

**PUBLIC VERSION**

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

**In the Matter of**

**CERTAIN MALE PROPHYLACTIC  
DEVICES**

**Investigation No. 337-TA-546**

OFFICE OF THE  
SECRETARY  
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**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,

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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”),<sup>1</sup> which manufactures both accused products.<sup>2</sup>

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,

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<sup>1</sup> Medtech and Intellx have the same representation in this proceeding and their filings are joint. We reference their arguments as those of “Medtech.”

<sup>2</sup> 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.

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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.<sup>3</sup> 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.

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

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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

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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

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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

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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

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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



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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:

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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

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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.

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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

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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

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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.”<sup>4</sup> 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

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<sup>4</sup> 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.

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“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:

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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



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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.<sup>5</sup> The limitations in claim 1

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<sup>5</sup> 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

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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

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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.

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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;

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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

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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

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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

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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<sup>6</sup> 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.

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<sup>6</sup> 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.

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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 axis 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



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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  $\pm$  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  $\pm$  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

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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  $0.11 \text{ mm} \pm 0.04 \text{ mm}$  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

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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  $0.11 \text{ mm} \pm 0.04 \text{ mm}$ . 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

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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:

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32. The prophylactic pouch of claim 31<sup>7</sup>, 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

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<sup>7</sup> 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.

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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**

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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

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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



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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.

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### 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.<sup>8</sup> 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

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<sup>8</sup> 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.

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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

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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

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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.<sup>9</sup> 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

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<sup>9</sup> 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.

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apply for finding that claim 31 is not anticipated by the '255 patent.<sup>10</sup>

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).<sup>11</sup> 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

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<sup>10</sup> 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.

<sup>11</sup> 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.

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- (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, 100<sup>th</sup> Cong., 1<sup>st</sup> 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

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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).<sup>12</sup> 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.

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<sup>12</sup> Subparagraph (C) is not at issue in this investigation.



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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.<sup>13</sup> 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

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<sup>13</sup> Foiling, lubricating, and quality testing are referred to as “second staging.”

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¶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

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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.<sup>14</sup> Final ID at 124.<sup>15</sup>

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

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<sup>14</sup> We agree with the ALJ that adding in the cost of fancier packaging, which is not necessary for the production of the Pleasure Plus, is inappropriate. Final ID at 125-26.

<sup>15</sup> 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).

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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.

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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

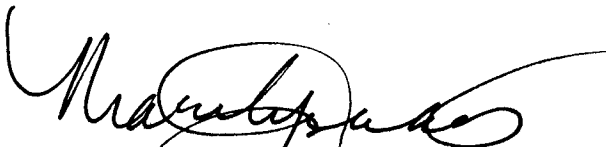
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are such that three companies, C&D among them, account for 98 percent of all domestic sales; that brand recognition is crucial in the prophylactic business; and that C&D's Trojan brand is 90 years old. RX-105, Q. 15-16; Tr. at 810. PTI is only a small 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.

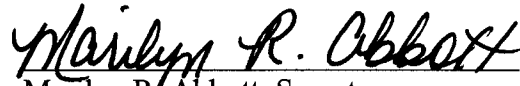


Marilyn R. Abbott  
Secretary to the Commission

Issued: August 1, 2007

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.



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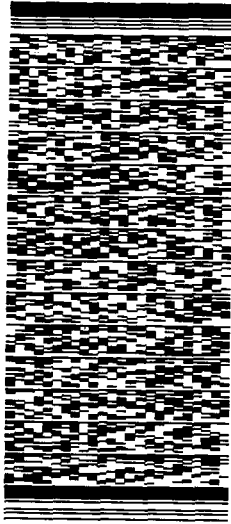
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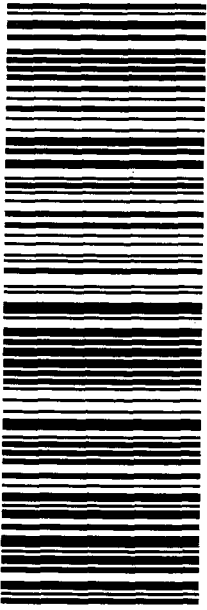
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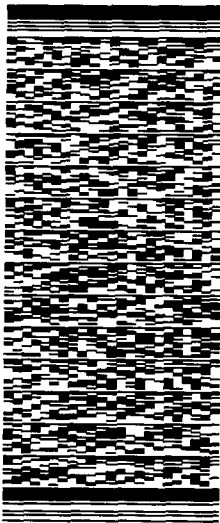
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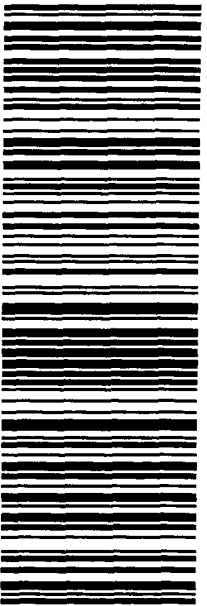
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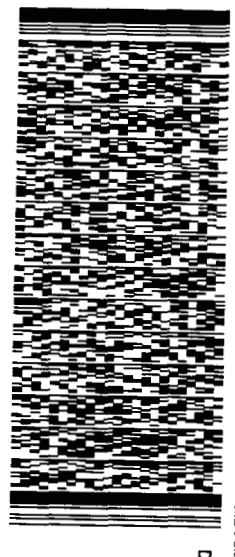
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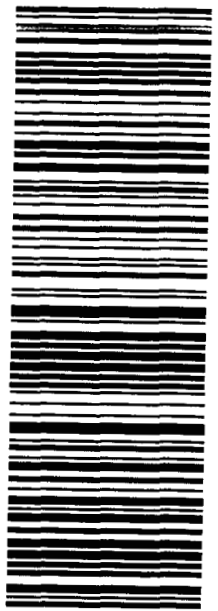
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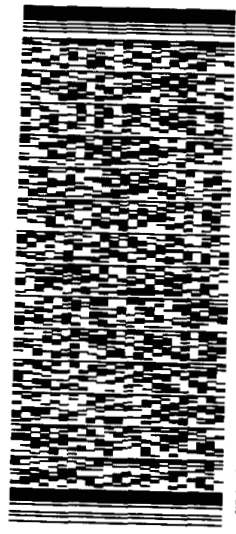
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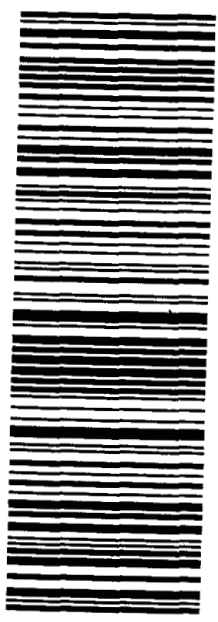
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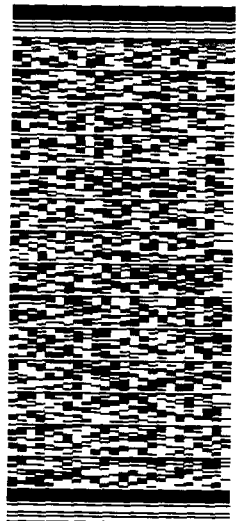
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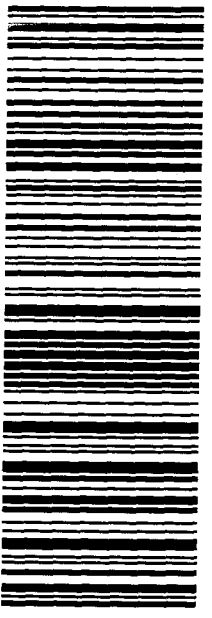
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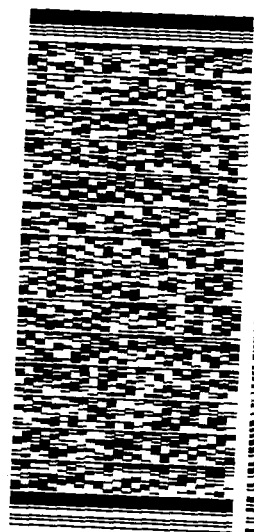
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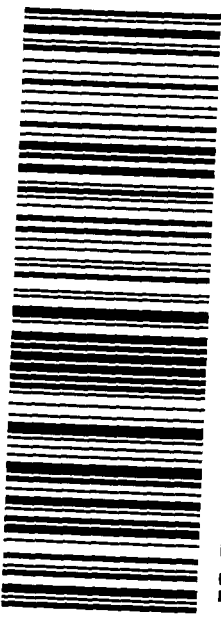
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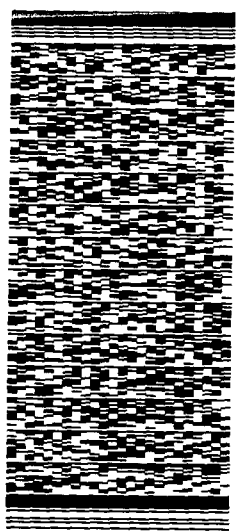
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