Filed on behalf of Atrium Medical Corporation
By: David L. Cavanaugh, Reg. No. 36,476
Larissa Park, Reg. No. 59,051
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
Tel: (202) 663-6025
Email: David.Cavanaugh@wilmerhale.com
Larissa.Park@wilmerhale.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATRIUM MEDICAL CORPORATION
Petitioner

v.

Patent Owner of
U.S. Patent No. 7,785,334 to Ford et al.

IPR Trial No. TBD

PETITION FOR *INTER PARTES REVIEW* OF CLAIMS 99-126 OF U.S. PATENT NO. 7,785,334 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

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I. MANDATORY NOTICES

A. Real Parties-in-Interest

Atrium Medical Corporation ("Petitioner") is the real party-in-interest and submits this *inter partes* review Petition ("Petition") for review of certain claims of U.S. Patent No. 7,785,334 (the "'334 patent").

B. Related Matters

The following litigation matter would affect or be affected by a decision in this proceeding: *Davol, Inc. v. Atrium Medical Corp.*, No. 1:12-cv-00958 (D. Del. filed July 20, 2012). Davol, Inc. is a subsidiary of the Assignee of record C.R. Bard, Inc. ("BARD"). The litigation involves three patents: the '334 patent, U.S. Patent No. 7,806,905 (the "'905 patent"), and U.S. Patent No. 7,824,420. The '334 patent and the '905 patent share a common parent. Claims 99-126 of the '334 patent are the subject of this Petition. Three separate *inter partes* review petitions, filed concurrently, will address (i) claims 1-23 and 78-98 of the '334 patent (ii) claims 24-49 of the '334 patent, and (iii) claims 50-77 of the '334 patent. Two other *inter partes* review petitions, also filed concurrently, will address the claims of the '905 patent. Because the technology and disclosure in the patents is similar, and for the sake of administrative efficiency and consistent outcome, Petitioner requests that the Patent Trial and Appeals Board ("PTAB") have a single Administrative panel address these *inter partes* reviews.

C. Counsel

Lead Counsel: David L. Cavanaugh (Registration No. 36,476)

Backup Counsel: Larissa B. Park (Registration No. 59,051)

Petitioners request authorization to file a motion for Mr. Wayne Stoner to appear *pro hac vice*. Mr. Stoner has over 22 years of experience as a patent litigator in this technology and has worked with the Petitioner on patent litigation matters for 21 years. As such, Mr. Stoner is experienced and has an established familiarity with the technology that is at issue in this proceeding. Petitioners request authorization to file a motion seeking admission of Mr. Stoner to appear *pro hac vice*.

D. Service Information

Email: David.Cavanaugh@wilmerhale.com

Post and hand delivery: Wilmer Cutler Pickering Hale and Dorr LLP

1875 Pennsylvania Ave, NW

Washington, DC 20006

Telephone: 202-663-6025 Facsimile: 202-663-6363

II. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies, pursuant to Rule 42.104(a), that the patent for which review is sought is available for *inter partes* review and that Petitioner is not

barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

III. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104 (b)(1)-(2), Petitioner challenges claims 99-126 of the ’334 patent (Ex. 1301). As noted above, three other *inter partes* review petitions that address (i) claims 1-23 and 78-98 , (ii) claims 24-49, and (iii) claims 50-77 of the ’334 patent have been filed concurrently.

A. Prior Art Patents and Printed Publications

Petitioner relies upon the following patents and printed publications:

1. U.S. Patent No. 5,258,000 (“Gianturco”; Ex. 1302), which issued on November 2, 1993, and is prior art to the ’334 patent under 35 U.S.C. § 102(b).
2. U.S. Patent No. 5,496,345 (“Kieturakis”; Ex. 1303), which has a priority date of June 2, 1992, and is prior art to the ’334 patent under 35 U.S.C. § 102(b).
3. U.S. Patent Application Publication No. 2002/0103494 (“Pacey”; Ex. 1304), which was published on August 1, 2002, was filed on January 30, 2002, has a priority date of January 31, 2001, and is prior art to the ’334 patent under 35 U.S.C. § 102(a) and (e).

4. International Publication No. WO 02/022047 ("Cherok"; Ex. 1305), which was published on March 21, 2002, and is prior art to the '334 patent under 35 U.S.C. § 102(e).
5. Patent Owner April 12, 2001 Webpage "Composix Kugel Hernia Patch," which is available from the Internet Archive at http://web.archive.org/web/20010412200712/http:/davol.com/kugcomp.htm ("Kugel Patch"; Ex. 1306) and which is prior art to the '334 patent under 35 U.S.C. § 102(b).
6. Patent Owner 510(K) No. K003323 Summary of Safety and Effectiveness for the Composix E/X Mesh (submitted to the Food and Drug Administration ("FDA") on October 23, 2000, and approved by FDA on January 22, 2001) ("Composix Kugel Mesh 510(K)"; Ex. 1307), which is prior art to the '334 patent under 35 U.S.C. § 102(b).
7. U.S. Patent No. 5,545,178 ("Kensey '178"; Ex. 1308), which issued on August 13, 1996, and is prior art to the '334 patent under 35 U.S.C. § 102(b).
8. Patent Owner 510(K) No. K021736 Summary of Safety and Effectiveness for the Ventralex Patch (submitted to the FDA May 23, 2002 and approved by FDA on July 16, 2002) (the "Ventralex Patch

510(K)"; Ex. 1309), which is prior art to the '334 patent under 35 U.S.C. § 102(a).

9. Patent Owner Instructions for Use of the Ventralex Patch (submitted to the FDA May 23, 2002) (the "2002 Ventralex Instructions"; Ex. 1310), which is prior art to the '334 patent under 35 U.S.C. § 102(a).
10. Irving A. Knight & Gordon Brown, *The Repair of Large Incisional Hernias*, 108 Calif. Med. 96 (1968) ("Knight"; Ex. 1319), which is prior art to the '334 patent under 35 U.S.C. § 102(b).
11. U.S. Patent No. 5,593,441 ("Lichtenstein"; Ex. 1320), which issued on January 14, 1997, and is prior art to the '334 patent under 35 U.S.C. § 102(b).

B. Grounds for Challenge

Petitioner requests cancellation of claims 99-126, the challenged claims, as unpatentable under 35 U.S.C. § 102 and § 103.

This Petition, supported by the declaration of Dr. Adrian Park ("Park Declaration" or "Park Decl."; Ex. 1316) filed with this Petition, demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited in this petition. *See* 35 U.S.C. § 314(a).

IV. LEGAL PRINCIPLES

The challenged claims are unpatentable based on anticipation and obviousness under 35 U.S.C. sections 102 and 103, respectively. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1977); *see also Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001) ("When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.").

Even if the claimed invention is not anticipated under 35 U.S.C. § 102, the claim is invalid if it would have been obvious—that is,

> if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which [the] subject matter pertains.

35 U.S.C. § 103; *see also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1364 (Fed. Cir. 1998).

In *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 415 (2007), the U.S. Supreme Court addressed the issue of obviousness and provided an "expansive and flexible" approach that is consistent with the "broad inquiry" set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). According to the Supreme

Court, a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton," *KSR*, 550 U.S. at 421, and "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle," *id.* at 420. The Court held that

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421. Thus, *KSR* focused on whether a combination of known elements could be patentable if it yielded predictable results. The Court's guidance was clear: it may not. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. Further, "[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

The Board must ask, as guided by *KSR*, whether the challenged claims recite an improvement that is "more than the predictable use of prior art elements according to their established functions." *Id.* at 417. The Board should conclude, based on the information in this Petition, that the challenged claims are merely a

predictable combination of known elements that are used according to their established functions, and that they are therefore unpatentable.

V. CLAIM CONSTRUCTION

In an *inter partes* review proceeding, the claim terms should be given their "broadest reasonable construction[s] in light of the specification." 37 C.F.R. § 42.100(b). The claim terms can be understood by their plain and ordinary meanings, except where construed in the specification. In construing the claims, "adapted to" clauses that do not require steps to be performed or limit a claim to a particular structure are satisfied by prior art that is capable of or suitable for being used in the recited manner. *See* MPEP § 2111.04.

VI. OVERVIEW OF THE '334 PATENT

A. Brief Description

The application that issued as the '334 patent (Ex. 1301) was filed on August 23, 2006, and is a continuation of U.S. Patent No. 7,101,381 (the "'381 patent"), which was filed on August 2, 2002.

The '334 patent describes an implantable prosthesis for repairing an anatomical defect, such as a tissue or muscle wall hernia. *See, e.g.*, '334 patent abstract (Ex. 1301). A prosthesis is an artificial body part used to replace or repair tissue. *See* Park Decl. ¶ 20 (Ex. 1316). A hernia occurs when an organ projects

through tissue (usually muscle) that would normally contain it.[1] *Id.* ¶ 20 (Ex. 1316). As described and claimed, the prosthesis of the '334 patent includes two components: (1) a patch having two mesh layers, a barrier layer, and a reinforcing/support member; and (2) one or more positioning tethers or straps that are long enough to extend from the patch through the defect and that may be manipulated by the surgeon from outside the body to position the patch relative to the repair site or to secure the patch relative to the opening in the muscle wall. *See, e.g.*, '334 patent 4:50-57 (Ex. 1301). Figures 1 and 7 (reproduced above) illustrate the prosthesis (21) described in the '334 patent, including a patch (22), a support member (98), and a positioning tether or strap (24). *See, e.g.*, *id.* 6:12-37 (Ex. 1301).

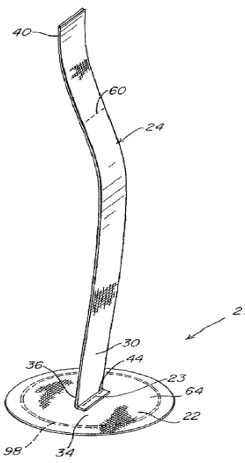


Fig. 1

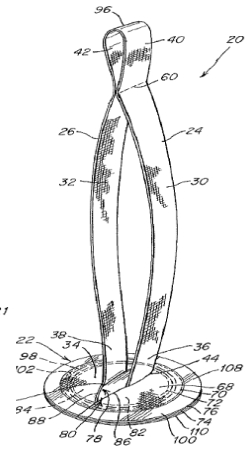


Fig. 7

[1] There are several types of hernias. *See* Park Decl. ¶¶ 16-18 (Ex. 1316), citing Ex. 1311, Ex. 1312, Ex. 1313, Ex. 1314, and Ex. 1315. Additional relevant background information related to hernias, hernia repair and laparoscopic hernia repair techniques is in these references, and also in Ex. 1324 and Ex. 1325. *See* Park Decl. ¶ 11 (Ex. 1316).

None of these components of the prosthesis is new. The patch itself is merely the Patent Owner's own prior art, as evidenced by, for example, the Kugel Patch (Ex. 1306) and the Composix Kugel Mesh 510(K) (Ex. 1307). BARD offers a product called the VENTRALEX™ Hernia Patch ("Ventralex") that corresponds to the prosthesis in the '334 patent. In submissions to the FDA in 2002, which anticipate claims 99-126, the Patent Owner admitted that Ventralex was a successor to and substantially equivalent to the BARD Composix Kugel Mesh product, and that Ventralex simply amounts to the prior art Composix Kugel Hernia Patch and Composix Kugel Mesh products with the addition of a strap. *See* Ventralex Patch 510(K) § F (Ex. 1309); *see also* 2002 Ventralex Instructions (Ex. 1310).

As shown by the Exhibits and the Park Declaration, the claimed patch with one or more tethers extending from the patch through the defect for manipulating the patch from outside the body was known to those of ordinary skill in the art.

B. Summary of the Prosecution History of the '334 Patent

During prosecution of the '334 patent, the Examiner issued an office action rejecting the pending claims. *See* '334 Patent File History, Feb. 17, 2010 Office Action, Summary (Ex. 1318). The Patent Owner filed a response and held an in-person interview with the Examiner, at which the Patent Owner agreed that "the claims would be amended to include functional language directed to the extension

of the anchoring strap through an abdominal wall defect." '334 Patent File History, Apr. 6, 2010 Interview Summary at 1 (Ex. 1321).

On April 12, 2012, the Applicants submitted a supplemental response amending all independent claims to recite the following (or a substantially similar) limitation:

> the at least one positioning strap having a length sufficient, when the patch is on one side of the defect, to extend through the abdominal wall defect, so that a portion thereof is on the other side of the defect and is adapted to be manipulated to position the patch relative to the defect.

See '334 Patent File History, Apr. 12, 2010 Suppl. Amend. at 5 (claim 76) (Ex. 1322). The Examiner subsequently allowed the pending claims based on the addition of this language. '334 Patent File History, June 25, 2010 Notice of Allowance (Ex. 1323).

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The challenged claims recite features long known by clinicians in the field of hernia surgery. *See* Park Decl. ¶ 27 (Ex. 1316). The purported invention is a known combination of features, all of which (including the combination itself) were old and well known to those skilled in the art before and at the time to which the '334 patent claims priority. *See id.* (Ex. 1316). In the claimed combinations, the structures all have known functions that perform in expected ways. *See id.* (Ex.

1316). Based on the prior art cited above and described below, the claimed limitations of the alleged invention perform known functions with an expected result. *See id.* (Ex. 1316).

The prior art falls into three categories: (1) prior art references that anticipate and/or render obvious independent claim 99 (the "Primary References"); (2) prior art references other than the Primary References that disclose or make obvious all of the claimed aspects of the patch (the "Patch References"); and (3) prior art references other than the Primary References that disclose or make obvious all of the aspects of the claimed "straps" or "tethers" (the "Tether References"). The Tether References also teach, make obvious, and provide one of ordinary skill in the art with ample reason and motivation to add a strap or tether to a hernia patch.

A. The Primary References

The Primary References, each of which anticipates and/or renders obvious independent claim 99, include Pacey (Ex. 1304), Kieturakis (Ex. 1303), and Gianturco (Ex. 1302).

Pacey discloses a hernia patch prosthesis with an adherence-provoking polypropylene mesh layer that is attached to an adhesion-resistant barrier layer; a metal or plastic frame of concentric circles supporting these layers; and one or more tethers that may consist of a "fabric element," (Pacey claim 4; Ex. 1304), and

that extend from the surface of the patch through the defect to allow manipulation from outside the body to position or secure the patch relative to the defect. *See, e.g.*, *id.* ¶¶ 17, 30-33, claims 1, 4, 6 (Ex. 1304).

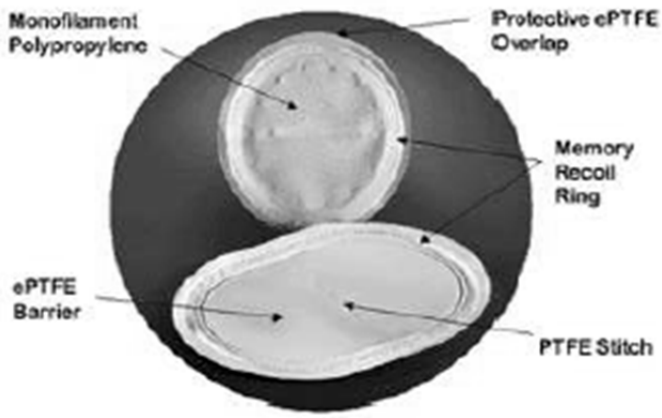
Kieturakis discloses a mesh hernia repair patch with a reinforcing disc that is secured to the top of the patch and an approximately ½-inch-wide strap that is secured to the top of the reinforcing disc. *See* Kieturakis 8:42-61 (Ex. 1303). The strap may be formed of either the same material as the patch or expanded polytetrafluoroethylene ("ePTFE"). *Id.* (Ex. 1303).

Gianturco discloses a hernia patch device having two mesh layers, a barrier layer, a circular elastic stiffener between the two mesh layers, and an affixation suture or suture loop that extends from the patch, passes through the hernial rings, and is adapted to be affixed to the surrounding tissue. *See, e.g.*, Gianturco 2:45-51, 3:10-43, 4:34-48, 5:25-33, 8:45-68 (Ex. 1302).

B. The Patch References

The Patch References, which disclose and/or render obvious all of the "patch" limitations of the challenged claims, include the Kugel Patch (Ex. 1306) and Cherok (Ex. 1305), as well as the Primary References. The Patch References describe the prior art hernia patch products, including multi-layer hernia patches made of the same materials as those disclosed and claimed in the '334 patent.

The ***Kugel Patch*** (Ex. 1306) describes the "Bard® Composix® Kugel™ Hernia Patch" product. This reference was available on the Patent Owner's website at least as early as April 12, 2001.[2] The webpage describes the Patent Owner's product (above) as:



> constructed of a double layer of monofilament polypropylene . . . [and] a barrier of ePTFE. The patch also contains a patent-protected "memory recoil ring," which causes the patch to spring open and maintain its shape during placement.

Kugel Patch (Ex. 1306).

On October 23, 2000, the Patent Owner filed a premarket notification for Composix Kugel Mesh pursuant to Section 510(K) of the Federal Food, Drug, and Cosmetics Act. This notification included a "510(K) Summary of Safety and Effectiveness" for the Composix Kugel Mesh (***Composix Kugel Mesh 510(K)***). FDA issued a notice of allowance on January 22, 2001. *See* Composix Kugel

[2] Attached as Ex. 1317 is a declaration of authentication by Christopher Butler, Office Manager at the Internet Archive, that the webpage printout is a true and accurate copy of the Internet Archive's records.

Mesh 510(K) (Ex. 1307). The Composix Kugel Mesh is the same product disclosed in the Kugel Patch.

Cherok, which is also owned by the Patent Owner, is directed toward a "prosthesis . . . formed of a biologically compatible, flexible layer of repair fabric suitable for reinforcing tissue or muscle and closing anatomical defects, and a barrier layer" so that the mesh promotes tissue ingrowth while the barrier layer impedes tissue adherence. Cherok 2:6-9 (Ex. 1305). Cherok discloses a prosthesis with a layer of mesh repair fabric, an adhesion-resistant barrier layer, and a peripheral support ring. *See, e.g.*, *id.* 4:5-7, 5:19-20 (Ex. 1305).

C. The Tether References

The Tether References—Knight (Ex. 1319) and Kensey (Ex. 1308), teach a hernia-repair device with one or more tethers that serve the purposes discussed in the '334 patent. These representative references, as well as the Primary References, explicitly teach the feature—a tether long enough to extend from a patch through the abdominal wall defect—that the Examiner apparently did not find in the art.

Published in 1968, ***Knight*** teaches an "old technique for the repair of incisional hernias, but with the use of Marlex mesh" (Knight at 96; Ex. 1019) wherein a plurality of 2 cm-wide mesh tethers are attached to a hernia-repair prosthesis and are adapted to extend through the abdominal wall defect to be tied

together on the other side of the peritoneum. Thus, as early as the 1960's, clinicians were adopting "new" and different material for the repair of hernias. The adoption of new and different material would continue and increase in the 1990s. Knight at 96 (Ex. 1319).

Kensey discloses a hernia-repair device for sealing a tissue opening. *See, e.g.*, Kensey 5:27-33 (Ex. 1308). The ends of a positioning filament (i.e,. tether), which comprises "a very thin flexible member," extend through the puncture and allow the surgeon to position and secure the device to the surrounding tissue. *Id.* 9:34-65 (Ex. 1308).

VIII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Park Declaration show in detail the prior art disclosures that render the challenged claims unpatentable.

A. Independent Claim 99

Challenged claim 99 requires an implantable prosthesis for repairing an abdominal wall defect that includes (a) a patch of biologically compatible material including a first layer; (b) a second layer; (c) a support member located between the first layer and the second layer; and (d) at least one tether including a strap portion extending away from the patch, the strap portion having a cross-section

wider than it is thick and a length sufficient, when the patch is on one side of the defect, to extend through the abdominal wall defect, so that a portion of tether is on the other side of the defect and is adapted for attachment to tissue with an attachment device. The prior art shows all these features.

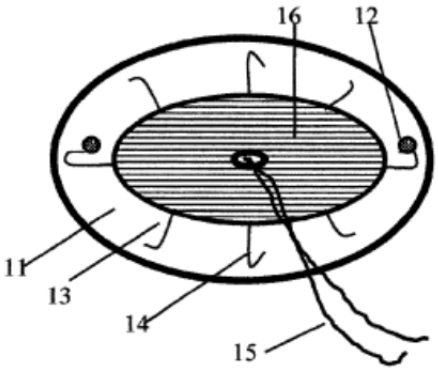
1. Claim 99 Is Anticipated or Obvious over Pacey

As shown in the summary chart below and in the Park Declaration, Pacey anticipates (or itself makes obvious) independent claim 99 of the '334 patent.

a) Claim 99 is Anticipated by Pacey

Claim 99 recites a patch of biologically compatible material including a first layer. Pacey discloses a "nitinol or metal reinforced plastic fabric patch," Pacey abstract (Ex. 1304), wherein the "plastic used must be nonreactive to prevent adhesion formation and an alternate material may be silicon sheet bonded to prolene mesh," *id.* ¶ 17 (Ex. 1304). One surface of the patch may be ePTFE and the opposite surface may be a knitted fabric (*i.e.*, a "velour"). *See id.* ¶¶ 10, 31 (Ex. 1304). All of these materials are biocompatible and would have been recognized as such by one of ordinary skill in the art. *See* Park Decl. ¶ 31 (Ex. 1316). Thus, Pacey discloses a patch of biologically compatible material according to claim limitation 99(a).

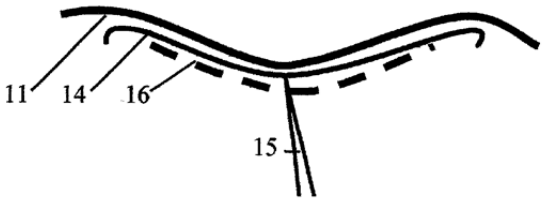
FIG.3



Claim 99 further recites a patch having a second layer. As shown in Pacey Figure 3 above, the patch also includes an adhesion-resistant fabric layer (11) comprising ePTFE, silicone, or another material and overlying at least a portion of the surface of the mesh layer (16). Pacey ¶ 10, claim 6 (Ex. 1304). Thus, Pacey discloses a second layer according to claim limitation 99(b). This second layer functions as a barrier layer. *See* Park Decl. ¶ 32 (Ex. 1316).

Claim 99 further recites a support member located between the first and second layers. The Pacey patch includes a frame of radiating arms or concentric circles of metal or plastic members supporting the fabric layers (14 in Pacey Figures 3 and 4 above). *Id.* ¶¶ 8, 30-32, claims 1-2 (Ex. 1304). This frame is between the fabric layer (11) and the mesh layer (16), as shown above. Preferably, the Pacey frame is superelastic nitinol metal that permits the patch to be placed through a cannula and have a predetermined shape (for example, a ring) that completely recovers after placement by material memory. *Id.* ¶¶ 3, 8 (Ex. 1304). Pacey's frame is positioned between the adhesion-resistant layer (11) and the fabric adherence layer (16). Thus, Pacey discloses a support member according to claim limitation 99(c).

FIG. 4



Claim 99 also recites at least one tether including a strap portion extending away from the patch, the strap portion having a width greater than its thickness. The patch taught by Pacey comprises positioning tethers, such as the centrally attached tethers in Pacey Figure 3 (15), extending from the surface of the patch. *Id.* ¶ 31, fig.3 (Ex. 1304). To position and prevent migration of the patch in the intraperitoneal space, the surgeon holds the tethers outside of the abdomen and uses them to manipulate and attach the patch to the tissue. *Id.* ¶¶ 12, 30, 32-33 (Ex. 1304). Because the tether may be a "fabric element," *id.* claim 4 (Ex. 1304), one skilled in the art would understand that the tether may be a woven material consisting of a network of fibers. *See* Park Decl. ¶ 34 (Ex. 1316). Such a material has a cross-section with a width that is inherently greater than its thickness. *Id.* ¶ 34 (Ex. 1316). Thus, Pacey discloses at least one tether according to claim limitation 99(d).

b) Claim 99 is Obvious over Pacey

To the extent that the Patent Owner argues that Pacey does not anticipate claim 99, the prosthesis of claim 99 is obvious in view of Pacey. *Id.* ¶ 35 (Ex. 1316). Pacey discloses tethers that serve the same purpose and achieve the same result as the strap recited in claim 99. *Id.* (Ex. 1316). As can be seen from the Tether References, the use of a strap or tether was well known to those skilled in the art by the effective filing date of the '334 patent. *Id.* (Ex. 1316).

For example, if the Patent Owner argues that the tethers disclosed by Pacey do not have a cross-section wider than they are thick, it would have been obvious to a person of ordinary skill in the art to modify the dimensions of the tethers disclosed by Pacey so that the width of the tethers would be greater than their thickness. *Id.* ¶ 36 (Ex. 1316). Such a dimension modification is generally not patentable. *See* MPEP § 2144.04; *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1345-46 (Fed. Cir. 1984) (affirming that dimensional limitations are not patentably significant where the only difference between the prior art and the claims are the relative dimensions and there is no change in performance or operation).

There is no unexpected change in the function of the tethers due to the dimensions recited in the claim nor is there an unexpected result from the changed dimension. The choice of the dimensions is a mere matter of selecting between a limited set of options. *See* Park Decl. ¶ 37 (Ex. 1316). In this case, the particular tether or strap can have any dimension or shape that would be suitable to assist in the positioning and attachment of the patch. *Id.* (Ex. 1316). Numerous references teach or suggest using a tether with a greater width than thickness. *See, e.g.*, Knight at 96-97 (Ex. 1319); Kensey 4:50-55 (Ex. 1308). It would have been obvious to use tethers with a greater width than thickness, and doing so would have been the use of a known element according to its established function, yielding predictable results. *See* Park Decl. ¶ 37 (Ex. 1316).

2. Claim 99 Is Anticipated or Obvious over Kieturakis

As shown in the summary chart below and the Park Declaration, Kieturakis anticipates (or itself makes obvious) independent claim 99 of the '334 patent.

a) Claim 99 is Anticipated by Kieturakis

Claim 99 recites a patch of biologically compatible material including a first layer. Kieturakis discloses a patch formed from "a non-absorbable synthetic surgical mesh, as for example from polypropylene." Kieturakis 10:37-41; *see also id.* 8:42-49 (Ex. 1303). All of these materials are biocompatible and would have been recognized as such by one of ordinary skill in the art. *See* Park Decl. ¶ 39 (Ex. 1316). Thus, Kieturakis discloses a patch of biologically compatible material, according to claim limitation 99(a).

Claim 99 further recites a patch having a second layer. Kieturakis discloses a tail that can be split into portions that are secured to the reinforcing disk (153a and 153b in Kieturakis Figure 13 below). *Id.* 8:51-59 (Ex. 1303). One skilled in the art would understand from Figures 12 or 13, for example, that the split portions at least partly overlie the mesh layer of the patch. *See* Park Decl. ¶ 40 (Ex. 1316). The tail can be formed of ePTFE, *id.* (Ex. 1316), which is a second, or barrier, layer material

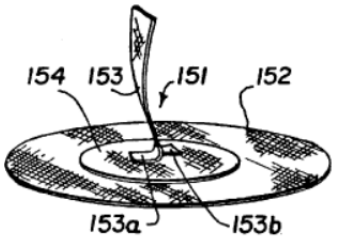


FIG.12

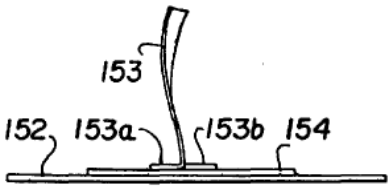


FIG. 13

according to the '334 patent. *See, e.g.*, '334 patent 14:60-63, 16:56-60 (Ex. 1301). Thus, Kieturakis discloses a second layer according to claim limitation 99(b), which functions as a barrier layer.

Claim 99 further recites a support member located between the first and second layers. As shown in Kieturakis Figure 12 above, Kieturakis discloses a reinforcing disk (154) within the patch. Kieturakis 8:51-57 (Ex. 1303). This disk is located between the tail portions (153a and 153b) and the mesh patch (152). Kieturakis therefore teaches a support member according to claim limitation 99(c). This member, a disk, is ring-shaped.

Claim 99 also recites at least one tether including a strap portion extending away from the patch, the strap portion having a width greater than its thickness. The patch comprises a tether or tail (153 in Kieturakis Figure 19, right) extending from the patch through the abdominal wall and having a cross-section with a width that is greater than it is thick. *Id.* 9:20-31, 9:47-52, figs.12-14, 19 (Ex. 1303). The tail allows the patch to be positioned in an anatomically correct position and prevents migration because it may be attached to tissue with an attachment device, such as a staple (167 in Kieturakis Figure 19

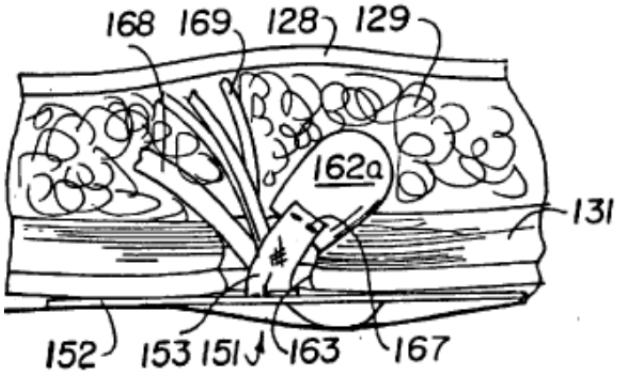


FIG. 19

below). *Id.* (Ex. 1303). Thus, Kieturakis discloses at least one tether according to claim limitation 99(d).

b) Claim 99 is Obvious over Kieturakis

If the Patent Owner argues that Kieturakis does not disclose a second layer, one of ordinary skill in the art would recognize the need for a second layer and understand how to apply it to an existing prosthesis to prevent unwanted adhesions when implanted. *See* Park Decl. ¶ 43 (Ex. 1316). Numerous references teach or suggest using a barrier layer to solve this problem. *See, e.g.*, Pacey abstract, ¶ 10 (Ex. 1304); Gianturco abstract, 4:34-48 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:5-14, 7:25-8:6 (Ex. 1305). It would have been obvious to apply a second layer to the Kieturakis patch, and doing so would have been a combination of known elements according to their established functions, yielding predictable results. *See* Park Decl. ¶ 43 (Ex. 1316).

3. Claim 99 Is Obvious over Gianturco

As shown in the summary chart and in the Park Declaration, independent claim 99 of the ’334 patent is obvious over Gianturco.

Claim 99 recites a patch of biologically compatible material including a first layer. Gianturco discloses a patch comprising a foldable sheet of “a porous prosthetic mesh material such as MARLEX material or other commercially available biocompatible materials for reinforcing or strengthening the tissue

positioned about the tissue aperture or hernial ring and for providing a structure for tissue ingrowth about the aperture." Gianturco 4:34-48 (Ex. 1302). The patch may also include

> material such as silicone, GORTEX [*sic*] polymer material, polytetrafluoroethylene, or other commercially available ***biocompatible material*** [to] be used for preventing tissue ingrowth when positioned, for example, against the organs contained within the peritoneal or other internal cavity. This nonporous material may also be biodegradable.

Id. 5:25-33 (Ex. 1302) (emphasis added). All of these materials are biocompatible and would have been recognized as such by one of ordinary skill in the art. *See* Park Decl. ¶ 45 (Ex. 1316). Thus, Gianturco discloses a patch of biologically compatible material including a first layer according to claim limitation 99(a).

Claim 99 further recites a patch having a second layer. The Gianturco prosthesis includes an additional sheet of material—for example, silicone, GORE-TEX polymer, PTFE, or a biodegrable material that can be used to prevent tissue ingrowth when the prosthesis is positioned against internal organs (*i.e.*, a barrier layer). Gianturco 5:25-33 (Ex. 1302). Thus, Gianturco discloses a second layer according to claim limitation 99(b). This layer also functions as a barrier layer. *See* Park Decl. ¶ 46 (Ex. 1316).

Claim 99 further recites a support member located between the first and second layers. The Gianturco prosthesis includes a "stiffener," such as an elastic metallic wire, that "advantageously expands the foldable sheet" and conforms "to the circumference of the foldable sheet to maintain the foldable sheet in an unfolded shape" following deployment of the prosthesis. Gianturco abstract, 2:24-44 (Ex. 1302). The stiffener is located between the two mesh layers. *See, e.g.*, *id.* fig.6 (Ex. 1302). Thus, Gianturco discloses a support member according to claim limitation 99(c). The support member may be ring-shaped because the stiffener is "advantageously elliptical or circular in shape" or coiled. *Id.* 3:10-23; *see also* 6:11-14, claims 1-4, 6, 8 (Ex. 1302).

Claim 99 also recites at least one tether including a strap portion extending away from the patch, the strap portion having a width greater than its thickness. The Gianturco prosthesis has an attachment device, such as a suture loop extending from the patch, to fix the patch in a position over the defect. *Id.* 2:45-51, 3:24-43, 8:45-68, claims 10, 17, 25 (Ex. 1302). The Gianturco suture or suture loop serves the same purpose and achieves the same result as the positioning tether recited in claim limitation 99(d). *See* Park Decl. ¶ 48 (Ex. 1316). As can be seen from the Tether References, the use of a tether was well known to those skilled in the art by the effective filing date of the '334 patent. *Id.* ¶ 48 (Ex. 1316).

To the extent the Patent Owner argues that the suture disclosed by Gianturco does not have a cross-section wider than it is thick, it would have been obvious to a person of ordinary skill in the art—in light of, for example, the Kieturakis tether—to modify the dimensions of the suture disclosed by Gianturco so that the width of the suture would be greater than its thickness. *Id.* ¶ 49 (Ex. 1316). Such a dimension modification is generally not patentable. *See* MPEP § 2144.04; *Gardner*, 725 F.2d at 1345-46.

Moreover, there is no unexpected change in the function of the sutures due to the dimensions recited in the claim nor is there unexpected result from the changed dimension. The choice of the dimensions is a mere matter of selecting between a limited set of options. *See* Park Decl. ¶ 50 (Ex. 1316). In this case, the particular tether can have any dimension or shape that would be suitable to assist in the positioning and attachment of the patch. *Id.* (Ex. 1316). It would have been obvious to use tethers with a greater width than thickness, and doing so would have been the use of a known element according to its established function, yielding predictable results. *Id.* ¶ 51 (Ex. 1316).

4. Claim 99 Is Obvious over Kugel Patch in View of Either Knight or Kensey

As shown in the summary chart below and in the Park Declaration, the prosthesis of claim 99 is obvious in view of Kugel Patch combined with either Knight or Kensey.

The Kugel Patch, pictured *supra* at page 14, discloses a patch composed of biocompatible materials, including "a double layer of monofilament polypropylene" (the claimed "first layer" according to limitation 99(a)), "a barrier of ePTFE" (the claimed "second layer" according to limitation 99(b)), and a "'memory recoil ring,' which causes the patch to spring open and maintain its shape during placement" (the claimed "support member" of limitation 99(c)). Kugel Patch (Ex. 1306). BARD's memory recoil ring is located between polypropylene and the ePTFE barrier—that is, between the first and second layers. To the extent that the Patent Owner argues that Product's support ring is not located between the first and second layers, it would have been obvious to one of ordinary skill in the art to place the support layer between the first and second layers. *See* Park Decl. ¶ 54 (Ex. 1316).

Kugel Patch does not teach at least one tether as recited in claim limitation 99(d). However, as detailed below, it would have been obvious to one skilled in the art to add a tether because both Knight and Kensey disclose an implantable

prosthesis with at least one tether meeting the requirements of claim limitation 99(d), thus providing a reason to add a tether to Kugel Patch. *See* Park Decl. ¶ 55 (Ex. 1316).

a) Claim 99 is Obvious over Kugel Patch in View of Knight

Claim 99 is obvious over Kugel Patch in view of Knight. Knight discloses using straps that are long enough to extend through an abdominal wall to secure a Marlex® (polypropylene) mesh in place when repairing a large incisional hernia.

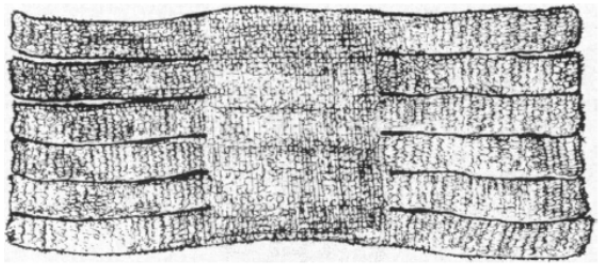


Figure 1.—Prepared Marlex mesh prosthesis.

See Knight at 96 (Ex. 1319). As shown in Knight Figure 1 (reproduced above), strips about 2 cm wide (that is, with a cross-section wider than they are thick) are cut from each side of a mesh sheet. *Id.* at 96-97 (Ex. 1319). The strips are adapted to extend through the abdominal wall. *Id.* at 97 (Ex. 1319). Using gallie fascia needles, a surgeon may bring the strips through the peritoneum on both sides of the defect. The ends of the straps may then be tied together. *Id.* at 96, 98 (Ex. 1319). Thus, Knight discloses at least one positioning tether according to claim limitation 99(d). Kugel Patch in view of Knight discloses all of the elements of claim 99. *See* Park Decl. ¶ 56 (Ex. 1316).

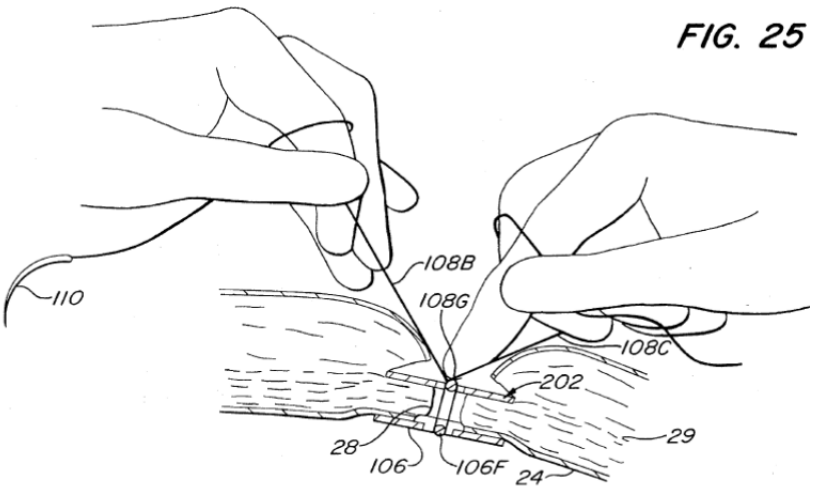
Knight discloses a hernia repair patch with anchoring straps, and Kugel Patch teaches a multi-layered hernia repair with a support member. It would have

been obvious to one skilled in the art to use a different type of patch, such as that disclosed in Kugel Patch, with anchoring straps with a patch such as disclosed in Knight. Doing so would be nothing more than a combination of known elements used for their established purpose and yielding predictable results. *See* Park Decl. ¶ 57 (Ex. 1316). *See, e.g.*, Knight at 96 (Ex. 1319) (describing a new material for this simple and "old technique" for hernia repair).

b) Claim 99 is Obvious over Kugel Patch in View of Kensey

Claim 99 is obvious over Kugel Patch in view of Kensey. Kensey discloses a positioning filament comprising "a very thin flexible member," Kensey 9:34-37 (Ex. 1308), that is attached to a patch or plug that is introduced "through a percutaneous puncture into some internal tissue" formed during surgery "to seal the opening and/or prevent the egress of tissue into the puncture," *id.* 5:27-33 (Ex. 1308). Two end portions of the filament extend through the puncture for positioning the patch or plug and securing it to the surrounding tissue. *Id.* 9:34-65, fig.25 (reproduced below) (Ex. 1308). Kensey also describes a prior art filament as synonymous with a "ribbon (either apertured or unapertured)," which

FIG. 25



inherently suggests a filament cross-section with a width greater than its thickness. *Id.* 4:50-55 (Ex. 1308). Thus, Kensey discloses at least one positioning tether according to claim limitation 99(d). Together, Kugel Patch and Kensey disclose all the elements of claim 99. *See* Park Decl. ¶ 58 (Ex. 1316).

It would have been obvious to one skilled in the art to combine the teachings of Kugel Patch with Kensey—so that a hernia patch may be positioned to seal a defect "by the application of a pulling force," Kensey 3:10-25 (Ex. 1308), from outside the body and be attached to "tissue contiguous with the opening in the skin after the [patch] is properly seated within the puncture to aid in holding or locking the [patch] in place." *See, e.g.*, *id.* 9:60-65 (Ex. 1308). Combining old tether elements from Kensey with old patch elements from Kugel Patch would have yielded nothing but predictable results. *See* Park Decl. ¶ 59 (Ex. 1316).

5. Claim 99 Is Obvious over Cherok in View of Either Knight or Kensey

As shown in the summary chart below and in the Park Declaration, the prosthesis of claim 99 is obvious in view of Cherok combined with either Knight or Kensey.

Cherok discloses a patch "formed of a biologically compatible, flexible layer of repair fabric suitable for reinforcing tissue or muscle and closing anatomical defects, and a barrier layer for physically isolating at least a portion of one side of

the fabric from areas likely to form adhesions." Cherok 2:6-9; *see also id.* 4:5-11, 7:14-24 (Ex. 1305) (suggesting knitted polypropylene monofilament mesh fabric such as BARD MESH). Thus, Cherok discloses a patch of biologically compatible material including a first layer according to claim 99(a).

Cherok also discloses a prosthesis with "a layer of [polypropylene] tissue infiltratable repair fabric 22, an adhesion resistant [ePTFE] barrier layer 24 overlying at least a portion of one side of the fabric, and a peripheral barrier 26." Cherok 4:5-7 (Ex. 1305). Thus, Cherok discloses a patch of repair fabric including a second layer according to claim limitation 99(b). This second layer functions as a barrier layer. *See* Park Decl. ¶ 62 (Ex. 1316).

Cherok further discloses a support member, such as the peripheral barrier (26) shown in Cherok Figure 3 below. This peripheral barrier (26) is located between the barrier layer (24) and the repair fabric (22). *See* Cherok 5:29-6:4, fig.3 (Ex. 1305). If the Patent Owner argues that the peripheral barrier layer (26) is not located between the barrier (24) and the repair fabric (22), it would have been obvious to one of ordinary skill in the art to modify the teachings of Cherok to have the repair fabric (22) overlay the peripheral barrier (26). This type of support was well known in the art, and was taught, for example, by Pacey and Gianturco. *See* Park Decl. ¶ 63

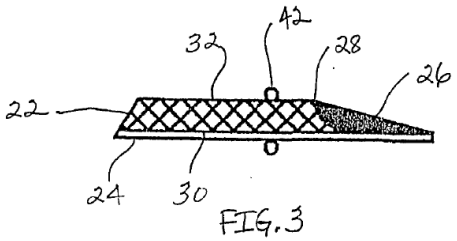


FIG. 3

(Ex. 1316); Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302). Thus, Cherok discloses or suggests a support member per claim limitation 99(c).

Cherok does not teach at least one tether as recited in claim limitation 99(d). However, as detailed below, it would have been obvious to one skilled in the art to add a tether because both Knight and Kensey disclose an implantable prosthesis with at least one tether per claim limitation 99(d), thus providing a reason to add a tether to Cherok. *See* Park Decl. ¶ 64 (Ex. 1316).

a) Claim 99 is Obvious over Cherok in View of Knight

Claim 99 is obvious over Cherok in view of Knight. For the same reasons discussed above, Knight discloses at least one tether according to claim limitation 99(d). *See* discussion *supra* Section VIII.A.4. Together, Cherok and Knight disclose all the elements of claim 99. *See* Park Decl. ¶ 65 (Ex. 1316).

It would have been obvious for one of ordinary skill in the art to use a different type of patch, such as the Cherok patch, with anchoring straps with a patch such as disclosed in Knight. *See* Park Decl. ¶ 66 (Ex. 1316). *See, e.g.*, Knight at 96 (Ex. 1319) (describing a new material for this simple and "old technique" for hernia repair). Combining the known tether elements of Knight with the old patch elements of Cherok would have been a combination of familiar

elements according to known methods yielding predictable results. *See* Park Decl. ¶ 66 (Ex. 1316).

b) Claim 99 is Obvious over Cherok in View of Kensey

Claim 99 is obvious over Cherok in view of Kensey. For the same reasons discussed above, Kensey discloses at least one tether according to claim limitation 99(d). *See* discussion *supra* Section VIII.A.4. Together, Cherok and Kensey disclose all the elements of claim 99.

It would have been obvious to one skilled in the art to combine the teachings of Cherok Kensey for the reasons provided in the Kensey—so that a hernia patch may be positioned to seal a defect "by the application of a pulling force," Kensey 3:10-25 (Ex. 1308), from outside the body and be attached to "tissue contiguous with the opening in the skin after the [patch] is properly seated within the puncture to aid in holding or locking the [patch] in place," *see, e.g.*, *id.* 9:60-65 (Ex. 1308). Such a combination is nothing more than a predictable use of prior art elements according to their established functions.

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 99 of the '334 patent.

Claim 99: An implantable prosthesis for repairing an abdominal wall defect, the implantable prosthesis comprising:
See, e.g., Pacey abstract, claim 1 (Ex. 1304); Kieturakis 1:8-10, 2:29-32, 8:42-44, figs.12-14, 16-19 (Ex. 1303); Gianturco 1:5-10 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok abstract (Ex. 1305); Kensey 5:27-33, claims 11, 31 (Ex. 1308);

Knight at 96 (Ex. 1319).
(a) a patch of biologically compatible material including a first layer and
See, e.g., Pacey ¶¶ 1, 4, 10, 17, 30-31, fig.3, claims 6, 10 (Ex. 1304); Kieturakis 8:42-49, 10:37-41, figs.12-14 (Ex. 1303); Gianturco 4:34-48, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 2:6-9, 4:5-11, 7:14-24 (Ex. 1305); Kensey abstract, 8:56-63, 9:1-7, 9:66-10:4, 13:44-49, fig.8 (Ex. 1308); Knight at 96, fig.1 (Ex. 1319).
(b) a second layer;
See, e.g., Pacey abstract, ¶ 10, fig.3, claim 6 (Ex. 1304); Kieturakis 1:32-37, 8:51-59, 10:3-8 (Ex. 1303); Gianturco 5:25-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:11-14 (Ex. 1305); Kensey abstract, 8:56-63, 9:1-7, 9:66-10:4, 13:44-49, fig.8 (Ex. 1308).
(c) a support member located between the first and second layers; and
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Kieturakis 8:51-57, figs.12-14 (Ex. 1303); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 3:4-6, 4:23-26, 5:8-10, 5:19-21, 9:31-10:6, figs.1-5, 8-9 (Ex. 1305); Kensey abstract, 8:6-12, 8:29-37, 8:56-67, 9:1-8, 9:66-10:4, 13:38-49, fig.8 (Ex. 1308).
(d) at least one tether including a strap portion extending away from the patch, the strap portion having a cross-section with a width and thickness, the width being greater than the thickness, the tether having a length sufficient, when the patch is on one side of the defect, to extend through the abdominal wall defect, so that a portion of the tether is on the other side of the defect and is adapted to be attached to tissue with an attachment device.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kieturakis 8:51-61, 9:20-35, 9:47-52, figs.12-14, 16-19 (Ex. 1303); Gianturco abstract, 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

B. The Dependent Claims Reciting Features Related to the Patch

Each of the dependent claims discussed below is directed to subsidiary features of the claimed patch, and their respective limitations are either anticipated

or made obvious by the References. In the following sections, essentially identical claims are grouped and discussed together, including claims related to (1) absorbable and non-absorbable patch materials; (2) a barrier layer and features thereof; (3) a mesh layer and features thereof; (4) tissue ingrowth features; and (5) features of the support ring or member.

1. The References Disclose Absorbable and Non-Absorbable Patch Materials Recited in Claims 101 and 103-104

Claim 101 depends from independent claim 99, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claims 103 and 104 depend from claim 102, which as discussed *infra*, is also unpatentable in view of the prior art. Claims 101 and 103 are anticipated by Kieturakis, and are obvious over any of Kieturakis, Gianturco, Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight. Claim 104 is obvious over any of Gianturco, Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight.

Claim 101 recites a patch that includes both "absorbable and non-absorbable materials." Kieturakis, Gianturco, Cherok, and Kensey all recite patches that include both absorbable and non-absorbable materials.

Claim 101: The prosthesis according to claim 99, wherein the patch includes absorbable and non-absorbable materials.
See, e.g., Kieturakis 8:42-49, 10:37-41, 11:46-50, figs.12-14, 27 (Ex. 1303); Gianturco abstract, 4:34-48, 4:63-5:1, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Cherok

4:5-11, 4:21-24, 7:14-24, 7:25-8:6 (Ex. 1305); Kensey abstract, 8:22-37, 8:56-9:11, 9:66-10:4, 13:44-49, fig.8 (Ex. 1308).

Claim 103 recites a patch "wherein at least one of the first and second layers includes a non-absorbable material," such as PROLENE™ or Bard® Mesh (polypropylene), GORE-TEX® (ePTFE), Teflon® (PTFE), DACRON® or polyester (polyethylene terephthalate), nylon, Marlex® (high density polyethylene), etc. *See* Park Decl. ¶ 73 (Ex. 1316). Non-absorbable materials such as these are disclosed in Kieturakis, Gianturco, Pacey, Kugel Patch, Cherok, Kensey, and Knight. *See id.* (Ex. 1316).

Claim 103: The prosthesis according to claim 102, wherein at least one of the first and second layers includes a non-absorbable material.
See, e.g., Pacey abstract, ¶¶ 1, 4, 10, 17, 30-31, fig.3, claims 6, 10 (Ex. 1304); Kieturakis 8:42-49, 10:37-41, figs.12-14 (Ex. 1303); Gianturco abstract, 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:5-11, 4:21-24, 7:14-24, 7:25-8:6 (Ex. 1305); Kensey abstract, 8:22-37, 8:56-9:11, 9:66-10:4, 13:44-49, fig.8 (Ex. 1308); Knight at 96, fig.1 (Ex. 1319).

Claim 104 recites a patch "wherein at least one of the first and second layers includes an absorbable material." Cherok states that "***[a]bsorbable materials***, including polyglactin (VICRYL) and polyglycolic acid (DEXON), may be suitable for applications involving temporary repair of tissue or wall defects." Cherok 7:19-21 (Ex. 1305) (emphasis added). Likewise, "[a]bsorbable materials, such as SEPRAFILM available from Genzyme Corporation and oxidized, regenerated cellulose (Intercede (TC7)) may be employed" for the barrier layer. *Id.* 8:3-6 (Ex.

1305). Gianturco suggests using a biodegradable material, such as polyglycolic acid, along with polypropylene, polyester, nylon, or ePTFE materials. *See* Gianturco 5:25-33 (Ex. 1302). Kensey discloses forming its hernia sealing and anchoring members from non-absorbable (*e.g.*, polyester) mesh layered with "any resorbable material, such as a resorbable lactide/glycolide polymer." Kensey 8:56-63 (Ex. 1308).

Claim 104: The prosthesis according to claim 102, wherein at least one of the first and second layers includes an absorbable material.
See, e.g., Gianturco 4:39-46, 4:63-5:1, 5:25-33 (Ex. 1302); Cherok 4:5-11, 4:21-24, 7:14-24, 7:25-8:6 (Ex. 1305); Kensey abstract, 8:22-37, 8:56-9:11, 9:66-10:4, 13:44-49, fig.8 (Ex. 1308).

Because absorbable and non-absorbable materials were already commonly used in patches, it would have been obvious to one of ordinary skill in the art to use either absorbable, non-absorbable, or both types of materials in the prosthesis of claim 99. The use of absorbable and non-absorbable materials in patches would have been a combination of familiar elements according to known methods, yielding predictable results. *See* Park Decl. ¶ 75 (Ex. 1316). Furthermore, it would have been obvious to select a known material for one of the layers that could include an absorbable material or a non-absorbable material. This amounts to a selection of a known material that is useful for its known purpose, and the

results of this combination would be predictable. *See id.* (Ex. 1316). Accordingly, claims 101, 103 and 104 are not patentable.

2. The References Disclose a Barrier Layer and Features Thereof Recited in Claims 102 and 105-109

Claim 102 depends from claim 101, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claims 105-109 depend from claim 102. Claim 102 is anticipated by Kieturakis, and is obvious over any of Kieturakis, Gianturco, Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight. Claims 106-109 are obvious over any of Gianturco, Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight. Claim 105 is obvious over Cherok in view of either Kensey or Knight, Kieturakis in view of Lichtenstein, Pacey in view of Kensey and Licthenstein, or Kugel Patch in view of Kensey and further in view of Lichtenstein.

Claim 102 recites a patch "wherein at least one of the first and second layers includes a barrier layer." Pacey discloses an adhesion-resistant fabric layer (11 in Pacey Figure 4) comprising ePTFE, silicone, or another material and overlying at least a portion of the surface of the mesh layer. *See* Pacey ¶ 10, claim 6, figs.3-4 (Ex. 1304). Kieturakis discloses a tail that can be made of ePTFE and split into portions that at least partly overlie the mesh layer of the patch (153a and 153b in

Kieturakis Figure 13). Kieturakis 8:51-59, fig.13 (Ex. 1303). The Gianturco prosthesis also includes an additional sheet of material—for example, silicone, GORE-TEX polymer, PTFE, or a biodegrable material can be used for preventing tissue ingrowth when the prosthesis is positioned against internal organs (*i.e.*, a barrier layer), Gianturco 5:25-33 (Ex. 1302)—and Cherok discloses a prosthesis with "an adhesion resistant [ePTFE] barrier layer 24 overlying at least a portion of one side of the fabric." Cherok 4:5-7 (Ex. 1305).

Because the benefits of adhesion resistance were well understood and adhesion-resistant barrier layers were already commonly used in such patches, it would have been obvious to one of ordinary skill in the art to use an adhesion-resistant barrier layer in the prostheses of claim 99, and would be a combination of known elements yielding predictable results. *See* Park Decl. ¶ 78 (Ex. 1316).

Claim 102: The prosthesis according to claim 101, wherein at least one of the first and second layers includes a barrier layer.
See, e.g., Pacey abstract, ¶ 10, fig.3, claim 6 (Ex. 1304); Kieturakis 1:32-37, 8:51-59, 10:3-8 (Ex. 1303); Gianturco abstract, 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:5-14, 7:25-8:6 (Ex. 1305).

Claims 106-109 recite a barrier layer that resists tissue adhesions to the patch. Kugel Patch, Pacey, Gianturco, and Cherok teach locating a barrier layer on the opposite surface of the patch from the defect to, for example, "minimize[] tissue attachment to the prosthesis, while helping to protect against erosion of the

mesh into vital organs." Kugel Patch (Ex. 1306). The prosthesis in Pacey uses ePTFE as an adhesion barrier on the patch surface "exposed to the bowel and omentum." Pacey ¶ 29 (Ex. 1304). Gianturco discloses that "the side of the foldable sheet anticipated for exposure to internal body organs may be coated with a well-known antifibrogenic coating for inhibiting tissue ingrowth." Gianturco 6:24-28 (Ex. 1302). Cherok teaches "a barrier layer for physically isolating at least a portion of one side of the fabric from areas likely to form adhesions." Cherok 2:6-9 (Ex. 1305).

Because barrier layers that reduce, minimize, and resist tissue adhesion or attachment to the patch were well known, it would have been obvious to one of skill in the art to include such a layer on a prosthesis of claim 99. This would be a combination of known elements yielding predictable results. Park Decl. ¶ 80 (Ex. 1316).

Claim 106: The prosthesis according to claim 102, wherein the barrier layer resists tissue adhesions to the patch.
See, e.g., Pacey abstract, ¶ 10, fig.3, claim 6 (Ex. 1304); Gianturco 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:11-14, 7:25-8:6 (Ex. 1305).
Claim 107: The prosthesis according to claim 102, wherein the barrier layer minimizes tissue attachment to the patch.
See, e.g., Pacey abstract, ¶ 10, fig.3, claim 6 (Ex. 1304); Gianturco 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:11-14, 7:25-8:6 (Ex. 1305).
Claim 108: The prosthesis according to claim 102, wherein the barrier layer

reduces adhesions to the patch.
See, e.g., Pacey abstract, ¶ 10, fig.3, claim 6 (Ex. 1304); Gianturco 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:11-14, 7:25-8:6 (Ex. 1305).
Claim 109: The prosthesis according to claim 102, wherein the patch includes a first surface that is to face the defect and a second surface that is to face away from the defect, the barrier layer being located at the second surface.
See, e.g., Pacey abstract, ¶¶ 1, 4, 10, 17, 29-31, fig.3, claims 6, 10 (Ex. 1304); Gianturco 4:34-48, 5:5-33, 6:18-28, 8:5-44, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 2:1-9 (Ex. 1305).

Claim 105 recites a patch "wherein the barrier layer includes an absorbable material." '334 patent claim 105 (Ex. 1301). Gianturco discloses that the material "used for preventing tissue ingrowth when positioned, for example, against the organs contained within the peritoneal or other internal cavity . . . may also be biodegradable." Gianturco 5:25-33 (Ex. 1302). Cherok discloses using an absorbable material for the adhesion-resistant barrier layer "such as SEPRAFILM available from Genzyme Corporation and oxidized, regenerated cellulose (Intercede (TC7))." Cherok 8:1-6 (Ex. 1305). In addition, Lichtenstein teaches using absorbable oxidized regenerated cellulose in a barrier layer. See, e.g., Lichtenstein 3:66-4:30 (Ex. 1320).

It would have been obvious to one of ordinary skill in the art to select a known material for the barrier layer that could include an absorbable material. *See* Park Decl. ¶ 82 (Ex. 1316). This is the selection of a known material that is useful

for its known purpose, and the results of this combination would be predictable. *Id.* (Ex. 1316).

Claim 105: The prosthesis according to claim 102, wherein the barrier layer includes an absorbable material.
See, e.g., Gianturco 4:34-48, 5:5-33, 6:18-28, fig.3 (Ex. 1302); Cherok 4:11-14, 7:25-8:6 (Ex. 1305); Lichtenstein 3:66-4:30 (Ex. 1320).

Accordingly, claims 102 and 105-109 are not patentable.

3. The References Disclose a Mesh Layer and Features Thereof Recited in Claim 100

Claim 100 depends from independent claim 99, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 100 is anticipated by either Pacey or Kieturakis, and is further obvious over any of Pacey, Kieturakis, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey.

Claim 100 recites a patch "wherein at least one of the first and second layers includes a mesh fabric." Pacey, Kieturakis, Gianturco, Cherok, Kensey, Knight, and Kugel Patch all discuss the use of mesh layers. Park Decl. ¶ 84 (Ex. 1316).

Claim 100: The prosthesis according to claim 99, wherein at least one of the first and second layers includes a mesh fabric.
See, e.g., Pacey ¶¶ 1, 4, 10, 17, 30-31, fig.3, claims 6, 10 (Ex. 1304); Kieturakis 8:42-49, 10:37-41, figs.12-14 (Ex. 1303); Gianturco 4:34-48, fig.3 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 2:6-9, 4:5-11, 4:21-24, 7:14-24, 7:25-8:6 (Ex. 1305); Kensey abstract, 8:56-63, 9:1-7, fig.8 (Ex. 1308); Knight at 96, fig.1 (Ex. 1319).

Because mesh was already commonly used in such patches, it would have been obvious to one of ordinary skill in the art to use a mesh layer in the prosthesis of claim 99. This is a combination of familiar elements according to known methods that does nothing more than yield predictable results. *See* Park Decl. ¶ 85 (Ex. 1316). Accordingly, claim 100 is not patentable.

4. The References Disclose Tissue Ingrowth Features Recited in Claim 110

Claim 110 depends from claim 109, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 110 is obvious over any of Gianturco, Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight.

Claim 110 recites patch configurations "to allow tissue ingrowth from the first surface into at least one [layer]." Pacey discloses a patch configured to allow tissue ingrowth into the "surface of the patch in direct contact with the abdominal wall peritoneum" so that "part of the prosthesis having an adherent nature is interactive with the patients tissues and so will form a permanent bond. This material will either be different from ePTFE, which does not bond well to tissue or else have an ePTFE velour texture." Pacey ¶ 10 (Ex. 1304). Gianturco says that the mesh "sheet of material positioned against the tissue aperture advantageously provides for the ingrowth of repair tissue." Gianturco 3:41-43 (Ex. 1302).

The polypropylene mesh layer in the Kugel Patch "stimulates tissue in-growth," Kugel Patch (Ex. 1306), while the repair fabric layer in Cherok "includes a plurality of interstices or openings which allow sufficient tissue ingrowth to secure the prosthesis to host tissue after implantation," Cherok 4:9-11 (Ex. 1305). Even in Kensey, the sealing and anchoring members are configured to enhance the opportunity for scar tissue ingrowth. *See, e.g.*, Kensey 18:21-26 (Ex. 1308).

Claim 110: The prosthesis according to claim 109, wherein the patch is configured to allow tissue ingrowth from the first surface into the at least one of the first and second layers.
See, e.g., Pacey ¶¶ 4, 10, 31 (Ex. 1304); Gianturco 3:41-43, 4:39-46 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 4:9-11 (Ex. 1305); Kensey 8:29-31, 17:55-58, 18:21-26, 18:37-45, claims 9, 19, 29, 39, 54, 67 (Ex. 1308).

The benefits as well as the means for achieving tissue ingrowth were already well understood. Someone skilled in the art would know when tissue ingrowth was desirable and when it should be minimized. *See* Park Decl. ¶ 89 (Ex. 1316). The prior art discloses many materials for achieving that purpose. It would have been obvious to one of ordinary skill in the art to select components and configure the patches recited in claim 99 to allow tissue ingrowth on the surface facing the peritoneum for greater repair stability. *See id.* (Ex. 1316). This is nothing more than the predictable use of prior art elements according to their established functions. *See id.* (Ex. 1316). Accordingly, claim 110 is not patentable.

5. The References Disclose Features of the Support Ring or Member Recited in Claims 121-124

Claims 121-124 depend from independent claim 99, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claims 121-123 are anticipated by either Pacey or Kieturakis, and are obvious over any of Pacey, Kieturakis, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey. Claim 124 is anticipated by Pacey, and is obvious over any of Pacey, Gianturco, or Kugel Patch in view of either Knight or Kensey.

Claim 121 recites a patch "wherein the support member is ring-shaped." The Primary References and the Patch References disclose or render obvious a ring-shaped support member. *See* Park Decl. ¶ 91 (Ex. 1316). For example, Pacey discloses a nitinol metal frame that may take the shape of a ring, as shown in Pacey Figure 3. *See* Pacey ¶¶ 3, 8 fig.3 (Ex. 1304). Similarly, Kieturakis discloses a reinforcing disk (154 in Kieturakis Figure 12), Kieturakis 8:51-57, fig.12 (Ex. 1303), and Gianturco discloses a stiffener that is "advantageously elliptical or circular in shape" or coiled. Gianturco 3:10-23; *see also id.* 6:11-14, claims 1-4, 6, 8 (Ex. 1302).

Because of the shape of a hernia defect, it would have been obvious to one of ordinary skill in the art to use a ring-shaped support member in the prosthesis of

claim 99, and doing so would have been a combination of known elements with predictable results. *See* Park Decl. ¶ 92 (Ex. 1316).

Claim 121: The prosthesis according to claim 99, wherein the support member is ring-shaped.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Kieturakis 8:46-57, figs.12-14 (Ex. 1303); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 3:4-6, 4:23-26, 5:8-10, 5:19-21, 5:23-p.6. l.4, 9:31-10:6, figs.1-5, 8-9 (Ex. 1305).

Claims 122 and 123 recite a support member that "reinforces the patch" and "contributes to the stability of the patch," respectively. Pacey teaches using a concentric frame with "a design ***enabling support*** to be given to the ePTFE patch." Pacey ¶ 8 (Ex. 1304) (emphasis added). Likewise, the Kieturakis disc is a "***reinforcing disk***." Kieturakis 8:54 (emphasis added); *see also id.* 8:51-57 (Ex. 1303). Gianturco discloses that "[t]he support means includes a stiffener such as an elastic metallic wire for applying force to the foldable sheet and maintaining the sheet in its unfolded shape." Gianturco 2:24-26 (Ex. 1302).

In Cherok, "the peripheral barrier 26 may act to increase the stiffness of the outer margin of the barrier layer, such that the outer edge of the barrier layer may become more resistant to being inadvertently folded back. Additionally, the outer margin of the barrier layer may tend to soften and thereby reduce the brittleness of the peripheral barrier." Cherok 5:19-21 (Ex. 1305). Kugel Patch teaches a patch that "contains a patent-protected 'memory recoil ring,' which causes the patch to

spring open and ***maintain its shape during placement***." Kugel Patch (Ex. 1306) (emphasis added).

Because the benefits of a support member were well understood and already commonly used in such patches, it would have been obvious to one of ordinary skill in the art that a support ring or member could be designed to reinforce or contribute to the stability of claim 99. This is nothing more than the combination of known elements according to their established functions yielding predictable benefits. *See* Park Decl. ¶ 95 (Ex. 1316).

Claim 122: The prosthesis according to claim 99, wherein the support member reinforces the patch.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Kieturakis 8:46-57, figs.12-14 (Ex. 1303); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 3:4-6, 4:23-26, 5:8-10, 5:19-21, 9:31-10:6, figs.1-5, 8-9 (Ex. 1305).
Claim 123: The prosthesis according to claim 90, wherein the support member contributes to the stability of the patch.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Kieturakis 8:46-57, figs.12-14 (Ex. 1303); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302); Kugel Patch (Ex. 1306); Cherok 3:4-6, 4:23-26, 5:8-10, 5:19-21, 9:31-10:6, figs.1-5, 8-9 (Ex. 1305).

Claim 124 recites a support ring that "aids in expansion of the patch." Pacey discloses how its superelastic concentric frame allows a "delivery size of 4-10 mm diameter but the patch will enlarge to a size of 40-100 mm when opened to a planar shape inside the abdomen." Pacey ¶ 8 (Ex. 1304). In Gianturco, "[t]he

stiffener in the cavity ***expands the foldable sheet*** of material by conforming to the circumference of the foldable sheet to maintain the foldable sheet in an unfolded shape." Gianturco 2:40-44 (Ex. 1302) (emphasis added). Kugel Patch discloses that the "'memory recoil ***ring***' . . . ***causes the patch to spring open*** and maintain its shape during placement." Kugel Patch (Ex. 1306) (emphasis added).

Because the benefits of a support member were well understood and already commonly used in such patches, it would have been obvious to that a support ring or member could be designed to aid in the expansion of the patches of claim 99. Again, this is a combination of known elements with no unpredictable results. *See* Park Decl. ¶ 97 (Ex. 1316).

Claim 124: The prosthesis according to claim 99, wherein the support member aids in expansion of the patch.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1304); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig.3, claims 1-4, 6, 8 (Ex. 1302); Kugel Patch (Ex. 1306).

Accordingly, claims 121-124 are not patentable.

C. The Dependent Claims Reciting Features Related to the Tether(s)

Each of these dependent claims is directed to subsidiary features of the claimed tether(s) or straps(s). In the following sections, essentially identical claims are grouped and discussed together, including claims related to (1) a pair of straps and features and (2) features of the strap/tether or attachment device.

1. The References Disclose a Pair of Tethers and Features Thereof Recited in Claims 111-113

Claim 112 depends from independent claim 99, and claim 111 depends from claim 109, which as discussed *supra*, are unpatentable in view of the previously discussed prior art. Claim 113 depends from claim 112. Claims 111 and 113 are obvious over Pacey in view of Kensey, Kugel Patch in view of Kensey, or Cherok in view of either Kensey or Knight. Claim 112 is anticipated by Pacey, and is obvious over Pacey, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey.

Claims 111 and 112 recite a prosthesis "wherein the at least one tether includes a pair of strap portions." As discussed *supra* in Sections VIII.A.1 and VIII.A.4, Pacey, Kensey and Knight disclose this additional limitation.

Because the use of a pair of strap portions was well known and already commonly used in such patches, it would have been obvious that a pair of strap portions could be used with the prosthesis of claim 99. This is nothing more than the combination of known elements according to their established functions yielding predictable results. Park Decl. ¶ 101 (Ex. 1316).

Claim 111: The prosthesis according to claim 109, wherein the at least one tether includes a pair of strap portions.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kensey abstract, 3:14-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-98, figs.1, 3-5 (Ex. 1319).

Claim 112: The prosthesis according to claim 99, wherein the at least one tether includes a pair of strap portions.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kensey abstract, 3:14-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-98, figs.1, 3-5 (Ex. 1319).

Claim 113 recites "a pair of strap portions [that] are adapted to be pulled away from each other." Kensey discloses a pair of "filament ends [that] extend out of the puncture tract when the device is in place so that the surgeon may grasp both of the ends to knot them together when suturing the filament to the skin and/or underlying tissue to secure the sealing device 100 in place." Kensey 15:32-37 (Ex. 1308). Knight discloses multiple pairs of mesh straps spaced apart on opposite sides of a mesh patch and pulled apart "through the peritoneal-fascial layer from the intraperitoneal side" to be tied above the layer. Knight at 96 (Ex. 1319). Gianturco discloses a spaced apart suture loop that is drawn through the hernial ring, abdominal wall, and skin of the patient. Gianturco 8:48-60 (Ex. 1302). Pacey also discloses a pair of tethers that can each be "pulled snugly and fixed to complete the repair." Pacey ¶ 12; *see also id.* fig.3 (Ex. 1304).

It would have been obvious that a pair of strap portions that are adapted to be pulled apart would improve the placement and securement of the prosthesis. This old and familiar modification would have yielded nothing more than predictable results. *See* Park Decl. ¶ 103 (Ex. 1316).

Claim 113: The prosthesis according to claim 112, wherein the pair of strap portions are adapted to be pulled away from each other.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kensey abst., 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319); Gianturco 3:29-36, 8:48-60, fig.6 (Ex. 1302).

Accordingly, claims 111-113 are not patentable.

2. The References Disclose Features of the Tether or Attachment Device Recited in Claims 114-115, 117-120, and 126

Claims 114, 117, 119, 120, and 126 depend from independent claim 99, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 115 depends from claim 114, and claim 118 depends from claim 117. Claims 114, 117, 118, and 119 are anticipated by either Pacey or Kieturakis, and are obvious over any of Pacey, Kieturakis, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey. Claim 115 is anticipated by Pacey, and is obvious over any of Pacey, Kugel Patch in view of Knight, or Cherok in view of Knight. Claim 120 is anticipated by Kieturakis, and is obvious over any of Pacey, Kieturakis, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey. Claim 126 is anticipated by Pacey, and is obvious over any of Pacey, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey.

Claim 117 recites adapting the strap or the strap portion of a tether to be "manipulated by a user to selectively position the patch to cover an opening to the defect." This limitation is disclosed by any of Pacey, Kieturakis, Gianturco, or Kensey, as discussed *supra* in Sections VIII.A.1-4. Because various straps and tethers were already known and used for selectively positioning such prostheses, it would have been obvious to one of ordinary skill in the art to use the strap or tether to pull and/or manipulate the patches of claim 99, and doing so would have been merely the implementation of a predictable variation. *See* Park Decl. ¶ 105 (Ex. 1316).

Claim 117: The prosthesis according to claim 99, wherein the at least one tether is adapted to be manipulated by a user to selectively position the patch to cover an opening to the defect.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kieturakis 9:20-35, 9:47-52, figs.12-14, 16-19 (Ex. 1303); Gianturco abstract, 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Claim 126 recites a prosthesis wherein the strap or strap portion "is adapted to lie flat relative to the patch." This limitation is disclosed by the Pacey tether, the Gianturco suture loop, the Kensey flexible member, and the Knight mesh strips, which are all adapted to lie flat relative to a patch as discussed *supra* in Sections VIII.A.1, VIII.A.3 and VIII.A.4. It would have been obvious to one of ordinary skill in the art to adapt the strap or strap portion to lie flat relative to the patches of

claim 99, particularly to ease deployment of the prosthesis. Doing so would have been nothing more than the predictable use of known elements according to their established function. *Id.* ¶ 106 (Ex. 1316).

Claim 126: The prosthesis according to claim 99, wherein the strap portion is adapted to lie flat relative to the patch.
See, e.g., Pacey ¶¶ 8, 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Gianturco abstract, 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.7, 12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Claim 115 recites a strap or tether having "a length of from approximately 2.5 inches to approximately 20 inches." Based on its disclosure of a patch ranging in size from 40-100 mm and Pacey Figure 3, which shows tethers at least as long as the patch itself, Pacey describes tethers approximately 100 mm, or 2.5 inches, long. *See, e.g.*, Pacey ¶ 8 (Ex. 1304). Based on its disclosure of a patch with a minimum width of 4 cm taken from a Marlex sheet at least 25 cm in length, Knight discloses straps approximately 21 cm, or 8.3 inches, long. *See, e.g.*, Knight at 96-97 (Ex. 1319). *See* Park Decl. ¶ 107 (Ex. 1316). Because the strap or tether requires sufficient length to extend from the patch through the abdominal wall defect and be attached to tissue, it would have been obvious to use a strap or tether from approximately 2.5 inches to approximately 20 inches long. Such a strap length was old and would have yielded only predictable results. *Id.* (Ex. 1316).

Claim 115: The prosthesis according to claim 114, wherein the at least one

tether has a length of from approximately 2.5 inches to approximately 20 inches.
See, e.g., Pacey ¶¶ 8, 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Claim 120 recites a strap or tether that "includes a layer of mesh fabric." Kieturakis discloses a strap "made of a suitable plastic mesh." Kieturakis 8:44-46 (Ex. 1303). Kensey discloses that the reinforcing filament or ribbon can be formed of the same material as the anchoring member (*i.e.*, mesh). *See, e.g.*, Kensey 4:50-55, 9:1-13, 18:45-50 (Ex. 1308). The straps in Knight are cut from a sheet of Marlex® mesh. *See* Knight at 96 (Ex. 1319). Pacey also teaches the use of a "fabric element" as an alternative to an anchor chord, and somebody skilled in the art would understand that such a fabric element could be a mesh layer. See Pacey cl. 4 (Ex. 1304); Park Decl. ¶ 108 (Ex. 1316). Because mesh is commonly used in such prostheses, it also would have been obvious to use a mesh fabric in the strap or tether, and using this old, well-known material in the strap or tether would have been merely a predictable use of prior art elements according to their established functions. Park Decl. ¶ 108 (Ex. 1316).

Claim 120: The prosthesis according to claim 99, wherein the at least one tether includes a layer of mesh fabric.
See, e.g., Pacey claim 4 (Ex. 1304); Kieturakis 8:42-59, 9:27-31, 9:47-52, figs.12-14, 16-19 (Ex. 1303); Kensey abstract, 3:20-29, 4:50-55, 9:1-13, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.8, 12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Claims 118 and 119 recite a prosthesis "wherein the strap portion of the at least one tether is adapted to secure the patch at the defect." Pacey, Kieturakis, Gianturco, Kensey, and Knight all disclose this additional limitation, as discussed *supra* in Sections VIII.A.1-4. Because various straps and tethers were already known and used for securing such prostheses at the defect, it would have been obvious to one of ordinary skill in the art to use the strap or tether to secure the patches of claim 99 at the defect, and doing so would have been merely the implementation of an old technique yielding only predictable results. *See* Park Decl. ¶ 109 (Ex. 1316).

Claim 118: The prosthesis according to claim 117, wherein the strap portion of the at least one tether is adapted to secure the patch at the defect.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kieturakis col. 8 l.51-61, 9:20-35, 9:47-52, figs.12-14, 16-19 (Ex. 1303); Gianturco abstract, 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).
Claim 119: The prosthesis according to claim 99, wherein the strap portion of the at least one tether is adapted to secure the patch at the defect.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1304); Kieturakis col. 8 l.51-61, 9:20-35, 9:47-52, figs.12-14, 16-19 (Ex. 1303); Gianturco abstract, 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Claim 114 recites a prosthesis "wherein the attachment device includes a suture, staple or tack, for anchoring the patch over the defect." Kieturakis teaches

attaching the strap to the tissue with staples. *See* Kieturakis 9:22-32 (Ex. 1303). Pacey discloses using sutures and hooked elements and discloses that the tethers can be tied to the musculofascial tissue. *See, e.g.*, Pacey ¶¶ 12, 32-33, claim 4 (Ex. 1304); *see also* Gianturco 8:48-60 (Ex. 1302); Kensey 12:10-16 (Ex. 1308); Knight at 96 (Ex. 1319). Because sutures, staples, and tacks were well known and commonly used attachment devices, it would have been obvious to one of ordinary skill in the art to use them to attach the strap or strap portion to adjacent tissue, thus anchoring the patch, and doing so would be nothing more than a combination of known elements yielding predictable results. *Id.* ¶ 110 (Ex. 1316).

Claim 114: The prosthesis according to claim 99, wherein the attachment device includes a suture, staple or tack, for anchoring the patch over the defect.
See, e.g., Pacey ¶¶ 1, 12, 32-33, claim 4 (Ex. 1304); Kieturakis 9:22-32, fig.17 (Ex. 1303); Gianturco abst., 2:45-51, 3:24-43, 5:18-22, 8:45-68, fig.3, claims 10, 17, 25 (Ex. 1302); Kensey abstract, 3:20-29, 4:50-55, 9:34-65, 11:12-21, 12:10-16, 15:6-55, 18:45-50, figs.12, 23, 25 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

Accordingly, claims 114-115, 117-120, and 126 are not patentable.

D. The Dependent Claims Reciting Features Related to Defects

Each of these dependent claims is directed to the anatomical defects to be treated with the prosthesis. They include claims related to the prosthesis (1) when the anatomy is a margin of the defect and (2) for particular defects.

1. The References Disclose the Prosthesis When the Anatomy Is a Margin of the Defect Recited in Claim 116

Claim 116 depends from claim 114, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 116 is anticipated by either Pacey or Kieturakis, and is obvious over any of Pacey, Kieturakis, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey.

Claim 116 recites a prosthesis "wherein the anatomy is a margin of the defect." Pacey, Kieturakis, Gianturco, Cherok, Kensey, and Knight all disclose this additional limitation, as discussed *supra* in Section VIII.A. For example, Kieturakis describes placement of the prosthesis "across the inguinal ring" (163 in Kieturakis Figure 19). Kieturakis 9:22-32, fig.19 (Ex. 1303). Similarly, Knight describes placement of the prosthesis relative to the "strong fascial edges of the defect." Knight at 96 (Ex. 1319).

Claim 116: The prosthesis according to claim 114, wherein the anatomy is a margin of the defect.
See, e.g., Pacey abstract (Ex. 1304); Kieturakis 9:22-32, 9:47-52, figs.12, 17, 19 (Ex. 1303); Gianturco 5:50-60, 8:48-60 (Ex. 1302); Cherok 4:15-18, 9:9-20 (Ex. 1305); Kensey 5:28-36, 7:39-56, 8:1-7 (Ex. 1308); Knight at 96-97, figs.1, 3-5 (Ex. 1319).

It would have been obvious to one of ordinary skill in the art that the anatomy is a margin of the defect for any abdominal wall repair. Attaching a

tether to a margin of the abdominal wall defect is an old technique, and certainly yields nothing more than predictable results when applied to the patch of claim 99. *See* Park Decl. ¶ 114 (Ex. 1316). Accordingly, claim 116 is not patentable.

2. The References Disclose the Prosthesis for Particular Defects Recited in Claim 125

Claim 125 depends from claim 99, which as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 125 is anticipated by Pacey, and is obvious over Pacey, Gianturco, Kugel Patch in view of either Knight or Kensey, or Cherok in view of either Knight or Kensey.

Claim 125 recites a prosthesis "wherein the defect is one of an umbilical hernia, incisional hernia or a trocar puncture." Gianturco discloses that its repair device is "suited . . . for any . . . tissue aperture occurring anywhere in the body." Gianturco 9:61-65 (Ex. 1302).

More specifically, Pacey indicates repair of "[i]nguinal and other Hernias." *See* Pacey abstract (Ex. 1304). Knight also explicitly references umbilical hernias. *See* Knight at 98 (Ex. 1319). Some references explicitly indicate incisional or ventral hernias. *See, e.g.*, Knight at 96 (Ex. 1319); Cherok 4:2-5 (Ex. 1305). Kensey addresses trocar punctures. *See* Kensey title, 2:3-10 (Ex. 1308).

Claim 125: The prosthesis according to claim 99, wherein the defect is one of an umbilical hernia, incisional hernia or a trocar puncture.
See, e.g., Pacey abstract (Ex. 1304); Gianturco abstract, 9:61-65 (Ex. 1302); Cherok 4:2-5 (Ex. 1305); Kensey title, 1:9-14, 2:3-10, 5:28-36, 7:39-56, 8:1-7,

17:32-39 (Ex. 1308); Knight at 96-98 (Ex. 1319).

It would have been obvious to one of skill in the art that the prosthesis of claim 99 would be suitable for numerous abdominal wall defects, including an umbilical hernia, an incisional hernia, or a trocar puncture. This use of known elements according to known methods does no more than yield predictable results. *See* Park Decl. ¶ 118 (Ex. 1316). Accordingly, claim 125 is not patentable.

Based on the foregoing, claims 99-126 of the '334 patent recite subject matter that is either anticipated or obvious. The Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

Atrium Medical Corporation,
Petitioner

Customer Number: 24395

Tel: (202) 663-6025
Fax: (202) 663-6363

By: /David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476
Wilmer Cutler Pickering
Hale and Dorr LLP

CERTIFICATE OF SERVICE

I hereby certify that, on March 14, 2013, I caused a true and correct copy of the foregoing materials:

- Petition for *Inter* Partes Review of Claims 99-126 of U.S. Patent No. 7,785,334 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibits 1301-1325
- List of Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 7,785,334, Claims 99-126 (Exhibits 1301-1325)
- Fee Authorization
- Atrium Medical Corp. Power of Attorney

to be served via Federal Express on the following attorney of record as listed on PAIR:

WOLF GREENFIELD & SACKS, P.C.
Attn. James Hanifin, Jr.
600 ATLANTIC AVENUE
BOSTON MA 02210-2206

/David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476

LIST OF EXHIBITS FOR
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 7,785,334, CLAIMS 99-126

Exhibit	Description
1301	U.S. Patent No. 7,785,334, entitled "Implantable Prosthesis," to Ford *et al.*, issued August 31, 2010.
1302	U.S. Patent No. 5,258,000, entitled "Tissue Aperture Repair Device," to Gianturco, issued Nov. 2, 1993. ("Gianturco")
1303	U.S. Patent No. 5,496,345, entitled "Expansible Tunneling Apparatus for Creating An Anatomic Working Space," to Kieturakis *et al.*, issued Mar. 5, 1996. ("Kieturakis')
1304	U.S. Patent Application Publication No. 2002/0103494, entitled "Percutaneous Cannula Delivery System for Hernia Patch," to Pacey, published Aug. 1, 2002. ("Pacey")
1305	PCT Publication No. WO 2002/022047, entitled "Implantable Prosthesis," to Cherok *et al.*, published March 21, 2002. ("Cherok")
1306	Bard Composix Kugel Hernia Patch Website, dated April 12, 2001, available at http://web.archive.org/web/20010412200712/http:/davol.com/kugcomp.htm (obtained via Internet Archive). ("Kugel Patch")
1307	510(K) Summary of Safety and Effectiveness for the Composix E/X Mesh and Letter of Substantial Equivalence from FDA, Dated January 22, 2001, K003323. ("Composix Kugel Mesh 510(K)")
1308	U.S. Patent No. 5,545,178, entitled "System for Closing a Percutaneous Puncture Formed by a Trocar to Prevent Tissue at the Puncture from Herniating," to Kensey *et al.*, issued Aug. 13, 1996. ("Kensey")
1309	510(K) Summary of Safety and Effectiveness for the Ventralex Patch and Letter of Substantial Equivalence from FDA, Dated July 16, 2002, K021736. ("Ventralex Patch 510(K)")
1310	Patent Owner Instructions for Use of the Ventralex Patch. ("2002 Ventralex Instructions")
1311	A. Park *et al.*, "Laparoscopic Repair of Large Incisional Hernias," *Surgical Laparoscopy & Endoscopy* 6:123-128 (1996).

Exhibit	Description
1312	J. Scott Roth *et al.*, "Laparoscopic incisional/ventral herniorrhaphy: a five year experience," *Hernia* 4:209-214 (1999).
1313	J. Scott Roth *et al.*, "General Surgery Board Review Manual: Minimally Invasive Abdominal Surgery: An Update," *General Surgery*, Vol. 5, Part 4, 2-11 (1999).
1314	F.K. Toy *et al.*, "Prospective, multicenter study of laparoscopic ventral hernioplasty: Preliminary results," *Surgical Endoscopy* 12:955-959 (1998).
1315	Robert J. Fitzgibbons, Jr. *et al.*, "Laparoscopic Inguinal Herniorrhaphy: Results of a Multicenter Trial," *Annals of Surgery* 221:3-13 (1995).
1316	Declaration of Adrian Park, M.D., Regarding U.S. Patent No. 7,785,334, Claims 99-126, Dated Mar. 13, 2013.
1317	Affidavit of Christopher Butler, Dated Dec. 11, 2012.
1318	File History for U.S. Patent No. 7,785,334, Feb. 17, 2010 Office Action.
1319	Irving A. Knight *et al.*, "The Repair of Large Incisional Hernias," 108 Calif. Med. 96 (1968). ("Knight")
1320	U.S. Patent No. 5,593,441, entitled "Method For Limiting The Incidence of Postoperative Adhesions," to Lichtenstein *et al.*, issued Jan. 14, 1997. ("Lichtenstein")
1321	File History for U.S. Patent No. 7,785,334, Interview Summary of April 6, 2010 Interview.
1322	File History for U.S. Patent No. 7,785,334, April 12, 2010 Supplemental Amendment
1323	File History for U.S. Patent No. 7,785,334, June 25, 2010 Notice of Allowance
1324	G. Piskun *et al.*, "Brief Clinical Report: Simplified Technique of Mesh Fixation during Laparoscopic Repair of Abdominal Ventral Hernia," *Journal of Laparoendoscopic & Advanced Surgical Techniques* 9:193-196 (1999). ("Piskun")
1325	Robert Bendavid, "New Techniques in Hernia Repair," 13 *World J. Surg.* 522-531 (1989).