

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESHAPE MEDICAL LLC
Petitioner,

v.

FULFILLIUM, INC.,
Patent Owner.

Case IPR2018-00957
Patent 9,456,915 B2

Before BARRY L. GROSSMAN, JAMES A. WORTH, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEYERS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

A. *Background*

On April 20, 2018, ReShape Medical LLC (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–30 of U.S. Patent No. 9,456,915 B2 (Ex. 1001, “the ’915 patent”) on grounds of unpatentability under 35 U.S.C. § 103. Paper 2 (“Pet.”).¹ On August 8, 2018, Fulfillium, Inc., (“Patent Owner”) filed a Preliminary Response. Paper 15 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4(a). Upon consideration of the Petition, Preliminary Response, and the associated evidence, we determine that Petitioner has failed to demonstrate a reasonable likelihood it would prevail with respect to at least one of the challenged claims. Accordingly, we deny institution of an *inter partes* review.

B. *Related Proceedings*

Petitioner identifies the following district court proceedings concerning the ’915 patent:

¹ In Petitioner’s Third Update Mandatory Notices, Petitioner added ReShape Lifesciences, Inc. as a real-party-in-interest. *Cf.* Prelim. Resp. 4 (stating “ReShape Lifesciences is a real party in interest that should have been named.”)

Fulfillium, Inc. v. ReShape Medical, Inc., No. 2:17-cv-08419- (C.D. Cal.), dismissed, on appeal to the Federal Circuit (Exhibit 1024) (Paper 21, 1);

Fulfillium, Inc. v. ReShape Medical LLC et al., No. 8:18-cv-01265 (C.D. Cal.) (Amended Complaint) (Exhibit 1025) (Paper 21, 1);

Fulfillium, Inc. v. SV Health Investors, LLC, No. 1:18-cv01315 (D. Del.) (Exhibit 1026) (Paper 21, 1);

Fulfillium, Inc. v. ReShape Medical LLC et al., No. 30-2018-01017328-CV-IP-CJC (Superior Court for Orange County, CA) (Exhibit 1027) (Paper 21, 1).

The following proceeding, before the Board, also involves the same parties: IPR2018-00957.²

C. The '915 Patent

The '915 patent is titled “Methods, Devices, and Systems for Obesity Treatment” and relates to medical apparatus and more particularly, to implantable devices and methods and systems for detecting actual or impending malfunction or failure. Ex. 1001, 1:23–27. The '915 patent describes a problem with prior art gastric balloons, i.e., the balloon structure itself is hazardous if accidentally deflated since it can pass and cause obstruction of the pyloric valve or the intestines distal to the pyloric valve. Ex. 1001, 2:40–45. Any such obstruction is a medical emergency. Ex. 1001, 2:45–46.

² In IPR2018-00958, Petitioner challenged claims 1–30 of U.S. Patent No. 9,445,930 B2 (the '930 patent) under 35 U.S.C. § 103(a) as being obvious over the same grounds of unpatentability asserted here. The '930 patent and the '915 patent each are based on continuation applications from the same parent application, application No. 11/282,224.

The '915 patent discloses that the claimed invention relates generally to improved gastric balloons comprising at least two principal structural components. Ex. 1001, 8:59–60, 9:8–9. The '915 patent describes the first principal structural as an expandable scaffold which “helps define a shape conforming to a gastric cavity, typically a crescent or ‘kidney’ shape, when expanded.” Ex. 1001, 9:9–12. The '915 patent describes further the second principal structural component as “include[ing] one or more inflatable or otherwise expandable space occupying structures or compartments which are secured to the interior and/or exterior of the expandable scaffold.” Ex. 1001, 9:24–27. The '915 patent discloses that “[t]he inflatable compartment(s) may be inflated with compressible fluids (gases), incompressible fluids (liquids), or in some cases mixtures of gases and liquids.” Ex. 1001, 10:8–10.

Reproduced below is Figure 14 of the '915 patent.

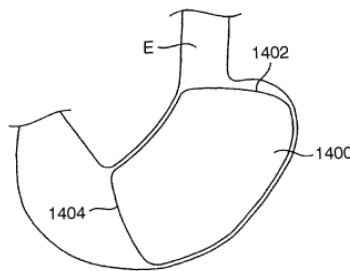


FIG. 14

FIG. 14 illustrates an exemplary gastric balloon geometry. Figure 14 depicts gastric balloon 1400 positioned adjacent to the esophagus E. Ex. 1001, 20:26–28. Balloon structures having this geometry may be deployed using a number of different expandable scaffolds, such as an exoskeleton comprising a spine. Ex. 1001, 20:38–44. Balloon 1400 may comprise one, two, or more separate inflatable compartments. Ex. 1001, 20:64–65. Reproduced below is Figure 15F of the '915 patent.

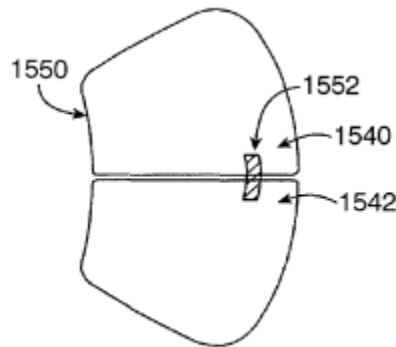


FIG. 15F

FIG. 15F illustrates an example gastric balloon having two inflatable space-filling compartments joined together by a spine structure.

Figure 15F depicts the balloon structure 1400 comprising a first internal inflatable compartment 1540 and second internal inflatable compartment 1542 held together by spine element 1550. Ex. 1001, 21:21–27. The '915 patent discloses that spine 1550 may be used to receive and deploy inflation tubes using valve assemblies to selectively deliver an inflation medium to each of the inflatable compartments. Ex. 1001, 21:44–47, 20:65–67. The '915 patent describes “adjust[ing] the size and/or buoyancy of the balloon for purposes of patient comfort, efficacy, or other reasons.” Ex. 1001, 13:53–55. The '915 patent also discloses

[a]fter all the principal structural components of the gastric balloon have been inflated or otherwise expanded and the associated inflation tubes released, any other anchors or tethers attached to the balloon may also be released, leaving the balloon free to “float” within the patient’s stomach. By properly selecting the ratio of liquid inflation medium to gas inflation medium, as discussed above, the weight, distribution, and the buoyancy of the gastric balloon may be such that the balloon rests within the stomach without exerting undue pressure at any particular point, thus reducing the risk of abrasions or other trauma to the stomach lining. The inflated gastric balloon may be left in place for extended periods of time, typically as long as weeks, months, or even years.”

Ex. 1001, 13:38–51.

D. Illustrative Claim

Petitioner challenges claims 1–30 of the '915 patent. Claims 1, 12, and 19³ are independent claims. Independent claim 1 is illustrative of the challenged claims, and is reproduced below:

1. 1. A gastric balloon structure for deploying in a gastric cavity of a patient, comprising:

at least two isolated non-concentric inflatable chambers, wherein each chamber of the at least two isolated non-concentric inflatable chambers has a respective inflated state volume such that deflation of any single chamber of the at least two isolated non-concentric inflatable chambers leaves the inflated state volume of the remaining chambers of the at least two isolated non-concentric inflatable chambers unaffected;

a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers; and

a flexible central spine spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated nonconcentric inflatable chambers;

wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated nonconcentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity; and

³ We note that independent claim 19 is drafted using means-plus-function language. See (Ex. 1001, 24:53–25:14. Although Petitioner's expert Dr. John C. Alverdy identifies the structure corresponding to each of the claimed functional limitations (see Ex. 1013 ¶¶ 28–29), the Petition itself does not set forth such a construction, and as such, fails to comply with 37 C.F.R. § 42.104(b)(3). See Pet. 6–7. ;

wherein a respective fluid volume for filling each chamber of the at least two isolated non-concentric inflatable chambers is selected based upon dimensions of the gastric cavity of the patient.⁴

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–30 as follows:

Reference(s)	Basis	Challenged Claims
Bangs ⁵ , Foster ⁶ , Lai ⁷ , and Jambor ⁸ or Gottschalk ⁹	§ 103(a)	1–30

⁴ The Board’s rules of practice and procedure require Petitioner, as a matter of pleading, to identify the claim and where each element of the claim is found in the prior art. See 37 C.F.R. 42.104(b)(1),(4). Petitioner does not reproduce the claim language in the Petition, instead referring to numbered and lettered elements (element 1[a], 1[b], 1[c], etc.), in mapping the claims to the prior art. However, the identity the elements, i.e., the claim language being mapped, cannot be understood without resort to Ex. 1002, which sets forth the claim language corresponding to each element. To the extent that Petitioner is attempting to rely on the language of Ex. 1002 to understand the claim mapping, that would be an inappropriate circumvention of the word count imposed by the Board’s rules of practice and procedure. See 37 C.F.R. § 42.24(a)(1). Petitioner’s violation of the Board’s rules in this regard is moot in view of the denial of the Petition.

⁵ U.S. Patent 5,234,454, iss. Aug. 10, 1993 (Ex. 1005, “Bangs”).

⁶ U.S. Patent 4,485,805, iss. Dec. 4, 1984 (Ex. 1006, “Foster”).

⁷ U.S. Patent 4,739,758, iss. Apr. 26, 1988 (Ex. 1007, “Lai”).

⁸ U.S. Patent 2005/0070937 A1, pub. Mar. 31, 2005 (Ex. 1008, “Jambor”).

⁹ U.S. Patent 3,570,494, iss. Mar. 16, 1971 (Ex. 1009, “Gottschalk”).

Reference(s)	Basis	Challenged Claims
Lointier ¹⁰ , Burnett, ¹¹ Lai, and Jambor or Gottschalk	§ 103(a)	1–30
Lointier, Foster, Lai, and Jambor or Gottschalk	§ 103(a)	1–30

To support its Petition, Petitioner proffers a Declaration of Dr. John C. Alverdy, MD. Ex. 1013.

II. ANALYSIS

A. Claim Construction

In this *inter partes* review, filed April 20, 2018, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016); *see also* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming that USPTO has statutory authority to construe claims according to 37 C.F.R. § 42.100(b)). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We must be careful not to read a particular embodiment appearing in the written description into the

¹⁰ WO 03/055420 A1, filed, Dec. 28, 2001, published June 23, 2003 (Ex. 1010, “Lointier”). Unless indicated otherwise, all subsequent citations to Lointier in this decision refer to its English language translation, which is Exhibit 1011.

¹¹ U.S. Patent 2005/0033331 A1, pub. Feb. 10, 2005 (Ex. 1012, “Burnett”).

claim if the claim language is broader than the embodiment. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

The Petitioner does not identify terms for construction or provide any proposed constructions. *See* Pet. 6¹². Neither does Patent Owner. *See generally* Prelim. Resp. For the purposes of this Decision, we determine that no claim term needs express interpretation. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need

¹² The Board’s rules of practice and procedure require Petitioner, as a matter of pleading, to provide construction for any means-plus-function claims under 35 U.S.C. § 112(f). *See* 37 C.F.R. § 42.104(b)(3). Petitioner’s declarant asserts that independent claim 19 is recited in means-plus-function language. Ex. 1013. We do not consider this opinion to be part of the Petition. To the extent that Petitioner is attempting to rely on claim construction interpretations put forward by its declarant, that would be an inappropriate circumvention of the word count imposed by the Board’s rules of practice and procedure. *See* 37 C.F.R. § 42.24(a)(1).

In any event, we agree with Petitioner’s declarant that claim 19 is a claim under 35 U.S.C. § 112 ¶ 6 because claim 19 recites “means for occupying,” “means for isolating,” and “means for distributing,” but the claim does not provide structure to perform the functions of occupying, isolating, or distributing. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc). Neither Petitioner nor Petitioner’s declarant identify structure in the Specification that would correspond to the recited functions. Petitioner thus fails to satisfy the pleading requirements with respect thereto, even when considering the opinion of Petitioner’s declarant. *Askeladden L.L.C. v. Digital Verification Systems LLC*, Case IPR2018-00745, slip op. at 15 (PTAB Aug. 24, 2018) (Paper 9) (“For this element, because Petitioner does not ‘identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function,’ as required by our Rules (37 C.F.R. § 42.104(b)), to enable us to determine if the asserted prior art teaches such structure, Petitioner’s contentions are inadequate for the alleged anticipation by claim 1 by Houser.”).

be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

B. Claims 1–30 as Obvious over Bangs, Foster, Lai, and Jambor or Gottschalk

Petitioner asserts that Bangs, Foster, Lai, and Jambor or Gottschalk renders claims 1–30 obvious. Pet. 7–27 (citing Pet.; Exs. 1002, 1005–1009, 1013). Patent Owner disagrees. Prelim. Resp. 22–34 (citing Exs. 1001, 1005, 1006, 1008, 1009, 1013).

1. Bangs (Ex. 1005)

Bangs is directed to a surgical method for controlling a patient’s body weight through the use of an intragastric balloon catheter which is inserted percutaneously into the patient’s stomach via a gastrostomy tract. Ex. 1005, 1:7–14, 3:35–36–39. 4:62–63. Bangs identifies the importance of “the present invention is that the percutaneous intragastric balloon catheter, utilizes a percutaneous route of deployment via a mature gastrostomy that avoids the complications with spontaneous deflation and transesophageal deployment and retrieval that accompany existing techniques for controlling obesity.” Ex. 1005, 4:68–5:6.

Reproduced below is Figure 9 of Bangs.

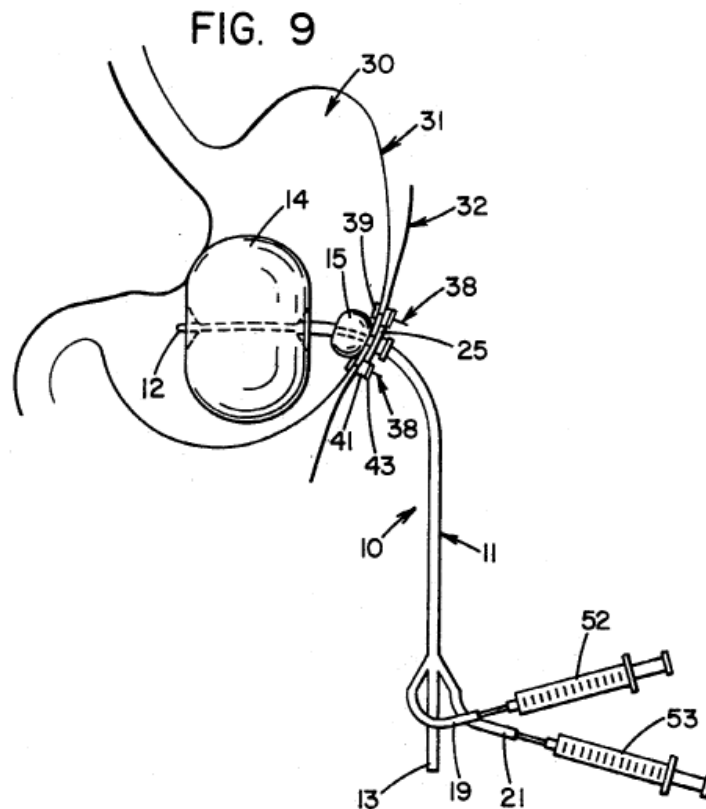


FIG. 9 illustrates the stomach and abdominal wall of a patient and the inflation of the catheter in the stomach.

Figure 9 depicts that Bangs' intragastric balloon catheter is comprised of an elongated shaft 11 which includes a first or proximal inflatable balloon 14 and "second inflatable balloon carried proximal to the first inflatable balloon, the second balloon having a lesser inflated volume than the first balloon." Ex. 1005, col. 3:40–45. Bangs describes balloon 14 is inflated to approximately 200 to 500 cc³ and balloon 15 is inflated to approximately 20 cc³. Ex. 1005, 5:54–58. Figure 9 further depicts second balloon 15 attached to abdominal wall 32 via anchor 25. Ex. 1005, 5:52–54. Bangs further discloses

[t]he surface of the balloon is smooth to help prevent gastric erosion. Spontaneous deflation or rupture may still occur;

however, the catheter is easily withdrawn and exchanged for a new one. The proximal balloon **15** prevents accidental withdrawal of the catheter associated with deflation of the distal balloon. Passage of the balloon distally into the small bowel is avoided because the catheter is anchored to the abdominal wall.

Ex. 1005, 6:1–9.

2. *Foster (Ex. 1006)*

Foster is directed to balloon type devices for effecting weight loss which “can be placed in a person’s stomach through the mouth and esophagus without great discomfort, or risk, and furthermore the structure used to properly place the balloon is entirely removed once the balloon is properly installed so that the balloon alone remains in the stomach.” Ex. 1006, 2:48–54. Foster discloses that its balloon 11 is placed without surgery using a standard nasogastric (N-G) tube 14. Ex. 1006, 5:21–25. Foster

discloses that its “balloon is designed to occupy the majority of the available intragastric space and float freely in the gastric cavity.” Ex. 1006, 6:18–20.

Reproduced below is Figure 3 of Foster.

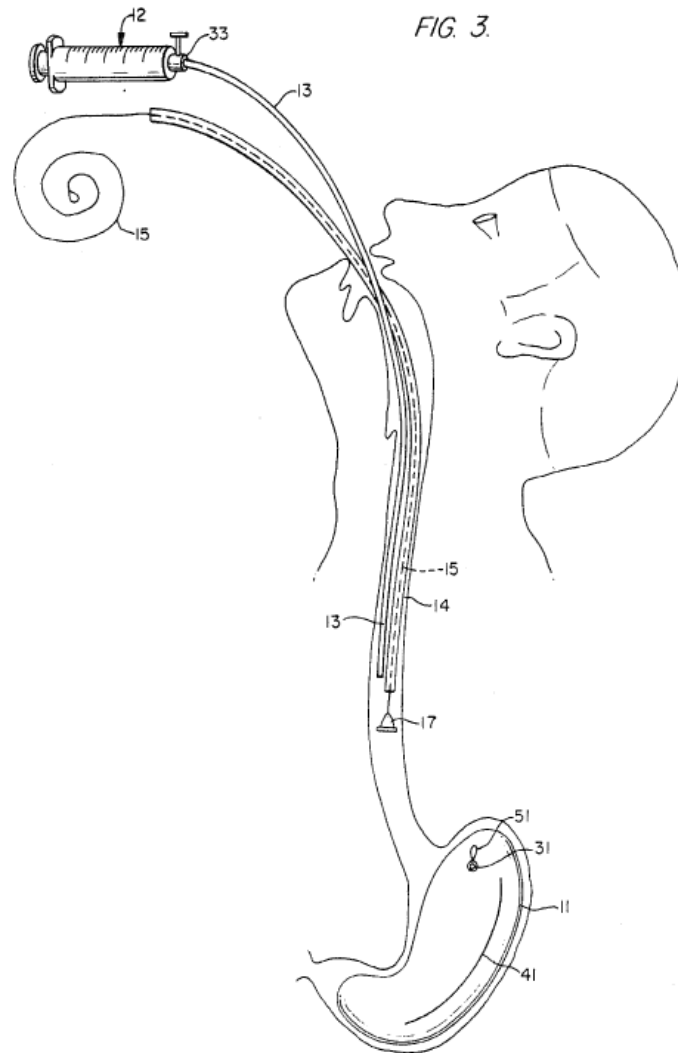


FIG. 3 illustrates balloon 11 after placement and inflation

Figure 3 depicts that Foster’s balloon 11 inflated to occupy the majority of the intragastric space and float freely in the gastric cavity after placement. Ex. 1006, 4:46–48; 5:1–2; 6:18–20. Foster discloses that “[i]f the balloon should suffer a spontaneous deflation, it could be passed through the

intestines physiologically or it could be regurgitated without harm to the user.” Ex. 1006, 6:35–38.

3. *Lai (Ex. 1007)*

Lai is directed to balloon which is inserted through a patient’s mouth and esophagus into the stomach for use in stomach cavity reduction treatment.” Ex. 1007, 1:58–59; 2:40–42. Lai discloses that its balloon, “when inflated, is generally spherical and measures approximately 2 ½ to 3 inches in diameter” and approximately 200 to 500 cubic centimeters. Ex. 1007, 1:61–63; 2:62–64. Lai discloses determining a proper balloon size for a particular patient by X-raying the patient’s stomach. Ex. 1007, 2:61–62. Reproduced below is Figure 1 of Lai.

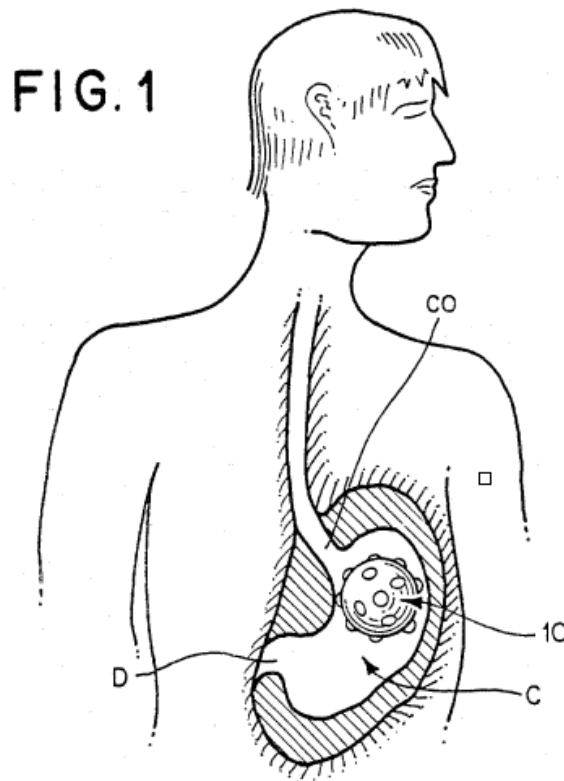


FIG. 1 illustrates a stomach cavity reduction balloon inflated in a patient’s stomach.

Figure 1 depicts inflated balloon 10 occupying “one-third or more of the available space in the stomach cavity C.” Ex. 1007, 3:35–37.

4. *Jambor*

Jambor is directed to “an easily insertable and removable gastric banding device that encircles and compresses a portion of the stomach thereby forming a stoma opening having a reduced diameter.” Ex. 1008 ¶ 1. Jambor discloses that its “[f]luid supply tube **24** has inlets **34** each of which correspond with and distribute the filling solution to each chamber **32**.” Ex. 1008 ¶ 23. In one example, Jambor discloses that a “fluid supply tube with inlet **34** including a duck bill type check valve **36** whereby the filling solution is allowed to enter chamber but is not allowed to escape via inlet **34**.” Ex. 1008 ¶ 23. In another example, Jambor discloses “it may be advantageous to use a two-way check valve where the two-way check valve only allows the filling solution to leave the chambers when the pressure in the fluid supply tube becomes less than the pressure of the filling solution in the chambers.” Ex. 1008 ¶ 23.

5. *Gottschalk*

Gottschalk is directed to “a self-retaining nasal or nasopharyngeal tampon” to control nasal hemorrhaging without the need of packing the nose with gauze. Ex. 1009, 1:1–6. More particularly, Gottschalk discloses that its nasal tampon

includes a plurality of inflatable members which can be readily inflated selectively when the device deflated inserted into the nasal passage, and preferably including a middle inflatable member forming a bag or balloon which substantially fills the nasal cavity and supplies the necessary pressure for hemostasis, with additional inflatable members provided at opposite ends of

the tube so that when inflated they retain the device in fixed position until such inflated bags are eflated for removal of the device from the nasal passage.

Ex. 1009, 1:6–15.

6. *Analysis*

a. *Claim 1*

Petitioner relies on Bangs in combination with Foster for the shape limitation, recited in independent claim 1, i.e.,

wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.¹³

Pet. 10–11.

Petitioner asserts that the intragastric balloon in Bangs “comprises elongated shaft means having first and second ends; a first inflatable balloon carried proximal to the first end and a second inflatable balloon carried proximal to the first inflatable balloon.” Pet. 8 (citing Ex. 1005, 3:40–43). Petitioner asserts that Foster describes an “intra-gastric weight loss system balloon” that “occupies the majority of the cavity inside the stomach and conforms to the shape of the stomach” and “conforms to the natural three-dimensional kidney shape of the gastric cavity such that the outer surface of the balloon aligns against greater and lesser curvatures of the gastric cavity.” Pet. 10–11 (citing Ex. 1006, 1:43–46; Fig. 3). Petitioner contends that “[a] POSITA would understand that the flexible shaft in Bangs would allow the

¹³ Petitioner refers to this as limitation 1e. See Ex. 1002, 1.

intragastric balloon to flexibly conform to the kidney shape of the stomach.” Pet. 10 (citing Ex. 1013 ¶ 88); *see also id.* at 43–44.

In response, Patent Owner argues that “[n]either Bangs nor Foster teaches or suggests obtaining the shape of the gastric cavity through the combination of multiple inflatable chambers. Instead, both Bangs and Foster teach a single balloon designed for filling the stomach.” Prelim. Resp. 24. Patent Owner asserts that there is a significant difference between the use of Bangs’ percutaneous catheter to inflate a gastric balloon and Foster’s use of a fill tube provided through the mouth down the esophagus and into the stomach. Prelim. Resp. 26. Patent Owner argues that the proposed modification of Bangs with Foster would require substantial reconstruction and redesign and would therefore change its principle of operation (e.g., go from the tethered design of Bangs to the free-floating design of Foster while depending upon the structural features of Bangs). Prelim. Resp. 25–27 (citing *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959)).

We are not persuaded by Petitioner’s argument. Instead, we are persuaded by Patent Owner that Petitioner’s proposed modification of Bangs with Foster would result in a substantial reconstruction of Bang’s design. *See Ratti*, 270 F.2d at 813 (modification would require would require a substantial reconstruction and redesign of its elements as well as a change in the basic principles under which its construction was designed to operate). We also agree with Patent Owner that

Petitioner and Alverdy fail to explain *how* the balloons, lumens, valves and other structures of Bangs might be modified in size, shape, and/or design to allow for the device of Bangs to be inserted into the patient and filled through the esophagus as

disclosed in Foster as opposed to the percutaneous method disclosed in Bangs.

Prelim. Resp. 27 (citing Ex. 1013). Petitioner contends that “[a] POSITA would understand that the flexible shaft in Bangs would allow the intragastric balloon to flexibly conform to the kidney shape of the stomach.” Pet. 10 (citing Ex. 1013 ¶ 88); *see also id.* at 43–44. The difficulty with Petitioner’s contention, however, is that Petitioner provides no reasoning as to how or why one of skill in the art would reconfigure the dual balloon design in Bangs to “assume[] a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity,” as required by independent claim 1.

Dr. Alverdy avers that “[a] POSITA would have recognized that by spacing the balloons apart from one another, as taught by Bangs (FIG. 9), the shaft would bend to conform the device to the shape of the stomach.” Ex. 1013 ¶ 88 (citing Ex. 1005, 4:37, 5:58–6:1, Figs. 8, 9). Dr. Alverdy opines that Foster’s disclosure of “a single balloon with a kidney shape so it will maximize displacement of the stomach volume” (Ex. 1013 ¶ 88 (citing Ex. 1006, 1:43–46, 4:20–21)) “would have motivated a POSITA to make the inflated balloon volumes of the modified Bangs device approximate the natural kidney shape of the stomach to to [sic] occupy a significant portion of the stomach capacity, as taught by Foster.” Ex. 1013 ¶ 88 (citing Ex. 1006, 1:43–52, Fig. 3). Dr. Alverdy, however, provides no factual support for his opinion that Bangs’s dual balloon design could have been modified to “assume[] a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity,” as required by independent claim 1, or that one of ordinary skill in the art would have recognized as much. *See* 37 C.F.R.

§ 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

Viewing the evidence as a whole, we determine that Petitioner has not provided adequate motivation for modifying Bang’s dual balloon device to space its balloons apart such that it would “assume[] a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity,” as required by independent claim 1. This would require a substantial reconstruction of Bang’s design and Petitioner has not provided sufficient countervailing rationale for doing so.

Petitioner further contends that a person of ordinary skill in the art would have modified Bangs based on the teachings of Foster. Pet. 9, 24. Petitioner asserts that “[a] POSITA would have been motivated to modify Bangs so that it was free-floating, like the device described in Foster, to avoid the need for and complications resulting from using a gastrostomy tract as taught in Bangs.” Pet. 9 (citing Ex. 1013, ¶ 85). Dr. Alverdy avers that “a POSITA also would have been highly motivated to avoid the use of a gastrostomy opening to avoid the leakage of stomach fluids into the abdomen and to reduce patient discomfort and infection risk, as taught by Foster.” Ex. 1013 ¶ 85 (citing Ex. 1006, 2:28–32, 2:48–54). However, as Patent Owner points out, Bangs discloses that one of its primary objectives is to provide a percutaneous intragastric balloon catheter “which is easily retrieved and replaced **without endoscopy**.” Prelim. Resp. 25–26 (citing Ex. 1005, 3:9–15) (emphases added). In fact, Bangs, with reference to Foster (U.S. Pat. No. 4,485,805) specifically disparages intragastric balloons placed using endoscopy. See Ex. 1005, 2:10–25. Thus, we are not persuaded that a person of ordinary skill in the art would have modified

Bangs based on Foster to avoid the need for and complications resulting from using a gastrostomy tract as taught in Bangs.

Petitioner also contends that a person of ordinary skill in the art would have modified Bangs based on the teachings of Foster because

[a] POSITA . . . would have been motivated to space the balloons of Bangs apart from one another on the shaft to prevent the entire device from passing through the pyloric valve if one of the balloons deflated. *Id.* A POSITA would have understood that the balloons in Bangs are separately inflated, and thus deflation of one balloon would leave the inflated state of the other balloon unaffected.

Pet. 9 (citing Ex. 1013 ¶ 85).

Patent Owner responds again that neither Petitioner nor Dr. Alverdy explains how the resulting modified Bangs device would be constructed, and as such, the Petition relies purely upon hindsight. Prelim. Resp. 30. Patent Owner asserts that Bangs expressly teaches a different mechanism to prevent the device from passing through the pyloric valve. Prelim. Resp. 30–31. We agree with Patent Owner.

In making this determination we note that Bangs discloses “proximal balloon **15** prevents accidental withdrawal of the catheter associated with deflation of the distal balloon” and “[p]assage of the balloon distally into the small bowel is avoided because the catheter is anchored to the abdominal wall.” Ex. 1005, 6:4–9. Thus, we agree with Patent Owner that “Petitioner’s assertion that a ‘POSITA would have recognized that one benefit of the double balloon construction of the intragastric device of Bangs is that deflation of one of the balloons would not affect the inflated volume of the other balloon’ is entirely contrary to the teaching of Bangs.” Prelim. Resp. 31.

Petitioner still further contends that a person of ordinary skill in the art would have modified Bangs based on the teachings of Foster because

[a] POSITA would have been motivated to use the spaced-apart double balloon structure of Bangs as a free-floating device to reduce the risk of trauma and erosion (*see, e.g.*, Ex. 1006, 2:28–32 and 48–54), as recited in claims 4, 17 and 25, and to reduce the risk that the free-floating device of Foster would pass through the pyloric valve, as recited in claim 19. (Ex. 1013, ¶¶ 85–88 and 93–94).

Pet. 23–24 (citing Ex. 1013, ¶¶ 85–88 and 93–94). However, neither Petitioner nor Dr. Alverdy explains how or why one of ordinary skill in the art would modify Bangs’ balloon structure to operate as a free-floating device, much less explain how the modified balloon would reduce the risk of trauma and erosion or prevent the modified balloon structure from passing through the pyloric valve. In this regard, we note that Bangs discloses that the surface of its “balloon is smooth to help prevent gastric erosion” (Ex. 1005, 6:1–2), and as discussed above, Bang describes reducing the risk of trauma by “utiliz[ing] a percutaneous route of deployment via a mature gastrostomy that avoids the complications with spontaneous deflation and transesophageal deployment and retrieval that accompany existing techniques,” such as the endoscopic technique described in Foster. *See* Ex. 1006 4:68–5:6, 2:10–25.

We, therefore, conclude that Petitioner has not provided adequate explanation or reasoning for the proposed combination of Bangs and Foster. 37 C.F.R. § 42.104(b)(4),(5); *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Petitioner does not rely on Lai, Jambor, or Gottschalk to remedy the deficiency. Accordingly, Petitioner has not shown a reasonable likelihood of success of prevailing on this combination.

b. Dependent claims 2–11

Petitioner’s assertions with respect to claims 2–11 are deficient for the same reasons as for independent claim 1, from which they each depend directly or indirectly.

c. Independent claims 12 and 19 and dependent claims 13–18 and 20–30

Independent claims 12 and 19 contain similar language and requirements as independent claim 1, i.e., require more than one inflatable chamber and that the structure conforms to the natural three-dimensional kidney shape of the gastric cavity. Accordingly, Petitioner’s assertions with respect to independent claims 12 and 19 are deficient for the same reasons as for independent claim 1.

Petitioner’s assertions with respect to claims 13–18 and 20–30 are deficient for the same reasons as for independent claims 12 and 19, from which they respectively depend.

C. Claims 1–30 as Obvious over Lointier, Burnett, Lai, and Jambor or Gottschalk

Petitioner asserts that the combination of Lointier, Burnett, Lai, and Jambor or Gottschalk renders claims 1–30 obvious. Pet. 27–46. Patent Owner disagrees. Prelim. Resp. 34–49.

1. Lointier (Ex. 1011)

Lointier is titled “Multiple-Pouch Intragastic Balloon, Surgical Device for Expanding Said Balloon and Method for Making Same” and relates to the technical field of artificial devices, and more particularly to an expandable intra-gastric balloon, for treating obesity and morbid obesity, e.g., by artificially reducing the volume of the gastric cavity to cause the patient to feel sated quickly. See Ex. 1010, [54]; Ex. 1011, 1:5–9. Lointier

describes disadvantages in prior art balloons, i.e., they were difficult for patients to accept because of the weight of the enclosed liquid; they were sometimes difficult to put into place, to expand and manipulate; and the outside shape of prior art balloons was not suitable for blocking the passage of food into the remainder of the digestive track in a manner that was sufficient and for a duration that was consequential. Ex. 1011, 3:7–21.

Lointier discloses an intra-gastric balloon with two pouches, having respective orifices arranged to receive a common connection member. Ex. 1011, 5:15–26. According to Lointier, the arrangement allows for lower total weight, and allows the use of lower density liquid or air in one of the pouches. *See id.* at 9:4–19. Lointier discloses embodiments with concentric balloons or with adjacent balloons. Figure 6 of Lointier (Ex. 1010, 50) is reproduced below:

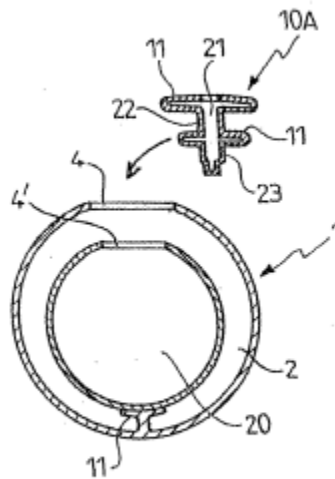


FIG. 6

Figure 6 depicts intra-gastric balloon 1, including at least one second pouch 20 which is disposed inside the first pouch 2, which is a preferred variant. Ex. 1011, 9:23–10:5.

Pouch 20 is preferably filled with a gas, e.g., air, while the first pouch 2 is filled with a liquid, e.g., physiological water. *Id.* at 10:6–12. In another variant embodiment, the pouches 2 and 20 may be adjacent each other, being interconnected via a common face, e.g., by means of adhesive, with the balloon being formed by the combination of the pouches. *Id.* at 9:20–22.

See Fig. 5 (Ex. 1010) reproduced below:

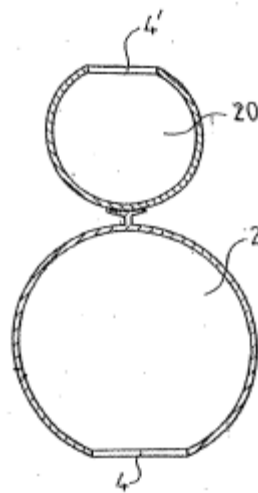


FIG.5

Figure 5 depicts two pouches 2 and 20 are stuck to each other via a free outside base plate at the outside face of the second pouch 20 at a location which is situated substantially opposite from or in register with the corresponding orifice 4'. Ex. 1011, 15:22–25.

The intra-gastric balloon may have outside wall 2A that is made up of facets or cells that are distributed in optionally regular manner over the entire surface of the balloon. *Id.* at 12:10–13. Lointier discloses an intent to provide a novel intra-gastric balloon of a shape that enables contact between the balloon and the stomach wall to be minimized to guarantee passage of food from the upstream zone towards the downwards zone, while nevertheless ensuring that the time taken for such passage is sufficiently

long to optimize the sensation of satiety that the balloon induces. *Id.* at 18:16–25; *see also id.* at 12:14–20.

Figure 7 (Ex. 1010, 51), reproduced below, shows projections against the wall:

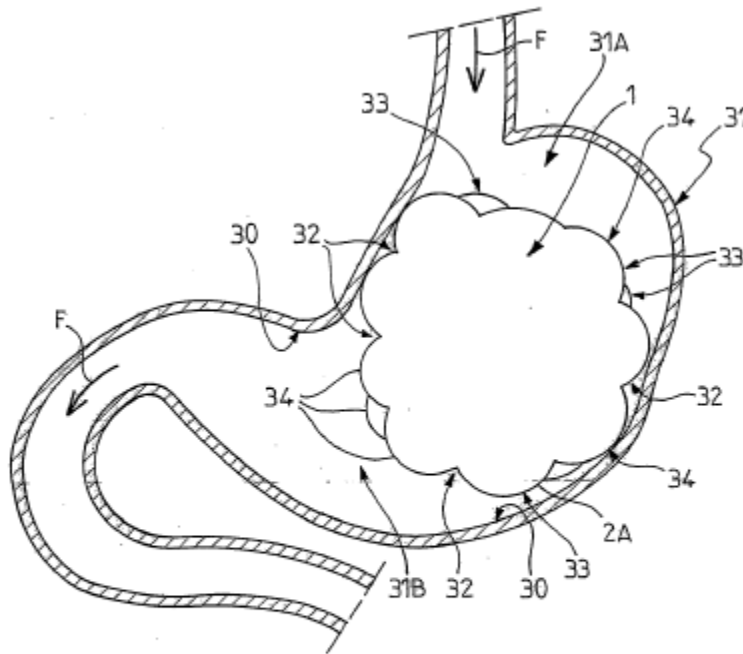


FIG. 7

Figure 7 is a diagrammatic section view of an intra-gastric balloon in accordance with the invention pressed against the stomach wall. Ex. 1011, 19:22–23. The intra-gastric balloon has a plurality of projections 33 disposed relative to one another in such a manner that the food-passing channels 32 going from the upstream zone 31A to the downstream zone 31B are defined firstly by the spaces or gaps between the projections 33, and secondly by the stomach wall 30 coming into contact with the tops 34 of said projections 33. *Id.* at 23:9–14.

2. *Burnett (Ex. 1012)*

Burnett is titled “Pyloric Valve Obstructing Devices and Methods” and relates to devices and methods for partially and/or intermittently obstructing a pyloric valve to decrease gastric emptying, such as for treating obesity. Ex. 1012, [54], ¶ 2. Burnett describes prior art techniques for slowing down the rate at which food passes through the stomach, including stimulating the gastric vagus nerve, severing the gastric vagus nerve, or placing implants or injecting bulking agents into tissue at or immediately adjacent to the pyloric valve. *Id.* ¶¶ 9–10. According to Burnett, such prior art techniques had drawbacks in that they were sometimes irreversible, the surgical techniques may have had adverse effects, and the approach of placing implants or bulking agents into the area of the pyloric valve had not been shown to be effective. *Id.*

Burnett discloses delivering devices into the stomach where they expand or are expanded to partially and/or intermittently obstruct the pyloric valve such that the contents of the stomach are retained longer. *Id.* ¶ 12. Burnett discloses a device with an expandable support portion and a tissue engagement portion that may be unitary or separate with coupling. *See id.* ¶ 14. In one embodiment the device may have an oblong or tubular shape. *Id.* ¶ 19. Figure 2A depicts one embodiment:

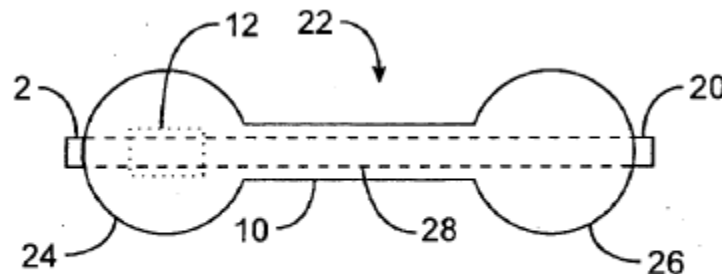


FIG. 2A

Figure 2 shows as a side view of a variations of the device utilizing occlusion members of certain shapes. *See id.* ¶ 42. Proximal and distal occlusion members 24, 26 have a cross-sectional shape along a longitudinal axis defined by device 22 in the form of circles, to form spherical occlusion members. *Id.* ¶ 71. In another embodiment (not reproduced here), the distal occlusion member may be omitted entirely, such that there would only be one occlusion member. *See id.* ¶ 77.

Figure 8D, reproduced below, depicts one embodiment with placement of the device:

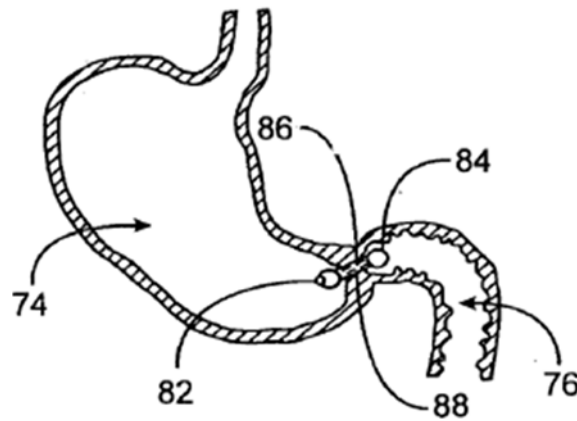


Figure 8D shows a cross-sectional view of the stomach and a variation for placement of a passive (or “self-expanding”) embodiment of device 80. *See id.* ¶¶ 49, 81.

Once the expansion or inflation has occurred, device 80 will remain in stomach 74 and eventually the distal occlusion member 84 may pass into duodenum 76. *Id.* ¶ 81.

Figures 15B and 17A, reproduced below, depict other embodiments:

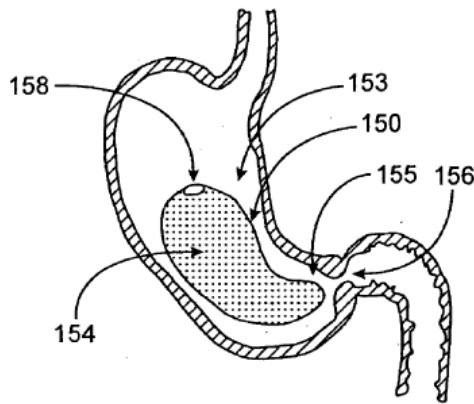


FIG. 15B

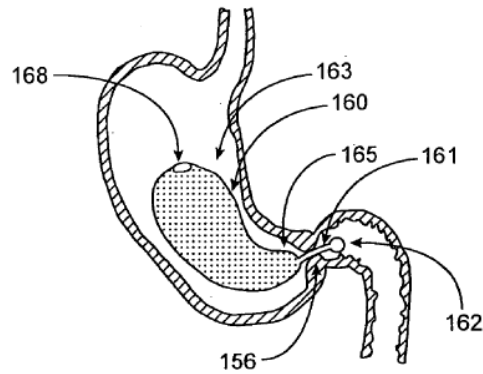


FIG. 17A

Figure 15B is a cross-sectional view showing an embodiment of device 150 for intermittently obstructing pyloric valve 156, and for partially filling the gastric space. *Id.* ¶¶ 56, 90. Item 158 is an inflation port for expanding device 150 and/or foam 154. *Id.* ¶ 90. FIG. 17A shows a cross-sectional view of a device having positioning member 161 and retaining member 162, for helping maintain the position of the device. *Id.* ¶¶ 58, 99. In one embodiment, positioning member 161 may be hollow, thus allowing for passage of fluids and/or gases through the device to allow proximal portion 163, distal portion 165 and retaining member 162 to be inflated. *Id.* ¶ 100.

3. Analysis

a. Claim 1

Petitioner relies on Lointier in combination with Burnett for the shape limitation, recited in independent claim 1, i.e.,

wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable

chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.¹⁴

Pet. 30–31.

Petitioner asserts

Lointier describes an “intra-gastric balloon” comprised of “a first flexible pouch defining a predetermined inside volume, said first flexible pouch being provided with first connection means including an orifice and a valve for receiving a connection member for connection to a first fluid source,” and at least one “second flexible pouch of predetermined volume,” that has a “second connection means with an orifice and a valve,” separate from the first connection means, capable of being connected to a second fluid source.

Pet. 28 (citing Ex. 1010, page 5, lines 1–14; Ex. 1011). Petitioner further asserts that Lointier discloses an embodiment wherein “pouches 2 and 20 may be adjacent to each other” and “retain their inflated shape when implanted.” Pet. 28 (citing Ex. 1010, page 9, lines 20–22; Ex. 1011).

Petitioner states that Lointier describes that its balloon has an “outside wall for coming into contact with the stomach wall . . . [and] shaped in such a manner as to co-operate with the stomach wall.” Pet. 30 (citing Ex. 1010, page 16, lines 17–25; Ex. 1011) (omission in original). Petitioner further states that Lointier discloses a balloon with “a perimetric band of greater or lesser width on the outside surface of the balloon [that] fits closely to the stomach walls.” Pet. 30–31 (citing Ex. 1010, page 17, lines 9–27; Ex. 1011). Petitioner contends that “a POSITA would have recognized that spacing the balloons of Lointier apart would cause the device to assume a

¹⁴ Petitioner refers to this as limitation 1e. See Ex. 1002, 1.

curved shape that fits closely the stomach walls.” Pet. 31 (citing Ex. 1013 ¶ 135); *see also* Pet. 43–44.

In response, Patent Owner argues that Lointier urges that contact area should be minimized, which runs counter to the proposed modification. Prelim. Resp. 43. Patent Owner asserts that Lointier addresses perceived problems with the prior art designs by “minimizing the total area of contact between the gastric wall 30 and the balloon 1” and thereby increasing the contact force between the stomach wall and the implant. *Id.* (quoting Ex. 1011, 26). Patent Owner asserts that Lointier teaches that the balloon should contact the stomach wall only around the periphery of single sphere so that the modulation of food passage was controlled by the channels or grooves patterned into the external balloon surface. *Id.* at 43–44 (citing Ex. 1011, 14, 18, 26–27). Patent Owner argues that the proposed modification of Lointier would therefore destroy its principle of operation (i.e., reduction of contact area to ensure good contact between the stomach wall and balloon). *Id.* at 44 (citing *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984)).

It is true that Lointier criticizes prior art balloons that acted as a plug, resulting in acidity of the stomach and heartburn. Ex. 1011, 18:1–3. Lointier’s device creates channels specifically to overcome this problem in the prior art, while avoiding the opposite problem of food traveling too quickly. *See* Ex. 1011, 18:1–3, 18:10–15, 21:20–23. Further, Lointier discloses that its intra-gastric balloon has a plurality of projections 33 disposed relative to one another in such a manner that the food-passing channels 32 going from the upstream zone 31A to the downstream zone 31B are defined firstly by the spaces or gaps between the projections 33, and secondly by the stomach wall 30 coming into contact with the tops 34 of

said projections 33. Ex. 1011, 23:9–14. In addition, while ensuring that food can indeed pass, the intra-gastric balloon 1 nevertheless generates a path that is tortuous, with multiple subdivisions to be followed by food between the walls of the stomach and of the balloon, because of the network being formed with more than two branching points for the channels 32. Ex. 1011, 22:14–23:2.

It is not entirely clear on this record that Lointier’s criticism would discourage a person of ordinary skill from using a balloon with more substantial contact with the wall of the stomach. We note that Petitioner’s expert avers that more substantial contact with the wall of the stomach would reduce the risk of trauma to the wall of the stomach. See Ex. 1013 ¶ 144 (discussing claim 4). Lointier appears to teach the contrary, and Dr. Alverdy appears to acknowledge Lointier’s teaching to this effect. See Ex. 1011, 18:10–15; see Ex. 1013 ¶ 188 (citing Ex. 1011, 19:1–2, 23:15–25) (“Lointier describes that its multiple balloon embodiment may include facets or lobes to reduce stomach contact and ‘considerably reduc[e] the risk of trauma’”). Accordingly, the evidence relied on by Petitioner to support Petitioner’s proffered rationale for the combination appears to point in both directions. We, therefore, consider the remaining arguments and evidence of record, with the understanding that the burden remains on Petitioner to establish adequate reasoning as to why a person of ordinary skill would have modified Lointier. See 35 U.S.C. § 316(e). See also *Intelligent Bio-Systems, Inc. v Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (“It was [Petitioner]’s burden to demonstrate both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan

would have had a reasonable expectation of success in doing so.”) (internal quotation marks removed).

Petitioner contends that a person of ordinary skill in the art would have modified Lointier based on the teachings of Burnett. Pet. 31, 43–44. Petitioner asserts that Burnett describes that embodiments of the device may have an oblong or tubular shape (citing Ex. 1012 ¶ 19), and that certain embodiments may also act as space-filling devices, as shown in Burnett’s Fig. 15B (citing Ex. 1012 ¶ 90). Pet. 31. Dr. Alverdy avers that Burnett, in Figures 15–18, teaches the advantage of having a single balloon with a kidney shape that conforms to the shape of the stomach. Ex. 1013 ¶ 135.¹⁵

In response, Patent Owner argues that neither Petitioner nor Dr. Alverdy explains how the resulting modified Lointier device would be constructed. Prelim. Resp. 41–43. Patent Owner points to Dr. Alverdy’s statement that “a POSITA would have recognized that by spacing the balloons of Lointier apart from one another on the common connection means as depicted in Burnett, the result[ing] modified Lointier device would not pass through the pyloric valve even if one of the balloons deflated,” and Patent Owner argues that Dr. Alverdy does not explain how this would be accomplished. *Id.* at 41–42 (quoting Ex. 1013 ¶ 131).

We agree with Patent Owner that Petitioner does not adequately explain how Lointier’s device, as modified by Burnett, would be configured. Notably, Burnett discloses an embodiment with a single inflatable compartment in the stomach and an optional second inflatable compartment

¹⁵ Dr. Alverdy also points to “Foster described in Ground 1” as “teach[ing] the benefit of using a kidney-shaped balloon to displace the majority of the stomach volume.” Ex. 1013 ¶ 135 (citing Ex. 1006, 1:43–52).

outside the stomach. *See* Ex. 1012, Fig. 17A. Petitioner does not explain how a person of ordinary skill in the art would have combined the references to arrive at the claimed invention.

Indeed, we agree with Patent Owner that Petitioner does not explain how it proposes to combine the references beyond spacing apart the compartments. For example, Petitioner does not explain whether the resulting modified device would result in two balloons inside the stomach or would result in one balloon inside the stomach and one balloon outside the stomach. Dr. Alverdy avers that the modified device would not pass through the pyloric valve (Ex. 1013 ¶ 131), but such a resulting device could include a configuration with one balloon that remains inside the pyloric valve despite a second balloon outside, as in Burnett. Nor does Petitioner reconcile the fact that Lointier already discloses that once its balloon is put in place, it is prevented from moving. *See* Ex. 1010 page 8, lines 5–10; Ex. 1011. We thus agree with Patent Owner that Petitioner has not explained how it intends to arrange the balloons of Lointier when modified, e.g., whether one or both balloons remains in the stomach and how. *See* 37 C.F.R. § 42.104(b)(4), (5).

Patent Owner also argues that a person of ordinary skill would not have spaced apart the balloons of Lointier, as taught by Burnett, because Lointier discloses embodiments of concentric balloons and adjacent balloons and teaches that it is important to balance the device. Prelim. Resp. 45 (citing Ex. 1011, 4, 10). We are persuaded by Patent Owner that placing one of the balloons of Lointier outside the stomach, as depicted in Figure 17A of Burnett, would result in a substantial reconstruction of Lointier's design. *See Ratti*, 270 F.2d at 813 (modification would require would require a

substantial reconstruction and redesign of its elements as well as a change in the basic principles under which its construction was designed to operate).

We agree with Patent Owner that Lointier discloses balloons inside the stomach and that it is important to balance the device. Ex. 1011, 4:3–5.

We observe that Burnett’s design is based on a design principle of obstructing the pyloric valve to decrease gastric emptying, e.g., for treating obesity, and of maintaining the device in place. Ex. 1012 ¶¶ 12, 99.

According to Burnett, positioning member 161 generally helps position the device 160 in a location for intermittently obstructing the pyloric valve 156, while retaining member 162 (outside the stomach) helps maintain the location or position of the device 160. Ex. 1012 ¶ 99. Patent Owner argues that Lointier’s device does not need a balloon outside the stomach to stay in place because of the size of Lointier’s two balloons inside the stomach, which each have fluid. *See* Prelim. Resp. 46; *see also* Ex. 1010 page 8, lines 5–10; Ex. 1011. We are persuaded by Patent Owner that Petitioner has not demonstrated a need to modify Lointier’s device with a balloon outside the stomach in order to keep it in place. For example, we agree with Patent Owner that there is already an element of redundancy to Lointier’s dual balloon structure and Petitioner has not shown that both balloons would fail if one fails. *See* Prelim. Resp. 46. Further, as above, Lointier already seeks to optimize the passage of food using a branching network of channels for food.

Viewing the evidence as a whole, we determine that Petitioner has not provided adequate motivation for modifying Lointier’s device to space its balloons apart such that one would lie outside the stomach. This would

require a substantial reconstruction of Lointier's design and Petitioner has not provided sufficient countervailing rationale for doing so.

To the extent that Petitioner contemplates a device that positions both of Lointier's balloons inside the stomach, Petitioner does not explain how this would be arranged in a way to conform the balloons to the shape of the stomach, or state that this would be done. Burnett does not disclose a plurality of inflatable compartments inside the stomach. The Petition is deficient for this additional reason.

Lointier's balloons are concentric or adjacent but Petitioner does not rely on Lointier for a teaching of making those balloons form to a shape of the stomach as recited in independent claim 1, i.e., "in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity." By way of comparison, the Specification of the '915 patent provides an exoskeleton for arranging its inflatable pouches relative to each other. *See, e.g.*, Ex. 1001, 21:6–20. Burnett does not explain how two balloons would be arranged relative to each other when both are inside the stomach. Instead, Dr. Alverdy merely opines that a person of ordinary skill would understand that two balloons connected to the same stem would have resulted in a shape conforming to the stomach. *See* Ex. 1013 ¶ 135. However, Petitioner does not provide support for a reasonable expectation of success in arranging the balloons of Lointier, when both spaced apart but both inside the stomach, to form to a shape of the to a curved shape conforming to a natural three-dimensional kidney shape of the stomach.

We, therefore, conclude that Petitioner has not provided adequate explanation or reasoning for the proposed combination of Lointier and

Burnett. 37 C.F.R. § 42.104(b)(4),(5); *KSR Int'l Co.*, 550 U.S. at 421.

Petitioner does not rely on Lai, Jambor, or Gottschalk to remedy the deficiency. Accordingly, Petitioner has not shown a reasonable likelihood of success of prevailing on this combination.

b. Dependent claims 2–11

Petitioner's assertions with respect to claims 2–11 are deficient for the same reasons as for independent claim 1, from which they each depend directly or indirectly.

c. Independent claims 12 and 19 and dependent claims 13–18 and 20–30

Independent claims 12 and 19 contain similar language and requirements as independent claim 1, i.e., require more than one inflatable balloon and that the structure conforms to a shape of the stomach. Accordingly, Petitioner's assertions with respect to independent claims 12 and 19 are deficient for the same reasons as for independent claim 1. Petitioner's assertions with respect to claims 13–18 and 20–30 are deficient for the same reasons as for independent claims 12 and 19, from which they respectively depend.

D. Claims 1–30 as Obvious over Lointier, Foster, Lai, and Jambor or Gottschalk

Petitioner asserts that the combination of Lointier, Foster, Lai, and Jambor or Gottschalk renders claims 1–30 obvious. Pet. 47–64. Patent Owner disagrees. Prelim. Resp. 49–57.

1. Analysis

a. Claim 1

Petitioner relies on Lointier in combination with Foster for the shape limitation, recited in independent claim 1, i.e.,

wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.¹⁶

Pet. 49–50.

Petitioner asserts

Lointier describes an “intra-gastric balloon” comprised of “a first flexible pouch defining a predetermined inside volume, said first flexible pouch being provided with first connection means including an orifice and a valve for receiving a connection member for connection to a first fluid source,” and at least one “second flexible pouch of predetermined volume,” that has a “second connection means with an orifice and a valve,” separate from the first connection means, capable of being connected to a second fluid source.

Pet. 48 (citing Ex. 1010, page 5, lines 1–14; Ex. 1011). Petitioner further asserts that Lointier discloses an embodiment wherein “pouches 2 and 20 may be adjacent to each other” and “retain their inflated shape when implanted.” Pet. 48 (citing Ex. 1010, page 9, lines 20–22; Ex. 1011).

Petitioner asserts that Foster describes an “intra-gastric weight loss system balloon” that “occupies the majority of the cavity inside the stomach and conforms to the shape of the stomach” and “conforms to the natural three-dimensional kidney shape of the gastric cavity such that the outer surface of the balloon aligns against greater and lesser curvatures of the gastric cavity.”

Pet. 50 (citing Ex. 1006, 1:43–46; Fig. 3; Ex. 1013 ¶ 183). Petitioner contends that

¹⁶ Petitioner refers to this as limitation 1e. See Ex. 1002, 1.

a POSITA would have recognized that the balloon of Lointier would have such a curved shape that fits closely the stomach walls. (Ex. 1013, ¶ 183). In addition, a POSITA would have recognized that by spacing the balloons apart from one another in Lointier, the common connection means would bend to conform the device to the shape of the stomach and assume a kidney shape.

Pet. 49 (citing Ex. 1013 ¶ 183).

In response, Patent Owner argues “[a]s with Ground II, neither Petitioner nor Alverdy attempt to explain exactly how the balloons would be supported, interconnected and inflated in the proposed combined system.” Prelim. Resp. 51. We agree with Patent Owner.

Petitioner contends the shape limitation, recited in independent claim 1 would have been obvious over the combined disclosures of Lointier and Foster. Pet. 47–64. This ground relies on Petitioner’s previous arguments directed to the shape limitation of independent claim 1 over the combination of Bangs and Foster (Ground I) and Lointier and Burnett (Ground II). *See, e.g.,* Ex. 1013 ¶ 183. However, Petitioner’s arguments and supporting evidence with respect to this ground does not resolve the deficiencies noted above with respect to the reasons to combine Bangs and Foster (Ground I) and Lointier and Burnett (Ground II) in the manner proposed in the Petition. That is, neither Petitioner nor Dr. Alverdy adequately explains how or why Lointier’s device, as modified by Foster, would be configured to “assume[] a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity,” as required by independent claim 1. *Cf.* Prelim. Resp. 49–56.

We, therefore, conclude that Petitioner has not provided adequate explanation or reasoning for the proposed combination of Lointier and

Foster. 37 C.F.R. § 42.104(b)(4),(5); *KSR Int'l Co.*, 550 U.S. at 421.

Petitioner does not rely on Lai, Jambor, or Gottschalk to remedy the deficiency. Accordingly, Petitioner has not shown a reasonable likelihood of success of prevailing on this combination.

b. Dependent claims 2–11

Petitioner's assertions with respect to claims 2–11 are deficient for the same reasons as for independent claim 1, from which they each depend directly or indirectly.

c. Independent claims 12 and 19 and dependent claims 13–18 and 20–30

Independent claims 12 and 19 contain similar language and requirements as independent claim 1, i.e., require more than one inflatable chamber and that the structure conforms to the natural three-dimensional kidney shape of the gastric cavity. Accordingly, Petitioner's assertions with respect to independent claims 12 and 19 are deficient for the same reasons as for independent claim 1.

Petitioner's assertions with respect to claims 13–18 and 20–30 are deficient for the same reasons as for independent claims 12 and 19, from which they respectively depend.

III. ORDER

After due consideration of the record before us, and for the foregoing reasons, it is ORDERED that the Petition is *denied* and no *inter partes* review is instituted.

IPR2018-00957
Patent 9,456,915 B2

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