UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Obalon Therapeutics, Inc.
Petitioner

v.

Tilak M. Shah
Patent Owner

Patent No. 6,712,832 B2

Inter Partes Review No. ______

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

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Petitioner Obalon Therapeutics, Inc. ("Petitioner") respectfully petitions for *inter partes* review of claims 1-18 of U.S. Patent No. 6,712,832 B2 ("the '832 patent" (Ex. 1001)) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. INTRODUCTION

The '832 patent broadly claims a method of manufacturing a low-pressure balloon by vacuum forming two half-sections and then bonding the two half-sections together. Independent claim 1 (the only independent claim) includes five basic, well-known steps for manufacturing a balloon: (a) provide a thin film; (b) heat the film; (c) form a first section by vacuum suction of the film; (d) form a second section by vacuum suction of the film; and (e) bond the two sections together to form the balloon.

Claim 1 of the '832 patent is anticipated by U.S. Patent No. 5,316,605 ("Rakonjac" (Ex. 1003)), which discloses Steps (a)-(e). In fact, Rakonjac discloses that Steps (a)-(e) were "old in the art" when Rakonjac filed the application in 1992. (Ex. 1003, Col. 4:25-29; Ex. 1008, Page 9.)

Moreover, claim 1 of the '832 patent would have been obvious over Patent Owner's own U.S. Patent No. 5,833,915 ("Shah '915" (Ex. 1004)), which discloses a method of welding two half-sections together to form medical products, such as catheter balloons. (Ex. 1004, Abstract.) Shah '915 does not teach vacuum forming, but that process was well known at the time of filing the ’832 patent. U.S. Patent No. 4,576,156 (“Dyck” (Ex. 1005)), for example, teaches vacuum forming medical products. (Ex. 1005, Abstract.)

The ’832 patent’s dependent claims specify the type of film, the film heating temperature, the method of welding the two half-sections, and features of the manufactured balloon. At least one of Rakonjac, Shah ’915, and Dyck teaches these limitations or the limitations were otherwise known in the art.

Accordingly, the claims of the ’832 patent are unpatentable under 35 U.S.C. § 102 and/or § 103. Petitioner respectfully submits that this Petition demonstrates a reasonable likelihood that Petitioner will prevail on at least one challenged claim and requests institution of *inter partes* review of the ’832 patent.

II. SUMMARY OF THE ’832 PATENT

The ’832 patent matured from U.S. Application No. 09/977,644 filed on October 15, 2001. (Ex. 1001, Cover Page.) The USPTO did not issue a substantive rejection during prosecution. (Ex. 1002.)

The ’832 patent is titled “Low-Pressure Medical Balloons and Method of Making Same.” Claim 1 reads:

> 1. A method for manufacturing [a] low-pressure balloon, comprising the steps of:
> (a) providing a thin film of thermoplastic polymeric material;

> (b) heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming thereof;
> (c) forming a first half section for a balloon on the thermoplastic polymeric thin film by vacuum suction;
> (d) forming a second half section for the balloon on a same or different thermoplastic polymeric thin film by vacuum suction; and
> (e) bonding the first half-section to the second half-section along edges of the half-sections to form the balloon.

The Background section of the ’832 patent describes the wide use of natural rubber latex (“latex”) for low-pressure balloons in various medical procedures. (Ex. 1001, Col. 1:14-18.) The Background explains that a large proportion of the population experiences allergic reactions to latex, leading governmental organizations (such as OSHA) to establish regulations on the use of latex. (Ex. 1001, Col. 1:27-40.)

The Background recognizes that thermoplastic elastomeric polyurethane is a good substitute for latex, but finds issues with manufacturing techniques such as dip molding, extrusion molding, and tubing blow molding for producing low-pressure catheter balloons. (Ex. 1001, Col. 1:48-2:18.) The Background also finds that film welding of two polyurethane sheets leads to non-uniform inflation (due to “pillowing”). (Ex. 1001, Col. 2:19-29.)

The ’832 patent seeks to overcome the above difficulties by “thermo-vacuum molding” a low-pressure balloon in two halves:

> The present invention in one aspect relates to a new method for manufacturing a low-pressure medical balloon used in connection with a catheter, including the steps of:
>
> providing a thin film of thermoplastic polymeric material;
>
> heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming thereof;
>
> forming a first half section for a balloon on the thermoplastic polymeric thin film by vacuum suction;
>
> forming a second half section for the balloon on a same or different thermoplastic polymeric thin film by vacuum suction; and
>
> bonding the first half-section to the second half-section along edges of the half-sections to form the balloon.
>
> Such method advantageously uses thermo-vacuum molding techniques for shaping the thin film thermoplastic polymeric material to form the half-sections for the balloon.

(Ex. 1001, Col. 2:40-56.)

Figures 3A and 3B illustrate forming a half section of the balloon by vacuum suction. In Figure 3A, a thermoplastic polymeric thin film 32 is positioned above a vacuum suction mold (generally identified as 34). (Ex. 1001, Col. 6:9-13.) A spherical cavity 36 in vacuum suction mold 34 includes vacuum suction holes 38 connected to a suction manifold 40. (Ex. 1001, Col. 6:14-20.)

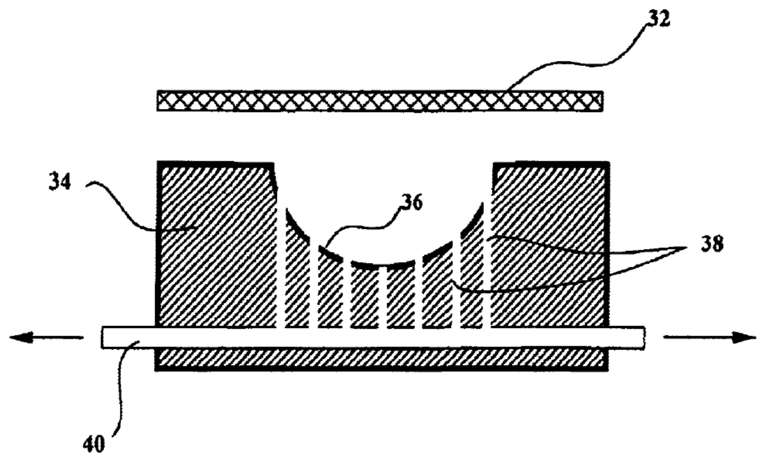


Figure 3A

In Figure 3B, a half section is formed from the thermoplastic film 32 by applying vacuum suction to the vacuum mold 34. (Ex. 1001, Col. 6:25-26.)

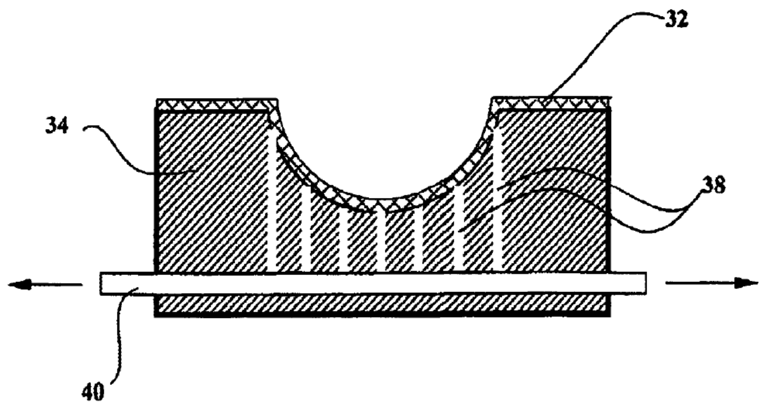


Figure 3B

Figures 4 and 5 illustrate two balloon half-sections bonding into a single balloon. A first half section 42 and a second half section 52 bond along edges 44 and 54 to form single balloon 60. (Ex. 1001, Col. 6:36-43.)

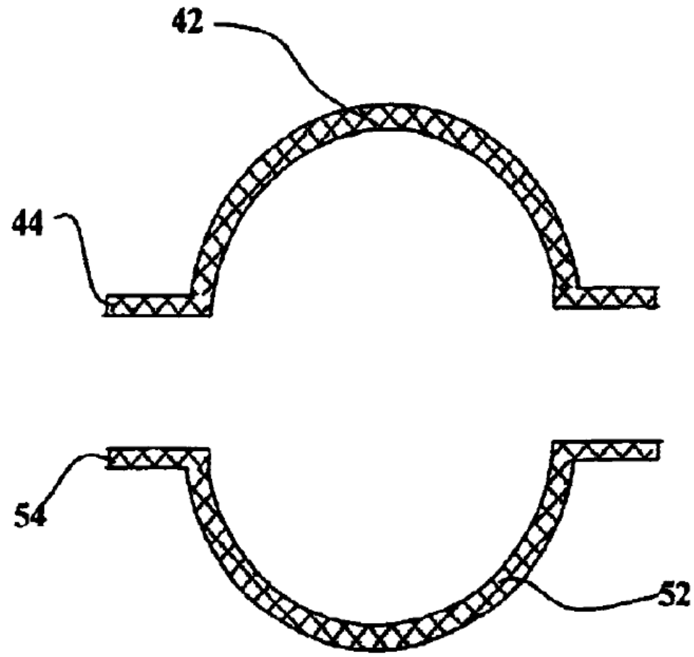


Figure 4

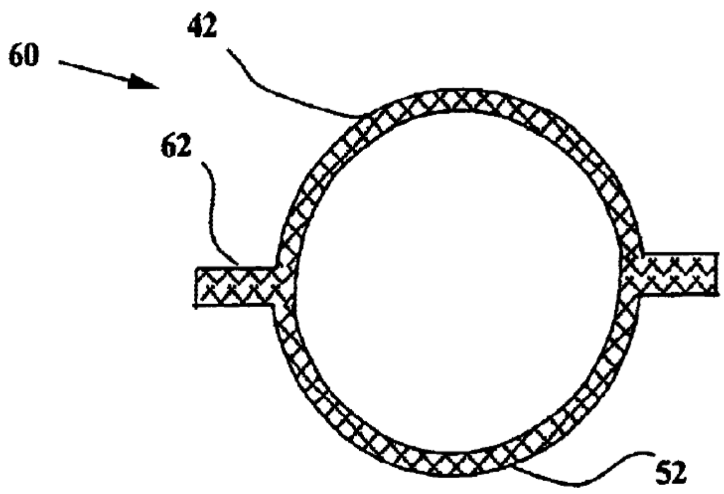


Figure 5

Dependent claims 2-4 describe characteristics of the film used. Dependent claim 2 specifies a non-allergenic film, claim 3 specifies the film is polyurethane or silicone, and claim 4 specifies polyurethane.

Dependent claims 5, 6, and 10-13 describe elements of the manufacturing processes. Claim 5 specifies heating the thin film to a temperature within a range from about 60° C to about 150° C, claim 6 specifies simultaneously forming the first and second half-sections on one thin film, claims 10-12 specify various bonding techniques, and claim 13 specifies an inverted balloon.

Dependent claims 7-9 and 14-18 describe various characteristics of the two half-sections and/or the final balloon. Claim 7 specifies uniform wall thickness for the two half-sections, claims 8 and 9 specify the shape of the two half-sections, claims 14 and 15 specify the balloon's wall thickness, and claims 16-18 specify the balloon's "neck to body ratio."

III. CLAIM CONSTRUCTION

Petitioner does not submit any claim constructions. Petitioner relies on the plain language of the claims and embodiments in the '832 patent to demonstrate that the prior art meets the limitations of the '832 patent. *Hakim v. Cannon Avent Group, PLC,* 479 F.3d 1313, 1318-19 (Fed. Cir. 2007) ("When there is no dispute as to the meaning of a term that could affect the disputed issues of the litigation, 'construction' may not be necessary."); *see also Vivid Techs., Inc. v. Am. Sci. &*

Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that only those terms that are in controversy need to be construed and only to the extent necessary to resolve the controversy).

IV. IDENTIFICATION OF CHALLENGE

Pursuant to 37 C.F.R. § 42.104(b), Petitioner respectfully requests cancellation of claims 1-18 of the '832 patent.

At a high level, Petitioner provides two invalidity arguments. The first invalidity argument focuses on Rakonjac, which teaches all the limitations of the independent claim and a number of the dependent claims. For some dependent claims, Petitioner supplements Rakonjac with known manufacturing techniques and objectives.

The second invalidity argument focuses on Shah '915, Patent Owner's own prior art. Shah '915 teaches most of the limitations of the independent claims and dependent claims. Shah '915 does not teach vacuum suction; Petitioner provides Dyck, which Shah '915 cites as teaching a vacuum suction manufacturing technique. For three dependent claims, Petitioner offers additional references.

The table below sets forth the statutory grounds for the challenge (all statutory citations are pre-AIA).

Ground	35 U.S.C.	Reference(s)	Claim(s)
Ground 1	§ 102	Rakonjac	Claims 1, 6, 7, 10, and 14-18
Ground 2	§ 103	Rakonjac	Claims 2 and 5
Ground 3	§ 103	Rakonjac, Shah ’915	Claims 3, 4, and 10-12
Ground 4	§ 103	Rakonjac, Araki	Claim 7
Ground 5	§ 103	Rakonjac, Meyer	Claims 8, 9, and 13
Ground 6	§ 103	Shah ’915, Dyck	Claims 1-8, 10-12, and 14-18
Ground 7	§ 103	Shah ’915, Dyck, Araki	Claim 7
Ground 8	§ 103	Shah ’915, Dyck, Meyer	Claims 9 and 13

A. Grounds based on Rakonjac

1. Ground 1: Rakonjac anticipates claims 1, 6, 7, 10, and 14-18.

Rakonjac issued on May 31, 1994 from an application filed on June 15, 1992. (Ex. 1003, Cover Page.) Rakonjac qualifies as prior art to the ’832 patent under 35 U.S.C. § 102(a), 35 U.S.C. § 102(b), and 35 U.S.C. § 102(e). Neither

Patent Owner nor the United States Patent and Trademark Office ("PTO") cited Rakonjac during the prosecution of the '832 patent.[1]

Rakonjac teaches a method of manufacturing inflatable three-dimensional shapes by vacuum forming thin sheets of thermoplastic material and securing the edges of the sheets together. (Ex. 1003, Abstract.) Rakonjac teaches that all the vacuum thermoforming steps of the '832 patent's claim 1 were "prior art developments:"

> It is known that flat flexible sheets of thin plastic material, e.g. polyvinyl chloride, can be reconfigured into two dimensional shapes by subjecting the sheet to a vacuum forming operation. The vacuum-forming process involves heating a sheet of plastic to its softening temperature, draping the softened sheet over a rigid mold member formed of a porous material, and applying a vacuum force to the underside of the mold member. Air is drawn through the pores (holes) in the mold member, such that the plastic sheet is drawn tightly against the mold member by air suction (vacuum) effect. As the sheet cools from its softened condition it is rigidified into the shape of the mold member surface.

(Ex. 1003, Col. 1:17-29.)

[1] The European Patent Office cited Rakonjac in prosecution of a related application and rejected the independent claims based on Rakonjac. (*See* Ex. 1012, Page 2; Ex. 1013, Pages 1-2; Ex. 1014, Page 2.) To overcome the Rakonjac rejection, Patent Owner amended the independent claims. (*See* Ex. 1015, Page 15.)

Rakonjac also teaches that the pre-existing skill in the art included making two half-sections and then joining the sections together to make a balloon:

> It is also known that two shaped plastic sheets can be secured together along their mating peripheral edges to form a hollow sealed figure, e.g. a toy clown, toy elephant, or toy football. Pressurized air or other gas can be pumped into the interior space within the hollow figure to define and maintain the desired three dimensional shape of the figure.

(Ex. 1003, Col. 1:40-46.)

Rakonjac teaches a refinement on the known balloon vacuum thermoforming steps (which correspond to the steps of the '832 patent's claim 1). Specifically, Rakonjac provides more precise projections on the surface of the balloon. (Ex. 1003, Col. 4:38-41; Figures 1, 2, and 9.)

Before Rakonjac describes that inventive contribution, the patent describes the known process of vacuum forming a balloon from a thin film: (1) "In the position of FIG. 8, frame structure 29 rests against support blocks 30 carried by housing 21, with thermoplastic sheet 27 located directly above heating coil 25." (Ex. 1003, Col. 3:37-40.); (2) "The heater can thus heat the sheet to a softened pliable condition wherein it can be reformed to a non-flat state." (Ex. 1003, Col. 3:40-42.); (3) "[B]lower 39 is energized to draw air downwardly through the holes in member 37, thereby achieving a vacuum-forming (reshaping) of sheet 27 to the surface contour of the mold member." (Ex. 1003, Col. 3:63-67.); (4) "The single thermoplastic sheet would then be used to form a plural number of contoured sheet sections." (Ex. 1003, Col. 4:25-27.); and (5) "Mating sheets can be heat welded together and then cut through to form and separate the multiple hollow bodies." (Ex. 1003, Col. 4:27-29.) Rakonjac concludes this description with "[t]he general process is old in the art." (Ex. 1003, Col. 4:29.)

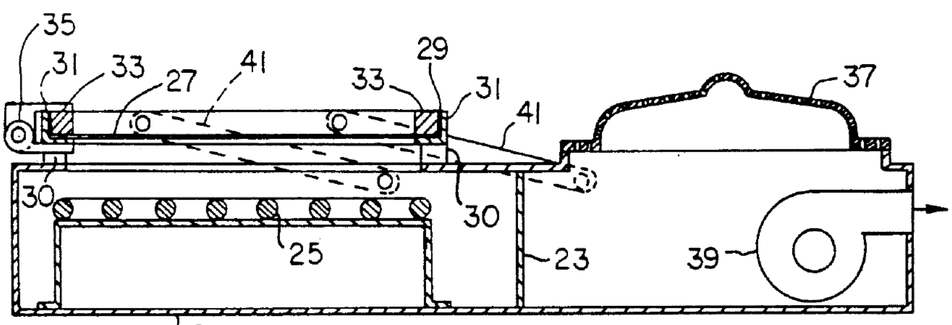


FIG. 8

Rakonjac does not explicitly state "low-pressure balloon." The '832 patent does not provide a definition of "low-pressure," nor recite any inflation pressures for the balloon. (Ex. 1011, ¶ 41.) The only description in the '832 patent with which to understand "low-pressure" is the balloon thickness because balloon thickness will determine the pressures required to inflate a balloon. (*Id.*) The '832 patent teaches balloons of thickness in the range from 0.5 mils to 10 mils. (*See, e.g.,* Claim 14.) Rakonjac teaches balloons of 5 mils thickness. (Ex. 1003, Col. 3:1-3.) Thus, Rakonjac teaches balloon thicknesses within the ranges disclosed by the '832 patent and thus teaches balloons capable of inflating at pressures covered by the ’832 patent. (Ex. 1011, ¶ 41.) Thus, Rakonjac teaches a “low-pressure” balloon in the context of the ’832 patent.

Petitioner notes that although the ’832 patent’s title includes “medical balloons” and the specification discusses “medical balloons” at various points, the ’832 patent does not refer to “medical balloons” consistently. Most importantly, the claims do not recite “medical balloon.”[2] Thus, the claims do not require medical balloons, and Rakonjac’s inflatable figures meet the term “low-pressure balloon.”

With respect to claim 7, the ’832 patent does not define or explain “uniform wall thickness.” The ’832 patent seems to indicate that its vacuum forming manufacturing process creates balloons having uniform wall thickness. (*See*, *e.g.*, Col. 4:28-37; Col. 5:46-48.) Although Rakonjac does not explicitly state that its

[2] During prosecution of a later patent application to a gastric balloon (i.e., a medical device balloon), Patent Owner’s counsel characterized the ’832 patent as “broadly claim[ing] methods for manufacturing low-pressure balloons from thin film polymeric materials.” (Ex. 1010, Page 12; *see also id.* Evidence Appendix (“Declaration of Tilak M. Shah”), ¶ 14 (“I note that I am the recipient of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials.”).)

process results in balloons having uniform wall thickness, to the extent vacuum thermoforming is deemed sufficient to create balloons with uniform wall thickness, under the broadest reasonable interpretation of claim 7, Rakonjac teaches vacuum thermoforming. (Ex. 1003, Col. 1:17-29.)

With respect to balloon thickness, Rakonjac teaches a pre balloon wall thickness of 0.005 inch, or 5 mils. (Ex. 1003, Col. 3:1-3.) After vacuum molding into the half-sections, each balloon will stretch, losing some thickness. (Ex. 1011, ¶ 155.) The resulting balloon will have a thickness of approximately 2.5 mils. (*Id.*, ¶¶ 72-81 (calculating the thickness of hemispheric balloon manufactured from a 5 mil film).) Thus, Rakonjac teaches a low-pressure balloon that has a wall thickness within a range from about 0.5 mils to about 10 mils (claim 14) and a balloon that has a wall thickness within a range from about 2 mils to about 6 mils (claim 15).

Claims 16-18 specify a neck to body ratio of less than 30%, 25%, or 10%, respectively. The ’832 specification does not provide a definition of “neck to body ratio” or any suggestion of how to measure such a ratio. (Ex. 1011, ¶ 84.) The ’832 specification, however, states that “the present invention relates to balloons of a type used in medical procedures, and to a method of making such balloons” employing a “thermo-vacuum molding techniques.” (Ex. 1001, Col. 2:37-56.) The ’832 specification also states that “[t]he neck to body ratio of balloons formed in accordance with the present invention may be less than 30%, preferably less than 25%, and more preferably less than 10%." (Ex. 1001, Col. 5:51-54.) To the extent employing thermo-vacuum molding techniques is deemed to lead to balloons with the "neck to body ratio" recited in claims 16-18 under the broadest reasonable interpretation, Rakonjac teaches thermo-vacuum molding techniques.

The claim chart below specifies where Rakonjac meets each element of claims 1, 6, 7, 10, and 14-18.

'832 Patent	Rakonjac
1. A method for manufacturing [a] low-pressure balloon, comprising the steps of:	Rakonjac teaches manufacturing a balloon: "Method of manufacturing [an] inflatable figure from flexible plastic sheet material." (Ex. 1003, Abstract.) Rakonjac teaches the balloon is low-pressure: "Commercially available thermoplastic material in sheet form having a thickness of about 0.005 inch can be used." (Ex. 1003, Col. 3:1-3.)
(a) providing a thin film of thermoplastic polymeric material;	Rakonjac teaches a thin film of thermoplastic polymeric material: "the entire figure is comprised of two thin plastic sheets . . . . Commercially available thermoplastic material in sheet form having a thickness of about 0.005 inch can be used." (Ex 1003, Col. 2:67-3:3.)

’832 Patent	Rakonjac
(b) heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming thereof;	Rakonjac teaches heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming: “The vacuum-forming process involves heating a sheet of plastic to its softening temperature, draping the softened sheet over a rigid mold member formed of a porous material, and applying a vacuum force to the underside of the mold member.” (Ex. 1003, Co1. 1:20-25; *see also* Col. 3:40-42 (“The heater can thus heat the sheet to a softened pliable condition wherein it can be reformed to a non-flat state.”).)
(c) forming a first half section for a balloon on the thermoplastic polymeric thin film by vacuum suction;	Rakonjac teaches forming a first half section for a balloon on the thermoplastic polymeric thin film by vacuum suction: “Air is drawn through the pores (holes) in the mold member, such that the plastic sheet is drawn tightly against the mold member by air suction (vacuum) effect. As the sheet cools from its softened condition it is rigidified into the shape of the mold member surface.” (Ex. 1003, Co1. 1:25-29; *see also* Col. 3:63-66 (“At the same time blower 39 is energized to draw air downwardly through the holes in member 37, thereby achieving a vacuum-forming (reshaping) of sheet 27 to the surface contour of the mold member.”).)
(d) forming a second half section for the balloon on a same or different thermoplastic polymeric thin film by vacuum suction; and	Rakonjac teaches forming a second half section for the balloon on a same or different thermoplastic polymeric thin film by vacuum suction: “An inflatable three dimensional body is formed out of two thin sheets of flexible thermoplastic material by vacuum-forming . . . and then securing the edge areas of the sheets together.” (Ex. 1003, Abstract; *see also* Col 4:25-29 (“The single thermoplastic sheet would then be used to form a plural number of contoured sheet sections. Mating sheets can be heat welded together and then cut through to form and separate the multiple hollow bodies. The general process is old in the art.”).)

’832 Patent	Rakonjac
(e) bonding the first half-section to the second half-section along edges of the half-sections to form the balloon.	Rakonjac teaches bonding the first half-section to the second half-section along edges of the half-sections to form the balloon: “An inflatable three dimensional body is formed out of two thin sheets of flexible thermoplastic material by vacuum-forming . . . and then securing the edge areas of the sheets together.” (Ex. 1003, Abstract; *see also* Col 4:25-29 (“The single thermoplastic sheet would then be used to form a plural number of contoured sheet sections. Mating sheets can be heat welded together and then cut through to form and separate the multiple hollow bodies. The general process is old in the art.”).)
6. A method according to claim 1, wherein the first and second half sections of the balloon are formed simultaneously on a same thin film of thermoplastic polymeric material by vacuum suction.	Rakonjac teaches the first and second half-sections of the balloon are formed simultaneously on a same thin film of thermoplastic polymeric material by vacuum suction: “The single thermoplastic sheet would then be used to form a plural number of contoured sheet sections. Mating sheets can be heat welded together and then cut through to form and separate the multiple hollow bodies. The general process is old in the art.” (Ex. 1003, Col 4:25-29.)
7. A method according to claim 1, wherein the first and second half sections of the balloon have uniform wall thickness.	Rakonjac teaches the first and second half sections of the balloon have uniform wall thickness: “An inflatable three dimensional body is formed out of two thin sheets of flexible thermoplastic material by vacuum-forming . . . and then securing the edge areas of the sheets together.” (Ex. 1003, Abstract; *see also* Col 4:25-29 (“The single thermoplastic sheet would then be used to form a plural number of contoured sheet sections. Mating sheets can be heat welded together and then cut through to form and separate the multiple hollow bodies. The general process is old in the art.”).)

’832 Patent	Rakonjac
10. A method according to claim 1, wherein the first and second half sections of the balloon are bonded together by a bonding method selected from the group consisting of: adhesive bonding, electromagnetic bonding, hot plate welding, impulse heating, induction bonding, insert bonding, radio-frequency welding, spin welding, thermostacking, ultrasonic sealing, and vibration welding.	Rakonjac teaches the first and second half-sections of the balloon are bonded together by . . . heating: “The two specially configured plastic sheets will have peripheral edge flanges that can be heat sealed together along a parting line to form a hollow sealed body, e g. the hollow body shown in FIGS. 1 and 2.” (Ex. 1003, Col. 4:11-14.)
14. A method according to claim 1, wherein the low-pressure balloon has a wall thickness within a range from about 0.5 mils to about 10 mils.	Rakonjac teaches a low-pressure balloon that has a wall thickness within a range from about 0.5 mils to about 10 mils: the resulting balloon will have a thickness of approximately 2.5-5 mils. (*Id.*)
15. A method according to claim 1, wherein the low-pressure balloon has a wall thickness within a range from about 2 mils to about 6 mils.	Rakonjac teaches a low-pressure balloon that has a wall thickness within a range from about 2 mils to about 6 mils: the resulting balloon will have a thickness of approximately 2.5-5 mils. (*Id.*)
16. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 30%.	Rakonjac teaches neck to body ratio of less than 30%: Rakonjac teaches thermo-vacuum molding techniques.

’832 Patent	Rakonjac
17. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 25%.	Rakonjac teaches neck to body ratio of less than 25%: Rakonjac teaches thermo-vacuum molding techniques.
18. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 10%.	Rakonjac teaches neck to body ratio of less than 10%: Rakonjac teaches thermo-vacuum molding techniques.

Petitioner respectfully submits that it has a reasonable likelihood of showing that Rakonjac anticipates claims 1, 6, 7, and 14-18.

2. Ground 2: Rakonjac renders claims 2 and 5 obvious.

Claim 2 recites: “the thermoplastic polymeric material is non-allergenic.” Rakonjac does not specifically describe its balloon as non-allergenic. Rakonjac uses polyvinyl chloride (Ex. 1003, Col. 2:67-3:1) and one of Patent Owner’s own patents describes PVC (Ex. 1016, Col. 4:59) in gastric balloons. One of skill in the art would recognize that a gastric balloon requires non-allergenic material. (Ex. 1011, ¶ 65; *see also* Ex. 1017 Page 1 (“This part of ISO 10993 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and delayed-type hypersensitivity.”).)

Rakonjac teaches a toy balloon (Ex. 1003, Col. 1:42-43). One of skill in the art would understand that toy sales benefit non-allergenic material. (Ex. 1011, ¶

66.) Toymakers target children and any feature that increases the market for toys would increase toy sales. By manufacturing Rakonjac's toys with non-allergenic material, a toymaker increases the market for toys because children with allergies are more likely to use the toy. Thus, one of skill in the art would be motivated to use non-allergenic material in Rakonjac's toys. (*Id.*)

Claim 5 recites: "A method according to claim 1, wherein the thin film of thermoplastic polymeric material is heated to a temperature within a range from about 60° C to about 150° C." Rakonjac does not explicitly teach heating the film in a range from about 60° C to about 150° C, but this step is obvious in light of Rakonjac's material properties.

Rakonjac teaches vacuum thermoforming polyvinyl chloride. (Ex. 1003, Col. 2:67-3:1.) To vacuum thermoform any material, the material must be heated above its softening temperature. (Ex. 1011, ¶ 67.)

Polyvinyl chloride has a Vicat softening temperature between 54 and 80° C and a distortion temperature of 92° C. (Ex. 1009.) In order to use polyvinyl chloride in Rakonjac's vacuum thermoforming process, the polyvinyl chloride would have to reach between 54 and 80° C and no more than 92° C. (Ex. 1011, ¶ 68.) Thus, it would have been obvious to one of skill in the art to heat Rakonjac's polyvinyl chloride to a temperature within a range from about 60° C to about 150° C. (*Id.*)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Rakonjac renders claims 2 and 5 obvious.

3. Ground 3: Rakonjac in view of Shah ’915 renders claims 3, 4, and 10-12 obvious.

Rakonjac does not explicitly teach a polyurethane film (claims 3 and 4) or specify the manner of welding two half-sections together (claims 10-12). Shah ’915, however, teaches each of these limitations.

a. Shah ’915 teaches polyurethane balloons formed of two half-sections and radio-frequency welding of the two half-sections.

Shah ’915 issued on November 10, 1998, and qualifies as prior art under 35 U.S.C. § 102(b). Shah ’915 is titled “Method of Welding Polyurethane Thin Film.” Patent Owner cited Shah ’915 during prosecution, but the PTO did not discuss Shah ’915 on the record.

Shah ’915 discloses the use of a polyurethane film

Shah ’915 generally teaches “[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer . . . to form a weld seam . . . to produce polyurethane barrier products.” (Ex. 1004, Abstract.) Shah ’915 identifies problems with latex including, *inter alia*: “[l]atex cannot provide barrier integrity for devices such as surgical gloves and condoms where barrier protection is of prime importance;” “[l]atex also has limited tensile strength and tear resistance and is highly susceptible to cuts and punctures;" and "the material has a limited shelf life, and will become more fragile and brittle over time." (Ex. 1004, Col. 1:63-2:14.) Shah '915 notes that those skilled in the art recognized polyurethane polymers as a solution to the disadvantages of latex. (Ex. 1004, Col. 2:43-49.) Shah '915 therefore teaches the use of a polyurethane film, as required by claims 3 and 4 of the '832 patent.

Shah '915 discloses methods of bonding two half-sections

Shah '915 also teaches the manner of welding two half-sections together, as required by claims 10-12 of the '832 patent. According to Shah '915, bonding or welding can form polyurethane products, but those techniques have resulted in "wrinkles, pin holes, discontinuities, holidays and burn or charring defects." (Ex. 1004, Col. 2:64-3:8.) To resolve the prior art problems, Shah '915 offers a method for "highly efficient R.F. welding of thermoplastic polyurethane elastomers." (Ex. 1004, Col. 5:21-22.) The R.F. welding method includes "heating the polymer to a temperature above the Vicat softening temperature (but below the heat distortion temperature or film distortion temperature), and subjecting the heated polymers to be joined to R.F. energy and pressure." (Ex. 1004, Col. 5:22-26.) Shah '915's techniques are "particularly useful for joining thin films of the polyurethane" (Ex. 1004, Col. 5:26-28), but Shah '915 notes that "the technique is equally applicable to thicker films and other forms of such polymers." (Ex. 1004, Col. 6:66-7:1.)

Figures 7 and 8 illustrate a balloon manufactured from two halves 46A and 46B joined at weld seam 44. (Col. 11:54-57.) Shah ’915 illustrates the seam on the front portion (as viewed in Figures 7 and 8) as a solid double-line 44, and the seam on the rearward portion as a dashed line. In figures for other embodiments (e.g., Figures 4-6 and 9-11), Shah ’915 uses the same solid double-lines to depict viewable seams and dashed lines to depict non viewable seams.

Although Shah ’915 mainly discusses welding “layers,” Shah ’915 also discloses welding edges, as required by claim 12 of the ’832 patent. The figures of Shah ’915 consistently demonstrate the seam on the edge. (*See, e.g.*, Ex. 1004, Figures 4-11 and 13.) Shah ’915 further notes those skilled in the art generally prefer “weld[ing] only at the seam areas and their immediate vicinity” since such welding “minimiz[es] the heat input.” (Ex. 1004, Col. 8:22-25.) Thus, Shah ’915 teaches welding on an edge.

Shah ’915 teaches low-pressure balloon manufacture

Shah ’915’s teachings low-pressure balloon manufacture. Shah ’915 teaches balloon manufacture explicitly: “FIG. 7 is a view of an non-inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter. FIG. 8 is an inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter.” (Ex. 1004, Col. 5:27-61.) Shah ’915 Figures 7 and 8 are reproduced below, with the balloon highlighted:

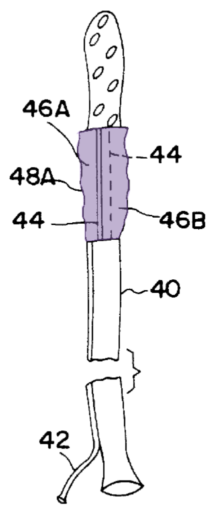


FIG.7

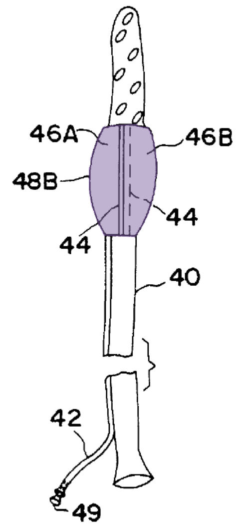


FIG.8

Shah ’915 does not explicitly state “low-pressure balloon,” but Shah ’915’s teachings disclose balloons that one of skill in the art would understood to be low-pressure in the context of the ’832 patent. As explained above, the ’832 patent does not provide a definition of “low-pressure” or recite any inflation pressures for the balloon. The only description in the ’832 patent with which to interpret “low-pressure” is balloon thickness. (Ex. 1011, ¶ 51.) Balloon thickness will determine the pressures required to inflate a balloon. (*Id.*) The ’832 patent teaches balloons of thickness in the range from 0.5 mils to 10 mils. (*See, e.g,* Claim 14.) Shah ’915 teaches balloons of up to 5 mils thickness. (Ex. 1004, Col. 5:26-29.) Thus, Shah ’915 teaches balloon thicknesses within the ranges disclosed by the ’832 patent and thus teaches balloons capable of inflating at pressures covered by the ’832 patent.

(Ex. 1011, ¶ 51.) Therefore, Shah ’915 teaches a “low-pressure” balloon in the context of the ’832 patent. (*Id*.)

Further, the ’832 patent states “the contents of [Shah ’915] hereby are incorporated herein by reference in their entirety, for all purposes.” (Ex. 1001, Col. 3:67-4:3.) Since the ’832 patent incorporates Shah ’915 in its entirety for all purposes and the ’832 patent claims low-pressure balloons, it follows that the ’832 patent incorporates Shah ’915 by reference for the method of making low-pressure balloons. Therefore, at least according to the ’832 patent itself, Shah ’915 teaches a process that is suitable for making low-pressure balloons.

b. One of skill in the art would apply the vacuum thermoforming process of Rakonjac to the polyurethane balloon of Shah ’915 because Shah ’915 does not teach how to form its balloon half-sections and Rakonjac teaches a process for forming balloon half-sections.

Rakonjac and Shah ’915 relate to the manufacture of thin film thermoplastic devices. (Ex. 1011, ¶ 90.) Shah ’915 discusses various medical devices including catheter balloons; Rakonjac discusses an inflatable balloon manufacturing process.

Shah ’915 describes a welding technique for bonding two portions of polyurethane, but does not teach how the polyurethane is first formed into the desired shape before the welding. (*Id.*, 91 .) Some forming is necessary to shape the two half-sections of the balloons and condoms before welding. (*Id*.)

Rakonjac teaches that "vacuum thermoforming" "is old in the art." (Ex. 1003, Col. 4:29.) Preforming Shah '915's half-sections using a vacuum thermoforming method (such as disclosed in Rakonjac) is simply the use of a known technique to arrive at a predictable result. (Ex. 1011, ¶ 92.)

In addition, the superior properties of polyurethanes, including structural strength, elasticity and the absence of porosity and permeability, were known in the art and are taught in Shah '915. (Ex. 1004, Col. 4:27-29.) Shah '915 teaches a "method of joining by a welding process, at least two layers of a thin polyurethane thermoplastic elastomer film having a thickness in the range of 0.5 to 5.0 mils (0.0127 mm to 0.127 mm), without wrinkling, causing pin-holes or holidays and without burning or charring the material." (Ex. 1004, Col. 1:9-14.) Hence one of skill in the art[3] would have a reason or motivation to use polyurethane to

[3] Expert Clair Strohl opines that a person of ordinary skill in the art relevant to the '832 patent would have had (1) at least a Bachelor degree in engineering or polymer science, or a similar field, and/or at least one year of experience in the principles for thermoforming thermoplastic materials and fabrication techniques of solvent bonding and RF bonding or (2) at least three years of experience in the principles for thermoforming thermoplastic materials and fabrication techniques of solvent bonding and RF bonding.. (Ex. 1011, ¶ 27.)

manufacture low-pressure balloons given the superior properties of polyurethanes. (Ex. 1011, ¶ 93.) One of skill in the art would also have a reason or motivation to employ the thermo-vacuum molding techniques taught in Rakonjac and the welding process taught in Shah ’915 for manufacturing low-pressure balloons made of polyurethanes without wrinkling, causing pin-holes or without burning or charring the polyurethane material during the manufacturing process. (*Id.,* 94)

To incorporate Rakonjac’s technique, one of skill in the art would change nothing in Shah ’915’s procedure. (*Id.,* 95.) Both Rakonjac and Shah ‘’915 teach balloons up to 5 mil thickness. (Ex. 1003, Col. 3:1-3 (“Commercially available thermoplastic material in sheet form having a thickness of about 0.005 inch can be used.”); Ex. 1004, Col. 5:26-29 (“The invention is particularly useful for joining thin films of the polyurethane, particularly films of 0.5 to 5.0 mils.”).) One of skill in the art would simply manufacture the two half-sections of Shah ’915’s catheter balloon using Rakonjac’s manufacturing technique, then continue with Shah ’915’s welding of two half-sections as disclosed in Shah ’915. (Ex. 1011, ¶ 95.)

The result of using Rakonjac and Shah ’915 is predictable: the catheter balloon illustrated in Shah ’915. (*Id*., 96.) Rakonjac teaches manufacture of balloons using 5 mil film; Shah ’915 teaches manufacture of balloons up to 5 mils. One of skill in the art would recognize that the Rakonjac process could manufacture Shah ’915’s half-sections; only the length of time in the mold may change to accommodate any difference in balloon thickness. (Ex. 1011, ¶ 96.)

The claim chart below specifies where the Rakonjac and Shah ’915 combination meets each element of claims 3, 4, and 10-12.[4]

’832 Patent	Rakonjac in view of Shah ’915
3. A method according to claim 1, wherein the thermoplastic polymeric material comprises a material selected from the group consisting of polyurethane and silicone.	Shah ’915 teaches the thermoplastic polymeric material comprises a material selected from the group consisting of polyurethane and silicone: “[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer.” (Ex. 1004, Abstract.)
4. A method according to claim 1, wherein the thermoplastic polymeric material comprises polyurethane.	Shah ’915 teaches the thermoplastic polymeric material comprises polyurethane: “[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer.” (Ex. 1004, Abstract.)

[4] Petitioner notes that although Ground 2 proposes Rakonjac’s method to manufacture Shah ’915’s catheter balloon, the analysis of Claim 1 under Rakonjac does not change. Whether Rakonjac’s process manufactures Rakonjac’s balloon or Shah ’915’s balloon, Rakonjac still teaches all the elements of claim 1: provide a thin film, heat the film, mold a first section using vacuum suction, mold a second section using vacuum suction, and weld the first section and second section to create a low-pressure balloon. (Ex. 1011, ¶ 97.)

’832 Patent	Rakonjac in view of Shah ’915
10. A method according to claim 1, wherein the first and second half sections of the balloon are bonded together by a bonding method selected from the group consisting of: adhesive bonding, electromagnetic bonding, hot plate welding, impulse heating, induction bonding, insert bonding, radio-frequency welding, spin welding, thermostacking, ultrasonic sealing, and vibration welding.	Shah ’915[5] teaches the first and second half-sections of the balloon are bonded together by . . . radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)
11. A method according to claim 1, wherein the first and second half sections of the balloon are bonded together by radio-frequency welding.	Shah ’915 teaches the first and second half-sections of the balloon are bonded together by radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)

[5] Petitioner proposes Rakonjac’s vacuum thermoforming technique to prepare two half sections for Shah ’915’s catheter balloon. Once the two half-sections are formed by Raknojac’s technique, Shah ’915’s process continues per Shah ’915’s description. Thus, Petitioner cites Shah ’915 for the bonding limitation of claim 10. However, Petitioner notes that Rakonjac teaches heat welding the seams: *see* Ground 1.

’832 Patent	Rakonjac in view of Shah ’915
12. A method according to claim 1, wherein the first and second halves of the balloon are bonded together by radio-frequency welding, comprising the steps of:	Shah ’915 teaches wherein the first and second halves of the balloon are bonded together by radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)
(a) preheating a welding platen to a temperature above a Vicat softening temperature and below a melting temperature of the thermoplastic polymeric material;	Shah ’915 teaches preheating a welding platen to a temperature above a Vicat softening temperature: “(a) pre-heating a welding platen to a temperature above a Vicat softening temperature and below a thermoplastic elastomer film deformation temperature of said thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, element a.)
(b) placing edges of the first and second half sections of the balloon on the preheated platen, said platen heating the edges of the first and second halves of the balloon to a temperature above the Vicat softening temperature and below a melting temperature of said thermoplastic polymeric material;	Shah ’915 teaches placing two layers of the balloon on the preheated platen, said platen heating the edges of the first and second halves of the balloon to a temperature above the Vicat softening temperature and below a melting temperature of said thermoplastic polymeric material: “(b) placing at least two layers of said polyurethane film on the preheated platen, said platen heating said thermoplastic polyurethane elastomer film to a temperature above the Vicat softening temperature of said thermoplastic polyurethane elastomer film and below a melting temperature of said thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, element b.)
(c) compressing the edges of the first and second halves of the balloon at edges thereof to form an interface therebetween;	Shah ’915 teaches compressing the edges of the first and second halves of the balloon at edges thereof to form an interface therebetween: “(c) compressing the layers of film in surface apposition to form an interface therebetween by applying pressure from a die and from said welding platen to said thermoplastic polyurethane elastomer film;” (Ex. 1004, Claim 1, element c.)

’832 Patent	Rakonjac in view of Shah ’915
(d) transmitting radio-frequency energy to the edges of the first and second half sections of the balloon while said edges are under pressure, and welding said edges at said interface, thereby forming a weld, and	Shah ’915 teaches transmitting radio-frequency energy to the edges of the first and second half-sections of the balloon while said edges are under pressure, and welding said edges at said interface, thereby forming a weld: “(d) transmitting radio-frequency energy to the layers of film while said thermoplastic polyurethane elastomer film is under said pressure, welding the film layers at said interface therebetween forming a weld.” (Ex. 1004, Claim 1, element d.)
(e) recovering said balloon comprising the welded first and second half sections.	Shah ’915 teaches recovering said balloon comprising the welded first and second half-sections: “(e) cooling said weld of the at least two layers of film, wherein said weld is free of holidays, pins holes, charring, burning, and wrinkles.” (Ex. 1004, Claim 1, element e.)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Rakonjac in view of Shah ’915 renders claims 3, 4, and 10-12 obvious.

4. Ground 4: Rakonjac in view of Araki renders claim 7 obvious.

Rakonjac does not explicitly teach uniform wall thickness. U.S. Patent No. 4,941,814 to Araki (“Araki”) does.

a. Araki teaches vacuum thermoforming with uniform wall thickness.

Araki issued on July 17, 1990 claiming priority to a U.S. application filed on July 13, 1987, and qualifies as prior art under 35 U.S.C. § 102(a), (b), and (e). Araki is titled “Vacuum Forming Apparatus.”

Araki teaches that a “plug-assist forming method” enhances traditional vacuum forming methods. (Ex. 1007, Col. 1:13-22.) Araki teaches a further improvement on the prior art plug-assist methods: “[i]t is an object of the invention to provide a vacuum forming method and apparatus which enable a drawing deeper than the conventional vacuum forming method and apparatus.” (Ex. 1007, Col. 2:14-17.)

Araki modifies the “conventional vacuum forming method” by adding plugs to assist the vacuum forming and moving the plugs in two directions. (Ex. 1011, ¶ 54.) First, the plugs stretch the sheet in a direction toward the bottom of the mold. (*See* plugs 12 in Figure 2(a), reproduced below.) Second, the plugs move away from one another in order to stretch a sheet further. (See plugs 12 in Figure 2(b), reproduced below, illustrating the plugs moving in the direction of the arrows.)

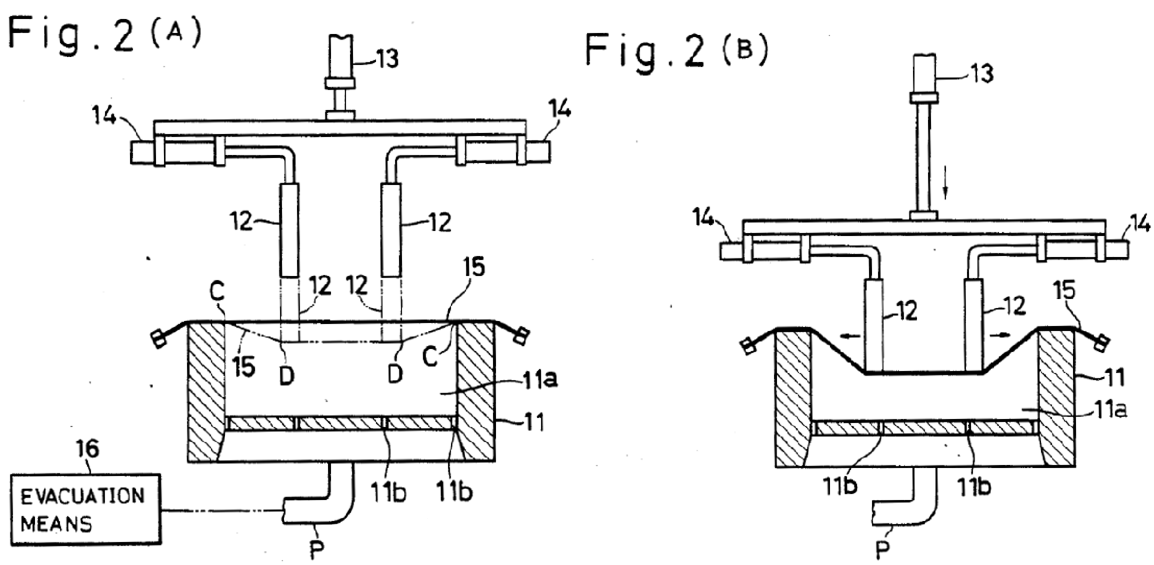
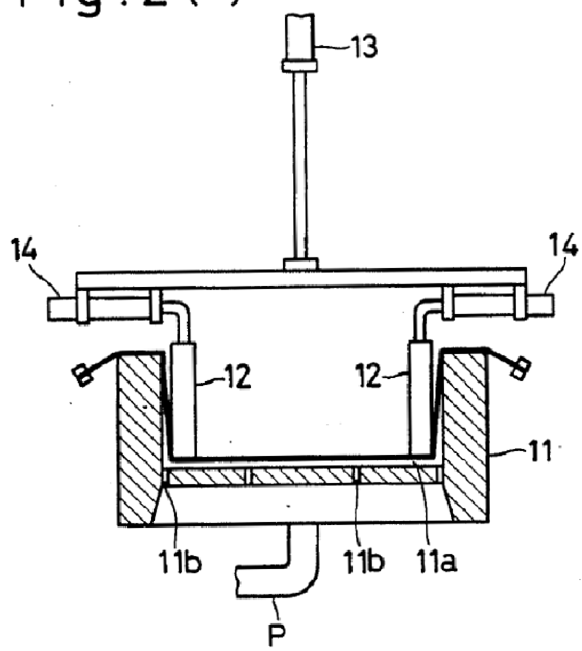


Figure 2(c) illustrates the plugs in their final position. Once the plugs are in their final position, the vacuum is switched on. (Ex. 1007, Col. 2:30-45.)

Fig. 2 (c)



Araki teaches that its manufacturing process "avoid[s] that the sheet material is partially or locally thinned excessively." (Ex. 1007, Col. 5:8-10; *see also* Col. 9:41-43 ("Consequently, it is possible to prevent the sheet material from being partially or locally thinned excessively.").) One of skill in the art would understand that Araki teaches more uniform wall thickness. (Ex. 1011, ¶ 56.)

b. One of skill in the art would combine the manufacturing process of Rakonjac with the manufacturing process of Araki because Araki teaches that Araki's process "avoid[s] that the sheet material is partially or locally thinned excessively."

Rakonjac and Araki both discuss vacuum forming of thermoplastic materials. (Ex. 1011, ¶ 111.) As explained, Rakonjac teaches vacuum thermoforming. Araki teaches that a "plug-assist forming method" enhances traditional vacuum forming methods. (Ex. 1007, Col. 1:13-22.) Araki teaches a further improvement on the plug-assist method. (Ex. 1007, Col. 2:14-17.)

One of skill in the art would combine Araki's plug-assisted vacuum forming method with Rakonjac's "to avoid that the sheet material is partially or locally thinned excessively." (Ex. 1007, Col. 5:8-10.) To combine Araki's technique, one of skill in the art would simply add Araki's plugs and associated machinery for moving the plugs. (Ex. 1011, ¶ 112.) The result of using Rakonjac and Araki is predictable: Rakonjac's balloon with more uniform wall thickness. (*Id.*)

The claim chart below specifies where the Rakonjac and Araki combination meets the additional element of claim 7.

’832 Patent	Rakonjac in view of Araki
7. A method according to claim 1, wherein the first and second half sections of the balloon have uniform wall thickness.	Araki teaches the balloon has uniform wall thickness. (Ex. 1007, Col. 5:8-10 (“[P]ossible [vacuum thermoforming] to avoid that the sheet material is partially or locally thinned excessively.”); *see also* Col. 9:41-43 (“Consequently, it is possible to prevent the sheet material from being partially or locally thinned excessively.”).)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Rakonjac in view of Araki renders claim 7 obvious.

5. Ground 5: Rakonjac in view of Meyer renders claims 8, 9, and 13 obvious.

Rakonjac does not explicitly teach two semi-spherical half-sections nor inverting a balloon. U.S. Patent 3,070,479 to Meyer (“Meyer”) does.

a. Meyer teaches a spherical balloon manufactured in two halves and inverted to hide a seam.

Meyer published on December 25, 1962, from an application filed December 16, 1958. Meyer qualifies as prior art to the ’832 patent under 35 U.S.C. § 102(a), 102(b), and 102(e).

Meyer “relates to inflatable balls and in particular to beach balls.” (Ex, 1006, Col. 1:8-9.) Meyer teaches that “beach balls are usually made out of a soft thin-walled material such as polyvinyl chloride.” (Ex. 1006, Col. 1:9-10.)

Beach balls, according to Meyer, "may be made by stretching the material to two hemispheric shapes . . ., arranging the hemispheres so that the borders lie opposite one another, [and] fusing the borders together." (Ex. 1006, Col. 1:10-15.)

Meyer teaches that these outwardly facing fused seams sacrifice "the beach ball's regular appearance, its otherwise smooth surface and ability to roll on a smooth floor." (Ex. 1006, Col. 1:17-20.) Meyer's solution inverts the ball after bonding the two halves: "In accordance with the invention one of the hemispheres is provided with an opening at its zenith and after fusion and cutting of the fusion seam, the ball is turned inside out." (Ex. 1006, Col. 1:28-32.)

b. One of skill in the art would apply the balloon manufacturing process of Rakonjac to manufacture the balloon of Meyer because Meyer does not teach how to form its balloon half-sections and Rakonjac teaches a process for forming balloon half-sections.

Rakonjac and Meyer relate to manufacture of thin film thermoplastic devices. (Ex. 1011, ¶ 114.) Meyer discusses beach balls specifically; Rakonjac discusses various inflatable devices, including balloons and toy footballs.

Meyer describes a technique for fusing two hemispheres of a beach ball along a seam and then inverting the ball to hide the seam, but fails to teach how to form the hemispheres into the desired shape before the fusing. (*Id.*, 115) Some forming is necessary to shape the two half-sections of the beach balls. (*Id.*)

Rakonjac teaches that the vacuum thermoforming process "is old in the art." (Ex. 1003, Col. 4:29.) Preforming Meyer's half-sections using a vacuum thermoforming method (such as taught in Rakonjac) is simply the use of a known technique to arrive at a predictable result. (Ex. 1011, ¶ 116.)

Meyer teaches that its inversion process avoids an "interfering seam projecting from the surface of the ball." (Ex. 1006, Col. 1:21-23.) Meyer also teaches that its process can produce a ball with a "smooth surface." (Ex. 1006, Col. 1:24-27.) One of skill in the art would have a reason or motivation to employ the thermo-vacuum molding techniques taught in Rakonjac and the teachings of Meyer for manufacturing inflatable devices with smooth surfaces and without interfering seam projections.

To combine Rakonjac's technique, nothing would change in Meyer's procedure. (Ex. 1011, ¶ 117.) One of skill in the art would simply manufacture the two half-sections of Meyer's beach ball using Rakonjac's manufacturing technique, then continue with Meyer's fusing of two half-sections and inverting of the balloon. (*Id.*)

The result of using Rakonjac and Meyer is predictable: the beach ball illustrated in Meyer. Rakonjac teaches manufacture of balloons from two halves made from thin films; Meyer teaches manufacture of beach balls from two halves made from thin films. One of skill in the art would recognize that the same process could be used. (Ex. 1011, ¶ 118.)

The claim chart below specifies where the Rakonjac and Meyer combination meets each element of claims 8, 9, and 13.[6]

'832 Patent	**Rakonjac in view of Meyer**
8. A method according to claim 1, wherein the first and second half sections of the balloon have a shape selected from the group consisting of semi-sphere, semi-cubic, semi-ellipsoid, and semi-hexagon.	Meyer teaches a spherical balloon wherein a first and second half section of the balloon have a shape selected from the group consisting of semi-sphere, semi-cubic, semi-ellipsoid, and semi-hexagon. (Ex. 1006, Col. 1:8-9 ("[R]elates to inflatable balls and in particular to beach balls.").)
9. A method according to claim 1, wherein the first and second half sections of the balloon are semispherical.	Meyer teaches a spherical balloon wherein a first and second half section of the balloon semispherical. (Ex. 1006, Col. 1:8-9 ("[R]elates to inflatable balls and in particular to beach balls.").)

[6] Petitioner notes that although Ground 5 proposes Rakonjac's method to manufacture Meyer's balloon, the analysis of Claim 1 under Rakonjac does not change. (Ex. 1011, ¶ 119.) Whether Rakonjac's process manufactures Rakonjac's balloon or Meyer's balloon, Rakonjac still teaches all the elements of claim 1: provide a thin film, heat the film, mold a first section using vacuum suction, mold a second section using vacuum suction, and weld the first section and second section to create a low-pressure balloon. (*Id.*)

’832 Patent	Rakonjac in view of Meyer
13. A method according to claim 1, further comprising the step of inverting the low-pressure balloon to dispose rough bonded edges of said first and second half sections of the balloon on an interior surface of said balloon.	Meyer teaches the step of inverting the low-pressure balloon to dispose rough bonded edges of said first and second half sections of the balloon on an interior surface of said balloon: “In accordance with the invention, one of the hemispheres is provided with an opening at its zenith and after fusion and cutting of the fusion seam, the ball is turned inside out. In this manner, the circumferential seam is on the inside of the ball.” (Ex. 1006, Col. 1:28-33.)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Rakonjac in view of Meyer renders claims 8, 9, and 13 obvious.

B. Grounds based on Shah ’915

1. Ground 6: Shah ’915 in view of Dyck renders claims 1-8, 10-12, and 14-18 obvious.

Shah ’915 teaches a method of welding two half-sections together to form medical products, such as catheter balloons. (Ex. 1004, Abstract.) Shah ’915 thus teaches all elements of claim 1, except for vacuum forming; U.S. Patent No. 4,576,156 to Dyck (“Dyck”) teaches vacuum forming. (Ex. 1005, Abstract.) One of skill in the art would combine the vacuum forming process in Dyck to manufacture the half-sections of Shah ’915 to “bring about a uniformity in wall thickness,” “result in a device having greater elasticity,” and “ensure the formation of a pinhole free device.”

Shah ’915 is described in detail above in Section IV.A.3.a. For efficiency, Petitioner does not repeat that discussion here.

a. Dyck teaches vacuum thermoforming.

Dyck published on March 18, 1986, from an application filed on April 17, 1978. Dyck qualifies as prior art to the ’832 patent under 35 U.S.C. § 102(a), 35 U.S.C. § 102(b), and 35 U.S.C. § 102(e). Patent Owner cited Dyck during prosecution but the PTO did not discuss Dyck on the record.

Dyck finds that prophylactic devices “made from thermoplastic polyurethanes have all of the . . . advantages but none of the disadvantages associated with the prior art [rubber-like] devices.” (Ex. 1005, Col. 1:41-44.) Dyck also notes that “[p]ast attempts at making polyurethane devices have . . . inherent disadvantages.” (Ex. 1005, Col. 2:10-17.)

Dyck proposes manufacturing prophylactic devices from thin thermoplastic polyurethane. (Ex. 1004, Col. 2:25-30.) Dyck teaches a “typical process” for manufacturing devices from thin polyurethane: (1) heat the thermoplastic polyurethane to a temperature high enough to soften, (2) bring the heated film and a mandril together, and (3) “[d]uring the period when the device is actually being formed, . . . apply a vacuum to the system in order to bring about a uniformity in wall thickness.” (Ex. 1005, Col. 3:36-50.) Dyck teaches that the “use of a vacuum results in a device having greater elasticity and ensures the formation of a pinhole free device.” (Ex. 1005, Col. 3:50-52.) Dyck therefore teaches vacuum thermoforming to "bring about a uniform wall thickness," "result in a device having greater elasticity," and "ensure the formation of a pinhole free device."

b. One of skill in the art would combine the vacuum suction manufacturing technique of Dyck with the balloon manufacturing technique of Shah '915 to "bring about a uniform wall thickness," "result in a device having greater elasticity," and "ensure the formation of a pinhole free device."

Shah '915 and Dyck relate to manufacture of thermoplastic medical devices. (Ex. 1011, ¶ 124.) Shah '915 discusses various medical devices, including condoms, gloves, and catheter balloons. Dyck also discusses medical devices, specifically condoms and gloves.

Shah '915 teaches that the prior art material, latex, is problematic; Dyck also teaches that the prior art material, latex, is problematic. Shah '915 teaches "thin film" polyurethane as a solution; Dyck also teaches "thin film" polyurethane as a solution, providing advantages such as "physical strength," "superior abrasion resistance," "superior tear resistance," "greater tensile strength," and no "significant amount of absorption of materials like body enzymes or other proteins." (Ex. 1005, Col. 3:19-28.)

Shah '915 describes a welding technique for two portions of polyurethane, but does not provide any teaching of how to form the polyurethane into the desired shape before the welding. (Ex. 1011, ¶ 91.) Some forming is necessary to shape the two half-sections of the balloons. (*Id.*)

Dyck teaches a superior polyurethane forming technique that includes heating the polyurethane and applying vacuum suction. Dyck teaches many advantages to the disclosed technique. (Ex. 1005, Col. 3:19-28.) Shah '915 is ready to be improved in the same way. (Ex. 1011, ¶ 127.)

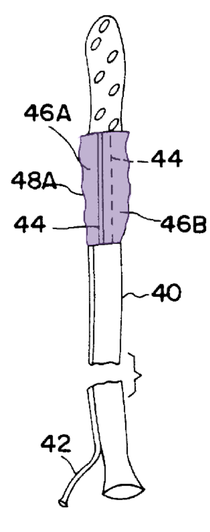
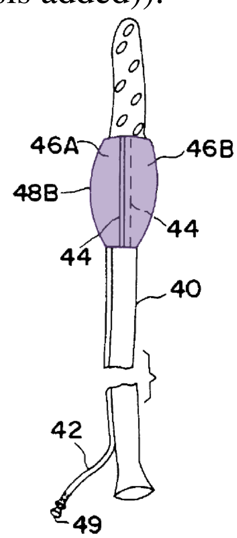
To combine Dyck's technique, nothing would change in Shah '915's procedure. (Ex. 1011, ¶ 128.) One of skill in the art would simply manufacture the two half-sections of Shah '915's catheter balloon using Dyck's manufacturing technique, then continue with Shah '915's welding of two half-sections as disclosed in Shah '915. (*Id.*)

The result of using Dyck's method to produce Shah '915's half-sections is predictable: the balloon illustrated in Shah '915. Dyck teaches a thermoforming process for medical devices and gives examples of 10 mils to 25 mils; Shah '915 teaches balloons of 5 mils. One of skill in the art would recognize that the same process could be used, but the welding time may change to accommodate any difference in balloon thickness. (Ex. 1011, ¶ 129.)

With respect to balloon thickness, Shah '915 teaches a pre balloon wall thickness of 0.005 inch, or 5 mils. (Ex. 1004, Col. 1:8-12 ("The present invention relates to a new method of joining by a welding process, at least two layers of a thin polyurethane thermoplastic elastomer film having a thickness in the range of 0.5 to 5.0 mils.”).) After vacuum molding into the half-sections, each balloon will stretch, losing some thickness. (Ex. 1011, ¶ 155.) The resulting balloon will have a thickness of approximately 2.5 mils. (*Id.,* ¶¶ 72-81(calculating the thickness of hemispheric balloon manufactured from a 5 mil film).) Thus, Shah ’915 teaches a low-pressure balloon that has a wall thickness within a range from about 0.5 mils to about 10 mils (claim 14) and a balloon that has a wall thickness within a range from about 2 mils to about 6 mils (claim 15).

As noted above, the ’832 specification does not provide for any definition of “neck to body ratio” ratios or any suggestion of how to measure. (Ex. 1011, ¶ 84.) The ’832 specification, however, states that “the present invention relates to balloons of a type used in medical procedures, and to a method of making such balloons” employing “thermo-vacuum molding techniques.” (Ex. 1001, Col. 2:37-56.) The ’832 specification also states that “[t]he neck to body ratio of balloons formed in accordance with the present invention may be less than 30%, preferably less than 25%, and more preferably less than 10%.” (Ex. 1001, Col. 5:51-54.) To the extent employing thermo-vacuum molding techniques, as in the ’832 patent, would lead to balloons with the “neck to body ratio” recited in those claims, Dyck teaches thermo-vacuum molding techniques.

The claim chart below specifies where the Shah '915 and Dyck combination meets each element of claims 1-8, 10-12, and 14-18.

'832 Patent	Shah '915 in view of Dyck
1. A method for manufacturing [a] low-pressure balloon, comprising the steps of:	Shah '915 teaches a method for manufacturing a low-pressure balloon: "[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer (10A,B) to form a weld seam (12) to produce polyurethane barrier products such as . . . inflatable catheter balloon cuffs (48A,B)." (Ex. 1004, Abstract.) "FIG. 7 is a view of an non-inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter. FIG. 8 is an inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter." (Ex. 1004, Col. 5:27-61; *see also* Figures 7 and 8, reproduced below (emphasis added)):  FIG.7  FIG.8
(a) providing a thin film of thermoplastic polymeric material;	Shah '915 teaches a thin film of thermoplastic polymeric material: "[a] method of welding at least two layers of a thin thermoplastic

’832 Patent	Shah ’915 in view of Dyck
	polyurethane elastomer.” (Ex. 1004, Abstract; *see also* Col. 1:8-11 (“The present invention relates to a new method of joining by a welding process, at least two layers of a thin polyurethane thermoplastic elastomer film having a thickness in the range of 0.5 to 5.0 mils.”).) Dyck teaches a thin film of thermoplastic polymeric material: “[t]he device is made from a thin pellicle or membrane of a thermoplastic polyurethane having a thickness of about 0.01mm, or less, to about 0.25mm.” (Ex. 1005, Col. 2:25-30.)
(b) heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming thereof;	Dyck teaches heating the thermoplastic polymeric thin film to a sufficient temperature for vacuum forming: “In a typical process, the thermoplastic polyurethane is heated prior to contacting it with a preformed mandril to a temperature high enough to soften the polymer but low enough to prevent chemical degradation. . . . During the period when the device is actually being formed, it is preferred to apply a vacuum to the system in order to bring about uniformity in wall thickness.” (Ex. 1005, Col. 4:36-50.)
(c) forming a first half section for a balloon on the thermoplastic polymeric thin film by vacuum suction;	Shah ’915 teaches forming a first half section for a balloon on the thermoplastic polymeric thin film:“[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer (10A,B) to form a weld seam (12) to produce polyurethane barrier products such as . . . inflatable catheter balloon cuffs (48A,B).” (Ex. 1004, Abstract.) “FIG. 7 is a view of an non-inflated thermoplastic polyurethane elastomer balloon

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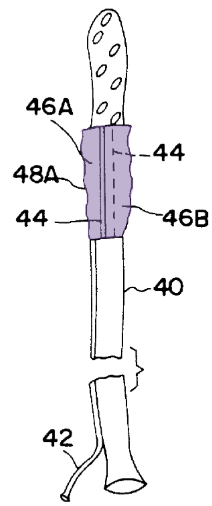
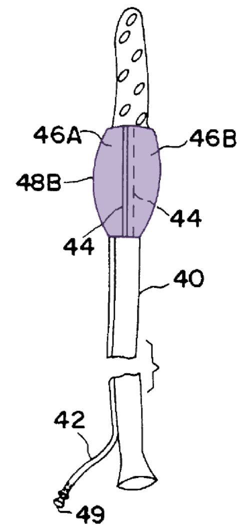
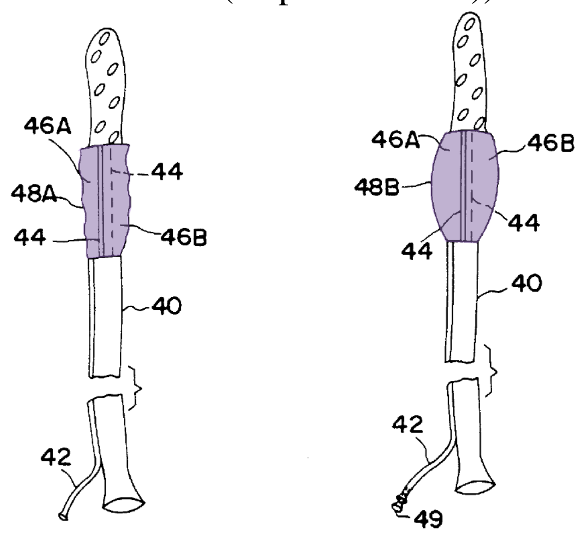
	cuff of an in-dwelling urinary bladder catheter. FIG. 8 is an inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter.” (Ex. 1004, Col. 5:27-61; *see also* Figures 7 and 8, reproduced below (emphasis added)):  FIG.7  FIG.8 Dyck teaches forming medical devices out of thermoplastic polymeric thin film by vacuum suction: “During the period when the device is actually being formed, it is preferred to apply a vacuum to the system in order to bring about uniformity in wall thickness.” (Ex. 1005, Col. 4:47-50.)
(d) forming a second half section for the balloon on a same or different thermoplastic polymeric thin film by vacuum suction; and	See above—Shah ’915 teaches forming two half-sections for the balloon on a same or different thermoplastic polymeric thin film; Dyck teaches forming medical devices out of thermoplastic polymeric thin film by vacuum suction.
(e) bonding the first half-section to the second half-section along edges of the half-	Shah ’915 teaches forming a first half section for a balloon on the thermoplastic polymeric thin film:“[a] method of welding at least two layers of a thin thermoplastic polyurethane

’832 Patent	Shah ’915 in view of Dyck
sections to form the balloon.	elastomer (10A,B) to form a weld seam (12) to produce polyurethane barrier products such as . . . inflatable catheter balloon cuffs (48A,B).” (Ex. 1004, Abstract.) “FIG. 7 is a view of an non-inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter. FIG. 8 is an inflated thermoplastic polyurethane elastomer balloon cuff of an in-dwelling urinary bladder catheter.” (Ex. 1004, Col. 5:27-61; *see also* Figures 7 and 8, reproduced below (emphasis added)):  FIG.7 FIG.8
2. A method according to claim 1, wherein the thermoplastic polymeric material is non-allergenic.	Shah ’915 teaches the thermoplastic polymeric material is non-allergenic: Shah ’915 teaches that OSHA determined that one problem with rubber latex was that it was not hypoallergenic and continues by teaching that polyurethane is an appropriate substitute to solve latex’s problems. (Ex. 1004, Col. 2:29-34 (“As a result of the frequency and severity of such problems, OSHA regulations and guidelines have recently been established requiring employers to provide workers

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	exposed to blood borne pathogens with an adequate hypo-allergenic substitute or other effective alternatives to contact with natural rubber latex products.”); *see also* Col. 2:43-46 (“It has been recognized that polyurethane polymers have properties desirable for many of the rubber goods heretofore made of natural rubber, particularly thermoplastic elastomer polyurethanes.”); Col. 4:30-39 (describing a prior art references hypoallergenic polyurethane gloves).)
3. A method according to claim 1, wherein the thermoplastic polymeric material comprises a material selected from the group consisting of polyurethane and silicone.	Shah ’915 teaches the thermoplastic polymeric material comprises a material selected from the group consisting of polyurethane and silicone: “[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer.” (Ex. 1004, Abstract.)
4. A method according to claim 1, wherein the thermoplastic polymeric material comprises polyurethane.	Shah ’915 teaches the thermoplastic polymeric material comprises polyurethane: “[a] method of welding at least two layers of a thin thermoplastic polyurethane elastomer.” (Ex. 1004, Abstract.)
5. A method according to claim 1, wherein the thin film of thermoplastic polymeric material is heated to a temperature within a range from about 60° C. to about 150° C.	Shah ’915 teaches the thin film of thermoplastic polymeric material is heated to a temperature within a range from about 60° C. to about 150° C: “In our invention, the thermoplastic polyurethane elastomer is heated to a temperature above the Vicat softening temperature of the polymer prior to the R.F. welding procedure. The Vicat softening temperature of such elastomers is ordinarily in the range of about 60° C. to 150° C.” (Ex. 1004, Col. 8:13-17.)
6. A method according to claim 1, wherein the first and second half sections of	Shah ’915 teaches the first and second half-sections of the balloon are formed simultaneously on a same thin film of

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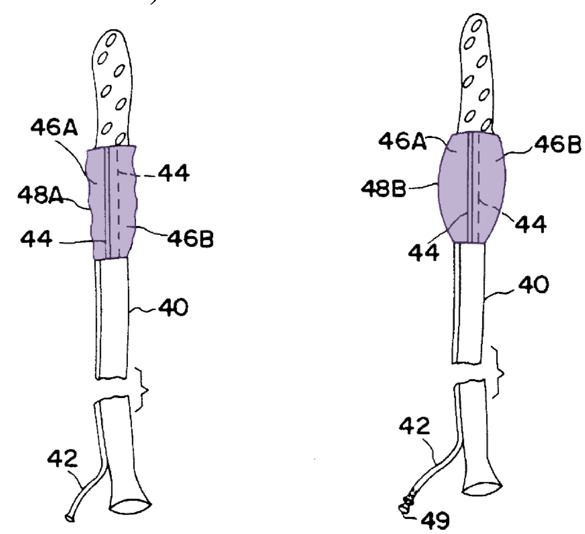
the balloon are formed simultaneously on a same thin film of thermoplastic polymeric material by vacuum suction.	thermoplastic polymeric material by vacuum suction: “[a] method of welding at least two layers of a thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, preamble.)
7. A method according to claim 1, wherein the first and second half sections of the balloon have uniform wall thickness.	Dyck teaches the first and second half sections of the balloon have uniform wall thickness: “During the period when the device is actually being formed, it is preferred to apply a vacuum to the system in order to bring about uniformity in wall thickness.” (Ex. 1005, Col. 3:47-50.)
8. A method according to claim 1, wherein the first and second half sections of the balloon have a shape selected from the group consisting of semi-sphere, semi-cubic, semi-ellipsoid, and semi-hexagon.	Shah ’915 teaches two half-sections of semi-ellipsoid shape: Figures 7 and 8 (half-sections 46A and 46B).  FIG.7 FIG.8
10. A method according to claim 1, wherein the first and second half sections of the balloon are bonded together by a bonding method selected from the group consisting of: adhesive bonding,	Shah ’915 teaches the first and second half-sections of the balloon are bonded together by . . . radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)

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electromagnetic bonding, hot plate welding, impulse heating, induction bonding, insert bonding, radio-frequency welding, spin welding, thermostacking, ultrasonic sealing, and vibration welding.	
11. A method according to claim 1, wherein the first and second half sections of the balloon are bonded together by radio-frequency welding.	Shah ’915 teaches the first and second half-sections of the balloon are bonded together by radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)
12. A method according to claim 1, wherein the first and second halves of the balloon are bonded together by radio-frequency welding, comprising the steps of:	Shah ’915 teaches wherein the first and second halves of the balloon are bonded together by radio-frequency welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1004, Col. 6:50-54.)
(a) preheating a welding platen to a temperature above a Vicat softening temperature and below a melting temperature of the thermoplastic polymeric material;	Shah ’915 teaches preheating a welding platen to a temperature above a Vicat softening temperature: “(a) pre-heating a welding platen to a temperature above a Vicat softening temperature and below a thermoplastic elastomer film deformation temperature of said thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, element a.)
(b) placing edges of the first and second half sections of the balloon on the preheated platen, said platen heating the edges of the first and second halves of the	Shah ’915 teaches placing two layers of the balloon on the preheated platen, said platen heating the edges of the first and second halves of the balloon to a temperature above the Vicat softening temperature and below a melting temperature of said thermoplastic polymeric material: “(b) placing at least two

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balloon to a temperature above the Vicat softening temperature and below a melting temperature of said thermoplastic polymeric material;	layers of said polyurethane film on the preheated platen, said platen heating said thermoplastic polyurethane elastomer film to a temperature above the Vicat softening temperature of said thermoplastic polyurethane elastomer film and below a melting temperature of said thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, element b.)
(c) compressing the edges of the first and second halves of the balloon at edges thereof to form an interface therebetween;	Shah ’915 teaches compressing the edges of the first and second halves of the balloon at edges thereof to form an interface therebetween: “(c) compressing the layers of film in surface apposition to form an interface therebetween by applying pressure from a die and from said welding platen to said thermoplastic polyurethane elastomer film.” (Ex. 1004, Claim 1, element c.)
(d) transmitting radio-frequency energy to the edges of the first and second half sections of the balloon while said edges are under pressure, and welding said edges at said interface, thereby forming a weld, and	Shah ’915 teaches transmitting radio-frequency energy to the edges of the first and second half-sections of the balloon while said edges are under pressure, and welding said edges at said interface, thereby forming a weld: “(d) transmitting radio-frequency energy to the layers of film while said thermoplastic polyurethane elastomer film is under said pressure, welding the film layers at said interface therebetween forming a weld.” (Ex. 1004, Claim 1, element d.)
(e) recovering said balloon comprising the welded first and second half sections.	Shah ’915 teaches recovering said balloon comprising the welded first and second half-sections: “(e) cooling said weld of the at least two layers of film, wherein said weld is free of holidays, pins holes, charring, burning, and wrinkles.” (Ex. 1004, Claim 1, element e.)
14. A method according to claim 1, wherein the low-	Shah ’915 teaches a low-pressure balloon that has a wall thickness within a range from about

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pressure balloon has a wall thickness within a range from about 0.5 mils to about 10 mils.	0.5 mils to about 10 mils: the resulting balloon will have a thickness of approximately 2.5-5 mils. (Ex. 1011, ¶¶ 72-81 .)
15. A method according to claim 1, wherein the low-pressure balloon has a wall thickness within a range from about 2 mils to about 6 mils.	Shah ’915 teaches a low-pressure balloon that has a wall thickness within a range from about 2 mils to about 6 mils: the resulting balloon will have a thickness of approximately 2.5-5 mils. (*Id.*)
16. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 30%.	Dyck teaches neck to body ratio of less than 30%: Dyck teaches thermo-vacuum molding techniques.
17. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 25%.	Dyck teaches neck to body ratio of less than 25%: Dyck teaches thermo-vacuum molding techniques.
18. A method according to claim 1, wherein the low-pressure balloon has a neck to body ratio of less than 10%.	Dyck teaches neck to body ratio of less than 10%: Dyck teaches thermo-vacuum molding techniques.

Petitioner respectfully submits that it has a reasonable likelihood of showing that Shah ’915 in view of Dyck renders claims 1-8, 10-12, and 14-18 obvious.

2. Ground 7: Shah ’915 in view of Dyck and further in view of Araki renders claim 7 obvious.

Araki teaches vacuum thermoforming to produce uniform wall thickness. Section IV.A.4.a explains the relevant portions of Araki. For efficiency, Petitioner does not repeat that discussion here.

Shah ’915, Dyck, and Araki all discuss thermoplastic materials. (Ex. 1011, ¶ 162.) One of skill in the art would combine Araki’s plug-assisted vacuum forming method with the balloon formed from the combination of Shah ’915 and Dyck “to avoid that the sheet material is partially or locally thinned excessively.” (Ex. 1007, Col. 5:8-10.) To combine Araki’s technique, one of skill in the art would simply add Araki’s plugs and associated machinery. (Ex. 1011, ¶ 162.) The result of using Shah ’915, Dyck, and Araki is predictable: a thin-walled balloon with more uniform wall thickness. (*Id.*)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Shah ’915 in view of Dyck and further in view of Araki renders claim 7 obvious.

3. Ground 8: Shah ’915 in view of Dyck and further in view of Meyer renders claims 9 and 13 obvious.

Neither Shah ’915 nor Dyck explicitly teaches a semi-spherical balloon or a step of inverting the low-pressure balloon to dispose of rough bonded edges of said first and second half-sections of the balloon on an interior surface of said balloon. Meyer does.

Section IV.A.5.a explains the relevant portions of Meyer. For efficiency, Petitioner does not repeat that discussion here.

One of skill in the art would combine the inversion technique of Meyer with the balloon cuff of Shah '915 in view of Dyck because a smooth seam, resulting from an inverted balloon as taught by Meyer, is less likely to cause irritation when inserted in a body lumen. (Ex. 1011, ¶ 163.)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Shah '915 in view of Dyck and further in view of Meyer renders claims 9 and 13 obvious.

V. NOTICES AND STATEMENTS

Pursuant to 37 C.F.R. § 42.8(b)(1), Obalon Therapeutics, Inc. is the real party-in-interest.

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies no pending related matters. However, Petitioner concurrently files *inter partes* review petitions for Patent Owner's U.S. Patent Nos. 7,682,306 B2 and 7,883,491 B2.

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following counsel (and a power of attorney accompanies this Petition).

Lead Counsel for Petitioner	Backup Counsel for Petitioner
Peng Chen pchen@mofo.com Registration No.: 43,543 MORRISON & FOERSTER LLP 12531 High Bluff Drive, Suite 100 San Diego, CA 92130 Tel: (858) 720-5117 Fax: (858) 720-5125	Desmond O'Sullivan dosullivan@mofo.com Registration No.: 67,576 MORRISON & FOERSTER LLP 12531 High Bluff Drive, Suite 100 San Diego, CA 92130 Tel: (858) 314-7794 Fax: (858) 523-2833

Pursuant to 37 C.F.R. § 42.8(b)(4), service information for lead and back-up counsel is provided above. Petitioner consents to electronic service by email to pchen@mofo.com, dosullivan@mofo.com, and 65925-Shah-IPR@mofo.com.

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '832 patent is eligible for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

VI. CONCLUSION

For the reasons detailed above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 1-18 of the '832 patent. Accordingly, Petitioner respectfully requests *inter partes* review of claims 1-18 of the '832 patent.

The USPTO is authorized to charge any required fees, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees, to Deposit Account No. **03-1952** referencing Docket No. **659250000006**.

Dated: March 3, 2017

Respectfully submitted,

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by U.S. Express Mail, which on the Patent Owner at the correspondence address indicated for U.S. Patent No. 6,712,832 B2.

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Dated: March 3, 2017

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Certification of Word Count (37 C.F.R. § 42.24)

I hereby certify that this Petition for *Inter Partes* Review has 11,891 words (as counted by the "Word Count" feature of the Microsoft Word™ word-processing system used to create this Petition), exclusive of "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: March 3, 2017

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