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

PATENT OWNER PRELIMINARY RESPONSE

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I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.120, Patent Owner Fulfillium, Inc. hereby submits the following Patent Owner Preliminary Response explaining why Petitioner's IPR arguments fail and why ReShape Medical, LLC failed to carry its burden to show that there is a reasonable likelihood that it would prevail with respect to at least one claim of Fulfillium's 9,456,915 Patent ("the '915 patent").

II. THE '915 PATENT

The '915 patent teaches an embodiment where "[u]pon filling multiple inflatable chambers of a gastric balloon structure in a patient's stomach, the gastric balloon structure assumes a natural three-dimensional kidney shape of the gastric cavity." (Ex. 1001 at Abstract.) "A flexible central spine may span a gap between two inflatable chambers and may include lumens for inflation of one or both chambers" and the "compartments, when in an inflated state, may form a cavity therebetween through which food may pass and may leave in a stomach a residual volume of 10 ml to 100 ml." (*Id.*)

FIG.15 of the '915 patent depicts an embodiment of the inventions claimed in the '915 patent. In relation to Figures 15A-F, the '915 patent teaches that "gastric balloon structures having the geometry of balloon 1400 in FIG. 14 may be deployed using a number of different expandable scaffolds. For example, as shown in FIG.

15A, the balloon structure 1400 may include an external 'exo-skeleton' 1510 comprising a spine 1512 and a plurality of ribs 1514 extending laterally from the spine. The spine 1512 and ribs 1514 may be made from elastic components, such as nickel titanium alloys or other super elastic materials, permitting them to be folded and compressed to a small width for introduction. The scaffold will then be deployed by releasing the scaffold from constraint after it has been positioned within the stomach." (Ex. 1001 at 20:38-50.)

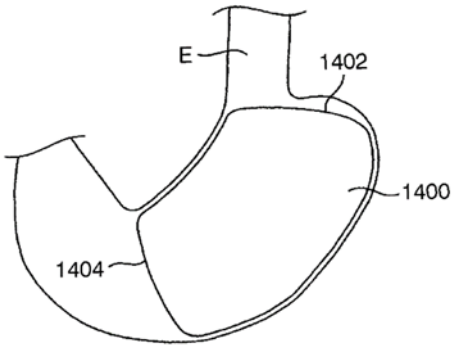

FIG. 14

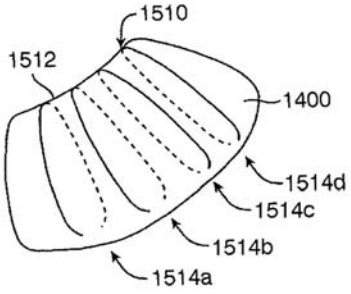

FIG. 15A

The '915 patent further teaches that in the embodiment disclosed in FIG. 15, "[t]he balloon 1400 may also be mated to an inflatable scaffold 1530, which may be conveniently formed into the shape of a saddle, as shown in FIGS. 15C and 15D. The balloon 1400 may comprise one, two, or more separate inflatable compartments. Each of these compartments, as well as the inflatable scaffold 1530, may require separate inflation, preferably using one of the valving mechanisms described below. The inflatable scaffold 1530 could have other configurations as well, such as being in the form of a lattice with a central

inflatable spine and multiple arms disposed laterally outwardly about the remainder of the balloon 1400." (*Id*. at 20:61-21:5.)

Figures 15E and 15F depict an embodiment in which "the balloon 1400 may comprise first and second internal inflatable compartments 1540 and 1542 having an external sheath or exoskeleton 1544." (*Id*. at 21:6-9.) The sheath 1544 may be "comprise a mesh, fabric, or other flexible containment member which holds the separate inflatable compartments 1540 and 1542 in place relative to each other." (*Id*. at 21:13-15.) The compartments 1540 and 1542 may be "held together by a spine element 1550, as shown in FIG. 15F." (*Id*. at 21:21-22.) "The spine 1550 can also optionally be used to receive and deploy inflation tubes." (*Id*. at 21:27-28.)

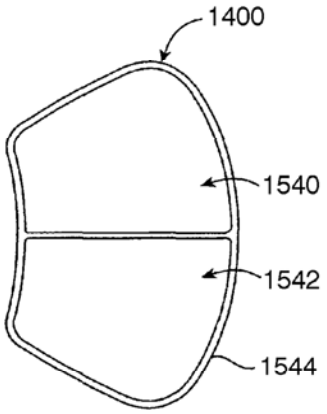

FIG. 15E

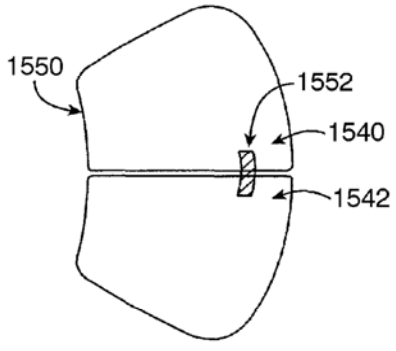

FIG. 15F

III. THE PETITION SHOULD BE DENIED FOR FAILURE TO NAME ALL REAL PARTIES-IN-INTEREST

ReShape Medical, LLC ("ReShape Medical") named only itself as the real party in interest despite acknowledging that it is a wholly owned subsidiary of ReShape Lifesciences, Inc. ("ReShape Lifesciences"). Paper No. 2 at 2. ReShape Medical's conscious decision to list only itself as the real party in interest should result in denial of its petition because the evidence establishes that ReShape Lifesciences is a real party in interest that should have been named.

The relationship between ReShape Lifesciences and ReShape Medical is so intertwined that it is difficult—even for ReShape Lifesciences—to determine where one company ends and the other begins. Indeed, the two companies share a Chief Executive Officer and several high-ranking employees. The tight knit relationship between the parties is so intertwined that it led ReShape Lifesciences to mistakenly inform its shareholders that it had been sued for patent infringement where ReShape Medical was the party named in the complaint. This type of intertwined relationship between a corporate parent and subsidiary requires disclosure of the parent as a real party in interest.

ReShape Lifesciences also should have been named as a real party in interest because it is the party that makes, sells, and offers to sell the devices Patent Owner has accused of infringement in the district court. ReShape Lifesciences stands to

directly benefit from ReShape Medical's petition and is a party at whose behest the petition was filed.

Finally, the evidence suggests that it is likely that ReShape Lifesciences has played some role in the financing of ReShape Medical's *inter partes* reviews. To date ReShape Lifesciences has absorbed more than $1,000,000 in liabilities from its subsidiary. And in the district court ReShape Medical has claimed it is without funds to defend against Fulfillium's infringement allegations. Yet, ReShape Medical apparently has the funds it needs to finance an *inter partes* review effort that will undoubtedly cost hundreds of thousands of dollars. Given this, it is likely that the publicly traded ReShape Lifesciences has played some role in the funding of these proceedings.

The petition should be denied for failure to list all real parties-in-interest.

A. Statement of Facts Relevant to ReShape Medical's Failure to Name ReShape Life Sciences as a Real Party in Interest

The named-petitioner "ReShape Medical LLC … is a wholly-owned subsidiary of ReShape Lifesciences, Inc." (Ex. 2001, ReShape Medical Fed. R. Civ. P. 7.1 Corporate Disclosure Statement.) "ReShape Medical, Inc. … was merged into a wholly-owned subsidiary of EnteroMedics Inc. on October 2, 2017, and the surviving subsidiary entity, a Delaware limited liability company, was subsequently renamed ReShape Medical LLC." (*Id.*) "EnteroMedics … acquired ReShape

Medical in a cash-and -stock deal worth $38 million." (Ex. 2002, "EnteroMedics acquires ReShape Medical in $38m cash-and-stock deal," available at: https://www.massdevice.com/enteromedics-acquires-reshape-medical-38m-cash-stock-deal/.)[1] "On October 23, 2017, [ReShape Life Sciences] announced that it had changed its name from 'EnteroMedics Inc.' to 'ReShape Lifesciences Inc.' effective October 23, 2017." (Ex. 2003, ReShape Lifesciences, Inc. 10-k Form for the Fiscal Year ended December 31, 2017 p. 77.)

After EnteroMedics acquired ReShape Medical, it announced that "Dan Gladney will continue as President, Chief Executive Office and Chairman of the Board of EnteromMedics." (Ex 2004, "EnteroMedics Announces Acquisition of ReShape Medical," available at: https://www.prnewswire.com/news-releases/enteromedics-announces-acquisition-of-reshape-medical-300529632.html.) Mr. Gladney also serves as ReShape Medical's CEO and signed its power of attorney in this proceeding. Paper 1 at 1.

Further as a result of the acquisition, "EnteroMedics … agreed to add two designees of ReShape Medical to the Board of Directors of EnteroMedics." (*Id.*) At

[1] Exhibits 2002 – 2005, and 2007 are authenticated by the declaration of Dr. Eugene Daneshvar, Ex. 2014.

ReShape Medical's designation, "Michael Y. Mashaal, M.D. … joined the Board effective as of the closing of the acquisition and one additional ReShape Medical designee [was to] be added at a later date." (*Id*.) As of December 31, 2017, Dr. Mashaal was "deemed to beneficially own" "8.5 % of [the] outstanding common stock," of ReShape Lifesciences. (Ex. 2005, ReShape Lifesciences, Inc. Form 8-K Filed 01/31/18 for the Period Ending 01/31/2018 p. 59.)[2] ReShape Lifesciences identified Mr. Mashaal's ownership position as being "able to influence matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions." (*Id*.)

ReShape Lifesciences and ReShape Medical have shared and currently share numerous employees. "Amy L. Scott served as Vice President and Marketing of Patient Access for ReShape Medical Inc. beginning in July 2013 and transitioned to ReShape Lifesciences under the same title as part of the ReShape Medical acquisition in October 2017." (*Id*. p. 56.) "Robert (Bob) C. Haggerty served as Vice President and U.S. Commercial Sales for ReShape Medical Inc. beginning in

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[2] Citations to documents in this section refer to the page number of the particular exhibit as affixed by Patent Owner rather than the native page number of the exhibit.

October 2016 and transitioned to ReShape Lifesciences under the same title as party of the ReShape Medical acquisition in October of 2017." (*Id.* p. 56.) ReShape Medical identified Mr. Haggerty as an employee of ReShape Medical on January 25, 2018—three months after he took on his role at ReShape Lifesciences. (Ex. 2006, ReShape Medical Rule 26(a)(1) Initial Disclosures p 3.) Scott Youngstrom, Senior Vice President Finance and Chief Financial Officer of ReShape Lifesciences, was identified by ReShape Medical as being a ReShape Medical employee on January 25, 2018. (*Id.*) Thus, it appears the two entities share a common CEO, CFO, and head of sales.

The acquisition of ReShape Medical was lauded by ReShape Lifesciences and ReShape Medical's shared CEO Mr. Gladney in press releases. For example, Mr. Gladney stated: "EnteroMedics and ReShape Medical are two innovative companies that share a strong strategic focus on providing proprietary, patient-friendly technologies to address the global obesity epidemic. We look forward to combining the complementary expertise and capability of both companies for the benefit of our customers, patients, employees, and stockholders." (Ex. 2004, "EnteroMedics Announces Acquisition of ReShape Medical," available at: https://www.prnewswire.com/news-releases/enteromedics-announces-acquisition-of-reshape-medical-300529632.html.)

ReShape Lifesciences "currently manufacture[s] the ReShape Balloon in [its] own facility," and has "trained the existing … sales team on the ReShape Balloon at (Ex. 2003, pp. 22, 41.) ReShape Lifesciences "market[s] directly to patients but [also] sell[s] [its] ReShape Balloon to surgical centers throughout the United States that have patients that would like to treat obesity and its comorbidities." (*Id*. p. 22.) Thus, it is ReShape Lifesciences that conducts the majority of the activities accused of infringement in the district court.

On April 20, 2017, Fulfillium filed a complaint asserting causes of action for patent infringement against ReShape Medical. (Ex. 2013, Complaint, p. 1) That complaint did not name ReShape Lifesciences because, among other reasons, it did not exist yet. Despite the fact that it was not named in the complaint, ReShape Lifesciences reported to its shareholders and the SEC in its annual report that "Fulfillium filed a Complaint against ***the Company*** in the United States District Court for the District of Delaware, which alleged misappropriation of trade secrets and infringement of two United States Patents." (Ex. 2003 p. 51.) ReShape Lifesciences further reported to its shareholders and the SEC that ReShape Lifesciences was "in the process of defending," against Fulfillium's infringement claims, even though it had not yet been named in the action. (*Id*. p. 47.) ReShape Lifesciences noted that the possibility of filing *inter partes* review proceedings

would be "both costly and time consuming and could result in substantial uncertainty to us." (*Id*. p. 47.)

B. Legal Standard for Determining whether an Entity Is a Real Party in Interest

"Pursuant to 35 U.S.C. § 312(a)(2), [the Board] may consider a petition for *inter partes* review 'only if . . . the petition identifies all real parties in interest.'" *Cisco Sys, Inc. v. Hewlett Packard Enter. Co.*, IPR2017-01933, Paper 9 at 9 (PTAB Mar. 16, 2018); 35 U.S.C. 312(a)(2). The Trial Practice Guide counsels that determining whether a non-party is a real party-in-interest is a "highly fact-dependent question" which considers how courts "describe relationships and considerations sufficient to justify applying conventional principles of estoppel and preclusion. 77 Fed. Reg. 48756, 48759 (Aug. 14, 2012). "Ultimately, that analysis seeks to determine whether the relationship between the purported 'privy' and the relevant other party is sufficiently close such that both should be bound by the trial outcome and related estoppels." (*Id*.) "In the context of an IPR, a real-party-in-interest is generally one that 'desires review' of the patent at issue and 'may be the petitioner itself, and/or it may be the party or parties at whose behest the petition has been filed.'" *Galderma S.A. & Q-Med AB v. Allergan Industrie, SAS, et al*, IPR2014-01422, 2015 WL 1022410, at * 4 (PTAB Mar. 5, 2015) (quoting Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48759 (Aug. 14, 2012).

"Whether a party who is not a named participant in a given proceeding nonetheless constitutes a real party-in-interest is a 'highly fact-dependent question." (*Id*.) "Although rarely will one fact, standing alone, be determinative of the inquiry a common consideration with whether the non-party exercised or could have exercised control over a party' participation in a proceeding." (*Id*.) (internal citations and quotations omitted). "The concept of control generally means that the non-party has the actual measure of control or opportunity to control that might reasonably be expected between two formal parties." (*Id*.) "In evaluating whether a non-party exercised or could have exercised control over a party's participation in the proceeding, [the Board] may also consider whether the entities are so intertwined that it is difficult for both insiders and outsiders to determine precisely where one end and another begins such that an actual measure of control or opportunity to control the filing of and participation in an IPR might reasonably be expected between entities in such a relationship." *Radware, Inc. v. F5 Networks, Inc*., IPR2017-01249, 2017 WL 4804527, at * 5 (PTAB Oct. 23, 2017).

While control is often a key factor in a real party in interest analysis, the "Practice Guide indicates that a non-party may be a real party in interest *even in the absence of control or an opportunity to control*." *Cisco*, IPR2017-01933 Paper 9 at 13 (emphasis in original). That control or the opportunity to control is not required

for a party to be named as a real party in interest was recently confirmed by the Federal Circuit in *Applications in Internet Time, LLC v. RPX Corp.*, No. 2017-1698, 2018 WL 3625165 (Fed. Cir. Jul. 9, 2018) ("We conclude that, with respect to the dispute in this case, § 315(b) is unambiguous: Congress intended that the term 'real party in interest' have its expansive common-law meaning.'").

"There is a rebuttable presumption that a petitioner's identification of real-parties-in-interest is accurate, but if Patent Owner provides sufficient rebuttal evidence, the ultimate burden of proof remains with the petitioner to establish that it has complied with the statutory requirement 35 U.S.C. § 312(a)(2) to identify all real parties-in-interest." *Cisco*, IPR2017-01933, Paper 9 at 11. "The allocation of the burdens of production and persuasion for identification of real parties in interest appropriately accounts for the fact that a petitioner is far more likely to be in possession of, or have access to, evidence relevant to the issue than is patent owner." *Radware*, 2017 WL 4804527 at * 2.

C. ReShape Lifesciences Should Have Been Named as a Real Party in Interest

ReShape Lifesciences plainly should have been identified as a real party in interest for at least three reasons. First, ReShape Lifesciences had sufficient opportunity to control ReShape Medical's activities with respect to the filing of the petition. The lines are so blurred between ReShape Medical and ReShape

Lifesciences that it is difficult—even for ReShape Lifesciences—to determine where one company ends and the other begins. Second, ReShape Lifesciences as the party who is making and selling the devices accused of infringement stands to benefit directly from a judgment awarded to ReShape Medical. Third, it seems likely that ReShape Lifesciences is ultimately funding these proceedings based on representations made by ReShape Lifesciences in its SEC reports and by ReShape Medical in the parallel district court proceeding.

1. ReShape Lifesciences Had the Opportunity to Control the Filing of the Petition due to the Close Relationship Between ReShape Medical and ReShape Lifesciences

ReShape Lifesciences acquired ReShape Medical for $38 million. It then promptly changed its name to ReShape Lifesciences from EnteroMedics because "[t]he ReShape brand name is strong and well-established in the marketplace…." (Ex. 2003, 10-K p. 5.) ReShape Medical now exists as a wholly-owned subsidiary of ReShape Lifesciences. Importantly, ReShape Lifesciences is not a mere holding company—it is actively involved in efforts to sell the ReShape technology accused of infringement in district court. In other words, ReShape Lifesciences is "an involved and controlling parent corporation," which should have been named as a real party in interest. *See Zoll Lifecor Corp. v. Philips Electronics North America*

Corp. and Koninklijke Philips N.V., IPR2013-00609, Paper 15 at 12, (PTAB March 20, 2014).

ReShape Lifesciences and ReShape Medical share a CEO—Mr. Gladney. Indeed, Mr. Gladney signed the power of attorney in this proceeding as CEO of ReShape Medical, LLC. (Paper No. 1, p. 2.) The Board has found that a common CEO between a parent and subsidiary required the parent to have been named as a real party in interest in *Galderma S.A.*, cited herein.[3]

In *Galderma,* the Board found that the petitioner Galderma should have named its parent Nestlé Skin Health S.A. as a real party in interest noting that the common CEO's "presence at the helm of both Galderma and its parent, Nestlé Skin Health S.A., strongly implies 'an involved and controlling parent corporation

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[3] The existence of a common CEO between a parent and subsidiary was also found to be relevant in *Zerto Inc. v. EMC Corp.*, IPR2014-01254, Paper 35 (PTAB Mar. 3, 2015) where the Board found Petitioner failed to identify all real parties in interest. *Zerto*, IPR2014-01254 at 10 ("As we have explained previously, even though Zerto, Inc. is a wholly-owned subsidiary of Zerto, Ltd., there is also evidence indicating the two entities hold themselves out as a single entiy. Ziv Kedem is the CEO of both Zerto, Ltd. and Zerto, Inc.") (internal citations omitted).

representing the united interests of itself and Petitioner.'" *Galderma*, 2015 WL 1022410 at *7. The Board further found that "as President and CEO of both parent and subsidiary, Mr. Antunes wields a significant degree of effective control over the present matter," finding further that it "need not consider whether Mr. Antunes did or did not directly or indirectly, exercise this control." (*Id*.) "It [was] sufficient that he had … the power to call the shots." (*Id*.) Here, Mr. Gladney as "CEO of both parent and subsidiary … wields a significant degree of effective control over the present matters," i.e., he has the "power to call the shots." Because Mr. Gladney had the power to call the shots for both ReShape Medical and ReShape Lifescienes, ReShape Lifesciences should have been identified as a real party in interest.

Beyond sharing a common CEO, the two purportedly separate entities share various high ranking corporate officials. For example, in its Rule 26(a)(1) Initial Disclosures in district court, ReShape Medical identified Scott Youngstrom as a ReShape Medical employee likely to have discoverable information concerning "financial information, including sales, revenues, costs, and profits of products accused of infringing the patents-in-suit." (Ex. 2006 p. 3.) Mr. Youngstrom is ReShape Lifesciences CFO according to its 10-K and 8-K forms. (Ex. 2003 p. 28, 116; Ex. 2005 p. 3.) In fact, Mr. Youngstrom signed both forms on behalf of ReShape Lifesciences at the same time he was an employee of ReShape Medical.

(*Id.; id*.) Robert Haggerty was also identified by ReShape Medical as an employee with knowledge concerning "sales, marketing, and advertising of products accused of infringing the patents-in-suit." (Ex. 2006 p. 3.) Not surprisingly, Mr. Haggerty also acts as ReShape Lifesciences Vice President of U.S. Commercial Sales—a role in which he no doubt directs the sale of the devices accused of infringement. (Ex. 2005 p. 55.) ReShape Lifesciences also employs Amy Scott who was previously Vice President and Marketing and Patient Access of ReShape Medical. (*Id.*)

A substantial degree of overlap among corporate officials has been identified as a significant data point in the real party in interest analysis in *Aceto Agricultural Chemicals Corp. v. Gowan Co*, IPR2015-01016, Paper 15 (PTAB Oct. 2, 2015). In *Aceto*, the patent owner argued that the parent corporation of the petitioner should have been named as a real party in interest. The Board agreed and "f[ound] the significant overlap in corporate leadership to also be relevant…," further noting that "Petitioner and Aceto Corp. not only appear to share the same CEO, but also several other high-ranking corporate leaders." (*Id*. p. 9.) In fact "at least one key employee of Aceto Corp. … signed the Power of Attorney document on behalf of Petitioner in this proceeding." (*Id*.) This led the Board to find that "the point at which these individuals have stopped acting for Petitioner and have started acting on behalf of Aceto Corp. is unclear." (*Id*.) The fact pattern in *Aceto* fits this case to a tee.

ReShape Lifesciences and ReShape Medical share common corporate leadership, including a key employee—the CEO of both entities—that signed the power of attorney on behalf of ReShape Medical.

It is further relevant that ReShape Medical designated Mr. Mashaal as one of its representatives to sit on the board of ReShape Lifesciences. *Cisco*, IPR2017-01933, Paper 9 at 14 ("Nevertheless, Patent Owner did present unrebutted evidence that Petitioner invest 34 million dollars into Springpath prior to the filing of the Petition and has attained 'board-level' representation at Springpath…."). ReShape Medical designee's ownership stake in ReShape Lifesciences is so significant that he has been identified as being "able to influence matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions." (Ex. 2003, p. 30)

In short, "rather than maintaining well-defined corporate boundaries, [ReShape Lifesciences and ReShape Medical] are so intertwined that it is difficult for both insiders and outsiders to determine precisely where one ends and another begins." *Galderma*, 2015 WL 1022410 at * 5; *see also Cisco,* IPR2017-01933 (Paper 9 at 13 (a real party-in-interest may be found where "the relationship between a nonparty parent corporation and the subsidiary petitioner blurred the lines of corporate separation such that the parent could control conduct of the *inter partes*

review."). Indeed, ReShape Lifesciences itself asserted to its shareholders and the SEC that it had been sued for patent infringement when, in fact, it was its subsidiary that had been sued. (Ex. 2003 p. 51.) This demonstrates that even within the companies, the lines are blurred. It is likely for that reason that ReShape Lifesciences admitted to its shareholders and the SEC that it would be "defending" against Patent Owner's infringement claims and defensive *inter partes* review proceedings would be both "costly and time-consuming" when it not yet even been named in the district court action. (*Id.* p. 46)

2. As the Party that Makes and Sells the Devices Accused of Infringement, ReShape Lifesciences Should Have Been Named as a Real Party in Interest Because It Is a Party that Desired Review of the Patents

ReShape Lifesciences's corporate documents reveal that it both manufactures the devices accused of infringement and markets and sells them throughout the United States. (Ex. 2003, pp. 22, 41.) Thus, it stands to gain a significant benefit if ReShape Medical's petition proves successful. In other words, it is apparent that ReShape Medical filed the petition at the behest of its parent ReShape Lifesciences—the party that apparently has committed the bulk of the activity accused of infringement.

"Thus, when it comes to evaluating the relationship between a party bringing a suit and a non-party, the common law seeks to ascertain who, from a 'practical and

equitable' standpoint, will benefit from the redress that the chosen tribunal might provides." *RPX*, 2018 WL 3625165 at * 10. This principle recently reaffirmed by the Federal Circuit was articulated in *Aceto* where the parent "appears to have its own vested interest in challenging the validity of [the patent at issue] …" because it sought to market a product, which on its face was covered by the patent at issue. *Aceto*, IPR2015-01016, Paper 15 at 8. Here ReShape Lifesciences is an active parent company making, selling, and offering for sale, devices accused of infringement. Yet, it was only its subsidiary that discloses itself as a real party in interest. In the circumstances here, ReShape Lifesciences should have been disclosed as a party as whose behest the petition was filed with a direct interest in the outcome of this proceeding.

3. The Evidence Suggests That ReShape Lifesciences Is Likely Funding These Proceedings

The evidence suggests that it is likely that ReShape Lifesciences has funded or is funding a substantial portion of ReShape Medical's *inter partes* review proceedings. *Zoll*, IPR2013-00609, Paper 15, (PTAB March 20, 2014) (citing 77 Fed. Reg. 48617 discussing the mandatory notice codified in 37 C.F.R. § 42.8) ("Factors for determining actual control or the opportunity to control include existence of a financially controlling interest in the petitioner."). For example, when ReShape Lifesciences acquired ReShape Medical in whole, it included ReShape

Medical's balance sheet and statement of operations with ReShape Lifesciences consolidated financial statements. (Ex. 2003 p. 77.) ReShape Lifesciences 10-Q report filed in May 2018 indicates that it had assumed $1,837,941 in liabilities from ReShape Medical. (Ex. 2007, 10-Q statement p. 13.) That same 10-Q form lists Patent Owner's allegation of infringement in district court against ReShape Medical in a section titled "Commitments and Contingencies." (*Id*. p. 16-17.) That ReShape Lifesciences absorbed significant liabilities from ReShape Medical and lists ReShape Medical's litigation with Patent Owner as a commitment and contingency of ReShape Lifesciences, strongly suggests that ReShape Lifesciences has in some way funded ReShape Medical's *inter partes* review proceedings.

The existence of funding beyond that which could be provided by ReShape Medical alone was suggested in the district court by counsel for ReShape Medical. In particular, counsel for ReShape Medical requested a meet and confer with counsel for Patent Owner. The substance of that meet and confer was summarized by lead counsel for petitioner here, Mr. Pisano:

> As you may recall, Mr. Patiño requested a meet and confer regarding a proposed continuance, which was expressly based on ReShape Medical LLC's current inability to support the expense of a three-patent patent infringement trial. The Court's decision to dismiss the patent infringement claims from the current trade secret case alleviated that

> concern, and unless retained anew, Foley is no longer responsible for representing ReShape Medical LLC for that action. If and when ReShape Medical LLC's finances enable it to respond to Fulfillium's newly filed patent infringement complaint, we expect that ReShape Medical LLC will retain suitable counsel to defend it in that new action.

(Ex. 2008, e-mail from Mr. Pisano to litigation counsel for Patent Owner dated July 23, 2018.)

Mr. Pisano's e-mail represents that ReShape Medical is without funds to defend itself against infringement claims. Yet, ReShape Medical apparently had the funds to file two petitions for *inter partes* review with filing fees alone totaling tens of thousands of dollars. ReShape's petitions were supported by a declarant that it compensated at an hourly rate. Presumably, if ReShape Medical wins institution it will need to spend additional funds. It is not unreasonable to suggest that the entire effort will costs hundreds of thousands of dollars. Yet, in the district court, ReShape Medical is claiming poverty. This begs the question, if ReShape Medical cannot afford to litigate, then how can it afford to participate in these IPR proceedings? The reasonable inference in response is that its well-funded publicly traded parent corporation, which paid $38 million to acquire it, has assisted with funding. At the very least, in light of the evidence set forth herein, the burden has shifted to ReShape

Medical to demonstrate that ReShape Lifesciences has not funded any portion of these proceedings.

D. Because ReShape Medical Did Not Identify ReShape Lifesciences as a Real Party in Interest, Its Petition Must be Denied

Because ReShape Lifesciences was not named as a real party in interest, ReShape Medical's petition cannot be considered under 35 U.S.C. § 312(a)(2). In that situation, the Board's precedent looks to whether the defect can be cured by the addition of a new real party in interest, which generally requires the assessment of a new filing date. *Galderama*, 2015 WL 1022410 at *8. Here, the defect cannot be cured because the complaint alleging infringement was served on April 20, 2017. Thus, under 35 U.S.C. § 315(b), the petition for *inter partes* review was due by April 20, 2018. If the petition were amended to name Reshape Lifesciences as a real party in interest and assigned a new filing date, it would be time-barred. Accordingly, the petition should be denied.

IV. GROUND I: BANGS, FOSTER, LAI, AND JAMBOR OR GOTTSCHALK DO NOT RENDER OBVIOUS CLAIMS 1-30

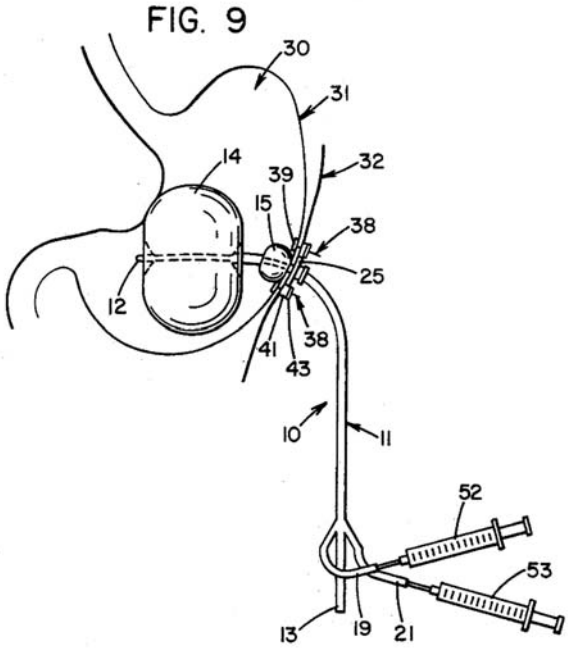
A person of ordinary skill in the art could not achieve a gastric balloon structure meeting independent claim 1, 12, or 19, including "at least two isolated non-concentric inflatable chambers" that "assumes a curved shape conforming to a

natural three-dimensional kidney shape of the gastric cavity" through the combination of Bangs, Foster, Lai and Jambor or Gottschalk, nor would one of skill in the art be motivated to combine these references in the manner described in the Petition.

Bangs and Foster each only provide for a single balloon designed for filling the stomach. Bangs' device is "anchored to the abdominal wall" such that only a single balloon is free-floating and fulfilling the purpose of providing a satiety through a sense of fulness within the abdominal cavity (Ex. 1005, col. 6:8-9, FIG. 9). Its other balloon, if free-floating rather than being anchored, is of minimal dimensions such that it would not contribute to "conforming to a natural three-dimensional kidney shape of the gastric cavity." Foster, conversely, discloses a single chamber that is kidney-shaped to follow the shape of the gastric cavity. Petitioner's proposed combination uses improper hindsight to match the structural elements of Bangs to the features of the independent claims, a task which would require significant redesign and experimentation to pursue and which inappropriately modifies Bangs' basic principle of operation.

A. Neither Bangs nor Foster Teaches Independent, Inflatable Chambers Capable of Assuming a Shape of the Gastric Cavity, and the Proposed Combination Would Require Substantial Reconstruction and Redesign of the Primary Reference

Neither 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. As illustrated below in FIG. 9 of Bangs, although Bangs includes a second balloon 15, the second balloon 15 is of minimal size compared to the main balloon 14 and is anchored against the abdominal wall, its purpose being to prevent accidental withdrawal of the catheter 10, thereby avoiding deflation of the distal balloon 14. (Ex. 1005 at 5:52-58, 6:4-6, FIG. 9.) As such, Bangs relies solely on the single distal balloon 14 for filling the stomach. Foster, conversely, discloses a single chamber (balloon) 11 that is "gastric shaped" to follow the shape of the gastric cavity as illustrated in a partial reproduction of FIG. 3 below. (Ex. 1006 at 3:9-11, FIG. 3.)



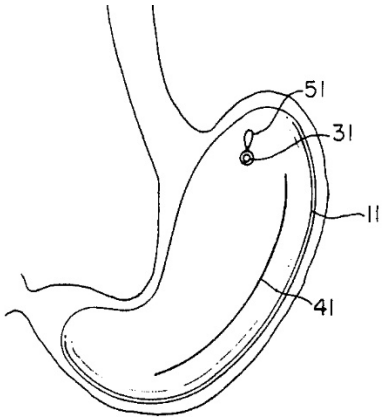


FIG. 3 Foster

Modifying Bangs in the manner recommended by the Petitioner and Alverdy changes the principle of operation of Bangs and would require a substantial reconstruction and redesign of the features of Bangs to support the untethered deployment. According to the Alverdy declaration, Petitioner proposes "us[ing] isolated, spaced-apart balloons as disclosed in Bangs, but in an entirely intragastric format that occupies the majority of the volume of the stomach and is inserted via the esophagus, as disclosed in Foster." (Ex. 1013 ¶ 77.) However, Bangs was not designed with such a deployment in mind and cannot be readily modified to support such a deployment. Bangs states that "a primary object of the present direction is to

provide a percutaneous intragastric balloon catheter for use as an adjunct to weight loss… which is easily retrieved and replaced without endoscopy." (Ex. 1005 at 3:9-15.)

As can be readily understood, there is a significant difference between the use of percutaneous catheter to inflate a gastric balloon as disclosed in Bangs and the use of a fill tube provided through the mouth down the esophagus and into the stomach as disclosed in Foster. Put differently, the entire principle of operation of Bangs would need be revisited and redesigned. A proposed combination of prior art that changes the principle of operation of the prior art invention being modified cannot support a *prima facie* showing of obvious. *Application of Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (C.C.P.A. 1959) (reversing rejection because the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.").

In reviewing the attempted mapping of the claim language to the combination as set forth by Alverdy, Foster is only relied upon for motivation and general shape, while all structural elements of independent claims 1 and 12 are taken from Bangs. (Ex. 1013 ¶¶ 84-90, 103-06.) In independent claim 19, Alverdy cites to Jambor or

Gottschalk for a serial valve arrangement, while obtaining all other structural elements from Bangs. (*Id*. ¶ 114, *see also* ¶ 97.) Notably, 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. (Ex. 1013, *supra*; Paper No. 2, *supra*.) Petitioner's failure to even attempt such an explanation dooms its petition. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.") (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).)

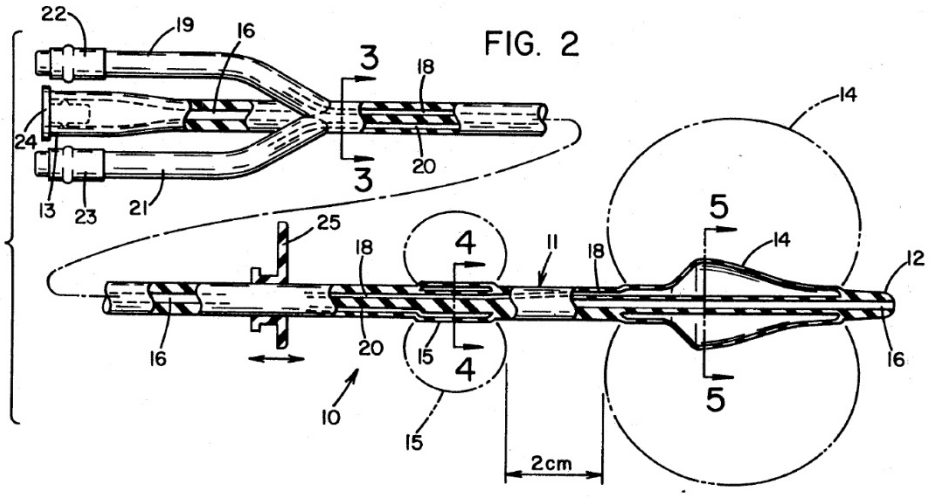
A person skilled in the art would have at least two significant problems in performing the substantial reconstruction and redesign from the tethered design of Bangs to the free-floating design of Foster while depending upon the structural features of Bangs: 1) Bangs is not designed to occupy a large enough volume of the gastric cavity to ever conform to its shape and there is no teaching or motivation in either Bangs or Foster to explain how the two balloons are supposed to conform to the shape generally illustrated by the single balloon of Foster, and 2) the flexible

shaft 11 of Bangs is designed to extend both proximally and distally beyond the balloon elements, thus demonstrating features capable of "exerting undue pressure against the gastric cavity at any particular point" as recited in independent claim 12 if scaled to conform to the shape generally illustrated by Foster's single balloon.

First, as demonstrated in FIG. 9 of Bangs, reproduced above, the two balloons occupy a limited space (e.g., less than half of the gastric cavity) as designed. Even if the two balloons were released to free-float within the gastric cavity, there is no teaching or motivation to guide one of skill in the art in reconfiguring the dual balloon design to "assume[] a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity" as recited in the challenged claims. To be sure, Petitioner did not articulate any such motivation or guidance. A combination imagined only in the mind of a petitioner to meet the claim language is the very embodiment of impermissible hindsight. *Star Scientific, Inc., v. R.J. Reynolds Tobacco Co*., 655 F.3d 1364, 1375 (Fed. Cir. 2011).

Second, Petitioner and Alverdy fail to explain how the "elongate flexible shaft 11", disposed between balloon 15 and inflatable lumen 18 as illustrated in FIG. 2 of Bangs (reproduced below), would be redesigned for cooperation with a valve system configured for untethered deployment within the gastric cavity. (Paper No. 2, p. 10.) Instead, Alverdy states that the feature of "an inflation lumen" "is present in the

original Bangs device… and plainly would have been carried over to the modified device." (Ex. 1013 ¶ 100.) However, it is not so plain to understand upon reviewing the structure and functionality of the Bangs inflation lumen, reproduced below in FIG. 2 of Bangs.



As described by Bangs, "the shaft 11 carries a central drainage lumen 16 which passes between the distal and proximal ends", "[a] first inflation lumen 18", and "a second inflation lumen 20." (Ex. 1005 at 4:45-53.) Alverdy concedes, in discussing independent claim 6, that the Bangs design suffers from "increase in stiffness and diameter … that would have resulted from using multiple separate lumens to inflate the balloons." (Ex. 1013 ¶ 97.) As shown in FIG. 2 above, the shaft 11, incorporating these elements, must extend beyond both balloons, distally to the outside of the gastric cavity to carry all of the lumens 16, 18, and 20. Importantly, Petitioner and Alverdy are silent as to how the distal end 12, illustrated in FIG. 2 and in FIG. 9

(reproduced above) as protruding beyond the main balloon 14, may be redesigned to avoid pressure against the gastric cavity in such a deployment that would occupy the majority of the gastric cavity.

B. Bangs Specifically Disparages the Foster Design; Petitioner Relies Purely Upon Hindsight

As discussed above, Petitioner and Alverdy have not explained how to combine Bangs and Foster to produce the gastric devices as claimed by the '915 patent. "Without any explanation as to how or why the references would be combined to arrive at the claimed invention, we are left with only hindsight bias that KSR warns against." *Metalcraft of Mayville, Inc. v. The Toro Co*., 848 F.3d 1358, 1367 (Fed. Cir. 2017) (citing *KSR at* 421). Metalcraft further counseled that "we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." (*Id*.) There is no reason save hindsight to space the Bangs balloons apart from each other in a free-floating implementation as suggested by Petitioner and Alverdy.

Despite Petitioners' assertion to the contrary, one skilled in the art would not have been motivated to space Bangs' balloons apart from one another on the shaft in a free-floating configuration "to reduce the risk that the device would pass through the pyloric valve if only one of the balloons were to deflate" without the benefit of the

teachings of the '915 patent. (Ex. 1013 ¶ 77.) Bangs, in fact, expressly taught a different mechanism to prevent the device from passing through the pyloric valve:

> 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 at 6:4-9.)

There must be some apparent reason or advantage associated with modifying the prior art – if the prior art already serves the function in question then achieving that function cannot serve as a motivation to modify the device. *KSR* at 398. Similarly, 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. (Paper No. 2 p. 23.) Rather, deflation of the proximal balloon 15 could result in "accidental withdrawal of the catheter associated with deflation of the distal balloon". (Ex. 1005 at 6:4-9.) Bangs, conversely, relies upon inflation of the proximal balloon to maintain inflation of the distal balloon.

Although Petitioner asserts that "[a] POSITA would have been motivated to [combine Bangs with Foster in this manner] to avoid the need for and complications resulting from using a gastrostomy tract as taught in Bangs", (Paper No. 2 p. 9, citing

Ex. 1013 ¶ 85.), Bangs teaches away from this combination, stating, in its Background section, the opposite concern regarding the Foster reference, by name. (Ex. 1005 at 2:10-19.) In particular, Bangs cautions that Foster, specifically, "rel[ies] greatly on endoscopy which is not only expensive, but also has given rise to complications such as pharyngeal and esophageal perforation and aspiration from its use during deployment and retrieval of the device." (*Id.*) A reference teaches away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken" in the claimed invention. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013). Upon reading Bangs and its disparagement of Foster, a skilled artisan would not be motivated to combine these two references.

C. A Skilled Artisan Would Not Have Considered Jambor or Gottschalk in Developing the Resulting Device of Petitioner's Combination of Bangs and Foster

Both Jambor and Gottschalk are relied upon, in the alternative, to demonstrate valve structures for introducing fluids into multiple inflatable chambers. Jambor's device is a gastric band that is external to the stomach. (Ex. 1008.) Gottschalk's device is a nasal tamponade. (Ex. 1009.) Neither reference relates to a gastric balloon or otherwise to the particular difficulties of selective inflation via an

esophagus of the patient, as described by the Petitioner in relation to the proposed combination. A skilled artisan would not have looked to these non-analogous art regions for teachings appropriate to inflating a gastric balloon via the esophagus. "Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed.Cir. 2004). In relation to the dependent claims of the '915 patent, the relevant problem is designing "a valve mechanism or assembly to permit selective inflation [of multiple inflatable compartments] with liquid fluids, gaseous fluids, or a combination thereof" using one or more inflation tubes which are deployed transesophageally while avoiding interference with device deployment and then detached such that "the inflation medium remains contained for extended periods of time" of free-floating deployment. (Ex. 1001 at 11:14-18, 12:1-12, 21:30-36.) For example, Gottschalk describes selectively inflating regions of the nasal tamponade by inserting a hypodermic needle through a series of plugs disposed between inflatable members. (Ex. 1009 at 4:6-75.) The Gottschalk device, requiring a needle to activate separate valves, would not be practical in the combined device proposed by Petitioner in

which the chambers must be inflated via the esophagus while situated in the gastric cavity, far from the reach of a syringe and awkward to align with any hypodermic needle. Conversely, the fluid supply tube of the Jambor device is permanently connected to the gastric band 20 and reachable through a "remotely located fluid injection port" which is "secured subcutaneously in the abdomen or other suitable location." (Ex. 1008 ¶¶ 21, 24-27.) Neither Gottschalk nor Jambor describe an alternative to the valve system and inflation tube of Bangs which, similar to Jambor, is designed for permanent subcutaneous placement and, similar to Gottschalk, is designed for inflation using a syringe. (Ex. 1005 at 5:52-58.)

V. GROUND II: LONTIER, BURNETT LAI, AND JAMBOR OR GOTTSCHALK DO NOT RENDER OBVIOUS CLAIMS 1-30

A person of ordinary skill in the art could not achieve a gastric balloon structure meeting independent claim 1 through the combination of Lointier and Burnett, nor would one of skill in the art be motivated to combine these references in the manner described in the Petition.

A. Review of the Lointier and Burnett References and the Proposed Combination

Lointier teaches a dual pouch system that reduces the overall weight of the balloon by filling one of the pouches with a lower density fluid such as air. (Ex. 1011 p. 4, p. 10 (Ex. 1010 p. 3 l. 23 - p. 4 l. 2, p. 9 ll. 8-13.) Lointier notes that balloon systems can "often turn out to be difficult for patients to accept because of the large weight of the balloon, which encloses a significant volume of liquid, of the order of 600 milliliters (mL)." (Ex. 1011 p. 3.) Accordingly, Lointier proposes a concentric balloon structure shown at right and teaches that one of the two balloons or pouches can be filled with a lighter fluid such as air, "reduc[ing] the total weight of the intra-gastric balloon while it is implanted in the stomach of the patient, thereby improving the tolerance of the organism to the balloon, and reducing side effects." (*Id.* pp. 4, 10.)

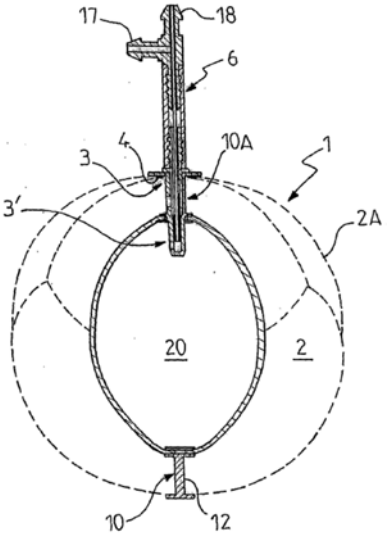
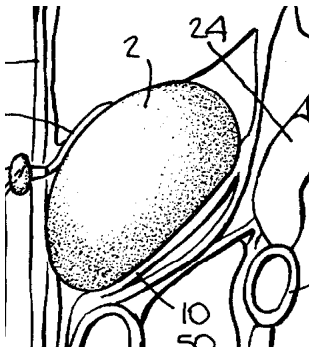


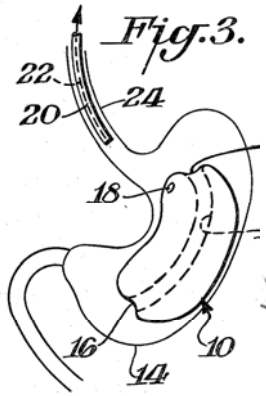
FIG. 2

Lointier teaches that another of his objectives is to avoid the kidney shaped design of previous balloon structures. Lointier explains that "it has been found that the outside shape of previously-known intra-gastric balloons is not suitable for blocking the passage of food into the remainder of the digestive tract in a manner that is sufficient and for a duration that is consequential, even though the specific

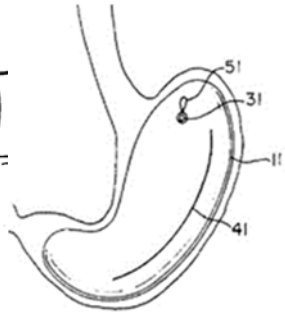
purpose of such a balloon is to prolong the sensation of being sated if possible." (*Id.* p. 3.) The "outside shape" to which Lointier refers is the kidney-shaped balloon taught by U.S. Patent No. 4,246,893 to Berson (Ex. 2009.), U.S. Patent No. 4,416,267 to Garren (Ex. 2010), Foster (Ex. 1006), and U.S. Patent No. 5,259,399 to Brown (Ex. 2011) (illustrated below), which was prolific in the decades preceding Lointier's filing date (2001). The Garren balloon was in clinical use in the 1980s. (Ex. 1015.)



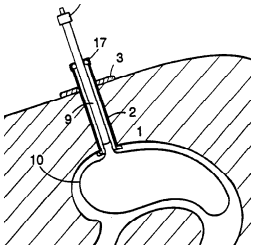
Berson (1978)



Garren (1981)



Foster (1982)



Brown (1992)

To solve this problem, Lointier proposes a concentric balloon system having an overall spherical shape which makes contact with the stomach wall over a smaller, circumferential area and having an outer surface that includes facets or cells which create channels through which food may pass. (Ex. 1011 pp. 14, 18, 26-27.) This design "minimiz[es] the total area of contact between the gastric wall 30 and the balloon 1" and thereby increases the contact force between the stomach wall and the implant. (*Id*. p. 26.) That, in turn, "serves to increase the probability of peripheral zones of contact with the stomach walls of the patient" and "increases the possibility and the probability of impeding the passage of food on a durable basis, thereby also tending to prolong the sensation of being sated." (*Id*. p. 14.)

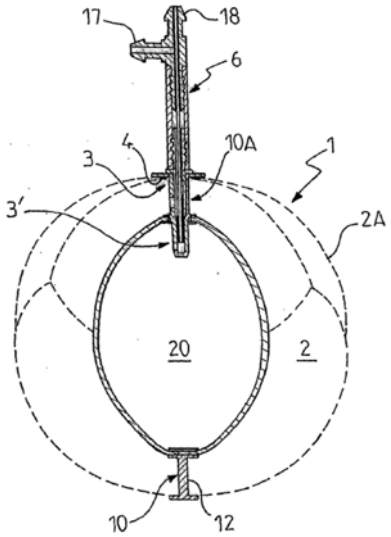


FIG. 2

In sum, Lointier's design solved the perceived problems by 1) providing a multi-chamber device to ***allow one chamber to be filled with air, reducing the overall device weight***, and 2) ***minimizing the total area of contact between the gastric wall and the balloon***, which improves the contact or seal between the wall and the balloon.

Turning now to the Burnett reference, Burnett in its background section identifies problems with space occupying devices like Lointier. Burnett reviewed a variety of obesity treatments such as surgical reduction of gastric volume or installation of implants adjacent the pyloric valve to slow the passage of food from the stomach into the small intestine. (Ex. 1012 ¶¶8-11.) Burnett specifically discussed the Geitz device described in U.S. Patent No. 6,755,869 (Ex. 2012, "Geitz"), shown at right, and explained that such devices have an "an unacceptably serious risk of collapsing, passing through the stomach, and lodging somewhere in the intestines, thus causing a serious and potentially fatal intestinal blockage." (Ex. 1012 ¶8, referring to Geitz, Ex. 2012.)

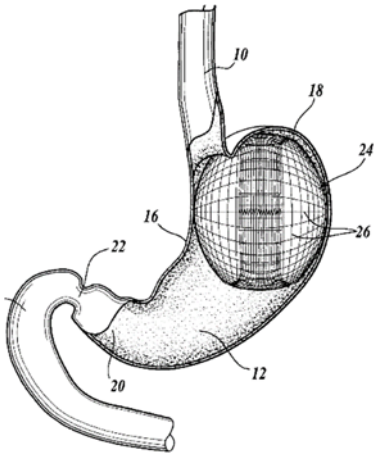
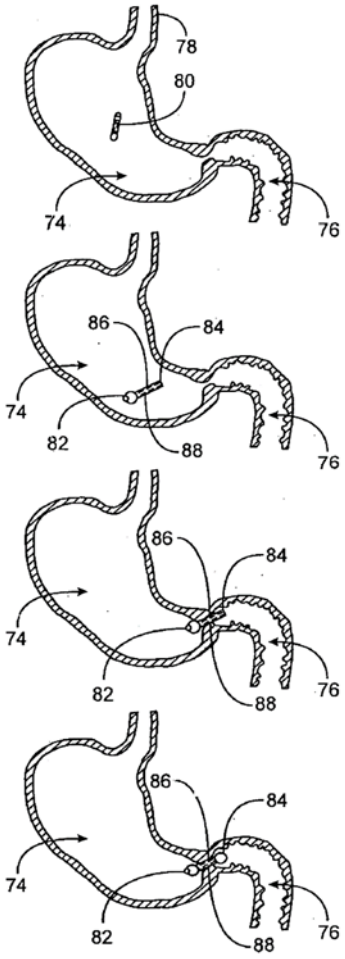


Fig. 1.

To avoid this problem, Burnett's pyloric valve plug is not meant as a space-filling device but simply a "cork" for the pyloric valve which is designed to "partially and/or intermittently obstruct a gastric opening, particularly the pyloric valve." (Ex. 1012 ¶63.) This ensures that the "contents of the stomach (i.e., food) are retained longer in the stomach, thus causing a patient to feel full sooner and longer, and thus leading to reduced food intake and weight loss." (*Id.* ¶12.)

The petition relies on the embodiment shown in Burn's Figure 8. (Paper No. 2 pp. 28-29; Ex. 1012.) This embodiment involves device 80 which is simply ingested. (Ex. 1012 ¶81.) The stomach acids erode a coating over occlusion member 82, which then "expand[s] or inflate[s]" as shown in Fig. 8B. (*Id*.) The cited passage of Burnett does not indicate how the expansion occurs, but earlier portions of the specification indicate that this may be accomplished by self-expanding foams or a self-expanding wire mesh of shape memory alloy such as Nitinol. (*Id*. ¶¶64-65.) The same process occurs with the occlusion member 84, which secures the device in place in a position bridging the pyloric valve. (*Id*. ¶81.)



In sum, Burnett proposes to overcome the deficiencies of air or liquid filled balloons (which have "an unacceptably serious risk of collapsing" and becoming lodged in the in the intestines) by using an expansion or inflation medium that is not subject to spontaneous deflation, such as self-expanding foam or self-expanding shape memory alloy mesh.

The Petition urges that "[a] POSITA would have been motivated to space the balloons of Lointier apart from one another on [Lointier's] common connection means 10A, as depicted in Burnett, the resulting modified Lointier device would not pass through the pyloric valve even if one of the balloons deflated." (Paper No. 2 p. 29, citing Ex. 1013 ¶ 131.) The cited paragraph of the Alverdy declaration asserts that "[a]s described in Lointier, the balloons could be disposed adjacent on the connection means, instead of one balloon inside the other." (Ex. 1013 ¶ 131, citing Ex. 1010 at p. 9, ll. 20-22). Alverdy concludes that "a POSITA would have been highly motivated to incorporate the foregoing teaching of Burnett into Lointier by spacing the balloons of Lointier apart on the flexible common connection means 10A." (Ex. 1013 ¶ 131.)

However, Lointier nowhere teaches that the balloons may be spaced side by side on a common connection member. Rather, Lointier teaches that "[i]n a first variant embodiment (not shown), 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." (Ex. 1011 p. 10.) In this embodiment, which is described in only this single sentence, there is no mention of a connection member. Rather, the two balloons share a common face or wall such that the balloon is formed by the "combination of two pouches." (*Id.*)

Returning to Alverdy, he posits that spacing Lointier's balloons apart from one another on a common connection member would provide the benefit that the "modified Lointier device would not pass through the pyloric valve even if one of the balloons deflated." (Ex. 1013 ¶ 131.) No other motivation is provided for combining the references in this respect.

B. The Petition Fails to Explain How Lointier Would be Modified to Achieved the Claimed Invention

As noted above, Lointier does not teach that the balloons may be spaced apart on member 10A. Rather, Lointier teaches in a single sentence that, in one variation, the two balloons share a common face or wall such that the balloon is formed by the combination of two pouches. (Ex. 1011 p. 10.)

As also noted above, the embodiment of Burnett relied upon in the petition does not involve inflation of the occlusion members 82 and 84. (Ex. 1012 ¶ 81.) To the contrary, Burnett uses self-expanding materials which expand when a coating has been eroded by stomach acids. (*Id*. ¶¶14-16.) Indeed, Burnett specifically counsels against inflation of the occlusion members.

Notwithstanding the foregoing deficiencies, neither Petitioner nor Dr. Alverdy explains how the modified Lointier device would be constructed. Alverdy merely posits that the "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 modified Lointier device would not pass through the pyloric valve even if one of the balloons deflated" without explaining how this would be accomplished. (Ex. 1013 ¶131.)

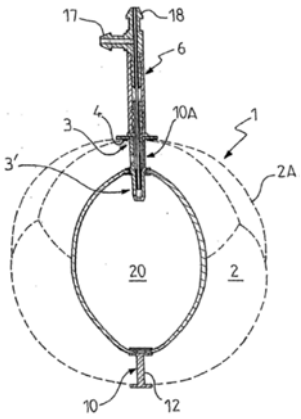


FIG. 2

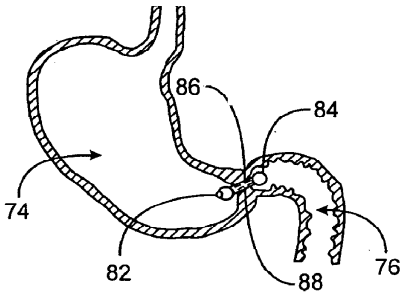


FIG. 8D

The Board is left to extrapolate how exactly the balloons would be supported, interconnected and inflated. While the Lointier balloons are supported at both ends, Petitioner does not provide even a proposal as to how the far ends of the balloons would be supported. If they are supported at their far ends, how it that accomplished? Would an inflation lumen pass through one or both of the balloons? Would the balloons instead be inflated by some port positioned on the exposed cylindrical side of connection means 10A? If so, how would the device be introduced down the esophagus of the patient? Would the connection means 10A be introduced sideways and, if so, how would that be possible? If the connection means is to be introduced lengthwise, how would the inflation catheter be connected

to the connection member 10A? Would the smaller, inner balloon of Lointier be reconfigured or resized in order contact the stomach walls?

Petitioner has not even attempted to address any of these questions, which are fundamental to understanding the structure and operation of the proposed modified system. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also KSR*, 550 U.S. at 418, 82 USPQ2d at 1396. Here, Petitioner merely asserts that the balloons in Lointier could be disposed on connection member in some unarticulated way. This is insufficient to support a conclusion of obviousness.

C. Lointier Urges that Contact Area with the Stomach Wall Should be Minimized, which Runs Counter to the Proposed Modification

As noted above, Lointier addressed the 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. (Ex. 1011 p. 26.) Lointier taught that the balloon should contact the stomach wall only around the periphery of single sphere so that the modulation of food

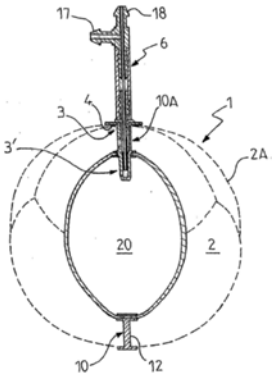


FIG. 2

passage was controlled by the channels or grooves patterned into the external balloon surface. (*Id*. pp. 14, 18, 26-27.)

In the proposed modification of Lointier, the contact area would presumably be increased by providing a separate balloon spaced apart from the first balloon. Thus, the dual balloon system would contact the stomach wall along the circumference of two balloons rather than one, which would double the contact area.[4] 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). *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir. 1984) (A person of ordinary skill generally would not be motivated to modify a reference by contradicting its basic teachings . . . or by making it "inoperable for its intended purpose.").

[4] The petition is silent on the size of the balloons and whether or how they contact the stomach wall. However, as discussed above, a balloon which does not contact the stomach wall would cut directly against the teachings of Lointier.

D. Lointier Urges that the Device Should Be "Particularly Well Balanced", which also Runs Counter to the Proposed Modification

Lointier teaches than an "object of the invention seeks to propose a novel intra-gastric balloon which is particularly well balanced while it is being expanded radially, and which is easy to implant." (Ex. 1011 p. 4.) Lointier accomplishes this by providing concentric balloons, which ensures that the device will be balanced evenly. While Lointier does mention in a single sentence an alternative embodiment in which two pouches are connected along a common face (Ex. 1011 at 10), this structure would at least keep the air-filled balloon and liquid filled balloon in tight proximity which would in turn help keep the device balanced.

If the balloons were spaced apart from one another, the device would become relatively unbalanced, which would defeat one of Lointier's primary objectives. Again, a POSITA would generally not attempt such a combination. *In re Gordon*, 733 F.2d at 902.

E. Lointier Already Serves the Function Purportedly Accomplished by the Proposed Modification

The sole "motivation" identified by Petitioner for the proposed modification of Lointier is that spacing Lointier's balloons apart from one another on a common connection member would provide the benefit that the "modified Lointier device

would not pass through the pyloric valve even if one of the balloons deflated." (Ex. 1013 ¶ 131.)

However, the unmodified Lointier device already serves this function. If the outer balloon deflates, the inner balloon is of ample size to prevent the passage of the device through the pyloric valve. Likewise, if the inner balloon were to deflate, the volume of the fluid held between the two balloons appears to be sufficient to prevent passage of the balloon through the pyloric valve.

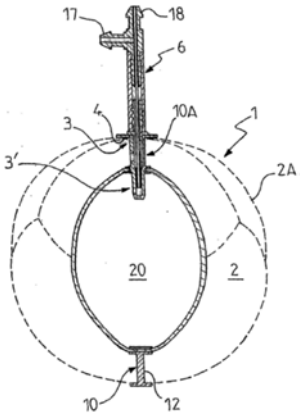


FIG. 2

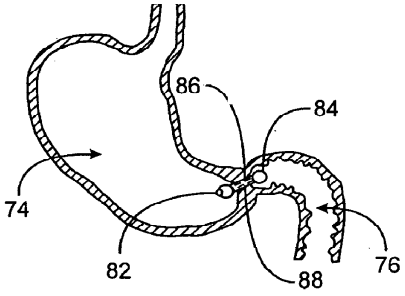


FIG. 8D

Petitioner does not explain how spacing the balloons of Lointier apart on connection means 10A would improve its functionality in this regard. There must be some apparent reason or advantage associated with modifying the prior art – if the prior art already serves the function in question then achieving that function cannot serve as a motivation to modify the device. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

F. A POSITA Would Not Attempt to Combine Lointier with Burnett because Burnett Specifically Cautions Against Use of Fluid-Filled Free-Floating Balloons Such as Those Taught in Lointier

As mentioned above, Burnett specifically teaches that fluid-filled balloons have an "an unacceptably serious risk of collapsing, passing through the stomach, and lodging somewhere in the intestines, thus causing a serious and potentially fatal intestinal blockage." (Ex. 1012 ¶ 8, referring to Geitz, Ex. 2012.) To solve this problem, Burnett uses inflation or expansion means which are not subject to deflation such as self-expanding foams and self-expanding shape memory alloys. (Ex. 1012 ¶ 15.) Burnett also relies not upon space-filling but rather providing a "cork" for the pyloric valve which is designed to "partially and/or intermittently obstruct a gastric opening, particularly the pyloric valve." (Ex. 1012 ¶ 63.)

Petitioner does not explain why a POSITA would take two references which work on fundamentally different operational principles and selectively combine their features in the manner proposed. A POSITA seeking to improve upon a fluid-filled balloon system such as that of Lointier would not look to art which attempted to address the problem in a fundamentally different way (*i.e.*, by blocking the pyloric valve with non-deflatable occlusion members 82 and 84).

G. A Skilled Artisan Would Not Have Considered Jambor or Gottschalk in Developing the Resulting Device of Petitioner's Combination of Lointier and Burnett

As discussed above in Section IV.C, a skilled artisan would not have looked to the non-analogous art of Jambor or Gottschalk for teachings appropriate to inflating a gastric balloon via the esophagus. In relation to the dependent claims of the '915 patent, the relevant problem is designing "a valve mechanism or assembly to permit selective inflation [of multiple inflatable compartments] with liquid fluids, gaseous fluids, or a combination thereof" using one or more inflation tubes which are deployed transesophageally while avoiding interference with device deployment and then detached such that "the inflation medium remains contained for extended periods of time" of free-floating deployment. (Ex. 1001 at 11:14-18, 12:1-12, 21:30-36.) The Gottschalk device, requiring a needle to activate separate valves, would not be practical in the device claimed by the '915 patent in which the chambers must be inflated via the esophagus while situated in the gastric cavity, far from the reach of a syringe and awkward to align with any hypodermic needle. Conversely, the fluid supply tube of the Jambor device is permanently connected to the gastric band 20 and reachable through a "remotely located fluid injection port" which is "secured subcutaneously in the abdomen or other suitable location." (Ex. 1008 ¶¶ 21, 24-27.) Neither Gottschalk nor Jambor describes a usable alternative to the connection

means 3 and 3' and orifices 4 and 4' of Lointier provided for inflating the concentric pouches 2 and 20. (Ex. 1011 p. 11.)

VI. GROUND III: LOINTIER, FOSTER LAI, AND JAMBOR OR GOTTSCHALK DO NOT RENDER OBVIOUS CLAIMS 1-30

A skilled artisan could not achieve a gastric balloon structure meeting independent claim 1, 12, or 19 through the combination of Lointier, Foster, Lai and Jambor or Gottschalk, nor would one of skill in the art be motivated to combine these references in the manner described in the Petition.

Each of Lointier and Foster teaches a single balloon designed for filling the stomach to provide satiety. Foster, as discussed above, discloses a single chamber that is kidney-shaped to follow the shape of the gastric cavity. As illustrated in FIG. 2, reproduced at right, Lointier describes an intra-gastric balloon 1 having two separate and independent pouches, one disposed internally to the other, which can be filled with two separate fluids of differing densities. (Ex. 1011 p. 9 (Ex. 1010 p. 8 l. 17 – p. 9 l. 3).) Petitioner's proposed combination uses improper hindsight to match the structural elements of Lointier to the features of the independent claims, a task which would require significant redesign and experimentation to pursue and which renders Lointier's device inoperable for its intended purposes.

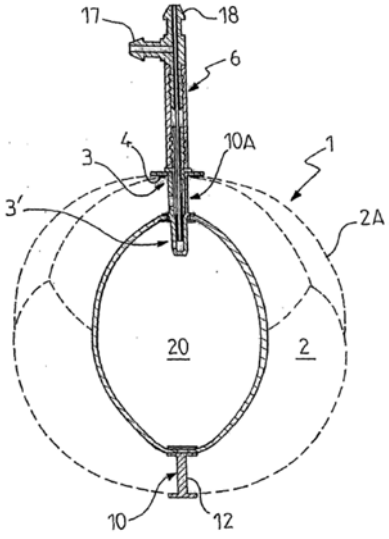


FIG. 2

A. The Proposed Combination of Lointier and Foster

In the proposed mapping of the claim language to the combination as set forth by Alverdy, Foster is only relied upon for motivation and general shape, while all structural elements of independent claims 1, 12 and 19 are taken from Lointier. (Ex. 1013 ¶¶ 174-85, 197-200, 205-10.) Petitioner and Alverdy propose modifying Lointier's construction to bring the second pouch 20 external to the main pouch 2 and tethered to the main pouch 2 by the spacer, while adjusting the shapes and sizes of pouches 2 and 20 to mimic the kidney-shaped design of Foster. (Paper No. 2 pp. 48-49; Ex. 1013 ¶¶ 174-185.)

The Petition asserts that "[a] POSITA would consider it a mere design expedient to space the Lointier balloons further apart on common connection means 10A to prevent the intragastric device from passing entirely through the pyloric valve if one balloon became deflated. (Ex. 1013 ¶¶ 176-80.) A POSITA reading Lointier also would have understood that if one pouch of Lointier were deflated, the other pouch would remain inflated." (*Id*.) The Alverdy declaration parrots this same rationale and adds that the elastomeric connection means 10A would not injure the duodenum in the event one of the balloons deflated and the connection means was drawn through the pyloric valve. (*Id*. ¶¶177-78.)

B. The Petition Again Fails to Explain How Lointier Would Be Modified to Achieve the Claimed Invention

As 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. While the Lointier balloons are supported at both ends, Petitioner does not provide even a proposal as to how the far ends of the balloons would be supported. If they are supported at their far ends, how it that accomplished? Does a lumen pass through to the far ends of the balloon? If there is a single point of contact between each balloon and the connection means 10A, is that sufficiently stable to remain leak-free and not cause a tear in the balloon? How is the inflation and deployment of the balloons accomplished? If the inflation is accomplished at the portion of the connection means 10A bridging between the balloons, is the device inserted sideways through the esophagus? Is the size of the second balloon modified to match the first? What is the mechanism of provision of the feeling of satiety? Is it space-filling, food modulation, or both?

Because the petition does not even attempt to address any of these issues, it fails to set forth articulated reasoning with sufficient rational underpinning to support the legal conclusion of obviousness. *KSR*, 550 U.S. at 418 ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements.")

C. Lointier Counsels Against the Proposed Modification for the Same Reasons Discussed Above in Connection with Ground II

As explained above, Lointier counsels against the provision of spaced-apart, adjacent balloons because i) it teaches that contact area with the stomach wall should be minimized, ii) it teaches that the device should be well-balanced, and iii) it already provides the benefit of prevention of pyloric valve passage if a single balloon deflates.

Lointier addressed the 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. (Ex. 1011 p. 26.) Lointier taught that the balloon should contact the stomach wall only around the periphery of the single sphere to control food passage modulation by the channels or grooves patterned into the external balloon surface. (*Id.* pp. 14, 18, 26-27.)

In the proposed modification of Lointier, the contact area would presumably be increased by providing a separate balloon spaced apart from the first balloon. Thus, the dual balloon system would contact the stomach wall along the circumference of two balloons rather than one, which would double the contact

area.[5] 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.) *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir. 1984) (A person of ordinary skill generally would not be motivated to modify a reference by contradicting its basic teachings . . . or by making it "inoperable for its intended purpose.")

Lointier teaches than an "object of the invention seeks to propose a novel intra-gastric balloon which is particularly well balanced while it is being expanded radially, and which is easy to implant." (Ex. 1011 p. 4.) Lointier accomplishes this by providing concentric balloons, which ensures that the device will be balanced evenly. While Lointier does mention in a single sentence an alternative embodiment in which two pouches are connected along a common face (Ex. 1011 p. 10), this structure would at least keep the air-filled balloon and liquid filled balloon in tight proximity which would in turn help keep the device balanced. If the balloons were spaced apart from one another, the device would become relatively unbalanced,

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[5] The petition is silent on the size of the balloons and whether or how they contact the stomach wall. However, as discussed above, a balloon which does not contact the stomach wall would cut directly against the teachings of Lointier.

which would defeat one of Lointier's primary objectives. Again, a POSITA would generally not attempt such a combination. *In re Gordon*, 733 F.2d at 902.

The sole motivation identified by Petitioner for the proposed modification of Lointier is that spacing Lointier's balloons apart from one another on a common connection member would provide the benefit that the "modified Lointier device would not pass through the pyloric valve even if one of the balloons deflated." (Ex. 1013 ¶131.) However, the unmodified Lointier device already serves this function. If the outer balloon deflates, the inner balloon is of ample size to prevent the passage of the device through the pyloric valve. Likewise, if the inner balloon were to deflate, the volume of the fluid held between the two balloons appears to be sufficient to prevent passage of the balloon through the pyloric valve.

Petitioner does not explain how spacing the balloons of Lointier apart on connection means 10A would improve its functionality in this regard. For that reason, the Petitioner's alleged motivation to combine is conclusory and lacks the rationale underpinning necessary to support a conclusion of nonobviousness. *KSR*, 550 U.S. at 418 ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

D. Petitioner Relies Upon Hindsight to Modify the Structure and Function of the Prior Art to Meet the Language of the Independent Claims

"The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims … is not by itself sufficient to support a finding of obviousness." *Ex parte Chicago Rawhide Mfg. Co*., 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). "Without any explanation as to how or why the references would be combined to arrive at the claimed invention, we are left with only hindsight bias that KSR warns against." *Metalcraft of Mayville, Inc. v. The Toro Co*., 848 F.3d 1358, 1367 (Fed. Cir. 2017) (citing *KSR at* 167). Metalcraft further counseled that "we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." (*Id*.)

There is no reason save hindsight to remove Lointier's inner pouch 20, relocate the connection means 10A such that it extends outwardly from the outer pouch, and then re-attach the inner pouch in some manner to the connection means 10A. Neither Petitioner nor Alverdy cite any teaching ***in the prior art*** which would motivate such a dramatic redesign of the Lointier device. Rather, the petition asserts essentially that this modification ***could be made*** and that doing so would be merely a "design expedient." (Paper No. 2 p. 48.) Petitioner's failure to provide any

meaningful detail as to how the resultant device would be structured is yet a further indication that the petition impermissibly relies on hindsight.

E. A Skilled Artisan Would Not Have Considered Jambor or Gottschalk in Developing the Resulting Device of Petitioner's Combination of Lointier and Foster

As discussed above in Section IV.C, a skilled artisan would not have looked to the non-analogous art of Jambor or Gottschalk for teachings appropriate to inflating a gastric balloon via the esophagus. In relation to the dependent claims of the '915 patent, the relevant problem is designing "a valve mechanism or assembly to permit selective inflation [of multiple inflatable compartments] with liquid fluids, gaseous fluids, or a combination thereof" using one or more inflation tubes which are deployed transesophageally while avoiding interference with device deployment and then detached such that "the inflation medium remains contained for extended periods of time" of free-floating deployment. (Ex. 1001 at 11:14-18, 12:1-12, 21:30-36.) The Gottschalk device, requiring a needle to activate separate valves, would not be practical in the device claimed by the '915 patent in which the chambers must be inflated via the esophagus while situated in the gastric cavity, far from the reach of a syringe and awkward to align with any hypodermic needle. Conversely, the fluid supply tube of the Jambor device is permanently connected to the gastric band 20 and reachable through a "remotely located fluid injection port" which is "secured

subcutaneously in the abdomen or other suitable location." (Ex. 1008 ¶¶ 21, 24-27.) Neither Gottschalk nor Jambor describes a usable alternative to the connection means 3 and 3' and orifices 4 and 4' of Lointier provided for inflating the concentric pouches 2 and 20. (Ex. 1011 p. 11.)

VII. CONCLUSION

For at least the reasons discussed above, the claims of the '915 patent have not been shown to be obvious. The prior art fails to teach critical claim elements and a skilled artisan would find no motivation to combine the prior art references. Moreover, because Petitioner was required to name ReShape Lifesciences as a real party in interest and failed to do so within the requisite timeframe, ReShape Medical's petition cannot be considered under 35 U.S.C. § 312(a)(2).

Respectfully submitted,

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Date: August 8, 2018

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WORD COUNT CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24 (d), I hereby certify that the foregoing Patent Owner Preliminary Response Brief to *Inter Partes* Review contains 11,863 words as measured by the word processing software used to prepare the document. This total does not include the table of contents, the table of authorities, the caption page, the table of exhibits, any signature blocks, the certificate of service, or this certificate of word count.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies service of this PATENT OWNER PRELIMINARY RESPONSE and EXHIBITS 2001-2014 on the counsel of record for the Petitioner by filing this document through the PTAB E2E System as well as delivering a copy via electronic mail to the following address(es):

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