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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 24-49 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 Party-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 24-49 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 50-77 of the '334 patent, and (iii) claims 99-126 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 are 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

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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 24-49 of the ’334 patent (Ex. 1101). As noted above, three other *inter partes* review petitions address (i) claims 1-23 and 78-98 of the ’334 patent, (ii) claims 50-77 of the ’334 patent, and (iii) claims 99-126 of the ’334 patent.

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. 1102), 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. 1103), 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. 1104), which was published on August 1, 2002, was filed on January 30, 2002, and 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. 1105), 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. 1106) 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. 1107), which is prior art to the '334 patent under 35 U.S.C. § 102(b).

7. U.S. Patent No. 5,545,178 ("Kensey"; Ex. 1108), 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. 1109), 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. 1110), 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. 1119), 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. 1120), 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 24-49, the challenged claims, as unpatentable under 35 U.S.C. § 103.

This Petition, supported by the declaration of Dr. Adrian Park ("Park Declaration" or "Park Decl."; Ex. 1116) 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 because they are obvious under 35 U.S.C. § 103. A 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 [35 U.S.C.] § 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. The broadest reasonable construction is the broadest reasonable interpretation of the claim language. *See In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 2004). 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* Manual of Patent Examining Procedure ("MPEP") § 2111.04.

VI. OVERVIEW OF THE '334 PATENT

A. Brief Description

The application that issued as the '334 patent (Ex. 1101) was filed on August 23, 2006, and is a continuation of U.S. Patent No. 7,101,381, 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. 1101). A prosthesis is an artificial body part used to replace or repair tissue. *See* Park Decl. ¶ 15 (Ex. 1116). A hernia occurs when an organ projects through tissue (usually muscle) that would normally contain it.[1] *Id.* ¶ 20 (Ex. 1116). As described and claimed, the prosthesis of the '334 patent includes two

[1] There are several types of hernias. *See* Park Decl. ¶¶ 16-18 (Ex. 1116), citing Ex. 1111, Ex. 1112, Ex. 1113, Ex. 1114, and Ex. 1115. Additional relevant background information related to hernias, hernia repair and laparoscopic hernia repair techniques is in these references, and also in Ex. 1124 and Ex. 1125. *See* Park Decl. ¶ 11 (Ex. 1116).

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/anchor the patch relative to the opening in the muscle wall. *See, e.g.*, '334 patent col.4 ll.50-57 (Ex. 1101).

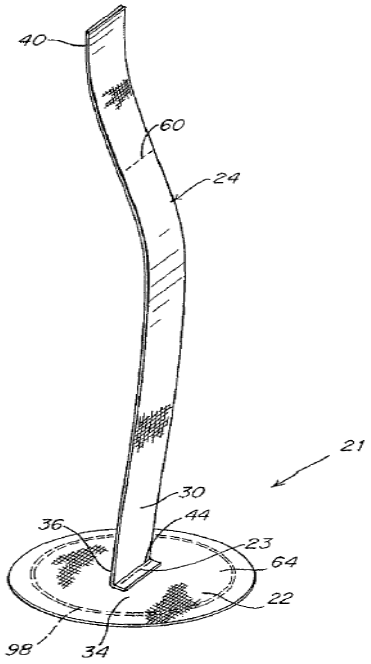


Fig. 1

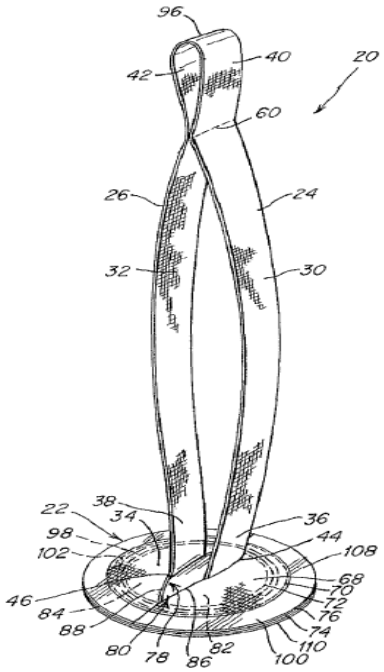


Fig. 7

Figures 1 and 7 (reproduced above) illustrate the prosthesis (21) described in the '334 patent, including a patch (22) and a positioning tether or strap (24). *See, e.g.*, *id.* col.6, ll.12-37 (Ex. 1101).

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. 1106) and the Composix Kugel Mesh 510(K) (Ex. 1107). 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 24-49, 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. 1109); *see also* 2002 Ventralex Instructions (Ex. 1110).

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. 1118). 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. 1121).

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. 1122). The Examiner subsequently allowed the pending claims based on the addition of this language. *See* '334 Patent File History, June 25, 2010 Notice of Allowance (Ex. 1123).

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. 1116). The purported invention is a known combination of features, all of which were old and well known to those skilled in the art before and at the time to which the '334 patent claims priority. In the claimed combinations, the structures all have known functions that perform in expected ways. *See id.* (Ex. 1116). Based on the prior art cited above and described below, the claimed limitations of the alleged invention perform known functions with an expected result.

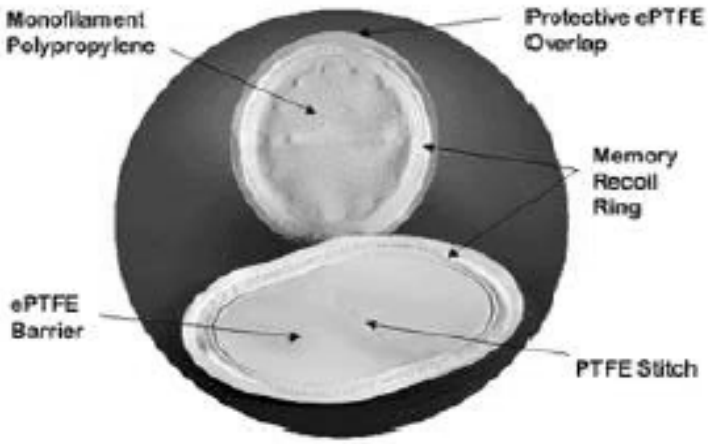
The prior art falls into two categories: (1) prior art references that disclose or make obvious all of the claimed aspects of the patch (the "Patch References"); and (2) prior art references that disclose or make obvious all of the aspects of the claimed "straps" (the "Strap References"). The Strap References also teach, make obvious, and provide one of ordinary skill in the art with ample reason and motivation to add a strap to a hernia patch.

A. 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. 1106), Cherok (Ex. 1105), Lichtenstein (Ex. 1120), and Gianturco (Ex. 1102). 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. 1106) 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]

[2] Attached as Ex. 1117 is an affidavit 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.



> The webpage describes the Patent Owner's product (shown above) as being constructed of a double layer of monofilament polypropylene . . . [and] a barrier of [expanded polytetrafluoroethylene ("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. 1106).

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)***). The FDA issued a notice of allowance on January 22, 2001. *See* Composix Kugel Mesh 510(K) (Ex. 1107). 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 p.2 ll.6-9 (Ex. 1105). 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.* p.4 ll.5-7, p.5 ll.19-20 (Ex. 1105).

Lichtenstein, owned by the Patent Owner, describes "a composite prosthesis . . . for limiting the incidence of postoperative adhesions." Lichtenstein abstract (Ex. 1120). The prosthesis includes a mesh fabric and a barrier layer. *See* Lichtenstein col.3 ll.7-9 (Ex. 1120). The barrier can be formed from oxidized, regenerated cellulose. *See id.* col.4 l.26 (Ex. 1120).

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 col.2 ll.45-51, col.3 ll.10-43, col.4 ll.34-48, col.5 ll.25-33, col.8 ll.45-68 (Ex. 1102).

B. The Strap References

The Strap References, which teach providing a hernia-repair device with one or more straps that serve the purposes discussed in the '334 patent, are Knight (Ex.

1119), Kensey (Ex. 1108), Pacey (Ex. 1104), and Kieturakis (Ex. 1103). These representative references explicitly teach the feature—a strap 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. 1119), wherein a plurality of 2 cm-wide mesh straps 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 1960s, 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. *Id.* (Ex. 1119).

Kensey discloses a hernia-repair device for sealing a tissue opening. *See, e.g.*, Kensey col.5 ll.27-33 (Ex. 1108). The ends of a positioning filament (*i.e.*, a 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.* col.9 ll.34-65 (Ex. 1108).

Pacey discloses a hernia patch prosthesis with an adherence provoking polypropylene mesh layer attached to an adhesion-resistant barrier layer; a metal or plastic frame of concentric circles supporting the layers; and one or more tethers

that may consist of a "fabric element," Pacey claim 4 (Ex. 1104), and that extend from the surface of the patch through the defect to allow manipulation from outside the body to position and/or secure the patch relative to the defect, *see, e.g.*, *id.* ¶¶ 17, 30-33, claims 1, 4, 6 (Ex. 1104).

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 col.8 ll.42-59 (Ex. 1103). The strap may be formed of either the same material as the patch or ePTFE. *Id.* (Ex. 1103).

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 24

Challenged claim 24 requires an implantable prosthesis for repairing an abdominal wall defect including: (a) a multi-layer patch including: (1) an absorbable mesh layer, (2) a non-absorbable mesh layer, and (3) a barrier layer; (b) a support member located between at least one of the mesh layers and the barrier layer, and (c) at least one anchoring strap extending away from the patch 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 the strap is on the other side of the defect, and is adapted to be secured to tissue by an attachment device. All of the features of claim 24 are shown in the prior art. *See* Park Decl. ¶ 29 (Ex. 1116).

1. Claim 24 is Unpatentable over Cherok in View of Any One of the Strap References

As shown in the summary chart below and in the Park Declaration, the prosthesis of claim 24 is obvious in view of Cherok combined with any one of the Strap References (*i.e.*, Knight, Kensey, Pacey, or Kieturakis).

Cherok discloses an implantable prosthesis comprising a patch of repair fabric including an absorbable mesh layer, a non-absorbable mesh layer, and a barrier layer, as required by limitation 24(a). Cherok 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 p.4 ll.5-7 (Ex. 1105). Cherok also discloses "that two or more sheets of fabric and/or barrier material may be implemented in one or more layers of the prosthesis." *Id.* p.4 ll.21-22 (Ex. 1105). Cherok's "repair fabric 22 is formed of a biologically compatible, flexible material . . . which allow[s] sufficient tissue ingrowth to secure the prosthesis to host tissue after implantation."

Id. p.4 ll.9-11 (Ex. 1105). Cherok further discloses that the repair fabric can be composed of an absorbable material. *Id.* p.7 ll.19-24 (Ex. 1105).

Cherok also discloses a support member required by limitation 24(b), such as the peripheral barrier (26 in Cherok Figure 3 below). The peripheral barrier (26) is located between the barrier (24) and the repair fabric (22). *See* Cherok fig.3, p.5 l.29-p.6 l.4 (Ex. 1105); Park Decl. ¶ 32 (Ex. 1116). 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), as taught by Pacey and Gianturco. *See id.* (Ex. 1116); Pacey abstract ¶¶ 3, 8, 31-32, fig. 3, cl. 1-2 (Ex. 1104); Gianturco abstract, 2:24-44, 3:10-23, 5:44-62, 6:11-14, fig. 3, cl. 1-4, 6, 8 (Ex. 1102).

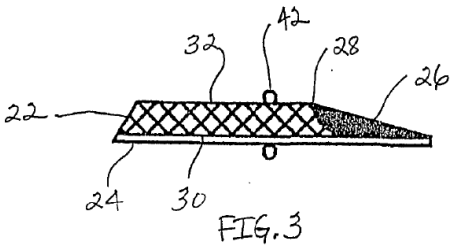


FIG. 3

Cherok, however, does not disclose the use of a strap as recited in the claims. As discussed below, the Strap References disclose or render obvious at least one anchoring strap extending away from the patch, as required by limitation 24(c). *See* Park Decl. ¶ 33 (Ex. 1116).

a) Claim 24 is Obvious over Cherok in View of Knight

Claim 24 is obvious over Cherok in view of Knight. Knight discloses at least one anchoring strap according to claim limitation 24(c) that has a length sufficient to extend through the abdominal wall defect. Knight discloses using straps that are long enough to extend through an abdominal wall and around a defect in the abdominal wall to secure a Marlex® (polypropylene) mesh in place when repairing a large incisional hernia. *See* Knight at 96 (Ex. 1119). As shown in Knight Figure 1 below, strips about 2 cm wide (that is, with a cross-section wider than they are thick) are cut from each side of the mesh sheet. *Id.* at 96-97 (Ex. 1119).

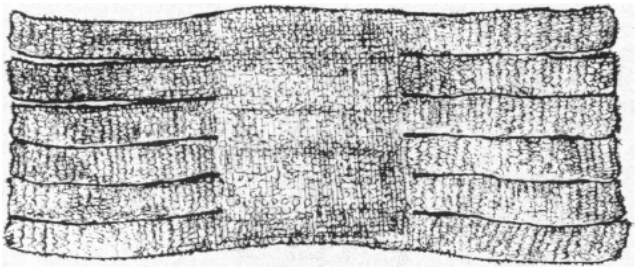


Figure 1.—Prepared Marlex mesh prosthesis.

The strips are adapted to extend through the abdominal wall as shown in Knight Figure 3 (reproduced below). *Id.* at 97 (Ex. 1119). 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, as shown in Knight Figure 5 (reproduced above). *Id.* at 96, 98 (Ex. 1119).

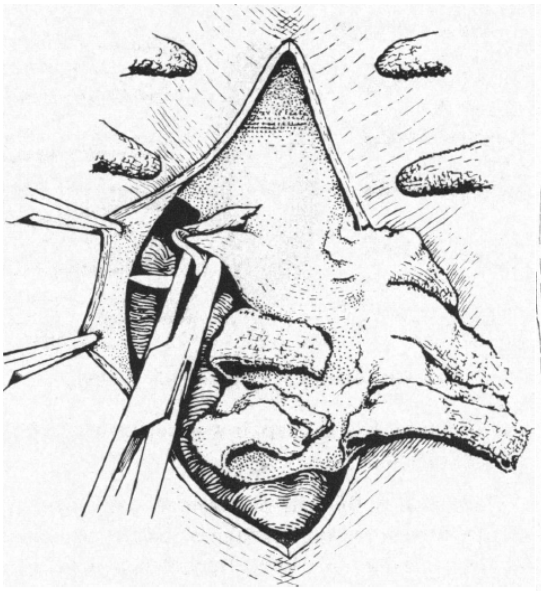


Figure 3.—Insertion of Marlex mesh prosthesis.

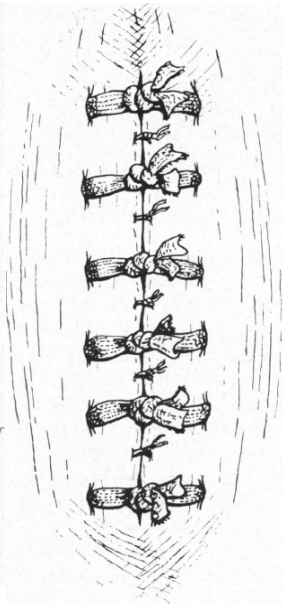


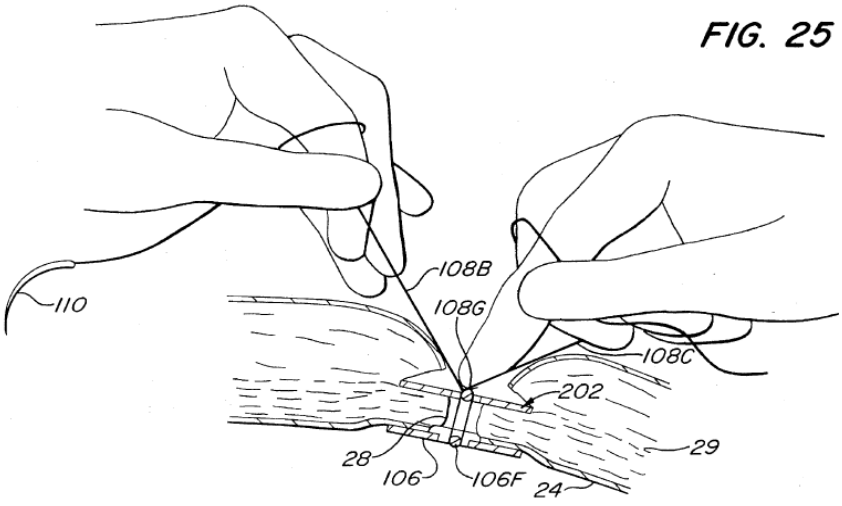
Figure 5.—Completed repair.

Because the straps are long enough to extend around the defect in the abdominal wall, they are necessarily long enough to extend directly through the defect in the abdominal wall, as claim limitation 24(c) requires. *See* Park Decl. ¶ 35 (Ex. 1116). Thus, Knight discloses at least one anchoring strap according to claim limitation 24(c). Together, Cherok and Knight disclose all the elements of claim 24. Knight discloses a hernia repair patch with anchoring straps, and Cherok teaches a multi-layered hernia repair patch with absorbable and non-absorbable mesh layers. 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. Doing so would be nothing more than a combination of known elements used for their known purpose and yielding predictable results. *See, e.g.*, *id.* ¶ 36 (Ex. 1116); Knight at 96 (Ex. 1119) (describing a new material for this simple and "old technique" for hernia repair).

b) Claim 24 is Obvious over Cherok in View of Kensey

Claim 24 is obvious over Cherok in view of Kensey. Kensey discloses a positioning filament, comprising "a very thin flexible member," Kensey col.9 ll.34-37 (Ex. 1108), that is attached to a patch or plug that is introduced "through a percutaneous puncture into some internal tissue," *id.* col.5 ll.27-33 (Ex. 1108), formed during surgery "to seal the opening and/or prevent the egress of tissue into the puncture," *id.* (Ex. 1108). Two end portions of the filament extend through the puncture for positioning and securement to the surrounding tissue. *Id.* col.9 ll.34-65, fig.25 (reproduced below) (Ex. 1108). Kensey also describes a prior art filament as synonymous with a "ribbon (either apertured or unapertured)," which inherently suggests a filament cross-section with a width greater than its thickness. *Id.* col.4 ll.50-55 (Ex. 1108); Park Decl. ¶ 37 (Ex. 1116).



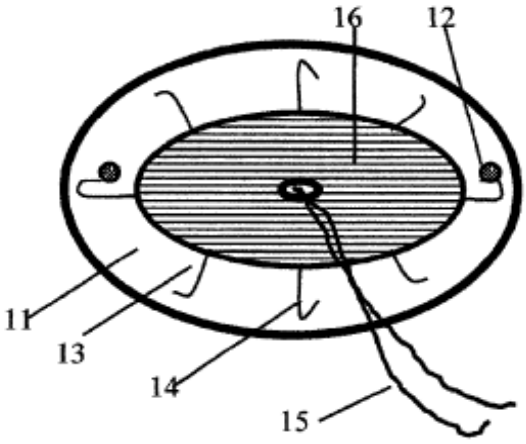
Thus, Kensey discloses at least one anchoring strap according to claim limitation 24(c). Together, Cherok and Kensey disclose all the elements of claim 24. *See id.* (Ex. 1116).

It would have been obvious to one of ordinary skill in the art to use the straps disclosed in Kensey to secure the patch disclosed in Cherok, so that a hernia patch may be positioned to seal a defect "by the application of a pulling force," Kensey col.3 ll.10-25, 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.* col.9 ll.60-65 (Ex. 1108). Doing so would be nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 38 (Ex. 1116).

c) Claim 24 is Obvious over Cherok in View of Pacey

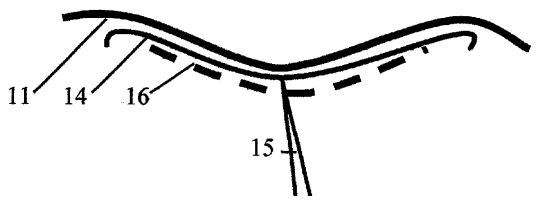
Claim 24 is obvious over Cherok in view of Pacey. Pacey discloses a patch prosthesis for laparoscopically repairing inguinal and other hernia defects. *See* Pacey abstract, claim 1 (Ex. 1104). The patch is constructed and arranged to cover at least a portion of the tissue or muscle wall defect. *Id.* ¶ 10 (Ex. 1104). The patch includes a fabric having an adherent layer (16 in Pacey Figure 3 below) on the side facing the patient's peritoneum in order to provide permanent fixation of the patch to the abdominal wall. *Id.* ¶¶ 4, 30-31, claim 6; *see also* fig.3 (Ex. 1104). In one embodiment, the material of this layer (16) is described to be PROLENE™, or polypropylene mesh. *Id.* ¶ 17, claim 10 (Ex. 1104).

FIG.3



The patch also comprises an adhesion-resistant fabric layer (11) comprising ePTFE or another material, such as silicone, and overlying at least a portion of the surface of the mesh layer 16. *Id.* ¶ 10, claim 6 (Ex. 1104) . In addition, the patch comprises a frame of radiating arms or concentric circles of metal or

FIG. 4



plastic members supporting the fabric layers. *Id.* ¶¶ 8, 31-32, claims 1-2 (Ex. 1104). Preferably, the frame is superelastic nitinol metal that permits the patch to be placed through a cannula and have a predetermined shape (*e.g.*, a ring) that recovers completely from material memory after placement. *Id.* ¶¶ 3, 8 (Ex. 1104).

With respect to the at least one anchoring strap, Pacey's patch includes centrally attached tethers (15 in Pacey Figure 3), which extend from the surface of the patch. *Id.* ¶ 31 (Ex. 1104). In order 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. 1104). Because the tethers may be a "fabric element," *id.* claim 4 (Ex. 1104), one skilled in the art would understand that the tethers may be a woven material consisting of a network of fibers. *See* Park Decl. ¶ 41 (Ex. 1116). Such a material has a cross-section with a width that is inherently greater than its thickness. *Id.* (Ex. 1116). Thus, Pacey discloses at least one anchoring strap according to claim limitation 24(c).

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. *See id.* ¶ 42 (Ex. 1116). 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).

Moreover, there is no unexpected change in the function of the tethers 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. ¶ 43 (Ex. 1116). In this case, the particular strap can have any dimension or shape that would be suitable to assist in the positioning and attachment of the patch. *Id.* (Ex. 1116). Numerous references teach or suggest using a strap with a greater width than thickness. *See, e.g.*, Knight at 96-97 (Ex. 1119); Kensey col.4 ll.50-55 (Ex. 1108).

It would have been obvious to one of ordinary skill in the art to use the tethers disclosed in Pacey to secure the patch disclosed in Cherok, and doing so would be nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 44 (Ex. 1116).

d) Claim 24 is Obvious over Cherok In View of Kieturakis

Claim 24 is obvious over Cherok in view of Kieturakis. Kieturakis discloses an implantable prosthesis with an anchoring strap.

Kieturakis' patch comprises a strap or tail (153 in Fig. 12 at right) extending from the patch through the abdominal wall and having a cross-section with a width that is greater than its thickness. Kieturakis col.9 ll.27-31, 47-52, figs.12-14, 19 (Ex. 1103).

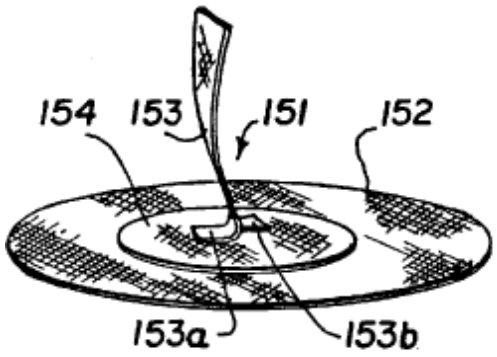


FIG. 12

The tail allows the patch to be positioned in an anatomically correct position and prevents migration through attachment to tissue with an attachment device such as a staple (167 in Fig. 19 at left). *Id.* (Ex. 1103). Thus, Kieturakis discloses one anchoring strap.

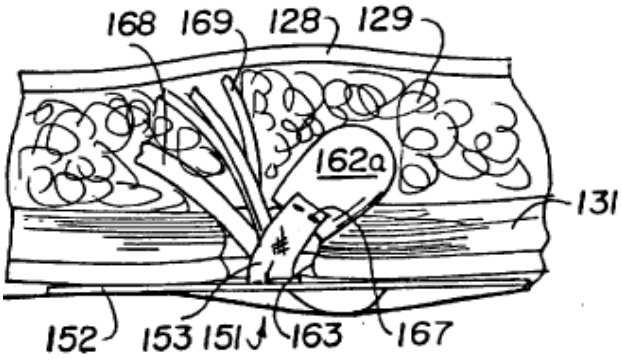


FIG. 19

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cherok with Kieturakis. Both references are in the same field of endeavor, *e.g.*, hernia repair prostheses. Kieturakis teaches using the tail to pull the disk upward into the inguinal ring.

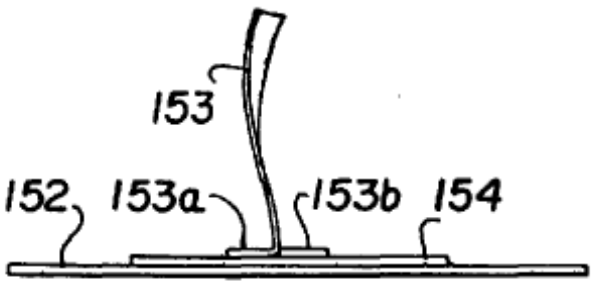


FIG. 13

Id. col.9 ll.27-31 (Ex. 1103); Park Decl. ¶ 47 (Ex. 1116). One of ordinary skill in the art would have been motivated to add a tail to the Cherok patch in order to position the Cherok patch in the defect, and doing so would be nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 47 (Ex. 1116).

2. Claim 24 is Obvious over Gianturco

Gianturco discloses or renders obvious all of the limitations of claim 24. Gianturco teaches an implantable prosthesis for repairing an abdominal wall defect, Gianturco col.1, ll.5-10 (Ex. 1102), a patch of repair fabric including an absorbable mesh layer, a non-absorbable mesh layer, and a barrier layer, *id.* col.5 ll.22-33, col.6 ll.18-24 (Ex. 1102), a support member located between at least one of the mesh layers and the barrier layer, *id.* col.2 ll.24-44 (Ex. 1102), and at least one anchoring suture extending away from the patch that can extend through the abdominal wall defect and be attached to the anatomy, *id.* col.8 ll.45-57, fig.6.

The prosthesis of Gianturco comprises affixation means such as a suture loop, having a pair of sutures extending from the patch to fixedly position the patch over the tissue aperture. Id. at cols. 2:45-51, 3:24-43, 8:45-68, claims 10, 17, 25 (Ex. 1102). Therefore, Gianturco discloses an affixation suture or suture loop which serves the same purpose and achieves the same result as the at least one anchoring strap recited in claim limitation 24(c). Park Decl. ¶ 49 (Ex. 1116). As

can be seen from the Strap 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. 1116).

If 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, *e.g.*, in light of the Kieturakis tether, to modify the dimensions of the suture disclosed by Gianturco so that the width of the suture is greater than the thickness. *Id.* ¶ 50 (Ex. 1116). 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 tethers 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. ¶ 51 (Ex. 1116). In this case, the particular strap can have any dimension or shape that would be suitable to assist in the positioning and attachment of the patch. *Id.* (Ex. 1116). Numerous references teach or suggest using a strap with a greater width than thickness. *See, e.g.*, Knight at 96-97 (Ex. 1119); Kensey col.4 ll.50-55 (Ex. 1108). It would have been obvious to modify the tethers of Gianturco to have a width greater than their thickness, and such a modification would have been the use of a known element with only predictable results. *See* Park Decl. ¶ 51 (Ex. 1116).

3. Claim 24 is Unpatentable over Gianturco in View of Any One of the Strap References

As discussed below, Gianturco in view of any of the Strap References render obvious at least one anchoring strap that has a width greater than its thickness, as required by limitation 24(c).

a) Claim 24 is Obvious over Gianturco in View of Knight

Claim 24 is obvious over Gianturco in view of Knight. As discussed *supra* in Section VIII.A.1, Knight discloses at least one anchoring strap according to claim limitation 24(c) that has a length sufficient to extend through the abdominal wall defect, and that has a thickness that is greater than its width. Together, Gianturco and Knight disclose all the elements of claim 24, and the combination is nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 53 (Ex. 1116). *See, e.g.*, Knight at 96 (Ex. 1119) (describing a new material for this simple and "old technique" for hernia repair).

b) Claim 24 is Obvious over Gianturco in View of Kensey

Claim 24 is obvious over Gianturco in view of Kensey. As discussed *supra* in Section VIII.A.1, Kensey discloses at least one strap that has a length sufficient to extend through the abdominal wall defect, and further teaches that ribbons can also be used, which implicitly have a width greater than their thickness. Together, Gianturco and Kensey disclose all of the elements of claim 24. It would have been

obvious to one of ordinary skill in the art to use the straps disclosed in Kensey to secure the patch disclosed Gianturco, so that a hernia patch may be positioned to seal a defect "by the application of a pulling force," Kensey col.3 ll.10-25 (Ex. 1108), 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.* col.9 ll.60-65 (Ex. 1108). Doing so would be nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 51 (Ex. 1116).

c) Claim 24 is Obvious over Gianturco in View of Pacey

Claim 24 is obvious over Gianturco in view of Pacey. As discussed *supra* in Section VIII.A.1, Pacey discloses at least one tether that has a length sufficient to extend through the abdominal wall defect, and further states that fabric elements can be used, suggesting the use of straps that have a width that is greater than their thickness. Together, Gianturco and Pacey disclose all the elements of claim 24, and the combination is nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 55 (Ex. 1116).

d) Claim 24 is Obvious over Gianturco in View of Kieturakis

Claim 24 is obvious over Gianturco in view of Kieturakis. As just discussed, Gianturco discloses all of the limitations of claim 24 except for straps

having a thickness that is greater than their width. Kieturakis teaches a patch having a strap or tail (153) extending from the patch through the abdominal wall and further having a cross-section with a width that is greater than its thickness. Kieturakis col.9, ll.27-31, 47-52, Figs.12-14, 19 (Ex. 1103). The tail allows the patch to be positioned in an anatomically correct position and prevents migration through attachment to tissue with an attachment device such as a staple (167). *Id.* (Ex. 1103). Thus, Kieturakis discloses at least one positioning strap according to claim limitation 24(c).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Gianturco with Kieturakis. Both references are in the same field of endeavor, *e.g.*, hernia repair prostheses. Kieturakis teaches using the tail to pull the disk upward into the inguinal ring. *Id.* col.9 ll.27-31 (Ex. 1103); Park Decl. ¶ 57 (Ex. 1116). The use of a strap having a width greater than its thickness is nothing more than a combination of known elements yielding predictable results, and is therefore not patentable in view of the references applied. *See* Park Decl. ¶ 58 (Ex. 1116).

4. Claim 24 Is Unpatentable over Kugel Patch in View of Lichtenstein and Further in View of Any One of the Strap References

As shown in the summary chart below and in the Park Declaration, the prosthesis of claim 24 is obvious in view of Kugel Patch combined with

Lichtenstein and any one of the Strap References (*i.e.*, Knight, Kensey, Pacey, or Kieturakis).

Kugel Patch teaches a multi-layer patch having two mesh layers, a barrier layer, and a support ring. *See* Kugel Patch (Ex. 1106). The patch disclosed by Kugel Patch includes "a double layer of monofilament polypropylene," "a barrier of ePTFE," and a "'memory recoil ring,' which causes the patch to spring open and maintain its shape during placement." *Id.* (Ex. 1106). Kugel Patch does not teach a mesh layer that is absorbable.

Lichtenstein discloses that the mesh fabric (12) can be made from absorbable meshes. *See* Lichtenstein col.4 ll.7-10 (Ex. 1120). Thus, the combination of Kugel Patch and Lichtenstein discloses a patch having an absorbable mesh layer, a non-absorbable mesh layer, and a barrier layer according to claim limitations 24(a)-(b).

Neither Lichtenstein nor Kugel Patch teach at least one anchoring strap according to claim limitation 24(c). As discussed below, the Strap References each disclose or render obvious an implantable prosthesis with at least one anchoring strap meeting the requirements of claim limitation 24(c). *See* Park Decl. ¶ 62 (Ex. 1116).

a) Claim 24 is Obvious over Kugel Patch in View of Lichtenstein and Further In View of Knight

Claim 24 is obvious over Kugel Patch in view of Lichtenstein and further in view of Knight. As discussed *supra* in Section VIII.A.1, Knight discloses at least one anchoring strap according to claim limitation 24(c) that has a length sufficient to extend through the abdominal wall defect and have a width that is greater than the thickness. Kugel Patch, together with Lichtenstein and Knight, disclose all the elements of claim 24, and the combination is nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 63 (Ex. 1116). Further, these references all disclose surgical prostheses for use in hernia repair, and a person of ordinary skill in the art would have combined the teachings of these references. *See id.* (Ex. 1116); *see also, e.g.*, Knight at 96 (Ex. 1119) (describing a new material for this simple and "old technique" for hernia repair).

b) Claim 24 is Obvious over Kugel Patch in View of Lichtenstein and Further In View of Kensey

Claim 24 is obvious over Kugel Patch in view of Lichtenstein and further in view of Kensey. As discussed *supra* in Section VIII.A.1, Kensey discloses a pair of straps that each have a length sufficient to extend through the abdominal wall defect, and further teaches that ribbons can also be used, which implicitly have a width greater than their thickness. Kugel Patch, together with Lichtenstein and Kensey, disclose all of the elements of claim 24. It would have been obvious to

one of ordinary skill in the art to use the straps disclosed in Kensey to secure the patch disclosed in Kugel Patch and Lichtenstein so that a hernia patch may be positioned to seal a defect "by the application of a pulling force," Kensey col.3 ll.10-25 (Ex. 1108), 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.* col.9 ll.60-65 (Ex. 1108). *See* Park Decl. ¶ 64 (Ex. 1116). Doing so would be nothing more than a combination of known elements yielding predictable results. Further, these references all disclose surgical prostheses for use in hernia repair, and a person of ordinary skill in the art would have combined the teachings of these references. *See id.* (Ex. 1116).

c) Claim 24 is Obvious over Kugel Patch in View of Lichtenstein and Further In View of Pacey

Claim 24 is obvious over Kugel Patch in view of Lichtenstein and further in view of Pacey. As discussed *supra* in Section VIII.A.1, Pacey discloses at least one tether that has a length sufficient to extend through the abdominal wall defect, and further states that fabric elements can be used, suggesting the use of straps that have a width greater than their thickness. Kugel Patch, together with Lichtenstein and Pacey, disclose all the elements of claim 24, and the combination is nothing more than a combination of known elements yielding predictable results. *See* Park

Decl. ¶ 65 (Ex. 1116). Further, these references all disclose surgical prostheses for use in hernia repair, and a person of ordinary skill in the art would have combined the teachings of these references. *See id.* (Ex. 1116).

d) Claim 24 is Obvious over Kugel Patch in View of Lichtenstein and Further In View of Kieturakis

Claim 24 is obvious over Kugel Patch in view of Lichtenstein and further in view of Kieturakis. As discussed *supra* in Section VIII.A.1.d, Kieturakis discloses a strap or tail extending from the patch that has a length sufficient to extend through the abdominal wall defect, having a cross-section with a width that is greater than its thickness. Kugel Patch, together with Lichtenstein and Kieturakis, disclose or suggest all the elements of claim 24, and the combination is nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 66 (Ex. 1116). Further, these references all disclose surgical prostheses for use in hernia repair, and a person of ordinary skill in the art would have combined the teachings of these references. *See id.* (Ex. 1116).

In summary, the chart below identifies where the above prior art references disclose and/or make obvious the limitations of claim 24 of the ’334 patent.

Claim 24: An implantable prosthesis for repairing an abdominal wall defect, the implantable prosthesis comprising:
See, e.g., Pacey abstract, claim 1 (Ex. 1104); Kieturakis col.1 ll.8-10, col.2 ll.29-32, col.8 ll.42-44, figs.12-14, 16-19 (Ex. 1103); Gianturco col.1 ll.5-10 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok abstract (Ex. 1105); Kensey col.5 ll.27-33, claims

11, 31 (Ex. 1108); Knight at 96 (Ex. 1119).
(a) a patch of repair fabric including an absorbable mesh layer, a non-absorbable mesh layer and a barrier layer;
See, e.g., Pacey ¶¶ 1, 4, 10, 17, 30-31, fig.3, claims 6, 10 (Ex. 1104); Kieturakis col.1 ll.32-37, col.8 ll.42-59, col.10 ll.3-8, col.10 ll.37-41, figs.12-14 (Ex. 1103); Gianturco col.4 ll.34-48, col.5 ll.25-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.2 ll.6-9, p.4 ll.5-11, p.7 ll.14-24 (Ex. 1105); Kensey abstract, col.8 ll.56-63, col.9 ll.1-7, col.9 l.66-col.10 l.4, col.13 ll.44-49, fig.8 (Ex. 1108); Knight at 96, fig.1 (Ex. 1119); Lichtenstein col.4 ll.7-10 (Ex. 1120).
(b) a support member located between at least one of the mesh layers and the barrier layer; and
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1104); Kieturakis col.8 ll.51-57, figs.12-14 (Ex. 1103); Gianturco abstract, col.2 ll.24-44, col.3 ll.10-23, col.5 ll.44-62, col.6 ll.11-14, fig.3, claims 1-4, 6, 8 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.3 ll.4-6, p.4 ll.23-26, p.5 ll.8-10, p.5 ll.19-21, p.5 l.29-p.6 l.4, p.9 l.31-p.10 l.6, figs.1-5, 8-9 (Ex. 1105); Kensey abstract, col.8 ll.6-12, col.8 ll.29-37, col.8 ll.56-67, col.9 ll.1-8, col.9 l.66-col.10 l.4, col.13 ll.38-49, fig.8 (Ex. 1108).
(c) at least one anchoring strap extending away from the patch, the at least one anchoring strap having a cross-section with a width and thickness, the width being greater than the thickness, the at least one anchoring 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, the at least one anchoring strap adapted to be secured to anatomy by an attachment device that includes a suture, staple or tack so as to anchor the patch over the defect.
See, e.g., Pacey ¶¶ 1, 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Kieturakis col.1 ll.32-37, col.8 ll.42-59, col.9 ll.22-32, col.9 ll.47-52, col.10 ll.3-8, figs.12-14, 16-19 (Ex. 1103); Gianturco abstract, col.2 ll.45-51, col.3 ll.24-43, col.5 ll.18-22, col.8 ll.45-68, fig.3, claims 10, 17, 25 (Ex. 1102); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

B. The Dependent Claims Reciting Features Related to the Patch Are Unpatentable

Each of the dependent claims discussed below is directed to subsidiary features of the claimed patch, and it would be obvious to add their respective limitations to the independent claims. 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 mesh layer and features thereof; (3) a second mesh layer and features thereof; (4) tissue ingrowth features; (5) a barrier layer and features thereof; and (6) features of the support ring or member.

1. The References Disclose a Mesh Layer and Features Thereof Recited in Claim 27

Claim 27 depends from claim 26, which as discussed *infra* is unpatentable. Claim 27 is obvious over Cherok in view of any of the Strap References, or by Kugel Patch in view of Lichtenstein and further in view of any of the Strap References.

Claim 27 recites a patch having a mesh layer that is fabricated from an absorbable material, *e.g.*, polyglactin. Cherok teaches a mesh of "*polyglactin* (VICRYL) and polyglycolic acid (DEXON)." Cherok p.7 ll.17-24 (Ex. 1105) (emphasis added). Lichtenstein discloses using a mesh fabric formed of absorbable polyglactin. Lichtenstein col.3 l.66-col.4 l.30 (Ex. 1120).

Claim 27: The prosthesis according to claim 26, wherein the absorbable mesh layer is fabricated from polyglactin.
See, e.g., Cherok p.4 ll.5-11, p.4 ll.21-24, p.7 ll.14-24 (Ex. 1105); Lichtenstein col.3 l.66-col.4 l.30 (Ex. 1120).

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 24, and doing so would have been nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 71 (Ex. 1116). Furthermore, it would have been obvious to one of ordinary skill in the art to select a known material for the mesh layer that could include an absorbable material, such as polyglactin. *Id.* (Ex. 1116). This amounts to the selection of a known material that is useful for its known purpose, and the results of this combination would be predictable. *Id.* (Ex. 1116). Accordingly, claim 27 is not patentable.

2. The References Disclose a Second Mesh Layer and Features Thereof Recited in Claims 25 and 26

Claim 25 depends from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 26 depends from claim 25. Claims 25 and 26 are obvious over Cherok in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References. Claims 25 and 26 are also obvious over Gianturco alone or over Gianturco in view of any of the Strap References.

Claim 26 recites a mesh layer that is fabricated from polypropylene. Claim 25 recites a non-absorbable mesh layer that is located between the absorbable mesh layer and the barrier layer. Gianturco discloses two layers fabricated from non-absorbable *polypropylene* mesh. *See, e.g.*, Gianturco col.4 ll.34-48 (Ex. 1102). The prosthesis disclosed in Kugel Patch is "constructed of a double layer of monofilament *polypropylene*." Kugel Patch (Ex. 1106) (emphasis added). Regarding its mesh fabric (made of, *e.g.*, non-absorbable *polypropylene*), Cherok contemplates that "two or more sheets of fabric and/or barrier material may be implemented in one or more layers of the prosthesis. . . . A separate layer of material may be employed between the repair fabric and the barrier layer." Cherok p.4 ll.21-24 (Ex. 1105).

Claim 25: The prosthesis according to claim 1, wherein the non-absorbable mesh layer is located between the absorbable mesh layer and the barrier layer.
See, e.g., Gianturco abstract, col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.4 ll.5-11, p.4 ll.21-24, p.7 ll.14-24 (Ex. 1105).
Claim 26: The prosthesis according to claim 25, wherein the non-absorbable mesh layer is fabricated from polypropylene.
See, e.g., Gianturco abstract, col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.4 ll.5-11, p.4 ll.21-24, p.7 ll.14-24 (Ex. 1105).

Because double mesh layers were already commonly used in such patches, it would have been obvious to one of ordinary skill in the art to use a second mesh

layer in the prosthesis of Claim 24. *See* Park Decl. ¶ 74 (Ex. 1116). Furthermore, it would have been obvious to one of ordinary skill in the art that the mesh layer could include a non-absorbable material, such as polypropylene, and this would be nothing more than a combination of known elements yielding predictable results. *Id.* (Ex. 1116). Accordingly, claims 25 and 26 are not patentable.

3. The References Disclose Tissue Ingrowth Features Recited in Claim 30

Claim 30 depends from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 30 is obvious over Cherok in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References. Claim 30 is also obvious over Gianturco alone or Gianturco in view of any of the Strap References.

Claim 30 recites a patch that is configured "to allow tissue ingrowth from the first surface into at least one [mesh 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. 1104). Gianturco discloses that the mesh "sheet of material positioned against the tissue aperture

advantageously provides for the ingrowth of repair tissue." Gianturco col.3 ll.41-43 (Ex. 1102).

The polypropylene mesh layer in the Kugel Patch "stimulates tissue in-growth," Kugel Patch (Ex. 1106), 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 p.4 ll.9-11 (Ex. 1105). Even in Kensey, the sealing and anchoring members are configured to enhance the opportunity for scar tissue ingrowth. *See, e.g.*, Kensey col.18 ll.21-26 (Ex. 1108).

Claim 30: The prosthesis according to claim 24, wherein the patch is configured to allow tissue ingrowth from the first surface into at least one of the mesh layers.
See, e.g., Pacey ¶¶ 4, 10, 31 (Ex. 1104); Gianturco col.3 ll.41-43, col.4 ll.39-46 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.4 ll.9-11 (Ex. 1105); Kensey col.8 ll.29-31, col.17 ll.55-58, col.18 ll.21-26, col.18 ll.37-45, claims 9, 19, 29, 39, 54, 67 (Ex. 1108).

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. ¶ 78 (Ex. 1116). 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 patch recited in claim 24 to allow tissue ingrowth on the surface facing the

peritoneum for greater repair stability, and doing so would have yielded predictable results. *See id.* (Ex. 1116). Accordingly, Claim 30 is not patentable.

4. The References Disclose a Barrier Layer and Features Thereof Recited in Claims 28-29, 32 and 40-42

Claims 28, 32 and 40-42 depend from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 29 depends from claim 28. Claims 28-29, 32, and 40-42 are obvious over Cherok in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References. Claims 28-29, 32, and 40-42 are also obvious over Gianturco alone or Gianturco in view of any of the Strap References.

Claims 32 and 40-42 recite locating a barrier layer on the opposite surface of the patch from the defect to resist or minimize tissue adhesions to the patch. Kugel Patch discloses a barrier layer to "minimize[] tissue attachment to the prosthesis, while helping to protect against erosion of the mesh into vital organs." Kugel Patch (Ex. 1106). The prosthesis in Pacey uses ePTFE as an adhesion barrier on the patch surface "exposed to the bowel and omentum." Pacey ¶ 29 (Ex. 1104). 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 col.6 ll.24-28 (Ex. 1102). 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 p.2 ll.6-9 (Ex. 1105).

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 prosthesis of claim 24. *See* Park Decl. ¶ 81 (Ex. 1116). It would have been obvious that such a barrier layer would reduce, minimize, and resist tissue adhesion or attachment. Such a use of an adhesion-resistant barrier layer on a patch was nothing more than a combination of known elements yielding predictable results. *See id.* (Ex. 1116).

Claim 32: The prosthesis according to claim 24, 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. 1104); Gianturco col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, col.8 ll.5-44, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.2 ll.1-9 (Ex. 1105).
Claim 40: The prosthesis according to claim 24, wherein the barrier layer resists tissue adhesions to the patch.
See, e.g., Pacey abstract, ¶¶ 10, 29, fig.3, claim 6 (Ex. 1104); Gianturco col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.2 ll.6-9, p.4 ll.11-14, p.7 l.25-p.8 l.6 (Ex. 1105).
Claim 41: The prosthesis according to claim 24, wherein the barrier layer minimizes tissue attachment to the patch.
See, e.g., Pacey abstract, ¶¶ 10, 29, fig.3, claim 6 (Ex. 1104); Gianturco col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.2 ll.6-9, p.4 ll.11-14, p.7 l.25-p.8 l.6 (Ex. 1105).

Claim 42: The prosthesis according to claim 24, wherein the barrier layer reduces tissue adhesions to the patch.
See, e.g., Pacey abstract, ¶¶ 10, 29, fig.3, claim 6 (Ex. 1104); Gianturco col.4 ll.34-48, col.5 ll.5-33, col.6 ll.18-28, fig.3 (Ex. 1102); Kugel Patch (Ex. 1106); Cherok p.2 ll.6-9, p.4 ll.11-14, p.7 l.25-p.8 l.6 (Ex. 1105).

Claim 28 recites a patch "wherein the barrier layer includes an absorbable material," while claim 29 recites oxidized regenerated cellulose as an absorbable material. 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, col.5 ll.25-33 (Ex. 1102). 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 p.7 l.25-p.8 l.6 (Ex. 1105) (emphasis added). In addition, Lichtenstein teaches using absorbable oxidized regenerated cellulose in a barrier layer. *See, e.g.*, Lichtenstein col.3 l.66-col.4 l.30 (Ex. 1120).

Because the benefits of adhesion resistance were well understood and barrier layers were already commonly used in such patches, it would have been obvious to one of ordinary skill in the art that the barrier layer could include an absorbable material, such as oxidized regenerated cellulose. *See* Park Decl. ¶ 83 (Ex. 1116). Such a use of an barrier layer of absorbable material on a patch was nothing more

than a combination of known elements yielding predictable results. *See id.* (Ex. 1116).

Claim 28: The prosthesis according to claim 24, wherein the barrier layer includes an absorbable material.
See, e.g., Cherok p.4 ll.11-14, p.7 l.25-p.8 l.6 (Ex. 1105); Lichtenstein col.3 l.66-col.4 l.30 (Ex. 1120); Gianturco, col.5 ll.25-33 (Ex. 1102).
Claim 29: The prosthesis according to claim 28, wherein the barrier layer is fabricated from oxidized regenerated cellulose.
See, e.g., Cherok p.4 ll.11-14, p.7 l.25-p.8 l.6 (Ex. 1105); Lichtenstein col.3 l.66-col.4 l.30 (Ex. 1120); Gianturco, col.5 ll.25-33 (Ex. 1102).

Accordingly, claims 28-29, 32, and 40-42 are not patentable.

5. The References Disclose Features of the Support Ring or Member Recited in Claims 39 and 43-45

Claims 39 and 43-45 depend from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 39 is obvious over Cherok in view of any of the Strap References, over Gianturco in view of either Pacey or Kieturakis, or over Kugel Patch in view of Lichtenstein and further in view of either Pacey or Kieturakis. Claims 44-45 are obvious over Cherok in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References, or over Gianturco in view of either Pacey or Kieturakis. Claim 43 is obvious over Cherok in view of Pacey, or over Gianturco in view of Pacey, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References.

Claim 39 recites a patch "wherein the support member includes a polymer ring." Plastic is typically a "polymer." *See* Park Decl. ¶ 85 (Ex. 1116). Pacey discloses a support frame of concentric circles of members made of plastic. *See* Pacey ¶ 31 (Ex. 1104). Likewise, Kieturakis discloses a reinforcing disk formed of a plastic mesh. *See* Kieturakis col.8 ll.42-57 (Ex. 1103). Cherok discloses a support ring of melted polypropylene. *See* Cherok p.9 ll.31-33 (Ex. 1105).

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 1. *See* Park Decl. ¶ 86 (Ex. 1116). Moreover, because polymers are commonly used in such patches, it would have been obvious that a support ring could comprise a polymer. This is a combination of known elements used for their intended purpose with predictable results. *Id.* (Ex. 1116).

Claim 39: The prosthesis according to claim 24, wherein the support ring includes a polymer ring.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1104); Kieturakis col.8 ll.42-57, figs.12-14 (Ex. 1103); Cherok p.3 ll.4-6, p.4 ll.23-26, p.5 ll.8-10, p.5 ll.19-21, p.9 l.31-p.10 l.6, figs.1-5, 8-9 (Ex. 1105).

Claims 44-45 recite a support ring that "reinforces the patch" and "contributes to the stability of the patch." Pacey teaches using a concentric frame with "a design enabling support to be given to the ePTFE patch." Pacey ¶ 8 (Ex. 1104). Likewise, the Kieturakis disc is intended for "***reinforcing***" the patch. *See*

Kieturakis col.8 ll.51-57 (Ex. 1103) (emphasis added). 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 p.5 ll.19-23 (Ex. 1105). Kugel Patch teaches: "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. 1106).

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 the patch of claim 24. *See* Park Decl. ¶ 88 (Ex. 1116). This is nothing more than the combination of known elements according to their established functions yielding predictable benefits. *See id.* (Ex. 1116).

Claim 44: The prosthesis according to claim 24, wherein the support member reinforces the patch.
See, e.g., Pacey abstract, ¶¶ 3, 8, 31-32, fig.3, claims 1-2 (Ex. 1104); Kieturakis col.8 ll.46-57, figs.12-14 (Ex. 1103); Kugel Patch (Ex. 1106); Cherok p.3 ll.4-6, p.4 ll.23-26, p.5 ll.8-10, p.5 ll.19-23, p.9 l.31-p.10 l.6, figs.1-5, 8-9 (Ex. 1105).
Claim 45: The prosthesis according to claim 24, 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. 1104); Kieturakis col.8 ll.46-57, figs.12-14 (Ex. 1103); Kugel Patch (Ex. 1106); Cherok p.3 ll.4-6,

p.4 ll.23-26, p.5 ll.8-10, p.5 ll.19-23, p.9 l.31-p.10 l.6, figs.1-5, 8-9 (Ex. 1105).

Claim 43 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. 1104). The Kugel Patch discloses that the "'memory recoil ring' . . . causes the patch to spring open and maintain its shape during placement." Kugel Patch (Ex. 1106).

Because the benefits of a support member were well understood and already commonly used in such patches, it would have been obvious that a support ring or member could be designed to aid in the expansion of the patch of claim 24. *See* Park Decl. ¶ 90 (Ex. 1116). Again, this is a combination of known elements with no unpredictable results. *See id.* (Ex. 1116).

Claim 43: The prosthesis according to claim 24, 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. 1104); Kugel Patch (Ex. 1106).

Accordingly, claims 39 and 43-45 are not patentable.

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

Each of these dependent claims is directed to subsidiary features of the claimed 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 thereof; (2) a pair of strap portions and features thereof; and (3) features of the strap or attachment device.

1. The References Disclose a Pair of Straps and Features Thereof Recited in Claims 31 and 33-35

Claims 31 and 35 depend from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 33 depends from claim 32, discussed *supra*, and claim 34 depends from claim 33. Claims 31 and 34-35 are obvious over Cherok in view of any of Knight, Pacey, or Kensey, or over Gianturco in view of any of Knight, Pacey, or Kensey, or over Kugel Patch in view of Lichtenstein and further in view of any of Knight, Pacey, or Kensey. Claim 33 is obvious over Cherok in view of either Kensey or Knight, or over Gianturco in view of either Kensey or Knight, or over Kugel Patch in view of Lichtenstein and further in view of either Kensey or Knight.

Claim 31 recites a prosthesis "wherein the at least one anchoring strap includes a pair of anchoring straps." Pacey, Kensey, and Knight disclose or render obvious this limitation of claim 31 for the same reasons they render obvious claim limitation 24(c), discussed *supra* in Section VIII.A.1. For example, Pacey Figure 3 shows a pair of centrally attached tethers (15) extending from the surface of the patch. Pacey ¶ 31, fig.3 (Ex. 1104). Likewise, 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. *See* Knight at 96 (Ex. 1119). Kensey discloses a position filament in which two end portions extend through the puncture for positioning the patch or plug and ***securing*** it to the surrounding tissue. *See* Kensey col.9 ll.34-65, fig.25 (Ex. 1108).

Because pairs of positioning straps were already commonly used with such prostheses, it would have been obvious to one of ordinary skill in the art that a second anchoring strap could be added to the prosthesis of claim 24. *See* Park Decl. ¶ 94 (Ex. 1116). This claim is nothing more than a combination of known elements yielding predictable results. *Id.* (Ex. 1116).

Claim 31: The prosthesis according to claim 24, wherein the at least one anchoring strap includes a pair of anchoring straps.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Claims 33-35 recite one or more anchoring straps "that extend from the first surface of the patch at spaced apart locations," "are adapted to be pulled away from each other," and are "adapted to be moved outwardly and in a direction towards the patch." 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 col.15 ll.31-36 (Ex. 1108).

Knight discloses multiple pairs of mesh straps spaced apart on opposite sides of a mesh patch and pulled apart "through the peritoneum from the intraperitoneal side" to be tied above the layer. Knight at 96 (Ex. 1119). 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. 1104).

Because pairs of positioning straps were already commonly used with such prostheses, it would have been obvious that a pair of opposing straps or straps that are adapted to be pulled apart would improve the placement and securement of the prosthesis. *See* Park Decl. ¶ 96 (Ex. 1116). These claims are nothing more than a combination of known elements yielding predictable results. *Id.* (Ex. 1116).

Claim 33: The prosthesis according to claim 32, wherein the at least one anchoring strap includes a pair of anchoring straps that extend from the first surface of the patch at spaced apart locations.
See, e.g., Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).
Claim 34: The prosthesis according to claim 33, wherein the pair of anchoring straps are adapted to be pulled away from each other.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).
Claim 35: The prosthesis according to claim 24, wherein the at least one anchoring strap is adapted to be moved outwardly and in a direction towards the patch.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-

55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Accordingly, claims 31 and 33-35 are not patentable.

2. The References Disclose Features of the Strap or Attachment Device Recited in Claims 36, 38, 46, 47, and 49

Claims 38, 46, 47, and 49 depend from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 36 depends from claim 35, discussed *supra*. Claims 46 and 47 are obvious over Cherok in view of any of the Strap References, or over Gianturco alone, or over Gianturco in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of the Strap References. Claim 49 is obvious over Cherok in view of any of Knight, Pacey, or Kensey, or over Gianturco alone, or over Gianturco in view of any of any of Knight, Pacey, or Kensey, or over Kugel Patch in view of Lichtenstein and further in view of any of Knight, Pacey, or Kensey. Claim 36 is obvious over Cherok in view of Pacey or Knight, or over Gianturco in view of Pacey or Knight, or over Kugel Patch in view of Lichtenstein and further in view of Pacey or Knight. Claim 38 is obvious over Cherok in view of any of Pacey, Knight, Kensey, or Kieturakis, or over Gianturco in view of any of Pacey, Knight, Kensey, or Kieturakis, or over Kugel Patch in view of Lichtenstein and further in view of any of Pacey, Knight, Kensey, or Kieturakis.

Claim 46 recites adapting the strap[s] to be "manipulated by a user to selectively position the patch to cover an opening to the defect." This claim limitation is obvious for the same reasons that the Primary References and the Strap References disclose or render obvious claim limitation 24(c), discussed *supra* in Section VIII.A.1.

Because various straps 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 to pull or manipulate the patch of claim 24 to cover an opening to the defect, and this would have been a combination of known elements used for their intended purpose with predictable results. *See* Park Decl. ¶ 99 (Ex. 1116).

Claim 46: The prosthesis according to claim 24, wherein the at least one anchoring strap 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. 1104); Kieturakis col.9 ll.20-35, col.9 ll.47-52, figs.12-14, 16-19 (Ex. 1103); Gianturco abstract, col.2 ll.45-51, col.3 ll.24-43, col.5 ll.18-22, col.8 ll.45-68, fig.3, claims 10, 17, 25 (Ex. 1102); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Claim 49 recites a prosthesis wherein the strap or strap portion "is adapted to lie flat relative to the patch." This claim limitation is obvious for the same reasons that the Strap References disclose or render obvious claim 24(c), discussed *supra*

at Section VIII.A.1. The Pacey tether, the Gianturco suture loop, the Kensey flexible member, and the Knight mesh strips are all adapted to lie flat relative to a patch. It would have been obvious to adapt the strap or strap portion to lie flat relative to the patch of claim 24, particularly to ease deployment of the prosthesis, and this would have been a predictable use of a known element according to its established function. Park Decl. ¶ 100 (Ex. 1116).

Claim 49: The prosthesis according to claim 24, wherein the at least one anchoring strap is adapted to lie flat relative to the patch.
See, e.g., Pacey ¶¶ 8, 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Gianturco abstract, col.2 ll.45-51, col.3 ll.24-43, col.5 ll.18-22, col.8 ll.45-68, fig.3, claims 10, 17, 25 (Ex. 1102); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.7, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Claim 36 recites a strap 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, fig.3 (Ex. 1104). 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. 1119). Because the strap 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 from approximately 2.5 inches to approximately 20 inches long, and this would have been a combination of known elements according to their known methods with predictable results. *See* Park Decl. ¶ 101 (Ex. 1116).

Claim 36: The prosthesis according to claim 35, wherein the at least one anchoring strap 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. 1104); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Claim 38 recite a strap that "includes a layer of mesh fabric." Kieturakis discloses a strap "made of a suitable plastic mesh." Kieturakis col.8 ll.42-46 (Ex. 1103). 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 col.4 ll.50-55, col.9 ll.1-13, col.18 ll.45-50 (Ex. 1108). The straps in Knight are cut from a sheet of Marlex® mesh. *See* Knight at 96 (Ex. 1119). 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. 1104); Park Decl. ¶ 102 (Ex. 1216). Also, because mesh is commonly used in such prostheses, it also would have been obvious to use a mesh fabric in the strap. *See* Park Decl. ¶ 102 (Ex. 1116). This is a predictable use of known prior art elements according to their known functions. *See id.* (Ex. 1116).

Claim 38: The prosthesis according to claim 24, wherein the at least one anchoring strap includes a layer of mesh fabric.
See, e.g., Pacey claim 4 (Ex. 1104); Kieturakis col.8 ll.42-59, col.9 ll.27-31, col.9 ll.47-52, figs.12-14, 16-19 (Ex. 1103); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.1-13, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.8, 12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Claim 47 recites a prosthesis wherein "the at least one anchoring strap is adapted to secure the patch at the defect." This claim limitation is obvious for the same reasons that the Strap References disclose or render obvious claim limitation 24(c), discussed *supra* at Section VIII.A.1. Because various straps were already known and used for selectively positioning such prostheses, it would have been obvious to use the strap to secure the patch at the defect, and this would have been merely the predictable use of a prior art element according to its established function. *See* Park Decl. ¶ 103 (Ex. 1116).

Claim 47: The prosthesis according to claim 24, wherein the at least one anchoring strap is adapted to secure the patch at the defect.
See, e.g., Pacey ¶¶ 12, 30-33, figs.1-8, claim 4 (Ex. 1104); Kieturakis col.9 ll.20-35, col.9 ll.47-52, figs.12-14, 16-19 (Ex. 1103); Kensey abstract, col.3 ll.20-29, col.4 ll.50-55, col.9 ll.34-65, col.11 ll.12-21, col.12 ll.10-16, col.15 ll.6-55, col.18 ll.45-50, figs.12, 23, 25 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

Accordingly, claims 36, 38, 46, 47, and 49 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 37

Claim 37 depends from claim 35, which was discussed *supra*. Claim 37 is obvious over Cherok in view of any of Knight, Pacey, or Kensey, or over Gianturco in view of any of Knight, Pacey, or Kensey, or over Kugel Patch in view of Lichtenstein and further in view of any of Knight, Pacey, or Kensey.

Claim 37 recites a prosthesis "wherein the anatomy is a margin of the defect." These claim limitations are obvious for the same reasons that the Patch References and the Strap References disclose or render obvious claim 24, discussed *supra* in Section VIII.A.1. For example, Kieturakis describes placement of the prosthesis "across the inguinal ring" (163 in Kieturakis Figure 19). Kieturakis col.9 ll.22-32, fig.19 (Ex. 1103). Similarly, Knight describes placement of the prosthesis relative to the "strong fascial edges of the defect." Knight at 96 (Ex. 1119).

Claim 37: The prosthesis according to claim 35, wherein the anatomy is a margin of the defect.
See, e.g., Pacey abstract (Ex. 1104); Kieturakis col.9 ll.22-32, col.9 ll.47-52, figs.12, 17, 19 (Ex. 1103); Gianturco col.5 ll.50-60, col.8 ll.48-60 (Ex. 1102);

Cherok p.4 ll.15-18, p.9 ll.9-20 (Ex. 1105); Kensey col.5 ll.28-36, col.7 ll.39-56, col.8 ll.1-7 (Ex. 1108); Knight at 96-97, figs.1, 3-5 (Ex. 1119).

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, and the results of attaching straps to a margin of the defect would have had predictable results. *See* Park Decl. ¶ 107 (Ex. 1116). Accordingly, claim 37 is not patentable.

2. The References Disclose the Prosthesis for Particular Defects Recited in Claim 48

Claim 48 depends from independent claim 24, which, as discussed *supra*, is unpatentable in view of the previously discussed prior art. Claim 48 is obvious over Cherok in view of any of the Strap References, or over Gianturco alone or Gianturco in view of any of the Strap References, or over Kugel Patch in view of Lichtenstein and further in view of any of Pacey, Kensey, or Knight.

Claim 48 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 col.9 ll.61-65 (Ex. 1102).

More specifically, Pacey indicates repair of "Inguinal and other Hernias." Pacey abstract (Ex. 1104). Knight also explicitly references umbilical hernias. *See* Knight at 98 (Ex. 1119). Some references explicitly indicate incisional or ventral

hernias. *See, e.g.*, *id.* at 96 (Ex. 1119); Cherok p.4 ll.2-5 (Ex. 1105). Kensey addresses trocar punctures. *See* Kensey title, col.2 ll.3-10 (Ex. 1108).

Claim 48: The prosthesis according to claim 24, wherein the defect is one of an umbilical hernia, incisional hernia or a trocar puncture.
See, e.g., Pacey abstract (Ex. 1108); Gianturco abstract, col.9 ll.61-65 (Ex. 1102); Cherok p.4 ll.2-5 (Ex. 1105); Kensey title, col.1 ll.9-14, col.2 ll.3-10, col.5 ll.28-36, col.7 ll.39-56, col.8 ll.1-7, col.17 ll.32-39 (Ex. 1108); Knight at 96-98 (Ex. 1119).

It would have been obvious to one of ordinary skill in the art that the prosthesis of Claim 24 would be suitable for various abdominal wall defects, including umbilical hernias, incisional hernias, or trocar punctures, and this would have been nothing more than a combination of known elements yielding predictable results. *See* Park Decl. ¶ 111 (Ex. 1116). Thus, claim 48 is not patentable.

Based on the foregoing, claims 24-49 of the '334 patent recite subject matter that is obvious. The Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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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 24-49 of U.S. Patent No. 7,785,334 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibits 1101-1125
- List of Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 7,785,334, Claims 24-49 (Exhibits 1101-1125)
- Fee Authorization
- Atrium Medical Corp. Power of Attorney

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

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LIST OF EXHIBITS FOR
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 7,785,334, CLAIMS 24-49

Exhibit	Description
1101	U.S. Patent No. 7,785,334, entitled "Implantable Prosthesis," to Ford *et al.*, issued August 31, 2010.
1102	U.S. Patent No. 5,258,000, entitled "Tissue Aperture Repair Device," to Gianturco, issued Nov. 2, 1993. ("Gianturco")
1103	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')
1104	U.S. Patent Application Publication No. 2002/0103494, entitled "Percutaneous Cannula Delivery System for Hernia Patch," to Pacey, published Aug. 1, 2002. ("Pacey")
1105	PCT Publication No. WO 2002/022047, entitled "Implantable Prosthesis," to Cherok *et al.*, published March 21, 2002. ("Cherok")
1106	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")
1107	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)")
1108	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")
1109	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)")
1110	Patent Owner Instructions for Use of the Ventralex Patch. ("2002 Ventralex Instructions")

Exhibit	Description
1111	A. Park *et al.*, "Laparoscopic Repair of Large Incisional Hernias," *Surgical Laparoscopy & Endoscopy* 6:123-128 (1996).
1112	J. Scott Roth *et al.*, "Laparoscopic incisional/ventral herniorrhaphy: a five year experience," *Hernia* 4:209-214 (1999).
1113	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).
1114	F.K. Toy *et al.*, "Prospective, multicenter study of laparoscopic ventral hernioplasty: Preliminary results," *Surgical Endoscopy* 12:955-959 (1998).
1115	Robert J. Fitzgibbons, Jr. *et al.*, "Laparoscopic Inguinal Herniorrhaphy: Results of a Multicenter Trial," *Annals of Surgery* 221:3-13 (1995).
1116	Declaration of Adrian Park, M.D., Regarding U.S. Patent No. 7,785,334, Claims 24-49, Dated March 13, 2013.
1117	Affidavit of Christopher Butler, Dated Dec. 11, 2012.
1118	File History for U.S. Patent No. 7,785,334, Feb. 17, 2010 Office Action.
1119	Irving A. Knight *et al.*, "The Repair of Large Incisional Hernias," 108 Calif. Med. 96 (1968). ("Knight")
1120	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")
1121	File History for U.S. Patent No. 7,785,334, Interview Summary of April 6, 2010 Interview.
1122	File History for U.S. Patent No. 7,785,334, April 12, 2010 Supplemental Amendment
1123	File History for U.S. Patent No. 7,785,334, June 25, 2010 Notice of Allowance

Exhibit	Description
1124	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")
1125	Robert Bendavid, "New Techniques in Hernia Repair," 13 *World J. Surg.* 522-531 (1989).