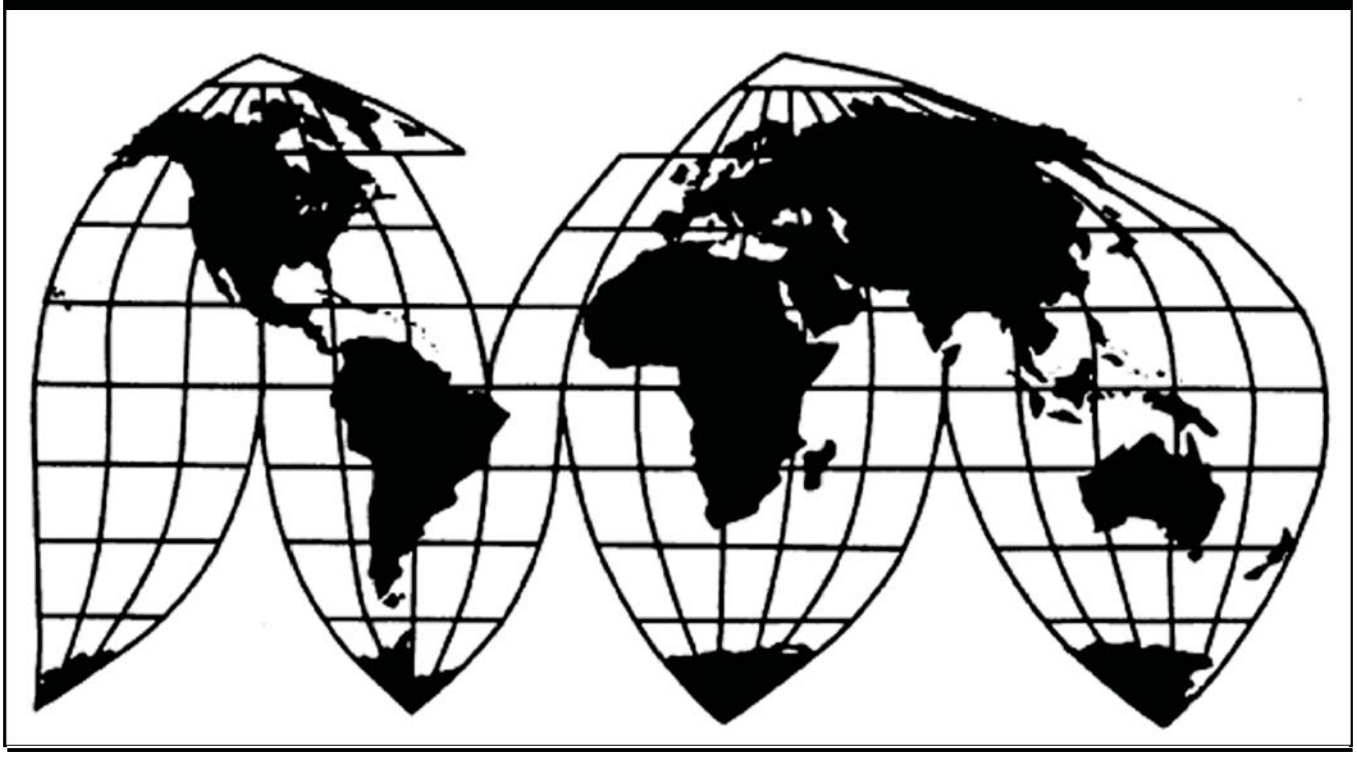
In the Matter of

Certain Nitrile Gloves and Certain Nitrile Rubber Gloves

Investigation Nos. 337-TA-608, -612

Publication 4143 **April 2010**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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In the Matter of

Certain Nitrile Gloves
and
Certain Nitrile Rubber Gloves

Investigation Nos. 337-TA-608, -612

Publication 4143

April 2010

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

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

NOTICE OF COMMISSION DETERMINATION OF NO VIOLATION OF SECTION 337; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that there is no violation of 19 U.S.C. § 1337 by respondents in the above-referenced investigation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Inv. No. 337-TA-608 on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing Company ("Tillotson"). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and

the sale within the United States after importation of certain nitrile gloves by reason of infringement of various claims of United States Patent No. Re. 35,616 ("the '616 patent"). The complaint named over thirty respondents. The Commission instituted a second investigation, Inv. No. 337-TA-612, on August 22, 2007, based on a complaint filed by Tillotson. That complaint also 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 nitrile gloves by reason of infringement of various claims of the '616 patent and named seven respondents. On September 19, 2007, the ALJ consolidated Inv. No. 337-TA-608 with Inv. No. 337-TA-612.

On August 25, 2008, the ALJ issued a final ID and recommended determination on remedy and bonding in the above-referenced consolidated investigation, finding that the active respondents did not violate section 337. Specifically, he found that while the majority of accused gloves infringe claims 17, 18, and 19 of the '616 patent, the asserted claims are invalid. He concluded that when the patentees amended the claims through a reissue application filed more than two years after the grant of the original patent, they improperly enlarged the scope of the claims, rendering them invalid. The ALJ further concluded that the claims are invalid because the patentees filed a defective reissue declaration when applying for the reissue patent. He rejected other arguments of invalidity and unenforceability. Accordingly, the ALJ concluded that respondents had not violated section 337.

On September 8, 2008, complainant Tillotson filed a petition for review, as did several respondents. On September 16, 2008, respondents filed a response to complainant's petition and complainant filed a response to respondents' petition.

On October 24, 2008, the Commission determined to review a portion of the ALJ's ID and requested briefing from the parties on the issues under review and on remedy, the public interest, and bonding. On November 10, 2008, complainant Tillotson, certain respondents, and the Commission investigative attorney ("IA") each filed responses to the Commission's request for written submissions. On November 17, 2008, complainant, certain respondents, and the IA filed reply submissions.

Having examined the record of this investigation, including the ALJ's ID and the submissions of the parties, the Commission has determined to affirm the ALJ's determination that the respondents did not violate section 337 because the asserted claims are invalid under 35 U.S.C. § 251 and 37 C.F.R. § 1.175(a) (1996), but will clarify a portion of his claim construction in a separate opinion.

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

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: December 22, 2008

CERTAIN NITRILE GLOVES AND CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION OF NO VIOLATION OF SECTION 337; TERMINATION OF THE INVESTIGATION** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on December 23, 2008.

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

COMMISSION OPINION

The Commission issued a notice on December 22, 2008, affirming the administrative law judge's ("ALJ") determination that there is no violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the above-referenced investigation. The Commission adopts the ALJ's final initial determination ("ID") issued on August 25, 2008, and his order construing the disputed claim terms issued on March 14, 2008. In this opinion, the Commission clarifies the ALJ's discussion of the claim term "predetermined pressure" in light of assertions made by the parties. The Commission's clarifications are not intended to change his claim construction and do not affect his conclusions with regard to invalidity.

I. BACKGROUND

A. Procedural History

The Commission instituted Investigation No. 337-TA-608 on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing Company ("Tillotson"). 72 *Fed. Reg.* 37052 (July 6, 2007). The complaint 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 nitrile gloves by reason of infringement of claims 1, 17, 18, and 19 of United States Reissue Patent No. Re. 35,616 ("the '616 patent"). The complaint named thirty-one respondents. The Commission instituted a second investigation, Investigation No. 337-TA-612, on August 22, 2007, based on another complaint filed by Tillotson. 72 *Fed. Reg.* 47072 (Aug. 22, 2007). The complaint similarly 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 nitrile rubber gloves by reason of infringement of the same four claims. The complaint named seven additional respondents. On September 19, 2007, the ALJ consolidated the two investigations and allowed Tillotson to name fifteen additional respondents.

On December 13, 2007, Judge Essex held a *Markman* hearing to consider the meaning of several claim terms. On March 14, 2008, he issued an order construing the terms. *See* Order No. 63: Order Construing the Terms of the Asserted Claims of the Patents at Issue ("*Markman* Order"). The ALJ held an evidentiary hearing on May 19-27, 2008, and thereafter received post-hearing briefing from the parties.

On August 25, 2008, the ALJ issued his final ID, finding that the respondents did not

violate section 337 and also including his recommended determination on remedy and bonding. He found that while the vast majority of accused gloves infringe claims 1, 17, 18, and 19 of the '616 patent and that the domestic industry requirement was met, the asserted claims are invalid. ID at 48-49 & 111-17. Specifically, he found that when the patentees amended the claims through a reissue application filed more than two years after the grant of the original patent, they improperly enlarged the scope of the claims, rendering them invalid. ID at 54-66. The ALJ also found the claims invalid because the patentee filed a defective reissue declaration when applying for the reissue patent. ID at 66-74. He rejected respondents' arguments, however, that the claims are invalid as anticipated and obvious and that they are invalid for failing to disclose the best mode, for lack of enablement, and for being indefinite. ID at 75-101. He also rejected respondents' arguments that the patent is unenforceable for inequitable conduct. ID at 101-10. Accordingly, the ALJ concluded that respondents did not violate section 337.

On September 8, 2008, Tillotson filed a petition for review, challenging the ALJ's interpretation of the original claim phrase "predetermined pressure" and his conclusion that the asserted claims are invalid. On the same day, certain respondents filed a contingent petition for review, challenging another claim construction and the ALJ's infringement determinations.[1] In addition, they challenged the ALJ's conclusions that the claims are not invalid for failing to disclose the best mode and for lack of enablement, but did not challenge his conclusions with regard to anticipation or obviousness. Finally, they challenged the ALJ's conclusion that the patent

[1] Under the Commission's rules, contingent petitions for review are treated as petitions for review. 19 C.F.R. § 210.42(b)(3).

is not unenforceable for inequitable conduct.

On October 24, 2008, the Commission determined to review a portion of the ALJ's final ID. Specifically, the Commission determined to review (1) the ALJ's claim construction of the term "predetermined pressure;" (2) his determination that the claims are invalid under 35 U.S.C. § 251 because of a broadening reissue; (3) his determination that the claims are invalid because of a deficient reissue declaration filed under 37 C.F.R. § 1.175(a) (1996); (4) his determination that the claims are not invalid for failing to disclose the best mode; and (5) his determination that the claims are not invalid for lack of enablement. The Commission determined not to review the remaining issues. Finally, the Commission requested briefing on the issues on review, remedy, the public interest, and bonding.

On November 10, 2008, Tillotson, certain respondents, and the Commission investigative attorney ("IA") each filed responses to the Commission's request for written submissions. *See* Complainant's Memorandum in Response to the Commission's Determination to Review-in-Part the Administrative Law Judge's Final Initial Determination ("Comp. Submission"); Respondents' Written Submission on the Issues Under Review by the Commission; Office of Unfair Import Investigations' Response to Questions Posed in the Commission Notice of October 24, 2008 and Briefing on the Issue of Remedy, Public Interest, and Bonding. On November 17, 2008, Tillotson, the respondents, and the IA each filed reply submissions.

B. Patent at Issue

The '616 patent is entitled "Elastomeric Covering Material and Hand Glove Made Therewith." It is a reissue of United States Patent No. 5,014,362 ("the '362 patent"), which issued

on May 14, 1991, based on an application filed on May 11, 1990. The reissue application that resulted in the '616 patent was filed on November 13, 1995, and issued on September 30, 1997. The '616 patent has twenty-four claims, three of which have been cancelled, but only claims 1, 17, 18, and 19 are asserted in this investigation. The claims are generally directed to gloves that are designed to conform to the shape of the hand when stretched and then to relax so the pressure on the hand is substantially reduced.

II. ANALYSIS

The claim term "predetermined pressure" does not appear in the reissued claims, but appeared in original claim 1 of the '362 patent and is relevant to the broadening reissue question raised by the parties. Claim 1 of the '616 patent, with its additions shown in italics, its deletions in brackets, and the disputed claim term in bold, recites:

> 1. A *closely fitting* glove comprising a layer of elastomeric material (a) *comprising nitrile butadiene rubber, (b)* having an initial configuration adapted to receive *and fit closely about a hand,* and *(c)* characterized by *(i)* being substantially impermeable to water vapor and liquid water, *(ii)* having a tensile strength of at least about 1500 psi as measured according to ASTM D-412 on a sample of the elastomeric material having a thickness from about 4.0 to about 4.5 mils, and *(iii)* having *a thickness and* elastic properties such that *the glove is capable of being stretched to fit closely about the hand and* when stretched from the initial configuration to fit closely about the hand, the elastomeric material conforms to the configuration of the hand, **initially exerting [a predetermined] *an initial* pressure** on the hand and thereafter *still fitting closely about the hand, but* relaxing, *within about 6 minutes after the glove is stretched to fit about said hand,* to exert on the hand a reduced pressure which is [substantially] less than about [80%] *50%* of the **[predetermined] *initial* pressure**.

JX-3 ('616 patent), col. 6, ll. 33-50.

The ALJ construed the claim term "predetermined pressure" to mean "the amount of

pressure decided in advance that will be exerted on the hand by the glove after the glove is donned." *Markman* Order at 14. In reaching this interpretation, he disposed of complainant's assertion that the terms "predetermined" and "initial" have the same meaning by relying on the inventor's explanation in the reissue prosecution history that the "term 'predetermined' has been replaced with the term 'initial' in amended claim 1 to more clearly define the glove in claim 1 in accordance with p. 11 line 22 of the applicant's description." *Id.* at 14 (citing JX-4 at TLC000035); *see also* JX-4 at TLC000178. The ALJ's conclusion is further supported by the fact that the inventor distinguished the two terms when he stated during prosecution that claim 1 recites a glove that "when stretched from an initial configuration to fit closely about the hand, *exerts an initial, rather than predetermined*, pressure on the hand . . ." JX-4 at TLC000011 & TLC000178 (emphasis added); *see also* ID at 59-60. The ALJ also relied on the '616 patent specification to support his conclusion, finding that the specification only uses the term "initially" to describe when the predetermined pressure is exerted on the hand, *i.e.*, "initially exerting a predetermined pressure on the hand," and does not use the term interchangeably with the term "predetermined." *Markman* Order at 15. He concluded therefore that giving them the same meaning would render the term "predetermined" superfluous. *Id.*

The ALJ also found that the intrinsic evidence did not suggest that the patentees were their own lexicographers. *Markman* Order at 14. As such, the ALJ gave the term "predetermined pressure" what he regarded as its ordinary and customary meaning to a person of ordinary skill in the art, namely, "the amount of pressure decided in advance that will be exerted on the hand by the glove after the glove is donned." *Id.* at 15. It is our understanding that by citing *Phillips v. AWH*

Corp., 415 F.3d 1303, 1322 (Fed. Cir. 2005) (*en banc*), he was indicating that he based his claim construction on dictionary definitions, and that, although he did not cite specific dictionaries, the dictionaries that he relied upon were those identified by respondents: MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 915 (10th ed. 2002); THE RANDOM HOUSE COLLEGE DICTIONARY REVISED EDITION 1044 (Revised ed. 1988); THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1382 (4th ed. 2000).

In discussing whether the inventors improperly enlarged the scope of the claims through a reissue application filed more than two years after the grant of the original patent under 35 U.S.C. § 251, the ALJ further discussed his interpretation of the term "predetermined pressure." He stated that the "initial pressure" can be "any pressure that is first exerted, while the amount of pressure for 'predetermined pressure' requires that the amount be 'decided in advance.'" ID at 61. He labeled the requirement that the pressure be decided or determined in advance as a "cognitive function." ID at 61. Complainant Tillotson seizes on the phrase "cognitive function" to argue that the ALJ required a mental step, which according to Tillotson is not appropriate in a product claim. Comp. Submission at 15-16. Tillotson improperly attributes meaning to the phrase "cognitive function" that was not intended by the ALJ. Claim 1 does not require a mental step insomuch as no one needs to select a specific pressure in designing a glove. Indeed, the ALJ said so in his opinion. He stated in footnote 12 of his ID that his "claim construction does not require a *specific selection or determination* of a *specific pressure* in advance, rather the [ALJ's] claim construction requires a determination in advance of what amount of pressure will be exerted on the hand by the glove after the glove is donned." ID at 61 n.12 (emphasis added). Thus, a glove maker need not design a

glove to achieve a particular pressure; it is sufficient that the amount of the pressure for a particular glove is known in advance of putting the glove on. ID at 65-66. One way this is done, according the specification and to the ALJ, is by simulating the predetermined pressure with the 100% Modulus Test. JX-3 ('616 patent), col. 6, ll. 11-26 & Figures 1 & 2; ID at 64.

Tillotson further attempts to read ambiguity into the ALJ's opinion where none is warranted by arguing that his statement in footnote 12 quoted above is inconsistent and unclear. However, the ALJ simply said that the claim term "predetermined pressure" requires that the amount of the pressure that will be exerted on the hand be determined before it is exerted. ID at 61 n. 12; *see also* ID at 62 ("What this demonstrates is not a specific amount of pressure or that the patentees had any 'foreknowledge' of what the actual amount of pressure would be, rather it evidences that the amount of pressure on the hand when the glove is donned was *decided in advance*." (emphasis in original)). He went on to explicitly reject respondents' argument that claim 1 requires selection of a specific pressure in advance. He explained that "[t]here is no requirement that [the] 'predetermined pressure' be a specific starting pressure or that the designer of the glove 'knowingly select a specific pressure.'" ID at 63. His opinion is consistent throughout: the specific pressure exerted by the glove need not be selected when designing the glove. ID at 62 & 64. Nor is it enough for the predetermined pressure to be fixed by basic physics, he found. We agree with his reasoning for this conclusion and note that Tillotson's argument essentially boils down to an assertion that the pressure is determinable, when the claims clearly require that the pressure be determined in advance. ID at 64-66. Thus, in our view, there is no confusion as to the meaning of the ALJ's claim construction.

Because we agree with the ALJ that the claim term "predetermined pressure" means "the amount of pressure decided in advance that will be exerted on the hand by the glove after the glove is donned," we agree with him regarding the invalidity of the asserted claims. Accordingly, the Commission affirms the ALJ's determination that there is no violation of section 337. Further, the Commission adopts the ALJ's ID and *Markman* Order in their entirety with the clarifications provided above.

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: January 15, 2009

CERTAIN NITRILE GLOVES AND CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **COMMISSION OPINION (PUBLIC VERSION)** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on January 15, 2009.

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

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

Administrative Law Judge Theodore R. Essex

(August 25, 2008)

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PUBLIC VERSION

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PUBLIC VERSION

Pursuant to the Notices of Investigation, 72 Fed. Reg. 37052 and 72 Fed. Reg. 47072 (2007), this is the Initial Determination of the consolidated investigations in the matter of *Certain Nitrile Gloves*, United States International Trade Commission Investigation No. 337-TA-608, and *Certain Nitrile Rubber Gloves*, United States International Trade Commission Investigation No. 337-TA-612. *See* 19 C.F.R. § 210.42(a).

It is held that no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain nitrile rubber gloves by reason of infringement of one or more of claims 1, 17 through 19 of United States Patent No. Re. 35,616.

The following abbreviations may be used in this Initial Determination:

CDX	Complainants' demonstrative exhibit
CFF	Complainants' proposed findings of fact
CIB	Complainants' initial post-hearing brief
CORFF	Complainants' objections to Respondents' proposed findings of fact
COSFF	Complainants' objections to Staff's proposed findings of fact
CPX	Complainants' physical exhibit
CRB	Complainants' reply post-hearing brief
CX	Complainants' exhibit
Dep.	Deposition
JSUF	Joint Statement of Undisputed Facts
JX	Joint Exhibit
RDX	Respondents' demonstrative exhibit
RFF	Respondents' proposed findings of fact
RIB	Respondents' initial post-hearing brief
ROCFF	Respondents' objections to Complainants' proposed findings of fact
ROSFF	Respondents' objections to Staff's proposed findings of fact
RPX	Respondents' physical exhibit
RRB	Respondents' reply post-hearing brief
RRX	Respondents' rebuttal exhibit
RX	Respondents' exhibit
SFF	Staff's proposed findings of fact
SIB	Staff's initial post-hearing brief
SOCFF	Staff's objections to Complainants' proposed findings of fact
SORFF	Staff's objections to Respondents' proposed findings of fact
SRB	Staff's reply post-hearing brief
Tr.	Transcript

I. BACKGROUND

A. Institution and Procedural History of This Investigation

By publication of a notice in the *Federal Register* on July 6, 2007, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted Investigation No. 337-TA-608 with respect to U.S. Patent No. Re. 35,616 ("the '616 Patent") to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain nitrile gloves by reason of infringement of one or more of claims 1 and 17-19 of U.S. Patent No. Re. 35,616, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

72 Fed. Reg. 37052 (2007).

Tillotson Corporation d/b/a Best Manufacturing Company ("Tillotson") of Menlo, Georgia, is the complainant. *Id.* The respondents named in the Notice of Investigation were: Top Glove Corporation Bhd. of Selangor. D.E., Malaysia; Ansell Ltd. of Victoria, Australia; Beijing Huateng Rubber Plastic of Beijing, China; Glovco(m) Sdn. Bhd. of Selangor D.E., Malaysia; Hartalega Holdings Bhd. of Kuala Lampur, Malaysia; Ideal Healthcare Group Co. Ltd. of Ningbo, China; JDA (Tianjin) Plastic Rubber Co. Ltd. of Tianjin, China; Kossan Rubber Industries Bhd. of Selangor D.E., Malaysia; Laglove (M) Sgn. Bhd. of Selangor, Malaysia; PT Medisafe Technologies of Utar, Indonesia; PT Shamrock Manufacturing Corporation of Sumatra, Indonesia; Riverstone Resources Sdn. Bhd. of Kuala Lumpur, Malaysia; Seal Polymer Industries Bhd. of Perak, Malaysia; Smart Glove Holdings Sdn. Bhd. of Selangor D.E., Malaysia; Supermax Corporation Bhd. of Selangor D.E., Malaysia; Yee Lee Corporation Bhd. of Perak Darul Ridzuan, Malaysia; YTY Holdings Sdn. Bhd. of Selangor D.E., Malaysia; Adenna, Inc. of Santa Fe Springs, California; Basic Medical Industries, Inc. of Chino, California; Cypress

Medical Products LLC of Chicago, Illinois; Darby Group Companies, Inc. of Jericho, New York; Dash Medical Gloves of Franklin, Wisconsin; Delta Medical Systems, Inc. d/b/a The Delta Group of Alpharetta, Georgia; Dentexx/First Medica Infection Control Assoc. of Greensboro North Carolina; Dynarex Corp. of Orangeburg, New York; Liberty Glove and Safety Co. of Walnut, California; Magla Products LLC of Albemarle, North Carolina; Protective Industrial Products, Inc. of Alpharetta, Georgia; QRP Inc. d/b/a QRP Gloves, Inc. of Tuscon, Arizona; Tronex International, Inc. of Denville, New Jersey and West Chester Holdings, Inc. of Monroe, Ohio. *Id.* The Commission Investigative Staff ("Staff") of the Commission's Office of Unfair Import Investigations is also a party in this investigation. *Id.* The investigation was originally assigned to Administrative Law Judge Bullock. *Id.*

On August 2, 2007, Judge Bullock issued an initial determination terminating respondent Cypress Medical Products, LLC from the investigation based on withdrawal of the Complaint. (*See* Order No. 7.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation as to Respondent Cypress Medical Products, LLC Based on Withdrawal of Complaint (August 22, 2007).)

On August 3, 2007, Judge Bullock issued an initial determination terminating respondent Westchester Holdings, Inc. from the investigation based on settlement agreement. (*See* Order No. 8.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation as to Respondent West Chester Holdings, Inc. On the Basis of a Settlement Agreement (August 29, 2007).)

By publication of a notice in the *Federal Register* on August 22, 2007, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted Investigation No. 337-TA-612 with respect to the '616 Patent to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain nitrile gloves by reason of infringement of one or more of claims 1 and 17-19 of U.S. Patent No. Re. 35,616, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

72 Fed. Reg. 47072 (2007).

Tillotson is the complainant. *Id.* The respondents named in the Notice of Investigation are: Cardinal Health, Inc. of Dublin, Ohio; Cardinal Health 200, Inc. of McGaw Park, Illinois; Cardinal Health Malaysia 211 Sdn. Bhd. of Bayan Lepas, Malaysia; Henry Schein, Inc. of Melville, New York; HSI Gloves Inc. of Melville, New York; Latexx Partners Berhad of Darul Ridzuan, Malaysia; and Medtexx Partners Inc. of Englewood, New Jersey. *Id.* Staff was also named a party to the investigation. *Id.* The investigation was originally assigned to Administrative Law Judge Bullock. *Id.*

On August 30, 2007, Judge Bullock issued an initial determination terminating respondent Beijing Huateng Rubber Plastic & Latex Products Co., Ltd. from the investigation based on consent order. (*See* Order No. 13.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Beijing Huateng Rubber Plastic & Latex Products Co., Ltd. Based On Consent Order (September 26, 2007).)

On September 4, 2007, Judge Bullock issued an initial determination terminating respondent Delta Medical Systems, Inc. from the investigation based on settlement agreement.

(*See* Order No. 15.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Delta Medical Systems, Inc. On the Basis of a Settlement Agreement (September 26, 2007).)

On September 19, 2007, the Complaint and Notice of Investigation were amended to add fourteen additional respondents. (*See* Order No. 21.) The respondents named are subsidiaries of already named respondents, namely: Ansell (Thailand) Ltd.; Ansell Healthcare Products LLC; Ansell Protective Products Inc.; Top Glove Sdn. Bhd.; TG Medical (USA) Inc.; Hartalega Sdn. Bhd.; Pharmatex USA Inc.; Perusahaan Getah Asas Sdn. Bhd.; Kossan Gloves Inc. d/b/a Sintex; PT Haloni Jane; Shamrock Manufacturing Company Inc.; Smart Glove Corporation Sdn. Bhd.; YTY Industry (Manjung) Sdn. Bhd.. Respondent Delta Medical Supply Group, Inc. d/b/a The Delta Group was also added as a respondent. The Commission determined not to review the order amending the Complaint and Notice of Investigation. (*See* Notice of Commission Decision Not to Review Initial Determination Granting Complainant's Motion to Amend the Complaint and Notice of Investigation (October 17, 2008).)

On September 19, 2007, Judge Bullock consolidated Investigation Nos. 337-TA-608 and 337-TA-612. (*See* Order No. 19.) The Commission determined not to review the order consolidating the investigation. (*See* Notice of Commission Decision Not to Review Order No. 19 (October 11, 2007).)

On the same day, Judge Bullock also issued an initial determination terminating respondent Magla Products LLC from the investigation based on settlement agreement. (*See* Order No. 20.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation

With Respect to Respondent Magla Products LLC On the Basis of a Settlement Agreement (October 11, 2007).)

On September 25, 2007, Judge Bullock found respondents Basic Medical Industries, Inc.; Glovco (M) Bhd.; and Ideal Healthcare Group Co. Ltd. in default. (*See* Order No. 22.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Finding Three Respondents in Default (October 15, 2007).)

On October 16, 2007, the Commission reassigned the consolidated investigations to this Court. (*See* Notice of a Commission Decision to Reassign Certain Section 337 Investigations.)

On November 27, 2008, the Court issued an initial determination terminating respondent Delta Medical Supply Group, Inc. d/b/a The Delta Group from the investigation based on settlement agreement. (*See* Order No. 41.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Delta Medical Supply Group, Inc. On the Basis of a Settlement Agreement (December 21, 2007).)

On December 13, 2007, the Court held a *Markman* hearing in the consolidated investigations. On March 14, 2008, the Court issued its Order Construing the Terms of the Asserted Claims of the Patent at Issue. (*See* Order No. 63.)

On January 8, 2008, the Complaint was amended to reflect changes in Tillotson's domestic industry, namely to reflect the recent sale of its manufacturing operations and subsidiaries and to include recently concluded license agreements. (*See* Order No. 47.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review Initial Determination Granting Complainant's Motion to Amend the Complaint (January 22, 2008).)

On February 8, 2008, the Court issued an initial determination terminating respondents Supermax Corporation Bhd. and Seal Polymer Industries Bhd. from the investigation based on settlement agreement. (*See* Order No. 55.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondents Supermax Corporation Bhd. and Seal Polymer Industries Bhd. On the Basis of a Settlement Agreement (February 22, 2008).)

On March 10, 2008, the Court found respondent Yee Lee Corporation Bhd. in default. (*See* Order No. 61.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Finding Respondent Yee Lee Corporation Bhd. in Default (March 28, 2008).)

On May 6, 2008, the Court found that Tillotson had satisfied the economic prong of the domestic industry requirement. (*See* Order No. 79.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not to Review an Initial Determination Granting a Motion for Summary Determination That Economic Prong of the Domestic Industry Requirement Has Been Met (May 30, 2008.).)

On May 19, 2008, the Court issued an initial determination terminating respondent Darby Group Companies, Inc. from the investigation based on consent order. (*See* Order No. 87.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Darby Group Companies, Inc. Based On Consent Order (July 7, 2008).)

The evidentiary hearing on the question of violation of section 337 commenced on May 19, 2008, and concluded on May 27, 2008. Tillotson; Cardinal Health Inc., Cardinal Health 200, Inc. and Cardinal Health Malaysia 211 Sdn. Bhd (collectively "Cardinal Health"); Ansell

Limited, Ansell (Thailand) Ltd., Ansell Healthcare Products LLC, and Ansell Protective Products Inc. (collectively "Ansell"); Hartelega Holdings Bhd., Hartelega Sdn. Bhd. and Pharmtex U.S.A. Inc. (collectively "Hartelega"); JDA (Tianjin) Plastic Rubber Co., Ltd. ("JDA"); Kossan Rubber Industries Bhd, Kossan Gloves d/b/a Sintex, and Perusahaan Getah Asas Sdn. Bhd. (collectively "Kossan"); PT Shamrock Manufacturing Corporation and PT Haloni Jane (collectively "PT Shamrock"); PT Medisafe Technologies ("PT Medisafe"); Riverstone Resources Sdn. Bhd. ("Riverstone"); Top Glove Corporation Bhd., Top Glove Sdn. Bhd., and TG Medical (U.S.A.), Inc. (collectively "Top Glove"); YTY Holdings Sdn. Bhd. and YTY Industry (Manjung) Sdn. Bhd. (collectively "YTY"); Dynarex Corporation ("Dynarex"); Protective Industrial Products ("PIP"); Smart Glove Holdings, Sdn. Bhd. and Smart Glove Corporation Sdn. Bhd. (collectively "Smart Glove"); Henry Schein, Inc. and HSI Gloves, Inc. (collectively "Henry Schein"); Laglove (M) Sdn. Bhd.; and Staff, were represented at the hearing. (Hearing Tr. 1:1-6:8.)

On June 19, 2008, the Court found respondent Medtexx Partners, Inc. in default. (*See* Order No. 88.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Finding Respondent Medtexx Partners, Inc. in Default (July 11, 2008).)

On June 30, 2008, the Court issued an initial determination terminating respondent Tronex International, Inc. from the investigation based on settlement agreement. (*See* Order No. 89.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Tronex International, Inc. On the Basis of a Settlement Agreement (July 18, 2008).)

On July 23, 2008, Court issued an initial determination terminating respondent Dynarex Corporation from this investigation based on settlement agreement. (*See* Order No. 91.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation With Respect to Respondent Dynarex Corporation Based on Settlement Agreement (August 8, 2008).)

On August 1, 2008, the Court found respondent Dash Medical Gloves, Inc. in default. (*See* Order No. 92.) The Commission determined not to review the order. (*See* Notice of Commission Decision Not To Review an Initial Determination Finding Respondent Dash Medical Gloves, Inc. in Default (August 20, 2008).)

B. The Parties

1. Tillotson Corporation

Tillotson Corporation designed, developed, and manufactured hand protection products, including nitrile hand gloves. (Am. Complaint, ¶¶ 11-13.) On or about October 1, 2007, Tillotson sold its Best Manufacturing operations and all subsidiaries to Showa Glove Co., which resulted in Showa's subsidiary, Best Glove Inc. ("Best Glove"), acquiring Tillotson's manufacturing operations and facilities in Fayette, Alabama, and Menlo, Georgia. As part of this transaction, Tillotson retained its corporate headquarters in Lexington, Massachusetts, and ownership of the '616 Patent, which it licensed to Best Glove. After the sale, Best Glove has continued to manufacture nitrile gloves at the Fayette facility and it maintains the Menlo manufacturing headquarters. (CX-788C (Tillotson Direct) at Q&A 159-172; (CX-790C (Groce Direct) at Q&A 7-17).

2. Ansell Respondents

Ansell Ltd. ("Ansell") is an Australian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 16.)[1]

Ansell (Thailand) Ltd. is a wholly-owned subsidiary of Ansell, which is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 18, 30.)

Ansell Healthcare Products, LLC (New Jersey) is a wholly-owned subsidiary of Ansell, which is allegedly engaged in the importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 26, 31-32.)

Ansell Protective Products, Inc. (New Jersey) is a wholly-owned subsidiary of Ansell, which is allegedly engaged in the importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 25, 33.)

3. Top Glove Respondents

Top Glove Corporation Bhd. ("Top Glove") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 34-36.)

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[1] "Am. Complaint" refers to the Amended Complaint in Inv. No. 337-TA-608. "Complaint" refers to the Complaint in Inv. No. 337-TA-612.

Top Glove Sdn. Bhd. (Malaysia) is a wholly-owned subsidiary of Top Glove which is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 patent. (Am. Complaint, ¶ 35-36, 45-46.)

TG Medical (USA) Inc. (California) is a wholly-owned subsidiary of Top Glove which is allegedly engaged in the importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 43-44, 47-48.)

4. Hartalega Respondents

Hartalega Holdings Bhd. ("Hartalega") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 49.)

Hartalega Sdn. Bhd. (Malaysia) is a wholly-owned subsidiary of Hartalega that is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 50-52, 55-57.)

Pharmatex USA, Inc. (California) is a wholly-owned subsidiary of Hartalega that is allegedly engaged in the importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 53-54, 58.)

5. Kossan Respondents

Kossan Rubber Industries Bhd. ("Kossan Rubber") is a Malaysian entity that is

allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 60.)

Perusahaan Getah Asas Sdn. Bhd. (Malaysia) is a wholly-owned subsidiary of Kossan Rubber that is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 63-65, 69-71.)

Kossan Gloves Inc. d/b/a Sintex (Texas) is a wholly-owned subsidiary of Kossan Rubber that is allegedly engaged in the importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 patent. (Am. Complaint, ¶ 72 .)

6. PT Shamrock Respondents

PT Shamrock Manufacturing Corporation ("PT Shamrock") is an Indonesian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 73-74.)

PT Haloni Jane (Indonesia) is under common control with PT Shamrock. PT Haloni Jane is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 75, 84.)

Shamrock Manufacturing Company, Inc. (California) is under common control with PT Shamrock. Shamrock Manufacturing Company Inc. is allegedly engaged in the, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves

that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 77-79, 85-87.)

7. Smart Glove Respondents

Smart Glove Holdings Sdn. Bhd. ("Smart Glove") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 88.)

Smart Glove Corporation Sdn. Bhd (Malaysia) is a wholly-owned subsidiary of Smart Glove that is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 89-91, 100-102.)

8. YTY Respondents

YTY Holdings Sdn. Bhd. ("YTY") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 patent. (Am. Complaint, ¶ 103.)

YTY Industry (Manjung) Sdn. Bhd. (Malaysia) is a subsidiary of YTY that is allegedly engaged in the manufacture, importation, offer for sale after importation, sale and/or use after importation into the United States of gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 109-110.)

9. Delta

Delta Medical Systems, Inc. ("Delta Medical") of Georgia is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent.

(Am. Complaint, ¶ 111.)

10. JDA (Tianjin)

JDA (Tianjin) Plastic Rubber Co. Ltd. ("JDA") is a Chinese entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 120-21.)

11. Laglove

Laglove (M) Sdn. Bhd. ("Laglove") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 122-23.)

12. PT MediSafe

PT MediSafe Technologies ("PT MediSafe") is an Indonesian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 124.)

13. Riverstone

Riverstone Resources Sdn. Bhd. ("Riverstone") is a Malaysian entity that is allegedly engaged in the manufacture, importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 125-126.)

14. Adenna

Adenna, Inc. ("Adenna") of California is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 153-156.)

15. Darby Group

Darby Group Companies, Inc. ("Darby") of New York is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 160-161.)

16. Dash

Dash Medical Gloves, Inc. ("Dash") of Wisconsin is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 166-67.)

17. Dentexx

Dentexx/First Medica Infection Control Assoc. ("Dentexx") of North Carolina is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 170.)

18. Dynarex

Dynarex Corp ("Dynarex") of New York is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United

States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 171-172.)

19. Liberty Glove

Liberty Glove and Safety Co. ("Liberty Glove") of California is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 176-177.)

20. Protective Industrial Products

Protective Industrial Products, Inc. ("PIP") of New York is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 180-181.)

21. QRP

QRP, Inc. D/b/a GRP Gloves Inc. ("QRP") of Arizona is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 182-83.)

22. Tronex

Tronex International, Inc. ("Tronex") of New Jersey is allegedly engaged in the importation, sale for importation, offer for sale after importation, sale and/or use after importation into the United States of nitrile gloves that infringe certain claims of the '616 Patent. (Am. Complaint, ¶ 184-85.)

23. Cardinal Health Respondents

Cardinal Health, Inc. ("Cardinal Health") of Ohio, purportedly the parent corporation of Cardinal Health 200 Inc. and Cardinal Health Malaysia 211 Sdn. Bhd., allegedly manufactures abroad, imports into, and sells in the United States, either alone or through its subsidiaries, nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 8, ¶¶ 35-37.)

Cardinal Health 200 Inc. (Illinois) is allegedly a wholly-owned subsidiary of Cardinal Health and purportedly imports into and sells in the United States nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 9, ¶¶ 38-39.)

Cardinal Health Malaysia 211 Sdn. Bhd. is a Malaysian entity and a foreign subsidiary of Cardinal Health, Inc., which purportedly imports into and sells in the United States nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 10, ¶ 40.)

24. Henry Schein Respondents

Henry Schein, Inc. ("Henry Schein") of New York, purportedly the parent corporation of HSI Gloves, Inc., allegedly imports into and sells in the United States, either alone or through its subsidiaries, nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 11, ¶ 41.)

HSI Gloves, Inc. of Melville, New York, allegedly a wholly-owned subsidiary of Henry Schein, Inc., purportedly imports into and sells in the United States nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 12, ¶ 42.)

25. Latexx Partners

Latexx Partners Berhad is a Malaysian entity that allegedly manufactures abroad, imports into, and sells in the United States through its subsidiaries nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 13, ¶¶ 43-44.)

26. Medtexx Partners, Inc.

Medtexx Partners, Inc. (New Jersey) purportedly imports into and sells in the United States nitrile rubber gloves that infringe certain claims of the '616 Patent. (Complaint ¶ 14, ¶ 45.)

Some of the respondents listed above have been terminated from the investigation based on settlement agreement and/or consent order or have been found in default. (*See supra* Section I.A.) The remaining respondents are Adenna, Inc. ("Adenna"); Ansell, Ltd., Ansell (Thailand) Ltd., Ansell Healthcare Products LLC (collectively "Ansell"); Cardinal Health, Inc., Cardinal Health 200, Inc., Cardinal Health Malaysia 211 Sdn. Bhd. (collectively "Cardinal Health"); Hartalega Holdings Bhd., Hartalega Sdn. Bhd., JDA (Tianjin) Plastic Rubber Co. Ltd., Kossan Gloves Inc. d/b/a Sintex, Kossan Rubber Industries Bhd., Laglove (M) Sdn. Bhd., Latexx Partners Berhad, Perusahaan Getah Asas Sdn. Bhd., Pharmatex USA Inc., PT Haloni Jane, PT Medisafe Technologies, PT Shamrock Manufacturing Corporation, Riverstone Resources Sdn. Bhd., Shamrock Manufacturing Company Inc., TG Medical (USA) Inc., Top Glove Corporation Bhd., Top Glove Sdn. Bhd., YTY Holdings Sdn. Bhd., and YTY Industry (Manjung) Sdn. Bhd. (collectively "the K&E Respondents"); Henry Schein, Inc. and HIS Gloves Inc. (collectively "Henry Schein"); Liberty Glove, Inc. d/b/a Liberty Glove and Safety Co.; Protective Industrial Products, Inc.; QRP, Inc. d/b/a QRP Glove, Inc.; and Smart Glove Holdings Sdn. Bhd. and Smart Glove Corporation Sdn. Bhd. (collectively "Smart Glove") (collectively "Respondents").

C. Overview of the Technology

The products at issue are nitrile rubber gloves. (Am. Complaint, ¶ 188.) These nitrile rubber gloves are made from a nitrile butadiene latex rubber elastomeric material, are substantially impermeable to water vapor and liquid water, and have a relatively high tensile strength. (Am. Complaint, ¶¶ 188-190.)

D. The Patent At Issue

This investigation pertains to U.S. Patent No. Re. 35,616 ("the '616 Patent"), entitled "Elastomeric Covering Material and Hand Gloves Made Therewith," which is a reissue of U.S. Patent No. 5,014,362 ("the '362 Patent"). The '362 Patent was filed on May 11, 1990, and issued on May 14, 1991. (*See* JX-1 ('362 Patent)). On November 13, 1995 Mr. Tillotson and Tillotson Corporation filed a reissue patent application, which resulted in the '616 Patent now at issue in these investigations. The '616 Patent issued on September 30, 1997. (*See* JX-3 ('616 Patent)).

The asserted claims of the '616 Patent in these investigations are claims 1, 17-19. Claim 1 reads as follows:

> 1. A *closely fitting* glove comprising a layer of elastomeric material *(a) comprising nitrile butadiene rubber, (b)* having an initial configuration adapted to receive *and fit closely about a hand* and *(c)* characterized by *(i)* being substantially impermeable to water vapor and liquid water, *(ii)* having a tensile strength of at least about 1500 psi as measured according to ASTM D-412 on a sample of the elastomeric material having a thickness from about 4.0 to about 4.5 mils, and *(iii)* having a *thickness and* elastic properties such that *the glove is capable of being stretched to fit closely about the hand and* when stretched from the initial configuration to fit *closely* about the hand, the elastomeric material conforms to the configuration of the hand initially exerting [a predetermined] *an initial* pressure on the hand and thereafter *still fitting closely about the hand, but* relaxing, *within about 6 minutes after the gloves is stretched to fit about said hand,* to exert on the hand a reduced pressure which is [substantially] less than about [80%] *50%* of the [predetermined] *initial* pressure.

Claims 17, 18 and 19 read as follows:

> *17. A glove as in Claim 1, wherein the layer of elastomeric material has a thickness up to about 4.5 mils.*
>
> *18. A glove as in Claim 1 wherein the layer of elastomeric materila has a thickness from about 4 to about 4.5 mils.*
>
> *19. A glove as in Claim 1, therein the layer of elastomeric material is further characterized by having an elongation of greater than about 800 lbs/in.*

(*Id.* at 6:33-50, 8:9-15) (emphasis in original). The '616 Patent names Mr. Neil Tillotson and Mr. Luc DeBecker as the inventors. (*Id.*)

The '616 Patent discloses a closely-fitting latex glove made of nitrile rubber having the initial shape of a hand. The '616 Patent further discloses a glove that is impermeable to water, has a tensile strength of at least about 1500 psi, and is capable of being stretched to fit on the hand of a wearer as the glove is donned. (JX-3 at 2:6-21 ('616 Patent).) The '616 Patent discloses a glove that exerts an initial pressure on the hand when the glove is donned and then relaxes within a few minutes to substantially reduce the pressure on the hand while retaining a close fit. (*Id.*) Claim 1 is the only independent claim. The remaining claims at issue, claims 17-19, depend directly from claim 1. The '616 Patent is assigned and owned by Tillotson. (Am. Complaint, ¶ 199; Complaint Ex. 2.)

E. The Products At Issue

The products at issue in this investigation are nitrile gloves. The accused products are listed by respondent(s) in Appendix B.

II. IMPORTATION OR SALE

The importation or sale requirement of section 337 has not been contested. (RIB at 6.) Thus, it is found that Respondents sell for importation, import and, or, sells after importation articles accused in this investigation. The importation or sale requirement of section 337 is satisfied. (CX-162; CX-235C; CX-238C; CX-264C;CX-308C; CX-456C; CX-457C; CX-458C; CX-460C;CX-461C; CX-462C; CX-463C; CX-464C; CX-465C; CX-466C; CX-467C; CX-468C; CX-785C; CX-789C at Q&A 166-78, 190-206, 210-15, 217-23, 270-76, 230-43, 263-76; CX-

939C; CX-943C; CX-946C; CX-947C; CX-948C; CX-949C;CX-950C; ROCFF IV.11-501; ROSFF 73-94.)

III. CLAIM CONSTRUCTION

A. Applicable Law

Pursuant to the Commission's Notices of Investigation, these consolidated investigations are patent-based investigations. *See* 72 Fed. Reg. 37052, 47072 (2007). Accordingly, all of the unfair acts alleged by Tillotson to have occurred are instances of alleged infringement of the '616 Patent. Any finding of infringement or non-infringement requires a two-step analytical approach. First, the asserted patent claims must be construed as a matter of law to determine their proper scope.[2] Second, a factual determination must be made as to whether the properly construed claims read on the accused devices. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995)(*en banc*), *aff'd*, 517 U.S. 370 (1996).

Claim construction begins with the language of the claims themselves. Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). With respect to claim preambles, the Court of Appeals for the Federal Circuit has explained that:

> [A] Claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.

[2] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1339 (Fed. Cir. 2003) (quoting *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995)).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. In such circumstances, general purpose dictionaries may be helpful. In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood disputed claim language to mean, by analyzing the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, as well as the meaning of technical terms, and the state of the art. *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Id.* at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman*, 52 F.3d at 979. However, the specification is always highly relevant to the claim construction analysis. The specification is usually dispositive. It is the single best guide to the meaning of a disputed term. *Phillips*, 415 F.3d at 1315. Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the

prosecution history,, including inventor testimony, expert testimony and learned treatises. *Id.* at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

B. The Disputed Claim Terms and Their Proper Construction

On March 14, 2008, the Court issued *Order No. 63: Construing the Disputed Terms of the Asserted Claims of the Patent at Issue*. Order No. 63 is incorporated herein in its entirety.

1. "Less than about 50%"

In Order No. 63, this Court construed "about 50%" to mean approximately 50%, which literally encompassed values between 45% to 55%. (*See* Order No. 63 at 41.) The parties now dispute the construction of "less than about 50%"

Respondents argue that "less than about 50%" "*must* include only values less than 45%." (RIB at 7-8.) Respondents argue that "[t]o hold otherwise would be contrary to the ordinary meaning of 'less than' and would broaden the scope of the claim term to read 'less than *or equal to* about 50% of the initial pressure." (*Id.* at 8.) Respondents argue that Tillotson has impermissibly read the term "less than" out of claim 1 for those accused gloves whose relaxation values fall within 45% to 55%. (*Id.* at 8.)

Tillotson argues that relaxation values of less than 55% would fall within the range of 45% to 55% and meet the limitation of claim 1. (CRB at 1.) Tillotson further argues that such

an interpretation is consistent with how both Respondents' and Tillotson's experts applied the Court's claim construction. (*Id.* at 1.) Tillotson further argues that Respondents' interpretation contradicts the plain language of the claims of the '616 Patent, file history, and understanding and interpretation by one of ordinary skill in the art. (*Id.* at 1.) Staff agrees and further argues that the Court construed about 50% to encompass values between 45% to 55%, which would include values as high as 54%. (SIB at 12, note 20.)

In response, Respondents argue that since the applicants chose to use the adjectives "less than," then it must exclude values equal to the range of numbers encompassed by "about 50%." (RRB at 31-32.) Respondents argue that had the applicants sought to include the matters within the range, then the applicants would have used adjectives such as "at least" or "within," which the applicants had used to modify other "about" terms. (*Id.* at 31-32.)

The Court finds that "less than about 50%" encompasses values between 45% to 55% and is not limited to values that fall below 45%. The Court noted in Order No. 63 that the intrinsic evidence supported its construction of "about 50%." (*See* Order No. 63 at 41-42.) The intrinsic evidence further supports the Court's findings in this instance. Claim 13 of the original reissue application also uses the terms "less than about 50%":

> A glove as in Claim 1, further characterized by having elastomeric properties such that the reduced pressure is *less than about 50%* of said predetermined pressure.

(JX-4 at TLC000013 ('616 Prosecution History)) (emphasis added.) In rejecting Claim 13 in the original reissue application, the examiner stated that "the value of 54%, which was reached with the 5 mil sample, is sufficiently close to meet a limitation of "about 50%" such as in Claim 13." (*Id.* at TLC00153-154.) Thus, the examiner found that the value of 54% was sufficient to fall within the limitation of Claim 13, which is the exact same claim language at issue here. As such, to accept Respondents interpretation of "less than about 50%" to be limited to values that are less

than 45% would blatantly ignore the prosecution history. *Phillips*, 415 F.3d at 1317 ("In addition to consulting the specification, we have held that a court "should also consider the patent's prosecution history, if it is in evidence.") (citations omitted.); see also *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966) ("An invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office.").

IV. INFRINGEMENT DETERMINATION

A. Applicable Law

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Certain Flooring Products*, Inv. No. 337-TA-443, Commission Notice of Final Determination of No Violation of Section 337, 2002 WL 448690 at 59, (March 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376 (Fed. Cir. 1998).

Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.,* when the properly construed claim reads on the accused device exactly. *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. The Supreme Court has described the essential inquiry of the doctrine of equivalents analysis in terms of whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40 (1997).

Under the doctrine of equivalents, infringement may be found if the accused product or process performs substantially the same function in substantially the same way to obtain substantially the same result. *Valmont Indus., Inc. v. Reinke Mfg. Co.,* 983 F.2d 1039, 1043 (Fed. Cir. 1993). The doctrine of equivalents does not allow claim limitations to be ignored. Evidence must be presented on a limitation-by-limitation basis, and not for the invention as a whole. *Warner-Jenkinson*, 520 U.S. at 29; *Hughes Aircraft Co. v. U.S.*, 86 F.3d 1566 (Fed. Cir. 1996). Thus, if an element is missing or not satisfied, infringement cannot be found under the doctrine of equivalents as a matter of law. *See, e.g.*, *Wright Medical*, 122 F.3d 1440, 1444 (Fed. Cir. 1997); *Dolly, Inc. v. Spalding & Evenflo Cos., Inc.*, 16 F.3d 394, 398 (Fed. Cir. 1994); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991); *Becton Dickinson and Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 798 (Fed. Cir. 1990).

The concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims. *Athletic Alternatives v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996). In applying the doctrine of equivalents, the Commission must be informed by the fundamental principle that a patent's claims define the limits of its protection. *See Charles Greiner & Co. v. Mari-Med. Mfg., Inc.*, 92 F.2d 1031, 1036 (Fed. Cir. 1992). As the Supreme Court has affirmed:

> Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Warner-Jenkinson, 520 U.S. at 29.

Prosecution history estoppel may bar the patentee from asserting equivalents if the scope of the claims has been narrowed by amendment during prosecution. A narrowing amendment

may occur when either a preexisting claim limitation is narrowed by amendment, or a new claim limitation is added by amendment. These decisions make no distinction between the narrowing of a preexisting limitation and the addition of a new limitation. Either amendment will give rise to a presumptive estoppel if made for a reason related to patentability. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139-41 (Fed. Cir. 2004), *cert. denied*, 545 U.S. 1127 (2005)(citing *Warner-Jenkinson*, 520 U.S. at 22, 33-34; and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 733-34, 741 (2002)). The presumption of estoppel may be rebutted if the patentee can demonstrate that: (1) the alleged equivalent would have been unforeseeable at the time the narrowing amendment was made; (2) the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue; or (3) there was some other reason suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent. *Honeywell*, 370 F.3d at 1140 (citing, *inter alia, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 344 F.3d 1359 (Fed. Cir. 2003)(*en banc*)).

B. Analysis of the Accused Products

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1. Claim 1

Tillotson has accused Respondents of infringement of independent claim 1 and dependent claims 17-19 of the '616 Patent by the importation, the sale for importation or the sale after importation of nitrile gloves in the United States.

a) Literal Infringement

Tillotson argues that the gloves identified in Table A attached to its post-hearing brief meet all of the limitations of claim 1 of the '616 Patent. The gloves identified in CX-33, CX-80 and CX-802 were evaluated to determine whether they met the limitations of the asserted claims

of the '616 Patent. (CX-786C at Q&A 34-41 (Moalli Direct).) Specifically, the gloves were tested to evaluate the fit of the glove, composition, water and water vapor permeability, tensile strength, stress relaxation, thickness and puncture resistance. (*Id.* at Q&A 34.) Tillotson presented its conclusions on each of the limitations in CX34-50, CX-81-90 and CX-803-805. (*Id.* at Q&A 123-128.) The column headings and associated footnotes all refer to specific limitations of claim 1. (*Id.* at Q&A 129.) Each glove is identified by the respondent, a description of the glove and assigned an identification number by Tillotson's expert, Dr. John E. Moalli. (*Id.* at Q&A 130.) If the glove meets the specific limitation, then an affirmative response (Y) is placed in that column. (*Id.* at Q&A 131 and 135.) If a claim limitation is not met, then a negative response (N) is place in that column. (*Id.* at Q&A 131.) If a certain parameter was not tested, then an "N/A" is placed in that column. (*Id.* at Q&A 134.) This identification and determination are consistent for all of the gloves listed in CX34-50, CX-81-90 and CX-803-805. (*Id.* at Q&A 136-139.)

(1) A closely fitting glove; an initial configuration adapted to receive and fit closely about a hand; and a thickness and elastic properties such that the glove is capable of being stretched to fit closely about the hand and when stretched from the initial configuration to fit closely about the hand

In order to evaluate whether the gloves were met these closely fitting limitations of Claim 1, Dr. Moalli, conducted a "fit test" by performing a visual inspection of the glove and donning the glove:

> Analysis of "having an initial configuration adapted to receive and fit closely about the hand" was initially assessed by visual inspection of the glove geometry and verified by hand insertion. Analysis of "closely fitting" and "fitting closely" was also performed by hand insertion (and subsequently wearing the glove for at least 7 minutes) and noting whether or not the glove followed the contours of, and generally conformed to, the hand; it was determined by tactile means if the glove exerted an initial pressure on the hand at this time as well. Finally, "thickness and

> elastic properties such that the glove is capable of being stretched to fit closely about the hand" was also evaluated during hand insertion by observation of the ability to stretch the glove such that it fit closely while donning it.

(CX-786C at Q&A 44 (Moalli Direct).) If the gloves met these limitations, then a "Y" is placed in the columns labeled "Closely Fitting," "Initial Configuration," "Capable of Being Stretched to Fit Closely," and "Exerts an Initial Pressure." (*Id.* at Q&A 140-148 and 190-202; CX-34-50, CX-81-90, and CX-803-805.)

The parties do not dispute that Respondents' gloves meet certain of the limitations of Claim 1 of the '616 Patent. (CIB at 21-22; RIB at 67-88; SIB at 10-11. CX-106-183C; CX-241; CX-460-468C; CX-908C; CX-238C;CX-235C; CX-457-458C; CX-785C.) Respondents do not argue that its gloves fail to satisfy the limitations "closely fitting," to "have an initial configuration adapted to receive and fir closely about a hand," to "have a thickness and elastic properties such that the glove is capable of being stretched to fit closely about the hand", and when so stretched to "conform[] to the configuration of the hand, initially exerting an initial pressure on the hand." (RRCPFF V.B.43; ROCPFF V.B.43-816; CX-33, CX-80, CX-802; CX-34-50, CX-81-90, CX-803-805; CX-786C at Q&A 42-47 (Moalli Direct).) Staff also does not dispute that Respondents' gloves meet this limitation. (SIB at 11.)

The Court finds that the evidence shows that Respondents' tested gloves elastically conform to the shape of the hand when stretched to fit the hand. (CX-34-50; CX-81-90 and CX-803-805; CPX 2-55; CPX 57-78; CPX 80-172; CPX 193-217.) Therefore, the Court finds that all of Respondents' gloves listed in CX-34-50, CX-81-90 and CX-803-805 with a "Y" in the column labeled "Closely Fitting," "Initial Configuration," "Capable of Being Stretched to Fit Closely," and "Exerts an Initial Pressure" meet the limitations of claim 1 of the '616 Patent that require "a closely fitting glove;" "an initial configuration adapted to receive and fit closely about

a hand;" and "a thickness and elastic properties such that the glove is capable of being stretched to fit closely about the hand and when stretched from the initial configuration to fit closely about the hand." (CX-34-50, CX-81-90 and CX-803-805.)

(2) Comprising nitrile butadiene rubber

In order to determine the composition of the gloves, Dr. Moalli used a Fourier Transform Infrared Spectrometer ("FTIR"). (CX-786 C at Q&A 49-50 (Moalli Direct).) The FTIR allowed Dr. Moalli to determine whether there was a nitrile peak in the FTIR spectra for each sample and, therefore, determine whether the glove was made from nitrile. (*Id.* at Q&A 51.) The FTIR data for each of the tested gloves is listed in CX-68; CX-75; CX-102 and CX 809. (*Id.* at Q&A 52-56.) Dr. Moalli determined that if the peak in the graph was about 2240 wave numbers, then it is indicative of nitrile and a layer of elastomeric material comprised of nitrile rubber. (*Id.* at Q&A 151-156.) Thus, if the glove met this limitation of being comprised of nitrile butadiene rubber, then a "Y" is placed in the column labeled "NBR Rubber." (*Id.* at Q&A 149-159 and 190-202; CX-34-50, CX-81-90, and CX-803-805.)

Respondents do not dispute that its gloves comprise a layer of elastomeric material comprising nitrile butadiene rubber. (RROCPFF-V.B.825; 826-1008; CIB at 21-22; RIB at 67-88.) Staff also does not dispute that Respondents' gloves meet this limitation. (SIB at 11.)

The Court finds that, with the exception of the Ambi-Gard Pre-Powdered Nitrile Exam Gloves Surgi-Grip Textured Finish and Ambi-Gard Powder-Free Nitrile Exam Gloves Surgi-Grip Textured Finish gloves (*see* CX-43 ("N" under column labeled "NBR Rubber"), the evidence shows that respondents gloves listed in CX-34-50, CX-81-90 and CX-803-805 with a "Y" in the column labeled "NBR Rubber" are comprised of nitrile butadiene rubber. (CX-34-50;

CX-81-90 and CX-803-805.) Therefore, the Court finds that those gloves listed meet the claim limitation of being comprised of nitrile butadiene rubber.

(3) Being substantially impermeable to water vapor and liquid water

In order to determine whether the glove was impermeable to liquid water and water vapor, Dr Moalli designed a test setup that would measure the amount of weight loss from a portion of a finger excised from each glove and filled with water over the course of a four hour period. (CX-786C at Q&A 57-60 (Moalli Direct).) He recorded the data gathered from this test in CX-69, CX-76, CX-103 and CX-810. (*Id.* at Q&A 61-66.) Thus, if the glove met this limitation of being impermeable to water vapor and liquid water, then a "Y" is placed in the column labeled "Impermeable to Water Vapor." (*Id.* at Q&A 131-139, 161-169 and 190-202; CX-34-50, CX-81-90, and CX-803-805.)

Respondents do not dispute that its gloves are substantially impermeable to water vapor and liquid water. (ROCPFF V.B.1453-1644; CIB at 21-22; RIB at 67-88.) Staff also does not dispute that Respondents' gloves meet this limitation. (SIB at 11.)

The Court finds that the evidence shows that Respondents' gloves listed in CX-34-50, CX-81-90 and CX-803-805 with a "Y" in the column labeled "Impermeable to Water Vapor" are impermeable to liquid water and water vapor and, therefore, meet the claim limitation of being "substantially impermeable to water vapor and liquid water." (CX-34-50, CX-81-90, and CX-803-805.)

(4) Having a tensile strength of at least about 1500 psi as measured according to ASTM D-412 on a sample of the elastomeric material having a thickness from about 4.0 to about 4.5 mils

In order to determine the glove's tensile strength, Dr. Moalli performed the test in accordance with ASTM D-412. (CX-786 C at Q&A 79-81 (Moalli Direct).) Dr. Moalli created a dog bone shaped, also known as dumbbell shaped, sample from each glove using a punch die that was certified to the Type C dimensions of ASTM D-412 and had a thickness of 3.5 to 5.0 mils. (*Id.* at Q&A 74-78; 87.) To measure the thickness of the glove samples for purposes of testing tensile strength, stress relaxation and puncture resistance, Dr. Moalli measured the thickness of the gloves using a Mitutoyo Model 7326 flat anvil-type dial thickness gauge. (*Id.* at Q&A 67-71.) (See *infra* part B.2.a.i) The sample was then conditioned pursuant to the ASTM D-412 standard and placed in an Instron mechanical testing machine to evaluate the tensile strength of the accused gloves. (*Id.* at Q&A 82-84.) The Instron machine was programmed in accordance with ASTM D-412 standards, which allowed Dr. Moalli to evaluate the tensile strength of the sample. (*Id.* at Q&A 85-88.) The data collected by Dr. Moalli is set forth in CX-71; CX-78; CX-105 and CX-812. (*Id.* Q&A 89-93.) Thus, if the glove met this limitation of having a tensile strength of at least 1500 psi, then a "Y" is placed in the column labeled "Tensile strength of at least 1,500 psi." (*Id.* at Q&A 131-139, 182-189 and 190-202; CX-34-50, CX-81-90, and CX-803-805.)

For those samples from which Dr. Moalli could not obtain sample that had a thickness from 3.5 to 5.0 mils, Dr. Moalli still evaluated the sample in accordance with ASTM D-412. (CX-786 C at Q&A 203-204 (Moalli Direct).) He recorded the data in CX-91 and CX-51 and concluded that "if the measured value is at least about 1,500 psi, and the thickness of the sample is greater than 5.0 mils, the sample of the elastomeric material will more likely than not have a tensile strength of at least 1,500 psi." (*Id.* at Q&A 205-207.) Dr. Moalli bases his conclusion on the fact that "tensile strength often goes down with increased thickness," so if samples have a

thickness greater than 5.0 mils and it meets the tensile strength limitation, then it unlikely that a thinner sample would fail to meet the limitation as well. (*Id.* at Q&A 208-209.)

Respondents do not dispute that its gloves have a tensile strength of at least 1500 psi as measured on a sample of elastomeric material with a thickness of about 4.0 to 4.5 mils. (ROCPFF-V.B.1039-1221.) Staff also does not dispute that Respondents gloves meet this limitation. (SIB at 11.)

The Court finds that the evidence shows that all of Respondents' gloves from which Dr. Moalli could obtain an sample of elastomeric material with a thickness of 3.5 to 5.0 mils had a tensile strength of at least 1400-1600 psi, *e.g.* those listed in CX-34-50, CX-81-90, and CX-803-805 with a "Y" under the column labeled "Tensile strength of at least 1500 psi" and, therefore, meet the claim limitation of "having a tensile strength of at least 1500 psi as measured on a sample of elastomeric material with a thickness of about 4.0 to 4.5 mils." (CX-34-50, CX-81-90, and CX-803-805.)

For those samples from which a sample of 3.5 to 5.0 mils could not be obtained, the Court finds that Tillotson had failed to meet its burden of proving by a preponderance of the evidence that these gloves meet this claim limitation. Dr. Moalli provided no additional support for his contention that the thinner thickness would meet the limitation if the thicker thickness did. (Moalli, Tr. 388:9-389:18.) Therefore, those gloves for which Dr. Moalli could not obtain a sample of 3.5 to 5.0 mils do not meet this limitation of claim 1.

(5) Initially exerting an initial pressure on the hand and thereafter still fitting closely about the hand, but relaxing, within about 6 minutes after the gloves is stretched to fit about said hand, to exert on the hand a reduced pressure which is less than about 50% of the initial pressure.

(a) 100% Modulus Test

The main dispute between the parties focuses on whether Respondents' gloves meet the relaxation limitation of claim 1. (CIB at 22; RIB at 67; SIB at 11.) Tillotson argues that Respondents' gloves meet the relaxation requirements of claim 1 under the 100% modulus test set forth in the '616 Patent. (CIB at 22.) Dr. Moalli analyzed Respondents' accused gloves using the 100% modulus test and in accordance with the industry standard guidelines of ASTM D-412. (*Id.* at 22-23.) Dr. Moalli directed trained technicians at Exponent, Dr. Moalli's employer, to perform the test on the Instron tensile test machine, which is an industry accepted machine. (*Id.* at 23; CX-786 C at Q&A 102-106 (Moalli Direct).) According to Dr Moalli, the test was performed as follows:

> The strip sample was placed into grips on the Instron. As with the tensile test, one grip is fixed at the machine's base while the other is attached to a moveable crosshead. The Instron was programmed to move the crosshead upward at 20 inches per minute, in accordance with ASTM D412, until the specimen reached the required strain level (the strain was measured using a device called an extensometer). The strain was then held constant, and the load required to maintain the sample at this strain was measured for 8 minutes. The load at 6 minutes was compared to the initial load in order to evaluate the percentage of relaxation.

(CX-786C at Q&A 102 (Moalli Direct).) For each glove type, five (5) gloves were tested and 3 tests were performed on strip sample from each glove. (*Id.* at Q&A 172.) Dr. Moalli recorded the results of the relaxation tests in CX-70. (*Id.* at Q&A 171.) Dr. Moalli then took the average value of the relaxations tests performed on a particular glove and determined whether that value met the relaxation claim limitation, *i.e.*, whether the glove relaxed to less than about 50% of the pressure. (*Id.* at Q&A 173-181.) If the glove met this limitation of relaxing to less than about 50% of the initial pressure, then a "Y" was placed in the column labeled "Relaxes to Less Than About 50% of Initial Pressure." (*Id.* at Q&A 131-139, 173-179 and 190-202; CX-34-50, CX-81-90, and CX-803-805.) Thus, Tillotson argues that under the 100% modulus test performed by Dr.

Moalli, well over 90% of the 200 different glove types tested were found to infringe the '616 Patent. (CIB at 23.)

Respondents argue that its accused gloves do not meet the relaxation limitation for a variety of reasons. First, Respondents argue that Dr. Moalli's 100% modulus test cannot establish that Respondents' accused gloves infringe Claim 1 because of the high variability in test results, which apply only to the specific lots of gloves tested and cannot support a general exclusion order. (RIB at 67-70.) Respondents further argue that Dr. Moalli's 100% modulus test fails to show that Respondents' accused gloves meet the relaxation limitation because Dr. Moalli conducted the 100% modulus tests improperly and selectively picked data to maximize his results while ignoring test reports that showed that the data he had relied upon were unreliable and faulty. (*Id.* at 70.) Specifically, Respondents argue that Dr. Moalli improperly began recording relaxation data before the cross head in the Instron machine had stopped moving, rather than waiting until the sample had reached a constant deformation. (*Id.* at 70-71.) As a result of this, Respondents argue that the data collected by Dr. Moalli is unreliable and inaccurate. (*Id.* at 71-72.) Respondents argue that the proper method of performing the 100% modulus test involves only taking into consideration relaxation data after the cross head had stopped moving and the sample had reached constant deformation. (*Id.* at 72-73.)

Second, Respondents argue that the 100% modulus test fails to show that Respondents' accused gloves meet the relaxation limitation of claim 1 of the '616 Patent because Dr. Moalli cannot correlate the results of the 100% modulus test with the actual relaxation in pressure on the hand. (*Id.* at 74.) Respondents argue that the claim language, *e.g.* "to exert on the hand the reduced pressure which is less than about 50% of the initial pressure," requires a measurement of the actual pressure exerted on the hand by the glove based on the ordinary meaning of the words.

(*Id.* at 74.) Respondents further argue that this is supported by the specification, prosecution history, and testimony of one of the inventors, Mr. Luc DeBecker. (*Id.* at 74-76.) Respondents further argue that its construction does not conflict with the Court's claim construction, which Respondents argue only construed the term "initial pressure" as not requiring a direct measurement of the actual pressure on the hand. (*Id.* at 76.) Respondents further argue that while any measurements may be taken, such measurements must be used to show a reduction in pressure on the hand. (*Id.* at 76-77.) Respondents argue that Dr. Moalli was unable to show how the data generated by the 100% modulus test correlate with an actual reduction in pressure on the hand by the glove and, therefore, cannot show that Respondents' accused gloves infringe any claim of the '616 Patent. (*Id.* at 77.)

Third, even if the Court were to accept the 100% modulus test data, Respondents argue that none of the accused gloves infringe because an "adjustment factor" must be applied to account for the difference in degree of relaxation when the glove is stretched 100% instead of 10%, which more accurately reflects the amount of stretch when the gloves are on the hand. (*Id.* at 88.) Respondents argue that "one needs to adjust the 100%-stretch figure upwardly by 24%" to obtain the correct stretch relaxation figure for a glove that is donned on the hand. (*Id.* at 88.) Taking into consideration that adjustment factor, Respondents argue that all of the accused gloves would fail to satisfy the relaxation limitation of claim 1. (*Id.* at 88.)

Staff argues that Tillotson has met its burden of demonstrating by a preponderance of the evidence that certain of Respondents' gloves meet the relaxation requirement of claim 1. (SIB at 11.) Staff argues that Dr. Moalli's use of the 100% modulus test to determine the amount of relaxation to prove infringement is appropriate in light of the Court's *Markman* Order, Dr. Moalli's testimony that the test is an appropriate surrogate for measuring actual pressure, and

similar testing of elastomeric materials by other third parties. (*Id.* at 11-12.) Staff further argues that Dr. Moalli's 100% modulus test was performed in accordance with the method and protocol set forth in the ASTM D-412 standard. (*Id.* at 13.) Staff further argues that Respondents' arguments requiring that the actual pressure on the hand be measured in order to meet the relaxation requirement is simply a re-argument of its claim construction argument for claim 1. (*Id.* at 13.) Staff argues that Respondents' argument is contradicted by Dr. Moalli's testimony, the patent specification, and the Court's *Markman* order, which all acknowledge that the 100% modulus test can assess reduction in pressure on the hand. (*Id.* at 13-14.)

Both Tillotson and Staff argue that small differences in the relaxation results does not mean that the 100% modulus test performed by Dr. Moalli is inconsistent or unreliable such that Respondents gloves cannot be found to infringe. (CRB at 37-38; SRB at2-3.) The Court agrees. Respondents argument that any variability in results automatically negates Dr. Moalli's relaxation results and a finding of infringement fails in light of the evidence and expert testimony.[3] First, Dr. Moalli performed the 100% modulus test in accordance with ASTM D-412 standards and found that most of Respondents' gloves infringe Claim 1. (CX-786 C at Q&A 102-108; 131-139, 170-179 and 190-202 (Moalli Direct); CX-34-50, CX-81-90, and CX-803-805.) Dr. Moalli testified that if a particular glove style was found to infringe, then all gloves of the same style that were manufactured under the same conditions would yield the same results:

> Q. And, sir, the differences between lot numbers that counsel questioned you about earlier, do you recall that testimony generally?
> A. Yes.
> Q. Would you, based on all the testing you have done in this case, do you have an opinion in general as to whether if you found a particular glove style to

[3] Respondents' argument also fails in light of its own expert's test results. Respondents' own expert, Mr. Del Vecchio, tested only 88 glove styles, which Respondents argued was a "statistically valid sample of Respondents overall glove population." (RIB at 79; *infra* Section IV.B.1. a) (5) (b).) Dr. Moalli tested over 200 different styles of gloves. (CX-786C at Q&A 35-41 (Moalli Direct); CX-33, CX-80 and CX-802.) If Mr. Del Vecchio provided a "statistically valid sample", then Dr. Moalli has as well.

> infringe, it would be likely that all gloves of that style would likewise infringe, absent contrary information?
> A. I do have an opinion, yes.
> Q. And what is that opinion, sir?
> A. I would, provide the gloves are made consistently, I would have no reason to believe why one would infringe and another wouldn't.

(Moalli, Tr. 513:11-514:1.) Dr. Moalli testified that some small variations in results are expected given certain conditions such as different manufacturing conditions, different testing conditions, and different glove styles. (Moalli, Tr. 444:16-21; 457:19-23; 502:8-12; 1608:10-16.)

In response to Respondents' argument that the 100% modulus test was improperly conducted, both Staff and Tillotson argue that Dr. Moalli properly performed the 100% modulus test according to ASTM D-412 standards and the '616 Patent. (CRB at 38-41; SRB at 3-4.) The Court agrees. First, Dr. Moalli explained that he properly performed the 100% modulus test in accordance with the procedures set forth in ASTM D-412 standards and the '616 Patent. (CX-786 C at Q&A 102 (Moalli Direct).) Second, Respondents have mischaracterized the test data in an attempt to argue that Dr. Moalli improperly performed the 100% modulus test and produced unreliable data. Dr. Moalli explained the effect of the crosshead movement during the 100% modulus test on the Instron machine and the effect that had on the data that Respondents argue is evidence of unreliability:

> THE WITNESS: Okay. So as Mr. Pieja said, our instrument is very productive here. In this span of one second, we probably gathered 100, 200 data points. So it is sampling very quickly. But you need to understand what happens. Otherwise it can be very confusing and misleading.
>
> So the machine, we tell the machine to pull to this 100 percent extension, right. And so as Mr. Pieja described, the cross-head moves up, all right? When it gets to 100 percent extension, it can't stop just like that. What it does is it slows down. So we have this, we have a load cell and attached to that load cell are some grips. And they are, compared to the weight of the sample, they are fairly beefy, they are pneumatic and they're used to clamp the sample title.

> So as that cross-head comes up and slows down, it is just like putting on the brakes in your car. What happens to you? You go forward and you are sort of restrained by your seatbelt.
>
> So what happens here is that the grip that's holding the sample doesn't instantaneously stop? It moves up. Okay? And so what happens is the load cell thinks that everything is getting lighter. And the reason is it is being unloaded by this inertia of what we call the sprung mass. Okay?
>
> So even though this little blip which happens over, what, a tenth of a second, something like that, shows that there is a drop in the load here, there is actually not. What is really happening is this grip is trying to slow down. And when it does that, it takes load off of the load cell.
>
> So the sample still feels and, in fact, if you look at the extension at this time, I was just looking at that, it is actually going up, right? Or the strain in the extensometer. So what the sample is actually feeling is different than the load output. And anyone who is skilled in testing will understand that this is a phenomena that happens and you just -- it happens over such a small time frame, we don't even consider it. We disregard it.

(Moalli, Tr. 474:8-476:6.) Dr. Moalli even testified that one of ordinary skill would understand this process and disregard it. Thus, the minor fluctuation in the data that Respondents argue evidences unreliability is not a result of changes in the elastomeric sample, but rather a result of the mechanics of the Instron machine. The Court finds Respondents' arguments unpersuasive. Dr. Moalli properly performed the 100% modulus test in accordance with ASTM D-412 standards and the '616 Patent, and the data he relied upon to show the relaxation qualities of Respondents' accused gloves were accurate and reliable.

Both Tillotson and Staff also disagree with Respondents contentions that the amount of actual pressure on the hand must be determined. Staff and Tillotson argue that the 100% modulus test is an appropriate surrogate for evaluating a reduction in pressure on the hand. (SIB 12-25; CRB at 40-41.) As the Court explained in the *Markman* Order, the amount of stress measured by the 100% modulus test can be used to simulate the amount of pressure on the hand. The Court noted that this was supported by the specification:

The specification of the '616 Patent discusses the pressure exerted by the elastomeric material in the context of discussing the resilience and relaxation of the material:

> The invention fulfills these and other objects by providing an elastomeric material characterized by . . . having a relatively high tensile strength, and having a relatively low level of resilience. More specifically, the elastomeric material of the present invention is characterized by having a tensile strength . . . and having elastic properties such that when the elastomeric material is stretched from an initial configuration to fit about an object, the elastomeric material conforms to the configuration of the object, initially exerting a predetermined pressure on the object and thereafter relaxing to exert on the object a reduced pressure which is substantially less than about 80% of the predetermined pressure. ('616 Patent 2:5-21)
> . . . The relatively low resilience, allows the elastomeric material of the present invention and gloves made therewith to relax after being stretched while the stretch is maintained. In other words, the elastomeric material of the present invention has elastic properties such than [sic] when the elastomeric material is stretched from an initial configuration to fit about an object such as a hand, the elastomeric material conforms to the configuration of the object, initially exerting a predetermined pressure on the object and thereafter relaxing to exert on the object a reduced pressure which is substantially less than about 80% or [sic] the predetermined pressure. ('616 Patent 4:46-57.)

Thus, while the patent does not explicitly state that the relaxation in stress and resilience directly correlates to the reduction in pressure, the patent repeatedly discusses the elastomeric material's low resiliency as affecting the ability of the elastomeric material to relax, i.e. to reduce the pressure on an object. The specification further describes the manner in which the resilience is measured, namely the 100% modulus test:

> The resilience of the gloves made according to Example 1 and a conventional natural rubber latex glove was tested as follows. A sample was cut from each glove and stretched to 100% of its length to determine the initial 100% modulus according to ASTM D - 412 . . . As can be seen from FIGS 1 and 2, the stress required to maintain the 100% stretch of the Example 1 glove sample was substantially zero within six minutes after the initial stretch, while the stress required to maintain the 100% stretch of the conventional glove sample dropped to only about 80% of the initial stress over the 30 minute period. ('616 Patent 6:11-26.)

> The amount of relaxation of the elastomeric material is measured according to the 100% modulus test. As noted above, the specification repeatedly discusses the elastomeric material's relaxation properties as affecting the material's ability to exert pressure. As such, the relaxation measurements from the 100% modulus test can be used to "simulate" the reduction in pressure on the hand.

(Order No. 63 at 35-36.) The Court further noted that the prosecution history supported the use of the 100% modulus test to measure relaxation:

> The prosecution history also supports the use of the 100% modulus test in simulating the measurements of the "amount of pressure." In rejecting Claim 1, the examiner stated:
>
> > With regard to the recitation in Claim 1 of the glove "relaxing to exert on the hand a reduced pressure which is substantially less than about 80% of the initial pressure", Applicant's Table 5 (see Declaration Under 37 C.F.R. § 1.132) shows that the 5mil sample of Miller's material exerts a pressure of less than about 80% of the initial pressure after about 1 minute. (Tillotson App., Ex. 2 at TLC000152)
> >
> > . . .
> >
> > Applicant's table 5 (see Declaration Under 37 C.F.R. §1.132) shows values of remaining stress after specified time periods for a two samples of material disclosed in the Miller '189 patent. It can be seen that such values approach 50% such as in Claim 13, but the testing was extended only to a time which showed 54% of the pressure remaining. Thus, if the testing continued on for a longer period of time, it appears that the value of 50% would have been reached. Morever, the value of 54%, which was reached with the 5 mil sample, is sufficiently close to meet a limitation of "about 50%" such as in Claim 13.
> >
> > Alternatively, even if the 54% reduction of the 5 mil sample is not sufficient to meet the limitation of about 50%, and if the sample used in the testing for Table 5 would at no time reach 54% of pressure remaining, Miller '189 teaches that various modifications may be made in the amount used of the components of the material. . . . (Tillotson App., Ex. 2 at TLC000153-TLC000154)
>
> The examiner used the data obtained in the stress-relaxation test as the measurement of the amount of reduced pressure, e.g. "[a]pplicant's Table 5 . . . shows that the 5 mil sample of Miller's material exerts a pressure of less than about 80% of the initial pressure after about 1 minute." (Tillotson App., Ex. 2 at TLC000152) Thus, the prosecution history supports the use of the 100% modulus

> test to measure the "amount of pressure." There is no evidence in the patent or prosecution history that shows or requires that the actual pressure on the hand had been measured or that it must be measured.

(Order No. 63 at 36-37.) Dr. Moalli also testified that the 100% modulus test was a "fantastic surrogate" for measuring the actual pressure on the hand because "the pressure on the hand is caused by the stress in the glove." (Moalli, Tr. 414:21-415:9.) Even Respondents' expert, Mr. Del Vecchio, acknowledged the relationship between stress and pressure:

> Q. When you report pressure remaining, in fact, what you're evaluating is force, true?
> A. That's true. There is actually no such thing as a direct measurement of pressure.
> Q. And the thing that causes the force on the spherical indenter in your test is the stress in the glove sample that is being pushed down on the spherical indenter, true?
> A. Actually, the indenter exerts a force on the rubber, so to speak, and that's what's being measured by the force cell, but, yes, the stress in the rubber has to equal the force that's being actually exerted. So whether you say it's the rubber exerting force on the rubber or the indenter exerting, actually, the indenter exerts strain on the rubber.
> And the strain on the rubber generates a force in the rubber which is reflected through the inventor piston down to the load cell.
> Q. And that force in the rubber would be referred to as stress, true?
> A. Yes.

(Del Vecchio, Tr. 1008:21-1009:18.) Respondents continue to seek a measurement of actual pressure on the hand, but points to nothing in the language of the '616 Patent or the prosecution history that requires a measurement of *actual pressure* on the hand. As noted above, there is clearly a correlation between the reduction in pressure and the stress of the elastomeric material, *i.e.,* the resiliency and relaxation properties of the elastomeric material. That correlation is taught both in the specification and in the prosecution history and has been confirmed by those of skill in the art. Thus, the 100% modulus test can be used to determine the relaxation properties

and reduction in pressure of the gloves without any need to measure and/or provide a direct correlation to the actual pressure, or reduction thereof, on the hand.

In response to Respondents' argument that an "adjustment factor" must be applied to the results of the 100% modulus test, Tillotson and Staff argue that no adjustment factor needs to be applied to the test results. (CRB at 44-45; SRB at 5.) The Court agrees. Respondents provide no basis for the "adjustment factor" nor do they point to anything in the record that would indicate that such an adjustment factor is "necessary" or how it would function to "more accurately reflect what the relaxation in pressure on the hand would be." (*See* RIB at 88.)

Thus, the Court finds that the 100% modulus test was properly conducted by Dr. Moalli and that the results from the test are an acceptable means of determining the relaxation properties of the Respondents accused gloves and whether those gloves infringe the '616 Patent.

(b) Del Vecchio Test

In addition to arguing that Tillotson failed to prove infringement, Respondents argue that they affirmatively have proven non-infringement of their gloves using a test designed by Mr. R.J. Del Vecchio ("the Del Vecchio Test"). (RIB at 77-78.) Respondents argue that the Del Vecchio Test was designed to measure the "relaxation behavior of a glove when worn on a user's hand" and that it "closely mirror[s] both the degree and the type of stretching that a glove sample would experience in actual use." (*Id.* at 78.) The Del Vecchio Test took such measurements by measuring the actual pressure exerted by the accused gloves and by measuring the relaxation of a sample of the accused gloves. (*Id.* at 78-79.)

Specifically, Mr. Del Vecchio created a device that could measure the actual pressure exerted by the accused gloves by mounting six thin pressure sensors on the outside of a thin, form fitting cotton glove. (*Id.* at 78.) This device was then placed on the hand of one of the

engineers assisting Mr. Del Vecchio and samples of the accused gloves were donned over the cotton glove. (*Id.* at 78.) Based on the data produced by the device, Mr. Del Vecchio determined that the pressure exerted on the hand by any of the accused gloves was approximately 1.50 pounds per square inch (psi). (*Id.* at 79.)

Mr. Del Vecchio then took a circular sample of material from the accused glove and mounted it in on a drum, which was secured on vertical mount and lowered until the sample came into contact with a piston with a spherical indenter mounted on it. (*Id.* at 79.) The sample was lowered until the load cell, which was located under the piston to measure the force exerted by the glove sample on the indenter, recorded a value equivalent to a pressure of 1.50 psi. (*Id.* at 79.) At that point, the drum was locked into place and an initial pressure value was recorded. (*Id.* at 79.) The decay in force was recorded over the course of seven minutes, from which Mr. Del Vecchio calculated the relaxation in the samples. (*Id.* at 79.)

Mr. Del Vecchio tested 88 different types of gloves produced by the K&E Respondents in this investigation and determined that 85 retained more than 55% of their initial stress after six minutes of testing. Based on this test, Respondents argue that these accused gloves failed to satisfy the relaxation requirement of claim 1. Respondents further argue that the Del Vecchio Test was of crucial significance because he tested 10 styles of gloves that Dr. Moalli argued had the greatest degree of stress relaxation. (*Id.* at 79.) Respondents further argue that while Mr. Del Vecchio did not test all of the accused gloves, he had tested a large enough sampling such that it provided a statistically valid sampling of Respondents' overall accused gloves. (*Id.* at 79-80.)

Respondents argue that the Del Vecchio Test should be credited over the 100% modulus test because "Mr. Del Vecchio's tests were conducted under conditions designed to more closely approximate the relaxation claimed in the '616 [P]atent" and more closely replicates the

conditions that a glove would experience when it is actually worn on the hand. (*Id.* at 80.) Respondents further argue that the Del Vecchio Test takes into account the fundamental chemistry of carboxylated nitrile rubber ("XBNR"), which dictates that it will relax more if it is subject to a higher degree of strain and that Dr. Moalli has failed to address the chemistry of relaxation in XNBR and, instead, resorted to collateral attacks.[4] (*Id.* at 81-84.)

Respondents also argue that Tillotson's attacks on the validity and acceptability of the Del Vecchio Test are irrelevant and disingenuous in light of the fact that the 100% modulus test has not been accepted as a standard test for stress relaxation. (*Id.* at 86.) Similarly, Respondents argue that Tillotson's attacks on the Del Vecchio Test data because of too much "pre-stress" on the sample are unfounded and inaccurate because the samples were not greatly stressed when they were loaded on the drum nor were the samples subject to stress for too long of a period before secured into the proper position before taking relaxation measurements. (*Id.* at 87.)

Tillotson argues that the Del Vecchio Test has fundamental flaws in the manner in which it was conceived, executed, and presented to the Court and, as such, is entitled to no weight. (CIB at 24.) Tillotson argues that Mr. Del Vecchio admitted that the Del Vecchio Test is wildly imprecise and gives results varying by as much as 50% for gloves taken from the same box. (*Id.* at 24-25.) Tillotson further argues that the relaxation values of the Del Vecchio Test are artificially depressed because the engineers were untrained and inexperienced in using an uncalibrated prototype device and because engineers placed stress on the sample, which caused some relaxation, prior to beginning to record relaxation data. (*Id.* at 25.) Tillotson further argues that the Del Vecchio Test actually refutes Respondents' non-infringement contentions because

[4] In further support of the validity of the Del Vecchio Test, Respondents point to laboratory data from third party Zeon Corporation. (RIB at 84.) The laboratory data showed that tests performed on two commercially available nitrile gloves yielded consistent results, namely that the more a glove stretched, the more it relaxed. (RIB at 84-85.) Thus, Respondents argue that the relaxation of XNBR is dependent on the degree of strain. (RIB at 85.)

some gloves were actually found to infringe the '616 Patent, but that Mr. Del Vecchio and the engineers continued to test those gloves until they produced non-infringing results. (*Id.* at 25-26.) Tillotson further argues that had the Del Vecchio Test been performed using an "automatic operation" for lowering the drum as Dr. Moalli had done in recreating the Del Vecchio Test, the test results would have shown relaxation values significantly lower than 50%. (*Id.* at 26-27.)

Staff argues that the manner in which the Del Vecchio Test was conducted was flawed, resulting in inaccurate and unreliable results. (SIB at 16.) Staff further argues that the drum portion of the Del Vecchio Test failed to accurately measure the stress relaxation of the gloves to simulate the pressure on the hand due to the unintentional stretching of the elastomeric sample over the drum and the delay in recording the pressure. (*Id.* at 16-17.) Staff argues that Mr. Del Vecchio's failure to record any data prior to the sample being locked into place failed to take into account the force that was being applied to the sample and the relaxation of the sample during that time. (*Id.* at 17.) Staff argues these flaws render the test results an inaccurate measure of the stress relaxation of the properties of the gloves examined. (*Id.* at 17.) Staff further argues that the Del Vecchio Test is not easily reproduced and that, even with correction of some deficiencies, Dr. Moalli notes that it would be nearly impossible to consistently perform the Del Vecchio Test compared to the 100% modulus test. (*Id.* at 17.)

The Court finds that the Del Vecchio Test produced unreliable results and fails to show non-infringement. As an initial matter, the Court notes that neither the 100% modulus test nor the Del Vecchio Test are accepted ASTM standards for measuring stress relaxation. The 100% modulus test is a modification of the ASTM D-412 test for tensile strength. (RX-10) The Del Vecchio Test was designed solely in response to this litigation in order to "closely mirror both the degree and the type of stretching that a glove sample would experience in actual use." (RIB

at 78.) However, the Del Vecchio Test suffers from some serious flaws compared to the 100% modulus test and those flaws have a significant impact on test results and on Respondents' proof on non-infringement.

First, the Del Vecchio Test requires the elastomeric sample be subject to some stretching when the sample is being mounted to the drum. At the hearing, the Court viewed a video showing the placement of the elastomeric sample on the drum while the engineer explained what he was doing:

> THE NARRATOR: First thing we do is cut out a section of the glove to use as test film. We're going to mount the film across this cup, it's a -- cup, and it has a square groove with a square O-ring. We've affixed the edges of the film in place. The goal is to have the film stretched smoothly, but not tightly across the cup. So we get the O-ring in place, to lock the film in place, and then we kind of pull it to make sure we have a nice surface to test.

(Del Vecchio, Tr. 992:14-24.) The video shows the engineer pulling and stretching the sample into place, which Mr. Del Vecchio admitted, would result in some stress relaxation. (Del Vecchio, Tr. 997:3-19.) Dr. Moalli also testified that some degree of stress relaxation occurred during the mounting of the elastomeric sample. (CX-839C at Q&A 209-210 (Moalli Rebuttal).) Thus, even before actual testing has begun, the elastomeric sample was already subject to a degree of stress relaxation.

The Del Vecchio Test is further and more significantly flawed by the significant delay in time between the point when force was applied to the sample by the spherical indentor and the point where the engineers began to collect data. Mr. Del Vecchio explained the process as follows:

> A. That's correct. As best I understand this process, the process involves lowering a frame with the rubber sheath or diaphragm fixed on it until it contacts the indenter and to apply pressure, and you keep doing that until you get to the pressure neighborhood, preferably 1.5, that you wish to be in.

(Del Vecchio, Tr. 971:25-972:6; RX-114B.) Thus, once the sheath came into contact with the indentor, force was applied to the sample and continued to be applied while the engineer manually adjusted the machine until it reached approximately 1.5 psi, the pressure that was determined in the first part of the Del Vecchio Test when it was placed on the sensor-mounted cotton glove. (Del Vecchio, Tr. 970:22-24.) During this adjustment time, the force applied to the sample was essentially ignored by the engineers and Mr. Del Vecchio even though there was admittedly a degree of stress relaxation. (Del Vecchio, Tr. 970:24-971:16.) This initial, unrecorded relaxation resulted in depressed, unreliable test results. (CX-896C at Q&A 195 (Moalli Rebuttal).)

In addition to failing to take into account the stress relaxation that occurred to the sample during mounting and the adjustment period, the Del Vecchio Test is also subject to significant human error. Mr. Del Vecchio himself admitted that the test was subject to a significant amount of data scatter due to "the fact that a human operator is lowering this is a major source of scatter in itself." (Del Vecchio, Tr. 1025:22-24.) Moreover, when questioned by the Court about the varying test results, Mr. Del Vecchio admitted that several adjustments to the Del Vecchio Test were necessary:

> I would center the ball better, I would probably find other ways to make the specimen mounted more evenly. So the test is clearly subject to more scatter than I wish it were...

(Del Vecchio, Tr. 1026:17-22.) Thus, the Del Vecchio Test, as it was conducted for this consolidated investigation, is flawed enough such that the Court finds that the data produced is unreliable.

Respondents argue that any such stress relaxation is de minimus and no more significant than those of the 100% modulus test. (Del Vecchio, Tr. 997:3-19.) In particular, Respondents

argue that the adjustment period for most of the samples tested by Mr. Del Vecchio was only 6-9 seconds before the sample was locked into place and readings of the sample were collected. (RIB at 86-87.) Respondents argue that this time frame is almost identical to the amount time the samples were stressed in the 100% modulus test. (*Id.* at 87.) A cursory review of RX-328, however, shows that the adjustment varied from 4 seconds to as much as 25 seconds. (RX-328 at RJD0002708-9 and RJD0003616-7.) Moreover, as Mr. Del Vecchio acknowledged, since the engineer was manually trying to adjust the sample, the adjustment period was longer and more varied due to human error compared with the 100% modulus test where the stretching of the sample was automated on the Instron machine. (Del Vecchio, Tr. 969:3-12.)

Thus, given the unreliability of the data generated by the Del Vecchio Test, the Court finds that Respondents have failed to show non-infringement of the accused gloves.

(c) Conclusion

Based on the reasons set forth above, the Court finds that the evidence shows that the 100% modulus test can be used to determine whether the accused gloves meet the relaxation limitation of claim 1. The Court further finds that Dr. Moalli properly conducted the 100% modulus test and that those test results are acceptable to show whether the Respondents' accused gloves meet the relaxation limitation. The Court finds that the evidence shows that Respondents gloves listed in CX-34-50, CX-81-90, and CX-803-805 with a "Y" under the column labeled "Relaxes to Less than 50% of Initial Pressure" relax to "initially exerting an initial pressure on the hand and thereafter still fitting closely about the hand, but relaxing, within about 6 minutes after the gloves is stretched to fit about said hand, to exert on the hand a reduced pressure which is less than about 50% of the initial pressure." (CX-34-50; CX-81-90 and CX-803-805.) Therefore, the Court finds that those gloves meet the relaxation claim limitation.

b) The Doctrine of Equivalents

Tillotson did not offer any evidence that Respondents' nitrile gloves infringe the '616 Patent under the doctrine of equivalents. Pursuant to Ground Rules 8(f) and 11.1,[5] Tillotson has waived the opportunity to raise this issue.

c) Conclusion

As set forth *supra*, the evidence shows that certain of Respondents' gloves listed in CX-34-50, CX-81-90 and CX-803-805 meet some or all of the claim limitations of claim 1 of the '616 Patent. (CX-34-50; CX-81-90 and CX-803-805.) Those gloves that meet every limitation of claim 1 have been consolidated into a single list attached hereto as Appendix C. Therefore, the Court finds those of Respondents gloves listed in Appendix C literally infringe Claim 1 of the '616 Patent.[6]

2. Claims 17, 18 and 19

Claims 17, 18 and 19 depend on independent claim 1 of the '616 Patent. Inasmuch as each claim limitation must be present in an accused device in order for infringement to be found (either literally or under the doctrine of equivalents), a device cannot infringe a dependent claim

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[5] Ground Rule 8(f) states (emphasis added):

A statement of the issues to be considered at the hearing that sets forth with particularity a party's contentions on each of the proposed issues, including citations to legal authorities in support thereof. **Any contentions not set forth in detail as required herein shall be deemed abandoned, or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-hearing statements**. . . .

Ground Rule 11.1 states (emphasis added):

The post-trial brief shall discuss the issues and evidence tried within the framework of the general issues determined by the Commission's Notice of Investigation, the general outline of the briefs as set forth in **Appendix B**, and those issues that are included in the pre-trial brief and any permitted amendments thereto. **All other issues shall be deemed waived**. . . .

[6] Those accused gloves that fail to meet each and every limitation of claim 1 have been consolidated into a single list attached hereto as Appendix D.

if it does not practice every limitation of the independent claim from which it depends. See *Warner-Jenkinson Co.*, 520 U.S. at 40; *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007). Furthermore, the Federal Circuit explained that:

> One may infringe an independent claim and not infringe a claim dependent on that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.

Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1552 (Fed.Cir.1989).

As noted above, those accused gloves listed in Appendix C have been found to literally infringe independent Claim 1 of the '616 Patent. (*Supra* B.1.a.) Therefore, the Court must now determine whether those gloves that infringe independent claim 1 infringe dependent claims 17, 18 and/or 19 as well.

a) Literal Infringement

(1) Claim 17: A glove as in Claim 1, wherein the layer of elastomeric material has a thickness up to about 4.5 mils;

And

Claim 18. A glove as in claim 1 wherein the layer of elastomeric material has a thickness from about 4 to about 4.5 mils.

As set forth in B.1.a.iv above, Dr. Moalli measured the thickness of a sample of elastomeric material using a Mitutoyo Model flat anvil-type thickness gauge. Dr. Moalli described how he measured the thickness of the gloves:

> The gauge has a 10-mm (0.394-in) diameter anvil attached to a spring-loaded spindle to provide a consistent applied force to the sample; this insured that the same pressure was applied to each sample during measurement and minimized any error associated with compressing the rubber samples. Three thickness measurements were taken from each specimen and the mean value was computed (median values of thickness were used for the calculation of stress in accordance with ASTM D412). For each glove type, I tested 5 individual gloves. From each glove, I excised 3 relaxation samples (15 total) and 1 tensile sample (5 total).

> Because I measured the thickness of each of these samples in 3 locations, I actually measured the thickness of each glove type 60 times.

(CX-786C at Q&A 70 (Moalli Direct).) Dr. Moalli then reported the results of his analysis as to whether the gloves met the claim limitation of Claim 17, *i.e.* whether the gloves had a thickness of up to about 4.5 mils. (*Id.* at Q&A 212-219.) Those results are contained in CX-52-CX-67; CX-92-101; CX-806-808. (*Id.* at Q&A 212-219; 228-235.) If the glove met this limitation of having a thickness of at least 4.5 mils, then a "Y" is placed in the column labeled "Up to About 4.5 mils." (*Id.*; CX-52-67; CX-92- 101; CX-806-808.)

Similarly, if the gloves met the claim limitation of Claim 18, then a "Y" is placed in the column labeled "From About 4 to About 4.5 mils." (CX-786C at Q&A 220-223; 228-235 (Moalli Direct); CX-52-67; CX-92-101; CX-806-808.)

The parties do not dispute that to the extent certain of Respondents' gloves meet claim 1 of the '616 Patent, then those gloves meet the limitations of Claims 17 and 18 of the '616 Patent. (CIB at 20; RIB at 67-88; SIB at 18) Respondents do not dispute that certain of its gloves have a thickness up to 4.5 mils. (ROCPFF-V.B.1811-1975.)[7] Respondents also do not dispute that certain of its gloves have a thickness of about 4.0 to about 4.5 mils. (ROCPFF- 1982-2134.)[8] Staff also does not dispute that Respondents gloves meet this limitation. (SIB at 18.)

The Court finds that the evidence shows that Respondents' gloves listed in CX-52-67, CX-92-101, CX-806-808 with a "Y" in the column labeled "From About 4 to About 4.5 Mils" have a thickness of about 4.0 to 4.5 mils and, therefore, meet the claim limitation of Claim 17. (CX-52-67, CX-92-101, CX-806-808.) The Court finds that the evidence shows that

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[7] In ROCPFF V.B. 1913-1921, PIP argues that the description do not identify a class of gloves imported and/or distributed by it. However, does not dispute that it meets this limitation.

[8] In ROCPFF V.B. 2077-2085, PIP argues that the description do not identify a class of gloves imported and/or distributed by it. However, does not dispute that it meets this limitation.

Respondents' gloves listed in CX-52-67, CX-92-101, CX-806-808 with a "Y" in the column labeled "Up to About 4.5 Mils" have a thickness up to about 4.5 mils and, therefore, meet the claim limitation of claim 18. (CX-52-67, CX-92-101, CX-806-808.)

(2) Claim 19. A glove as in claim 1, therein the layer of elastomeric material is further characterized by having an elongation of greater than about 800 lbs/in.

In order to determine the puncture resistance of the gloves, Dr. Moalli tested the accused gloves using a puncture test that comprised of testing round samples of the gloves with a needle. Dr. Moalli described his test as follows:

> In the puncture test, round samples were cut from the palms and backs of gloves, and then positioned between two plates mounted to a mechanical testing machine. A needle was attached to the crosshead of the testing machine, and as the crosshead was lowered at 20 inches per minute, the needle was pushed against the round specimen until was punctured. In the first picture [CDX-155], we can see the testing machine, the sample sandwiched between the two circular plates, and the needle, attached to the crosshead, that is used to puncture the sample. The second picture [CDX-154] is a close-up view of the needle about to contact the sample sandwiched between the metal plates.

(CX-786 C at Q&A 115 (Moalli Direct).) Dr. Moalli reported his findings in CX-52-67 and CX-92-101. (*Id.* at Q&A 210-214; 224-232.) If the gloves met the limitation of have a puncture resistance of greater than about 800 lbs/in, then a "Y" was placed in the column labeled "Puncture Resistance Greater Than About 800 lbs/in." (*Id.*; CX-52-67; CX-92-101.)

The parties do not dispute that to the extent certain of Respondents' gloves meet claim 1 of the '616 Patent, then those gloves meet the limitations of Claim 19 of the '616 Patent. (CIB at 20; RIB at 67-88; SIB at 18.) Respondents do not dispute that certain of its gloves have a

puncture resistance of greater than about 800 lbs/in. (ROCPFF-V.B1648-1810.)[9] Staff also does not dispute that the respondents gloves meet this limitation. (SIB at 18.)

The Court finds that the evidence shows that respondents gloves listed in CX-52-67 and CX-92-101 with "Y" in the column labeled "Puncture Resistance Greater Than About 800 lbs/in" have a puncture resistance of about 800 lbs/in and, therefore, meet the claim limitation of claim 19. (CX-51-67; CX-92-101.)

b) The Doctrine of Equivalents

Tillotson did not offer any evidence that respondents' nitrile gloves infringe the '616 Patent under the doctrine of equivalents. Pursuant to Ground Rules 8(f) and 11.1, Tillotson has waived the opportunity to raise this issue.

c) Conclusion

As set forth *supra*, the evidence shows that certain of Respondents' gloves listed in CX-52-67, CX-92-101, CX-806-808 meet the claim limitations of Claims 17, 18 and/or 19 of the '616 Patent. (CX-52-67, CX-92-101, CX-806-808.) Those gloves that meet the claim limitations of claim 17, 18 and/or 19 have been consolidated into a single list attached hereto as Appendix C. Therefore, the Court finds those of Respondents gloves that literally infringe claims 17, 18 and/or 19 of the '616 Patent are listed in Appendix C and identified as infringing therein.

V. VALIDITY

A. Background

[9] In ROCPFF V.B. 1749-1756, PIP argues that the description do not identify a class of gloves imported and/or distributed by it. However, does not dispute that it meets this limitation.

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). However, the claims of a patent are presumed to be valid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986). Although a complainant has the burden of proving a violation of section 337, it can rely on this presumption of validity. A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption by "clear and convincing" evidence of invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

B. 35 U.S.C. §251(Broadening Reissue)

35 U.S.C. § 251 ¶ 4 states:

> No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

35 U.S.C. § 251. In determining whether claims "enlarge the scope," the test is whether any reissue claim "contains within its scope any conceivable apparatus or process which would not have infringed the original patent." *In re Ruth*, 278 F.2d 729, 730 (CCPA 1960); *see also Tillotson Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1037 note 2 (Fed. Cir. 1987) ("*Tillotson*"). A reissue claim that is broader in any respect is considered to be broader than the original claims even though it may be narrower in other respects. *Id.* (internal citations omitted) A new claim enlarges if it includes within its scope any subject matter that would not have infringed the original patent. *Thermalloy, Inc. v. Aavid Eng'g,* 121 F.3d 691, 692 (Fed. Cir. 1997) Whether amendments enlarge the scope of a claim is a matter of claim construction. *Id.; see also In re Freeman*, 30 F.3d 1459, 1464(Fed Cir. 1994).

Respondents argue that the '616 Patent is invalid because Tillotson improperly broadened the scope of the '362 Patent through a reissue application filed more than two years after the '362 Patent issued. (RIB at 9.) Specifically, Respondents argue that Tillotson improperly broadened the scope of the claims by amending the claims of the '362 Patent from claiming a glove that initially exerted a "predetermined" pressure to a glove that exerted an "initial" pressure in the '616 Patent. (*Id.* at 10.) Respondents argue that in light of the Court's claim construction and Federal Circuit precedent, the amendment invalidates the '616 Patent. (*Id.* at 10.)

Respondents argue that Tillotson has based the entirety of its argument as to why the amendment was not broadening on its claim construction position that "predetermined pressure" and "initial pressure" mean the same thing. (*Id.* at 11.) Respondents argue that Tillotson's amended claim of "initial pressure" fails to include the "predetermined" limitation in the original claim. (*Id.* at 11.) Respondents further argue that the Court rejected Tillotson's argument noting that since the concept of initial pressure was already in the original claim, then Tillotson's argument would render the term "predetermined" superfluous. (*Id.* at 11-12.)

Respondents argue that the Court's claim construction has given clear and independent meaning to the "predetermined" limitation and that Tillotson omitted that limitation during the reissue and that by omitting that limitation Tillotson relieved itself of the need to prove that the pressure that is actually initially exerted on the hand upon the donning of gloves is an amount of pressure that has been decided in advance. (*Id.* at 12.)

Respondents further argue that another test shows that Tillotson improperly broadened the scope of the '616 Patent, namely that claim 1 of the '616 Patent encompasses gloves that would not have been found to infringe the '362 Patent. (*Id.* at 12.) Respondents argue that the

use of the 100% modulus test produces results that are in no way influenced by either the size or shape of the hand or by the geometry of the glove. (*Id.* at 13.) Respondents argue that under the 100% modulus test, which Tillotson and the Court have linked to determining the "initial pressure," an Ansell glove was found to infringe claim 1 of the '616 Patent. (*Id.* at 13-14.) Respondents argue, however, that there is no such link between "predetermined pressure" and the 100% modulus test and that Tillotson has, instead, argued that "predetermined pressure is a function of the size and shape of the hand and the geometry of the glove." (*Id.* at 14.) Respondents then create a correction factor based on Tillotson's sworn interrogatory answer where Tillotson calculated the percentages of initial stress retained after 6 minutes with respect to a sample stretched 100%, *e.g.* "initial pressure," and a sample stretched 0.10 inches, which more closely simulates the performance of the glove when properly donned on one's hand, *e.g.* "predetermined pressure." (*Id.* at 14.) Respondents argue that by adding the correction factor, the Ansell glove goes from infringing to non-infringing. (*Id.* at 14-15.) As such, Respondents argue that Tillotson has improperly broadened the scope of the claims under either the limitation omission test or the infringing to non-infringing test and that, therefore, the asserted claims are invalid. (*Id.* at 15.)

Tillotson argues that Respondents have failed to meet their burden of showing by clear and convincing evidence that Tillotson improperly broadened its claims. (CIB at 67-68.) Tillotson argues that there is no evidence that the initial pressure limitation encompasses any glove that would not have also infringed the predetermined pressure limitation. (*Id.* at 68.) Specifically, Tillotson argues that since the initial stress is determined in advance as dictated by physics and mechanical properties, then there is no glove that would meet the "initial pressure limitation" that would not also meet the "predetermined pressure" limitation. (*Id.* at 69-70.)

Thus, Tillotson argues that while the terms "initial pressure" and "predetermined pressure" have different meaning, physics dictates that they encompass the same limitations. (*Id.* at 70.)

Tillotson further argues that the Court's construction of "predetermined pressure" does not require that an individual knowingly select a specific pressure in designing a glove. (*Id.* at 70.) Tillotson argues that there is nothing in the ordinary and customary meaning of "predetermined" that imposes such a requirement and nothing in the file wrapper or prosecution history that teaches such a requirement. (*Id.* at 70-72.) Tillotson argues that the specification does not show any "foreknowledge" or "knowing selection in advance" of particular pressure. (*Id.* at 72.) Tillotson further argues that a glove designer would not be able to design a glove such that the 100% modulus test would result in a glove with a specific initial stress result and that such an impossibility is supported by the data submitted to the PTO where the initial stress for each of the gloves was different. (*Id.* at 72-73.)

Tillotson further argues that the Court's claim construction establishes that the amendment was not broadening. (*Id.* at 73.) Tillotson argues that since "predetermined pressure" is used only in the context of measuring relaxation and the Court determined that the 100% modulus test measures relaxation, then "predetermined pressure" is clearly tied to the 100% modulus test. (*Id.* at 73-74.) Tillotson further argues that the Court's understanding that the teaching of the patent is the reduction in pressure between the first pressure and the second pressure and that the reduction can be measured by the 100% modulus test, regardless of whether the first pressure is the "initial pressure" or "predetermined pressure," supports its position that knowingly selecting the pressure in advance is not required. (*Id.* at 74.)

Staff argues that the '616 Patent is invalid under 35 U.S.C. § 251 ¶4 because Tillotson improperly broadened the scope of the claims by replacing "predetermined pressure" in the '362

Patent with "initial pressure" in the '616 Patent. (SIB at 36-38.) Staff argues that Tillotson relies on the same logic it used to argue that "predetermined pressure" and "initial pressure" have the same meaning to argue that they have the same scope. (*Id.* at 39.) Staff argues that, based on the Court's claim construction, Tillotson's argument fails and "initial pressure" is broader than "predetermined pressure." (*Id.* at 39.) Staff argues that the critical difference between the Court's construction of the two terms is that "predetermined pressure" requires that the amount of pressure be decided in advance and that absent this critical difference, both terms would merely measure the amount of pressure exerted on the hand after the glove is donned. (*Id.* at 39-40.)

Staff argues that the intrinsic record refutes Tillotson's position that the scope of "initial pressure" and "predetermined pressure" are the same. (*Id.* at 40.) Staff argues that the plain language of "predetermined" requires that one decide in advance the amount of pressure that will be exerted. (*Id.* at 40.) Staff argues that Tillotson attempts to read this limitation out of the claim by arguing that the "predetermined pressure" can be any pressure. (*Id.* at 40.) Staff further argues that the specification discloses the predetermination as evidenced by Figure 2 of the '616 Patent. (*Id.* at 40.) Staff argues that Figure 2 shows that the inventors actually determined the stress of the gloves in actual psi over time rather then just a percentage comparison of relaxation over time. (*Id.* at 40.) Staff argues that this evidences not a specific predetermined pressure, but rather evidences that the amount of pressure on the hand when the glove is donned must be decided in advance. (*Id.* at 40.) Staff argues that this is distinct from "initial pressure," which only requires that there be an amount of pressure when the glove is donned. (*Id.* at 41.)

Staff further argues that it is clear that claim 1 of the '616 Patent is broader than the '362 Patent because it contains within its scope a glove that would not have infringed Claim 1 of the

'362 Patent. (*Id.* at 41.) Staff argues that a glove could have an arbitrary "initial pressure" on a hand where it was not decided or known in advance what the pressure was when the glove was donned, *i.e.,* there was no "predetermined pressure." As such, the glove would fall outside the scope of claim 1 and not infringe the '362 Patent. (*Id.* at 41.)

First, the parties do not dispute that the reissue application for the '616 Patent (November 13, 1995) was filed more than two years after the issuance of the '362 Patent (May 14, 1991). (RIB at 10; CIB 67-74; SIB at 39, note 31.) The Court finds that the reissue application for the '616 Patent was filed more than two years after the issuance of the original '362 Patent. (JX-3, cover page ('616 Patent).) The question remaining is whether the amended claims of the '616 Patent are broader than those of the original '362 Patent. For the reasons set forth below, the Court finds that Tillotson has improperly broadened the scope of the original claims of the '362 Patent more than two years after its issuance.[10]

During the reissue, Tillotson replaced the term "predetermined pressure" in claim 1 with "initial pressure." Specifically, the term was replaced in the relaxation limitation of the claim:

> initially exerting [a predetermined] *an initial* pressure on the hand and thereafter *still fitting closely about the hand, but* relaxing, *within about 6 minutes after the glove is stretched to fit about said hand,* to exert on the hand a reduced pressure which is [substantially] less than about [80%] *50%* of the [predetermined] *initial* pressure.

(JX-3 at 6:44-50 ('616 Patent)) (emphasis in original, where "Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue" *Id.* at 1:4-8.). During the reissue proceedings, Mr. Tillotson submitted a Supplemental Reissue Declaration and Power of Attorney, in which he explained that "[a]mended Claim 1 differs from claim 1 of the original patent in that amended

[10] Claims 17, 18, and 19 of the '616 Patent depend from and contain all the limitations of claim 1 of the '616 Patent. '616 Patent at col. 8:9-15.

claim 1 describes a glove . . . capable of being stretched to fit closely about the hand and when stretched from an initial configuration to fit closely about the hand, exerts an *initial, rather than predetermined, pressure* on the hand." (JX-4 at TLC000178 ('616 Prosecution History) (emphasis added)). Mr. Tillotson further explained that "[t]he term 'predetermined' has been replaced with the term 'initial' in amended claim 1 to more clearly define the glove of claim 1 in accordance with p. 11 line 22 of the applicant's description," which forms part of a sentence reciting, *inter alia*, "the initial 100% modulus." *Id.*[11] Mr. Tillotson also explained that "[t]he term initial pressure more definitely describes the elastomeric properties of the glove." (*Id.* at TLC000182.)

The Court construed the claim terms in dispute in the *Markman* Order. (*See* Order No. 63.) Specifically, the terms "a predetermined pressure on the hand" and "the predetermined pressure" were construed to mean "the amount of pressure decided in advance that will be exerted on the hand by the glove after the glove is donned." (*Id.* at 14.) In rejecting Tillotson's argument that "initial pressure" and "predetermined pressure" were synonymous, the Court explained:

> There is no evidence in the patent itself or the prosecution history that the patentees were their own lexicographers or that any special meaning for the term "predetermined" can be ascertained from the intrinsic evidence, *i.e.*, nothing in the '362 Patent or in the prosecution history indicates that the patentees defined "predetermined" to mean "initial."... In the reissue declaration, the patentee stated "[t]he term 'predetermined' has been replaced with the term 'initial' to more clearly define the glove of claim 1 in accordance with p. 11 line 22 of the applicant's description." (Tillotson Br., App., Ex. 2 at TLC000035.) Such a basis indicates that, at a minimum, the terms "predetermined" and "initial" have a different meaning. Similarly, the specification does not support Tillotson's construction because the specification uses the term "initially" only in the context of describing at what point the predetermined pressure is exerted on an object, *i.e.* "initially exerting a predetermined pressure on the object." ('616 Patent 3:33-34.)

[11] The complete sentence on lines 21-23 of page 11 of the applicant's description corresponds to that description in the specification of the '616 Patent: "A sample was cut from each glove and stretched 100% of its length to determine the initial 100% modulus according to ASTM D-412." (JX-3 at 6:13-15 ('616 Patent).)

> The fact that the terms are coupled together does not, as Tillotson asserts, support its contention that the terms should be construed to have the same meaning. Rather, the fact that "predetermined" and "initial" are coupled together in claim 1 of the '362 Patent would indicate that the terms have separate meanings and are not interchangeable. Indeed, if such were the case then "predetermined" would be superfluous and such a construction is impermissible.

(*Id.* at 14-15.). The Court went on to find that the claim terms "an initial pressure on the hand" and "the initial pressure" were construed to mean "the amount of pressure first exerted on the hand by the glove after the glove is donned." (*Id.* at 33.) The Court further found that this pressure can be determined by the 100% modulus test and need not be a measurement of the actual pressure on the hand. (*Id.* at 38.)

A simple comparison of the Court's construction of "predetermined pressure" and "initial pressure" shows a clear difference between the two constructions.

Predetermined Pressure	**Initial Pressure**
the amount of pressure *decided in advance that will be exerted* on the hand by the glove after the glove is donned	the amount of pressure *first exerted* on the hand by the glove after the glove is donned

(*Id.* at 14, 33) (emphasis added). At a minimum, it is clear that the "predetermined pressure" requires that the amount of pressure be "decided in advance" as opposed to simply the amount of pressure that was "first exerted." The amount of pressure for the "initial pressure" can be any pressure that is first exerted, while the amount of pressure for "predetermined pressure" requires that the amount be "decided in advance." This requires a "cognitive function", *i.e.*, that the pressure be decided or determined in advance.[12] Failure to make that decision or determination effectively reads that limitation out of the claim as noted by Staff and Respondents. *See Pannu v.*

[12] Tillotson argues that the dictionary definition of "predetermined" does not require "conscious intent on the part of an individual to select a particular pressure." (CIB at 71-72.) Tillotson misunderstands the Court's claim construction. The Court's claim construction does not require a specific selection or determination of a specific pressure in advance, rather the Court's claim construction requires a determination in advance of what amount of pressure will be exerted on the hand by the glove after the glove is donned.

Storz Instruments, Inc., 258 F.3d 1366, 1371 (a reissue claim that does not include a limitation present in the original claims is broader than the original claim). In other words, Tillotson improperly broadened the original claim by eliminating this limitation, *i.e.*, deciding the amount of pressure in advance, to instead accepting any arbitrary amount of pressure first exerted.

The specification and prosecution history show that the patentees themselves made such a predetermination. Figure 2 compares the stress required to maintain the stretch of the glove and is presented as stress in psi versus time. (JX-3 at 3:3-6; 6:11-26 ('616 Patent).). Figure 2 demonstrates that the patentees *determined* the stress of the gloves in *actual* psi over a measure of time. Similarly, Table 5 of the prosecution history of the '616 Patent shows that Mr. Tillotson and Mr. DeBecker *determined* the stress of the listed gloves in *actual* psi over a measure of time. (JX-4 at TLC000049 ('616 Prosecution History).) What this demonstrates is not a specific amount of pressure or that the patentees had any "foreknowledge" of what the actual amount pressure would be, rather it evidences that the amount of pressure on the hand when the glove is donned *was decided in advance*. This stands in stark contrast to the limitation in reissued claim 1 that merely requires an "initial pressure," which does not require any advanced determination of that pressure when the glove is donned and only requires that there be an undetermined amount of pressure when the glove is donned. (JX-3 at 6:33-50 ('616 Patent, Claim 1).). Thus, the absence of the limitation requiring that the amount of pressure be *decided in advance* in the construction of "initial pressure" results in a broadening of claim 1.

Moreover, claim 1 of the '616 Patent is broader because it contains within its scope a glove that would not have infringed original claim 1 of the '362 Patent. For example, one could have a glove with an arbitrary amount of "initial pressure," without any advance determination of the amount pressure exerted by that glove will be when it is donned, but which met every

other limitation of claim 1 and all other elements of the relaxation limitation of claim 1 of the '616 Patent, *e.g.* was shown to relax to less than about 50% of the of the "initial pressure." However, since there is no determination or decision in advance as to the amount of pressure that will be exerted on the hand by the glove after the glove is donned, then the "predetermined pressure" claim limitation of the original '362 Patent is not met. In other words, as aptly stated by Staff "a glove that exerts an undetermined amount of initial pressure and that otherwise satisfies all of the limitations of reissued Claim 1 would infringe the reissued claim, but would not infringe original claim 1 of the '362 patent, which requires that the glove exert a predetermined pressure, *i.e.*, an amount of pressure determined in advance." (SIB at 41.) *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("A claim of a reissue patent application is broader in scope than the original claims if it contains within its scope any conceivable apparatus or process which would not have infringed the original patent.").

Respondents have added an additional step to the Court's construction, namely requiring that a *specific* amount of pressure that will be exerted on the glove will be decided in advance, *e.g.* "predetermining [ ] a starting pressure." (RRB at 2; RIB at 12.) The Court's construction does not require this – it only requires that the amount of pressure that will be exerted on the hand after the glove is donned be decided in advance, not that a specific amount of pressure that was decided in advance, or a "preset" specific amount of pressure, be exerted by the glove. (Order No. 63, at 10-14.) In other words, to satisfy claim 1 of the '362 Patent under the Court's claim construction, one only needs to determine the amount of pressure to be exerted by the glove, whatever that number may be, but that number need not be decided in advance.[13] There

[13] The plain and ordinary meaning of "decide" as defined by the American Heritage Dictionary is "1a. To settle conclusively all contention or uncertainty about. b. To make up one's mind about." *See American Heritage Dictionary of the English Language, Fourth Edition* (2000). Here, one must "settle conclusively all contention or

is no requirement that "predetermined pressure" be a specific starting pressure or that the designer of the glove "knowingly select a specific pressure." (*See* RIB at 12; CIB at 70-73.)

Moreover, there is nothing in the specification or prosecution history that requires the amount of pressure be a specific amount or that the designer of the glove have any "foreknowledge" of a specific amount. The term "predetermined pressure" is used multiple times throughout the specification in describing the relaxation qualities of the elastomeric material and glove, but there is no reference to a specific amount of pressure or selecting a specific pressure. (*See generally* JX-3 specification ('616 Patent).) Rather, the original claim language requires a "predetermined pressure," which requires, quite simply, that the amount of pressure must be decided or determined in advance. There is no requirement that a specific amount of pressure be determined in advance.

There also is no requirement that the "predetermined pressure" be a measurement of actual pressure on the hand as asserted by Respondents. (RIB at 14-15.) As the Court explained *supra* Section IV.B.1. a)(5) and in the *Markman* Order, there need not be any measurement of actual pressure on the hand. Rather, the amount of stress measured by the 100% modulus test can simulate the pressure on the hand. (*See* Order No. 63 at 34-38.)

Tillotson argues that while the claim constructions of "predetermined pressure" and "initial pressure" are different, the scope and limitations of the claims encompass the same glove. (CIB at 68-69.) The reason for this, Tillotson argues, is because the stress of a glove is "dictated by the physics and mechanical properties of the sample." (*Id.* at 69-70.) The Court does not dispute the fact that basic physics will dictate that the stress of the glove or its physical properties. However, the repeated use of "predetermined pressure" in the specification and its use in the

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uncertainty about" in advance the actual amount of pressure that will be exerted on the hand when the glove is donned. It is not required that a specific amount of pressure that will be exerted on the hand be decided in advance.

original claim indicate that more was intended than just a simple acknowledgement of basic physics. Tillotson's argument would effectively read the term "predetermined" out of the claim and make its repeated usage in the specification of the patent completely meaningless,[14] as every glove in the world will provide some pressure on the hand as dictated by the laws of physics and mechanical properties. Rather, it is the "cognitive function", the determination of what "basic physics had decided in advance," *e.g.,* the physical property of stress of the gloves, that is required. It is deciding or determining in advance the amount of pressure that will be exerted by the glove when the glove is donned, *i.e.*, knowing in advance the amount of pressure. In contrast, "initial pressure" means only that some initial pressure be exerted without knowing in advance what it is. If this predetermination is not performed, claim 1 of the '362 Patent would not be satisfied, whereas failure to determine in advance the amount of pressure that will be exerted on the hand has no bearing on whether claim 1 of the '616 Patent is satisfied. There only needs to be some initial pressure. Therefore, the scope of these two terms is not the same.

The Federal Circuit's discussion in *Koito Mfg. Co., Ltd. v. Turn-key-tech, LLC*, 381 F.3d 1142 (Fed. Cir. 2004) is instructive. In *Koito*, the parties disputed the term "predetermined general direction" relating to plastic flow direction in injection molding. *Id.* at 1145-48. The district court construed this term to mean that the direction must be chosen or at least known in advance of the injection, despite the plaintiff's argument that the term simply meant any direction following the shape of the mold cavity. *Id.* at 1150. The Federal Circuit upheld the jury's finding of non-infringement based on a showing that the defendant did not know beforehand (*i.e.*, predetermined) the direction of its flow. *Koito,* 381 F.3d at 1151. As in *Koito*, the term "predetermined" in the clams at issue requires actual knowledge of the pressure. Also,

[14] Indeed, the patentees use the term "predetermined pressure" repeated throughout the entire specification. (*See generally* JX-3 specification ('616 Patent).)

as in *Koito*, it is not enough that one could later attempt to reconstruct the initial pressure or flow after the fact. Rather, one needs to know the amount of pressure that will be exerted on the hand when the glove is first donned.

In sum, it is clear that Claim 1 of the '616 Patent is broader because the critical limitation of "decided in advance" has been omitted from the claim and because there are embodiments within the scope of the claim 1 of the '616 Patent that would not have been within the scope of the '362 Patent. As such, the asserted claims of the '616 Patent, independent claim 1 and dependent claims 17, 18 and 19, which depend from claim 1, are invalid under 35 U.S.C. § 251, ¶ 4.

C. Defective Reissue Certificate

The provision for the reissue of defective patents is 35 U.S.C. § 251 ¶ 1, which states:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

35 U.S.C. § 251,¶ 1. "The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application." *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986). Rather, the reissue procedure is only available to correct "error" in claims in patents as originally issued. *Nupla Corp. v. IXL Mfg. Co., Inc.*, 114F.3d 191, 195 (Fed. Cir. 1997). "[Tlhe 'error' must only be the 'claiming of more or less than he [or she] had a right to claim' for some excusable reason." *Id.* at 194. In light of these strictures, the reissue regulations require full explanation of what is claimed to be an "error" in the original claims. *Id.* at 195.

Under the reissue regulations in effect at the time that the reissue application at issue in this consolidated investigation was pending, an applicant was required to file a statement under oath or declaration as follows: (1) when the applicant verily believes the original patent to be wholly or partly inoperative or invalid, stating such belief and the reasons why; (2) when it is claimed that such patent is inoperative or invalid by reason of a defective specification or drawing, particularly specifying such defects; (3) when it is claimed that such patent is inoperative or invalid by reason of the patentee claiming more or less than he had a right to claim in the patent, distinctly specifying the excess or insufficiency in the claims; (4) particularly specifying the errors relied upon, and how they arose or occurred; (5) stating that such errors arose without any deceptive intention on the part of the applicant; and (6) acknowledging the duty to disclose all information known to the applicant to be material to patentability. See 37 C.F.R.§ 1.175(a)(1996). See *Dethmers Mfg. Co., Inc. v. Automatic Equipment Mfg. Co.*, 272 F.3d 1365, 1369 (Fed. Cir. 2001). A patentee seeking reissue must also include in the reissue affidavit or declaration an explanation of how and when the asserted error was discovered. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1565 (Fed. Cir. 1989).

As aptly noted by the Federal Circuit, "[tlhe Manual of Patent Examining Procedure, at 1414.03, illustrate[d] the scope of the regulatory provision, by stating, in part:

> It is particularly important that the reissue oath or declaration specify in detail how the errors arose or occurred . . . . If the reissue oath or declaration does not particularly specify 'how,' *i.e.*, the manner in which the errors arose or occurred, the Office will be unable to adequately evaluate reissue applicant's statement in compliance with §1.175(a)(6) that the 'errors arose "without deceptive intention" on the part of the applicant'. *See* §1414.04.

Whether a declaration satisfies the requirements of 37 C.F.R. § 1.175 is reviewed *de novo*, without deference to previous determinations of the U.S. Patent and Trademark Office.

Dethmers, 272 F.3d at 1370. When applicants fail to submit declarations satisfying these requirements, the affected reissue claims are invalid. *See, e.g., Dethmers*, 272 F.3d at 1374-76; *Nupla*, 114 F.3d at 194-95; *In re Constant*, 827 F.2d at 729, and *Certain Magnetic Resonance Injection Systems and Components Thereof*, Inv. No. 337-TA-434, Order No. 16 (October 17, 2000).

Respondents argue that the'616 Patent is invalid because of a deficient reissue declaration. (RIB at 15.) Respondents argue that, assuming *arguendo,* that use of the term "predetermined pressure" was in error, Tillotson failed to comply with Rule 175, and all of the asserted claims are invalid. (*Id.* at 16.) Respondents argue that Tillotson failed to submit a statement under oath or declaration with its reissue application that "(1) particularly specified that the use of the term "predetermined pressure" in Claim 1 of the original '362 Patent was an error; (2) particularly specified how any purported error in using the term "predetermined pressure" arose or occurred; (3) specified when and how any purported error in using the term "predetermined pressure" in Claim 1 of the original '362 Patent was discovered; and (4) stated that the purported error in using the term "predetermined pressure" in Claim 1 of the original '362 Patent arose 'without any deceptive intention on the part of the applicant.'" (*Id.* at 16.) Respondents further argue that Tillotson failed to state that the replacement of "predetermined" with "initial" was to correct an error or defect, but instead that the replacement was "to more clearly define the glove of claim 1 in accordance with p. 11 line 22 of applicant's description." (*Id.* at 16, note 8.) Respondents argue that sincecClaims 17, 18 and 19 depend from claim 1 and Tillotson failed to comply with Rule 175, the asserted claims of the'616 Patent are invalid. (*Id.* at 16-17.)

Tillotson counters that Respondents arguments rely on two incorrect premises. (CIB at 59.) First, Tillotson argues that it was not required to separately explain the amendment from

"predetermined pressure" to "initial pressure" in a reissue declaration because it was a small language change that did not alter the scope of the claims.[15] (*Id.* at 59.) Tillotson argues that the Federal Circuit has held that substitution of a term to clarify and more clearly describe the claimed invention does not materially change the scope of the claims and, as such, does not require a separate and detailed explanation. (*Id.* at 59-61.)

Second, Tillotson argues that the Supplemental Reissue Declaration adequately discussed the substitution of "initial" for "predetermined" by specifically addressing the change in the original claims and specifying how the reissue overcomes the defect. (*Id.* at 62.) Tillotson further argues that both the "Errors" section and the "Claim 1" section in the Supplemental Reissue discuss how the errors arose and were discovered by reference to the discussion of newly discovered prior art and states that all of the errors occurred without deceptive intent. (*Id.* at 62-64.)

Lastly, Tillotson argues that the patent examiner fully considered and allowed the substitution of "initial" for "predetermined" to clarify claim 1; that the examiner did not find a deficiency with the substitution in the Supplemental Reissue Declaration since she did not specifically point the substitution out as a deficiency as required by the MPEP; and that the fact that the examiner accepted the substitution weighs heavily against a finding of invalidity on that basis.[16] (*Id.* at 61-66.)

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[15] Tillotson cites to the statement in both the Reissue Declaration and Supplemental Reissue Declaration that plainly states that the substitution of "initial" for "predetermined" was "to more clearly define the glove of claim 1 in accordance with p. 11 line 22 of the description." (CIB at 61, JX-4 at TLC000034-35 ('616 Prosecution History).)

[16] In its reply brief, Tillotson asserts a new argument for the first time. In Section III B-D, Tillotson argues for the first time that a deficient reissue declaration is not an invalidity defense under 35 U.S.C. § 282; allowing a deficient reissue declaration to invalidate the '616 Patent would be unjust; and Rule 1.175 exceeds the PTO's authority and is invalid. (CRB at 8-16.) Tillotson's Reply Brief Section III B-D is subject to a motion to strike by Ansell. (Motion Docket No. 608-158.) For the reasons set forth in Order No. 93, the Court GRANTED Ansell's motion to strike. (*See* Order No. 93)

Staff agrees with Respondents and argues that the '616 Patent is invalid based on deficient reissue declaration. (SIB at 42.) Staff argues that neither the Reissue Declaration nor the Supplemental Reissue Declaration specifies that the use of "predetermined pressure" was in error. (*Id.* at 45.) Staff argues that the Supplemental Reissue Declaration fails to state in its "Summary" section or in the "Claim 1" "The Errors" subsection that the use of "predetermined pressure" was in error. (*Id.* at 45-46.) Staff further argues that even if Mr. Tillotson's statement that "[t]he term 'predetermined' has been replaced with the term 'initial' in amended claim 1 to more clearly define the glove of claim 1. . . ." (JX-4 at TLC000178 ('616 Prosecution History)) were to be accepted as a statement of error, the other reissue requirements still have not been satisfied, "including specifying how any such error arose or occurred and when and how any such error was discovered." (SIB 46.) Staff further argues that Tillotson's explanation of the reason for the substitution is absent from the Reissue Declaration and Supplemental Reissue Declaration, despite Tillotson's explanation in response to a motion in this investigation. (*Id.* at 46.)

Staff further argues that the one of ordinary skill in the art would not consider the change from "predetermined" to "initial" to be a small change in language that does not affect the scope of the claims such that no explanation in the reissue declaration is required. (*Id.* 46-47.) Staff is of the view, therefore, that the clear and convincing evidence shows that the reissue certificate is defective and the reissued claims are invalid. (*Id.* at 47.)

During the prosecution of the reissue application, Mr. Tillotson submitted a Reissue Declaration for the '616 Patent. (JX-4 at TLC00029-50 ('616 Prosecution History).) The patent examiner found the Reissue Declaration to be defective for failure to meet the requirements of 37 C.F.R. § 1.175 and rejected all of the claims in the reissue application. (*Id.* at TLC000146-160.)

In response to the first Office Action, Mr. Tillotson filed a Supplemental Reissue Declaration that addressed the deficiencies cited by the examiner. (*Id.* at TLC000171-184.)

In the "Summary" section of the Supplemental Reissue Declaration, Mr. Tillotson describes the "errors" that prompted the reissue and stated:

> I believe the original U.S. Patent 5,014,362 (hereinafter "the Original Patent") to be partly **inoperative or invalid by reason of Patentee claiming more than Patentee had a right to claim in the Original Patent, an inadvertent drafting error, and the specification not providing proper antecedent basis for a claim as amended by this reissue application.** More particularly, the claims of the Original Patent are too broad in view of prior art that has come to the attention of the Applicant and its attorneys since issuance of the Original Patent. The prior art includes elastomeric gloves, both nitrile rubber and natural rubber gloves, that have relaxation properties such that the prior art gloves would relax from an initial pressure to a reduced pressure substantially less than 80% of the initial pressure. This prior art is cited in the Information Disclosure Statement filed with the reissue application. In addition, due to an inadvertent drafting error, one of the dependent claims of the Original Patent, claim 15, broadens the independent claim of the Original Patent, by broadening the degree of relaxation described, instead of narrowing the degree of relaxation as was intended. **These errors in the Original Patent claims and specification, described generally above and in detail below, arose without any deceptive intention on the part of the Applicant.**
>
> With the Amendment to be filed concurrently with this Supplemental Reissue Declaration and Power of Attorney, claims 1, 2, 7, 14 and 15 of the Original Patent are amended, new claims 17-24 are added, claims 12, 13, and 16 of the Original Patent are cancelled, and claims 25-43 initially added in the reissue application are cancelled. The claims of the reissue patent application now define a glove which I believe is novel and nonobvious over the prior art cited in the Information Disclosure Statement.

(JX-4 at TLC000184A-N ('616 Prosecution History)) (emphasis added).[17] There is no mention, however, of replacing the term "predetermined" with "initial."

In the "Claim 1" section, "The Errors" subsection, of the Supplemental Reissue Declaration, Mr. Tillotson further stated, *inter alia*, that "[C]laim 1 of the Original Patent does

[17] The Supplemental Reissue Declaration begins on TLC000171-184, but it appears that a page is missing. The full Supplemental Reissue Declaration was submitted to the PTO and immediately follows on TLC000184A-N. (JX-4 ('616 Prosecution History).)

not specify the chemical nature of the elastomer, the type of fit of the glove, or the thickness of the elastomeric material from which the glove is made." (JX-4 at TLC000184C ('616 Prosecution History).) Mr. Tillotson then proceeds to explain the prior art and how the '362 Patent is too broad in light of the prior art. (*Id.* at TLC000184C-E.) Mr. Tillotson concludes by stating that "Claim 1 of the Original Patent is defective in that it does not specify the chemical name of the elastomer, does not clearly define the fit of the glove, does not clearly define the thickness of the glove, and describes the relaxation properties of the glove too broadly." (*Id.* at TLC000184C-E.) Again, there is no mention of replacing the term "predetermined" with "initial."

In the "How and When Errors Occurred" and "How and When the Errors Were Discovered" subsections, Mr. Tillotson again makes no mention of replacing the term "predetermined" with "initial." (JX-4 at TLC000184E-G ('616 Prosecution History).) The first mention of replacing the term "predetermined" with "initial" comes under the subsection titled "Amended Claim 1," where Mr. Tillotson states:

> Amended claim 1 differs from Claim 1 of the original patent in that amended claim 1 describes a glove which is closely fitting and comprises a later of elastomeric material which fits closely about a hand, comprises nitrile butadiene rubber, has an initial configuration adapted to fir closely about a hand, and has a thickness and elastic properties such that the glove is capable of being stretched to fit closely about the hand and when stretched from an initial configuration to fit closely about the hand, exerts an **initial, rather than predetermined, pressure** on the hand, and thereafter still fits closely about the hand, but relaxes, within about 6 minutes after the glove is stretched to fit about the hand, to exert on the hand a reduced pressure which is less than about 50% of the initial pressure, rather than a reduced pressure which is merely substantively less than about 80 % of the initial pressure. These changes to claim 1 are discussed in more detail below.
>
> More particularly, amended claim 1 defines the glove as having an initial configuration adapted to receive and fit closely about a hand. **The term "predetermined" has been replaced with the term "initial" in amended claim**

> **1 to more clearly define the glove of claim 1 in accordance with p. 11 line 22 of the applicant's description [*i.e.*, the 100% modulus test]. . . .**
>
> . . . .
>
> **The amendments of claim 1 overcome the defects of the Original Patent by specifying the chemical name of the elastomer, further defining the fit of the glove, and further defining the thickness and elastomeric properties of the glove, including the degree of relaxation of the glove. . . .**

(*Id.* at TLC000184H-I.) (emphasis added). However, there is no mention or explanation of how the use of "predetermined pressure" in the '362 Patent was in error. Rather, Mr. Tillotson explains that the use of "initial" was intended to "more clearly define the glove" in accordance with the 100% modulus test. (*Id.* at TLC000184H.) Tillotson argues that this is sufficient to explain "how the reissue declaration overcomes the defect" and "how the amended claim differs from the ['362 Patent]." (CIB at 62.) The Court disagrees. First, there is no indication in the Supplemental Reissue Declaration or even the original Reissue Declaration that the use of "predetermined" instead of "initial" in the '362 Patent was actually a defect. In addition, this statement does not show that "predetermined" was erroneously used, nor does it explain how or why "predetermined" was erroneously used, or how it was discovered that "predetermined" was erroneously used. (*See* 37 C.F.R. § 1.175(a).)

The "error" that the inventors sought to correct does not become clear until this investigation. In response to Ansell's Motion for Summary Determination of Invalidity of the Asserted Claims of the '616 Patent By Reason of Broadening Amendment More Than Two Years After the Issuance of the Original Patent, Tillotson stated that it "realized that 'predetermined pressure' could be misinterpreted to mean something other than 'initial pressure" and that this "possible misinterpretation" constituted the error that Tillotson corrected in the Reissue Patent. (Tillotson's Opposition Motion for Summary Determination of Invalidity of the

Asserted Claims of the '616 Patent By Reason of Broadening Amendment More Than Two Years After the Issuance of the Original Patent at 31; *see also* Tillotson, Tr. 1228:8-19.) This explanation, however, does not cure the deficient reissue declaration or Tillotson's failure to explain the "error" of mistakenly using "predetermined" instead of "initial" in claim 1 of the '362 Patent during the reissue application process.

Tillotson argues that "[t]he substitution of 'initial' for "predetermined" in amended claim 1 . . . is the correction of an error that is allowed during reissue. Because this correction is a 'small language change{} that {did} not affect the scope of the claims,' however, it is not a change that must be separately 'explained in the reissue declaration.'" (CIB at 61.) Based on the Court's ruling *supra* Section V.B., the substitution of "initial" for "predetermined" in claim 1 significantly changed the scope of the claims. It was not a simple clarification, but instead broadened the scope of the claims and, as such, is not a "small language change." In addition, the substitution of "initial" for "predetermined", where it was repeatedly used in the specification and claims of the '362 Patent hardly seems to be a "small" language change, especially when such a change occurs in the only independent claim of the patent. Moreover, the use of the phrase "initial, rather than predetermined, pressure" indicates a change of meaning and not a mere substitution of words.

Based on the reasons set forth above, the Court finds that the evidence clearly and convincingly shows that Tillotson failed to submit a reissue declaration that specified that the use of "predetermined pressure" in claim 1 of the '362 Patent was an error, failed to specify how the erroneous use of the term "predetermined pressure" arose or occurred, or how it was discovered that "predetermined" was erroneously used. Therefore, the asserted claims of the '616 Patent are invalid based on a deficient reissue declaration.

D. Anticipation

A patent may be found invalid as anticipated under 35 U.S.C. § 102(a) if "the invention was known or used by others in this country, or patented or described in a printed publication in this country, or patented or described in a printed publication in a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). A patent may be found invalid as anticipated under 35 U.S.C. § 102(b) if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Under 35 U.S.C. § 102(e), a patent is invalid as anticipated if "the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent." 35 U.S.C. § 102(e). Anticipation is a question of fact. *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1177 (Fed. Cir. 1993) ("*Texas Instruments II*"). While anticipation is a question of fact, it is determined by properly construing the claims and then comparing the claims, as construed, to the prior art. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346 (Fed. Cir. 2002). It is axiomatic that claims are construed the same way for both invalidity and infringement. *W.L. Gore v. Garlock, Inc.,* 842 F.2d 1275, 1279.

In order to prove anticipation, Respondents must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim. *Cruciferous Sprout,* 301 F.3d at 1349. A claim is anticipated and therefore invalid when "the four corners of a single, prior art document describe[s] every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent*

State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 904 (2001). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000); *In re Paulsen,* 30 F.3d 1475, 1478 (Fed. Cir. 1994). But, the degree of enabling detail contained in the reference does not have to exceed that contained in the patent at issue. *Paulsen*, 30 F.3d at 1481 n.9.

Further, the disclosure in the prior art reference does not have to be express, but may anticipate by inherency where the inherency would be appreciated by one of ordinary skill in the art. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir.), *cert. denied*, 516 U.S. 988 (1995). To be inherent, the feature must necessarily be present in the prior art. *See Finnigan Corp. v. U.S. Int'l Trade Comm'n*, 180 F.3d 1354, 1365-66 (Fed. Cir. 1999). Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. This modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges. *See Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991); *Finnigan*, 180 F.2d at 1365.

Respondents argue that the '616 Patent is invalid as anticipated by U.S. Patent No. 2,880,189 ("the Miller Patent"). Respondents argue that the Miller Patent contains all the

information one of ordinary skill in the art would need to manufacture what was claimed in the '616 Patent. (RIB at 37.) Respondents argue that PTO found the '616 Patent as anticipated by the Miller Patent because while the Miller Patent failed to disclose specific relaxation values, the relaxation data submitted by the inventors on Miller Patent sample showed them to be sufficiently close to those of the '616 Patent. (*Id.* at 38.) Respondents further argue that the inventors effectively conceded that the Miller Patent contained all of the limitation of the '616 Patent by failing to argue that the Miller Patent did not contain all of the limitations of the '616 Patent. (*Id.* at 39.) Respondents argue that, instead, the inventors merely argued that the Miller Patent failed to give one of ordinary skill in the art the means and motivation to enhance the relaxation properties of the Miller Patent invention. (*Id.* at 39.)

Tillotson argues that Respondents have failed to prove anticipation by the Miller Patent. (CIB at 31.) As an initial matter, Tillotson argues that Respondents' arguments ignore the fact that the PTO had considered the Miller Patent during the prosecution of the reissue application and had found that the Miller Patent did not anticipate the '616 Patent. (*Id.* at 31.) Tillotson further argues that the Miller Patent does not anticipate the '616 Patent because the '616 Patent contains numerous claim limitations that the Miller Patent does not, such as providing a targeted amount of relaxation, *i.e.* a reduced pressure that is 50% of the initial pressure, and providing for a closely fitting glove of certain tensile strength, elasticity and thickness that is impermeable to water and water vapor. (*Id.* at 32.)[18]

Staff argues that Respondents have failed to show by clear and convincing evidence that the Miller Patent anticipates the '616 Patent. (SIB at 29.) Staff argues that the relaxation

[18] Tillotson then discusses that the '616 Patent is not inherently anticipated by the Zeon reference and Dr. Mill's testimony regarding the same. (CIB at 33-35.) However, Respondents have made no inherency argument (see RIB at 33-45) and, in fact, notified Staff and Tillotson of their decision not to rely on the Zeon data for any purpose (SIB at 30.) As such, the Court finds that Respondents have waived any arguments that assert that the Miller Patent inherently discloses the relaxation limitations of the '616 Patent. (*See* Ground Rule 11.1.)

properties of the '616 Patent are not taught or suggested by the Miller Patent. (*Id.* at 29-30.) Staff further argues that other limitations in the '616 Patent are not disclosed in the Miller Patent, namely "a closely fitting glove (or any other nitrile composition) that relaxes from an initial pressure to a reduced pressure that is less than about 50% of the initial pressure within about six minutes after the glove is donned." (*Id.* at 30.) Staff further argues that the Miller Patent fails to discuss stress relaxation or how to use metal oxides to manipulate the relaxation and it further fails to discuss the resilience or relaxation behavior of the elastomers. (*Id.* at 30.) Staff further argues that Dr. Mills testimony regarding the nitrile films disclosed in the Miller Patent are unsupported and that they are contradicted by the inventors' own Miller Patent samples and data. (*Id.* at 30-31.)

The Court finds that Respondents have failed to show by clear and convincing evidence that the Miller Patent discloses each claim limitation of claim 1 of the '616 Patent. The Miller Patent was considered during the prosecution of the '616 Patent, but the examiner still found the '616 Patent to be patentable over the prior art. (JX-4 at TLC000150-152; TLC000160 ('616 Prosecution History)); *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F. 2d 1464, 1467 (Fed. Cir. 1990) (particularly heavy burden in establishing invalidity on the same prior art that was examined in the PTO). The evidence shows that the Miller Patent fails to disclose the several limitations of the '616 Patent including the relaxation limitation of relaxing to less than about 50% of the initial pressure. (RX-5; CX-839C at 83, 95, 107 (Moalli Rebuttal); Mills, Tr. 866:3-13.) The evidence further shows that the Miller Patent fails to discuss the relaxation or resilience behaviors of the elastomers described therein or even disclose a closely fitting glove (RX-5; CX-839C at Q&A 88, 91-92, 107 (Moalli Rebuttal); Mills, Tr. 866:3-13.) Moreover, even assuming that relaxation was disclosed in the Miller Patent, the patentee's experiments on

the Miller Patent samples shows that they did not meet the relaxation limitations of the '616 Patent because they relaxed to only 63-64% of their initial stress. (JX-4 at TLC00040,44-49,174-175,180 (616 Prosecution History); CX839C at Q&A 150,161-163, 285-188 (Moalli Rebuttal).) Therefore, the Court finds that the evidence shows that the Miller Patent fails to disclose all of the limitations in independent claim 1 of the '616 Patent.

E. Obviousness

Obviousness is grounded in 35 U.S.C. § 103, which provide, *inter alia*, that:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

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

Once claims have been properly construed, "[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of non-obviousness" (also known as "objective evidence").

Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1354 (Fed. Cir. 1999), citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

The Federal Circuit case law required that, in order to prove obviousness, the patent challenger must demonstrate, by clear and convincing evidence, that there is a "teaching, suggestion, or motivation to combine. The Supreme Court has rejected this "rigid approach" employed by the Federal Circuit in *KSR Int'l Co. v. Teleflex Inc.*, 500 U.S. – (2007), 127 S.Ct. 1727, 1739. The Supreme Court stated:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Sakraida and Anderson's-Black Rock are illustrative–a court must ask whether the improvement is more than the predictable use of prior art elements according to their established function.
>
> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicitly. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusions of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.
>
> [. . .]

> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advance that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at – ; 127 S.Ct. at 1740-41.

"Secondary considerations," also referred to as "objective evidence of non-obviousness," such as "commercial success, long felt but unsolved needs, failure of others, etc." may be used to understand the origin of the subject matter at issue, and may be relevant as indicia of obviousness or non-obviousness. *Graham*, 383 U.S. at 17-18. Secondary considerations may also include copying by others, prior art teaching away, and professional acclaim. *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 857 (1984); *Avia Group Int'l, Inc. v. L.A. Gear California*, 853 F.2d 1557, 1564 (Fed. Cir. 1988) (copying by others); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (prior art teaching away; invention contrary to accepted wisdom); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. ir. 1986), *cert. denied*, 479 U.S. 1034 (1987) (wide acceptance and recognition of the invention).

Evidence of "objective indicia of non-obviousness," also known as "secondary considerations," must be considered in evaluating the obviousness of a claimed invention, but the existence of such evidence does not control the obviousness determination. A court must consider all of the evidence under the Graham factors before reaching a decision on obviousness. *Richardson-Vicks Inc.*, 122 F.3d at 1483-84. In order to accord objective evidence substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed

invention, and a prima facie case is generally made out "when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988), cert. denied, 488 U.S. 956 (1988); *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Commission Opinion (March 15, 1990),15 U.S.P.Q.2d 1263, 1270 ("*Certain Crystalline*"). Once the patentee has made a prima facie case of nexus, the burden shifts to the challenger to show that the commercial success was caused by "extraneous factors other than the patented invention, such as advertising, superior workmanship, etc." *Id.* at 1393.

The Federal Circuit has harmonized the KSR opinion with many prior circuit court opinions by holding that when a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007)(citing *Medichem S.A. v. Rolabo S.L.*, 437 F.3d 1175, 1164 (Fed. Cir. 2006)); *Noelle v. Lederman*, 355 F.3d 1343, 1351-52 (Fed. Cir. 2004); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1121 (Fed .Cir. 2000) and *KSR*, 127 S.Ct. at 1740 ("a combination of elements 'must do more than yield a predictable result'; combining elements that work together 'in an unexpected and fruitful manner' would not have been obvious").

The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying findings of fact. *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999).

1. Analysis of the Asserted Claims

Respondents argue that the '616 Patent is obvious in light of the prior art, namely the Miller Patent and U.S. Patent No. 3,094,704 ("the Abildgaard Patent"), prior art gloves available on the market and common knowledge about latex rubber chemistry and rubber compounding.[19] (RIB at 33-34.) Specifically, Respondents argue that closely fitting rubber articles, with good relaxation and without excess pressure on the wearer, were known in the art; that high resilience and low relaxation were only desirable depending on the use of the article in question; and that there were a number of contemporaneous patent applications for which low stress relaxation was not desirable. (*Id.* at 34-35.)

Respondents argue that the asserted claims 1, 17, 18 and 19 are obvious in light of the Miller Patent combined with what of one of ordinary skill in the art knew about modifying material to achieve specific elastic and relaxation properties. (*Id.* at 37-38.) Respondents further argue that in light of the Supreme Court's decision in *KSR*, the need to show a teaching, suggestion or motivation to enhance the relaxation properties of the Miller Patent need not be shown. (*Id.* at 39.) Instead, it is sufficient to show that market pressures and/or designs would lead one of ordinary skill in the art to try a finite number of identified, predictable solutions to arrive at what was claimed in the '616 Patent. (*Id.* at 39-40.) Respondents argue that the two phenomena contemporaneous with the application for the '616 Patent, namely the natural rubber

[19] Respondents further argue that the Abildgaard Patent combined with other prior art further renders the '616 Patent obvious. (RIB at 44-45, RX-156.) However, the Court finds no evidence of the Ablidgaard Patent in Respondents' pre-hearing brief or testimony during the hearing relating to this prior art. (See Respondents' prehearing brief at 106-123.) Therefore, the Court finds that, pursuant to Ground Rule 8(f), Respondents have waived any argument related to the Abildgaard Patent.

latex allergies of healthcare providers and the AIDS epidemic, would have made the creation of nitrile butadiene rubber gloves obvious to one of ordinary skill in the art. (*Id.* at 40.)

Respondents further argue that the Miller Patent combined with the gloves commercially available during the prosecution of the '616 Patent, namely the SOLVEX® and DERMA-THIN™ gloves, would render the '616 Patent obvious. (*Id.* at 41.) Respondents argue that the thickness, stress relaxation, and tensile strength properties of the '616 Patent were already present in the combination of the Miller Patent and the SOLVEX® and DERMA-THIN™ gloves. (*Id.* at 41-44.) Specifically, Respondents argue that the DERMA-THIN™ glove disclosed a closely fitting glove with a tensile strength of at least 1500 psi, the SOLVEX® glove disclosed a nitrile butadiene rubber glove with a tensile strength of 1500 psi and relaxation properties such as those in the '616 Patent, and the Miller Patent disclosed a 5mil glove, all of which combined with the understanding of the alteration of chemical properties would lead one of ordinary skill in the art to find the '616 Patent obvious. (*Id.* at 43-44.)

Tillotson argues that the Miller Patent, alone or in combination with the state of art, fails to render the '616 Patent obvious. (CIB at 38.) Tillotson argues that the SOLVEX® glove is a fundamentally different glove from that of the '616 Patent, namely that it is a thick, stiff, loose-fitting industrial glove that cannot be stretched to fit about a hand and will restrict blood flow. (*Id.* at 38-39.) Tillotson argues that the DERMA-THIN™ glove is a natural rubber glove that only relaxes to 67% of its initial stress after 6 minutes and, as such, fails to meet the relaxation and nitrile butadiene limitations of the '616 Patent glove. (*Id.* at 39-40.) Tillotson further argues that the state of the art teaches away from the '616 Patent because it taught that stress relaxation

was an undesirable feature and it taught the use of high levels of zinc oxide when making nitrile films.[20] (*Id.* at 40.)

Staff argues that the Miller Patent alone does not render the '616 Patent invalid for obviousness based on the same reasons that the Miller Patent fails to render the '616 Patent anticipated and invalid. (SIB at 32.) Staff argues that the physical and mechanical differences between the glove claimed in the '616 Patent and the SOLVEX® and DERMA-THIN™ gloves fails to render the '616 Patent obvious, even in combination with the Miller Patent. (*Id.* at 32, note 27.) Staff further argues that the state of the art also fails to render the '616 Patent obvious because it did not teach the combination of thickness, modulus, tensile strength and relaxation that would create a close fitting glove that solved the squeezing caused by pressure on the hand. (*Id.* at 33.) Staff further argues that the '616 Patent solved the long standing problem of a close fitting glove that applied excessive pressure on the hand by using a solution, *i.e.,* stress relaxation to reduce pressure, that ran against conventional thought, which taught that relaxation was an undesirable feature of rubber composition. (*Id.* at 33.) Staff further argues that the use of the relaxation characteristics of nitrile rubber to solve the squeezing problem on the hand by a closely fitting glove and the level of relaxation taught in the '616 Patent was not known at the time of the invention. (*Id.* at 34.)

The Court finds that Respondents have failed to show by clear and convincing evidence that the '616 Patent is obvious in light of the prior art, including the Miller Patent, alone, or in combination with the SOLVEX® and DERMA-THIN™ gloves. As an initial matter, Respondents argue that the "teaching, suggestion, or motivation" test has been completely "eviscerated" in light of the Supreme Court's decision in *KSR.* (RRB at 21.) Respondents blatantly ignore the language of *KSR,* which still requires that there still needs to be a "reason to

[20] The '616 Patent teaches the use of lower zinc oxide levels. (CIB at 40.)

combine the known elements in the fashion claimed by the patent at issue." *KSR*, 127 S. Ct. at 1731. Respondents also ignore the Federal Circuit's recent decisions, which still use the "teaching, suggestion or motivation" test under a flexible approach rather than the past rigid approach, which was rejected by the Supreme Court. (*See Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364-65 (Fed. Cir. 2008) ("The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence--teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)--that arise before the time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans."); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1356-1357 (Fed Cir. 2007); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007.))

The Court finds that Respondents have failed to show how one of ordinary skill in the art with knowledge of modifying material to achieve certain elastic and relaxation properties would, combined with the Miller Patent, come up with the '616 Patent. Respondents argue that market forces would motivate one to modify the Miller Patent. Respondents have, however, failed to show how the Miller Patent combined with market forces of natural rubber latex allergies and the AIDS epidemic would lead one of ordinary skill in the art to create a closely fitting glove that relaxed to a reduced pressure of less than 50% of the initial pressure. (See RIB at 37-41; RRB at 20-22.) In other words, even assuming Respondents' argument of "evisceration" of the "teaching, suggestion, or motivation" test were correct, the Respondents still have failed to provide a correlation between, at a minimum, the relaxation properties of the '616 Patent and natural rubber latex allergies and the AIDS epidemic. Moreover, the Miller Patent was

considered by the patent examiner during the prosecution of the '616 Patent, but the examiner still found the '616 Patent to be patentable. (JX-4 at TLC000150-152; TLC000160 ('616 Prosecution History)); *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F. 2d 1464, 1467 (Fed. Cir. 1990) (particularly heavy burden in establishing invalidity on the same prior art that was examined in the PTO).

The Court further finds that the Miller Patent, in combination with the SOLVEX® and DERMA-THIN™ gloves fails to render the '616 Patent obvious. The Miller Patent combined the SOLVEX® and DERMA-THIN™ gloves were considered by the patent examiner during the prosecution of the '616 Patent, but, as noted above, the examiner still found the '616 Patent to be patentable. (JX-4 at TLC000150-152; TLC000160 ('616 Prosecution History)). The evidence shows that these prior art references fail to disclose various limitations of the '616 Patent. The SOLVEX® glove is a thick, stiff, loose-fitting industrial glove; the DERMA-THIN™ glove is a natural rubber glove that did not exhibit the relaxation properties of the claimed glove; and the Miller Patent fails to teach a glove that includes the relaxation properties disclosed in the '616 Patent. (*Id.* at TLC00040-50, TLC000184G-L; CX-839C at Q&A 83, 95, 107-8, 275, 282-83, 288, 333-37 (Moalli Rebuttal); Moalli, Tr. 1455:13-1456:14; Mills Tr. 866:6-13.) Moreover, Respondents fail to point to any reason to combine these different prior art references.[21] (*See* RIB at 41-44; RRB at 20-23.) Rather, the state of the art actually teaches away from the '616 Patent by teaching that stress relaxation was undesirable and that low stress relaxation was preferred. (CX-839C at Q&A 30-34, 71-76, 110; Mills, Tr. 867:17-868:17; Moalli Tr. 1546:13-24, 1602:16-1603:10; RX-183; Moalli, Tr. 1544:8-14; RX-12.)

[21] Tillotson argues that Respondents have improperly used hindsight in combining the prior art references. (CRB at 25-26.) The Court agrees. The relaxation data relied upon by Respondents were all collected by the applicants during the prosecution of the '616 Patent. In other words, Respondents use previously unknown data generated after the date of the invention to argue that such data was known prior to the invention.

2. Secondary Considerations

As indicated above, one of the *Graham* factors that must be considered in an obviousness analysis, is "objective evidence of nonobviousness," also called "secondary considerations." *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1536 (Fed. Cir. 1983) ("Thus evidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness."). However, secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l*, 127 S.Ct. at 1745 (commercial success did not alter conclusion of obviousness).

Respondents argue that the evidence of commercial success of the N-DEX glove cannot overcome the overwhelming evidence of obviousness. (RIB at 45-46.) Respondents further argue that Tillotson cannot show the required nexus between N-DEX's commercial success and the features of '616 Patent. (*Id.* at 45-46.) Specifically, Respondents argue that Tillotson has failed to show that the commercial success of the N-DEX gloves was a direct result of the relaxation features and that such success could be attributed to the natural rubber latex allergies and AIDS epidemic. (*Id.* at 46-47.)

Tillotson argues that the commercial success of the N-DEX glove, the commercial embodiment of the '616 Patent, supports the validity of the '616 Patent. (CIB at 40.) Tillotson argues that there was a long felt, unsolved need for the invention and that the industry recognized Tillotson for fulfilling that need. (*Id.* at 40-41.) Tillotson further argues that many in the glove industry have copied its invention and that, prior to the issuance of the '362 Patent, many were unable to create a thin nitrile glove, despite repeated efforts. (*Id.* at 41-42.) Tillotson further argues that the '616 Patent was and continues to be a major commercial success with Best

Manufacturing grossing tens of millions of dollars and cornering nearly 80% of the market. (*Id.* at 42-43.) Tillotson further argues that several manufacturers and distributors have taken licenses from Tillotson, while others, including Respondents, have continued to sell infringing gloves. (*Id.* at 43.) Tillotson argues that these secondary considerations clearly demonstrate that the '616 Patent is not obvious. (*Id.* at 44.)

Staff argues that the long felt need for the invention claimed in the '616 Patent and the significant commercial success are objective indicia showing non-obviousness. (SIB at 35.) Staff argues that the commercial success of the N-DEX glove, combined with Best Industry's market share, copying by others in the industry, and industry awards and recognition all indicate that the '616 Patent was not obvious. (*Id.* at 35.)

The Court further finds that secondary considerations weigh heavily against a finding of obviousness. Tillotson fulfilled a long felt but unsolved need by creating a closely fitting glove that allowed for dexterity without applying excessive pressure to the hand. (CX-838C at Q&A 30-54, 60, 62, 66 (Tanger Rebuttal); CX-839C Q&A 6-7 (Moalli Rebuttal).) Tillotson achieved great commercial success with its N-DEX glove, which embodied the glove disclosed in the '616 Patent, receiving industry recognition and awards (CX-787C at Q&A 43, 70 (Tanger Direct); CX-837 at Q&A 62, 85B, 105, 125 (Tillotson Rebuttal); CX-841C; CX-842C; CX-848C; CX-849C; CX-895-897C) and generating tens of millions in sales and capturing more than 80% of the non-vinyl synthetic examination glove market. (CX-838C at Q&A 52-53 (Tanger Rebuttal); CX-821C at TLC038438-441; CX-824C at TLC104783; CX-837C at Q&A 47 (Tillotson Rebuttal).). This commercial success is related to the improved comfort and dexterity of the N-DEX glove compared to traditional natural rubber gloves. (CX-838C at Q&A 36-40, 48 (Tanger Rebuttal); Tillotson Tr. 1253:5-15; Tanger Tr., 1360:10-1363:17; CX-822C; CX-846C.)

Tillotson also currently continues its success by licensing the '616 Patent, which generated nearly $ 5 million in revenue in 2006 and 2007, respectively. (CX-838C Q&A 63-70 (Tanger Rebuttal).) Thus, the Court finds that the forgoing considerations evidence non-obviousness of the '616 Patent.

Therefore, the Court finds that Respondents have failed to meet their burden of showing by clear and convincing evidence that the asserted claims of the '616 Patent are invalid for obviousness.

F. Best Mode

Section 112, ¶ 1 of Title 35 of the United States Code sets out the best mode requirement, stating in relevant part that "[t]he specification shall contain . . . and shall set forth the best mode contemplated by the inventor of carrying out the invention." 35 U.S.C. § 112 ¶ 1. The Court of Appeals for the Federal Circuit has held that "[t]he purpose of the best mode requirement is to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention." *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 418 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989). The determination of whether the best mode requirement is satisfied is a question of fact, which must be proven by clear and convincing evidence. *Transco Products Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 559-60 (Fed. Cir. 1994).

In determining compliance with the best mode requirement, two inquires are undertaken. The first inquiry is whether, at the time of filing the patent application, the inventor possessed a best mode of practicing the invention. *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001); *see also Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1223 (Fed.Cir. 2006); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed. Cir. 1987)

(The specificity of disclosure necessary to meet the best mode requirement is determined "by the knowledge of facts within the possession of the inventor at the time of filing of the application."). This first inquiry is subjective and focuses on the inventor's state of mind at the time the patent application was filed. *Eli Lilly*, 251 F.3d at 963. The second inquiry is, if the inventor did possess the best mode, whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. *Id.* This second inquiry is objective and depends on the scope of the claimed invention and the level of skill in the relevant art. *Id.*

The "contours of the best mode requirement are defined by the scope of the "claimed invention" and thus, the first task in any best mode analysis is to define the invention. *Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1286-87 (Fed. Cir. 2000). "The definition of the invention, like the interpretation of the patent claims, is a legal exercise, wherein the ordinary principles of claim construction apply." *Id.* Once the invention is defined, the best mode inquiry moves to determining whether a best mode of carrying out that invention was held by the inventor. If so, that best mode must be disclosed. In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), the Federal Circuit summarized its best mode jurisprudence as follows:

> We held that the best mode requirement does demand disclosure of an inventor's preferred embodiment of the claimed invention. However, it is not limited to that. We have recognized that best mode requires inventors to disclose aspects of making or using the claimed invention [when] the undisclosed matter materially affects the properties of the claimed invention.

Pfizer, 518 F.3d at 1364 (internal quotations and citations omitted).

Respondents argue that the '616 Patent is invalid for failure to disclose the best as required under 35 U.S.C. § 112, ¶ 1. (RIB at 48.) Specifically, Respondents argue that the inventors failed to disclose their preferred mode for practicing the claimed invention, namely the

use of Reichhold 68073 as the nitrile butadiene rubber. (*Id.* at 48-49.) Respondents argue that the inventors failed to disclose their preference of using Reichhold 68073, even though Mr. DeBecker considered it one of the components that made their invention unique. (*Id.* at 50-52.) Respondents further argue that the inventors failed to disclose the fact that they considered Reichhold 68074 to be an inferior rubber for their claimed invention and that the inventors' laboratory notebook confirmed their preference for Reichhold 68073. (*Id.* at 52-55.)

Respondents argue that Tillotson concealed its best mode, noting that "Example 1 Latex Formulation" contained trade names for some of the "relatively minor" ingredients yet failed to identify Reichhold 68073 as the preferred nitrile butadiene rubber. (*Id.* at 55-56.) Respondents argue that the inventors specifically deleted the trade name for their preferred nitrile butadiene rubber even though the inventors considered it to be the most critical aspect of their invention. (*Id.* at 56.)

Respondents further argue that Tillotson's legal arguments incorrectly state the law: (1) Tillotson incorrectly focuses on the superiority of Reichhold 68073 when the focus should be on the inventor's subject belief at the time of the application is controlling; (2) Tillotson incorrectly focuses on whether the inventors deliberately concealed Reichhold 68073 when deliberate concealment is not an element of best mode defense; (3) Tillotson incorrectly argues that nitrile rubber latex was not claimed when the best mode need only relate to an aspect recited in the claims but need not be the entire claimed invention; (4) the commercial availability of Reichhold 68073 does not absolve Tillotson of the obligation to disclose its best mode; (5) Tillotson confuses the best mode requirement with the enablement requirement; and (6) Tillotson's argument that its selection of Reichhold 68073 was merely a "production detail" is

not enough to meet its best mode requirement because Tillotson is required to disclose any specific techniques recognized at the time of filing. (*Id.* at 58-60.)

Tillotson argues that Mr. DeBecker testified that he did not believe that the particular latex made the N-DEX glove different from earlier gloves and that he and Mr. Tillotson believed that they could get "good relaxation" from other types of latex as well. (CIB at 52.) Tillotson further argues that the decision to use Reichhold 68073 was based on reasons other than the relaxation properties of latex, namely production details and commercial and manufacturing considerations. (*Id.* at 52-53.) Tillotson further argues that there is no evidence that Reichhold 68073 was any better than other nitrile lattices and that one of ordinary skill in the art would realize that other brands of nitrile latex could be used. (*Id.* at 53.) Tillotson further argues that it continued to experiment with different nitrile lattices even after the '362 Patent and the '616 Patent had been issued. (*Id.* at 53.) Tillotson further argues that there is no evidence of "deliberate concealment" because, as Mr. DeBecker testified, the "patentable" portion of the invention was that it was a nitrile glove and that all other ingredients of the N-DEX formula were relatively minor. (*Id.* at 53.)

Staff agrees and argues that Respondents have failed to show by clear and convincing evidence that Mr. DeBecker and Mr. Tillotson failed to disclose the best mode. (SIB at 23-24.) Staff argues that the '616 Patent does not claim nitrile rubber latex or a manner of making such latex; that the specification identifies carboxylated nitrile butadiene rubber as one of the starting materials in producing the glove; and that the inventors' failure to list the particular brand of nitrile butadiene rubber does not rise to a best mode violation. (*Id.* at 23.) Staff argues that the inventors' decision to use a particular brand of latex was a commercial consideration and, as such, was not required to be disclosed under the best mode requirement. (*Id.* at 24.)

Staff further argues that the disclosure a production or routine detail, such as a particular brand of commercially available nitrile latex is not required since it would be readily apparent to one of ordinary skill in the art. (*Id.* at 23.) Staff further argues that Mr. DeBecker explained his reasons as to why he chose Reichhold 68073, namely the large quantities of that latex at the plant, which Staff argues is a commercial consideration not related to the quality or nature of the invention. (*Id.* at 24.) Staff further argues that since the inventors disclosed nitrile butadiene rubber and one of ordinary skill in the art would be able to choose any brand of commercially available latex, then the disclosure of a specific brand is merely routine detail. (*Id.* at 24.)

The Court finds that Respondents have failed to show by clear and convincing evidence that the inventors, Mr. DeBecker and Mr. Tillotson, failed to disclose their best mode for practicing the claimed invention. Respondents argue that Mr. DeBecker's statement that "We felt we could get a better glove with [Reichhold 680]73" and his lab notebook, which Respondents argue shows a clear preference for Reichhold 68073, is evidence that the inventors preferred Reichhold 68073 and that their failure to disclose this preference violates the best mode requirement. The Court disagrees. First, the evidence shows that Mr. DeBecker did not consider Reichhold 68073 the "best" latex and that he believed that he could get "good relaxation with other latexes as well." (DeBecker, Tr. 702:16-17.) Second, Mr. DeBecker specifically stated that the decision to use Reichhold 68073 was based on reasons other than those related to the relaxation properties of that latex:

> Q. Yet somehow between the time your laboratory notebook was written and the time this '362 application was filed, the key element, the latex designation, 68073, was deleted, other trade names were maintained and other trade names were actually added to the recipe that you disclose in example 1, correct?
>
> A. I don't know deleted. It is not there.
>
> Q. Okay.

A. At the time we knew that we could get good relaxation with other latexes. I think it shows in my lab book we could get good relaxation with a 68074 also. So we realized that what we needed was a carboxylated nitrile butadiene latex, not that we necessarily needed the specific 68073 latex.

Q. You didn't need it, but it was the best one you found, wasn't it?

A. Not for relaxation specifically.

Q. But for your glove, it was the best one, wasn't it?

A. But for other reasons. The patent is about relaxation.

(DeBecker, Tr. 702:6-703:4.) Mr. DeBecker testified that the other reasons for preferring Reichhold 68073 included its ready availability at the plant since it was being used to manufacture other gloves and since there were already appropriate storage tanks for large quantities of it. (DeBecker, Tr. 851:17-25.) Mr. DeBecker further testified that to introduce "a different raw material" would require addition storage tanks and that the decision to use Reichhold 68073 was because "it was really simpler to use that which we already had on hand." (DeBecker, Tr. 851:7-852:5.) Thus, the evidence does not show clearly and convincingly that Mr. DeBecker preferred Reichhold 68073 because it was better than any other latex. Rather, the evidence shows that decision to test and use Reichhold 68073 was based on a production detail, *i.e.*, what Tillotson already had available in large quantities.

Even assuming that Mr. DeBecker considered the use of Reichhold 68073 to be the best mode, the Court finds that the evidence does not clearly and convincingly show that the written description failed to disclose the best mode such that one of ordinary skill could not practice it. The claimed invention is directed to "a closely fitting glove comprising a layer elastomeric material (a) comprising nitrile butadiene rubber." (JX-3 at 6:33-34 ('616 Patent).) The claimed invention is not directed to a specific brand of nitrile rubber or even the production of nitrile

rubber such that absent the preferred brand of latex, one could not practice the claimed invention. Moreover, the '616 Patent specification further lays out a specific formula for one of ordinary skill in the art to practice the invention and lists carboxylated nitrile butadiene rubber as its first ingredient. ('616 Patent, 5:35-45.)

The fact that Mr. DeBecker and Mr. Tillotson had a preferred brand of commercially available nitrile butadiene rubber, Reichhold 68073, which was not disclosed in the '616 Patent, does not rise to a best mode violation. Rather, "the best mode requirement does not extend to production details or routine details." *Eli Lilly*, 251 F.3d at 963. The Federal Circuit explained:

> However, the best mode requirement does not require an inventor to disclose production details so long as the means to carry out the invention are disclosed. This includes providing supplier/trade name information where it is not needed, i.e., where such information would be "mere surplusage -- an addition to the generic description." Such supplier/trade name information must be provided only when a skilled artisan could not practice the best mode of the claimed invention absent this information.

Transco Prods. v. Performance Contracting, 38 F.3d 551, 560 (Fed. Cir. 1994) (internal citations omitted). Here, there is no evidence that one of ordinary skill in the art could not practice the invention based absent the disclosure of the use of Reichhold 68073.

Therefore, the Court finds that the '616 Patent is not invalid for failure to disclose best mode.

G. Enablement

Section 112, ¶ 1 of Title 35 requires that the specification describe the manner and process of making and using the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."

The issue of whether a disclosure is enabling is a matter of law. *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1575 (Fed. Cir. 1996). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). "Patent protection is granted in return for an enabling disclosure of an invention, not for vague, intimations of general ideas that may or may not be workable." *Id.* at 1366. Although a specification need not disclose minor details that are well known in the art, "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement," and in so doing the specification cannot merely provide "only a starting point, a direction for further research." *Id.* On the other hand, "[i]t is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification." *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). "Undue experimentation" is "a matter of degree" and "not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ...." *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

It is well-settled that in order to be enabling under Section 112, "the patent must contain a description sufficient to enable one skilled in the art to make and use the full scope of the claimed invention." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988); *see also Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (inventor's disclosure must be "sufficient to enable one skilled in the art to carry out the

invention commensurate with the scope of his claims"). Section 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to such persons. *Application of Fischer*, 427 F.2d 833, 839 (C.C.P.A. 1970).

Respondents argue that the specification of the '616 Patent does not enable the full scope of the claims. (RIB at 62.) Specifically, Respondents argue that the specification fails to specify whether the nitrile butadiene rubber ("NBR") is carboxylated or non-carboxylated and the '616 claims can encompass both possibilities. (*Id.* at 62.) Respondents' expert, Dr. Mills, concluded that while some carboxylated NBR gloves could be made, it would take a substantial amount of experimentation to make non-carboxylated NBR gloves due to the large number of candidate materials and parameters. (*Id.* at 63.) Dr. Mills further testified that the limited information and failure to disclose a working embodiment of a non-carboxylated NBR glove in the '616 Patent would cause undue experimentation. (*Id.* at 63-64.) Respondents further argue that if one of the inventors, Mr. DeBecker, could not make embodiments within the scope of the claims without undue experimentation, then clearly one of ordinary skill in the art also could not. (*Id.* at 64-65.)

Tillotson argues that Respondents have failed to meet their burden of showing by clear and convincing evidence that the asserted claims fail to satisfy the enablement requirement. (CIB at 46-47.) Tillotson argues that Respondents proffer only conclusory statements from Dr. Mills and that Dr. Mills only testified that it would take a substantial amount of experimentation and not "undue" experimentation to produce a non-carboxylated NBR glove. (*Id.* at 47.) Tillotson argues that one of ordinary skill in the art could create a non-carboxylated NBR glove without undue experimentation because the composition of both carboxylated and non-carboxylated NBR are similar; because they are compounded in the same manner to produce articles; and because the mechanical properties of both are affected in a similar manner. (*Id.* at

47-48.) Tillotson further argues that Mr. DeBecker and Dr. Moalli testified that while neither had made a non-carboxylated NBR glove, that it was possible to create one with the properties claimed in the '616 Patent. (*Id.* at 48.) Tillotson further argues that one of ordinary skill in the art could create a non-carboxylated NBR glove based on the teachings of the '616 Patent without undue experimentation because of the information available on non-carboxylated NBR in 1990. (*Id.* at 48-49.) Staff agrees and argues that Respondents have failed to meet their burden for the same reasons argued by Tillotson above. (SIB at 25-27.)

The Court finds that Respondents have failed to show by clear and convincing evidence that the '616 Patent fails to meet the enablement requirement. First, Dr. Mills testified that it would only take "substantial experimentation" to produce a non-carboxylated NBR glove, but did not testify that it would require "undue experimentation." (RX-162C at Q&A 135 (Mills Direct).) Undue experimentation is required for a patent to fail the enablement requirement. *See Genentech,* 108 F.3d at 1365; *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed.Cir.1986) (enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive"); *Wands*, 858 F.2d at 737 ("a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed"). Dr. Mills further testified that there was information in 1990 regarding the use of non-carboxylated NBR in the thin film. (*Id.* at Q&A 137.) The evidence further shows that: (1) both carboxylated and non-carboxylated NBR contain essentially the same constituents (butadiene and acrylonitrile) with carboxylated NBR having an acid group for additional cross-linking; (2) there was some knowledge in the art as to the effect of non-carboxylated NBR on relaxation; (3) when formulating products, both non-

carboxylated and carboxylated NBR are typically combined with the same materials such as sulfur; and (4) the mechanical properties of both are affected to a similar degree by the various links and sulfur cross-links (which affect mechanical properties including tensile strength and stress relaxation), as well as by the length and structure of the individual polymer chains. (Moalli, Tr. 1465:9-1466:11; 1469:20-24; CX-839C at Q&A 8-24 (Moalli Rebuttal); RX- 162C at Q&A 34, 117, 137 (Mills Direct).).

The evidence further shows that information relating to changes in the chemistry and processing of both carboxylated and non-carboxylated NBR that led to increased tensile strength would also reduce relaxation was readily available, thereby allowing persons of skill in the art obtain the desired relaxation for a given non-carboxylated NBR glove in view of such information. (CX-839C at Q&A 16-17, 22-23 (Moalli Rebuttal).) The evidence further shows that it would be possible to formulate a glove meeting the limitations of claim 1 using non-carboxylated NBR as well as carboxylated NBR. (Moalli, Tr. 1465:1-18; DeBecker, Tr. 854:5-16.)

Therefore, the Court finds that Respondents have failed to meet their burden of showing by clear and convincing evidence that the '616 Patent fails to meet the enablement requirement.

H. Definiteness

Respondents did not address definiteness in its invalidity section in its post-hearing brief, and Respondents have waived any arguments with regard to this affirmative defense. Respondents extensively briefed this issue in their combined pre-hearing brief and presented expert testimony at the hearing. (*See* Respondents Combined Pre-hearing Brief at 131-137; l *see also* RX-162C (Mills Direct) and RX-324 (Begley Direct); *see generally* Mills, Tr. 863- Begley, Tr. 1115-1124 .) However, Respondents did not address definiteness at all in its initial post-

hearing brief. (*See generally* RIB at 48-67.) Therefore, pursuant to Ground Rule 11.1, Respondents have waived any arguments relating to indefiniteness.

VI. UNENFORCEABILITY

A. Applicable Law

A patent is unenforceable on grounds of "inequitable conduct" if the patentee withheld material information from the PTO with intent to mislead or deceive the PTO into allowing the claims. *LaBounty Mfr., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1070-1074 (Fed. Cir. 1992). Both materiality and intent must be proven by clear and convincing evidence. *Id.*; *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989); *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, Unreviewed Initial Determination at 76, 1995 WL 1049822 (U.S.I.T.C. November 6, 1995), *aff'd sub nom. Kaken Pharmaceutical Co., Ltd. v. U.S. Int'l Trade Comm'n*, 111 F.3d 143 (Fed. Cir. 1997) (Table) (nonprecedential) ("*Salinomycin*"). When inequitable conduct occurs in relation to one or more claims of a patent, the entire patent is unenforceable. *Kingsdown*, 863 F.2d at 874.

According to the rules of the PTO, the duty to disclose information "exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim." 37 C.F.R. § 1.56(a).

Generally, when withheld information is highly material, a lower showing of deceptive intent will be sufficient to establish inequitable conduct. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir.), *cert. denied*, 469 U.S. 821 (1984). Moreover, "[d]irect proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." *LaBounty*, 958 F.2d at 1076; *Salinomycin*, ID at 77. The conduct at issue must be viewed in light of all the evidence, including evidence of good faith. *Kingsdown*, 863 F.2d at 876; *Salinomycin*, ID at 77.

"Information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *LaBounty*, 958 F.2d at 1074; *Salinomycin*, ID at 77. A patent applicant, however, has no obligation to disclose a reference that is cumulative or less pertinent than those already before the examiner. *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439-40 (Fed. Cir. 1991). Under the rules of the PTO, information is material when it is not cumulative to information of record and it either (i) "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim"; or (ii) "it refutes, or is inconsistent with, a position the applicant takes" in either opposing the PTO's argument of unpatentability or asserting the applicant's own argument of patentability. 37 C.F.R. § 1.56(b). Close cases, however, "should be resolved by disclosure, not unilaterally by applicant." *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002) *quoting LaBounty,* 958 F.2d at 1076.

Respondents argue that the asserted claims of the '616 Patent are unenforceable by reason of inequitable conduct for three reasons. First, Mr. Tillotson submitted a false reissue declaration to the PTO during the prosecution of the '616 Patent. (RIB at 24.) The second reason is the failure to disclose the unreliability of the Scott Tester data upon which the inventors

relied upon to support the reissue of Claim 23. (*Id.* at 28.) The third reason is the failure to disclose that the Q-Test was used instead of the Scott Tester to obtain the test results to overcome prior art. (*Id.* at 32.)

B. Reissue Declaration

Respondents argue that "Tillotson could only avoid a finding that the failure to originally disclose the prior art DERMA-THIN™ and SOLVEX ® gloves was with deceptive intent by further deceptive intent – representing to the PTO that it had not been aware of those gloves until after the original '362 patent issued. It willfully did just that." (RIB at 25.) Respondents argue that the patent examiner relied on these false statements that the inventors were unaware of the DERMA-THIN™ and SOLVEX ® gloves and that such reliance is evidenced by the fact that the '616 Patent issued. (*Id.* at 25-26.) Respondents argue that the evidence shows that the inventors were aware of the prior art gloves and that Tillotson has not and cannot present any evidence to the contrary. (*Id.* at 27.) Respondents argue that the intentional misrepresentation of the inventors' alleged ignorance of the DERMA-THIN™ and SOLVEX ® gloves clearly constitutes inequitable conduct rendering the '616 Patent invalid. (*Id.* at 27-28.)

Tillotson argues that the Reissue Declaration did not contain any false statements and that Respondents have failed to meet their burden of showing by clear and convincing evidence that such statement was material or that it was made with intent to deceive the PTO. (CIB at 83.) Tillotson argues that the Reissue Declaration and the Supplemental Reissue Declaration further state that the inventors were not aware of the elastic properties of the DERMA-THIN™ and SOLVEX ® gloves and that the PTO was well aware of the fact that the DERMA-THIN™ gloves were manufactured by Tillotson's wholly owned subsidiary. (*Id.* at 84.) Tillotson further argues that Respondents failed to present evidence that the inventors were aware of the SOLVEX

® glove or its relaxation properties prior to 1993 or that Mr. Tillotson, the declarant on the Reissue and Supplemental Reissue Declaration, was aware of the relaxation properties of the DERMA-THIN™ glove. (*Id.* at 85.) Tillotson further argues that, even assuming that the statements were false, Respondents have failed to show that the statements were considered material to patentability. (*Id.* at 85.) Tillotson further argues that Respondents have failed to show that the statements were made with an intent to deceive the PTO. (*Id.* at 85-86.)

Staff argues that, while it is a close call, the evidence does establish that the inventors acted with intent to deceive the PTO. (SIB at 48-49.) Staff acknowledges that while the statements are material, there is evidence that shows that there was no intent to deceive the PTO with the false statements. (*Id.* at 49.) Specifically, Staff argues that Mr. DeBecker's limited role in the actual reissue application process, outside of providing test data, evidences a material mistake which does not rise to an actual intent to deceive the PTO. (*Id.* at 49-50.)

The Court finds that Respondents have failed to show by clear and convincing evidence that the inventors acted with intent to deceived the PTO. As an initial matter, the Court finds that the inventors' knowledge of the DERMA-THIN™ and SOLVEX ® gloves prior to 1993 is material. More than just knowing of the gloves existence, the inventors would have to realize that the property of the gloves made them relevant to the invention. The DERMA-THIN™ glove was a natural latex glove, the SOLVEX ® was a thick industrial glove. While the inventors may have known the two existed, they did not realize they could be relevant to the invention. These gloves form the basis for reissue application and are listed in the Information Disclosure Statement of the reissue application. (JX-4 at TLC000184B-G and at TLC00059-61 ('616 Prosecution History).) Specifically, the Court finds that it was not merely the inventors' knowledge of the existence of the gloves that is material, but whether the inventors realized that

the properties of these gloves made them relevant to the invention claimed in the '616 Patent. Therefore, the inventors' knowledge of the properties of these prior art gloves is highly material to the '616 Patent.

The Court finds, however, that the evidence fails to establish by clear and convincing evidence that the inventors intended to deceive the PTO. First, statements within the Supplemental Reissue Declaration and Reissue Declaration weigh against finding an intent to deceive. Respondents argue that Mr. Tillotson's statement that neither he nor Mr. Pappas were aware of the prior art in the information disclosure statement prior to the issuance of the '362 Patent is plainly false and that Mr. Tillotson lied about his knowledge in order to deceive the PTO in order to obtain the reissue patent. (RIB at 24-28.) The Court notes, however, that Mr. Tillotson further explained in the declaration that "[n]either Applicant nor his attorney were aware of the *elastic properties* of the SOLVEX ® or DERMA-THIN™ glove prior to 1993." (JX-4 at TLC000184F ('616 Prosecution History) (emphasis added).) Such a clarification evidences a good faith effort on the inventors' part to explain their position, *i.e.*, what they did not know, to the examiner and the PTO and provide more complete and full disclosure. In addition, the inventors conducted extensive testing of the prior art samples, indeed they went through great efforts to recreate certain samples, in an effort to disclose the properties of these gloves. (CX-836C at Q&A 291-293 (DeBecker Rebuttal); DeBecker Tr., at 694:16-695:2.) This further evidences good faith on the part of the inventors during the reissue application process. The conduct at issue must be viewed in light of all the evidence, including evidence of good faith. *Kingsdown*, 863 F.2d at 876; *Salinomycin*, ID at 77.

In addition, the Court had the opportunity to take testimony from one of the inventors, Mr. DeBecker, and found him to be an extremely credible and honest witness. Mr. DeBecker

testified that he knew about the SOLVEX ® or DERMA-THIN™ gloves. (DeBecker, Tr. 779:23-780:6.) Mr. DeBecker further testified, however, that he had a limited role in the reissue prosecution and did not recall having a role in preparing any declaration. (CX-786C at Q&A 54-59 (Moalli Direct); DeBecker, Tr. 767:4-14; 770:14-771:4; 776:10-20.) Mr. DeBecker further testified that he did not review the reissue declaration and did not see the statement about not knowing about the relaxation properties of the prior art gloves. (DeBecker Tr., 783:15-20.) While Mr. DeBecker acknowledged receiving information about the reissue application and the process, he candidly admits that he probably did not read the "legal stuff." (DeBecker Tr., 772:6-25.) Quite simply, it appears that Mr. DeBecker chose to focus on his job, which was to create the samples and test them, and neglected to follow Mr. Pappas's instructions to carefully read over the "legal stuff" and the reissue declaration. Such neglect, however, does not appear to be based on a purposeful decision to ignore Mr. Pappas's instructions so much as the fact that, based on Mr. DeBecker's testimony and demeanor at the hearing, Mr. DeBecker was focused on the task assigned to him – namely to test the prior art samples.

Moreover, there is no clear and convincing evidence that Mr. Tillotson, the declarant in the reissue declaration, knew of the SOLVEX ® glove prior to 1993.[22] Respondents' main argument appears to be that Mr. Tillotson should have known about this glove (DeBecker Tr., 780:12-782:4.) and that should suffice for the Court infer that Mr. Tillotson did know and that he purposefully lied about knowing, without having to identify "specific evidence." (RRB at 15-16.) While Respondents are correct in that intent to deceive is often "proven by the acts, the natural consequences of which are presumed intended by the actor," the Federal Circuit has also stated that "the involved conduct viewed in light of all the evidence, including evidence indicative of

[22] Mr. DeBecker stated that he did not discuss the test results of relaxation properties of the DERMA-THIN™ gloves that he obtained in 1990 with Mr. Tillotson because, at the time, Mr. DeBecker did not consider that glove to be pertinent to the '362 Patent. (CX-836C at Q&A 263-266 (DeBecker Rebuttal).)

good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown*, 863 F.2d at 876. Therefore, given the totality of circumstances, the Court finds that Respondents have failed to meet their burden of showing by clear and convincing evidence that the reissue declaration was submitted with an intent to deceive.

C. Scott Tester Data

Respondents argue that the inventors were aware that the Scott Tester was unreliable, particularly at low stress levels. (RIB at 28.) Respondents argue that the inventors knew that the Scott Tester and Q-Tester machine differed by 44 percentage points; that as the pressure approached zero, the Scott Tester became unreliable;[23] that the inventors still submitted unreliable Scott Tester data to the PTO; and that the inventors withheld the known unreliability of the Scott Tester data from the PTO. (*Id.* at 28-29.)

Respondents argue that the unreliability of the Scott data was highly material and that such information should have been disclosed to the PTO because the PTO relied on the data generated by the Scott Tester in granting claim 23. (*Id.* at 30.) Respondents argue that Mr. Tillotson purposely withheld this information and that Mr. Tillotson's failure to disclose this information to his patent attorney where he knew, or should have known, that the information would be material implied intent to deceive the PTO. (RIB at 30.) Respondents further argue that this failure to disclose information regarding the unreliability of the Scott Tester to Mr. Tillotson's own patent attorney, Mr. Pappas, coupled with the high materiality of the information, creates a strong inference of intent to deceive. (*Id.* at 30-31.) Respondents argue that this is clear evidence of inequitable conduct on the part of Mr. Tillotson and renders the claims of the '616 Patent invalid.

[23] Claim 23 claims "[a] glove as in claim 1, wherein the layer of elastomeric material is further characterized by having elastomeric properties such that said reduced pressure is about zero." (JX-3 at 8:25-28 ('616 Patent).)

Tillotson argues that Respondents have failed to show by clear and convincing evidence that the prosecution of Claim 23 was inequitable because of the inventors' reliance on the data generated by the Scott Tester. (CIB at 86-87.) Tillotson argues that the evidence shows that the data generated by the Scott Tester and submitted to the PTO was accurate and that Mr. Tillotson reasonably believed and relied on this fact without intent to deceive. (*Id.* at 86-87.) Tillotson argues that the evidence shows that the Scott Tester was an accurate testing device, despite the fact that it sometimes produced variable results. (*Id.* at 87.) Tillotson further argues that Mr. Tillotson's preference for the Scott Tester was based on his own repeated use of the throughout the course of his working life. (*Id.* at 87-88.) As noted below, Mr. DeBecker confirmed this and testified that Mr. Tillotson preferred the Scott Tester and believed it to be reliable.

Staff argues that the evidence is far from clear and convincing to establish inequitable conduct. (SIB at 50.) Staff argues that, even assuming that such information was material, the evidence only shows that one inventor, Mr. Tillotson, preferred the Scott Tester while the other inventor, Mr. DeBecker, preferred the Q-tester. (*Id.* at 50.) Staff further argues that Mr. DeBecker did not think the Scott Tester was per se unreliable, but that he questioned the results of the Scott Tester at low pressure levels given his own experience and belief with the N-DEX gloves, which he felt relaxed to zero pressure. Staff further argues that Dr. Moalli testified that his own tests on the N-DEX gloves using the Instron machine yielded similar results to those reported in the Scott Tester and that the use of different machines to measure the properties set forth in the '616 Patent is contemplated in the ASTM D-412 standard. (*Id.* at 50-51.) The use of different machines will still yield similar results, assuming that the machines are properly calibrated and the tests are done in a similar manner. (*Id.* at 51.)

The Court finds that Respondents have failed to meet their burden of proving by clear and convincing evidence that the inventors committed inequitable conduct. First, the parties dispute whether the examiner found the test data generated by the Scott Tester to be material in granting claim 23.[24] (RIB at 28-29; CRB at 21; RRB at 17-18.) The Court finds that Respondents have failed to show that the reliability of the Scott Tester was material. Rather, Respondents simply make the statement that Tillotson's attorney, Mr. Pappas, would have found the information regarding the unreliability of the Scott Tester data "important to the PTO" and that "but for the withholding of this information, Claim 23 of the '616 reissue Patent would not have been allowed." (RIB at 30.) Respondents point to nothing in the prosecution history, however, evidencing that the examiner relied on any inaccurate data generated by the Scott Tester in granting Claim 23 of the '616 Patent.

Even assuming, however, that the reliability Scott Tester data at lower pressures was highly material, the Court further finds that Respondents have failed to show by clear and convincing evidence that Mr. Tillotson's failure to disclose this information was based on intent to deceive the PTO. Respondents argue that such intent is evidenced by a "standing policy" to report to the PTO only results that give the inventors the greatest advantage in defending their patent and a willingness to manipulate data that the inventors both recognized might be considered cheating. (RRB at 19.) The evidence shows, however, that the decision to submit the Scott Tester data came down to a matter of preference rather than intent to deceive. Mr. Tillotson preferred the Scott Tester data because of his familiarity with the machine, which he had used for several years, and his confidence in the results. (CX-836C at Q&A 217-218

[24] Respondents argue that Staff does not dispute the materiality of the Scott Tester data. However, the Court notes that the Staff never addresses the materiality of the data, rather the Staff specifically states that it "even assuming such information was material" that it did not find that Respondents had proven by clear and convincing evidence that there was intent to deceive the PTO. (SIB at 50.)

(DeBecker Rebuttal); CX-837C at Q&A 42-46 (Tillotson Rebuttal).) The evidence further shows that the decision not to disclose the fact that the Scott Tester produced unreliable and sometimes physically impossible results was based simply on the fact that the inventors *truly believed* that such results were unreliable based on their own experience, and not, as Respondents assert, on an intent to hide such results from the PTO. (CX-836C at Q&A 219-35 (DeBecker Rebuttal); RX-55C.00001; DeBecker, Tr. 737:4-8, 790:18-791:12,808:19-809:1, 810:13-16.) Moreover, the evidence further shows that the N-DEX gloves, do, in fact, reach zero pressure and, as such, the inventors belief in such results was reasonable. (CX-836C at 228-229 (DeBecker Rebuttal); CX-839C at Q&A at 289-91, 317-23 (Moalli Rebuttal); Moalli Tr. 1441:15-1445:9; CX-45; CX-74.)

Therefore, the Court finds that Respondents have failed to show by clear and convincing evidence that the inventors conducted inequitable conduct by failing to disclose the unreliability of the Scott Tester at lower stress levels.

D. Q-Test Machine

Respondents argue that the inventors committed inequitable conduct by failing to disclose the fact that they used the Q-Test to obtain the test results needed to overcome the prior art Miller patent instead of using the Scott Tester, which the inventors used on their own N-DEX gloves. (RIB at 32-33.) Respondents failed to raise this basis as evidence of inequitable conduct in their pre-hearing brief.[25] (See Respondents Combined Pre-hearing Brief at 157-168.) Therefore, pursuant to Ground Rule 8(f), Respondents have waived any arguments relating to this inequitable conduct defense.

[25] Indeed, it appears that Respondents originally only intended to rely on two bases for inequitable conduct because it specifically stated in the introduction to its unenforceability arguments that "[t]he '616 reissue patent is unenforceable by reason of Tillotson's inequitable conduct in *two* independent regards." (RIB at 22) (emphasis added.)

VII. DOMESTIC INDUSTRY

As stated in the notice of investigation, a determination must be made as to whether an industry in the United States exists as required by subsection (a)(2) of section 337. Section 337 declares unlawful the importation, the sale for importation or the sale in the United States after importation of articles that infringe a valid and enforceable U.S. patent only if an industry in the United States, relating to articles protected by the patent . . . concerned, exists or is in the process of being established. There is no requirement that the domestic industry be based on the same claim or claims alleged to be infringed. 19 U.S.C. § 1337(a)(2).

The domestic industry requirement consists of both an economic prong (*i.e.,* there must be an industry in the United States) and a technical prong (i.e., that industry must relate to articles protected by the patent at issue). *See Certain Ammonium Octamolybdate Isomers,* Inv. No. 337-TA-477, Comm'n Op. at 55, USITC Pub. 3668 (Jan. 2004). The complainant bears the burden of proving the existence of a domestic industry. *Certain Methods of Making Carbonated Candy Products,* Inv. No. 337-TA-292, Comm'n Op. at 34-35, USITC Pub. 2390 (June 1991).

Thus, in this investigation Tillotson must show that it satisfies both the technical and economic prongs of the domestic industry requirement with respect to the '616 Patent. As noted, and as explained below, it is found that these domestic industry requirements have been satisfied.

A. Technical Analysis

A complainant in a patent-based Section 337 investigation must also demonstrate that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *also see Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Commission Opinion at 8, 1996 WL 1056095 (U.S.I.T.C., January 16, 1996) ("*Certain Microsphere Adhesives*"), *aff'd sub nom.*

Minnesota Mining & Mfg. Co. v. U.S. Int'l Trade Comm'n, 91 F.3d 171 (Fed. Cir. 1996) (Table); *Certain Encapsulated Circuits*, Commission Opinion at 16. The complainant, however, is not required to show that it practices any of the claims asserted to be infringed, as long as it can establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40, 2005 ITC LEXIS 374, *26 (April 11, 2005). Fulfillment of this so-called "technical prong" of the domestic industry requirement is not determined by a rigid formula, but rather by the articles of commerce and the realities of the marketplace. *Certain Diltiazem Hydrochloride and Diltiazem Preparations*, Inv. No. 337-TA-349, U.S.I.T.C. Pub. No. 2902, Initial Determination at 138, 1995 WL 945191 (U.S.I.T.C., February 1, 1995) (unreviewed in relevant part) ("*Certain Diltiazem*"); *Certain Double-Sided Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-215, 227 U.S.P.Q. 982, 989 (Commission Opinion 1985) ("*Certain Floppy Disk Drives*").

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C., May 21, 1990) ("*Certain Doxorubicin*"), *aff'd*, Views of the Commission at 22 (October 31, 1990). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Id.* As with infringement, the first step of claim construction is a question of law, whereas the second step of comparing the article to the claims is a factual determination. *Markman,* 52 F.3d at 976. The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery*, Inv. No. 337-TA-419, Order

No. 43, 1999 ITC LEXIS 245, *7 (July 30, 1999). The patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. *See Bayer,* 212 F.3d at 1247.

1. N-DEX Gloves

Tillotson argues that its nitrile rubber gloves practice claim 1 of the '616 Patent. (CIB at 28.) Specifically, Tillotson argues that its (1) N-DEX; (2) N-DEX Nighthawk Defender Nitrile Powder Free Textured Fingertips Accelerator-Free; (3) Ultimate N-DEX Free Nitrile Medical Examination Gloves Powder Free; (4) N-DEX Nitrile Medical Examination Gloves Powder Free; (5) N-DEX Free Nitrile Medical Examination Gloves Powder Free; (6) N-DEX Nitrile Glove; (7) Best 8 mil compound (4 mil); (8) Best Black compound (4 mil); and (9) Best NitriCare compound (4 mil) (collectively, the "Tillotson Gloves") practice claim 1 of the '616 Patent. (*Id.* at 28.) Dr. Moalli performed the same tests on the Tillotson Gloves that he did on respondents' accused gloves as set forth *supra* IV.B., *e.g.*, glove fit, composition, water and water vapor permeability, tensile strength, thickness and puncture resistance. (CIB at 29; CX-45; CX-74; CPX-173-181.) Dr. Moalli concluded that Tillotson's Gloves practice those claim limitations of claim 1 of the '616 Patent. (CIB at 29; CX-45; CX-74.) Staff also does not dispute that Tillotson's Gloves practice these claim limitations. (SIB at 53.) Respondents do not dispute that Tillotson's Gloves practice these claim limitations. (RIB at 89.)

Respondents argue, however, that the Tillotson Gloves do not practice the relaxation limitation of claim 1 of the '616 Patent. (RIB at 89.) Respondents argue that the Tillotson Gloves fail to satisfy the relaxation limitation of claim 1 as set forth in Section IV.B.1.a.)(5). (RIB at 89.) Respondents likewise argue that the Tillotson Gloves failed to meet the relaxation limitation under the Del Vecchio Test. (RIB at 89; *supra* Section IV.B.1.a.)(5).) Respondents

state that the Tillotson Gloves do not practice claim 1 of the '616 Patent and that Tillotson fails to meet the technical prong of the domestic industry requirement.

Staff argues that it views the 100% modulus test as the test that should be applied to determine if the relaxation is met. Staff argues that the results of Dr. Moalli's 100% modulus test show that the Tillotson Gloves have met the relaxation limitation of claim 1. (SIB at 53.)

For the reasons set forth above in Section IV.B.1.a)(5), the Court found that the 100% modulus was an acceptable test to determine whether the relaxation requirement of claim 1 was satisfied. (*See supra* Section IV.B.1.a)(5)(a).) The Court further found that the Del Vecchio Test was not an acceptable test for determining whether the relaxation requirement had been satisfied and found the data produced from the test unreliable. (*See supra* Section IV.B.1.a)(5)(b).) Therefore, the Court finds that the evidence shows that, based on the 100% modulus test, the Tillotson Gloves relax to initially exerting an initial pressure on the hand and thereafter still fitting closely about the hand, but relaxing, within about 6 minutes after the gloves is stretched to fit about said hand, to exert on the hand a reduced pressure which is less than about 50% of the initial pressure. (CX-45; CX-74.) The Court finds that the Tillotson Gloves meet the relaxation claim limitation and other limitations of claim 1 of the '616 Patent. Therefore, the Court finds that the Tillotson Gloves satisfy the technical prong of the domestic industry requirement.

Assuming that Tillotson failed to establish that the Tillotson Gloves practice the '616 Patent, Tillotson still satisfies the domestic industry requirement as set forth below. *See infra* Section VII.B.

B. Economic Analysis

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

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark or mask work concerned –
>
> (A) Significant investment in plant and equipment;
> (B) Significant employment of labor or capital; or
> (C) Substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

The economic prong of the domestic industry requirement is satisfied by meeting the criteria of any one of the three factors listed above.

The economic domestic industry requirement has been satisfied as per the Initial Determination of the Court of May 6, 2008 (Order No. 79: Initial Determination Finding That Complainant Has Satisfied the Economic Prong of the Domestic Industry Requirement). The Commission determined not to review the order. (*See* Notice of Commission Decision Not to Review an Initial Determination Granting A Motion for Summary Determination That The Economic Prong of the Domestic Industry Requirement Has Been Met (May 30, 2008).)

As the Staff briefly noted in its initial post hearing brief, Tillotson is also exploiting the '616 Patent through its licensing activities. (SIB at 54-55.)

Section 337(a)(3)(C) provides for domestic industry based on "substantial investment" in the enumerated activities, including licensing of a patent. *See Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-559, Initial Determination at 88 (May 11, 2007) ("*Certain Digital Processors*"). Mere ownership of the patent is insufficient to satisfy the domestic industry requirement. *Certain*

Digital Processors at 93. (Citing the Senate and House Reports on the Omnibus Trade and Competitiveness Act of 1988, S.Rep. No. 71. However, entities that are actively engaged in licensing their patents in the United States can meet the domestic industry requirement. *Certain Digital Processors* at 93. In establishing a domestic industry under Section 337(a)(3)(C), the complainant does not need to show that it or one of its licensees is practicing a patent-in-suit. *See Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-432, Order No. 13, at 11, (Jan. 24, 2001) ("*Certain Semiconductor Chips*"). The complainant must, however, receive revenue, e.g. royalty payments, from its licensing activities. *Certain Digital Processors,* at 93-95 ("Commission decisions also reflect the fact that a complainant's receipt of royalties is an important factor in determining whether the domestic industry requirement is satisfied...[t]here is no Commission precedent for the establishment of a domestic industry based on licensing in which a complainant did not receive any revenue from alleged licensing activities. In fact, in previous investigations in which a complainant successfully relied solely on licensing activities to satisfy section 337(a)(3), the complainant had licenses yielding royalty payments.") (citations omitted). *See also Certain Video Graphics Display Controllers and Products Containing Same*, Inv. No. 337-TA-412, Initial Determination at 13 (May 14, 1999) (*"Certain Video Graphics Display Controllers"*); *Certain Integrated Circuit Telecommunication Chips and Products Containing Same Including Dialing Apparatus*, Inv. No. 337-TA-337, U.S.I.T.C. Pub. No. 2670, Initial Determination at 98 (March 3, 1993) (*"Certain Integrated Circuit Telecommunication Chips"*); *Certain Zero-Mercury-Added Alkaline Batteries, Parts Thereof and Products Containing Same*, Inv. No. 337-TA-493, Initial Determination at 142 (June 2, 2004) (*"Certain Zero-Mercury-Added Alkaline Batteries"*); *Certain Semiconductor Chips*, Order No. 13 at 6 (Jan. 24, 2001); *Certain Digital*

Satellite System DSS Receivers and Components Thereof, Inv. No. 337-TA-392, Initial and Recommended Determinations at 11 (Dec. 4, 1997) ("*Certain Digital Satellite System DSS Receivers*").

The evidence shows that Tillotson continues its licensing-related activities of the '616 Patent at its headquarters in Lexington, Massachusetts and at its New Hampshire location where it employs seven people substantially involved in licensing and licensing-related activities, including identifying, approaching and negotiating with potential licensees, and maintaining and enforcing licensing agreements. (CX-788C at Q&A 105-115 (Tillotson Direct).) Tillotson also expends over $350,000 a year in connection with its licensing of the '616 Patent, which has resulted in over twenty-two license agreements. (*Id.* at Q&A 103, 116.) These licenses generate revenue of approximately $4 million per year. (*Id.* at 118.) The evidence shows that the '616 Patent plays an important role in Tillotson's licensing activities thereby provides a sufficient nexus those licensing activities and the '616 Patent. (*See also* Order No. 78 at 5 listing Undisputed Findings of Fact.) Therefore, the Court finds that Tillotson has also satisfied the domestic industry requirement under 337(a)(3)(C).

VIII. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties, and subject-matter jurisdiction over the accused products.
2. The importation or sale requirement of section 337 is satisfied.
3. The accused gloves listed in Appendix C literally the asserted claims of the '616 Patent
4. The accused gloves listed in Appendix C do not infringe the asserted claims of the '616 Patent under the doctrine of equivalents.
5. The asserted claims of the '616 Patent are invalid under 35 U.S.C. § 251 ¶ 4 based on a broadening reissue amendment more than two years after the issuance of the original claims.
6. The asserted claims of the '616 Patent are invalid based upon a deficient reissue certificate.
7. The asserted claims of the '616 Patent are not invalid under 35 U.S.C. § 102 for anticipation.
8. The asserted claims of the '616 Patent are not invalid under 35 U.S.C. § 103 for obviousness.
9. The asserted claims of the '616 Patent satisfy the best mode requirement of 35 U.S.C. § 112 ¶ 1.
10. The asserted claims of the '616 Patent satisfy the enablement requirement of 35 U.S.C. § 112 ¶ 1.
11. The asserted claims of the '616 Patent satisfy the definiteness requirement of 35 U.S.C. § 112 ¶ 2.

12. The asserted claims of the '616 Patent are enforceable.

13. A domestic industry exists, as required by section 337.

14. It has not been established that a violation exists of section 337.

IX. INITIAL DETERMINATION AND ORDER

Based on the foregoing, it is the INITIAL DETERMINATION ("ID") of this Court that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain nitrile rubber gloves by reason of infringement of one or more of claims 1, 17, 18 and 19 of United States Patent No. Re. 35, 616. The Court further determines that a domestic industry exists that practices U.S. Patent No. Re. 35,616.

Further, this Initial Determination, together with the record of the hearing in this investigation consisting of:

(1) the transcript of the hearing, with appropriate corrections as may hereafter be ordered, and

(2) the exhibits received into evidence in this investigation, as listed in the attached exhibit lists in Appendix A,

are CERTIFIED to the Commission. In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the undersigned under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order (Order No. 1.) issued in this investigation, and upon the Commission investigative attorney.

RECOMMENDED DETERMINATION ON REMEDY AND BOND

I. Remedy and Bonding

The Commission's Rules provide that subsequent to an initial determination on the question of violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, the administrative law judge shall issue a recommended determination containing findings of fact and recommendations concerning: (1) the appropriate remedy in the event that the Commission finds a violation of section 337, and (2) the amount of bond to be posted by respondents during Presidential review of Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

A. General Exclusion Order

Under Section 337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order instructs the U.S. Customs and Border Protection ("CBP") to exclude from entry all articles that are covered by the patent at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the CBP to exclude from entry all articles that are covered by the patent at issue, without regard to source.

A general exclusion order may issue in cases where (a) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named respondents; or (b) there is a widespread pattern of violation of Section 337 and it is difficult to identify the source of infringing products. 19 U.S.C. § 1337(d)(2). The statute essentially codifies Commission practice under *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, Commission Opinion at 18-19, USITC Pub. 119 (Nov. 1981) ("*Spray Pumps*"). *See Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing the Same,* Inv. No. 337-TA-372 ("*Magnets*"), Commission Opinion on Remedy, the

Public Interest and Bonding at 5 (USITC Pub. 2964 (1996)) (statutory standards "do not differ significantly" from the standards set forth in *Spray Pumps*).

In *Magnets*, the Commission confirmed that there are two requirements for a general exclusion order: a "widespread pattern of unauthorized use;" and "certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles." The Commission went on to state the following factors as relevant to determining whether there is a "widespread pattern of unauthorized use":

> (1) a Commission determination of unauthorized importation of the infringing article into the United States by numerous foreign manufacturers; or
>
> (2) the pendency of foreign infringement suits based on foreign patents corresponding to the U.S. patent; [or]
>
> (3) other evidence which demonstrates a history of unauthorized foreign use of the patented invention.

Magnets, Commission Opinion on Remedy, the Public Interest, and Bonding at 6 (citing *Spray Pumps*).

In addition, the Commission listed the following factors as relevant to showing whether "certain business conditions" – the second *Spray Pumps* factor – exist:

> (1) the existence of an established demand for the article in the U.S. market and conditions of the world market;
>
> (2) the availability to foreign manufacturers of U.S. marketing and distribution networks;
>
> (3) the cost for foreign entrepreneurs to build a facility that can produce the patented articles;
>
> (4) the number of foreign manufacturers whose facilities could be converted to manufacture the patented article; and

(5) the foreign manufacturers' cost to convert a facility to produce the patented articles.

Id.

Tillotson requests that a general exclusion order be issued that prohibits the importation of all infringing nitrile gloves. (CIB at 90.)

1. Widespread Pattern of Unauthorized Use

Tillotson argues that there is a widespread pattern of unauthorized use of the invention described and claimed in the '616 Patent. (CIB at 90.) Tillotson argues that Respondents have imported and sold approximately 11.7 billion nitrile gloves in the United States since January 2003 and that over 90% of the approximately 230 gloves manufactured and/or sold by Respondents infringe claim 1 of the '616 Patent. (*Id.* at 90.) Tillotson further argues that it has entered into license agreements with more than 40 manufacturers and distributors and that the licensees have admitted to importing and selling infringing gloves in United States. (*Id.* at 90.)

Respondents argue that Tillotson deliberately chose not to name a majority of accused infringers, despite having the ability to track them down. (RIB at 94.) Respondents point to the fact that Tillotson filed a complaint in the Northern District of Georgia one day after filing a complaint with the ITC, which named 253 defendants,[26] but Tillotson failed to name those defendants in the current investigation. (*Id.* at 94.) Respondents further argue CBP would likely be incapable of administering the general exclusion order due to the limited resources available to it. (*Id.* at 94-95.) Respondents further argue that since it is difficult for CBP to determine whether an imported product infringes since specialized testing and equipment is often required, Respondents assert that should the Commission find a violation, then a limited exclusion order

[26] Respondents argue that none of the defendants in the U.S. District Court case are domestic producers of gloves.

along with a certification by the respondent that the imported goods are not covered by the asserted claims of the patent. (*Id.* at 95-96.)

Staff argues that the evidence shows that a vast majority of Respondents' gloves in this investigation infringe the '616 Patent and are imported in significant quantities into the United States. (SIB at 58.)

2. Business Conditions

Tillotson argues that there is an established demand for nitrile gloves embodied in the '616 Patent; that Tillotson's licensee, Best Glove Inc., continues to manufacture and sell the N-DEX glove; that Respondents have imported and sold billions of infringing nitrile gloves; and that the nitrile glove market is expected to continue to grow and expand. (*Id.* at 91.) Tillotson further argues that marketing and distribution networks exist for use by foreign manufacturers, including the networks of Best Glove, Tillotson's other licensees, those of certain Respondents and other distributors. (*Id.* at 91-92.) Tillotson further argues that it would not be costly for a foreign manufacturer to construct a new nitrile glove production line or to retool latex glove production lines, of which there are hundreds, to produce nitrile gloves. (*Id.* at 91-93.)

Staff argues that certain business conditions exist such that other foreign manufacturers may attempt to enter the U.S. market; that there is an established market and demand for nitrile gloves; there are a significant number of distributors that could be utilized by foreign manufacturers; and that there are minimal barriers to foreign manufacturers constructing a new nitrile production line or retooling an existing glove line. (SIB at 59-60.) As such, should the Commission find a violation of Section 337, Staff supports the general exclusion order. (*Id.* at 60.)

3. Risk of Circumvention

Tillotson further argues that there is a substantial risk of circumvention absent a general exclusion order. (CIB at 93.) Tillotson argues that a general exclusion order is required to capture all of the infringing nitrile gloves imported and sold in the United States. (*Id.* at 93.) Tillotson argues that it is impossible to identify all of the companies currently importing and selling nitrile gloves in the United States because they are not required to identify the imported goods as "nitrile gloves," but can use other descriptions such as "medical synthetic glove" instead. (*Id.* at 93-94.) Tillotson further argues that given the numerous different companies in different countries who manufacture, distribute, sell and market disposable medical gloves, it is even more difficult to identify the companies and increases the likelihood of circumvention and that a limited exclusion order would simply cause other companies to enter into the glove market. (*Id.* at 94.)

Respondents argue that Tillotson has failed to present any evidence showing that circumvention would occur. (RIB at 91.) Respondents further argue that the mix of allegedly infringing and non-infringing products that compete on equal footing makes a general exclusion order inappropriate and that there is no incentive for circumvention. (*Id.* at 91-92.) Respondents further argue that should the Commission issue a general exclusion order, it would provide powerful incentive for unlicensed manufacturers and importers to develop and purchase nitrile gloves that design around the limitations of the '616 Patent and avoid the significant legal risks in attempting to circumvent the exclusion order. (*Id.* at 92-93.)

Staff argues that ample evidence exists to demonstrating the need for a general exclusion order to prevent circumvention of a limited exclusion order. (SRB at 20-21.) Staff further argues that the Commission can also craft a general exclusion order that includes a certification

requirement in order to alleviate the burden on the CBP in enforcing the general exclusion order.[27] (*Id.* at 21-22.)

4. Conclusion

The Court agrees that the evidence supports a general exclusion order should the Commission find a violation of Section 337. The evidence shows that there is a widespread pattern of unauthorized use: over 90% of Respondents' accused nitrile gloves were found to infringe the '616 Patent and Respondents have imported and sold approximately 11.7 billion nitrile gloves in the U.S. since January 2003. (*See supra* Section II (Importation); Section IV (Infringement); CX-787C at Q&A 104 (Tanger Direct); ROCFF VII. 2.) The evidence further shows that certain business conditions exist supporting the issuance of a general exclusion order. Specifically, the evidence shows that there is an established demand for nitrile gloves and that such a market is expected to continue to grow in the coming years (CX-308, ¶ 4; CX-457, ¶ 4; CX-460C ¶ 18; CX-467C ¶14; CX-492C; CX-825; CX-788C (Tillotson Direct) at Q&A 32; CX-787C at 73, 86 (Tanger Direct); Tanger, Tr. 541:8-16, 565:7-11.); marketing and distribution networks are readily available to foreign manufacturers (Tanger, Tr. 599:20-600:8; CX-282C; CX-176C ¶ 333; CX-308C ¶ 4; CX-457C ¶14; CX-460C ¶ 18; CX-467C ¶ 14; CX-501C ¶ 333; CX-503C ¶ 333; CX-506C ¶ 333; CX-508C ¶ 333; CX-509C ¶ 333; CX-531 ¶ 333; CX-535C ¶ 333; CX-787C at Q&A75-76 (Tanger Direct); CX-837C at Q&A 67 (Tillotson Direct); CX-838C at Q&A 75 (Tanger Rebuttal)); and the cost for foreign manufacturers to start-up a nitrile production line or retool a latex glove production line are relatively low in light of the profit potential (Tanger Tr., 538:1-18 , 566:5-9, 569:10-25, 572:2-24; CX-291C; CX-787C at Q&A 83-86, 88-95, 191, 216 (Tanger Direct); CX-783). The evidence further shows that a general

[27] Tillotson argues that the Commission should not include a certification provision, but that should the Commission decide to do so Tillotson requests the opportunity to work with Staff and the CBP in fashioning an appropriate certification provision. (CRB at 45.)

exclusion order is appropriate to prevent circumvention of a limited exclusion order, especially since there is a significant market and demand for nitrile gloves, the barrier to entry into the nitrile glove market is minimal, and extensive marketing and distribution networks are available to foreign manufacturers. (*See supra*; *See also* Tanger, Tr. 583:5-17, 1393:16-1395:9).

The Court further recommends that the Commission should include a certification provision in the exclusion order in order.

B. Limited Exclusion Order

Under Section 337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order directed to respondents' infringing products is among the remedies that the Commission may impose, as is a general exclusion order that would apply to all infringing products, regardless of their manufacturer. *See* 19 U.S.C. § 1337(d).

Tillotson requests that, should the Commission deny its request for general exclusion order, a limited exclusion order be issued that prohibits the importation of all infringing nitrile gloves by Respondents and all of their affiliated companies, parents, subsidiaries, or other related business entities of their successors or assigns. (CIB at 94-95.)

Respondents assert that should a limited exclusion order be issued, the Commission should include a certification requirement given the large number of non-infringing gloves. (RIB at 95; RRB at 45.).

Staff asserts that a limited exclusion order as to the infringing nitrile gloves imported by or on behalf of Respondents would be appropriate and that any such limited exclusion order should apply to Respondents and any affiliated companies, parents, subsidiaries or other related business entities, or their successor or assigns. (SIB at 60-61.) Staff argues, however, that the exclusion order should apply only to the gloves identified by Tillotson as infringing, but should

not apply to all nitrile gloves imported, sold for importation or sold after importation by Respondents. (*Id.* at 61.) Staff argues that the limited exclusion order should be limited to those gloves identified in Appendix B of its initial post-hearing brief.

The Court agrees that the evidence shows that, if a violation is found and the Commission decides not to issue a general exclusion order, a limited exclusion order would be proper. The limited exclusion order should apply to Respondents and all of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns and should be limited to those of Respondents' gloves that have been found to infringe the '616 Patent, as set forth in Appendix C. The Court further recommends that the Commission should include a certification provision in the exclusion order in order.

C. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm'n Op. at 26-28 (Aug. 27, 1997).

Tillotson requests a cease and desist order against each of the Respondents based in the United States as they all have, or the Court should infer that they have, significant inventories of nitrile gloves in the United States. (CIB at 95-97.)

Staff argues that a cease and desist order should be issued only against those Respondents for which the evidence shows that these entities maintain a commercially significant inventory of nitrile gloves.[28] (SIB at 63.) Staff argues, however, that Tillotson has failed to present any evidence of commercially significant inventories for the remaining respondents and that the Court should not infer that these entities contain significant inventories of nitrile gloves based on mere affiliation. (*Id.* at 63.)

The Court agrees that the evidence shows that Ansell Healthcare Products LLC, Ansell Protective Products Inc., Protective Industrial Products Inc., Adenna, Inc., Liberty Glove, Inc., QRP Inc., Dentexx Nevada Inc., Henry Schein Inc., HSI Inc., Cardinal Health 200, Inc. maintain significant inventories of nitrile gloves in the United States and that if a violation is found, a cease and desist order is warranted. (CX-461C, Ex. D; CX-308, ¶ 5; CX-238, ¶ 3; CX-460C, ¶ 10; CX-235C ¶ 4; CX-458C, ¶ 3; CX-456C, ¶ 4; CX-467C, Ex. E.) The Court further agrees that for those domestic respondents found in default, Basic Medical Industries, Medtexx Partners, Inc. and Dash Medical, a cease and desist order is also warranted. The Court, however, will not "infer" that Kossan Gloves, Inc. d/b/a Sintex, Pharmatex USA Inc., Shamrock Manufacturing Co., Inc., and TG Medical have significant inventories and, as such, does not recommend a cease and desist order be issued against those entities.[29]

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[28] Staff argues that these include Ansell Healthcare Products LLC, Ansell Protective Products Inc., Protective Industrial Products Inc., Tronex International, Adenna, Inc., Liberty Glove, Inc., QRP Inc., Dentexx Nevada Inc., Henry Schein Inc., HSI Inc., Cardinal Health 200, Inc. (SIB at 63.)

[29] On May 7, 2008, Tillotson filed a motion for sanctions against these respondents, each of which is a subsidiary of a foreign named respondent, for failing to comply with Order No. 75. On May 19, 2008, these respondents responded to the motion for sanctions arguing that as a subsidiary of a parent respondent, any responsive information in the possession of the subsidiary was produced by the parent respondent prior to the addition of the subsidiary in this investigation. On May 21, 2008, the Court denied the motion for sanctions. (Tr. 622:2-7.)

D. Bond During Presidential Review Period

The Administrative Law Judge and the Commission must determine the amount of bond to be required of a respondent, pursuant to section 337(j)(3), during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. a 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41 (1995). A 100 percent bond has been required when no effective alternative existed. *See, e.g., Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997)(a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

Tillotson requests a bond be set in the amount of 100% of the entered value of accused products, or a bond be set at the minimum royalty rate paid by Tillotson's licensees, which is approximately $2.00 per thousand nitrile gloves. (CIB at 97-98.) Respondents argue that the bond should be set at Tillotson's minimum royalty rate of $2.00 per thousand nitrile gloves.

(RIB at 96.) Staff agrees that the bond should be set at Tillotson's standard royalty rate of $2.00 per thousand nitrile gloves. (SIB at 64.)

In this case, a reasonable royalty rate can be ascertained, namely Tillotson's standard royalty rate of $2.00 per thousand nitrile gloves. Accordingly, the Court recommends a bond in the amount of $2.00 per thousand nitrile gloves.

II. Conclusion

In accordance with the discussion of the issues contained herein, it is the RECOMMENDED DETERMINATION ("RD") of the Court that in the event the Commission finds a violation of section 337, the Commission should issue a general exclusion order that includes a certification provision. Should the Commission decide not to issue a general exclusion order, the Commission should issue limited exclusion order directed only to those Respondents' nitrile gloves that were found to infringe the '616 Patent as listed in Appendix C. The Commission should also issue a cease and desist order directed toward the domestic respondents identified *supra*. (*See* Remedy, Section I.C.) Furthermore, if the Commission imposes a remedy following a finding of violation, Respondents should be required to post a bond of $2.00 per thousand nitrile gloves imported during the Presidential review period.

Within seven days of the date of this document, each party shall submit to the office of the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version. The parties' submissions must be made by hard copy by the aforementioned date.

Any party seeking to have any portion of this document deleted from the public version thereof must submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information by the aforementioned date. The

parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Theodore R. Essex
Administrative Law Judge

CERTIFICATE OF SERVICE - Page 2

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JDA (TIANJIN) PLASTIC RUBBER CO. LTD
KOSSAN RUBBER INDUSTRIES Bhd. Ltd.
LAGLOVE (M) Sdn. Bhd.
LATEXX PARTNERS BERHAD
PT MEDISAFE TECHNOLOGIES
PT SHAMROCK MANUFACTURING CORPORATION
RIVERSTONE RESOURCES Sdn. Bhd.
YTY HOLDINGS Sdn. Bhd.
TOP GLOVE CORPORATION Bhd.:

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IN THE MATTER OF CERTAIN NITRILE GLOVES **337-TA-608 & 337-TA-612**

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **INITIAL DETERMINATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND** has been served by hand upon the Commission Investigative Attorney, **Erin D.E. Joffre, Esq.,** and the following parties as indicated below on February 10, **, 2009.**

Marilyn R. Abbott
Marilyn R. Abbott, Secretary
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CERTIFICATE OF SERVICE - Page 3

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RESPONDENTS ADENNA, INC.:

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DASH MEDICAL GLOVES, INC. c/o Robert J. Sullivan 1018 South 54th Street Franklin, WI 53132	( ) Via Hand Delivery (✓) Via Overnight Mail ( ) Via First Class Mail ( ) Other
DENTEXX/FIRST MEDICA INFECTION CONTROL ASSOCIATE 3704C Boren Drive Greensboro, NC 27407	( ) Via Hand Delivery (✓) Via Overnight Mail ( ) Via First Class Mail ( ) Other

CERTIFICATE OF SERVICE - Page 4

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Ansell Healthcare Products LLC 200 Schulz Drive Red Bank, NJ 07701	( ) Via Hand Delivery (✓) Via Overnight Mail ( ) Via First Class Mail ( ) Other
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Top Glove Sdn. Bhd. Lot 4968 Jalan Teratai Batu 6 Off Jalan Meru,41050 Klang Selangor D.E. Malaysia	( ) Via Hand Delivery (✓) Via Overnight Mail ( ) Via First Class Mail ( ) Other
TG Medical (USA) Inc. 165 North Aspen Ave. Azusa, CA 91702	( ) Via Hand Delivery (✓) Via Overnight Mail ( ) Via First Class Mail ( ) Other
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CERTIFICATE OF SERVICE - Page 5

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CERTIFICATE OF SERVICE - Page 6

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

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT DASH MEDICAL GLOVES, INC. IN DEFAULT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 92) in the above-referenced investigation finding respondent Dash Medical Gloves, Inc. ("Dash") in default.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation, on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing Company ("Tillotson"). The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nitrile gloves by reason of infringement of various claims in United States Patent No. Re. 35,616. The complaint named over thirty respondents, including Dash. On September 19, 2007, the ALJ consolidated Inv. No. 337-TA-608 with Inv. No. 337-TA-612.

On July 1, 2008, Tillotson filed a motion for an order to show cause and default against respondent Dash. On July 18, 2008, the ALJ issued Order No. 90 ordering respondent Dash to show cause why it should not be found in default for failing to respond to the complaint and notice of investigation by July 25, 2008.

As of August 1, 2008, no response to the order had been filed by respondent Dash and the ALJ issued the subject ID finding Dash in default. As a consequence, the ALJ found that Dash had waived its right to appear, to be served with documents, and to contest the allegations against it. No petitions for review of this ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: August 20, 2008

CERTAIN NITRILE GLOVES AND CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT DASH MEDICAL GLOVES, INC. IN DEFAULT** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on August 21, 2008.

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RESPONDENTS:

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Dentexx/First Medica Infection Control Association 3704C Boren Dr. Greensboro, NC 27407	( ) Via Hand Delivery ( ) Via Overnight Mail (x) Via First Class Mail ( ) Other: _____
Medtexx Partners, Inc. 102 Engle St. FL2 Englewood, NJ 07631	( ) Via Hand Delivery ( ) Via Overnight Mail (x) Via First Class Mail ( ) Other: _____

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

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT MEDTEXX PARTNERS, INC. IN DEFAULT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 88) in the above-referenced investigation finding respondent Medtexx Partners, Inc. ("Medtexx") in default.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation, on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing Company ("Tillotson"). The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nitrile gloves by reason of infringement of various claims in United States Patent No. Re. 35,616. The complaint named over thirty respondents. On September 19, 2007, the ALJ consolidated Inv. No. 337-TA-608 with Inv. No. 337-TA-612.

On April 25, 2008, Tillotson filed a motion for an order to show cause and default against respondent Medtexx Partners, Inc. ("Medtexx"). On May 21, 2008, the ALJ issued Order No. 85 ordering respondent Medtexx to show cause why it should not be found in default for failing to respond to the complaint and notice of investigation.

As of June 20, 2008, no response to the order had been filed by respondent Medtexx and the ALJ issued the subject ID finding Medtexx in default. As a consequence, the ALJ found that Medtexx had waived its right to appear, to be served with documents, and to contest the allegations against it. No petitions for review of this ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: July 11, 2008

CERTAIN NITRILE GLOVES AND CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT MEDTEXX PARTNERS, INC. IN DEFAULT** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on JULY 11, 2008.

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Medtexx Partners, Inc. 102 Engle St. FL2 Englewood, NJ 07631	( ) Via Hand Delivery ( ) Via Overnight Mail (✓) Via First Class Mail ( ) Other: _____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT YEE LEE CORPORATION BHD. IN DEFAULT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 61) in the above-referenced investigation finding respondent Yee Lee Corporation Bhd. ("Yee Lee") in default.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Inv. No. 337-TA-608 on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing Company ("Tillotson"). The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nitrile gloves by reason of infringement of various claims in United States Patent No. Re. 35,616. The complaint named over thirty respondents. On September 19, 2007, the ALJ consolidated Inv. No. 337-TA-608 with Inv. No. 337-TA-612.

On August 22, 2007, Tillotson filed a motion for an order to show cause and default against six respondents: Basic Medical Industries, Inc.; Blovco (M) Bhd.; Ideal Healthcare Group Co. Ltd.; Seal Polymer Industries Bhd. ("Seal Polymer"); Supermax Corporation Bhd. ("Supermax"); and Yee Lee. On September 10, 2007, the ALJ issued Order No. 17 ordering these respondents to show cause why they should not be found in default for failing to respond to the complaint and notice of investigation.

Respondents Seal Polymer, Supermax, and Yee Lee all filed responses requesting more time to respond to the complaint. Yee Lee subsequently submitted two more requests for additional time. On November 27, 2008, Tillotson filed a motion for a finding of default against Yee Lee. On February 21, 2008, the ALJ issued another order to show cause why Yee Lee should not be held in default for failing to respond to the complaint and notice of investigation. No responses were received. On March 10, 2008, the ALJ issued the subject ID finding Yee Lee in default. The ALJ also found that Yee Lee had waived its right to appear, to be served with documents, and to contest the allegations against it. No petitions for review of this ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42).

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: March 28, 2008

CERTAIN NITRILE GLOVES AND CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING RESPONDENT YEE LEE CORPORATION BHD. IN DEFAULT** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on March 28, 2008.

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN NITRILE GLOVES**	**Investigation No. 337-TA-608**

AND

In the Matter of **CERTAIN NITRILE RUBBER GLOVES**	**Investigation No. 337-TA-612**

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING THREE RESPONDENTS IN DEFAULT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 22) finding three respondents in default.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted Inv. No. 337-TA-608 on July 6, 2007, based on a complaint filed by Tillotson Corporation d.b.a. Best Manufacturing

Company ("Tillotson"). The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nitrile gloves by reason of infringement of various claims in United States Patent No. Re. 35,616. The complaint named over thirty respondents. On September 19, 2007, the ALJ consolidated Inv. No. 337-TA-608 with Inv. No. 337-TA-612

On August 22, 2007, Tillotson filed a motion for an order to show cause and default against six respondents: Basic Medical Industries, Inc. ("Basic Medical"); Glovco (M) Bhd. ("Glovco"); Ideal Healthcare Group Co. Ltd. ("Ideal Healthcare"); Seal Polymer Industries Bhd. ("Seal Polymer"); Supermax Corporation Bhd. ("Supermax"); and Yee Lee Corporation Bhd. ("Yee Lee"). On September 10, 2007, the ALJ issued Order No. 17 ordering these respondents to show why they should not be found in default for failing to respond to the complaint and notice of investigation.

Respondents Seal Polymer, Supermax, and Yee Lee all filed responses requesting more time to respond to the complaint. The ALJ granted these requests. However, the ALJ found pursuant to Commission Rule 210.16, 19 U.S.C. § 210.16, that Basic Medical, Glovco, and Ideal Healthcare were in default because they failed to respond to the complaint and notice of investigation and failed to respond to the ALJ's order to show cause why they should not be found in default. The ALJ also found that they have waived their rights to appear, be served with documents, and to contest the allegations against them. No petitions for review of this ID were filed. The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42).

By order of the Commission.

William R. Bishop
Acting Secretary to the Commission

Issued: October 15, 2007

CERTAIN NITRILE RUBBER GLOVES

337-TA-608 and 612 (Consolidated)

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION FINDING THREE RESPONDENTS IN DEFAULT** has been served by hand upon the Commission Investigative Attorney Vu Q. Bui, Esq., and the following parties as indicated, on October 17, 2007.

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