at GPC's facilities. Foiling of a prophylactic is the process whereby the rolled balloon is enclosed in an air-tight, two-sided square of foil. Harrison, Tr. 785. Lubrication is injected into the prophylactic just prior to the sealing of the foil. Potter, Tr. 948. Davin Wedel also stated that the testing done at GPC includes water-leak and package integrity testing. CX-244 (Davin Wedel DWS) Q&A 79. GPC then bills Complainant for the amount of labor that GPC expends in doing these facts for the Pleasure Plus. JSUMF ¶ 33.

2. Amount Spent on Labor

Staff states that from 1999 to the end of 2004, Complainant has incurred [ ] in payroll-related expenses. SIB at 48. This amount necessarily includes the [ ] GPC billed Complainant for the fourteen month period ending in February 2005. See Second Amended Complaint ¶ 50; JSUMF ¶ 34. Staff relies upon David Chabon's testimony for this assertion. SIB at 48. Respondents correctly point out that there is doubt about the accuracy of much of the financial evidence presented at trial. RCDIB at 50. David Chabon, Complainant and GPC's accountant, testified that Complainant's numbers for the year 2003 were "off" because there were about six months where "a lot of garbage in and garbage out was going on." Chabon, Tr. 593:1-594:13.

Complainant's witness Mr. Chabon conceded that some of the numbers for labor billed to Complainant for some portion of 2003 are not accurate. Because Complainant has not provided any evidence of how to break these numbers down, I am unable to segregate the unreliable numbers from

numbers that are accurate. I will not rely on the numbers asserted by Staff from 1999 to 2004 because Staff only presents an aggregate number. If Staff had broken the number down by month and/or year so that I could discount the unreliable numbers from 2003, then I would consider those numbers. Instead, I will rely upon the evidence that Complainant has presented detailing the amount of hours GPC billed Complainant for labor in the fourteen-month period ending in February 2005. See Second Amended Complaint ¶ 48; JSUMF ¶ 34.

3. Number of Full-Time Employees

In addressing the number of employees that Complainant employs as part of its employment of labor in the United States, Staff asserts that GPC employs approximately [ ] individuals, virtually all of whom devote some time to the Pleasure Plus. SIB at 47. However, the record evidence does not show how much time GPC's employees spend working on the Pleasure Plus. Therefore, I will focus on how many hours GPC billed Complainant for labor instead of the number of employees of GPC, who only devote some time to Complainant's products.

C&D points out that Complainant alleges that in the fourteen-month period ending in February 2005, GPC billed Complainant for approximately [ ] of time spent by GPC employees on production of the Pleasure Plus. RCDIB at 56; Second Amended Complaint ¶ 48; JSUMF ¶ 34. As I pointed out in Order No. 22, "Complainant has not specified that these payments are directly related to the production of the Pleasure Plus condom." Order No. 22 at 19-20. In that order I stated that, "for purposes of this motion I will assume the total amount was paid to support the workforce necessary for domestic production." Id. at 20 (emphasis added). Although it was appropriate to assume this fact for the purpose of a summary determination motion prior to

trial, Complainant was obligated to produce this information at trial. Complainant has provided testimony that the only product it produces is the Pleasure Plus. CX-242 (Rogers DWS) Q&A 128. Staff agrees with this assertion. SIB at 46. Respondents have not disputed this assertion. See RCDIB at 42-69. Therefore, I will consider the entire amount that Complainant was billed for payroll as a part of its employment of labor in the United States with respect to the Pleasure Plus.

Respondent's expert, Dr. Seth Kaplan, prepared an analysis showing that, for this fourteen month period, Complainant employed the equivalent of approximately [ ] full-time production employees. RX-111C (Kaplan DWS, Q&A 44.) In performing his analysis, Dr. Kaplan broke down the [ ] billed to Complainant during a fourteen month period and determined that Complainant was being billed for [ ] per month. RX-113C. He then multiplied the average number of hours per month by twelve months in a year and found that Complainant would have been billed an average of] per year. Id. He then assumed a forty-hour work week and multiplied that by 52 weeks per year, which came out to an average of [ ] worked per employee per year. Id. Dividing the number of hours that Complainant had been billed by the number of hours an average employee works per year, Dr. Kaplan determined that Complainant employed approximately the equivalent of [ ] full time employees. Id.

It might be more accurate, instead of converting the number of hours that Complainant was billed into an average year, to look at the number of weeks contained in the actual period that Complainant was billed for and calculate the number of full-time employees that Complainant employed in that period. The information Dr. Kaplan used to perform his calculations is included in paragraph 48 of Complainant's second amended complaint and not paragraph 50 as Dr. Kaplan cited in RX-113C. The fourteen month period that Complainant references runs from December

2003 until February 2005. See Second Amended Complaint ¶ 48. There were sixty-five work weeks between December 2003 and February 2005. Dividing the [ ] that Complainant was billed during this period by the number of work weeks, I determine that Complainant was billed for an average of [ ] per week. Given that an average worker works forty hours per week, Complainant employed an average of [ ] full time employees during the fourteen month period Complainant cited in its Second Amended Complaint. However, because Dr. Kaplan's analysis produced a larger number of full-time employees utilized by Complainant than the above analysis, and thus is more favorable to Complainant, I will utilize Dr. Kaplan's calculation of [ ] full time employees for purposes of evaluating Complainant's domestic industry.

d. Space Rented by GPC

GPC rents approximately 14,900 square feet of space at 12 Channel Street in Boston, Massachusetts, for which GPC pays [ ] per month. RCDIB at 51; Amended Complaint, Ex. 14 at ¶ 2-3; CX-244C (Wedel DWS) Q.5 & 112. GPC's facility is used not only for the Pleasure Plus but also for the other products that GPC manufactures, sells, and distributes. RCDIB at 51; CX-244C (Wedel DWS) Q 117. The space rented by GPC includes a 400-square foot clean room which is used to process the Pleasure Plus as well as other GPC prophylactics. RCDIB at 51; CX-244C (Wedel DWS) Q. 114, 115. Davin Wedel testified that the clean room is used for the Pleasure Plus "the majority of the time, and I would say the range is between seventy to ninety percent of the time it is used for Pleasure Plus condoms." CX-244C (Wedel DWS) Q 116.

Staff does not rely upon the amount of space rented by GPC for its contention that Complainant has satisfied the economic prong of the domestic industry. See SIB at 45-51. The only

fact that Staff points to, without discussing it, is Mr. Wedel's testimony that the clean room is used for the Pleasure Plus from 70 to 90 percent of the time. Id. at 48. Complainant alludes to the money that it contends it spent to build out the clean room at GPC's facility (CRB at 38) but does not further discuss GPC's building space. See CIB at 37-40; CRB 16-18. I have already discussed the clean room expenses. See supra at V.B.5.c. Because Staff and Complainant do not rely upon this information for their analyses, I will not consider GPC's expenditure as part of Complainant's domestic industry.

7. Absolute Analysis

The only expenditure that Complainant has proven is that it employs an average of the equivalent of [ ] full time employees. Given the problems with Complainant's evidence of a domestic industry and the relatively low number of employees that Complainant has shown, I conclude that Complainant's investment is not absolutely significant. See Certain In-Line Roller Skates with Ventilated Boots and In-Line Roller Skates with Axle Aperture Plugs and Component Parts Thereof, Inv. No. 337-TA-348, Commission Determination, 1993 WL 338410 (reversing and remanding the ALJ's Initial Determination that Complainant was entitled to summary determination for the existence of a domestic industry based upon the employment of five people in the United States, 1993 WL 852393).

I am aware of the realities of the marketplace that Staff referenced (See SIB at 51; specifically [

__] All of these factors could explain why Complainant may have a relatively small investment in terms of the amount of dollars spent and still have a significant domestic industry. Nevertheless, given the meager evidence Complainant has introduced to support its domestic industry, I cannot conclude that the industry is absolutely significant. Therefore, I will proceed to discuss a comparative analysis.

8. Comparative Analysis

a. Lubricating & Foiling the Condoms in the U. S.

Staff asserts that a strong factor weighing in favor of finding the economic prong satisfied is that the latex balloons imported by Complainant into the United States do not practice two of the patent claims that Complainant relies upon to establish the domestic industry. SIB at 49-50. Staff points out that claims 9 and 25 require the application of lubrication to the inner surface of the second pouch, and it is not until these bulk prophylactics are processed at GPC that these claims are practiced. Id. Staff further contends that because these activities are directly related to the practice of the patent, they weigh heavily in favor of a determination that the domestic activities of GPC are significant. Id. Respondents argue that while this point may be relevant to whether or not the technical prong of the domestic industry requirement is met, it is not pertinent to whether the economic prong of the domestic industry is met. RCDRB at 39.

In Encapsulated Circuits the ALJ found it significant that the entire process claimed in the patent was practiced in the United States. Encapsulated Circuits, supra, at 88 (U.S.I.T.C. October 16, 1991). That is not the case here. Here the bulk prophylactics (practicing a part of the '004 patent) are imported from China and then the bulk prophylactics are lubricated and foiled (practicing

part of some claims of the '004 patent.) Therefore, I find the Encapsulated Circuits case easily distinguishable from the present case, and I agree with Respondents that this point by Staff is not persuasive.

Staff further asserts that it is significant that the Pleasure Plus prophylactics are not saleable to consumers as imported in their bulk form. SIB at 49-50. Staff contends that the prophylactics' exposure to light and air would cause the latex to oxidize and become brittle and that it is not until the prophylactics are sealed in foil and tested according to FDA standards that they are merchantable. Id. Staff contends that in this respect the Pleasure Plus is analogous to the bulk drug at issue in Diltiazem that was not merchantable as imported. Id. Staff contends that Complainant's domestic industry is stronger than that of the Complainant in Diltiazem, because the domestic activities in Diltiazem satisfied the economic prong even though they did not directly concern the patent; that is, the foreign manufacturing process practiced the patent in full while the domestic activities related to the Pleasure Plus are directed to the practice of certain patent claims. Id.

Staff's reliance on Diltiazem is misplaced. In Diltiazem, the ALJ went through the history of Commission cases where ALJs or the Commission had found that a protected article was the whole of the article, when only a portion of that protected article was produced in the United States and much of the production of the protected article that practiced the asserted patent was completed abroad. Diltiazem, supra, at 140-141. After doing so, the ALJ concluded that he would consider the protected article to be the entire pharmaceutical product (diltiazem HCl), even though the drug was manufactured abroad. In determining this he concluded that "without the work carried out by MMD [domestic contractor], Tanabe's [Complainant's] diltiazem HCl [protected article] would be worthless as a pharmaceutical product." Id. at 141. The ALJ then went on to analyze the investment

of the Complainant's domestic contractor and concluded that this investment was significant and that Complainant had established a significant domestic industry. Id. at 141-145.

I have already determined that the Pleasure Plus is the article I will consider to be the protected article. I am considering the entirety of Complainant's domestic industry in assessing whether or not the industry is significant. Staff's reliance on Diltiazem suggests that because in this case the lubricating performed by GPC relates to additional claim limitations in two dependent claims, Complainant therefore has a domestic industry. Staff is skipping the intermediate step of assessing the value of Complainant's domestic industry. Therefore, I find that the Diltiazem case is not on point.

b. Asset Comparison

Respondents claim that when an article is partially manufactured abroad it is necessary to assess the relative importance of the domestic activities to the non-domestic activities in connection with the product under criteria (A) or (B) of Section 337(3)." RCDIB at 46-47. Respondents assert that because Complainant failed to produce sufficient information to permit a fair evaluation of this factor, its domestic industry claim should fail. RCDIB at 47. Staff points out that the Commission declined to adopt the part of Microlithographic that Respondents rely upon. SRB at 27 citing Microlithographic, Notice of Commission Non-Review (March 17, 2003). Because the Commission in Microlithographic declined to adopt the Judge's rationale, I agree with Staff that it is not controlling authority.

Staff argues that Commission precedent does not require a comparison of foreign to domestic assets. SRB at 26. Staff suggests that this practice is in keeping with the 1988 Amendments to

Section 337 that sought to streamline the domestic industry analysis because, under the previous statute, such analyses had been deemed cumbersome and costly. Id. citing Certain Static Random Access Memories and Integrated Circuit Devices Containing Same, Processes for Making Same, Components Thereof, and Products Containing Same, Inv. No. 337-TA-325, Order No. 9 at 4 (May 14, 1991).

I agree with Staff that the Commission has not required a comparison of foreign to domestic assets in every instance. As I stated in Order No. 22, "Complainant is not required to produce evidence necessary to conduct comparative or value-added analysis to meet its burden of proof. However, should Complainant be unable to establish that its investments are significant under the 'absolute' analysis, the lack of an evidentiary basis on which to make a comparative analysis would provide no other basis on which to find its investments 'significant.' Additionally, as discussed below, information allowing for a comparative analysis can assist in determining 'the realities of the marketplace.'" Order No. 22 at 21. Complainant chose not to produce the evidence necessary to compare foreign assets to domestic assets. I will not, as Respondents advocate, find that Complainant has failed to prove a domestic industry simply because Complainant chose not to produce the evidence that would have been necessary to compare its contractor's (Guilin's) foreign assets to its contractor's (GPC's) domestic assets. However, Complainant is obviously not entitled to rely on any such analysis to prove its domestic industry.

c. Value-Added Analysis

Staff states that the latex balloons used for the Pleasure Plus are purchased from Guilin South Rubber Corp. ("Guilin") in China. SIB at 48; CX-244 (Wedel DWS) Q&A 65. The balloons are

sometimes referred to as "bulk" or "raw" prophylactics. Guilin first manufactured the Pleasure Plus bulk prophylactics in 1999 and Complainant began selling Pleasure Plus in the United States the same year. SIB at 48; CX-244 at Q&A 71-73. The per unit cost to Complainant of the balloons has been [ ] for some time, although Complainant alleges that it recently negotiated a reduction of that price to [ ] SIB at 48; CX-244 at Q&A 121. The direct per unit cost associated with domestic activities for the foiling, lubricating, and testing is [ ] SIB at 48; CX-37; CX-243 (Chabon DWS) Q&A 18. This includes the labor associated with foiling, lubricating and testing the Pleasure Plus as well as the cost of the other "raw material," that is the foil (purchased as front and back squares) and the silicone lubrication (Silicone TBF 8-250), which are purchased from domestic sources. SIB at 48; CX-243 (Chabon DWS) Q&A 21-24; CX-37; CX-32 at 12-15. Staff states that, "[t]he per unit cost of domestic overhead has been approximated at [ ] as averaged out over the past three years (and includes Complainant's apportionment of such items as rent, utilities, office labor, and shipping). CX-37 at 4. Combining direct and overhead costs, the total per unit value added by domestic activities is approximately [ ] CX-37." SIB at 49.

Respondents assert that Davin Wedel testified that the cost of producing a single foil-packaged Pleasure Plus prophylactic, without accounting for the box and sleeve, is between [ ] RCDIB at 62 citing Wedel Tr. 536:3-11. Respondents then claim that of the [ ] cents is attributable to the cost of the unlubricated balloons purchased in bulk from Guilin in China, [ ] is attributable to lubrication, which occurs in the United States, and [ ] is attributable to foiling, which occurs in the United States. RCDIB at 62. Respondents assert that, based upon this information, Seth Kaplan calculated that the value added in the United States for a single prophylactic is between [ ] RCDIB at 63.

1. Sleeves and Metal Boxes

Respondents further assert that it is inappropriate to exclude the cost of the metal box from the value added analysis. Id. Respondents rely upon Davin Wedel's testimony that the boxes for the Pleasure Plus 12-pack are manufactured in China and that they currently cost [ ] per box (approximately [ ] per prophylactic) but that the boxes cost more than [ ] per box before 2005. RCDIB at 63. Respondents also rely upon Davin Wedel's testimony that the sleeves used with the Pleasure Plus prophylactics cost between [ ] per 12-pack (approximately [ ] per prophylactic. Id. Adding these costs into the value added analysis, Respondents claim that the value added in the United States for a single prophylactic lubricated in the United States would be between [ ] Id. at 63-64.

Staff asserts that it is proper to include the cost of the foils in which the prophylactics are placed in the value added analysis but that it is not proper to include the cost of the metal boxes and the sleeves. SRB at 35-36. Staff asserts that packaging should only be considered as a part of the value added analysis to the extent the packaging is "integral" and necessary for the sale and use of the product. Id. citing Certain Doxorubicon and Preparations Containing Same, Inv. No. 337-TA-300, Initial Determination at 118-120 (May 21, 1990). Staff relies upon Dr. Potter's testimony for the proposition that the foils are necessary for the use and sale of the Pleasure Plus. SRB at 36. Staff asserts that the metal boxes and sleeves are not necessary for the use and sale of the Pleasure Plus and points out that the boxes are not used for the Pleasure Plus prophylactics that are sold to health organizations. Id. citing Chabon, Tr. 620-621. Staff asserts that it would be inappropriate to consider this packaging because it would have the domestic industry analysis turn on whether a complainant sells its product in expensive or inexpensive packaging. SRB at 36.

I agree with Staff that it is appropriate to include the cost of the foils but not the cost of the metal boxes and sleeves in the value added analysis. The foils are necessary in order for the prophylactics to be useable and saleable. The metal boxes and sleeves that Complainant uses to package the prophylactics that it sells directly to individual consumers are not as integral to the use of the Pleasure Plus. While fancier packaging may make the product more appealing to a consumer, it is a cosmetic feature and not a necessary part of the manufacturing and production of the Pleasure Plus. Furthermore, Complainant sells a certain portion of its prophylactics in bulk to health organizations without the metal boxes and sleeves. Chabon, Tr. 621:21-622:10.

2. Overhead

Respondents criticize David Chabon's value added analysis basically because they assert that he is allocating too much money to domestic overhead and too little money to foreign overhead. See RCDIB 67-69. Respondents took issue with the fact that Chabon used the full depreciation and amortization values on Complainant's books, because Respondents claim that Chabon did not know what these values reflected. RCDIB at 67-68. Respondents also claim that Chabon incorrectly included general and administrative expenses in his value added analysis. Id. at 68-69. Respondents criticized the [ ] figure that Chabon used to calculate international overhead because Chabon was not sure that this number was correct. Id. at 68. Respondents further criticized Chabon's value added analysis because he does not have any information about general administrative expenses or overhead incurred by Guilin in China. Id. Furthermore, Respondents object to the use of the full amounts attributable to the lubricating and foiling machine because this machine is used for products other than the Pleasure Plus. Id. at 68.

Staff's value-added analysis includes domestic overhead costs but not foreign overhead costs. See SIB at 48-50. Staff agrees with Respondents that, for the most part, general and administrative expenses are not included in a value-added analysis, but that such components as "factory overhead and sales expenses," (Certain Nonwoven Gas Filter Elements, 337-TA-275, Order No. 13 at 6 (March 1, 1988) (nonreviewed)), including rent and property maintenance (Certain Display Controllers and Products Containing Same, Inv. No. 337-TA-49, Initial Determination at 181 (nonreviewed in relevant part)), should and can be considered. SRB at 36. Staff also states that because the Pleasure Plus is the only product sold by Complainant, it may be proper to include general and administrative expenses in this "unusual case." Id. However, Staff does not explain how it has broken down the numbers in its value-added analysis only to include factory overhead and sales expenses as opposed to other general and administrative expenses. Because neither Complainant nor Staff has pointed to anywhere in the record that contains a breakdown of the expenses incurred by GPC so that I could perform a proper value-added analysis, I am unable to determine the appropriate value that is added to Complainant's products by domestic activities.

9. Domestic Industry Conclusion

Complainant has only proven that it employs an average of [ ] employees. Complainant has not provided the evidence sufficient to perform a proper value-added analysis in accordance with Commission precedent. Although Staff presents arguments in favor of a finding of domestic industry, these do not suffice given Complainant's woeful failure to produce cogent evidence of a domestic industry. Based upon this failure of proof, I conclude that Complainant has not satisfied its burden to prove the existence of a domestic industry.

VI. REMEDY AND BONDING

Because I have found that no violation of Section 337 has occurred, I recommend that no remedy or bond be imposed. If a violation were found, I agree with the recommendations made by Staff in section VII of Staff's Post Hearing Brief. Specifically, a limited exclusion order should issue and should require Complainant to report on the status of its domestic industry to the Commission. Additionally, as the evidence indicates that Respondents maintain commercially significant inventories of the accused products, a cease and desist order should also be issued. Respondents argue that there are public interests at issue which should preclude the issuance of either a cease and desist order or an exclusion order. However, such concerns will not be addressed here and should be submitted to the Commission under Commission Rule 210.50(b)(1) which states:

> Unless the Commission orders otherwise, and except as provided in paragraph (b)(2) of this section, an administrative law judge shall not address the issue of the public interest for purposes of an initial determination on violation of section 337 of the Tariff Act under Sec. 210.42(a)(1)(i).

On the issue of bonding, Complainant asserts that Respondents should "be required to post a bond of 80% of the entered value of their products during the Presidential review period." CIB at 47. Respondents assert that a nominal bond of $1000 would be appropriate because Complainant has not produced evidence relevant to the issue of bonding. RCDIB at 75. Staff correctly notes that "the Commission typically has considered the differential in sales price between the patented product made by domestic industry and the lower price of the infringing product." SIB at 67 (quoting Certain Microsphere Adhesives, Process for Making Same and Products Containing Same, Including Self-Stick Repositionable Notes, Inv. No. 337-TA-366, Commission Opinion at 24, 1996 WL 1056298 (U.S.I.T.C. January, 1996)).

Neither Complainant nor Respondent provide a basis for the bonding levels that they propose. The evidence, correctly summarized by Staff, shows that the prophylactics at issue are sold to retailers as a specific price per unit: 1) Complainant's Pleasure Plus at [ ] 2) Respondent Church & Dwight's Twisted Pleasure at [ ] and 3) Respondents Medtech/Intellx's Inspiral at 30 cents. CX-132 at 10; CX-146 at 9; CX-245 at 3; SIB at 67-68. Respondents agree with this assessment of the appropriate price differentials in their Post Hearing Reply Briefs. RCDRB at 49, RMIRB at 33. Thus, should the Commission issue an exclusion order or cease and desist order, an appropriate bond for the Twisted Pleasure would be[ ] and an appropriate bond for the Inspiral would be [ ] per unit.

VII. CONCLUSIONS OF LAW

1. The Commission has subject matter, in rem, and in personam jurisdiction.

2. There has been an importation of certain male prophylactic devices, which are the subject of the alleged unfair trade allegations.

3. No domestic industry exists in the United States, as required by subsection (a)(2) of section 337, that exploits the male prophylactic devices that are covered by the U.S. Patent No. 5,082,004.

4. The Pleasure Plus prophylactic practices claims 1-4, 9, 22, 25, and 31 but not claim 8 of the '004 patent.

5. Respondent C&D's accused product infringes claims 1, 13, 18 and 31 of U.S. Patent No. 5,082,004. Respondent C&D's accused product does not infringe claims 2-4, 15, 16, 22, 25, 32 and 36 of U.S. Patent No. 5,082,004.

6. Respondents Medtech/Intellx's accused product infringes claims 1, 6, 9, 22, 25, and 31 of U.S. Patent No. 5,082,004. Respondents Medtech/Intellx's accused product does not infringe claims 2-4 and 8 of U.S. Patent No. 5,082,004.

7. Claims 1, 6, and 9 of U.S. Patent No. 5,082,004 are invalid as anticipated by U.K. Patent No. 1,252,255.

8. Claims 2-4, 8, 13, 15-16, 18, 22, 25, 31-32, and 36 of U.S. Patent No. 5,082,004 are not invalid.

9. There is no violation of 19 U.S.C. § 1337.

10. If a violation were found, the record supports issuance of a limited exclusion order, a cease and desist order, and a bond during Presidential review.

VIII. ORDER

Based on the foregoing, and the record as a whole, it is my Final Initial Determination that there is no violation of section 337 in the importation into the United States, sale for importation, and the sale within the United States after importation of certain male prophylactic devices. It is also my recommendation that because a violation of section 337 should not be found, limited exclusion orders and cease and desist orders should not issue.

I hereby CERTIFY to the Commission my Final Initial and Recommended Determinations together with the record consisting of the exhibits admitted into evidence. The pleadings of the parties filed with the Secretary and the transcript of the pre-hearing conference and the hearing, including closing arguments are not certified since they are already in the Commission's possession in accordance with Commission rules.

Further it is ORDERED that:

1. In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the Administrative Law Judge under 19 C.F.R. § 210.5 is to be given in camera treatment.

2. The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the protective order issued by the Administrative Law Judge in this investigation, and upon the Commission Investigative Staff Attorney. To expedite service of the public version, counsel are hereby ordered to serve on the Administrative Law Judge by no later than July 14, 2006 a copy of this ID with those sections considered by the party to be confidential bracketed in red.

3. This ID shall become the determination of the Commission 45 days after its date of service unless the Commission within those 45 days shall have ordered review of this ID, or certain issues herein, pursuant to 19 C.F.R. § 210.43(d) or § 210.44.

/ Robert L. Barton, Jr.

Robert L. Barton, Jr.
Administrative Law Judge

Issued: June 30, 2006

CERTAIN MALE PROPHYLACTIC **Inv. No. 337-TA-546**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **INITIAL DETERMINATION** was served upon, Rett Snotherly, Esq., Commission Investigative Attorney, and the following parties via first class mail and air mail where necessary on _____, 2006.

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112A
Washington, D.C. 20436

FOR COMPLAINANT PORTFOLIO TECHNOLOGIES, INC:

Paul J. Kozacky, Esq.
Jerome R. Weitzel, Esq.
Jeffrey S. Becker, Esq.
Christopher M. Saternus, Esq.
John M. Sheldon, Esq.
KOZACKY & WEITZEL, P.C.
One North LaSalle Street, Suite 3150
Chicago, IL 60602

Richard P. Beem, Esq.
Michael T. Griggs, Esq.
BEEM PATENT LAW FIRM
53 West Jackson Boulevard, Suite 1352
Chicago, IL 60604

Kent R. Stevens, Esq.
Eric G. Wright, Esq.
MORGAN & FINNEGAN, LLP
1775 Eye Street, N.W., Suite 400
Washington, D.C. 20006

CERTAIN MALE PROPHYLACTIC **Inv. No. 337-TA-546**

Mark J. Abate, Esq.
Eric L. Lane, Esq.
MORGAN & FINNEGAN, LLP
3 world Financial Center - 20th & 21st Floor
New York, NY 10281

FOR RESPONDENT CHURCH & DWIGHT CO., INC.:
Lewis E. Leibowitz, Esq.
Steven P. Hollman, Esq.
Susan M. Cook, Esq.
Jonathan T. Stoel, Esq.
HOGAN & HARTSON LLP
555 13th Street, N.W.
Washington, D.C. 20004-1109

James H. Shalek, Esq.
Alan Federbush, Esq.
Baldassare Vinti, Esq.
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036-8299

FOR RESPONDENTS MEDTECH PRODUCTS LTD., AND INTELLX, INC.:
Lizbeth R. Levinson, Esq.
GARVEY SCHUBERT & BARER
1000 Potomac Street, N.W.
5th Floor
Washington, D.C. 20007-3501

CERTAIN MALE PROPHYLACTIC **Inv. No. 337-TA-546**

PUBLIC MAILING LIST

Sherry Robinson
LEXIS - NEXIS
8891 Gander Creek Drive
Miamisburg, OH 45342

Ronnita Green
West Group
Suite 230
901 Fifteenth Street, N.W.
Washington, D.C. 20005

APPENDIX A

APPEARANCES OF COUNSEL:

COMPLAINANT PORTFOLIO TECHNOLOGIES, INC.:

PAUL J. KOZACKY, ESQ.
JEROME R. WEITZEL, ESQ.
JEFFREY S. BECKER, ESQ.
Kozacky & Weitzel, P.C.
One North LaSalle Street
Suite 1350
Chicago, Illinois 60602

RICHARD P. BEEM, ESQ.
MICHAEL T. GRIGGS, ESQ.
Beem Patent Law Firm
53 West Jackson Boulevard, Suite 1352
Chicago, Illinois 60604

RESPONDENTS CHURCH & DWIGHT CO., INC.:

LEWIS E. LEIBOWITZ, ESQ.
STEVEN P. HOLLMAN, ESQ.
SUSAN M. COOK, ESQ.
Hogan & Hartson LLP
555 13th Street, N.W.
Washington, D.C. 20004-1109

JAMES H. SHALEK, ESQ.
ALAN FEDERBUSH, ESQ.
BALDASSARE VINTI, ESQ.
Proskauer Rose LLP
1585 Broadway
New York, New York 10036
(212) 969-3000

RESPONDENT REDDY MEDTECH, LTD. AND INTELLX, INC..:

DAVID LIEBERWORTH, ESQ.
Garvey, Schubert, Barer
18th Floor
Second & Seneca Building
1191 Second Avenue
Seattle, Washington 98101

COMMISSION INVESTIGATIVE STAFF:

RETT SNOTHERLY, ESQ.
JEFFREY WHIELDON, ESQ.

APPENDIX B

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Hon. Robert L. Barton, Jr.

In the Matter of CERTAIN MALE PROPHYLACTIC DEVICES	Investigation No. 337-TA-546

JOINT STATEMENT OF UNDISPUTED MATERIAL FACTS

Pursuant to Ground Rule 8.3 and the Procedural Schedule, Complainant Portfolio Technologies, Inc. ("PTI") and Respondents Church & Dwight Co., Inc. ("C&D"), Medtech Products, Ltd. ("Medtech") and Intellx, Inc. ("Intellx") by agreement, hereby provide their joint statement of undisputed material facts:

I. INTRODUCTION

A. Procedural History

1. In 1999, PTI filed a patent infringement suit against Medtech, case No. 99-0889 (JAG) in the District of New Jersey. PTI's motion for preliminary injunction in that case was denied by the district court, which ruling was upheld by the Federal Circuit as not having been an abuse of discretion. An administrative termination was entered during the appeal which has recently been lifted. The district court has stayed entering a discovery schedule until after the post-trial briefing of this investigation.

2. In 2004, PTI filed a patent infringement suit against C&D in the Northern District of Illinois. The case was transferred to the District of New Jersey and is case No. 04-6340 (JAG). C&D filed a motion for summary judgment of non-infringement which was denied by the district court on February 6, 2006. The district court has stayed entering a discovery schedule until after the post-trial briefing of this investigation.

3. In 2005, PTI filed a patent infringement case against Intellx in the U.S. District Court for the Western District of Michigan, case No. 05 CV 0159. That case has been stayed pending the outcome of the New Jersey cases.

B. **The Parties**

4. PTI, the Complainant in this investigation, is an Illinois corporation, with its headquarters located at 55 East Monroe Street, Suite 4200, Chicago, Illinois 60603.

5. PTI has a management agreement with Global Protection Corp. ("GPC"), a shareholder of PTI, in Boston, Massachusetts.

6. MedTech, a Respondent in this investigation, is a corporation organized under the laws of India and has its principal place of business at S-59, 20th Street, Anna Nagar West, Chennai 600 040, Tamil Nadu, India

7. Medtech is engaged in the research, development, and manufacturing of prophylactics. Medtech was formed by A. V. K. Reddy, the inventor of the '004 patent. Medtech manufactures the two accused male prophylactics, the Inspiral and the Trojan Twisted Pleasure, in India. The accused products are then imported into the United States.

8. Intellx, a Respondent in this investigation, is a Michigan corporation with its principal place of business at 5696 U.S. 131 S., P.O. Box 42, Petoskey, Michigan 49770.

9. Intellx imports, markets and distributes the Inspiral prophylactic.

10. C&D, a respondent in this investigation, is a Delaware corporation with its principal place of business at 469 North Harrison Street, Princeton, New Jersey.

11. C&D imports, markets and distributes the Trojan Twisted Pleasure prophylactic.

C. Overview of the Technology

12. Male prophylactics are intended to minimize the risk of unwanted pregnancy and the transmission of sexually-transmitted diseases by encasing the male's penis in a flexible but secure covering that retains the male's ejaculated semen.

D. The Patent at Issue

13. The patent at issue in this investigation is U.S. Patent 5,082,004 ("the '004 patent"). The '004 patent was issued from United States application Serial No. 545,905, filed on June 29, 1990, which is a continuation-in-part of United States application Serial No. 526,843, filed on May 22, 1990, which issued as United States Patent 5,027,831 on July 2, 1991.

14. The inventor of the '004 patent, Alla V. K. Reddy, assigned all rights, title and interest in the '004 patent (except with respect to right, title and interest in the patent in India) to Reddy Laboratories International, Ltd. ("RLIL") on November 29, 1991.

15. The '004 patent has 36 total claims, of which 7 are independent.

E. The Products at Issue

16. The Inspiral prophylactic is manufactured by Medtech in India and distributed in the United States by Intellx.

17. The Trojan Twisted Pleasure is manufactured by Medtech in India and distributed in the United States by C&D.

III. INFRINGEMENT

A. The Inspiral

18. PTI's complaint alleged that the Inspiral infringes claims 1-12, 22, 25, 26 and 31. PTI has withdrawn its infringement allegations regarding claims 10-12 and 26.

19. The Inspiral is a male condom.

20. The Inspiral prophylactic has an open end.

21. The Inspiral prophylactic is made of latex.

B. The Trojan Twisted Pleasure

22. PTI's complaint alleged that the Twisted Pleasure infringes claims 1-7, 9-27, 31-33 and 36. PTI has withdrawn its infringement allegations regarding claims 10-12, 17, 21 and 26.

23. The Twisted Pleasure is a male condom.

24. The Twisted Pleasure prophylactic has an open end.

25. The Twisted Pleasure prophylactic is made of latex.

IV. DOMESTIC INDUSTRY

A. Technical Prong

26. The Pleasure Plus is a male condom.

27. The Pleasure Plus prophylactic has an open end.

28. The Pleasure Plus prophylactic has a closed end.

29. The Pleasure Plus prophylactic is made of latex.

B. Economic Prong

30. PTI operates its business in the United States by way of a management agreement ("Agreement") with GPC, a shareholder of PTI.

31. PTI paid [redacted] for intangibles, including the '004 patent.

32. GPC leases approximately 14,900 square feet of space for production, shipping and office work for work related to the Pleasure Plus and other GPC products. The facility is located at 12 Channel Street in Boston, Massachusetts. PTI is billed by GPC for its use of the space.

33. GPC has [ ] production and office employees who perform work related to the Pleasure Plus and other GPC products. The time spent by these employees on PTI matters is billed by GPC to PTI.

34. In the fourteen month period ending in February 2005, GPC charged PTI for approximately [ ] for time spent on PTI matters.

35. The number of Pleasure Plus prophylactics sold in 2005 which were lubricated, foiled, tested and packaged by GPC was [ ]

Respectfully submitted,

Paul J. Kozacky
Jerome R. Weitzel
KOZACKY & WEITZEL, P.C.
One North LaSalle St., Ste. 3150
Chicago, IL 60602-3935
Telephone: 312-696-0900
Facsimile: 312-696-0905

Richard P. Beem
Michael T. Griggs
BEEM PATENT LAW FIRM
53 W. Jackson Boulevard, Suite 1352
Chicago, IL 60604-3787
Telephone: 312-201-0011
Facsimile: 312-201-0022

Attorneys for Complainant
Portfolio Technologies, Inc.

HOGAN & HARTSON L.L.P.
Lewis E. Leibowitz
Steven P. Hollman
Susan M. Cook
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Phone: (202) 637-5600
Fax: (202) 637-5910

James H. Shalek
Alan Federbush
Baldassare Vinti
PROSKAUER ROSE LLP
1585 Broadway
New York, New York 10036
(212) 969-3000

Attorneys for Respondent
Church & Dwight Co., Inc

David Lieberworth by SPH with permission
David Lieberworth, WSBA #9329
GARVEY SCHUBERT BARER
1191 Second Avenue, 18th Floor
Seattle, WA 98101-2939
(206) 816-1493

Attorneys for Respondents

Medtech Products, Ltd. and
Intellx, In

CERTIFICATE OF SERVICE

I hereby certify a copy of the foregoing **INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BONDING** was served on the following on July 14, 2006.

The Honorable Robert L. Barton
Administrative Law Judge
U.S. International Trade Commission
500 E. Street, S.W., Suite 317-G
Washington, DC 20436
(*VIA* HAND DELIVERY – 2 copies)

Rett Snotherly, Esq.
Office of Unfair Import Investigations
U.S. International Trade Commission
500 E. Street, S.W., Suite 401-O
Washington, DC 20436
(*VIA* HAND DELIVERY – 1 copy)

Kimberly Parke, Esq.
Office of Unfair Import Investigations
U.S. International Trade Commission
500 E. Street, S.W., Suite 317-C
Washington, DC 20436
(*VIA* ELECTRONIC MAIL)

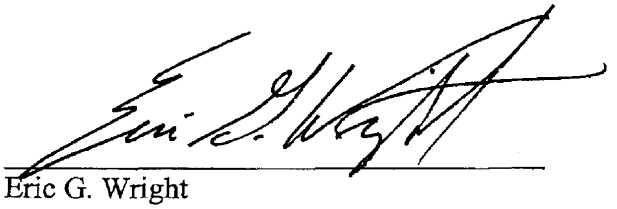
Counsel for Respondent Church & Dwight Co., Inc.:

Lewis E. Leibowitz, Esq.
Steven P. Hollman, Esq.
Susan M. Cook, Esq.
Jonathan T. Stoel, Esq.
Hogan & Hartson LLP
555 13th Street, N.W.
Washington, DC 20004
(*VIA* ELECTRONIC MAIL)

James H. Shalek, Esq.
Alan Federbush, Esq.
Baldassare Vinti, Esq.
Proskauer Rose LLP
1585 Broadway
New York, NY 10036-8299
(*VIA* ELECTRONIC MAIL)

Counsel for Respondent Reddy Medtech, Ltd. And Intellx, Inc.:

Lizbeth R. Levinson, Esq.
Garvey, Schubert, Barer
1000 Potomac Street, N.W.
5th Floor
Washington, DC 20007
(*VIA* ELECTRONIC MAIL)



Eric G. Wright
Morgan & Finnegan, LLP
1775 Eye Street, N.W., Suite 400
Washington, DC 20006
Telephone: 202-857-7887