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. 7,883,491 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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<u>Exhibit List for *Inter Partes* Review of U.S. Patent No. 7,883,491</u>

Exhibit Description	Exhibit #
U.S. Patent No. 7,883,491 B2 to Shah	1001
Prosecution History of U.S. Patent No. 7,883,491 B2	1002
U.S. Patent No. 6,712,832 B2 to Shah	1003
U.S. Patent No. 6,976,950 B2 to Connors et al.	1004
U.S. Patent No. 5,316,605 to Rakonjac et al.	1005
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Petitioner Obalon Therapeutics, Inc. ("Petitioner") respectfully petitions for *inter partes* review of claims 1-6, 10-18, 20, and 21 of U.S. Patent No. 7,883,491 B2 ("the '491 patent" (Ex. 1001)) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. INTRODUCTION

The '491 patent's independent claims (claim 1 and claim 22) each describe a gastric-occlusive device that comprises a balloon with an inflation element. The balloon when inflated is "non-pillowed" and spheroidal. The balloon is manufactured from a vacuum thermoforming process using a die having a substantially non-planar surface. The balloon is manufactured from two half-sections bonded along peripheral portions to create a seam.

The balloon comprises a multilayer film, where one layer is a "sealing film" and another layer is a "thermoplastic polymer film" laminated to the sealing film. The sealing film has gas barrier characteristics and the other layer does not.

Each of these limitations was well known. U.S. Patent No. 5,084,061 to Gau et al. ("Gau" (Ex. 1008)) provides a non-pillowed, spherical gastric-occlusive balloon with an inflation element. For manufacturing balloons in two half-sections, Patent Owner's own U.S. Patent No. 5,833,915 ("Shah '915" (Ex. 1006)) discloses bonding two half-sections together along peripheral seams. For multi-layer balloons, "Technology of Thermoforming" by Throne ("Throne" (Ex.

1007)) teaches a multi-layer sheet where one layer provides a sealing function and the other layer does not. Throne further discloses manufacturing the two-layer sheets using vacuum thermoforming.

One of skill in the art would have manufactured Gau's balloon using Shah '915's polyurethane method because, as Shah '915 teaches, those skilled in the art recognized that polyurethane offers many desirable properties for medical barrier products. Further, one of skill in the art would have used Throne's two-layer approach to make barrier products because, as Throne teaches, the approach is cost-effective and reduces waste material.

Petitioner also presents U.S. Patent No 6,976,950 B2 to Connors et al. ("Connors" (Ex. 1004)) that teaches a therapeutic method involving introducing and inflating a balloon. Connors teaches balloons manufactured from combinations of gas barrier layers, moisture barrier layers, and structural layers. Connors teaches balloons manufactured from two half-sections and bonded along peripheral portions to make seams. Connors does not explicitly teach a vacuum thermoforming process for fabricating the balloon, but Rakonjac teaches that vacuum thermoforming two half-sections and bonding them together is "old in the art."

The Patent and Trademark Office ("PTO") cited Connors during prosecution. To overcome Connors, Patent Owner submitted a declaration from himself. The Examiner maintained the rejection and Patent Owner appealed. The Board[1] reversed the Examiner because the Examiner did not address Patent Owner's declaration nor explain how Connors taught all the limitations of the claims. In addition to presenting Connors with a new reference (Rakonjac) to show vacuum thermoforming, Petitioner presents the testimony of Clair Strohl and supporting evidence to address the relevant portions of Patent Owner's declaration. (Ex. 1009.)

II. SUMMARY OF THE '491 PATENT

The '491 patent is titled "Extrusion Laminate Polymeric Film Article Gastric Occlusive Device Comprising Same" and includes two independent claims. Claim 1 reads:

> 1. A gastric occlusive device comprising:
>
> a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from two vacuum thermoformed half-sections of a multilayer film comprising:
>
> (A) a layer of sealing film, having main top and bottom surfaces; and

[1] For simplicity, Petitioner refers to the Patent Trials and Appeals Board and its predecessor, the Board of Patent Appeals and Interferences, as the "Board."

(B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein

the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and

wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character,

wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and

the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.

The ’491 patent’s Background describes a need for gas-barrier films in polymeric films less than 25 mils. (Ex. 1001, Col. 1:13-16.) The Background describes many uses for such gas barrier films, such as containing a specific gas when used to form gas receptacles or when used to isolate an article, structure, material, or region from an adverse gas environment. (Ex. 1001, Col. 1:17-34.)

The Background explains that the film may fail in such applications. (Ex. 1001, Col. 1:27-31). The Background further explains that physiological applications may also subject the films to biological fluids and variations of temperature, pressure, and pH. (Ex. 1001, Col. 1:32-37.) The Background concludes that there "is presently a compelling need in the art for readily manufacturable, soft and supple yet durable and reliable gas barrier films for manufacture of medical devices." (Ex. 1001, Col. 1:38-40.)

The Summary of Invention provides a number of "aspects of the invention." (Ex. 1001, Col. 1:53-3:8.) Each aspect includes a multilayer film having a sealing layer and a thermoplastic layer, where "the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) of thermoplastic polymer film alone lacks such gas barrier character." (Ex. 1001, Col. 1:57-67, 2:11-19, 2:23-26, 2:30-39, 2:41-52, 2:61-3:4.)

Figure 1 depicts a multilayer extruded laminate film 10. (Ex. 1001, Col. 6:42-44, 7:1-3.) The film 10 includes inner sealing layer film 12 and outer film layers 14 and 16 of thermoplastic material. (*Id.*, Col. 7:4-7.)

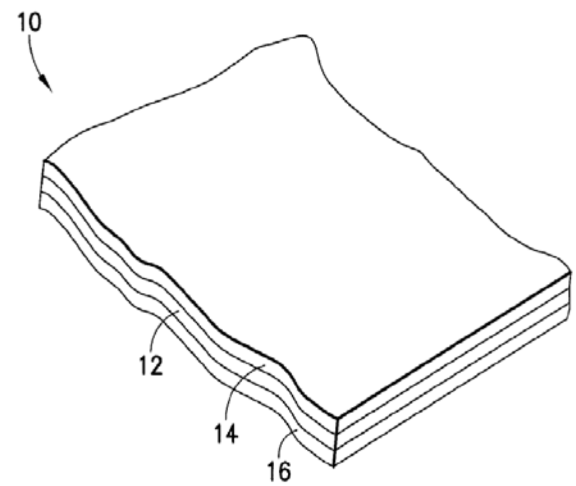


FIG.1

Figure 3 depicts a vacuum thermoforming assembly 50. (Ex. 1001, Col. 7:59-60.) The assembly includes a thermoforming die 52 with a generally hemispherical cavity 54. (*Id.* at Col. 7:62-64.) A vacuum source (not shown) extracts gas through withdrawal passages on the surface 60 of the cavity through a gas extraction plenum 56 and discharge passage 58. (*Id.* at Col. 7:64-8.) The process includes heating multilayer film 62 to sufficient temperature for vacuum thermoforming and applying a vacuum to assembly 50 so that the film conforms to cavity surface 60. (*Id.* at Col. 8:9-13.)

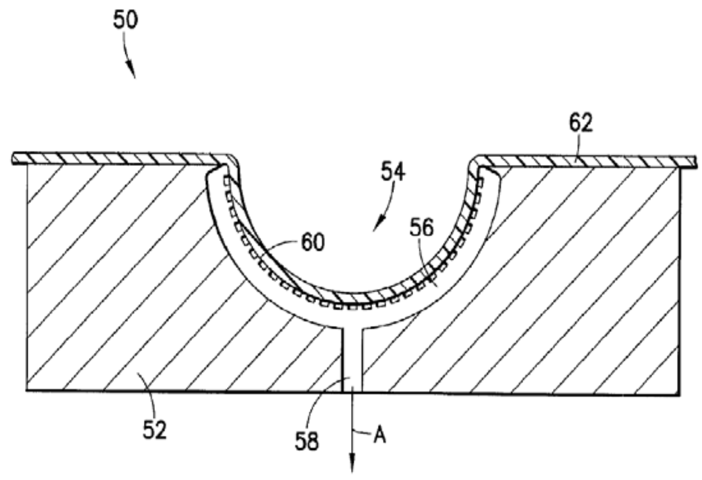


FIG.3

After forming the first and second half-sections, the process superimposes the two sections and bonds them together at the sections' margins. (Ex. 1001, Col. 8:36-38.) Figure 4 provides an exemplary frequency welding method where two sheets 62 and 64 lie in a cavity 82 and a radio frequency die (70) contacts the two sheets to bond the sheets circumferentially. (Ex. 1001, 8:42-52.)

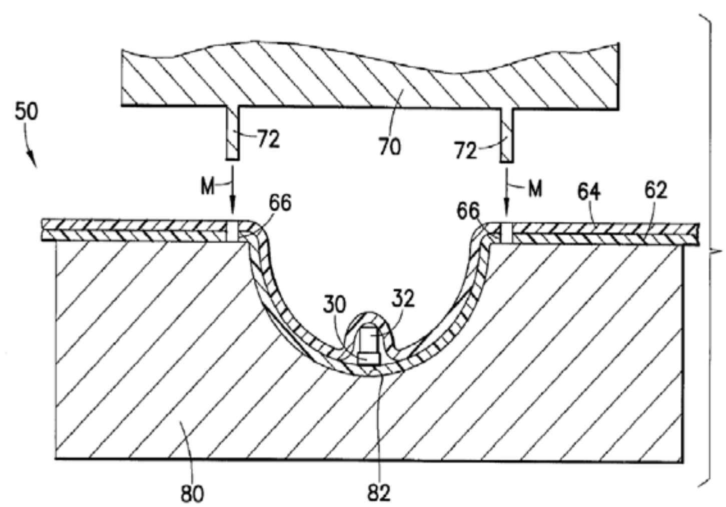


FIG.4

III. PROSECUTION HISTORY

The '491 patent matured from U.S. Application No. 10/815,282 (Ex. 1002) filed on April 1, 2004. (Ex. 1001, Cover Page.)

A detailed description of the prosecution history is included with the Declaration of Mr. Strohl. (Ex. 1009.) The following focuses on the context of an Appeal.

On October 2, 2007, Patent Owner filed a response arguing that Connors does not teach a non-pillowed and spheroidal balloon. (Ex. 1002 at 6.) Patent Owner also argued that "vacuum thermoforming represents the only way known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal" and argued that the "use of vacuum thermoforming to fabricate balloons from polymeric sheets was **pioneered by the same inventor** of the present application." (*Id.* at 7 (emphasis in original).) Patent Owner cited his own declaration to support the arguments. (*Id.*)

On December 19, 2007, the PTO issued a final rejection maintaining the rejection of all claims over Connors. (Ex. 1002, Final Rejection, mailed 12/19/07, Pages 2-4.) On January 30, 2008, Patent Owner filed a Notice of Appeal and a Pre-Appeal Brief request. (Ex. 1002.) On March 20, 2008, Patent Owner filed an

Appeal Brief. (Ex. 1002.) The Examiner's Answer followed on June 12, 2008 and Patent Owner's Reply followed on July 2, 2008. (Ex. 1002.)

On August 18, 2010, the Board reversed. (Ex. 1002.) In reversing, the Board found that the "Examiner has not specifically articulated in the Answer how Connors otherwise discloses or suggests, to one of ordinary skill in the art, how to construct a balloon with all of the characteristics required by each of the appealed claims." (Ex. 1002, Appeal Decision, mailed 08/18/2010, Page 5.)

The Board also faulted the Examiner's failure to consider Patent Owner's declaration. Specifically, the Board held that "the Examiner's failure to address and attempt to discredit the 37 C.F.R § 1.132 Declaration testimony of [Patent Owner] employed in support of Appellant's arguments . . . of itself, warrants reversal of the stated rejection."

The Board concluded:

> In sum and as correctly urged by Appellants, the Examiner does not reasonably explain how the referred to Patent Specification passages of Connors taken with the depicted embodiments represented in Figures 5 and 16C teach or suggest a balloon having all of the claimed characteristics to an ordinary skilled artisan given the additional non-rebutted information provided in the 37 C.F.R. § 1.132 Declaration testimony of [Patent Owner].
>
> The aforementioned failure on the part of the Examiner represents a dispositive issue that we resolve in Appellant's favor.

(Ex. 1002, Appeal Decision, mailed 08/18/2010, Page 5.)

IV. CLAIM CONSTRUCTION

The ’491 patent provides two explicit definitions:

> As used herein, the term “film” means a material in a sheet or web form, having a thickness of 50 mils (1.270 mm) or less.
> As used herein, the term “extrusion laminated” in reference to a film of thermoplastic material means that such film of thermoplastic material is deposited as an extruded melt film on (one or both sides of) the sealing layer film, so that the respective thermoplastic material and sealing layer films are consolidated with one another under elevated temperature conditions. The laminate preferably is formed under process conditions producing substantially uniform thickness of the multilayer film, with a thickness variation across the laminated film desirably being less than 20% and more preferably being less than 15% of the total thickness of the laminate.

(Ex. 1001, Col. 2:52-64.)

Petitioner does not submit any other claim constructions. Petitioner relies on the plain language of the claims and embodiments in the ’491 patent to demonstrate that the prior art meets the limitations of the ’491 patent. *Hakim v. Cannon Avent Group, PLC,* 479 F.3d 1313 (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).

V. IDENTIFICATION OF CHALLENGE

Pursuant to 37 C.F.R. § 42.104(b), Petitioner respectfully requests the Board cancel claims 1-6, 10-18, 20, and 21 of the '491 patent.

The '491 patent combines known features of intragastric balloons with known thermoplastic manufacturing processes. Gau, for example, teaches all the gastric balloon limitations recited in independent claim 1. Throne and Shah '915 teach the thermoplastic manufacturing techniques that result in the balloon described in claim 1. One or more of Gau, Throne, and Shah '915 teach the additional limitations for many dependent claims.

Connors teaches all limitations of independent claim 1, except manufacturing a balloon by vacuum thermoforming; Rakonjac teaches manufacturing a balloon by vacuum thermoforming. As explained below, Connors and Rakonjac, in conjunction with the evidence presented, addresses the Board's findings on appeal: Petitioner newly offers Rakonjac for vacuum thermoforming; and Petitioner provides an expert declaration and supporting evidence to address the declaration provided by Patent Owner during prosecution.

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

Ground	35 U.S.C.	Reference	Claims

Ground	35 U.S.C.	Reference	Claims
Ground 1	§ 103	Gau, Shah '915, Throne	Claims 1, 3-5, and 12-15
Ground 2	§ 103	Connors, Rakonjac	Claims 1-6, 10-18, 20, and 21

Pursuant to 37 C.F.R. § 42.104(b), Petitioner respectfully requests the Board cancel claims 1-6, 10-18, 20, and 21 of the '491 patent.

A. Grounds based on Gau in view of Shah '915 and Throne

1. Ground 1: Gau in view of Shah '915 and Throne renders claims 1, 3-5, and 12-15 obvious.

a. Gau teaches a spheroidal intragastric balloon with an inflation element.

Gau issued on January 28, 1992, claiming priority to an application filed on September 25, 1987. (Ex. 1008, Cover Page.) Gau qualifies as prior art to the '491 patent under 35 U.S.C. § 102(a), 35 U.S.C. § 102(b), and 35 U.S.C. § 102(e). The PTO did not cite Gau during the prosecution of the '491 patent.

Gau relates to implantable weight control devices. (Ex. 1008, Col. 1:13-14.) Gau notes that existing gastric devices are typically spherical, which can present a challenge to surgeons manipulating the device in the gastric cavity. (Ex. 1008, Col. 2:8-14.) To address this challenge, Gau offers a flattened spherical balloon allowing for "relative ease with which the important components of the balloon 20 can be visualized and manipulated while in the stomach." (Ex. 1008, Col. 7:38-41; *see also id.* at Col. 4:28-43.)

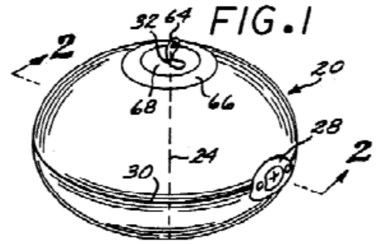


FIG. 1

Gau's gastric balloon also includes a self-sealing valve (element 28, Figure 2 reproduced below), a fill tube guide (element 54, Figure 2 reproduced below), and a removal tab (element 64, Figure 2 reproduced below).

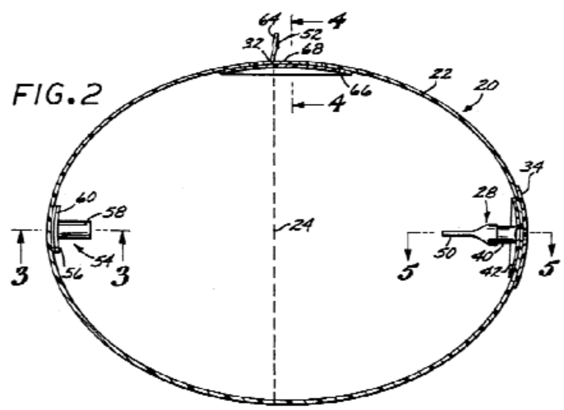


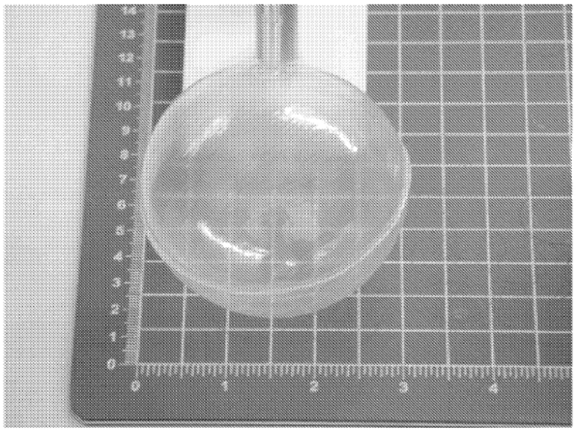
FIG. 2

"The purpose of the valve 28 is to permit inflation of the balloon 20 after it has been inserted into the stomach 26, and also its deflation before it is desired to remove the balloon 20 from the stomach 26." (Ex. 1008, Col. 4:56-60.) "The purpose of the fill tube guide 54 is to serve as a seat for the stiffening rod or stylette (not shown) which is used to make the fill tube and balloon rigid during the original insertion of the balloon 20 into the stomach 26." (Ex. 1008, Col. 6:51-55.)

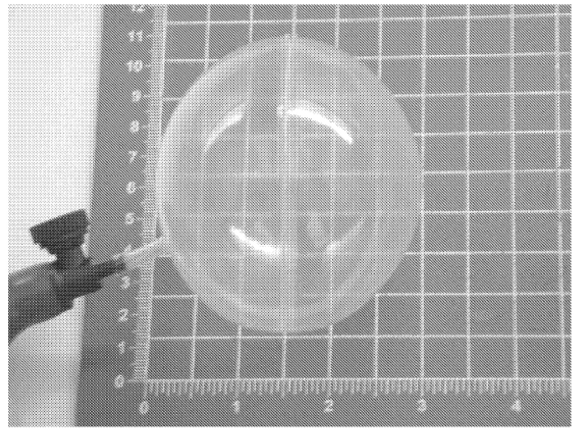
"The purpose of the tab 64 is to provide means through which the balloon 20 can be relatively easily captured or grasped after full or partial deflation and removed from the stomach 26." (Ex. 1008, Col. 7:2-5.)

The process includes mounting the balloon by passing a fill tube and stylette through the valve 28 and then seating the stylette in the fill tube guide. (Ex. 1008, Col. 6:57-60.) The balloon 20 "is placed into the stomach in a non-inflated form, and is filled after insertion with a suitable fluid, such as saline solution." (Ex. 1008, Col. 3:62-65.) The balloon can then be deflated by passing a filler tube through the valve 28. (Col. 5:19-23.)

As described above, Gau teaches introducing a balloon into a physiological locus of a patient and inflating the balloon. Gau also teaches that the balloon is non-pillowed and spheroidal. Although the '491 patent does not define those terms, during prosecution Patent Owner referred to the following shape as "a non-pillowed, spheroid" and stated that the "balloon pictured in Exhibits in B1-B3 corresponds to the claims of the instant application." (Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 11 & Exhibit B1-B3.)



TOP VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS



SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS

The balloon in Gau has a shape similar to the "non-pillowed, spheroid" shape in the image above, except slightly "flattened" in one plane (*see* Gau Figures 1 and 2 below) to produce a "non-pillowed[2], flattened spherical" balloon. (Ex. 1009, ¶ 55-56.)

[2] The '491 patent does not provide guidance on the term "non-pillowed." The only mention of the term is in claims 1 and 22, and a statement that vacuum thermoforming two half-sections together can result in a non-pillowed balloon. (Ex. 1001; Col. 3:63-67.) As explained below in the sections below, Petitioner proposes combining Throne with Gau for a vacuum thermoformed balloon. During prosecution, Patent Owner declared that certain images (as explained herein) were "non-pillowed." As shown herein, Gau's shape is essentially the same as the shape of the balloons described by Patent Owner as non-pillowed.

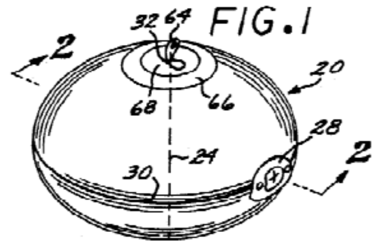


FIG.1

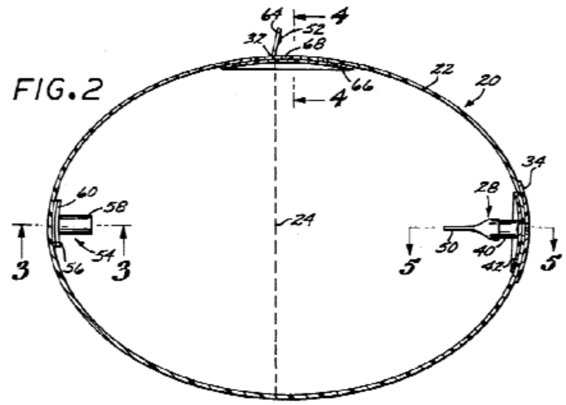


FIG.2

During prosecution, Patent Owner described "spheroidal" as encompassing "generally spherical or flattened spherical:"

> Thus, the phrase "generally spherical or flattened spherical" is well-encompassed by the conventional meaning (e.g., see Merriam-Webster's dictionary definition above) of "spheroidal" as "of approximately spherical shape." In view of the synonymous character of the term "spheroidal" to the "generally spherical or flattened spherical" disclosure of paragraph [0024] . . . no new matter issue has been presented by Applicant's claim amendments.

(Ex. 1002, Request for Continued Examination, filed 05/17/07, Pages 3, 4.) Given that Gau's balloon is "flattened spherical" and that the prosecution history describes "flattened spherical" as synonymous or encompassed by "spheroidal," Gau's balloon is "spheroidal" under its broadest reasonable construction.

b. Shah '915 teaches manufacturing balloons using polyurethane film, manufacturing those balloons in two half-sections, and welding the two half-sections together.

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."

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. 1006, Abstract.) Shah '915 notes that the art recognized the benefits of using polyurethane before the filing date of the '491 patent: "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." (Ex. 1006, Col. 2:43-46.) Shah '915 further teaches exemplary benefits for polyurethane products manufactured according to its method: "The products of this new method have high integrity, and are free from wrinkles, pin holes, holidays, burns or charring, mandatory in devices of this class." (Ex. 1006, Col. 6:13-16.)

As noted above, the '491 patent defines "film" to be "a material in a sheet or web form, having a thickness of 50 mils (1.270 mm) or less." Shah '915's polyurethane layers are "0.5 to 5 mils" thick and Shah '915 refers to the layers as "thin polyurethane film." (Ex. 1006, Col. 3:5-9.) Shah '915 therefore teaches the use of a film, as required by all claims, and a polyurethane film, as required by dependent claim 13. (Ex. 1009, ¶ .)

Shah '915 teaches the manufacture of balloons in two half-sections

Shah '915 teaches balloon manufacture explicitly: "FIG. 7 is a view of a 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. 1006, Col. 5:27-61.) Shah '915 Figures 7 and 8 are reproduced below, with the balloon highlighted:

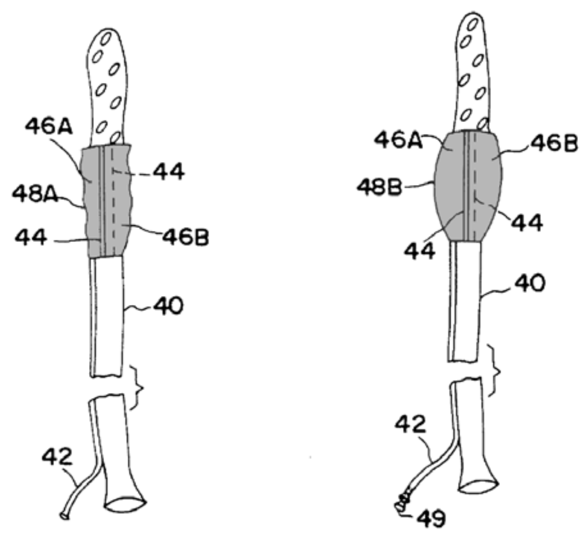


FIG.7 FIG.8

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 in a solid double-line 44 the front portion (as viewed in Figures 7 and 8), and illustrates the seam as a dashed line on the rearward portion. (Ex. 1009, ¶¶ 65-66.) 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. (*Id.*) The seams depict the joining line for the two half-sections of the balloons. (*Id.*)

Shah ’915 discloses methods of bonding the two half-sections

Shah ’915 also teaches bonding two half-sections together, as required by the claims of the ’491 patent. (*Id.*) According to Shah ’915, known techniques join polyurethanes using bonding or welding, but those techniques have resulted in “wrinkles, pin holes, discontinuities, holidays and burn or charring defects.” (Ex. 1006, Col. 2:64-3:8.) Shah ’915’s solution to the prior art problems is a method for “highly efficient R.F. welding of thermoplastic polyurethane elastomers.” (Ex. 1006, 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. 1006, Col. 5:22-26.) Shah ’915’s technique is “particularly useful for joining thin films of polyurethane” (Ex. 1006, Col. 5:26-28) but "the technique is equally applicable to thicker films and other forms of such polymers." (Ex. 1006, Col. 6:66-7:1.)

Although Shah '915 mainly discusses welding "layers," Shah '915 also discloses welding edges, as required by the claims of the '491 patent. (Ex. 1009, ¶¶ 67-68.) The figures of Shah '915 consistently depict the seam on the edge. (*See, e.g.*, Ex. 1006, Figures 4-11 and 13; Ex. 1009, ¶¶ 67-68.) Further, Shah '915 notes those in the art generally prefer "weld[ing] only at the seam area and their immediate vicinity" since seam-welding "minimiz[es] the heat input." (Ex. 1006, Col. 8:22-25.) Thus, Shah '915 teaches welding on an edge because Shah '915 depicts the seam on the edge and notes that those of skilled in the art preferred seam welding. (Ex. 1009, ¶¶ 67-68.)

As described below in Section V.A.1.c, Patent Owner argued during prosecution that one of skill in the art could not produce non-pillowed balloons without vacuum thermoforming. In Shah '832, Patent Owner argued something else: that RF welding technique results in a "non-pillowed" balloon.[3] (Ex. 1003,

[3] During prosecution, Patent Owner argued that Shah '832 published after the '491 patent's filing date. (Ex. 1002, Appeal Brief, filed March 20, 2008, Page 13, Note 52.) Patent Owner is mistaken; Shah '832 was publically available for almost one year. Although this means that Shah '832 is not available as prior art, it "has

Col. 2:20-25 ("Film welding methods . . . also experience difficulties. Inflation of such catheter balloons is usually non-uniform, due to "pillowing" or so-called "pillow effect.").) Shah '915 teaches R.F. welding (Ex. 1006, Col. 3:21-29), the same bonding technique[4] taught in Shah '832 (Ex. 1003, Col. 3:63-4:3).

c. Throne teaches manufacturing multi-layer shapes using vacuum thermoforming.

"Technology of Thermoforming" by Dr. James L. Throne was published in 1996. (Ex. 1007, Inside Cover.) Throne qualifies as prior art to the '491 patent under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(b). The PTO did not cite Throne during prosecution of the '491 patent.

Throne's 900-page textbook covers various aspects of thermoforming. In Section 1.5 ("Methods of Forming"), Throne describes a method for manufacturing multi-layer sheets. Throne explains that "[p]ackages that provide oxygen and

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long been the law that the motivation to combine need not be found in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art." *Nat. Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1337 (Fed. Cir. 2004) (internal citations omitted).

[4] Shah '832 incorporates Shah '915 by reference for the R.F. welding technique. (Ex. 1003, Col. 3:63-4:3.)

moisture barrier are sought." (Ex. 1007, Page 28.) However, the "most effective barrier materials . . . are usually quite expensive and so are used as thin films between layers of less expensive but durable polymers." (*Id.*)

As explained in Throne, the "most effective" and "quite expensive" material provide an oxygen and moisture barrier. (*Id.*) Thus, this material comprises "composition and thickness imparting gas barrier character" as required by the '491 patent's claims. (Ex. 1009.)

Throne does not explicitly teach that the "less expensive but durable polymers" lack such gas-barrier quality. However, the less expensive but durable polymers necessarily lack gas-barrier quality because, if they did not, Throne would not need "quite expensive" barrier materials. (Ex. 1009, ¶ 75.) Thus, the less expensive but durable polymers inherently "alone lack such gas barrier character." (*Id.*) Throne's multi-layer film provides a gas and moisture barrier, but the film also reduces costs by combining the barrier material (for gas barrier purposes) with a less expensive non-barrier material (for durability). (*Id.*) Further, Throne teaches that the "most effective barrier materials [include] PAN, EVOH, and PVDC" (Page 28); the '491 patent teaches the same materials as sealing layers (Ex. 1001, Col 5:12-16 ("illustrative sealing layer materials include polyvinylidene chloride (PVDC), . . . ethylene vinyl alcohol polymers (conventionally referred to as "EVOH" polymers), etc.").)

Throne further explains that known multi-layered sheets are "usually laminates of essentially incompatible plastic glued together." (*Id.*) This approach presented a known problem: discarded portions of the laminate "cannot be reprocessed successfully without degradation and gel formation." (*Id.*)

According to Throne, vacuum forming was a known alternative for producing multi-layer sheets, one that does not produce waste. (*Id.*)

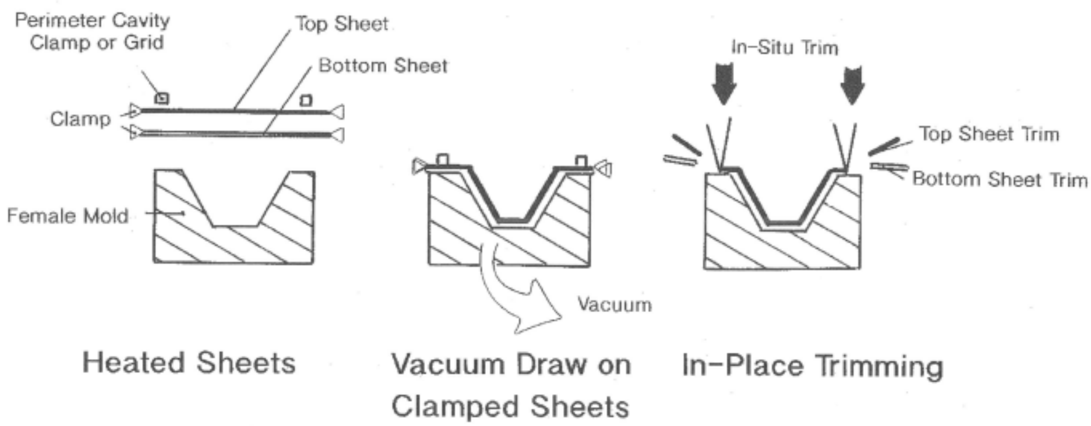


Figure 1.22 Thin-gage, simultaneous twin roll-fed sheet thermoforming. Here, sheets are heated separately and brought together at the forming station

Throne explains that two sheets are preheated and "then brought together right at the forming station. Once the multi-layer formed product has been trimmed, the individual layers in the web and trim are stripped from one another." (*Id.*) Using this vacuum thermoforming approach to producing multi-layer sheets, "[e]ach polymer web is therefore 'clean' and is recycled to produce new sheet[s]." (*Id.*)

As noted above, the '491 patent defines "film" to be "a material in a sheet or web form, having a thickness of 50 mils (1.270 mm) or less." Throne teaches that the multi-layer film is manufactured using "thin gage . . . sheet thermoforming." (Ex. 1007, Page 28 (caption for Figure 1.22).) (Ex. 1007, Page 28.) Throne elsewhere defines "thin-gage" to be "sheet thickness less than 0.060 inches [60 mils]," with subcategories of "[f]ilm forming, where the sheet thickness is less than about 0.010 in [10 mils] or 25 mm" and "[t]hin sheet forming, where the sheet thickness is between about 0.010 in [10 mils] or 0.025 mm and 0.060 in [60 mils] or 1.5 mm." (Ex. 1007, Page 12.) Throne therefore teaches the use of a film, as the '491 patent defines "film." (Ex. 1009, ¶ 73.)

Throne teaches a laminated multi-layer sheet. (Page 28.) Throne teaches that laminates can include "incompatible plastics glued together." However, one of skill in the art would understand that a laminate does not require glue. (Ex. 1009, ¶ 74.) Although Throne's multi-layer sheet does not have adhesive, Throne describes the multi-layer sheet as capable of "delaminat[ion] through misuse." (Ex. 1007, Page 28.) The '491 patent also forms multi-layer sheets without adhesive: first, the definition[5] of "extrusion laminate"[6] does not include adhesive

[5] *See also* Col. 3:36-4:2 (describing the "gas barrier film structure of the invention [as] a laminate" and not listing adhesive as a component of the structure).

[6] Petitioner notes that the '491 patent offers a definition of "extrusion laminate." The definition of "extrusion laminate" focuses on the extrusion process. The

(Ex. 1001, Col. 3:11-22); second, the ’491 patent states that extrusion lamination can be performed with or without adhesive. (Ex. 1001, Col. 6:62-67.) Finally, a laminate need not be “extruded” as evidenced by the qualifier “extrusion” in the definition “extrusion laminate.” (Ex. 1001, Col. 3:11.) Given Throne’s use of the term “laminate” and the ’491 patent’s discussion of “extrusion laminate,” one of skill in the art would understand Thorne’s multi-layer is a laminate as the ’491 patent uses that term. (Ex. 1009, ¶ 74.)

’491 patent does not claim an extrusion laminate. The ’491 offers some preferences for characteristics of the resulting extrusion laminate, but does not state that those characteristics apply to every laminate and, moreover, describes the characteristics as “preferred” and not required.

d. One of skill in the art would combine the teachings of Gau, Shah ’915, and Throne to arrive at a device that includes all the limitations of claims 1, 3-5, and 12-15.

(i) One of skill in the art would have manufactured Gau’s balloon using Shah ’915’s polyurethane method because, as Shah ’915 teaches, the art recognized polyurethane as having many desirable properties for medical barrier products.

Both Gau and Shah ’915 teach medical devices that are introduced into the body. (Ex. 1009, ¶ 98.) Gau uses rubber to contain fluid and gas within the balloon, and Shah ’915 teaches that those skilled in the art recognized polyurethane as a superior alternative to rubber for medical products in the body. (*Id*.) Thus, Shah explicitly motivates one of skill in the art to replace rubber in medical device applications, such as Gau’s application, with polyurethane. (*Id*.)

Gau teaches that its balloon shape is important. (Ex. 1010, Col. 50-53 (“It is still another object of the present invention to provide an intragastric balloon, the position of which in the stomach is relatively stable and non-traumatic to the patient due to the configuration of the balloon itself.”).) Gau does not speak to balloon manufacture. (Ex. 1009, ¶ 99.) Shah ’915 does; Shah ’915 teaches that those skilled in the art knew to manufacture balloons from two half-sections. (*Id.*)

Further, Shah '915 teaches advantages to using its two-section method of manufacture: less wrinkling, cracking, etc. (*Id*.)

Thus, not only does Shah '915 motivate one of skill in the art to replace Gau's rubber with polyurethane, Shah '915 also motivates one of skill in the art to form a thin film of polyurethane by bonding two half-sections along the seam. (*Id*., 100.)

(ii) One of skill in the art would have used Throne's two-layer approach to manufacture Gau's gastric balloon because, as Throne teaches, the approach is a cost-effective alternative for providing a gas and moisture barrier and reduces waste material.

Although Shah '915 motivates one of skill in the art to form thin film polyurethane balloons by bonding two half-sections, Shah '915 does not speak to two aspects needed for manufacture of Gau's balloon: (1) how to pre-manufacture the two half-sections and (2) how to provide sufficient barrier protection using polyurethane. (Ex. 1009, ¶ 101.)

Throne provides answers to both questions. Throne is a related technology: manufacture of thermoplastic products. (*Id*., 102.) Throne says that gas and moisture barrier materials are expensive. (*Id*.) Throne offers multilayer sheeting as a cost-effective solution. (*Id*.)

Throne also teaches that its vacuum thermoforming method reduces waste materials. (Id., 103) Reducing waste materials reduces manufacturing costs, and gives one of skill in the art an incentive to use Throne's method. (*Id.*)

In light of Throne's teachings for cost-effective manufacture of gas and moisture barriers, one of skill in the art would be motivated to apply Throne's methods in the manufacturing process of Gau's balloon using Shah '915's polyurethane bonding technique. (*Id.*, 104.)

(iii) Combining Gau, Shah '915, and Throne leads to predictable results.

Combining the teachings of Gau, Shah '915, and Throne does not require any changes to each reference. (*Id.,* 105.) Each reference operates in the same way but contributes to the overall device. (i.)

Gau provides the shape and other gastric balloon features. (*Id.,* 106.) Shah '915 simply says use polyurethane to manufacture the balloons in two halves, and then bond the two halves with R.F. welding. (Ex. 1009.) Throne teaches use of vacuum thermoforming to produce gas barrier layers. (Ex. 1009.)

Only Gau's balloon material changes; everything else stays the same. (*Id.,* 107.) Shah '915's teaches a method of RF welding two half-sections to create medical balloons. (Ex. 1006, *passim.*) That method does not change in the combination. (Ex. 1009, ¶ 107.) Throne teaches a vacuum thermoforming method of manufacturing multilayer sheets. (Page 29). That general method does not change in the combination. (Ex. 1009, ¶ 107.) One of skill in the art may adjust the length of time in the mold, if needed, to accommodate any difference in balloon thickness. (*Id*.)

The combination of Gau, Shah '915, and Throne provides predictable results: Gau's balloon manufactured from two half-sections of a multi-layer material, wherein the multi-layer material includes a polyurethane layer and a "more effective" barrier material. (*Id.*, 108)

Combining Gau, Shah '915, and Throne would lead to a non-pillowed balloon. (*Id.*, 109.) Gau provides a non-pillowed and spheroidal balloon. (*Id.*) The '419 patent itself teaches that vacuum thermoforming two half-sections results in a non-pillowed and spheroidal low-pressure balloon. (Ex. 1001, Col. 3:47-67.) Therefore, following Shah '915 and Throne's procedure would not require one of skill in the art to change the shape of Gau's balloon because Shah '915 and Throne collectively teach a vacuum thermoforming process from two half-sections for producing a non-pillowed and spheroidal low-pressure balloon. (Ex. 1009, ¶ 109.)

Patent Owner argued in prosecution that one of skill in the art could not manufacture non-pillowed balloons without vacuum thermoforming. (Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 9.) To the extent that one of skill in the art could not make non-pillowed balloons without vacuum thermoforming, Throne teaches vacuum thermoforming three-dimensional shapes.

One of skill in the art could manufacture the balloon illustrated and described in Gau using the teachings of Shah '915 and Throne. (Ex. 1009, ¶ 110.) The shape would not need to change. (*Id.*) The dimensions would not need to change. (*Id.*) The same inflation elements, filler tube, and tab could be added. (*Id.*)

(iv) Manufacturing Gau's balloon using Shah '915's and Throne's teachings renders Gau suitable for its intended purpose.

Throne notes that misuse of the contact adhered sheets may delaminate the layers. Throne's contact adhered layers would not delaminate in Gau's gastric balloon treatment. (Ex. 1009, ¶ 111.)

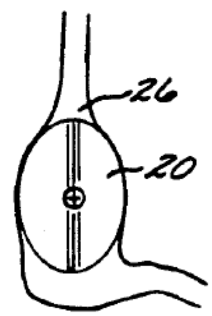
First, the layers in a multi-layer gastric balloon would not delaminate under the low pressures when inflated. (*Id.*, 112.) One of skill in the art expects pressures of 1-5 psi in a gastric balloon treatment. (*Id.*) Such pressures are insufficient to rupture or otherwise delaminate the multiple layers. (*Id.*)

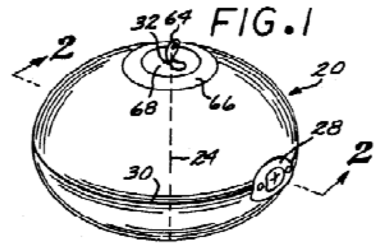
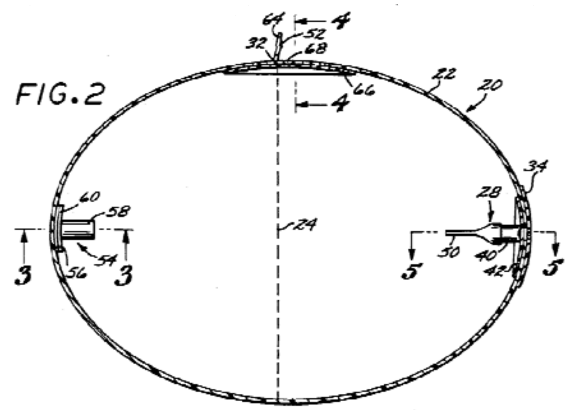
Second, and more importantly, the gas in Gau's balloon exerts radial pressure on the balloon. (*Id.*, 113.) The gas exerts pressure outward on both layers. (*Id.*) To the extent the inner layer undergoes more pressure, the outer layer contains the inner layer. (*Id*.) As a result, the layers do not move relatively; without such relative movement, the balloon will not delaminate. (*Id*.)

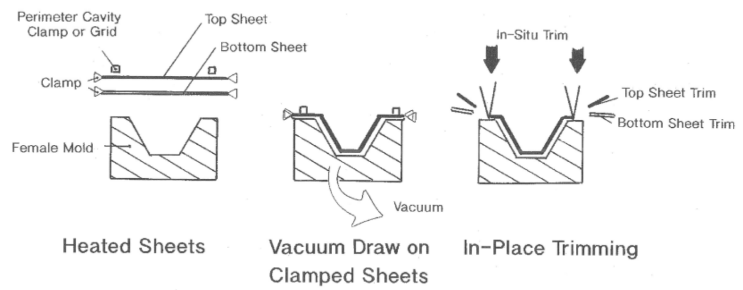
Delamination risk follows from forming the balloon without adhesive. (*Id*., 114.) As noted above, the ’491 patent’s definition[7] of “extrusion laminate” does not include adhesive. (Ex. 1001, Col. 3:11-22.) Further, the ’491 patent states that extrusion lamination can be performed with or without adhesive. (Ex. 1001, Col. 6:62-67.). One of skill in the art would be aware of, but not dissuaded by, Throne’s delamination risk in the same way that the ’491 patent teaches embodiments of non-adhered multi-layer sheets. (Ex. 1009, ¶ 114.) Throne itself provides a number of considerations (e.g., viscosity matching, temperature matching, biaxial orientation, and careful heating to prevent innerlayer interface overheating) necessary for successful lamination. (*Id.* (citing Ex. 1007, Page 78).)

The claim chart below specifies where Gau in view of Shah ’915 and Throne meets each element of claims 1, 3-5, and 12-15.

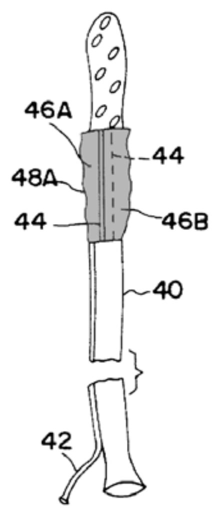
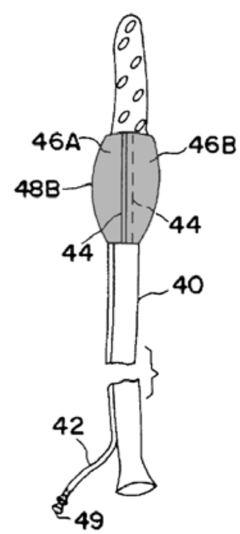
[7] *See also* Col. 3:58-4:2 (describing the “gas barrier film structure of the invention [as] a laminate” and not listing adhesive as a component of the structure).

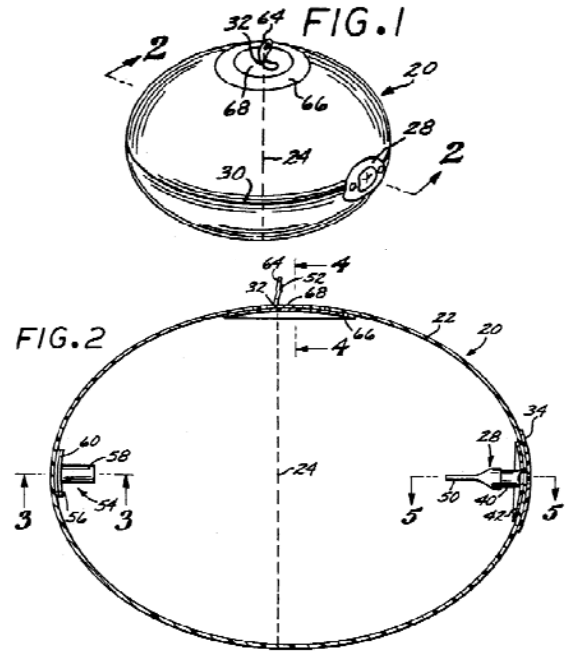
’491 Patent	Gau in view of Shah ’915 and Throne
1. A gastric occlusive device comprising:	Gau teaches a gastric occlusive device: “It is an object of the present invention to provide an intragastric balloon.” (Ex. 1008, Col. 2:42-43; *see also* Col. 1:32-35 (“Clinical experience of the prior art has shown that for many obese patients the intragastric balloons significantly help to control appetite and accomplish weight loss.”); Col. 3:41-42 (“FIG. 7 is a schematic view showing the balloon of the present invention disposed in the stomach.”).) FIG. 7  .)
a balloon that in an inflated state is non-pillowed	Throne teaches vacuum thermoforming and Shah ’915 teaches bonding two half-sections. As described above, vacuum thermoforming and bonding two half-sections results in non-pillowed balloons.

’491 Patent	Gau in view of Shah ’915 and Throne
and spheroidal in shape,	Gau teaches a spheroidal shape:  

’491 Patent	Gau in view of Shah ’915 and Throne
formed from two vacuum thermoformed half-sections of a multilayer film comprising	Throne teaches vacuum thermoforming thermoplastic multi-layer film:  Figure 1.22 Thin-gage, simultaneous twin roll-fed sheet thermoforming. Here, sheets are heated separately and brought together at the forming station (Ex. 1007, Page 28.) Shah ’915 teaches forming balloons from two-half-sections of 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. 1006, Abstract.)
(A) a layer of sealing film, having main top and bottom surfaces; and	Throne teaches a layer of sealing film: “The most effective barrier materials such as PAN, EVOH and PVDC are usually quite expensive and so are used as thin films between layers of less expensive but durable polymers such as PP, HDPE, PET and PS.” (Ex. 1007, Page 28.)
(B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces	Throne teaches at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces: “The most effective barrier materials such as PAN, EVOH and PVDC are usually quite expensive and so are used as thin films between layers of less expensive but durable polymers such as PP, HDPE, PET and PS.” (Ex. 1007, Page 28.)

’491 Patent	Gau in view of Shah ’915 and Throne
wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and	Throne teaches the sealing film has a composition and thickness imparting gas barrier character to the multilayer film: “The most effective barrier materials such as PAN, EVOH and PVDC are usually quite expensive.” (Ex. 1007, Page 28.)
wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character;	Throne teaches the at least one layer of thermoplastic polymer film alone lacks such gas barrier character: “layers of less expensive but durable polymers such as PP, HDPE, PET and PS.” (Ex. 1007, Page 28.)
wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and	Throne teaches the half-sections are processed in a vacuum thermoforming die: Figure 1.22 (reproduced above) depicts the multi-layer sheet processed in a vacuum thermoforming die. When Throne’s method is applied to Gau’s balloon, the two half-sections of the balloon are processed in a vacuum thermoforming die. (Ex. 1009, ¶ 94.)

'491 Patent	Gau in view of Shah '915 and Throne
the vacuum thermoformed half-sections are bonded together along peripheral portions thereof to form a peripheral seam; and	Shah '915 teaches the vacuum thermoformed half-sections are bonded together along peripheral portions thereof to form a peripheral seam: "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. 1006, 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. 1006, Col. 5:27-61; *see also* Figures 7 and 8, reproduced below (emphasis added)):  FIG.7  FIG.8

'491 Patent	Gau in view of Shah '915 and Throne
an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.	Gau teaches the balloon comprises an inflation element adapted to permit the inflation of the balloon at said physiological locus with a fluid: "Referring now primarily to FIGS. 1 and 2 of the drawings, a self-sealing valve 28 of the balloon 20 of the present invention is shown. The purpose of the valve 28 is to permit inflation of the balloon 20 after it has been inserted into the stomach 26." (Ex. 1008; Col. 4:54-58.) 
3. The gastric occlusive device of claim 1, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.	Gau teaches the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon: "Referring now primarily to FIGS. 1 and 2 of the drawings, a self-sealing valve 28 of the balloon 20 of the present invention is shown. The purpose of the valve 28 is to permit inflation of the balloon 20 after it has been inserted into the stomach 26." (Ex. 1008; Col. 4:54-58; *see also* Col. 6:18-20 ("The structure of the valve permits addition of liquid and also withdrawal of liquid with the filler tube (not shown) without leakage.").)

’491 Patent	Gau in view of Shah ’915 and Throne
4. The gastric occlusive device of claim 3, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.	Gau teaches a catheter or liquid feed tube communicatively coupled to the self-healing seal valve: “The structure of the valve permits addition of liquid and also withdrawal of liquid with the filler tube (not shown) without leakage.” (Col. 6:18-20.)
5. The gastric occlusive device of claim 3, wherein said fluid comprises a liquid or aqueous substance.	Gau teaches said fluid comprises a liquid or aqueous substance: “The structure of the valve permits addition of liquid and also withdrawal of liquid with the filler tube (not shown) without leakage.” (Col. 6:18-20.)
12. The gastric occlusive device of claim 1, wherein said multilayer film has a thickness of up to 10 mils.	Gau teaches a balloon with thickness of up to about 10 mils: “The intragastric balloon 20 comprises an inflatable elastomeric shell 22, which is preferably made from silicone rubber cast on a mandrel (not shown) to have a final thickness of approximately 0.006 to 0.025 inches [6 to 25 mils].” (Ex. 1008, Col. 4:6-9.) As noted above, the process of producing a multi-layer sheet using Shah ’915 and Throne would result in a sheet of the same thickness.
13. The gastric occlusive device of claim 1, wherein said sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer,	Throne teaches the sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer: “The most effective barrier materials such as PAN, EVOH and PVDC are usually quite expensive and so are used as thin films between layers of less expensive but durable polymers such as PP, HDPE, PET and PS.” (Ex. 1007, Page 28.)
said thermoplastic polymer film comprises polyurethane	Shah ’915 teaches polyurethane.

’491 Patent	Gau in view of Shah ’915 and Throne
said thermoplastic polymer film is laminated to the sealing film on both the main top and bottom surfaces thereof	Throne teaches said thermoplastic polymer film is laminated to the sealing film on both the main top and bottom surfaces thereof: “The most effective barrier materials such as PAN, EVOH and PVDC are usually quite expensive and so are used as thin films between layers of less expensive but durable polymers such as PP, HDPE, PET and PS.” (Ex. 1007, Page 28 (emphasis added).)
14. The gastric occlusive device of claim 1, wherein the seam is devoid of any neck or opening therein.	Shah ’915 teaches the seam is devoid of any neck or opening therein. See Figures 7 and 8.
15. The gastric occlusive device of claim 1, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.	Shah ’915 teaches the thermoformed half-sections are bonded to one another via radio frequency . . . welding: “the present invention is based on the discovery that R.F. welding of thermoplastic polyurethanes . . . is highly efficient.” (Ex. 1006, Col. 6:50-54.)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Gau in view of Shah ’915 and Throne renders claims 1, 3-5, and 12-15 obvious.

B. Grounds based on Connors

1. Ground 2: Connors in view of Rakonjac renders claims 1-6, 10-18, 20, and 21 obvious.

a. Connors teaches a spherical, multi-layer balloon manufactured from two half-sections.

Connors issued on December 20, 2005, from an application filed on March 17, 2003 and claiming priority to applications filed on April 14, 2000, November

27, 2000, and October 3, 2002. (Ex. 1004, Cover Page.) Connors qualifies as prior art to the ’491 patent under 35 U.S.C. § 102(e). The PTO rejected all claims over Connors during prosecution of the ’491 patent.

Connors “relates generally to methods and apparatus for attenuating and/or baffling transient pressure waves in . . . the human body: cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngeal and ophthalmic.” (Ex. 1004, Col. 1:17-24.) Connors introduces a balloon to the body and then inflates the balloon. (*See, e.g.,* Ex. 1004, Col. 11:54-57 (“The attenuation device 66 may thus be transurethrally deployed into the bladder in its first configuration, and enlarged to its second configuration once positioned within the bladder.”).)

Connors teaches a balloon manufactured from two half-sections: “Flexible wall 70 comprises a first component 74 and second component 76 bonded together such as by a seam 78. In the illustrated embodiment, the first component 74 and second component 76 are essentially identical, such that the seam 78 forms on the outer periphery of the inflatable container 68.” (Ex. 1004, 11:31-35.)

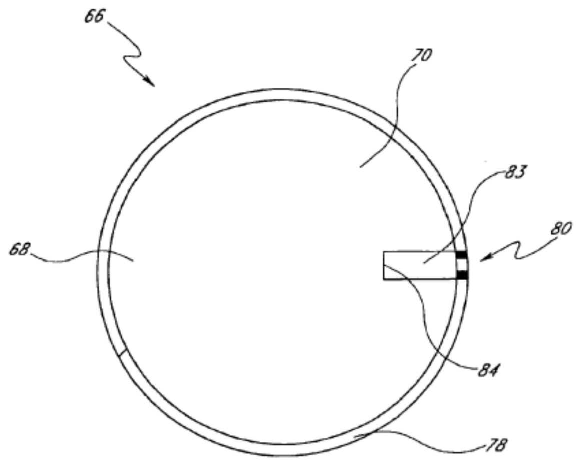


FIG. 5

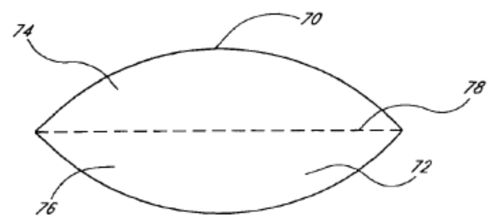


FIG. 5A

<u>*Connors Teaches a Spheroidal Balloon*</u>

Connors teaches various embodiments of spherical balloons or flattened spherical balloons. With respect to Figure 5 above, Connors teaches that "the specific dimensions and configuration of the inflatable container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein." (Ex. 1004, Col. 11:18-23.)

With respect to Figure 16C, Connors teaches "[a]ny of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section." (Ex. 1004, Col. 24:17-22.)

FIG. 16C

Petitioner notes that Figures 5, 5A, and 16C relate to variations of the same attenuation device. That is, Connors describes the variations of Figures 5, 5A, and 16C with respect to attenuation device 66. (*c.f.* Col. 11:6-8 ("Referring to FIGS. 5 and 5A, there is illustrated one embodiment of an **attenuation device 66** which comprises a moveable wall such as on an inflatable container 68.") (emphasis added); *with* Col. 22:27-29 ("Referring to FIG. 16[A-D], there is illustrated a variety of shapes for the **attenuation device 66** of the inflatable container variety.") (emphasis added).) Thus, the shape teachings of Figure 16 are variations of the embodiment in Figures 5 and 5A, including the seam.

<u>*Connors Teaches a Multilayer Film*</u>

Connors teaches "the wall of the attenuation device will comprise at least one gas barrier layer and at least one moisture barrier layer." (Ex. 1004, Col. 23:1-3.) Connors teaches that these multi-layer sheets can have any number of layers:

> The attenuation device can have three, four, five, or more layers. In one embodiment, the attenuation device has a gas barrier layer, a moisture barrier layer, and one or more layers composed

> of at least one high impact strength material. In another embodiment, the attenuation device has multiple gas barrier layers arranged in a nonconsecutive arrangement. In yet another embodiment, the attenuation device has multiple moisture barrier layers arranged in a nonconsecutive arrangement. With respect to those embodiments having multiple, nonconsecutive barrier layers, the other layers of the attenuation device can include high impact strength material layers and/or other types of barrier layers.

(Ex. 1004, Col. 23:32-43 (emphasis added).)

Connors teaches the sealing film has a composition and thickness imparting gas barrier character to the multilayer film: "[i]n general, the wall of the attenuation device will comprise at least one gas barrier layer and at least one moisture barrier layer." (Ex. 1004, Col. 23:1-3.) Connors does not explicitly teach that the non-gas barrier layer lacks the gas barrier characteristics of the gas-barrier layer, but the layer necessarily lacks such gas barrier characteristics because, otherwise, the non-gas barrier layer would serve the role of the structural layer and the gas barrier layer; a separate gas barrier layer would be unnecessary. (Ex. 1009, ¶ 81.)

As noted above, the '491 patent defines "film" to be "a material in a sheet or web form, having a thickness of 50 mils (1.270 mm) or less." Connors teaches the "overall thickness of the wall . . . will often be no more than about 0.030 inches [30 mils]. Preferably the wall will be no more than 0.006 inches [6 mils]." (Ex. 1004, Col. 23:44-46.) Thus, Connors teaches a film, as that term is defined in the ’491 patent.

b. Rakonjac teaches balloons manufactured by vacuum thermoforming.

Rakonjac issued on May 31, 1994, from an application filed on June 15, 1992. (Ex. 1005, Cover Page.) Rakonjac qualifies as prior art to the ’491 patent under 35 U.S.C. § 102(a), 35 U.S.C. § 102(b), and 35 U.S.C. § 102(e). The PTO did not discuss Rakonjac during the ’491 patent’s prosecution.

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. 1001, Abstract.) Rakonjac teaches that vacuum thermoforming was a “prior art development:”

> 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. 1001, Col. 1:17-29.)

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. 1001, Col. 1:40-46.)

c. One of skill in the art would use the vacuum thermoforming manufacturing method of Rakonjac to manufacture the balloon half-sections of Connors to reduce fabrication time and increasing economy.

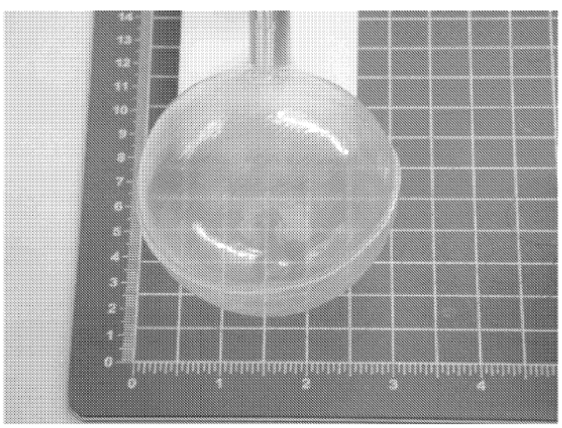
Connors and Rakonjac are related: both deal with creating pressurized balloons. (Ex. 1009, ¶ 114.)

Connors discusses many manufacturing methods. (*Id*., ¶ 141) But one of skill in the art could manufacture the balloons from a variety of methods. (*Id*.)

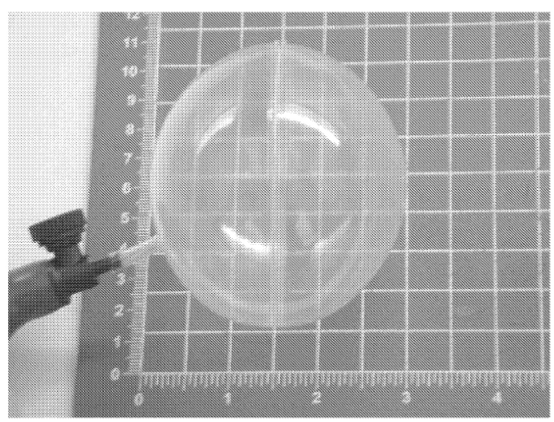
One of skill in the art would use Rakonjac's method because, as taught by Throne, "[f]or thin-walled products, [vacuum thermoforming] fabrication time is very short, making the process economical for products requiring high multiplication factors." (Ex. 1007, Page 11.) The manufacturing processes taught in Connors that are suitable for multi-layer sheets (dip molding, spray molding, and extrusion lamination) can take considerable time to manufacture a single balloon. (Ex. 1009, ¶ 142.) One of skill in the art would be motivated to use vacuum thermoforming to improve the fabrication time of Connors' balloon. (*Id.*) Further, one of skill in the art would not be dissuaded from using vacuum thermoforming for multi-layer balloons because, as taught by Throne, the result can be cost-effective with less waste. (Ex. 1007, Page 28.)

The '491 patent does not provide guidance on the term "non-pillowed." The only mention of the term is in claims 1 and 22, and a statement that vacuum thermoforming two half-sections together can result in a non-pillowed balloon. (Ex. 1001; Col. 4:19-23.) To the extent that vacuum thermoforming is required, Rakonjac teaches vacuum thermoforming.

Further, Patent Owner declared during prosecution that the following images are "non-pillowed:"



TOP VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS



SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS

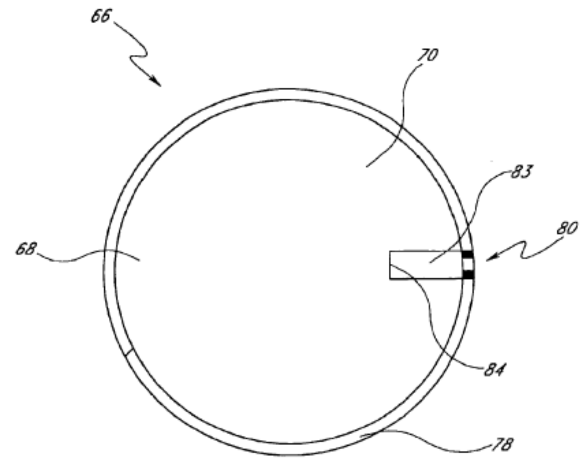
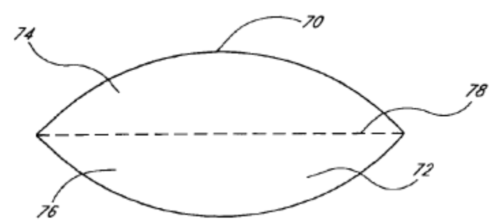
Connors teaches balloons with the same shapes:

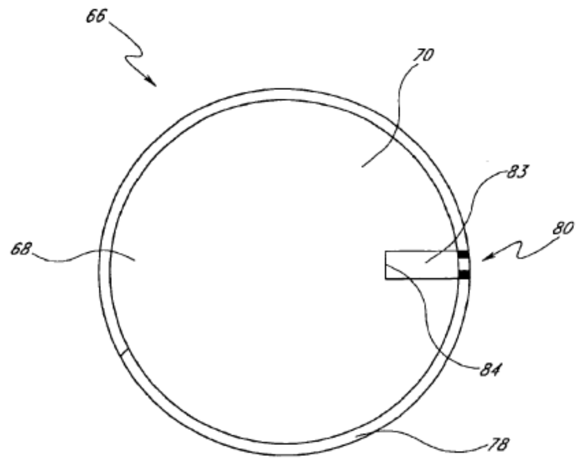
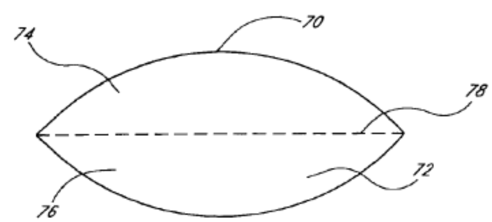
FIG. 16C

Further, as noted above, Connors teaches a generally spherical balloon, as is depicted in Patent Owner's declaration.

The claim chart below specifies where Connors in view of Rakonjac meets each element of claims 1-6, 10-18, 20, and 21.

'491 Patent	**Connors in view of Rakonjac**
1. A gastric occlusive device comprising	Connors teaches a gastric occlusive device: "The present invention relates generally to methods and apparatus for attenuating and/or baffling transient pressure waves in . . . the human body: cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngical and ophthalmic." (Ex. 1004, Col. 1:17-24.)
a balloon that in an inflated state is non-pillowed and spheroidal in shape	Connors teaches a balloon that in an inflated state is non-pillowed and spheriodal in shape: "In general, the specific dimensions and configuration of the inflatable container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein." (Ex. 1004, Col. 11:18-23.)

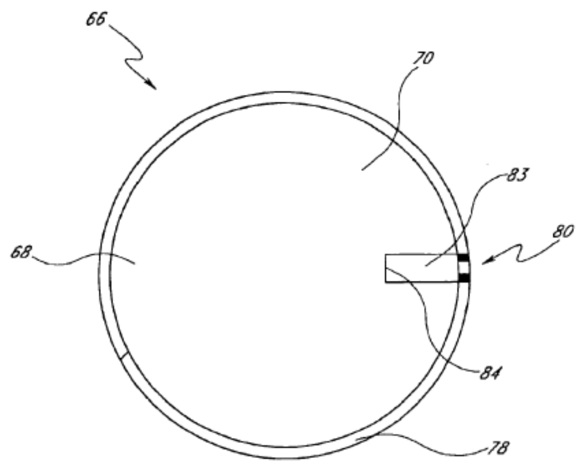
'491 Patent	Connors in view of Rakonjac
	 FIG. 5  FIG. 5A *See also* Col. 24:17-22: "Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section."
formed from two vacuum thermoformed half-sections of a multi-layer film:	Connors teaches formed from two half-sections: "Flexible wall 70 comprises a first component 74 and second component 76 bonded together such as by a seam 78. In the illustrated embodiment, the first component 74 and second component 76 are essentially identical, such that the seam 78 is formed on the outer periphery of the inflatable container 68." (Ex. 1004, 11:31-35.)

’491 Patent	Connors in view of Rakonjac
	 *FIG. 5*  *FIG. 5A* Connors teaches a multilayer film: “In general, the wall of the attenuation device will comprise at least one gas barrier layer and at least one moisture barrier layer.” (Ex. 1004, Col. 23:1-3.) Rakonjac teaches formed from two vacuum thermoformed half-sections: “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. 1005, 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

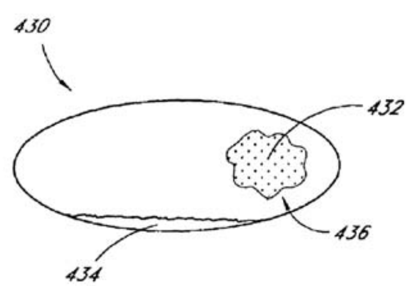
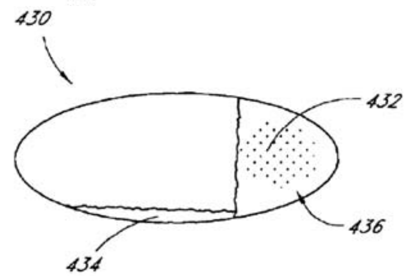
’491 Patent	Connors in view of Rakonjac
	cut through to form and separate the multiple hollow bodies. The general process is old in the art.”).)
(A) a layer of sealing film, having main top and bottom surfaces; and	Connors teaches a layer of sealing film: The attenuation device can have three, four, five, or more layers. In one embodiment, the attenuation device has <u>a gas barrier layer</u>, a moisture barrier layer, and one or more layers composed of <u>at least one high impact strength material</u>. In another embodiment, the attenuation device has multiple gas barrier layers arranged in a nonconsecutive arrangement. In yet another embodiment, the attenuation device has multiple moisture barrier layers arranged in a nonconsecutive arrangement. With respect to those embodiments having multiple, nonconsecutive barrier layers, the other layers of the attenuation device can include high impact strength material layers and/or other types of barrier layers. (Ex. 1004, Col. 23:32-43 (emphasis added).) A barrier layer for an attenuation device necessarily has a top and bottom surface. (Ex. 1009, ¶ 131.)
(B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces;	Connors teaches a “high impact strength material:” “For example, the attenuation device can have a gas barrier layer and a moisture barrier layer. An additional layer may be included to enhance the structural integrity of the attenuation device.” (Ex. 1004, Col. 23:18-19, 22-25). Connors teaches the high-impact strength material is at least one layer of thermoplastic material: “In one embodiment, at least one layer on, or the entire attenuation device comprises a blend of a barrier material and a flexible high impact strength material (e.g. polyurethane/polyvinylidene chloride,

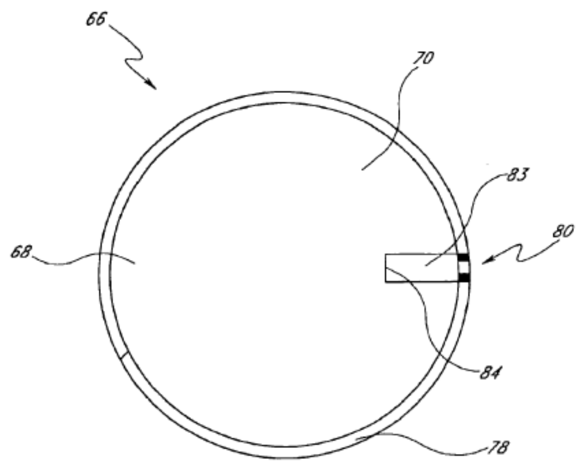
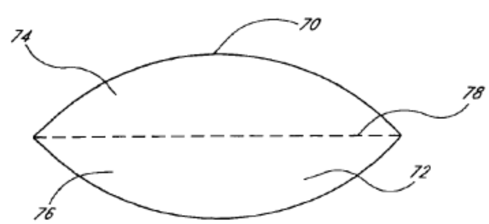
'491 Patent	Connors in view of Rakonjac
	polyethylene/ethyl vinyl alcohol, etc.)." (Ex. 1004, Col. 23:16-20.) Polyurethane and polyvinylidene chloride are thermoplastic polymers. (Ex. 1009, ¶ 133.) Connors discloses that the at least one layer of thermoplastic polymer film can be disposed on the top or the bottom (or both) of the sealing film: The attenuation device can have three, four, five, or more layers. In one embodiment, the attenuation device has a gas barrier layer, a moisture barrier layer, and one or more layers composed of at least one high impact strength material. In another embodiment, the attenuation device has multiple gas barrier layers arranged in a nonconsecutive arrangement. In yet another embodiment, the attenuation device has multiple moisture barrier layers arranged in a nonconsecutive arrangement. With respect to those embodiments having multiple, nonconsecutive barrier layers, the other layers of the attenuation device can include high impact strength material layers and/or other types of barrier layers. (Ex. 1004, Col. 23:32-43.) Connors teaches the layer of thermoplastic film is laminated to the sealing film: "The layers of the attenuation device can be formed in any number of ways known to those skilled in the art, including, but not limited to, lamination, coextrusion, dip molding, spray molding, or the like, etc." (Ex. 1004, Col. 23:62-65.)

’491 Patent	Connors in view of Rakonjac
wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and	Connors teaches the sealing film has a composition and thickness imparting gas barrier character to the multilayer film: “In general, the wall of the attenuation device will comprise at least one gas barrier layer and at least one moisture barrier layer.” (Ex. 1004, Col. 23:1-3.)
wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character,	Connors’s teaches a multi-layered wall, including a “gas barrier layer” and an “additional layer may be included to enhance structural integrity of the attenuation device.” (Ex. 2005, Col. 23:22-25.) It would have been obvious to choose a layer of structural integrity that does not have gas barrier characteristics because otherwise, the gas barrier layer would not be needed.
wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and	Rakonjac teaches the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam: “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. 1005, 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.”).)

’491 Patent	Connors in view of Rakonjac
an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.	Connors teaches the balloon comprises an inflation element adapted to permit the inflation of the balloon at said physiological locus with a fluid: “To facilitate filling the interior cavity 72 following placement of the attenuation device 66 within the bladder, the inflatable container 68 is preferably provided with a valve 80. In the illustrated embodiment, valve 80 is positioned across the seam 78, and may be held in place by the same bonding techniques utilized to form the seam 78.” (Ex. 1004, Col. 12:30-36.)  *FIG. 5*
2. The gastric occlusive device of claim 1, wherein the two vacuum thermoformed half-sections are substantially hemispherical in shape.	See above—Connors teaches a spherical balloon. Connors also teaches formation in half-sections (see claim 1). Thus, Connors teaches hemispherical half-sections.

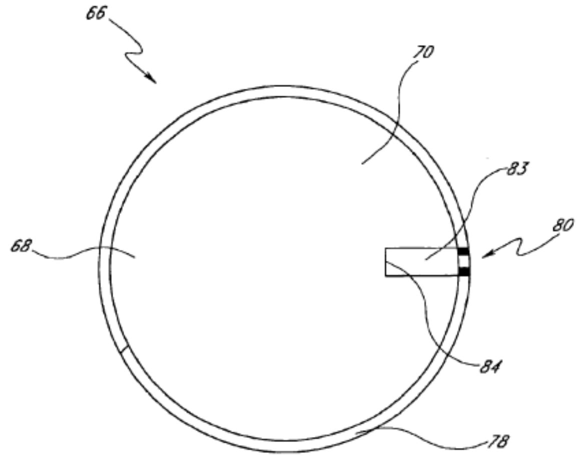
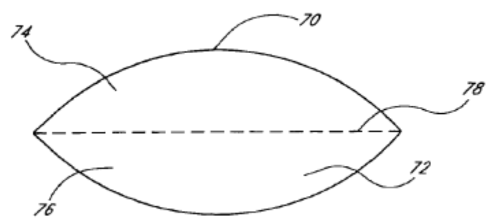
'491 Patent	**Connors in view of Rakonjac**
3. The gastric occlusive device of claim 1, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.	Connors teaches the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon: Valve 80 generally comprises an aperture 82, for receiving a filling tube therethrough. Aperture 82 is in fluid communication with the interior cavity 72 by way of a flow path 83. At least one closure member 84 is provided for permitting one way flow through flow path 83. In this manner, a delivery system and filling device can be utilized to displace closure member 84 and introduce compressible media into the interior cavity 72. Upon removal of the filling device, the closure member 84 prevents or inhibits the escape of compressible media from the interior cavity 72 through the flow path 83. (Ex. 1004, Col. 12:38-49.)
4. The gastric occlusive device of claim 3, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.	Connors teaches a catheter or liquid feed tube communicatively coupled to the self-healing seal valve: "In this manner, a delivery system and filling device can be utilized to displace closure member 84 and introduce compressible media into the interior cavity 72." (Ex. 1004, Col. 12:43-46.)
5. The gastric occlusive device of claim 3, wherein said fluid comprises a liquid or aqueous substance.	Connors teaches the fluid comprises a liquid or aqueous substance: "As is discussed elsewhere herein, interior cavity 72 preferably comprises a compressible media, such as gas, or foam." (Ex. 1004, Col. 11:42-44.)

’491 Patent	Connors in view of Rakonjac
6. The gastric occlusive device of claim 1, wherein the inflation element comprises an effervescent material contained in said balloon,	Connors teaches the inflation element comprises an effervescent material disposed within the balloon: “there is provided an implantable self-inflating pressure attenuation device that can inflate from a first, deflated configuration to a second, at least partially inflated configuration. Various transformable mediums can be used to inflate the housing of the attenuation device.” (Ex. 1004, Col. 31:54-58.)
and adapted to liberate gas when contacted with liquid for inflation of the balloon.	Connors teaches: With reference to FIGS. 47A-47C, in one embodiment, the transformable medium comprises a first reactant 432 and a second reactant 434. Here, the implantable self-inflating pressure attenuation device 430 (shown in its first, deflated configuration) generally comprises a first reactant 432 and a second reactant 434, which are physically separated from each other. When the first reactant 432 comes into contact the second reactant 434, a chemical reaction occurs within the attenuation device 430, thereby causing the attenuation device 430 to transform into at least a partially inflated configuration. (Ex. 1004, Col. 31:61-32:4.) FIG. 47A  FIG. 47B 

’491 Patent	Connors in view of Rakonjac
10. The gastric occlusive device of claim 1, wherein said balloon in an inflated state is generally spherical in shape.	Connors teaches the balloon in an inflated state is generally spherical in shape: “In general, the specific dimensions and configuration of the inflatable container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein.” (Ex. 1004, Col. 11:18-23.)  FIG. 5  FIG. 5A *See also* Col. 24:17-22: “Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section.”

’491 Patent	Connors in view of Rakonjac
11. The gastric occlusive device of claim 10, wherein said balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.	Connors teaches the balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches: “The diameter of the inflatable container 68 may be varied within the range of from about 0.25 inches to about 6 inches, in an application of the invention involving the implantation of only a single attenuation device. Many embodiments of the inflatable containers 68 will have a diameter within the range from about 1 inch to about 3 inches.” (Ex. 1004, Col. 11:11-17.)
12. The gastric occlusive device of claim 1, wherein said multilayer film has a thickness of up to 10 mils.	Connors teaches the multilayer film has a thickness of up to about 10 mils: “The overall thickness of the wall is preferably minimized, and will often be no more than about 0.03 inches. Preferably, the wall will be no more than about 0.006 inches, and, in some implementations, is no more than about 0.003 inches thick.” (Ex. 1004, Col. 23:44-48.) 0.003 inches is 3 mils.
13. The gastric occlusive device of claim 1, wherein said sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer,	Connors teaches the sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer: “Any of a variety of gas barrier materials (e.g. polyvinylidene chloride, ethyl vinyl alcohol, fluoropolymers, etc.), available in thin film constructions, may be implemented into the attenuation device design.” (Ex. 1004, Col. 23:3-6; *see also id.* Col. 23:48-54.)
said thermoplastic polymer film comprises polyurethane, and	Connors teaches said at least one layer of thermoplastic polymer film comprises a first and a second layer of polyurethane: “An outer layer may comprise a soft, conformable material such as polyurethane, EVA, PE, polypropylene, silicone or others, having a thickness within the range of from about 0.0025 inches to about 0.025 inches.” (Ex. 1004, Col. 23:48-51.)

'491 Patent	Connors in view of Rakonjac
said thermoplastic polymer film is laminated to the sealing film on both the main top and bottom surfaces thereof.	Connors teaches the layers of polyurethane are laminated to the sealing film: "The layers of the attenuation device can be formed in any number of ways known to those skilled in the art, including, but not limited to, lamination, coextrusion, dip molding, spray molding, or the like, etc." (Ex. 1004, Col. 23:62-65.) Connors teaches that the layers can include alternate barrier layers and high impact strength layers: "With respect to those embodiments having multiple, nonconsecutive barrier layers, the other layers of the attenuation device can include high impact strength material layers and/or other types of barrier layers." (Ex. 1004, Col. 23:39-43.) Thus, Connors teaches the first layer of polyurethane on a top surface and the second layer on a bottom surface of a gas barrier layer.
14. The gastric occlusive device of claim 1, wherein the seam is devoid of any neck or opening therein	Connors teaches the seam is devoid of any neck or opening therein.

’491 Patent	Connors in view of Rakonjac
	 *FIG. 5*  *FIG. 5A*
15. The gastric occlusive device of claim 1, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.	Connors teaches radio frequency and ultrasonic welding: “the attenuation device may be ultrasonically, radio frequency, adhesively or heat sealed in situ following inflation, in which case the valve may be omitted.” (Col. 13:12-15.)

'491 Patent	Connors in view of Rakonjac
16. The gastric occlusive device of claim 1, comprising a film material providing a seal that is degradable in exposure to physiological components in the gastric cavity of a patient	Connors teaches at least a portion of said balloon comprises a degradable material that is degradable in exposure to physiological components: In another embodiment, the removal procedure involves dissolving or degrading the material or a portion of the material of the attenuation device 66 in situ. Material selection and wall thickness of the attenuation device 66 may be optimized to provide the desired useful life of the attenuation device, 66 followed by dissolution in the aqueous environment of the bladder. (Ex. 1004, Col. 18:23-30.) Connors also teaches the balloon can be used in the gastrointestinal cavity: "The present invention relates generally to methods and apparatus for attenuating and/or baffling transient pressure waves in . . . the human body: cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngical and ophthalmic." (Ex. 1004, Col. 1:17-24.)

’491 Patent	Connors in view of Rakonjac
said film material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said patient and to deflate after said period of time by egress of said inflation medium through the film material.	Connors teaches said degradable material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the degradable material: In another embodiment, the removal procedure involves dissolving or degrading the material or a portion of the material of the attenuation device 66 in situ. Material selection and wall thickness of the attenuation device 66 may be optimized to provide the desired useful life of the attenuation device, 66 followed by dissolution in the aqueous environment of the bladder. (Ex. 1004, Col. 18:23-30.)
17. The gastric occlusive device of claim 16, wherein said film material comprises an ethylene vinyl acetate/hydroxycellulose blended material.	Connors teaches the film material comprises an ethylene vinyl acetate/hydroxycellulose blended material: “In one embodiment, at least one layer on, or the entire attenuation device comprises a blend of a barrier material and a flexible high impact strength material (e.g. polyurethane/polyvinylidene chloride, polyethylene/ethyl vinyl alcohol, etc.).” (Ex. 1004, Col. 23:16-20.)
18. The gastric occlusive device of claim 1, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.	Connors teaches the balloon comprises a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent: “In one embodiment, the attenuation device incorporates biocompatible coatings or fillers to minimize irritation to the bladder wall and mucosa and/or to inhibit the formation of mineral deposits (encrustation). The materials can be coated onto the surface or incorporated within the wall of the attenuation device.” (Ex. 1004, Col. 13:23-28.)

'491 Patent	Connors in view of Rakonjac
20. The gastric occlusive device of claim 1, wherein said multilayer film comprises an adhesive layer disposed between any of the sealing film and the at least one layer of thermoplastic polymer film.	Connors teaches the sealing layer comprises an adhesive layer disposed between any of (1) the first thermoplastic polymer film layer and the sealing layer, and (2) the second thermoplastic polymer film layer and the sealing layer: "If the attenuation device is fabricated by bonding two sides together, a bonding or tie layer may be provided on the barrier layer." (Ex. 1004, Col. 23:54-56.)
21. The gastric occlusive device of claim 1, wherein said layer of scaling [*sic*, sealing] film is extrusion bonded to said at least one layer of thermoplastic polymer film to form said multilayer film.	Connors teaches the layer of sealing film is extrusion bonded to said at least one layer of thermoplastic polymer film to form said multilayer film: "The layers of the attenuation device can be formed in any number of ways known to those skilled in the art, including, but not limited to, lamination, coextrusion, dip molding, spray molding, or the like, etc." (Ex. 1004, Col. 23:62-65.)

Petitioner respectfully submits that it has a reasonable likelihood of showing that Connors in view of Rakonjac renders claims 1-6, 10-18, 20, and 21 obvious.

2. This Petition presents Connors in a new combination and provides new arguments supported by new evidence.

The PTO cited Connors during prosecution. To overcome Connors, the Patent Owner amended the independent claims to include "non-pillowed and spheroidal in shape" and "half-sections processed in a vacuum thermoforming die having a substantially non-planar surface." Patent Owner also submitted a declaration by himself to support the arguments.

The Board reversed the Examiner, finding: (1) the Examiner did not adequately show that Connors taught a spherical balloon formed of two half-sections with a seam around the edges and (2) Examiner did not address Patent Owner's declaration. Petitioner addressed both findings above, but provides more detail in the sections below.

a. Petitioner combines Connors with Rakonjac to teach a vacuum thermoforming method for manufacturing Connors balloon.

As explained below, Patent Owner was mistaken when he testified that vacuum thermoforming is the only way to provide a non-pillowed and spheroidal balloon. In any event, Rakonjac teaches vacuum thermoforming of balloons in two halves. Thus, Petitioner presents a completely new ground.

b. The Examiner did not present all of Connors's teachings of a multi-layer, spheroidal balloon formed from two half-sections.

The Examiner stated that one of skill in the art would combine Connors Figures 5 and 16. The Board said that Examiner did not explain why one of skill in the art would combine the embodiment in Figure 5 with the embodiment in Figure 16 to teach a spherical balloon. The Examiner failed to observe two relevant facts: (1) both Figures 5 and 16 discuss "spherical balloons" and (2) Figures 5 and 16 are each variations of the same attenuation device 66.

With respect to Figure 5 above, Connors teaches that "the specific dimensions and configuration of the inflatable container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein." (Ex. 1004, Col. 11:18-23.) With respect to Figure 16C, Connors teaches "[a]ny of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section." (Ex. 1004, Col. 24:17-22.) Thus, the descriptions of Figures 5 and 16C each explicitly teach a spherical balloon.

In addition, Connors describes the variations of Figures 5, 5A, and 16C with respect to attenuation device 66. (*c.f.* Col. 11:6-8 ("Referring to FIGS. 5 and 5A, there is illustrated one embodiment of an **attenuation device 66** which comprises a moveable wall such as on an inflatable container 68.") (emphasis added); *with* Col. 22:27-29 ("Referring to FIG. 16[A-D], there is illustrated a variety of shapes for the **attenuation device 66** of the inflatable container variety.") (emphasis added).) Thus, one of skill in the art does not need a motivation to combine the devices in Figures 5, 5A, and 16; Connors explicitly teaches that these are variations of the same attenuation device 66.[8]

[8] Although the Board did not discuss Patent Owner's argument that Connors description of multi-layer is not the same embodiment of Figure 16, Petitioner

c. Mr. Strohl's declaration explains the errors in Patent Owner's declaration.

Petitioner provides the declaration of Clair Strohl, a biomedical engineer with over 40 years' experience in developing and manufacturing medical devices from thermoplastics.

Patent Owner's First Argument

"[O]ne skilled in the art would understand . . . that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors." (Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 7.)

As Mr. Strohl explains, the features relevant to the claimed shapes of the '491 patent (spheroidal) are possible with one or more manufacturing techniques (e.g., "dip molded," "spray molding") in Connors. (Ex. 1009, ¶ 170.) Whether all fabrication methods can make all shapes is simply irrelevant; Connors enables manufacture of spheroidal, non-pillowed balloons. (Ex. 1009, ¶ 172.)

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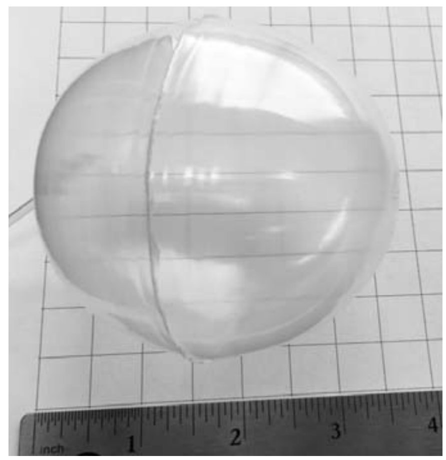
notes that this is incorrect. First, Connors introduces Figure 16 generally, then talks about multi-layer balloons, and then returns to Figure 16 description. Second, Connors specifically references the multi-layer as a way of forming the balloon 66.

Mr. Strohl provides evidence of a balloon manufactured according to the parameters described in Connors. (Ex. 1009, ¶ 171-72.) Mr. Strohl commissioned a balloon manufactured using dip molding techniques. (*Id.*) The balloon, reproduced below, is both spherical and non-pillowed:



__Patent Owner's Second Argument__

> Thermoplastics are generally understood to be non-elastic in character and the only method [of which Patent Owner was aware] to form a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multi-layer film comprising at least one thermoplastic polymeric film layer, is to first treat the sections of multilayer film by vacuum thermoforming.

(Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 9.)

As Mr. Strohl explains, fabrication methods discussed in Connors would result in non-pillowed and spheroidal balloons. (Ex. 1009, ¶ 174.) Once balloon half-sections are fabricated (as Connors teaches) to the correct specifications, one of skill in the art can make any shape. (Ex. 1009 *citing* Figures 16A-D and 21.) Mr. Strohl's commissioned balloon evidences that vacuum thermoforming is the only way to manufacture balloons that are non-pillowed. Further, "pillowing" results from errors in joining, in material selection, and in component shape; Shah incorrectly states that one of skill in the art could not manufacture non-pillowed balloons without vacuum thermoforming. (*Id.*)

Patent Owner's Third Argument

"[A] balloon formed by peripherally bonding two conventional non-elastic sheets (with such sheets not being vacuum thermoformed), pillowing along the peripheral seam is a natural and inevitable result." (Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 10.)

As Mr. Strohl explains, pillowing is not the natural and inevitable result of non-vacuum thermoforming and peripheral bonding of non-elastic sheets. (Ex. 1009, 175.) With correct material selection, correct shape fabrication, and correct joining techniques, non-vacuum thermoforming techniques are suitable for creating non-pillowed balloons. (*Id.*)

Patent Owner's Fourth Argument

> Nothing in Connors teaches or remotely suggests the use of vacuum thermoforming, or any other method suitable for forming a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from sections of a multilayer film that are peripherally bonded together, with the film comprising a layer of sealing film and at least one layer of thermoplastic polymer film.

(Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 12.)

As Mr. Strohl explains, several other methods (e.g., "dip molded" and "spray molding") provided in Connors will form non-pillowed, spheroidal balloons when inflated. (Ex. 1009, ¶ 170.) All of these methods were well within the skill in the art. (*Id.*)

Patent Owner's Fifth Argument

> One skilled in the art at the time the present invention was made would not have looked to vacuum thermoforming for fabricating balloons from multi-layer polymer sheets. Vacuum thermoforming has traditionally been used with thick films that are homogeneous in character, such as to create packaging trays and the like. The process of vacuum thermoforming tends to subject the working material to differential stresses as the material is deformed by heat and pressure to conform to the cavity of a vacuum thermoforming die. Such differential stresses have been generally considered to be detrimental in application to multi-layer polymer sheets – particularly composite

> sheets formed from different material layers – due to the possibility of local or even bulk delamination of the individual layers under application of such stress. Considering the desired end use of a balloon capable of retaining pressurized fluid, the risk of delamination would have led one of ordinary skill in the art at the time the invention was made to adopt a method other than vacuum thermoforming for forming a spherical balloon, such as dip molding or the like.

(Ex. 1002, Appeal Brief, filed March 20, 2008, Declaration of T. Shah, Paragraph 13.)

As Mr. Strohl explains, vacuum thermoforming processes used thin, multilayer films for many years. (Ex. 1009, ¶ 180.) As described above, Throne is one example of vacuum thermoforming multi-layer thin sheets. (*Id.*) Although one of skill in the art would consider the risk of delamination, that risk alone would not dissuade one of skill in the art from using vacuum thermoforming. (*Id.*, 182.) One of skill in the art would mitigate the risk, if necessary, by minimizing differential stresses. (*Id.*) One of skill in the art would minimize differential pressures by selecting suitable material and heating the material to a suitable softening temperature. (*Id.*, Ex. 1009.) Further, given the various advantages of vacuum thermoforming processes (e.g., low tooling costs, low engineering costs, fast turnaround time), skilled artisans would use thermoforming processes for making low pressure balloons while minimizing the risk of delamination. (*Id.*)

VI. 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. 6,712,832 B2 and 7,682,306 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**
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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 '491 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.

VII. CONCLUSION

For the reasons detailed above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 1-6, 10-18, 20, and 21 of the ’491 patent. Accordingly, Petitioner respectfully requests *inter partes* review of claims 1-6, 10-18, 20, and 21 of the ’491 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. **659250000005**.

Dated: January 30, 2017

Respectfully submitted,

By /Peng Chen/

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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 FedEx, which is a means at least as fast and reliable as U.S. Express Mail, on the Patent Owner at the correspondence address indicated for U.S. Patent No. 7,883,491 B2.

Dated: January 30, 2017

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Certification of Word Count (37 C.F.R. at the

I hereby certify that this Petition for *Inter Partes* Review has 13,392 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: January 30, 2017

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