

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

W.L. GORE & ASSOCIATES, INC.,  
Petitioner,

v.

LIFEPORT SCIENCES LLC,  
Patent Owner.

---

Case IPR2014-01323  
Patent 5,716,365

---

Before JOSIAH C. COCKS, PHILLIP J. KAUFFMAN, and  
BENJAMIN D. M. WOOD, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION  
Institution of *Inter Partes* Review  
37 C.F.R. § 42.108

## I. INTRODUCTION

Petitioner, W. L. Gore & Associates, Inc., (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–24 of U.S. Patent No. 5,716,365 (Ex. 1001, “the ’365 patent”). Patent Owner, LifePort Sciences LLC (“Patent Owner”), did not file a Preliminary Response. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in showing that claims 1–24 of the ’365 patent are unpatentable. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to claims 1–24.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner’s Response). This is not a final decision as to patentability of the claims for which *inter partes* review is instituted. Our final decision will be based on the record, as fully developed during trial.

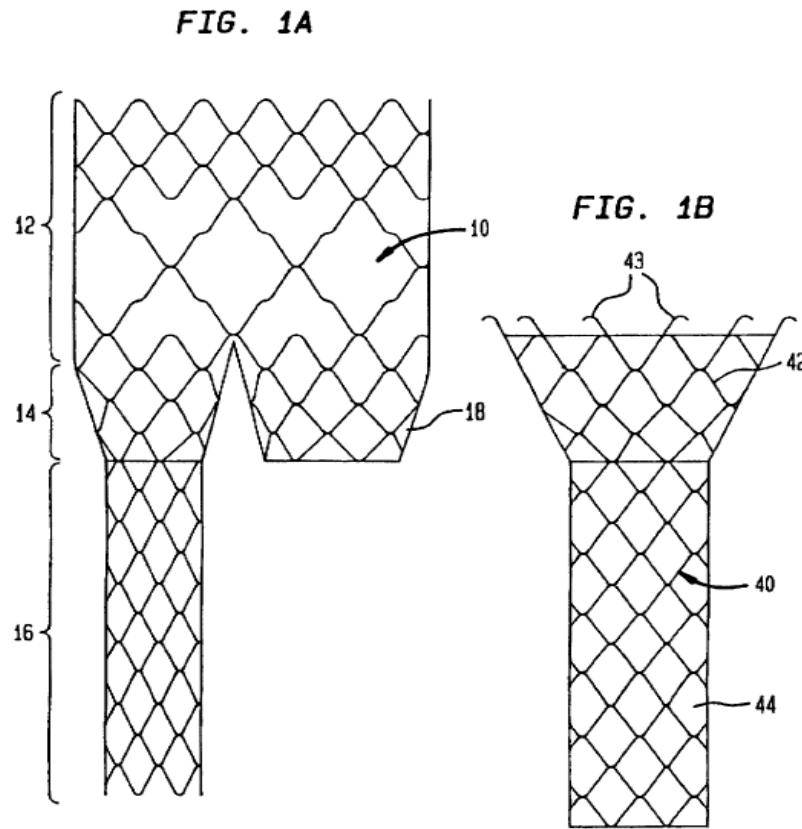
### A. Related Matters

The ’365 patent is the subject of litigation styled *LifePort Sciences LLC v. W.L. Gore & Associates, Inc.*, Case no. 12-cv-1792 (D. Del). Paper 6, 1; *see* Pet. 1.

*B. The '365 Patent (Ex. 1001)*

The '365 patent is titled "Bifurcated Endoluminal Prosthesis." Ex. 1001, Title. The invention is described as providing "a stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents." *Id.* at 2:18–21. According to the '365 patent, prior art stents and prostheses are "generally satisfactory for the treatment of aneurysms, stenosis and other angeological diseases at sites in continuous unbifurcated portions of arteries or veins." *Id.* at 1:57–60. The '365 patent goes on to discount the prior art in situations "where the site of desired application of the stent or prosthesis is juxtaposed or extends across a bifurcation in an artery or vein such, for example, as the bifurcation in the mammalian aortic artery into the common iliac arteries." *Id.* at 1:61–66.

Figure 1A of the '365 patent illustrates "a front view of a bifurcated intraluminal stent in accordance with the present invention constituting part of an endoluminal prosthesis," and Figure 1B illustrates "a front view of another stent which is adapted to be connected to the bifurcated stent of FIG. 1a." *Id.* at 7:41–45. Those figures are reproduced below:



As shown in Figure 1A above, bifurcated stent 10 is composed of a wire skeleton that is constructed of four separate parts: proximal part 12, frustoconical part 14, first distal part 16, and second frustoconical part 18. *Id.* at 8:45–49. As depicted in Figure 1B, second stent 40 includes proximal frustoconical part 42 and distal part 44. *Id.* at 11:10–14. The '365 patent explains that, in use, stent 40 is “compressed radially inwards” and “frustoconical proximal part 42 is guided, in the radially compressed state, into the second frustoconical part 18 of the bifurcated stent 10.” *Id.* at 11:27–32. Each of stent 10 and stent 40 may be made from “shape memory nitinol (nickel-titanium) wire,” which, after deformation of a stent, allows for the stent to “remember[],” and return to, a particular configuration after undergoing a process involving heating and cooling. *Id.* at 3:38–45. After second stent 40 is positioned with respect to bifurcated stent 10, stent 40 is

allowed “to re-expand towards its remembered configuration, . . . and the outer surface of the frustoconical proximal part **42** engages the interior surface of the second frustoconical part **18** of the bifurcated stent **10**.” *Id.* at 11:33–37. The ’365 also explains that barbs 43 operate to engage an inner wall of an artery. *Id.* at 39–44. The ’365 patent further generally describes the following with respect to the connection of two stents:

According to one aspect of the present invention there is provided a stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents, the stent connecting means including a first stent including a male engaging portion which can be compressed radially inwardly, and a second stent including a female cooperating portion. The male engaging portion may be entered into the female cooperating portion in a radially compressed state and thereafter caused to allowed to expand in the female cooperating portion; the arrangement being such that in service the interengagement of the male engaging portion and the female cooperating portion serves to resist longitudinal separation of the two stents one from the other.

*Id.* at 2:18–31.

The ’365 patent also explains that a stent of the disclosed invention may carry a “fabric graft layer . . . for use as an endoluminal prosthesis e.g. in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries.” *Id.* at 8:49–53; *see also* 11:14–18.

### *C. Illustrative Claims*

Claims 1, 19, 20, 22, 23, and 24 are independent claims. Independent claims 1, 22, 23, and 24 are each drawn to a stent joining means, and describe the first and second endoluminal stents, each having male and female engaging portions. The male portions are configured to “be

compressed radially inwardly,” and, in claim 1, the material of the stents is specifically a “shape memory alloy.” Upon expansion of the male portion, the male and female portions enter into “frictional inter-engagement” (claims 1 and 22) or “inter-engagement” (claims 23 and 24). Independent claim 19 is drawn to a method of joining first and second endoluminal stents. Independent claim 20 is drawn to a method of forming an endoluminal stent within the vasculature of a body and includes the insertion of a first stent portion into a second stent portion. Both claims require that a first stent, or portion thereof, “expand by thermal transformation” such that the two stents engage one another.

Claims 2–18 ultimately depend from claim 1. Claim 21 depends from claim 20.

Claims 1 and 19 are illustrative of the subject matter at issue, and are reproduced below:

1. A stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising:

a male engaging portion on said first endoluminal stent which has an outer surface and can be compressed radially inwardly; and

a female portion on said second endoluminal stent cooperating with said male engaging portion, said female portion having an inner surface;

wherein said first endoluminal stent and said second endoluminal stent consist of a shape memory alloy and the male engaging portion can be entered into the female portion in a radially compressed state and thereafter thermally induced to expand in the female portion and wherein a frictional inter-

engagement between said outer surface of the male engaging portion and said inner surface of the female portion prevents longitudinal movement of the first endoluminal stent relative to the second endoluminal stent.

19. A method of joining a first endoluminal stent having an outer surface with a second endoluminal stent having an inner surface within the vasculature of a body comprising the steps of inserting an end of said first endoluminal stent at least partially into an end of said second endoluminal stent, and allowing said end of said first endoluminal stent to expand by thermal transformation and contact said end of said second endoluminal stent such that said outer surface of said first endoluminal stent frictionally engages said inner surface of said second endoluminal stent to prevent relative longitudinal movement of said first and second endoluminal stents.

*D. References Relied Upon*

The Petition relies on the following references:

Cragg	US 5,405,377	Apr. 11, 1995	Ex. 1002
Schaer	John Schaer et al., “ <i>Treatment of malignant esophageal obstruction with silicone-coated metallic self-expanding stents</i> ,” <i>Gastrointestinal Endoscopy</i> , Vol. 38, No. 1, 7–11 (1992).		Ex. 1003
Lazarus	US 5,871,536	Feb. 16, 1999	Ex. 1004
Dumon	US 5,236,446	Aug. 17, 1993	Ex. 1005
Pinchuk	US 5,226,913	July 13, 1993	Ex. 1006
Andersen	US 5,366,504	Nov. 22, 1994	Ex. 1007

*E. The Alleged Grounds of Unpatentability*

Petitioner contends that claims 1–24 of the ’365 patent are unpatentable under 35 U.S.C. § 103 on the following grounds:

References	Claims challenged
Cragg and Schaer	1–4, 6–9, 11, 13–16, and 19–22
Cragg, Schaer, and Lazarus	5, 17, and 18
Cragg, Schaer, and Dumon	5, 17, and 18
Cragg, Schaer, and Pinchuk	10, 12, and 23
Cragg, Schaer and Andersen	24

II. ANALYSIS

*A. Claim Construction*

*1. Claim Construction of an Expired Patent*

Petitioner contends that “the ’365 Patent expires on February 10, 2015.” Pet. 11 (citing 35 U.S.C. §(c)(1)). February 10, 2015 has passed. We agree that, based on the record before us, the ’365 patent is now expired.

In an *inter partes* review, a claim in an *unexpired* patent is given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b). The Board’s review of the claims of an *expired* patent, however, is similar to that of a district court’s review. *In re Rambus, Inc.*, 753 F.3d 1253, 1255–1256 (Fed. Cir. 2014) (involving an *inter partes* reexamination of claims 26 and 28 of U.S. Patent No. 6,426,916 B2) (“If, as is the case here, a reexamination involves claims of an expired patent, a patentee is unable to make claim amendments and the PTO



applies the claim construction principles outlined by this court in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005)"); *see also In re Rambus, Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012) (involving an *ex parte* reexamination of claim 18 of U.S. Patent No. 6,034,918) ("the Board's review of the claims of an expired patent is similar to that of a district court's review.")

Accordingly, in this proceeding, the claims in the now expired '365 patent will be construed under the principles in *Phillips*, 415 F.3d at 1312–1313 (Fed. Cir. 2005) (en banc) (words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention).

We will not apply a rule of construction that claims should be construed to preserve their validity.<sup>1</sup> *See, e.g., Google Inc. and Yahoo! Inc. v. Createads LLC*, IPR2014-00200, Paper 19, 2, (PTAB July 16, 2014) ("[n]o presumption of validity is applied" to interpreting claims in an expired patent.) The different standard we use in construing the claims in an expired patent does not change the statutory requirement in this proceeding that Petitioner has the burden of proving a proposition of unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e).

## 2. Means Plus Function in the Preamble

As noted by Petitioner, claims 1–18 and 22–24 each recite "stent joining means for joining a first endoluminal stent . . . to a second endoluminal stent . . . comprising . . . ." Pet. 12. Petitioner urges that the

---

<sup>1</sup> "While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction." *Phillips*, 415 F.3d at 1327.

above-noted recitation, which appears in the preamble of each claim, does not invoke 35 U.S.C. § 112, sixth paragraph. *Id.* On this record, we agree.

A claim limitation that uses the word “means” invokes a rebuttable presumption that § 112, sixth paragraph applies. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). That presumption is rebutted, however, if the claim also recites “‘sufficiently definite structure’” in connection with the means. *Id.* (citation omitted). That is the case here. Although the preambles of the claims may not recite any corresponding structure, the bodies of the claims introduce numerous structural features that constitute part of the “stent joining means,” and which remove the pertinent feature from the province of § 112, sixth paragraph.

### 3. *Specific Terms*

Petitioner also urges particular constructions for the claim terms “proximal,” “distal,” and “shape memory alloy.” Pet. 15. The proposed constructions are as follows:

Term	Proposed construction and support
“proximal” (Claims 2, 5, 7, 9, 24)	“nearest to the heart” Ex. 1001, 2:15-16.
“distal” (Claims 5, 8, 10, 17, 18, 24)	“furthest from the heart” <i>Id.</i> at 2:16-17.
“shape memory alloy” (Claim 1)	“alloy that recovers original shape on being raised to a higher temperature” <i>Id.</i> at 3:35-63.

*See id.*

We observe that meanings proffered for “proximal” and “distal” are derived from explicit definitions appearing in the Specification of the ’365

patent. *See* Ex. 1001, 2:15–17. The proposed meaning of “shape memory alloy” is consistent with the Specification, and, on this record, we understand it to be the ordinary and customary meaning of the term.

At this time, we do not discern any ambiguity in any claim terms whose meaning has not been made explicit above. All other claim terms have been given their ordinary and customary meaning, and we do not make explicit the meanings for purposes of this decision.

## *B. Discussion*

### *1. Obviousness over Cragg and Schaer*

Petitioner contends that claims 1–4, 6–9, 11, 13–16, and 19–22 are unpatentable over Cragg and Schaer.

The Supreme Court has made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). Based on its precedent, the Court reaffirmed the principle that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* To reach that conclusion, however, requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under review. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). “Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.* Indeed, in many cases a person of ordinary skill, who is also a person of ordinary creativity, “will be able to fit the teachings of multiple

patents together like pieces of a puzzle.” *KSR*, 550 U.S. at 420–421.

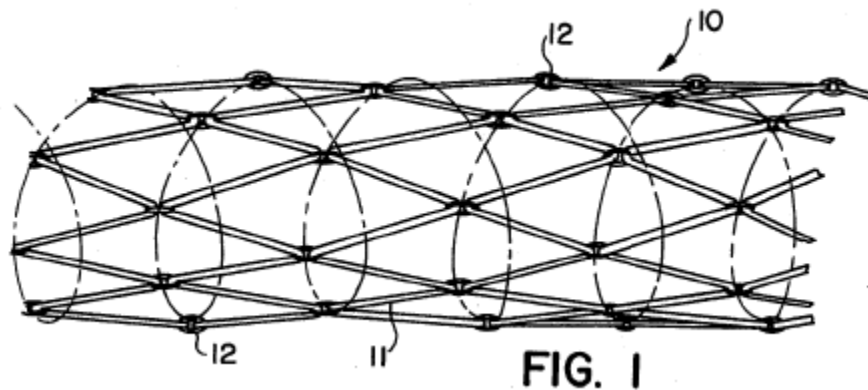
Against that general background, we consider the references, other evidence, and arguments on which Petitioner relies.

Cragg is titled “Intraluminal Stent.” Ex. 1002, Title. Cragg describes its inventive stent as follows:

The stent of the present invention has a flexible construction which allows it to follow the curvature of the vessel which receives it. It has an elastic construction which allows implantation without a balloon catheter. This elasticity further allows compression of the structure and recoil upon implantation to produce delayed dilation of the receiving vessel.

*Id.* at 1:44–51.

Cragg’s Figure 1 is described as “a perspective view of the intraluminal stent of the present invention,” and is reproduced below:

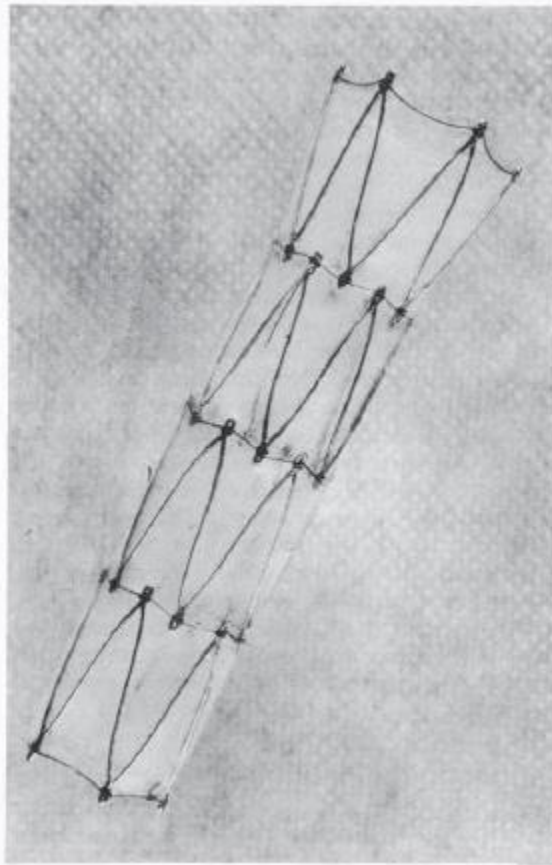


As shown in Figure 1 above, stent 10 includes wire body 11 made of wire having a “a sinuous or zig-zag configuration and defining a continuous helix with a series of connected spirals or hoops.” *Id.* at 2:40–45. Cragg further discloses that the wire body of the stent is an “elastic alloy which provides radial elasticity for the stent,” and preferably is “a nitinol alloy which has superior elasticity and fatigue resistance.” *Id.* at 2:50–53. Cragg

also explains that once the stent, in a compressed state, is inserted into a location with a subject's body, "body fluids warm the nitinol and place it in an austenitic phase which is the stable phase of this metal and which corresponds to a fully opened or expanded configuration of the stent." *Id.* at 4:11–16.

Petitioner contends that "Cragg discloses the basic, covered stent of the claims addressed in the instant Ground, with the exception of joining such stents in a male to female fashion in a fluid tight, non-separable manner, and the use of flares/tapers or barbs to help avoid stent movement." Pet. 22–23; *see also* Pet. 27–30 (claim charts). As discussed above, the claims of the '365 patent require stents with male and female portions for attachment to one another in a manner recognized as frictional inter-engagement. We do not discern that the claims include any explicit requirement of "flares/tapers or barbs" as a part of that engagement. Nevertheless, to account for mechanisms that facilitate the frictional inter-engagement, Petitioner relies on the teachings of Schaer.

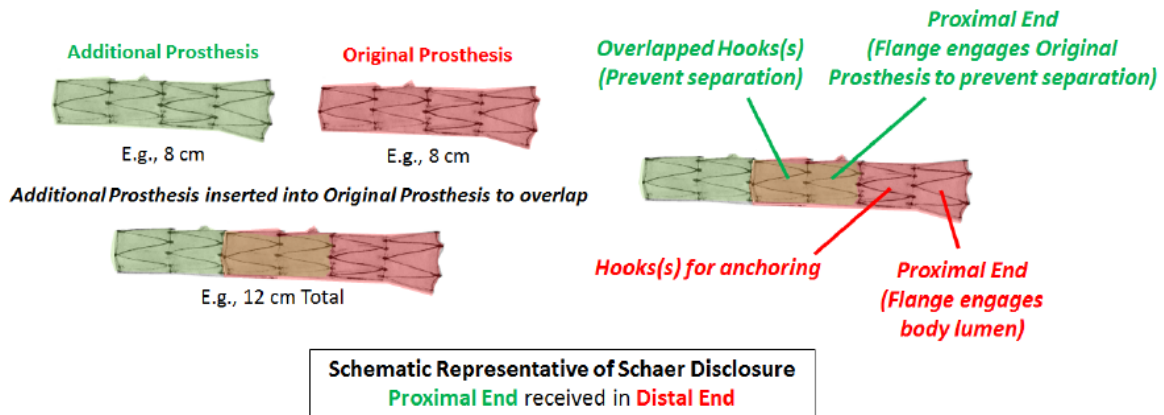
Schaer is a journal article titled "Treatment of malignant esophageal obstruction with silicone-coated metallic self-expanding stents." Ex. 1003, Title. Figure 1 from Schaer is reproduced below:



**Figure 1.** Stainless steel self-expanding Z stent with silicone membrane.

As noted in the caption of Figure 1 above, the illustrated stent is one characterized as a “self-expanding Z stent.” *Id.* at 8. In connection with such stents, Schaer explains the following: “[w]ith Z stents an overlapping stent can be placed at either end of the original stent to, in effect, extend the stented region.” *Id.* at 10. Schaer also discloses that its stents are equipped with “long wire hooks” on the exterior of the stent for anchoring the stent within a patient. *Id.* at 8.

Petitioner's declarant, Dr. Enrique Criado<sup>2</sup>, provides the following schematic drawing:



This drawing depicts Dr. Criado's a representation of some of the concepts described by Schaer, as would have been understood by a person of ordinary skill in the art. Ex. 1013 ¶ 120. According to Dr. Criado, Schaer teaches joining two endoluminal stents in a manner encompassed by the claims of the '365 patent. *Id.* ¶¶ 121, 123. Pointing to content of Schaer, Cragg, and the Declaration testimony of Dr. Criado, Petitioner contends the following:

[I]t would be apparent from Schaer to overlap covered shape memory alloy stents as disclosed by Cragg in the body, that they should remain joined in service and should not separate and they should forma continuous, and preferably fluid tight lumen with one another. Ex. 1013, ¶¶ 121,124. For example, a person of ordinary skill would recognize the advantages of

<sup>2</sup> Dr. Criado attests that he has over 20 years of academic and professional experience in vascular surgery and endovascular interventions. Declaration of Enrique Criado, M.D., Ex. 1013 ¶ 3. Dr. Criado also attests that he has experience in both developing and making stent grafts, in the surgical placement of grafts, and in the endovascular placement of stent grafts and stents. *Id.*

combining a shape memory alloy, sinuous or zig-zag structure covered stent as described in Cragg . . . with the advantages of incorporating structures for preventing stent migration and applying methods of overlapping covered stents such that they do not separate in service as taught by Schaer . . . Ex. 1013, ¶¶ 120-122. It would have been obvious from at least those disclosures to have graft layers on either inner or outer surfaces of stents to provide a fluid tight lumen, for example, and that those layers would necessarily be frictionally engaged to prevent separation in service. *E.g.*, Ex. 1003 at pp.7-8 (*Stents*, section); Ex. 1002 at 3:15-17, 27-28; Ex. 1013, ¶¶ 120, 121. It would also be apparent from Cragg that overlapping of such shape memory alloy structures would be accomplished by first thermally inducing one covered stent to expand in the vessel, inserting an additional covered stent within the original stent, and expanding that stent to form a male-female overlap between the two stents. *E.g.*, Ex. 1002 at 4:4-16; Ex. 1013, ¶ 125.

Pet. 23–24. Petitioner also reasons that combining the teachings of Schaer with those of Cragg “would have been known and desirable to a person of ordinary skill in the art,” and that “such a modification of Cragg would be readily apparent, desirable, and achievable to the person of ordinary skill in the art.” *Id.* at 23 (citing Ex. 1013 ¶¶ 120, 123).

In light of the record before us, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in its contention that claims 1–4, 6–9, 11, 13–16, and 19–22 are unpatentable over Cragg and Schaer.

## *2. Obviousness over Cragg, Schaer, and Lazarus*

Petitioner contends that claims 5, 17, and 18 are unpatentable over Cragg, Schaer, and Lazarus. Those claims depend, either directly or indirectly, from claim 1. Claims 5, 17, and 18 generally recite limitations



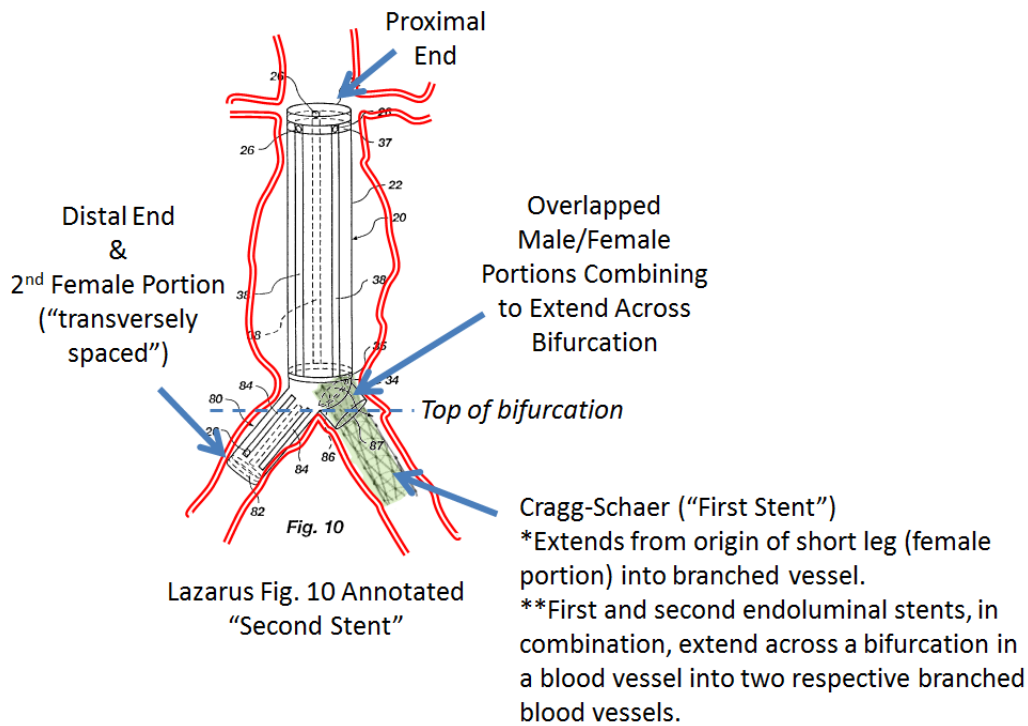
pertaining to the configuration of the first and second endoluminal stents such that the stents may be positioned to extend across a “bifurcation” in a blood vessel and extent within two respective branches of the blood vessel.

Lazarus is titled “Intraluminal Vascular Graft and Method.” Ex. 1004, Title. Lazarus describes that the vascular graft includes a frame structure with “circumferential” and “longitudinal” support structures. *Id.* at Abstract. Lazarus also describes the following:

The intraluminal vascular graft may include one or more leg portions suitable for repairing bifurcated vessels which, in conjunction with the circumferential and longitudinal support structures, assure positioning and support of the vascular graft within the vessel and against the crotch of the bifurcation. Also disclosed is a method of deployment of the vascular graft within the vessel.

*Id.*

Lazarus further discloses that the longitudinal support structures for the vascular graft may be adjustable in length, with one member telescopically positioned relative to the other. *Id.* at 10:28–41. Petitioner’s declarant, Dr. Criado, characterizes Lazarus’s disclosure as conveying support structures that are “self-expanding.” Ex. 1013 ¶ 129. According to Petitioner, it would have been obvious to combine the covered continuous stent designs and overlapping methodology provided by the combination of Cragg and Schaer with the bifurcated, self-expanding covered stent structure of Lazarus to arrive at the limitations of the challenged claims. Pet. 34 (citing Ex. 1013 ¶¶ 131). Lazarus’s Figure 10 depicts an embodiment of its invention showing a vascular graft positioned within an abdominal aorta and bifurcating iliac arteries. Ex. 1004, 12:1–5. An annotated version of Figure 10 is reproduced below:



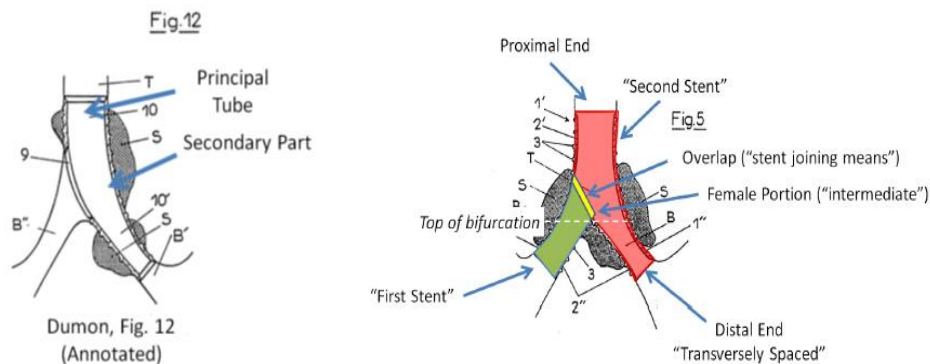
Ex. 1012 ¶ 135. This annotated version of Figure 10 of Lazarus is offered to explain how a skilled artisan would combine the teachings of Cragg, Schaer, and Lazarus. Dr. Criado testifies that a person of ordinary skill in the art would have had reason to apply the teachings of Schaer and Cragg in the bifurcated context of Lazarus to provide the ability to extend the length of the shorter leg or other distal opening following implantation of the bifurcated structure as disclosed in Lazarus according to the particular condition of the vessel being treated. *Id.* at ¶ 136. Based on the teachings of the prior art, and Dr. Criado's testimony, Petitioner urges that claims 5, 17, and 18 would have been obvious. Pet. 40.

In light of the record before us, and for purposes of this Decision, we are persuaded that Petitioner has shown a reasonable likelihood of prevailing in its challenge that claims 5, 17, and 18 would have been obvious over the teachings of Cragg, Schaer, and Lazarus.

3. *Obviousness over Cragg, Schaer, and Dumon*

Petitioner also contends that the subject matter of claims 5, 17, and 18 would have been obvious over Cragg, Schaer, and Dumon. Dumon is titled “Tubular Endoprosthesis for Anatomical Conduits.” Ex. 1005, Title. Dumon discloses a tubular endoprosthesis for anatomical conduits or channels, such as the trachea or bronchus. *Id.* at 1:8–14. As shown in Figure 5 of Dumon, the tubular endoprosthesis may have a principle tube extending into two divergent tubular branches. *Id.* at 2:37–40. The endoprosthesis can have any shape and any diameter adapted to the shape and the diameter of the conduits, channels, or vessels inside which it is to be placed. *Id.* at 2:41–44. The endoprosthesis can be made in any supple, semi-rigid, or rigid material, and may be reinforced by an internal reinforcement capable of being well tolerated by the organism. *Id.* at 2:44–47.

Petitioner provides the following two annotated figures from Dumon:



Pet. 45; *see* Ex. 1013 ¶ 140.

The annotated figures above are offered to illustrate the installation of a second independent tubular branch thereby creating a bifurcated endoprosthesis, as required by the challenged claims. Pet. 45. Petitioner, thus, relies on Dumon as teaching a bifurcated stent having two transversely

spaced female portions. Pet. 46–47. Petitioner asserts that “it would have been obvious to modify the endoprosthesis system of the Cragg-Schaer combination according to the bifurcated structure taught by Dumon for the treatment of bifurcated vessels.” *Id.* at 47 (citing Ex. 1005, 2:38–44, 48–51; FIGS. 12, 5; Ex. 1013 ¶¶ 144–147). Petitioner further contends “[s]uch a combination would achieve the benefits of treatment of a bifurcated structure according to Dumon, while also achieving the benefits of the Cragg-Schaer covered stent, including being self-expandable by thermal inducement, deployable by catheter, and incorporating a flexible, supported structure that follows the curvature of the vessel in which it is implanted.” *Id.* (citing Ex. 1003, 7–8 “Stents”; Ex. 1002, 1:41–51; 2:50–53; Ex. 1013, ¶¶ 145, 147).

Dr. Criado testifies that a rationale for combining Dumon with Cragg and Schaer is that “[w]hen implanted at a site of bifurcation, straight stents and stent grafts may block bloodflow to healthy branching vessels.” Ex. 1013 ¶ 145. Dr. Criado also states that “the diseased portion of the vessel may extend into the branching vessels, and therefore, the branching vessels may require treatment as well.” *Id.* In Dr. Criado’s opinion, “a person of ordinary skill would have known that bifurcated stents and stent grafts having a trunk and modular legs would be advantageous for providing added control over placement at the site of bifurcation in the anatomy.” *Id.*

Based on the record before us, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that the subject matter of claims 5, 17, and 18 would have been obvious over Cragg, Schaer, and Dumon.

*4. Obviousness over Cragg, Schaer, and Pinchuk*

Petitioner contends that claims 10, 12, and 23 are unpatentable over Cragg, Schaer, and Pinchuk. Claims 10 and 12 depend from claim 1. Claim 23 is independent. Claims 10 and 12 add features reflecting the configuration of the female portion. In that regard, claim 10 requires that the female portion is “tapered radially inwardly towards a distal end.” Claim 12 recites that the female portion “comprises a frustoconical wall tapering radially inwardly towards a longitudinal extremity.” Claim 23 requires particular structural characteristics of both the male and female portions, with the male portion having a “frustoconical wall which is flared radially outwardly,” and the female portion “defining a second frustoconical wall which is tapered radially inwardly.” Petitioner relies on Pinchuk to account for the above-noted features.

Pinchuk is titled “Method of Making a Radially Expandable Prosthesis.” Ex. 1006, Title. Pinchuk describes that its invention includes stents formed from “Nitinol” and may include a bifurcated structure for positioning at a branching location of a vascular system. *Id.* at 6:67–7:16. Pinchuk also teaches that its invention includes stents that may be “tapered, truncated, coneshaped stents.” Ex. 1006, 6:53–57. Based on that disclosure, Petitioner contends “Pinchuk teaches tapered (inwardly or outwardly), truncated cone-shaped (i.e., frustoconical) stent designs that are highly compatible with the covered stents disclosed in Cragg and Schaer.” Pet. 53 (citing Ex. 1006, 2:39–43, 60–63; 6:51–57; 7:16; FIGS.1–12; Ex. 1013, ¶¶ 149–150). Petitioner sets forth the following in its Petition in with respect to Pinchuk’s disclosure:

It would have been obvious to modify one or both of the covered stents of the overlapped, Cragg covered stents as modified by Schaer, to each have a tapered, truncated cone-shaped stent as taught by Pinchuk, for the reason of better tracking the shape of a vessel in which the prosthesis is implanted as taught by Cragg or to help further enhance stent fixation as taught by Schaer with regard to frustoconical flanges, for example. *E.g.*, Ex. 1002 at 3:10-12 (“...allows the stent to follow the curvature of the vessel...”); Ex. 1003 at p.10 (“...the flanged proximal stent body used to prevent migration...”); Ex. 1013, ¶¶ 149-150.

Schematic of Frustoconical Covered  
Stent Shape According to Pinchuk



So modified, the overlapped, covered stents of Cragg and Schaer, as further modified by Pinchuk would define a frustoconical male portion overlapped with a frustoconical female portion. Those overlapped portions would include the female portion being tapered radially inwardly towards a distal end (claim 10), the female portion comprising a frustoconical wall tapering radially inwardly towards a longitudinal extremity (claim 12), and frustoconical male and female portions, the male portion being flared radially outwardly and the female portion being tapered radially inwardly according [sic] (claim 23).

*Id.* at 54–55.

Based on the evidence and arguments in the Petition, at this time we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that the subject matter of claims 10, 12, and 23 would have been obvious over Cragg, Schaer, and Pinchuk.

*5. Obviousness over Cragg, Schaer, and Andersen*

Petitioner contends that claim 24 is unpatentable over Cragg, Schaer, and Andersen. Claim 24 is independent. Claim 24 is drawn to a stent joining means and includes a first stent having a male engaging portion and a second stent having a female cooperating portion. The first and second stents also have a first graft layer and a second graft layer, respectively. More particularly, claim 24 requires “a second graft layer disposed externally of said female cooperating portion and which folds over the distal end of said female engaging portion to form an inner sleeve which contacts said first graft layer to form a substantially blood-tight seal.”

Andersen is titled “Tubular Medical Prosthesis.” Ex. 1007, Title. Andersen characterizes its disclosed invention as a “tubular prosthesis including a tubular wall portion of loosely interlocked pattern, e.g. of knitted loops, constructed to function within a body lumen.” *Id.* at Abstract. In accounting for the above-quoted feature of claim 24, Petitioner asserts:

Andersen teaches a graft (“tubular knit structure”) that is rolled over the outside of the graft structure to form a cuff, “to secure the assembly together.” [Ex. 1007] 8:13-23. Cragg also teaches use of Dacron as a graft material, similar to Andersen. *E.g.*, Ex. 1002 at 3:17-26. It would have been obvious to incorporate an inner sleeve and a cuff taught by Andersen, for example at an end of the Schaer-Cragg overlapping prostheses, to help secure a Dacron graft such as that taught in Andersen or Cragg to the endoprosthesis. Ex. 1007 at 8:19-22; Ex. 1002 at 3:18- 20; Ex.1013, ¶ 152. So modified, and in view of teachings of Cragg as modified by Schaer relating to graft layers being inside and outside the stent, the graft layers of the covered stents would be overlapped and frictionally engaged. Moreover, as previously referenced with respect to the Cragg and Schaer combination, it would have been obvious that such overlapping structure would provide a substantially blood-tight seal. *E.g.*,

Ex. 1003 at p.10 (“an overlapping stent was successfully used to cover a defect in the silicone membrane”); p.11 (describing use for tracheoesophageal fistula, for which a liquid tight assembly would be necessary in treatment); Ex. 1002 at 3:17-26; Ex. 1013, ¶ 152.

Pet. 56–57.

In considering the content of the Petition, including that reproduced above, and the evidence offered in support thereof, we are satisfied, for purposes of this Decision, that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge that claim 24 is unpatentable over Cragg, Schaer, and Andersen.

### III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–24 are unpatentable. We have not made a final determination with respect to the patentability of claims 1–24, or the construction of any claim term.

### IV. ORDERS

After due consideration of the record before us, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the grounds that:

- A. Claims 1–4, 6–9, 11, 13–16, and 19–22 are unpatentable over Cragg and Schaer;
- B. Claims 5, 17, and 18 are unpatentable over Cragg, Schaer, and Lazarus;
- C. Claims 5, 17, and 18 are unpatentable over Cragg, Schaer, and Dumon;



D. Claims 10, 12, and 23 are unpatentable over Cragg, Schaer, and Pinchuk; and

E. Claim 24 is unpatentable over Cragg, Schaer, and Andersen;

FURTHER ORDERED that no other grounds are authorized for this *inter partes* review as to claims 1–24; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this Decision.

IPR2014-01323  
Patent 5,716,365

For PETITIONER:

Victor P. Jonas  
Victor.Jonas@FaegreBD.com

For PATENT OWNER:

Robert W. Ashbrook, Jr.  
Robert.ashbrook@dechert.com

Kevin M. Flannery  
Kevin.flannery@dechert.com