UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RECKITT BENCKISER LLC,
Petitioner,

v.

ANSELL HEALTHCARE PRODUCTS LLC,
Patent Owner.

Case No. To Be Assigned
Patent 9,074,029

PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,074,029
PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42.100
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I. **PRELIMINARY STATEMENT**

Petitioner and Patent Owner are competitors in the synthetic polyisoprene condom market. Patent Owner has asserted its family of four patents, including the ‘029 Patent, against Petitioner in district court litigation. The four United States patents are a chain of continuations sharing identical specifications and differing only in their claims.

As is made clear from the express language of the common specification, Patent Owner’s alleged invention is directed to the use of synthetic polyisoprene particles that are “pre-vulcanized” to allegedly improve the performance (e.g., strength and elasticity) of its condoms. Consistent with this specification, *each and every one of the seventy-one claims* filed in the provisional application, the first application (and the subsequently issued patent), and the second application (and the subsequently issued patent) were directed to, and expressly recited, this alleged inventive use of synthetic polyisoprene particles that were “*pre-vulcanized*” following the procedure set forth in the specification.

Almost *five years* after the initial patent application was filed, in its third and fourth applications that were filed as continuations of, and claimed priority to, the
earlier applications, Patent Owner attempted to broaden its claims by removing the requirement that the synthetic polyisoprene particles be pre-vulcanized. But based on well-settled Federal Circuit case law, these broader claims, which no longer require pre-vulcanization, are not entitled to claim priority to the earlier applications, which narrowly disclose only articles and methods using pre-vulcanized particles. And since these later claims, including the challenged claims of the ‘029 Patent, are not entitled to the benefit of these earlier filing dates, the published applications of the earlier applications are prior art to, and anticipate, the claims. Accordingly, IPR should be instituted as a reasonable likelihood exists that Petitioner will prevail in proving that the claims of the ‘029 Patent are unpatentable.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Reckitt Benckiser LLC as a real party-in-interest. In addition, Petitioner identifies the following parties as real parties-in-interest: Reckitt Benckiser Corporate Services Ltd., Reckitt Benckiser (ENA) B.V., Reckitt Benckiser Group plc, Reckitt Benckiser plc, and SSL Manufacturing (Thailand) Ltd.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following list of
judicial or administrative matters that would affect, or be affected, by a decision in this proceeding:

- Ansell Healthcare Products LLC v. Reckitt Benckiser LLC, C.A. No. 1:15-cv-00915-RGA (D. Del.)
- Petition for Inter Partes Review Of U.S. Patent No. 9,074,027 (Claims 1-20) (filed concurrently herewith)
- U.S. Patent No. 9,074,027 B2
- U.S. Patent No. 8,087,412 B2
- U.S. Patent No. 8,464,719 B2
- U.S. Application No. 14/725,040

C. Lead And Back-Up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following as lead and back-up counsel:

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<th>Lead Counsel</th>
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Pursuant to 37 C.F.R. § 42.10(c), Petitioner will file a Motion for Pro Hac Vice Admission of Douglas J. Nash as back-up counsel in this proceeding.

Pursuant to 37 C.F.R. § 42.10(b), Petitioner also concurrently files a power of attorney.

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), Petitioner states that papers concerning this matter should be served by overnight mail, by hand-delivery, or electronic mail (email) to lead and back-up counsel as shown above. Petitioner consents to, and requests, electronic service of a paper by email sent to all of the email addresses identified above for lead and back-up counsel.

III. WORD COUNT CERTIFICATION

Certification of the word count limit set forth in 37 C.F.R. § 42.24(a)(1)(i) is provided in the attached Certificate of Compliance.
IV. PAYMENT OF FEES

The undersigned authorizes the Office to charge the *inter partes* request fee of $9,000 as required by 37 C.F.R. § 42.15(a)(1), the *inter partes* post institution fee of $14,000 as required by 37 C.F.R. § 42.15(a)(2), and the excess claim post institution fee of $2,000 as required by 37 C.F.R. § 42.15(a)(4) for the filing of this Petition for *Inter Partes* Review, to Deposit Account No. 50-3010 (Barclay Damon, LLP). The undersigned further authorizes the payment for any additional fees, or credit for any overpayment, to Deposit Account No. 50-3010.

V. REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ‘029 Patent is available for IPR in accordance with 37 C.F.R. § 42.102(a)(1) or 37 C.F.R. § 42.102(a)(2), and that Petitioner is not barred or estopped from requesting IPR challenging the claims of the ‘029 Patent on the grounds identified in this Petition.

This Petition is filed within one year from the date on which Petitioner was served with the complaint in the related litigation, *Ansell Healthcare Products LLC v. Reckitt Benckiser LLC*, C.A. No. 1:15-cv-00915-RGA (D. Del.) (EX1030), which asserted infringement of the ‘029 Patent.

Neither Petitioner nor any privies of Petitioner have received a final written decision under 35 U.S.C. § 318(a) with respect to any claim of the ‘029 Patent on
any ground that was raised or could have been raised by Petitioner or privies of Petitioner in any IPR, post grant review, or covered business method patent review.

B. Identification of Challenge And Precise Relief Requested

Pursuant to 37 C.F.R. § 42.104(b), Petitioner identifies its challenge of claims 1-20 of the ‘029 Patent, and requests that these claims be found unpatentable over the asserted prior art for the reasons given herein.

1. Claims For Which Inter Partes Review Is Requested

Petitioner requests review of claims 1-20 of the ‘029 Patent.

2. Specific Art And Statutory Grounds On Which The Challenges Are Based


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1 The actual filing date of the ‘027 Patent is June 5, 2013 (i.e., after AIA), but the patent claims priority to several applications filed prior to enactment of AIA. As will be explained, the ‘027 Patent is not entitled to this claim of priority and is therefore subject to the provisions of AIA. However, for the anticipation analysis presented herein, it does not matter whether 35 U.S.C. § 102(a)(1) (AIA) or 35 U.S.C. § 102(b) (pre-AIA) is controlling.
3. **Supporting Evidence Relyed Upon To Support The Challenge**

In addition to the prior art, Petitioner relies upon the evidence listed in the Exhibit List, including the Declaration of William D. Potter, Ph.D. (EX1031.)

4. **Prior Art Qualification Of The Asserted Prior Art Reference**

The ‘029 Patent was filed on February 10, 2014. The asserted prior art (First Publication (‘384)) published on November 5, 2009. As will be demonstrated below, because the effective filing date of the ‘029 Patent is more than one year after the publication date of the First Publication (‘384), the First Publication (‘384) constitutes prior art under 35 U.S.C. § 102(a)(1) (AIA) or 35 U.S.C. § 102(b) (pre-AIA) with respect to the claims of the ‘029 Patent.

5. **How The Challenged Claims Are To Be Construed**

An explanation of how the challenged claims are to be construed is provided below.

VI. **OVERVIEW OF THE ‘029 PATENT**

A. **Summary Of The ‘029 Patent**

The ‘029 Patent is entitled “Dip-formed synthetic polyisoprene latex articles with improved intraparticle and interparticle crosslinks,” and is directed to synthetic polyisoprene articles such as condoms or gloves.² According to the inventors, existing methods of manufacturing synthetic polyisoprene particles

² Unless otherwise noted, all emphasis is added.
involving “the addition of a cross-linking agent tend[ed] to produce more inter-particle cross-links and less intra-particle cross-links during post-vulcanization, resulting in nonhomogeneous cure properties leading to latex film articles having poor strength and elongation properties, such as voids and cracks due to the formation of fractures in the inter-particle regions.” (EX1002 1:55-61.)

To overcome this problem, the inventors asserted that the “present invention provides a latex article that is formed by dipping a condom shaped former in a pre-vulcanized synthetic latex emulsion . . . and curing the condom thus produced. . . . The synthetic latex particles in the latex emulsion are pre-vulcanized by the incorporation of sulfur within the interstices of latex particles.” (EX1002 4:50-57.)

The inventors further stated that “using this methodology of using a pre-vulcanization accelerator package and post vulcanization accelerator package a substantially uniform cured synthetic latex condom film is produced.” (EX1002 5:23-27.) According to the inventors, this improved product resulted from enhanced inter-particle crosslinks (i.e., between synthetic polyisoprene particles) and intra-particle crosslinks (i.e., within synthetic polyisoprene particles) made by “using controlled pre-vulcanized particles of synthetic latex that is dip formed into a thin latex article from an aqueous latex emulsion.” (EX1002 1:23-26.)

More specifically, the inventors stated that the “present invention is predicated on the discovery that soluble sulfur, such as S₈ rings of sulfur, is catalyzed by a zinc
complex of dithiocarbamate in combination with potassium caprylate and sodium dodecyl benzene sulphonate (SDBS) surfactant creating pre-vulcanized, synthetic polyisoprene particles in a latex composition. . . . The articles that result comprise a high quality and uniform latex film.” (EX1002 8:36-50.)

The specification of the ‘029 Patent then provides examples of pre-vulcanization compositions and alleged tests to try to determine the degree of improvement in the uniformity of the cross-links resulting from the disclosed pre-vulcanization. (EX1002 11:65-16:58.)

As will be explained in detail below, despite the fact that the narrow disclosure of the ‘029 patent only discloses examples of the alleged invention involving “pre-vulcanization,” none of the claims of the ‘029 Patent require “pre-vulcanization.”

B. The Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) for the ‘029 Patent at the time of the filing of the application (and the earlier applications to which it claims priority) would have at least (1) a bachelor’s degree or an equivalent degree in chemistry, or a related field, (2) a master’s degree in polymer science and technology, or a related field, and (3) at least five years of experience in the area of latex technology, and, in particular, the production of polyisoprene (natural rubber) and synthetic polyisoprene articles. (EX1031 ¶34.)
The level of ordinary skill in the art for the ‘029 Patent is also reflected by the prior art of record in this proceeding, including the prior art cited and discussed (EXS1018-1022) in the Background of the Invention of the ‘029 Patent (EX1002 1:30-4:30). See Okajima v. Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001); In re GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995).

C. Patent Family Of The ‘029 Patent

The ‘029 Patent is the fourth patent to issue in a family of four related patents, all sharing the same written description and figures in a chain of continuation applications.


On February 10, 2014, Patent Owner filed U.S. Application No. 14/176,608 (“Fourth Application (‘608”) (EX 1009), as a continuation of the Third Application (‘364), which was a continuation of the Second Application (‘445), which was a continuation of the First Application (‘118), which claimed priority to the Provisional Application (‘637). The Fourth Application (‘608) issued as the ‘029 Patent (also referred herein as the “Fourth Patent (‘029”) (EX1002) on July 7, 2015.

As explained above and as can be seen in the diagram below, the First Publication (‘384) (EX1010) published on November 5, 2009, several years before
the February 10, 2014 filing date of the Fourth Application (‘608), which issued as
the Fourth Patent (‘029).

Since none of the claims of the ‘029 Patent are entitled to claim priority to
the filing dates of any of the Second Application (‘445), the First Application
(‘118), or the Provisional Application (‘637), the First Publication (‘384) is a 35
U.S.C. § 102(a)(1) (AIA) or 35 U.S.C. § 102(b) (pre-AIA) prior art reference to the
claims of the ‘029 Patent.

D. Prosecution History of the ‘029 Patent

As explained above, the ‘029 Patent issued from the Fourth Application (‘608) (EX1009), which was a continuation of the Third Application (‘364) (EX1008), which was a continuation of the Second Application (‘445) (EX1007), which was a continuation of the First Application (‘118) (EX1006), which claimed priority to the Provisional Application (‘637) (EX1005).

The prosecution history for this chain of applications demonstrates that the claims of at least the Second Application (‘445), the First Application (‘118), and the Provisional Application (‘637), all of which the ‘029 Patent claims priority to, expressly recited “pre-vulcanized” synthetic polyisoprene particles or methods that involved “pre-vulcaniz[ing]” the synthetic polyisoprene particles.

For example, the Provisional Application (‘637) included a claim set where all of the independent claims expressly recited either “pre-vulcanized” synthetic polyisoprene particles or “prevulcaniz[ing]” synthetic polyisoprene particles” to provide “substantially uniform” crosslinks. (EX1005)(Claim 1(“synthetic polyisoprene particles that are pre-vulcanized and cured”); Claim 8 (“a pre-vulcanization composition to pre-vulcanize synthetic polyisoprene particles”).

Similarly, all of the originally-filed, independent claims of the First Application (‘118) expressly recited either “pre-vulcanized” synthetic
polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles” to provide “substantially uniform” crosslinks. (EX1006)(Claims 1, 10 (“synthetic polyisoprene particles that are pre-vulcanized”); Claim 13 (“pre-vulcanizing the synthetic polyisoprene particles”).)

During prosecution of the First Application (‘118), these original claims were rejected in a first office action (EX1012) as either anticipated or obvious based on U.S. Patent Publication No. 2004/0169317 (“Wang”) (EX1022). In response, Patent Owner provided several arguments attempting to distinguish Wang, in each case reciting “the Applicant’s invention” as requiring either “pre-vulcanized” particles or a “pre-vulcanization composition” to provide “substantially uniform” crosslinks. (EX1013 at 8, 9, 12.)

[T]he Applicant’s invention, as recited in independent claim 1 is as follows: . . . synthetic polyisoprene particles that are pre-vulcanized. . . . (EX1013 at 8.)

The Applicant’s invention, as recited in independent claim 13 is as follows: . . . adding to an aqueous latex of synthetic polyisoprene particles a pre-vulcanization composition . . . . (EX1013 at 9.)

The Applicant’s invention, as recited in independent claim 10 is as follows: . . . synthetic polyisoprene particles that are pre-vulcanized. . . . (EX1013 at 12.)

The Examiner proceeded to allow the claims, which issued in the First
Patent (‘412), with all of the independent claims expressly reciting either “pre-vulcanized” synthetic polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles.” (EX1003 at Claims 1, 10, and 13.)

The single, originally-filed, independent claim of the Second Application (‘445) also expressly recited “pre-vulcanized” synthetic polyisoprene particles to provide “substantially uniform” crosslinks. (EX1007)(Claim 1(“synthetic polyisoprene particles that are pre-vulcanized”).) After a first office action rejecting the claims as indefinite (EX1014) and a response by Patent Owner amending the claims to address the indefiniteness rejection (EX1015), the Examiner proceeded to allow the claims, which issued in the Second Patent (‘719), with the only independent claim expressly reciting “pre-vulcanized” synthetic polyisoprene particles. (EX1004 Claim 1.)

After filing and prosecuting claims in the Provisional Application (‘637), the First Application (‘118), and the Second Application (‘445) with independent claims that all expressly recited either “pre-vulcanized” synthetic polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles,” Patent Owner filed the Third Application (‘364), which eventually issued as the Third Patent (‘027).

These original claims of the Third Application (‘364), which were filed almost five years after the First Application (‘118) and the Provisional Application
(‘637), included broader claims for the first time that did not expressly recite either “pre-vulcanized” synthetic polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles” in the independent claim. (EX1008 Claim 1.) Instead, the original claims of the Third Application (‘364) included dependent claims that expressly recited that “the article was formed from a polyisoprene latex that pre-vulcanized to increase the isopropanol index to about 3.” (EX1008 Claims 2, 6, 10, and 14.)

Less than two months after filing the original claims of the Third Application (‘364), Patent Owner then filed a preliminary amendment, canceling all claims (including the claims that recited “polyisoprene latex that pre-vulcanized”) and adding a whole new set of claims that did not even mention the words “pre-vulcanized” or “pre-vulcanization” in any of the claims. (EX1016 at 2-4.) The Examiner proceeded to allow these claims, which issued in the Third Patent (‘027), none of which expressly recite either “pre-vulcanized” synthetic polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles.” (EX1001.)

The single, originally-filed, independent claim of the Fourth Application (‘608), which eventually issued as the Fourth Patent (‘029), once again expressly recited “pre-vulcanized” synthetic polyisoprene particles to provide “substantially uniform” crosslinks. (EX1009)(Claim 1(“synthetic polyisoprene particles that are
“pre-vulcanized”). The next day, however, Patent Owner filed a preliminary amendment, canceling all claims (including the claims that recited “synthetic polyisoprene particles that are pre-vulcanized”) and adding a whole new set of claims that did not even mention the words “pre-vulcanized” or “pre-vulcanization” in any of the claims. (EX1017 at 3-5.) The Examiner proceeded to allow these claims, which issued in the Fourth Patent (‘029), none of which expressly recite either “pre-vulcanized” particles or “pre-vulcanizing the synthetic polyisoprene particles.” (EX1002.)

In summary, and as shown in the chart below, all of the claims in the patent family prior to the Third Patent (‘027) and the Fourth Patent (‘029) were limited to articles that included “pre-vulcanized” synthetic polyisoprene particles or methods that involved “pre-vulcanizing the synthetic polyisoprene particles.” However, in the Third Patent (‘027) and the Fourth Patent (‘029), all of the claims were broadened by removing all references to “pre-vulcanized” synthetic polyisoprene particles or “pre-vulcanizing the synthetic polyisoprene particles.”

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<td>(EX1005)</td>
<td>“a pre-vulcanization composition to pre-vulcanize synthetic polyisoprene particles” (Claim 8)</td>
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VII. CLAIM CONSTRUCTION

In an IPR, claim terms in an unexpired patent are given their broadest reasonable construction (or broadest reasonable interpretation ("BRI")) in light of the specification of the patent in which they appear.³

³ Because the BRI standard is different from that used in district court litigation, Petitioner’s claim constructions should not be viewed as constituting Petitioner’s interpretation of such claims for the purposes of the related litigation. See PPC
Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2144–46 (2016). Under the BRI standard, claim terms should be given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention in view of the specification. See In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Here, since the asserted prior art reference is a parent application to, and has an identical specification as, the challenged patent, no construction is necessary for the majority of the terms because the asserted prior art teaches the limitation regardless of how the claim terms are construed. See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”)Where not specified below, Petitioner asserts that a POSITA would

Broadband, Inc., v. Corning Optical Comms. RF, LLC, 815 F.3d 734, 741-43 (Fed. Cir. 2016)(holding that a claim term construed under the BRI would not be limited by the language in the specification regarding the operation and purpose of the invention, while the same term construed under Philips would be so limited).
have understood all claim terms to have their ordinary and customary meaning.⁴


Independent Claim 1 of the ‘029 Patent recites “synthetic polyisoprene particles”:

1. A synthetic polyisoprene elastomeric glove or condom made of a layer of elastomer comprising: synthetic polyisoprene particles; . . . wherein the intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks are substantially uniformly distributed among and between the synthetic polyisoprene particles.

All of the dependent claims (Claims 2-20) of the ‘029 Patent depend from Claim 1 and, therefore, also include the “synthetic polyisoprene particles” limitation.

Applying the BRI standard, the “synthetic polyisoprene particles” recited in the claims of the ‘029 Patent are not expressly limited to “pre-vulcanized” synthetic polyisoprene particles. In fact, the words “pre-vulcanized” or “pre-vulcanization” do not appear as a limitation in any of the claims of the ‘029 patent. (EX1002; EX1031 ¶82.) As will be explained, since they are silent with respect to

⁴ Petitioner has not included any indefiniteness arguments because the IPR procedure does not permit them, but may raise such arguments in other proceedings.
the terms “pre-vulcanized” or “pre-vulcanization,” under the BRI standard, the scope of all of the claims of the ‘029 are broad enough to encompass both (1) synthetic polyisoprene articles that include “pre-vulcanized” synthetic polyisoprene particles, and (2) synthetic polyisoprene articles that do not include “pre-vulcanized” synthetic polyisoprene particles. (EX1031 ¶84.)

This construction is consistent with the specification, which makes it clear in several instances that the ordinary and customary meaning of “synthetic polyisoprene particles” is not limited to “pre-vulcanized” synthetic polyisoprene particles. For example, the specification of the ‘029 Patent refers to the particles prior to pre-vulcanization simply as “synthetic polyisoprene particles.” (EX1031 ¶85.)

Preferably, the synthetic polyisoprene particles are cis-1,4-polyisoprene, have a diameter in the range of about 0.2 to 2 micrometers, and are maintained in an aqueous medium of the latex emulsion. (EX1002 5:62-65.)

The specification of the ‘029 Patent also makes it clear that the “synthetic polyisoprene particles” only become “pre-vulcanized” particles when they are permeated or penetrated with a pre-vulcanization composition. (EX1031 ¶86.)

Surfactants present in the pre-vulcanization composition wets synthetic polyisoprene particles and permeates small sized sulfur and accelerator molecules into the interior of these particles thereby pre-vulcanizing the particles” (EX1002 Abstract)
The synthetic latex particles in the latex emulsion are pre-vulcanized by the incorporation of sulfur within the interstices of latex particles. (EX1002 4:55-57.)

The aqueous latex emulsion is stirred and periodically examined for permeation of pre-vulcanization agents into the synthetic polyisoprene particles by using the isopropanol index test. (EX1002 11:42-45.)

Once the “synthetic polyisoprene particles” have been pre-vulcanized, the specification of the ‘029 Patent then refers to the particles as “pre-vulcanized synthetic polyisoprene particles.” (EX1031 ¶87.)

During post vulcanization cure, pre-vulcanized synthetic polyisoprene particles with the permeated sulfur also cure completely in the intra-particle regions. (EX1002 5:21-23.)

The latex emulsion with surfactants wets the synthetic polyisoprene particles, catalytic action of zinc dithiocarbamate breaks the ring of soluble S₈ molecule forming linear chain of soluble sulfur pre-vulcanizing particles of synthetic polyisoprene. (EX1002 9:41-45.)

Accordingly, applying the BRI standard, the use of the term “synthetic polyisoprene particles” in the specification of the ‘029 Patent makes it clear that the ordinary and customary meaning of “synthetic polyisoprene particles” in all of the claims of the ‘029 Patent is not limited to “pre-vulcanized” synthetic polyisoprene particles. (EX1031 ¶¶84-88.)
This ordinary and customary meaning under the BRI is further supported by a review of all of the claims of the family of patents, including the ‘029 Patent. 

See NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005)(Where multiple patents “derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents.”) As explained above and as shown again in the table below, all of the independent claims of the earlier applications and patents in the family expressly recited “pre-vulcanized” synthetic polyisoprene particles or methods that involved “pre-vulcanizing” the synthetic polyisoprene particles.” (EX1031 ¶¶ 77-81, 89.) The claims of the ‘029 Patent, however, do not recite “pre-vulcanized” synthetic polyisoprene particles. (EX1031 ¶¶ 82, 89.)

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<td>Third Patent (‘027)</td>
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<td>Fourth Application (‘608)</td>
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<td>(EX1009)</td>
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As shown in the chart, the absence of the term “pre-vulcanized” in all of the issued claims of the ‘027 Patent and the ‘029 Patent is especially noteworthy since the original claims for those patent applications (*i.e.*, Third Application (‘364) (EX1008) and Fourth Application (‘608) (EX1009)) included claims that required pre-vulcanization, which were later cancelled.

Accordingly, applying the BRI standard, the fact that all of the earlier independent claims in the patent family expressly required “pre-vulcanized” synthetic polyisoprene particles and the later claims of the ‘029 Patent (*filed five years later*) do not, makes it clear that the ordinary and customary meaning of “synthetic polyisoprene particles” in all of the claims of the ‘029 Patent is **not** limited to “pre-vulcanized” synthetic polyisoprene particles. (EX1031 ¶90.)

To hold otherwise under the BRI standard (*i.e.*, to limit “synthetic polyisoprene particles” in the claims of the ‘029 Patent to “pre-vulcanized”...
particles), would impermissibly read the “pre-vulcanized” limitation into claim 1 from the specification. Moreover, such a construction would improperly render the explicit recitation of “pre-vulcanized” in all of the other claims in the patent family superfluous. See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (“[I]nterpretations that render some portion of the claim language superfluous are disfavored.”). In other words, under the BRI standard, if the ordinary and customary meaning of “synthetic polyisoprene particles” was limited to “pre-vulcanized” synthetic polyisoprene particles, it would not have been necessary to expressly recite the term “pre-vulcanize” in all of the claims in the patent family that were filed and issued before the filing of the broader claims of the ‘029 Patent.

In summary and as repeatedly held by the Federal Circuit, “even if ‘all of the embodiments discussed in the patent included a specific limitation [i.e., pre-vulcanized], it would not be ‘proper to import from the patent’s written description limitations that are not found in the claims themselves.’” See Cadence Pharms., Inc. v. Exela PharmSci Inc., 780 F.3d 1364, 1369 (Fed. Cir. 2015) (quoting Flo Healthcare Solutions, LLC v. Kappos, 697 F.3d 1367, 1375 (Fed. Cir. 2012)); see also Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir.
2004)(“Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’”)(quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

So while it is correct that the only gloves or condoms disclosed as part of the “present invention” of the ‘029 Patent involve pre-vulcanization, the intentional omission of that claim limitation by Patent Owner results in broader claims in the ‘029 Patent that are not so limited.

**VIII. THE EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS**

**A. Priority Challenges Are Permitted In An IPR.**

As an initial matter, although a petitioner cannot challenge the validity of claims under 35 U.S.C. § 112 in an IPR, it is appropriate for the Board to determine whether challenged claims of a continuation have written description support in a parent to obtain the benefit of an earlier filing date under 35 U.S.C. § 120. *See, e.g.*, *SAP America, Inc. v. Pi-Net Int’l, Inc.*, IPR2014-00414, Paper 11 at 11-14 (P.T.A.B. Aug. 18, 2014) (relying on § 112 case law is proper in an IPR to establish effective filing date); *HTC Corp. v. Advanced Audio Devices, LLC*, IPR2014-01158, Paper 6 at 12 (P.T.A.B. Jan. 23, 2015)(Petitioner “does not challenge the patentability of claims 1-15 for failure to comply with the written
description requirement of 35 U.S.C. § 112 – which would be outside the scope of an *inter partes* review – but instead makes a proper challenge to priority as part of a ground of unpatentability based on 35 U.S.C. § 102.”).

As discussed above, the ‗029 Patent claims the benefit of priority under 35 U.S.C. § 120 to the Second Application (‘445), the First Application (‘118), and the Provisional Application (‘637). Under 35 U.S.C. § 120, “[a]n application for patent for an invention disclosed in the manner provided by section 112(a)\(^5\) [(AIA) or § 112, ¶1 (pre-AIA)] . . . shall have the same effect, as to such invention, as though filed on the date of the prior application . . . .” In turn, 35 U.S.C. § 112(a) (AIA) and 35 U.S.C. § 112, ¶1 (pre-AIA) require that the “specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .”

Accordingly, “in a chain of continuing applications, a claim in a later application receives the benefit of the filing date of an earlier application so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112,

\(^5\) Since the ‗027 Patent was filed after implementation of the AIA, 35 U.S.C. § 112(a) applies. However, even if 35 U.S.C. § 112, ¶1 (pre-AIA) applied, the result would be the same as the claims of the ‗027 Patent do not have written description support in the earlier applications.
P1, including the written description requirement, with respect to that claim.”

*Tech. Licensing Corp. v. Videotek, Inc.*, 45 F.3d 1316, 1326 (Fed. Cir. 2008); *see also Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997)(“In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.”)

Determination of whether a disclosure provides sufficient written description support for a claim is a question of fact. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

In this proceeding, Petitioner challenges the claims of priority of all claims of the ‘029 Patent to the earlier applications since the narrow disclosures of those applications do not provide written description support under 35 U.S.C. § 112(a) (AIA) (or 35 U.S.C. § 112, ¶1 (pre-AIA)) for the broader claims of the ‘029 Patent.™

During prosecution of the ‘027 Patent, the Patent Office did not make a finding on whether the claims of the ‘027 Patent were entitled to claim the benefit of priority to the earlier applications. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008)(“In the absence of an interference or rejection which would require the PTO to make a determination of priority, the PTO does not make such findings as a matter of course in prosecution.”).
B. The Inventors Were Not In Possession Of The Broad Subject Matter Of The Claims Of The ‘029 Patent When They Filed Their Earlier, Narrower Disclosures.

“The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)(internal quotations omitted). “The purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. *Id.* at 1563-1564 (emphasis in original) The written description requirement “guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.” *Id.* at 1561; see also *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009)(“[T]he purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.”)(internal quotations omitted). “[T]he description must clearly allow persons of ordinary skill in the art to recognize that [he or she]
invented what is claimed.” *Vas-Cath*, 935 at 1563-1564.

“The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.” *Lockwood*, 107 F.3d at 1572. “It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.” *Id.*

Here, Petitioner has already demonstrated that the claims of the ‘029 Patent are broad enough to encompass both (1) synthetic polyisoprene articles that include ‘*pre-vulcanized*’ synthetic polyisoprene particles, and (2) synthetic polyisoprene articles that do not include ‘*pre-vulcanized*’ synthetic polyisoprene particles. As will be explained, however, since the Second Application (‘445), the First Application (‘118), and the Provisional Application (‘637) to which the ‘029 Patent claims priority only provided written description support for synthetic polyisoprene articles that included ‘*pre-vulcanized*’ synthetic polyisoprene particles, this demonstrates that, when those earlier applications were filed, the inventors were not in possession of a broader invention commensurate with the scope of the later claims of the ‘029 Patent.
C. Later Filed Claims That Are Broader Than An Earlier, Narrower Disclosure Do Not Have Written Description Support.

It is well-settled in determining whether a claim has written description support under 35 U.S.C. § 112(a) (AIA) (or 35 U.S.C. § 112, ¶1 (pre-AIA)) that “a broad claim is invalid [for lacking written description support] when the entirety of the specification clearly indicates that the invention is of a much narrower scope.” Cooper Cameron Corp. v. Kvaerner Oilfield Prods., 291 F.3d 1317, 1323 (Fed. Cir. 2002); see also Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480 (Fed. Cir. 1998)(“[C]laims may be no broader than the supporting disclosure, and therefore . . . a narrow disclosure will limit claim breadth.”) Based upon this bedrock principle, the Federal Circuit has, on several occasions, rejected priority claims of later, broader claims seeking written description support from earlier, narrower disclosures.

For example, in Research Corp. Techs. v. Microsoft Corp., a case with nearly identical facts to those involved in this proceeding, the defendant was accused of infringing several related patents, including the ‘772 Patent. See 627 F.3d 859, 862 (Fed. Cir. 2010). The ‘772 Patent was part of a chain of continuation applications that all shared the same specification and claimed priority to a 1990 Application and a 1991 Application. Id. at 865, 870. Accordingly, the ‘772 Patent in Research Corp. was in an identical posture to the ‘029 Patent issue here: a later filed application that was a continuation of, and
claimed priority to, a chain of earlier-filed applications that shared the same specification. And as is the case here, the Federal Circuit had to determine whether the earlier applications (i.e., the 1990 and 1991 Applications) provided written description support under 35 U.S.C. § 112, ¶ 1 to the later-filed claims such that those claims would be entitled to the benefit of the earlier filing dates. As will be explained, the Court found that later claims were not entitled to the filing date of a parent because the later claims were broadened to cover more than what was disclosed in the narrower parent applications. See Research Corp., 627 F.3d at 872.

The patents in Research Corp. were directed to the “inventors’ halftoning technique us[ing] a blue noise mask, which was stored in a computer’s memory, to carry out a pixel-by-pixel comparison of the mask to the digital image . . . compar[ing] the gray level of each pixel in a digital image to the corresponding threshold number in the blue noise mask to produce a halftone image.” Id. at 862. But while the specification focused on the use of this “blue noise mask,” the claims at issue in the ‘772 Patent (i.e., claims 4 and 63) were broad enough to cover not only the blue noise masks described in the specification, but also additional masks. Id. at 871 (“Significantly, not all dot profiles that the claimed halftone masks produce need to have blue noise characteristics.”)

The Court then turned to a review of the 1990 and 1991 Applications (i.e.,
the parent applications) and found that “[i]n contrast” to these broad scope of these later claims, “the 1990 and 1991 Applications limit the invention to a “blue noise mask.”” *Id.* at 871. The Court based its findings that the earlier, narrower applications only supported claims limited to a “blue noise mask” on a number of aspects of the earlier applications that are also found in the applications to which the ‘029 Patent claims priority.

First, the Court emphasized that “the specifications repeatedly refer to a blue noise mask as ‘the present invention’ . . . .” *Id.* at 871. Similarly, in this proceeding, the specifications of each of the alleged priority applications repeatedly refer to the use of pre-vulcanization as the “present invention.” (EX1031 ¶[94].)

In view of the above, *the present invention provides a* surfactant-stabilized, *prevulcanized, synthetic polyisoprene latex composition* having a isopropanol index rating of 3.0 . . . The consistency of the coagulum indicates the degree of *pre-vulcanization* of the latex. As the latex becomes more *pre-vulcanized*, the coagulum loses more of its tackiness and becomes more crumbly. . . . The *prevulcanization* is monitored to assure that the synthetic latex emulsion is ready for dipping of polyisoprene condoms. (EX1006, EX1007 ¶[0031]; EX1005 ¶[0024].)

In view of the above, *the present invention provides* an article made from the above-described surfactant-stabilized, *pre-vulcanized,*
synthetic polyisoprene latex emulsion composition. (EX1006, EX1007 ¶[0059]; EX1005 ¶[0051].)

Thus, the present invention further provides a method of forming a synthetic polyisoprene latex article. The method comprises dipping a coagulant-free or coagulant coated former in the above-described pre-vulcanized synthetic polyisoprene aqueous latex emulsion composition at least once to form a thin layer of latex film with individual particles of pre-vulcanized synthetic polyisoprene on the surface of the former. (EX1006, EX1007 ¶[0044]; EX1005 ¶[0036].)

In fact, the specifications of each of the alleged priority applications go as far as stating that the “present invention is predicated on the discovery that soluble sulfur, such as S₈ rings of sulfur, is catalyzed by a zinc complex of dithiocarbamate in combination with potassium caprylate and sodium dodecyl benzene sulphonate (SDBS) surfactant creating pre-vulcanized, synthetic polyisoprene particles in a latex composition.” (EX1006, EX1007 ¶[0029]; EX1005 ¶[0022]; EX1031 ¶95.)

Second, in Research Corp., the Court found that the earlier applications only supported claims limited to a “blue noise mask” since the “specification also explains that the “objects of the invention are accomplished by generating a blue noise mask . . .” Research Corp., 627 F.3d at 872 (emphasis in original). Here, the specifications of each of the alleged priority applications emphasize that the alleged inventive pre-vulcanization was responsible for producing improved uniform inter-particle and intra-particle bonding and improved molecular weights.
The invention relates to producing synthetic polyisoprene articles and method therefor with improved inter particle and intra particle bond using controlled pre-vulcanized particles of synthetic latex that is dip formed into a thin latex article from an aqueous latex emulsion. (EX1006, EX1007 ¶[0002]; EX1005 ¶[0001].)

The present invention provides a latex article that is formed by dipping a condom shaped former in a pre-vulcanized synthetic latex emulsion without use of any coagulants and curing the condom thus produced. . . . Therefore using this methodology of using a pre-vulcanization accelerator package and post vulcanization accelerator package a substantially uniform cured synthetic latex condom film is produced. (EX1006, EX1007 ¶[0018]; EX1005 ¶[0017].)

The product thus produced has several distinguishing features that have imprints of this pre-vulcanization and post-vulcanization methodology. Since the synthetic polyisoprene thin film of latex is cured with improved crosslink density, the molecular weight between cross links exhibits a lower value. . . . (EX1006, EX1007 ¶[0019]; EX1005 ¶[0018].)

The present invention is predicated on the discovery that soluble sulfur, such as S₈ rings of sulfur, is catalyzed by a zinc complex of dithiocarbamate in combination with potassium caprylate and sodium dodecyl benzene sulphonate (SDBS) surfactant creating pre-vulcanized, synthetic polyisoprene particles in a latex composition. . . . The articles that result comprise a high quality and uniform latex film. (EX1006, EX1007 ¶[0029]; EX1005 ¶[0022].)
These express statements regarding the “present invention” convey to a POSITA that, at the time of the filing of these earlier applications, the inventors were only in possession of an invention that required “pre-vulcanized” synthetic polyisoprene particles, and were not in possession of the broader invention claimed in the ‘029 Patent that intentionally and belatedly omitted the “pre-vulcanized” limitation. (EX1031 ¶96.)

Third, the Research Corp. Court also found support for its determination that the 1990 and 1991 Applications limit the invention to a “blue noise mask” since “the figures in the patent only illustrate various aspects of a blue noise mask.” Research Corp., 627 F.3d at 872. Here, the only embodiments disclosed and figures shown in the specifications of each of the alleged priority applications involved the use of “pre-vulcanization.” (EX1006, EX1007 ¶[0022]; EX1005 ¶[0021])(“Fig. 1 is a transmission electron micrograph of the middle portion of a prevulcanized and post-vulcanized synthetic polyisoprene latex film prepared in accordance with the present invention . . . .”) Coupled with the “present invention” language in the specification, the fact that the only embodiments disclosed in the earlier applications require “pre-vulcanization” would convey to a POSITA that, at the time of the filing of these earlier applications, the inventors were not in possession of the broader invention claimed in the ‘029 Patent that intentionally and belatedly omitted the “pre-vulcanized” limitation. (EX1031
Fourth, the Court found it significant that “all fifteen approved claims of the 1990 Application and all ten approved claims of the 1991 Application recite a ‘blue noise mask.’” Research Corp., 627 F.3d at 872. Here, each and every independent claim (and therefore every claim) in each of the alleged priority applications (and the patents that issued from them (EX1003, EX1004)) recited pre-vulcanization. (EX1031 ¶98.)

1. A synthetic polyisoprene latex article comprising: a. synthetic polyisoprene particles that are **pre-vulcanized** and cured . . . . (EX1005 Claim 1.)

1. A synthetic polyisoprene elastomeric article comprising: synthetic polyisoprene particles that are **pre-vulcanized** and cured . . . . (EX1003, EX1006 Claim 1.)

10. A synthetic polyisoprene condom comprising: synthetic polyisoprene particles that are **pre-vulcanized** . . . and cured . . . . (EX1003, EX1006 Claim 10.)

1. A synthetic polyisoprene elastomeric glove or condom comprising: synthetic polyisoprene particles that are **pre-vulcanized** and cured . . . . (EX1004, EX1007 Claim 1.)

8. A method for manufacturing synthetic polyisoprene article comprising the steps of: a. adding to an aqueous synthetic polyisoprene latex a **pre-vulcanization composition** . . . to pre-
vulcanize synthetic polyisoprene particles in said latex . . . . (EX1005 Claim 8.)

13. A method for manufacturing a synthetic polyisoprene elastomeric article comprising the steps of: adding to an aqueous latex of synthetic polyisoprene particles a pre-vulcanization composition; prevulcanizing the synthetic polyisoprene particles in said latex . . . . (EX1003, EX1006 Claim 13.)

Coupled with the “present invention” language in the specification, the fact that all of the independent claims of the earlier applications expressly required “pre-vulcanization” would convey to a POSITA that, at the time of the filing of these earlier applications, the inventors were not in possession of the broader invention claimed in the ‘029 Patent that intentionally and belatedly omitted the “pre-vulcanized” limitation. (EX1031 ¶99.)

Based on all of these findings, the Research Corp. Court concluded that “the 1990 and 1991 Applications disclose only a blue noise mask.” Research Corp., 627 F.3d at 872. Accordingly, under nearly identical circumstances to those in this proceeding, the Federal Circuit determined that, since the claims of the later-filed ‘772 Patent “are broader than the invention disclosed in the 1990 and 1991 Applications . . . [a] person of ordinary skill in the art would not understand from the 1990 and 1991 Applications that the inventors had disclosed” the scope of those later claims, which were therefore “not entitled to claim the benefit of their
parent applications’ filing dates.” Id. at 872.

Similarly, in Tronzo v. Biomet, Inc., the Federal Circuit found that later, broader claims to a medical device that did not include any limitations to shape were not supported by the parent application’s narrower disclosure of a conical-shaped cup. 156 F.3d 1154, 1159 (Fed. Cir. 1998). In doing so, the Federal Circuit emphasized that the parent application’s “specification specifically distinguishes the prior art as inferior and touts the advantages of the conical shape of the . . . cup.” Tronzo, 156 F.3d at 1159. Here, the specifications of each of the alleged priority applications confirmed that there is no support for claims that do not require pre-vulcanization by repeatedly distinguishing the prior art for not using pre-vulcanization. (EX1031 ¶100.)

U.S. Pat. Nos. 6,653,380 and 7,048,977 to Dzikowicz disclose latex film compound with improved tear resistance. . . . The latex used is not synthetic polyisoprene and the addition of antioxidants does not pre-vulcanize the synthetic polyisoprene latex. (EX1006, EX1007 ¶[0013]; EX1005 ¶[0012]; EX1018; EX1019.)

U.S. Pat. No. 7,041,746 to Dzikowicz discloses accelerator system for synthetic polyisoprene latex. . . . The accelerators are not indicated to pre-vulcanize the synthetic polyisoprene particles . . . . (EX1006, EX1007 ¶[0015]; EX1005 ¶[0014]; EX1020.)

UK patent application GB 2,436,566 to Attrill et al. discloses minimizing prevulcanization of polyisoprene latex. This process for
making a polyisoprene latex comprises compounding a synthetic polyisoprene latex with compounding ingredients and maturing the latex at a low temperature so as to minimize pre-vulcanization. . . .

The absence of pre-vulcanization is verified by assuring the strength of a ring made has a prevulcanisate relaxed modulus has a value less than 0.1 MPa indicative of the absence of pre-vulcanization. . . . The’ 566 patent application teaches away from pre-vulcanization prior to dipping of latex articles. (EX1006, EX1007 ¶[0016]; EX1005 ¶[0015]; EX1021.)

Table 4 shows the mechanical properties of a synthetic polyisoprene latex film produced using the best synthetic polyisoprene disclosed in U.S. Pat. No. 6,828,387 (Wang) as compared to pre-vulcanized and post-vulcanized latex films of the subject invention. (EX1005 ¶[0041]; EX1022.)

In the absence of pre-vulcanization of the synthetic polyisoprene particles, crosslinking predominantly occurs in the periphery of the synthetic polyisoprene particles, resulting in weak particles. Attempts to crosslink the inter particle region within the particles only during post-vulcanization results in over crosslinking of the intra-particle regions, which, in turn, results in a latex product with poor stretch properties. (EX1006, EX1007 ¶[0046]; EX1005 ¶[0038].)

The fact that the specifications of the earlier applications all distinguish the prior art for not using pre-vulcanization would convey to a POSITA that, at the time of the filing of these earlier applications, the inventors were not in possession
of the broader invention claimed in the ‘029 Patent that intentionally and belatedly omitted the “pre-vulcanized” limitation. (EX1031 ¶101.)

Finally, in *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, the Federal Circuit found that a claim that did not expressly include a limitation reciting the one method (“maintaining updated sums”) for accomplishing the invention as disclosed in the specification did not have written description support:

The trouble with allowing claim 21 to cover all ways of performing DWT-based compression processes that lead to a seamless DWT is that *there is no support for such a broad claim in the specification*. The *specification provides only a single way* of creating a seamless DWT, which is by maintaining updated sums of DWT coefficients. There is no evidence that the specification contemplates a more generic way of creating a seamless array of DWT coefficients. 424 F.3d 1336, 1344 (Fed. Cir. 2005).

The Court then provided a useful analogy to illustrate the limitations on attempting to enlarge the scope of a claim based on a narrow disclosure:

By analogy, suppose that an inventor created a particular fuel-efficient automobile engine and described the engine in such detail in the specification that a person of ordinary skill in the art would be able to build the engine. *Although the specification would meet the requirements of section 112 with respect to a claim directed to that particular engine, it would not necessarily support a broad claim to every possible type of fuel-efficient engine*, no matter how different in structure or operation from the inventor’s engine. *Id.* at 1346;
Guided by this analogy, the Board should find that Patent Owner’s narrow disclosure in its earlier applications of an alleged invention that required “pre-vulcanization” to provide the desired intra-polyisoprene particle and intra-polyisoprene particle crosslinks does not support every possible solution that would provide those claimed features, including solutions that do not even involve pre-vulcanization. See also ICU Med., 558 F.3d at 1378 (holding that later added claims to a medical valve that removed the requirement of a spike did not have written description support since “the specification describes only medical valves with spikes” and that “[b]ased on this disclosure, a person of skill in the art would not understand the inventor . . . to have invented a spikeless medical valve”).

Here, since the specifications of each of the alleged priority applications only disclose embodiments that require pre-vulcanization to provide the desired article, they do not provide written description support for any of the broader, generic claims of the ‘029 Patent that do not recite such pre-vulcanization. (EX1031 ¶97.) A POSITA reading these earlier applications that only disclose using pre-vulcanization would understand that, at the time of the filing of these earlier applications, the inventors were not in possession of the broader invention claimed in the ‘029 Patent that intentionally and belatedly omitted the “pre-vulcanized” limitation. (EX1031 ¶97.)
D. Patent Owner’s Admissions In The European Patent Office Confirm That The Earlier Applications Narrowly Disclose An Invention That Requires Pre-Vulcanization.

As discussed above, the specifications of the earlier applications only disclose articles that included “pre-vulcanized” particles or methods that involved “pre-vulcanizing the synthetic polyisoprene particles.” In addition, Patent Owner has confirmed that narrow scope of its disclosed invention in admissions made during the prosecution of its corresponding patent application in the European Patent Office.

On April 27, 2009, Patent Owner filed a Patent Cooperation Treaty application, which published as WO2009134702 A (EX1023), claiming priority to the First Application (‘118) and Provisional Application (‘637). The PCT application has the same specification as the First Application (‘118). (Compare EX1023 and EX1006 (only difference is cross-reference paragraph [0001]).)

Patent Owner then entered the national stage of the European Patent Office in November 2010. (EX1024.) Like the claims in the U.S. patent applications, the EPO claims also all required either “pre-vulcanized” particles or methods that involved “pre-vulcanizing the synthetic polyisoprene particles.” (EX1024 Claims 1 and 11.)

In December 2015, the EPO rejected the claims in an office action. (EX1025.) After an Examiner Interview (EX1026), Patent Owner submitted a
response to the office action on April 15, 2016, emphasizing that the “[s]ubject matter of the present invention is a synthetic polyisoprene condom comprising pre-vulcanized and post-vulcanized polyisoprene particles.” (EX1027, Letter at 6.) Patent Owner then went further, stating:

According to the present invention, the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are uniform. This uniformity is achieved by monitoring and controlling the pre-vulcanization and controlling the postvulcanization. In particular, the pre-vulcanization is performed until the synthetic polyisoprene particles are no longer very tacky but exhibit a lower degree of tackiness with an isopropanol index of 3 (page 6, lines 20-23 of WO 2009/134702 A1). The post-vulcanization is performed in the usual manner, namely using conditions that obtain tensile strength values around 10% to 15% before the peak of the tensile strength value, as is well known in the art. (EX1027, Letter at 6)(emphasis in original.)

In doing so, Patent Owner admitted that the alleged inventive concept that Patent Owner claims produced the uniform crosslinks was not found in the disclosed post-vulcanization techniques, but, instead, resulted from “monitoring and controlling the pre-vulcanization” before the “post-vulcanization is performed in the usual manner.” (EX1027, Letter at 6.)

Applicants have found out that by controlling the pre-vulcanization as described in the present application, and controlling the post-vulcanization as usual, the claimed uniformity between intra-
polyisoprene particle crosslinks and interpolyisoprene particle crosslinks is obtained. (EX1027, Letter at 7.)

Then, in attempting to distinguish Wang (EX1022), Patent Owner once again emphasized that the focus of its invention was centered on pre-vulcanization:

US 2004/0169317 A1 fails to disclose, however, an optimum amount of the prevulcanization degree, and how to determine that the prevulcanization has reached an optimum. US 2004/0169317 A1, in fact, fails to teach any benefit of prevulcanization. . . . US 2004/0169317 A1 furthermore fails to teach or suggest a prevulcanization degree which allows for superior tensile properties in the final product, or a method for determining that such optimum prevulcanization degree has been accomplished. (EX1027, Letter at 9-10.)

Several months later, on August 2, 2016, the EPO responded, confirming its understanding that the specifications’ disclosure of “monitoring and controlling of the pre-vulcanization” was “essential” to the invention:

According to the applicant (letter dated 15-04-2016) and the description of the application (pages 6-9) the monitoring and controlling of the pre-vulcanization and the controlling of the post vulcanization in order to achieve the presence of sulfur within the polyisoprene particle and the uniform cross-links of the intra- and inter polyisoprene particles is essential. (EX1028 at 2.)

Since the controlling and monitoring of the pre-vulcanisable and post vulcanisable step is essential and is the distinguishing feature with the prior art, the applicant is invited to, looking at the above mention
points, clarify claim 1 making use of the disclosure found in the description of the present application. (EX1028 at 2.)

Accordingly, the EPO Application provides further evidence that the earlier specifications are narrow in scope and do not provide written description support for any of the later, broader claims of the ‘029 Patent.

E. The Effective Filing Date Of The ‘029 Patent Is No Earlier Than June 5, 2013, And Is More Than One Year After the Publication Of The First Publication (‘384).

Since none of the claims of the ‘029 Patent are entitled to claim the benefit of the priority dates of any of the Second Application (‘445), the First Application (‘118), or the Provisional Application (‘637), the earliest possible effective date of the ‘029 Patent is June 5, 2013, the actual filing date of the Third Application (‘364), which issued as the Third Patent (‘027). As explained above and as shown once again in the diagram below, since the First Publication (‘384) published on November 5, 2009, more than one year before the effective filing date of the ‘029 Patent.

7 Since the filing date of the Second Application (‘445) (October 20, 2011) is also more than one year after the publication date of the First (‘384) Publication (November 5, 2009), even if the claims of the ‘027 Patent were entitled to claim priority to the filing date of the Second Application (‘445), the First (‘384) Publication would still be a 35 U.S.C. § 102(b) prior art reference to the ‘027 Patent.
Patent, the First Publication (‘384) is prior art under 35 U.S.C. § 102(a)(1) (AIA) or 35 U.S.C. § 102(b) (pre-AIA) to all of the claims of the ‘029 Patent.

F. Since Petitioner Has Identified Prior Art That Existed Before The Actual Filing Date Of The ‘029 Patent, Patent Owner Must Now Try To Demonstrate Entitlement To Its Claimed Priority.

“In an inter partes review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that burden never shifts to the patentee.” Dynamic Drinkware, LLC v. Nat’l
Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015). This burden of persuasion remains with Petitioner, while the burden of production—the burden to come forward with evidence—shifts between the parties. *See Tech. Licensing*, 545 F.3d at 1327–29 (Fed. Cir. 2008).

As the Federal Circuit explained most recently in *Dynamic Drinkware*, a patent challenger has the burden of going forward to show that there is invalidating prior art. *See Dynamic Drinkware*, 800 F.3d at 1379. Although the patent challenger has the ultimate burden of persuasion, a patentee must demonstrate entitlement to a priority date when the patentee relies on that priority date to overcome an anticipation or obviousness argument. *See id.* at 1379–80; *In re NTP*, Inc., 654 F.3d 1268, 1276 (Fed. Cir. 2011)(noting “a patent’s claims are not entitled to an earlier priority date because the patentee claims priority . . . [r]ather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120“); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986)(“[T]he art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.”).

Here, Petitioner asserts that the First Publication (‘384), which published on November 5, 2009 and more than one year prior to the actual filing date of the ‘029 Patent, anticipates all of the challenged claims under 35 U.S.C. § 102(a)(1) (AIA)
or 35 U.S.C. § 102(b) (pre-AIA). Accordingly, the burden of production shifts to Patent Owner to demonstrate that its priority claim is proper.

IX. APPLICATION OF THE PRIOR ART TO CHALLENGED CLAIMS


A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a prior art reference. See Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Here, each and every limitation of claims 1-20 of the ‘029 Patent is expressly disclosed in the First Publication (‘384) (EX1010) to which the ‘029 Patent claims priority.

Since the First (‘384) Publication is a parent application to, and has an identical specification as, the ‘029 Patent, the demonstration of anticipation is straightforward as the claim language is disclosed verbatim in the prior art reference as shown in the detailed chart below. See Guangdong Xinbao Electrical Appliances Holdings Co., Ltd. v. Rivera, IPR2014-00042, Paper 50 at 22 (P.T.A.B. Feb. 6, 2015)(“Testimony from a technical expert is not a prerequisite for establishing unpatentability by a preponderance of the evidence, however, just as it is not a prerequisite for a petition seeking inter partes review.”); U.S. Bancorp v. Retirement Capital Access Management Co., CBM2013-00014, Paper 33 at 18–19 (P.T.A.B. Aug. 22, 2014); Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d
Prior to setting forth the claim chart, it should be noted that, as is the case here, it is well settled that the narrow disclosure of a parent or grandparent application in a chain of priority applications may not have adequate written description support for a later-filed broad claim, but nevertheless be sufficient to invalidate that later-filed broad claim. See, e.g., In re Lukach, 442 F.2d 967, 969-970 (C.C.P.A. 1971) (“[T]he description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes, whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure.”)(internal citations omitted); Chester v. Miller, 906 F.2d 1574, 1577 (Fed. Cir. 1990)(“[W]e see no impermissible anomaly or logical inconsistency in” finding that the “‘280 patent fails to provide sufficient written description to support his CIP claims and then find that the ‘280 patent anticipates those very claims.”); Lockwood, 107 F.3d at 1571-72 (parent application that did not provide written description support for a claim nevertheless invalidated the claim); Santarus, Inc. v. Par Pharm., Inc., 694 F.3d 1344, 1352 (Fed. Cir. 2012)(“Due to breaks in the chain of priority, Santarus is unable to claim an early enough priority
date to preclude use of [its] own ‘737 patent as prior art for some of the asserted claims.”)

Here, Petitioner has demonstrated that the Second Application (‘445), the First Application (‘118), and the Provisional Application (‘637) to which the ‘029 Patent claims priority only provided written description support for synthetic polyisoprene articles that included “pre-vulcanized” synthetic polyisoprene particles or methods that involved “pre-vulcanizing” the synthetic polyisoprene particles.” Petitioner has also demonstrated that the claims of the ‘029 Patent, which generically claim “synthetic polyisoprene particles,” are broad enough to encompass both (1) synthetic polyisoprene articles that include “pre-vulcanized” synthetic polyisoprene particles, and (2) synthetic polyisoprene articles that do not include “pre-vulcanized” synthetic polyisoprene particles. Accordingly, the disclosure of the narrower (species) embodiment that requires pre-vulcanized particles in the First Publication (‘384) anticipates the broader (genus) claims of the ‘029 Patent that encompass articles with or without pre-vulcanized particles. 

See In re Lukach, 442 F.2d at 969-970; Chester, 906 F.2d at 1577; Lockwood, 107 F.3d at 1571-72; Santarus, 694 F.3d at 1352.

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<tr>
<td>1. A synthetic polyisoprene elastomeric glove or condom made of a layer of elastomer comprising:</td>
<td>“The present invention provides a latex article that is formed by dipping a condom shaped former in a pre-vulcanized synthetic latex emulsion without use of any coagulants and curing the condom thus produced. Synthetic polyisoprene latex is available from Kraton, which is produced by anionic polymerization with a high cis-1,4 content.” ([¶][0018])</td>
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<td>“Thus, the present invention further provides a method of forming a synthetic polyisoprene latex article.” The method comprises dipping a coagulant-free or coagulant coated former in the above-described pre-vulcanized synthetic polyisoprene aqueous latex emulsion composition at least once to form a thin layer of latex film with individual particles of pre-vulcanized synthetic polyisoprene on the surface of the former. The former can be any suitable former as is known in the art. The present inventive composition is particularly useful for layering onto formers for condoms and gloves.” ([¶][0044])</td>
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<td>“The synthetic polyisoprene article is preferably a condom or a glove.” ([¶][0059])</td>
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<td>“1. A synthetic polyisoprene elastomeric article comprising: synthetic polyisoprene particles that are pre-vulcanized and cured; said synthetic polyisoprene particles bonded to each other through intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks; wherein the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are substantially uniform in said synthetic polyisoprene latex article.” (Claim 1)</td>
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<td>“2. The synthetic polyisoprene elastomeric article of claim 1, wherein said latex article is a condom or a glove.” (Claim 2)</td>
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See also Abstract, ¶¶[0002], [0051], [0052], [0057], Claims 10, 13.
**Patent Claim Language** | **U.S. Publication No. 2009/0272384 A1**  
**First (‘384) Publication - EX1010**

| polyisoprene particles; | wets *synthetic polyisoprene particles* and permeates small sized sulfur and accelerator molecules into the interior of these particles thereby pre-vulcanizing the particles.” (Abstract)  
“The *synthetic latex particles* in the latex emulsion are pre-vulcanized by the incorporation of sulfur within the interstices of latex particles.” ([¶][0018])

“During post vulcanization cure, *pre-vulcanized synthetic polyisoprene particles* with the permeated sulfur also cure completely in the intra-particle regions.” ([¶][0018])

“Preferably, the *synthetic polyisoprene particles* are cis-1,4-polyisoprene, have a diameter in the range of about 0.2 to 2 micrometers, and are maintained in an aqueous medium of the latex emulsion.” ([¶][0020])

“1. A synthetic polyisoprene elastomeric article comprising: *synthetic polyisoprene particles* that are pre-vulcanized and cured; said *synthetic polyisoprene particles* bonded to each other through intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks; wherein the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are substantially uniform in said synthetic polyisoprene latex article.” (Claim 1)

See also ¶¶ [0002], [0021], [0032], [0037], [0040], [0044], Claims 10, 13.

| inter-polyisoprene particle crosslinks; and intra-polyisoprene particle crosslinks, | “The film can be post-vulcanized by heating the film, e.g., to about 120 to 150° C. for about 8 to 15 min. During this period, the *inter-particle regions are cross-linked. The intra-particle regions also undergo further crosslinking*, producing a more homogeneous latex product. Then, the method comprises stripping the latex film from the former.” ([¶][0045])

“The article has *intra-particle and inter-particle crosslinking* and under transmission electron microscopy (TEM) a uniform distribution of dark stains with a deviation of less than about |
<table>
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<tbody>
<tr>
<td>5% from one location to other within the TEM micrograph. The synthetic polyisoprene article is preferably a condom or a glove.” (¶[0059])</td>
<td>“1. A synthetic polyisoprene elastomeric article comprising: synthetic polyisoprene particles that are pre-vulcanized and cured; said synthetic polyisoprene particles bonded to each other through intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks; wherein the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are substantially uniform in said synthetic polyisoprene latex article.” (Claim 1) See also ¶¶ [0002], [0022], [0058], Claims 10, 13.</td>
</tr>
</tbody>
</table>
| wherein the intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks are substantially uniformly distributed among and between the synthetic polyisoprene particles. | “The film can be post-vulcanized by heating the film, e.g., to about 120 to 150° C. for about 8 to 15 min. During this period, the inter-particle regions are cross-linked. The intra-particle regions also undergo further crosslinking, producing a more homogeneous latex product. Then, the method comprises stripping the latex film from the former.” (¶[0045]) “The article has intra-particle and inter-particle crosslinking and under transmission electron microscopy (TEM) a uniform distribution of dark stains with a deviation of less than about 5% from one location to other within the TEM micrograph. The synthetic polyisoprene article is preferably a condom or a glove.” (¶[0059]) “1. A synthetic polyisoprene elastomeric article comprising: synthetic polyisoprene particles that are pre-vulcanized and cured; said synthetic polyisoprene particles bonded to each other through intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks; wherein the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are substantially uniform in said synthetic polyisoprene latex article.” (Claim 1) “9. The synthetic polyisoprene elastomeric article of claim 1,
<table>
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<tr>
<td>wherein said <em>substantial uniformity of intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks</em> is verified by scanning electron microscopy of a fracture surface that passes through both inter-particle regions and intra-particle regions nonpreferentially.” (Claim 9)</td>
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</table>

See also Abstract, ¶¶ [0022], [0058], Claims 10, 13.

2. The glove or condom of claim 1, wherein such uniformity is measured by one or more of the following
(a) the glove or condom exhibits a substantially conchoidal fracture when fractured at liquid nitrogen temperature,

“FIG. 2 is a scanning electron micrograph of a cross section of a *synthetic polyisoprene condom that was frozen in liquid nitrogen and cleaved*. The sample was coated with a thin film of iridium to prevent charging of the insulating latex rubber condom by electron beam. Due to the low temperature of liquid nitrogen, the *synthetic polyisoprene condom material behaved as a brittle solid showing conchoidal or shell-like fracture surfaces along X1-X1 and X2-X2*. There were no grains visible in this fracture surface, indicating that the fracture strength at the intra grain region and inter grain region was very nearly the same and the therefore the fracture surface was nearly isotropic everywhere. A dimensional marker shows a line, which is calibrated to be 20 microns in length.” (¶[0023])
<table>
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<tbody>
<tr>
<td></td>
<td><strong>Fig. 2</strong></td>
</tr>
<tr>
<td></td>
<td><img src="image_url" alt="Image" /></td>
</tr>
</tbody>
</table>

(Figure 2)

“3. The synthetic polyisoprene elastomeric article of claim 1, wherein said \textit{latex article exhibits a substantially conchoidal fracture when fractured at liquid nitrogen temperature}.”

(Claim 3)

or (b) the glove or condom exhibits a fracture surface with an absence of scanning electron microscope-viewable intra-polyisoprene particle and inter-polyisoprene particle features when ruptured at room temperature,

“FIG. 5 is a \textit{scanning electron micrograph of the fracture surface of a condom that was ruptured} by blowing high pressure nitrogen to form a balloon that eventually burst. This test was done \textit{at room temperature}. The sample was coated with a thin film of iridium to prevent charging of the insulating latex rubber condom by electron beam. \textit{The fracture surface as shown in this figure shows a fracture surface that was very nearly planar with no features indicating intra particle or inter particle regions. This absence of intra-polyisoprene particle and inter-polyisoprene particle features} means that the fracture surface propagated with no preference for either the intra particle region or the inter particle regions indicating that both inter and intra particle regions were approximately equal.
<table>
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<tbody>
<tr>
<td>strength or were crosslinked nearly equally. The latex condom fractured at room temperature as an elastic solid showing planar fracture surface, not a conchoidal or shell-like fracture surface. There were no grains visible in this fracture surface, indicating that the fracture strength at the intra grain region and inter grain region was very nearly the same and the therefore the fracture surface was nearly isotropic everywhere. A dimensional marker shows a line, which is calibrated to be 20 microns in length.” (¶[0026])</td>
<td></td>
</tr>
<tr>
<td>“4. The synthetic polyisoprene elastomeric article of claim 1, wherein scanning electron microscopic observation of a fracture surface obtained by rupture of the article at room temperature shows absence of intra-polyisoprene particle and inter-polyisoprene particle features.” (Claim 4)</td>
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</table>

(Figure 5)

“A synthetic polyisoprene latex emulsion has pre-vulcanization composition and post vulcanization composition. … The dipped synthetic polyisoprene article is substantially uniformly cured both in the inter-particle and

or (c) osmium tetroxide staining.
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<tbody>
<tr>
<td>intra-particle regions and reliably exhibits high cross link density, uniform distribution of double bonds in TEM and zinc segregation at the boundaries or original particles by electron microprobe analysis.” (Abstract)</td>
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</tr>
<tr>
<td>“FIG. 1 shows a transmission electron micrograph of a pre-vulcanized and post-vulcanized synthetic polyisoprene condom latex taken from the middle portion of the condom thickness. . . . The sections were carefully relaxed by exposure to low levels of xylene vapor and transferred to Transmission Electron Microscopy (TEM) grids. The sections were then stained in osmium tetroxide vapor for one hour and examined by TEM. Osmium tetroxide reacts with carbon-carbon double bonds and, therefore, it imparts a dark stain to polymers containing unsaturated groups, while leaving the polystyrene unstained. The figure shows at 10 the original synthetic polyisoprene particles showing uniform distribution of cross-link networks. The intersection of these particles is shown at 11, and it shows a similar distribution of cross-link networks indicated by uniformity of dark stains, indicating that the synthetic polyisoprene latex film is cross-linked at the synthetic polyisoprene particle level and at intersections. The polystyrene remnants are seen at 13. The overall particle size is approximately 0.8 microns. This homogeneously cured, synthetic polyisoprene results in improved tensile strength at break, superior elongation, and tear properties. (¶[0058])</td>
<td></td>
</tr>
<tr>
<td>In view of the above, the present invention provides an article made from the above-described surfactant-stabilized, pre-vulcanized, synthetic polyisoprene latex emulsion composition. The article is free from defects and has a stretch to failure of at least about 600%. Table 5 shows an elongation of over 1000% at failure. The article has intra-particle and inter-particle crosslinking and under transmission electron microscopy (TEM) a uniform distribution of dark stains with a deviation of less than about 5% from one location to other within the TEM micrograph. The synthetic polyisoprene article is preferably a condom or a glove.”</td>
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<td>---------------------------------------------------------------------------</td>
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<tr>
<td>(¶[0059]) Fig. 1</td>
<td>“8. The synthetic polyisoprene elastomeric article of claim 1, wherein <em>TEM of an osmium tetroxide treated article shows uniformity of isoprene double bonds.</em>”</td>
</tr>
<tr>
<td>3. A condom of claim 2, wherein the glove or condom is formed of two or more thin layers of said elastomer consistent with dipping on a former without coagulant on the former.</td>
<td>“There is a need, therefore, for a stable synthetic polyisoprene latex emulsion composition that does not agglomerate or flock, providing usable emulsion lifetimes. The composition should achieve substantial intra-particle and inter-particle crosslinking in the final product. Such a composition would enable the <em>dip-forming of articles in the absence of a coagulant, such that articles having thinner, continuous, and defect-free layers</em> with enhanced strength and improved stretchability could be obtained.” (¶[0017])</td>
</tr>
<tr>
<td></td>
<td>“The present invention provides a latex article that is <em>formed by dipping a condom shaped former in a pre-vulcanized synthetic latex emulsion without use of any coagulants</em> and curing the condom thus produced.” (¶[00018])</td>
</tr>
</tbody>
</table>
|                                                                                   | “13. A method for manufacturing a synthetic polyisoprene elastomeric article comprising the steps of: adding to an aqueous latex of synthetic polyisoprene particles a pre-
<table>
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<tr>
<td>vulcanization composition comprising soluble sulfur, a zinc dithiocarbamate and a surfactant; pre-vulcanizing the synthetic polyisoprene particles in said latex; adding to said latex a post-vulcanization composition; dipping a coagulant-free or coagulant-coated former in the shape of a glove or a condom into said latex one or more times to form a latex film; curing said latex film during post-vulcanization to produce inter-particle crosslinks within the synthetic polyisoprene particles and produce intra-particle crosslinks between said particles; wherein the intra-polyisoprene particle crosslinks and the inter-polyisoprene particle crosslinks are substantially uniform.” (Claim 13)</td>
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<tr>
<td>“14. The method according to claim 13 wherein said article is a condom and said former is coagulant-free.” (Claim 14)</td>
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<tr>
<td>“Preferably, the synthetic polyisoprene particles are cis-1,4-polyisoprene, have a diameter in the range of about 0.2 to 2 micrometers, and are maintained in an aqueous medium of the latex emulsion.” ([0020])</td>
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</tr>
<tr>
<td>4. The glove or condom of claim 2, wherein the synthetic polyisoprene particles range in size from about 0.2 to about 2.0 micron.</td>
<td></td>
</tr>
<tr>
<td>“Tensile Properties of synthetic polyisoprene production condom measured according to ISO 4074:2002 test method is shown in the Table 4 below.</td>
<td></td>
</tr>
<tr>
<td>5. A condom of claim 1, wherein the condom has a tensile strength of at least 30 MPa.</td>
<td></td>
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</tbody>
</table>
6. The condom of claim 5, wherein the condom exhibits a fracture surface with an absence of scanning electron microscope-viewable intra-polyisoprene particle and inter-polyisoprene particle features when ruptured at room temperature. **Same as Claim 2(b).**

7. The condom of claim 1, wherein the condom is formed **Same as Claim 3.**
<table>
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<tr>
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<tbody>
<tr>
<td>of two or more thin layers of said elastomer consistent with dipping on a former without coagulant on the former.</td>
<td></td>
</tr>
<tr>
<td>8. The glove or condom of claim 1, wherein said glove or condom exhibits a substantially conchoidal fracture when fractured at liquid nitrogen temperature.</td>
<td>Same as Claim 2(a).</td>
</tr>
<tr>
<td>9. The glove or condom of claim 1, wherein the synthetic polyisoprene particles range in size from about 0.2 to about 2.0 microns.</td>
<td>Same as Claim 4.</td>
</tr>
<tr>
<td>10. The glove or condom of claim 9, wherein the glove or condom exhibits a fracture surface with an absence of scanning electron microscope-viewable intra-polyisoprene particle and inter-</td>
<td>Same as Claim 2(b).</td>
</tr>
<tr>
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<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>polyisoprene particle features when ruptured at room temperature.</td>
<td></td>
</tr>
<tr>
<td>11. The glove or condom of claim 1, wherein the glove or condom exhibits a fracture surface with an absence of scanning electron microscope-viewable intra-polyisoprene particle and inter-polyisoprene particle features when ruptured at room temperature.</td>
<td>Same as Claim 2(b).</td>
</tr>
<tr>
<td>12. A condom of claim 11, wherein the condom has an elongation at break of at least 945%.</td>
<td>In view of the above, the present invention provides an article made from the above-described surfactant-stabilized, pre-vulcanized, synthetic polyisoprene latex emulsion composition. The article is free from defects and has a stretch to failure of at least about 600%. Table 5 shows an elongation of over 1000% at failure.” (¶[0059])</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Batch No.</th>
<th>Sample Description</th>
<th>Median Tear Strength N/mm</th>
<th>Median Tear Force N</th>
<th>Average Tear Strength N/mm</th>
<th>Average Tear Force N</th>
</tr>
</thead>
<tbody>
<tr>
<td>612141816</td>
<td>Natural Rubber Unaged</td>
<td>54.26</td>
<td>3.62</td>
<td>53.29</td>
<td>3.57</td>
</tr>
<tr>
<td>612141816</td>
<td>Natural Rubber Aged 7 days 70°C</td>
<td>46.67</td>
<td>3.36</td>
<td>46.15</td>
<td>3.29</td>
</tr>
<tr>
<td>606040116</td>
<td>Synthetic polyisoprene Unaged</td>
<td>34.83</td>
<td>2.54</td>
<td>34.6</td>
<td>2.52</td>
</tr>
<tr>
<td>606040116</td>
<td>Synthetic polyisoprene Aged 7 days 70°C</td>
<td>34.13</td>
<td>2.33</td>
<td>34.65</td>
<td>2.37</td>
</tr>
</tbody>
</table>

(¶[0051], Table 5)

“12. The condom of claim 10 having an elongation at break of at least 945%.” (Claim 12)

13. A condom of claim 12, wherein said glove or condom exhibits a substantially conchoidal fracture when fractured at liquid nitrogen temperature. **Same as Claim 2(a).**

14. The glove or condom of claim 1, wherein the glove or condom exhibits scanning electron microscopic-viewable zinc and sulfur x-ray maps on a fracture surface when fractured at liquid nitrogen

“FIG. 7A is a set of three photographic images. A first image provides a scanning electron micrograph of the fracture at a selected location near the circular feature near the central location of FIG. 5. An image of a zinc x-ray map in the same area and an image of a sulfur x-ray map are also shown. It is recognized that generally, upon creation, x-ray maps of zinc and sulfur are usually a black background photograph with zinc or sulfur x-ray beams emitted from the sample providing a series of white dots. The zinc map and sulfur map of FIG. 7A, however, were inverted in contrast for clarity. A selected region marked P2 is shown in all three
temperature, or when ruptured at room temperature, or both, shows presence of sulfur within a polyisoprene particle that is decorated by zinc. images. As seen in the zinc x-ray map, the region P2 encompasses a series of zinc black dots that define a region, with no zinc black dots within the region. The corresponding sulfur x-ray map shows plurality of sulfur black dots. From this image, it is concluded that this was a single grain of polyisoprene particle in the polyisoprene latex emulsion. It is also concluded that during the pre-vulcanization stage, the sulfur molecule was catalyzed by the ZDBC allowing sulfur to enter the polyisoprene particle, as seen in the sulfur x-ray map. The zinc, on the other hand, was left behind due to the large molecular size of ZDBC decorating the exterior of the polyisoprene particle as seen in the zinc x-ray map. FIG. 7B shows the x-ray maps of zinc and sulfur in the region P2 that have been magnified for clarity, where the zinc black dots and sulfur black dots are clearly visible. The polyisoprene particle in the region P2 has an approximate dimension of 4 microns.” (¶[0028])

**Fig. 7A**

- SEM Micrograph
- Zinc Distribution Map
- Sulfur Distribution Map

**Fig. 7B**

- Zinc Distribution Map
- Sulfur Distribution Map
<table>
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<tr>
<td>(Figures 7A and 7B)</td>
<td>“5. The synthetic polyisoprene elastomeric article of claim 1, wherein <strong>scanning electron microscopic zinc and sulfur x-ray maps</strong> observation of a fracture surface obtained by fracture of the article at liquid nitrogen temperature, rupture at room temperature, or both shows presence of sulfur within a polyisoprene particle that is decorated by zinc.” (Claim 5)</td>
</tr>
<tr>
<td>15. The glove or condom of claim 1, wherein the glove or condom, exhibits, by microprobe elemental analysis, an accumulation of zinc surrounding said synthetic polyisoprene particles.</td>
<td>“There is <strong>an accumulation of zinc containing compound surrounds each of the original synthetic polyisoprene particles, and this microstructural feature can be readily observed by microprobe elemental analysis using an electron microscope.</strong>” ([¶][0019]) “7. The synthetic polyisoprene elastomeric article of claim 1, wherein <strong>microprobe elemental analysis by electron microscopy shows an accumulation of zinc surrounding said synthetic polyisoprene particles.</strong>” (Claim 7).</td>
</tr>
<tr>
<td>16. The glove or condom of claim 1, wherein TEM of an osmium tetroxide treated said glove or condom shows uniformity of isoprene double bonds.</td>
<td><strong>Same as Claim 2(c).</strong></td>
</tr>
</tbody>
</table>
| 17. The glove or condom of claim 1, wherein the glove or condom exhibits uniform intra-polyisoprene particle crosslinks and inter-polyisoprene | “FIG. 5 is a scanning electron micrograph of the fracture surface of a condom that was ruptured by blowing high pressure nitrogen to form a balloon that eventually burst. This test was done at room temperature. The sample was coated with a thin film of iridium to prevent charging of the insulating latex rubber condom by electron beam. The fracture surface as shown in this figure shows a fracture surface that was very nearly planar with no features indicating intra particle or inter particle regions. **This absence of intra-**
Table 1: Comparison of Patent Claim Language vs. U.S. Publication No. 2009/0272384 A1 (First ‘384 Publication - EX1010)

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<tr>
<td>particle crosslinks when fractured is such that a fracture surface passes through both inter-particle regions and intra-particle regions nonpreferentially.</td>
<td><em>polyisoprene particle and inter-polyisoprene particle features means that the fracture surface propagated with no preference for either the intra particle region or the inter particle regions indicating that both inter and intra particle regions were approximately equal strength or were crosslinked nearly equally.</em> The latex condom fractured at room temperature as an elastic solid showing planar fracture surface, not a conchoidal or shell-like fracture surface. There were no grains visible in this fracture surface, indicating that the fracture strength at the intra grain region and inter grain region was very nearly the same and the therefore the fracture surface was nearly isotropic everywhere. A dimensional marker shows a line, which is calibrated to be 20 microns in length.” (¶[0026])</td>
</tr>
</tbody>
</table>

(Figure 5)

“9. The synthetic polyisoprene elastomeric article of claim 1, wherein said **substantial uniformity of intra-polyisoprene particle crosslinks and inter-polyisoprene particle crosslinks is verified by scanning electron microcopy of a fracture**
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<tbody>
<tr>
<td>surface that passes through both inter-particle regions and intra-particle regions nonpreferentially.” (Claim 9)</td>
<td></td>
</tr>
<tr>
<td>18. A condom of claim 17, having an elongation at break of at least 945%.</td>
<td>Same as Claim 12.</td>
</tr>
<tr>
<td>19. The condom of claim 18, having a tensile strength of at least 30 MPa.</td>
<td>Same as Claim 5.</td>
</tr>
<tr>
<td>20. A condom of claim 1, having an elongation at break of at least 945%.</td>
<td>Same as Claim 12.</td>
</tr>
</tbody>
</table>

Since all the claim limitations are not only disclosed in the First Publication ('384), but are disclosed verbatim, claims 1-20 are clearly anticipated under 35 U.S.C. § 102(a)(1) (AIA) or 35 U.S.C. § 102(b) (pre-AIA).

X. CONCLUSION

Petitioner respectfully submits that it has demonstrated that there is a reasonable likelihood that claims 1-20 of the ‘029 Patent are unpatentable and requests that the IPR trial be instituted.

Date: October 12, 2016

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE WITH WORD COUNT

The undersigned hereby certifies that the foregoing Petition complies with the requirements of 37 C.F.R. § 42.24 and contains less than 14,000 words (13,898 words), excluding those contained in the following: Table of Contents, Table of Authorities, Grounds of Standing, Mandatory Notices, Certificate of Word Count, Certificate of Service, and the Exhibit List.
CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,074,029 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42.100 along with all cited exhibits are being filed via PTAB E2E and served via overnight mail on October 12, 2016, upon the following parties:

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