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Paper 7
Entered: February 25, 2015

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 IPR2014-01320
Patent 6,117,167

Before PHILLIP J. KAUFFMAN, BENJAMIN D. M. WOOD, and BARRY L. GROSSMAN, *Administrative Patent Judges.*

GROSSMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

W. L. Gore & Associates, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–82 (all the claims) of U.S. Patent No. 6,117,167 ("the '167 patent"). Paper 1 ("Pet."). Patent Owner, LifePort Sciences LLC ("Patent Owner"), did not file a Preliminary Response. We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition, based on the evidence and arguments before us, and for purposes of this Decision to institute an *inter partes* review, we determine that there is a reasonable likelihood that the petitioner will prevail in establishing that claims 1–82 are not patentable.

A. Related Proceedings

Petitioner states that the '167 patent is involved in a pending district court case, *LifePort Sciences LLC v. W.L. Gore & Associates Inc*.., No. 1:12-cv-01792 (D. Del. 2012). Pet. 1.

Patent Owner also identifies as a related proceeding a pending district court case, *Lifeport Sciences LLC v. Endologix, Inc*., No. 1:12-cv-01791 (D. Del. 2012)[1]. Paper 6, 2.

Petitioner also has filed another petition seeking *inter partes* review of the '167 patent on grounds and references different from those in this proceeding. The other petition is assigned case IPR2014-01319.

[1] Based on the Amended Complaint filed by LifePort Sciences LLC on August 12, 2014, and the original Complaint filed by LifePort Sciences LLC on December 28, 2012, the '167 patent also is involved in this district court case.

B. The '167 Patent

The '167 patent is titled "Endoluminal Prosthesis and System for Joining." The invention disclosed in the '167 patent relates to a bifurcated endoluminal prosthesis for use in a bifurcated blood vessel, such as the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries. Ex. 1001, col. 1, ll. 18–21. The disclosed invention also includes a connecting structure for connecting, for example, a stent that forms part of an endoluminal prosthesis to another stent. *Id.* at col. 1, ll. 21–24. Figures 1A and 1B are reproduced below.[2]

FIG. 1A

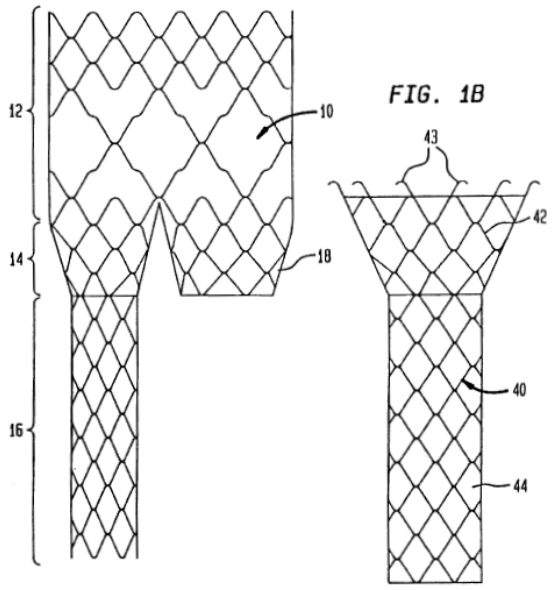


FIG. 1B

Figure 1A illustrates a bifurcated intraluminal stent; Figure 1B illustrates another stent, which is adapted to be connected to the bifurcated stent in Figure 1A.

As shown in Figure 1A , and as described in the Specification (*see* Ex. 1001, col. 8, ll. 50–54), bifurcated stent 10 comprises a wire skeleton constructed in four

[2] The Figures use the designation "1A" and "1B" while the description in the Specification refers to these Figures as "1*a*" and "1*b*."

separate parts: proximal part 12; first frustoconical part 14; first distal part 16; and second frustoconical part 18. Proximal part 12, first and second frustoconical parts 14, 18, and first distal part 16 may each be covered with a tubular graft layer of a biocompatible woven fabric, as shown in Figures 5, 6 and 7, for use as an endoluminal prosthesis. *Id.* at col. 8, ll. 54–58; col. 10, ll. 30–33.

In medical uses where it is required, a second prosthesis comprising second stent 40, as shown in Figure 1B, may be used. The second stent 40 includes a wire skeleton comprising proximal frustoconical part 42 and distal part 44. Distal part 44 of second stent 40 also may be covered with a tubular graft layer of a biocompatible fabric. Ex. 1001, col. 11, ll. 15–23. Frustoconical proximal part 42 may be formed with circumferentially spaced barbs or hooks 43, as shown in Figure 1B, which engage in the wire skeleton of the second frustoconical part 18 of the bifurcated stent 10. *Id.* at col. 11, ll. 44–48. Both stent 10 and stent 40 may be made from a shape memory alloy. *E.g.*, *id.* at col. 8, ll. 64–66.

In use, the second prosthesis is compressed radially inwards and is inserted into position using a catheter. *Id.* at col. 11, ll. 31–33. Frustoconical proximal part 42 is guided, in the radially compressed state, into second frustoconical part 18 of bifurcated stent 10. The catheter is then withdrawn allowing second stent 40 to re-expand towards its remembered configuration until distal part 14 engages the endoluminal surface of the other common iliac artery, and the outer surface of frustoconical proximal part 42 engages the interior surface of second frustoconical part 18 of bifurcated stent 10. *Id.* at col. 11, ll. 31–42. In this connected position, stent 10 and stent 40 are locked together to define a continuous lumen through the two stents and resist longitudinal separation. *Id.* at col. 11, ll. 52–54.

C. Representative Claim

The '167 Patent contains 82 claims. Claims 1–5, 13, 31–33, 51, 52, 71 and 72 are independent claims. Independent claims 1–5 and 72 claim a "stent joining means for adjoining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents." Independent claims 13, 31, 32, 52, and 71 claim an "endoluminal prosthesis system." Independent claims 33 and claim a "system for joining endoluminal prosthesis segments in a vessel."

Claim 1 is representative of the claimed invention and is 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, wherein said male engaging portion is flared radially outwardly towards a proximal end; 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 expanded in the female portion and wherein said outer surface of the male engaging portion and said inner surface of the female portion are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service.

D. References Relied Upon

Petitioner relies upon the following prior art references:

Reference	Date	Exhibit Number
Cragg, U.S. Pat. No. 5,405,377.	Issued Apr. 11, 1995	Ex. 1002
Schaer, *Treatment of Malignant Esophageal Obstruction with Silicone-Coated Metallic Self-expanding Stents*, Gastrointestinal Endoscopy, v. 38, 7–11.	1992	Ex. 1003
Pinchuk, U.S. Pat. 5,226,913.	Issued July 13, 1993	Ex. 1004
Wolff, U.S. Pat. No. 4,830,003.	Issued May 16, 1989	Ex. 1005
Lazarus, U.S. Pat. 5,871,536	Issued Feb. 16, 1999	Ex. 1006
Dumon U.S. Pat. 5,236,446	Issued Aug. 17, 1993	Ex. 1007

E. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	Statutory Basis	References
1, 3, 13–20, 24–28, 30, 31, 33–40, 44–48, 50, 52–60, 64–68, 70, and 71	103	Cragg and Schaer
2, 4 and 51	103	Cragg, Schaer, and Pinchuk
21–23, 32, 41–43, and 61–63	103	Cragg, Schaer, and Wolff
5–12, 29, 49, 69, and 72–79	103	Cragg, Schaer, and Lazarus

80–82	103	Cragg, Schaer, Lazarus, and Wolff
5–12, 29, 49, 69 and 72–79	103	Cragg, Schaer, and Dumon
80–82	103	Cragg, Schaer, Dumon, and Wolff

II. ANALYSIS

A. Claim Construction

1. Claim Construction of an Expired Patent

The Petition in this proceeding was filed on August 18, 2014. Shortly thereafter, the '167 patent expired. Pet. 13.[3] 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) ("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

[3] Petitioner asserts the '167 patent expired on September 27, 2014, based on its lineage to a priority claim as a "continuation-in-part" (CIP) of an application filed on September 27, 1994. A patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112. 35 U.S.C. § 120. *Mendenhall v. Cedarapids Inc.*, 5 F.3d 1557, 1566 (Fed.Cir. 1993), *see also Litton Sys., Inc. v. Whirlpool Corp.*,728 F.2d 1423, 1437–1438 (Fed.Cir.1984) (discussing filing dates of CIP applications). Thus, the '167 patent is entitled to the filing date of the application filed on September 27, 1994, only if that application discloses the subject matter now claimed by the '167 patent. We need not decide this issue because, even if not entitled to the September 27, 1994 filing date, the '167 patent expired on October 4, 2014, based on a priority claim of October 4, 1994.

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) ("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 '167 patent will be construed under the principles in *Phillips v. AWH Corp.*, 415 F.3d 1303, 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).[4] We will not apply a rule of construction that claims should be construed to preserve their validity.[5] *See also, e.g., Google Inc. v. Createads LLC*, Case IPR2014-00200, slip op. at 2, (PTAB July 16, 2014) (Paper 19) ("[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

Petitioner notes that the preambles of claims 1–12 and 72–82 each recite "stent joining means for joining . . . ." Pet. 14. It is Petitioner's position that the use of the "means" phrase in the preamble of the claims "appears directed to

[4] Petitioner states that "it is unclear whether the broadest reasonable construction or the *Phillips* standard applies to this proceeding." Pet. 13–14. We disagree; the standard we use in interpreting the claims of an expired patent has been well-established by the Board and our reviewing Court.

[5] "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.

stating the intended use of the claimed invention," and thus, Petitioner concludes that Section 112, paragraph 6 does not apply to the interpretation of claims 1–12 and 72–82. *Id.* For purposes of this Decision, we agree with Petitioner's position.

3. Specific Claim Terms

Petitioner proposes specific construction for several claim terms. Pet. 14–15. For this Decision, we determine that construction of the specific terms proposed by Petitioner is unnecessary.

B. Asserted Grounds of Unpatentability

1. Obviousness Based on Cragg and Schaer

Petitioner asserts that claims 1, 3, 13–20, 24–28, 30, 31, 33–40, 44–48, 50, 52–60, 64–68, 70 and 71 would have been obvious based on the disclosures in Cragg and Schaer. Pet. 15.

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). Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To reach this conclusion, however, requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination. *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.* As the Supreme Court recognized, in many cases a person of ordinary skill "will be able to fit the teachings of multiple patents together like pieces of a puzzle," recognizing that a

person of ordinary skill "is also a person of ordinary creativity, not an automaton." *Id.* at 420–421. Against this general background, we consider the references, other evidence, and arguments on which Petitioner relies.

Cragg discloses intraluminal stent that has a flexible and elastic tubular construction. Ex. 1002, col. 1, ll. 7–9. The stent includes a predetermined length of nitinol wire having a sinuous or zig-zag configuration and defining a continuous helix with a plurality of connected spirals or hoops. *Id.* at col. 1, ll. 55–58, col. 4, l. 4. The stent is compressible and self-expandable substantially to the configuration prior to compression. *Id.* at col. 1, ll. 60–61, col. 4, ll. 12–16. Cragg also discloses that a prosthetic graft may be disposed longitudinally of the wire helix within its central opening or, alternatively, around the wire helix. *Id.* at col. 1, ll. 65–67, col. 3, ll. 15–17, 27–28. Hoop members 12, which are ligatures of suture material, connect the graft to the wire body. *Id.* at col. 3, ll. 21–23. Petitioner cites and relies on the Declaration of Enrique Criado, M.D. (Ex. 1013) to support Petitioner's analysis of the cited references. *E.g.*, Pet. 16.

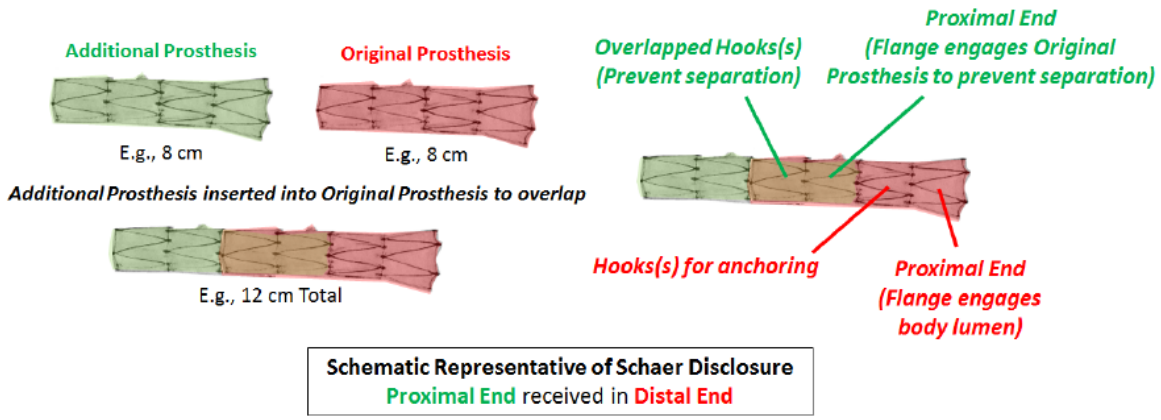
Schaer discloses that a self-expanding Z stent wherein multiple stent·bodies can be interconnected to increase the total stent length. Ex. 1003, p.8.

In describing the Cragg and Schaer disclosures, Petitioner cites and relies on the Declaration of Enrique Criado, M.D. (Ex. 1013). Dr. Criado has over 20 years of academic and professional experience in vascular surgery and endovascular interventions. Ex. 1013 ¶ 3. Dr. Criado 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.*

Dr. Criado acknowledges that Cragg does not disclose explicitly (1) entering one stent into a second stent and expanding the inner stent to resist longitudinal movement and prevent separation, (2) using a flared, tapered, or frustoconical

stent, or (3) using hooks or barbs to resist longitudinal movement relative to the surrounding body lumen. Ex. 1013 ¶ 118.

According to Dr. Criado, Schaer teaches joining two endoluminal stents in the same manner as claimed in the '167 patent. *Id.* ¶ 79. Dr. Criado opines that a person of ordinary skill would understand the disclosure of overlapping one covered stent with another covered stent to mean that at least a portion of the second stent was inserted in a radially compressed state into at least a portion of the first implanted stent and then deployed such that at least a portion of its length overlapped with at least a portion of the length of the first implanted stent. *Id.* ¶ 73. Dr. Criado provides the following schematic drawing, which he describes as representative of some of the concepts described by Schaer as would have been understood by a person of ordinary skill in the art.



Schematic drawing from Ex. 1013 ¶ 74 of Schaer Disclosure

Dr. Criado also opines that a person of ordinary skill would understand that the radiopacity of the materials being used impacts the visualization technique described in Schaer. Ex. 1013 ¶ 72. In Dr. Criado's opinion, it also would be apparent that the ability to locate, align and overlap such covered stents could be made easier by the incorporation of radiopaque materials into such covered stents. *Id.* Petitioner provides a claim chart further identifying where Cragg and Schaer

disclose the elements of the challenged claims. Pet. 29.

Petitioner asserts that modifying Cragg using the disclosure of Schaer to result in the invention recited in the challenged claims "would be readily apparent, desirable, and achievable" to the person of ordinary skill in the art. Pet. 25 (*citing* Ex. 1013 ¶¶ 76, 119–122). In the cited paragraphs, we are persuaded that, for purposes of this proceeding, based on the record before us, Dr. Criado provides the articulated reasoning with rational underpinning required to support a determination that there is a reasonable likelihood Petitioner will prevail in establishing that the challenged claims would have been obvious. *KSR*, 550 U.S. at 418.

Based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 1, 3, 13–20, 24–28, 30, 31, 33–40, 44–48, 50, 52–60, 64–68, 70, and 71 would have been obvious over Cragg and Schaer.

2. Obviousness Based on Cragg, Schaer, and Pinchuk

Petitioner asserts that claims 2, 4 and 51 would have been obvious based on the disclosures in Cragg, Schaer and Pinchuk. Pet. 34. These claims require that female portion of the stent is tapered radially inwardly (claims 2, 51) or that the female portion of the stent comprises a frustoconical wall tapering radially (claim 4).

Petitioner asserts that Pinchuk discloses "tapered (inwardly or outwardly), truncated cone-shaped (i.e., frustoconcial) stent designs that are highly compatible with the covered stents disclosed in Cragg and Schaer." Pet. 35 (*citing* Ex. 1004; Ex. 1013). According to Petitioner, it would have been obvious to further modify Cragg stents as modified by Schaer, as discussed above, "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, for example, or to help further enhance stent fixation as taught by Schaer with regard to flanges." *Id.*

Dr. Criado opines that that providing a tapered end to the female portion on one of the two Cragg stent grafts would enhance fixation between the two stents when overlapped. Ex. 1013 ¶ 124. He also opines that this is a "technically simple modification." *Id.* We are persuaded that, for purposes of this proceeding, and based on the record before us, this is a sufficient rationale to support the conclusion that that there is a reasonable likelihood that the petitioner will prevail in establishing that the challenged claims would have been obvious.

Based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 2, 4, and 51 would have been obvious over Cragg, Schaer, and Pinchuk.

3. Obviousness Based on Cragg, Schaer, and Wolff

Petitioner asserts that claims 21–23, 32, 41–43 and 61–63 would have been obvious based on the disclosures in Cragg, Schaer, and Wolff. Pet. 36. These claims require various limitations relating to the markers, and more specifically radiopaque markers.

Wolff discloses a tubular, intravascular stent made up of individual wires welded together which can be compressed along the axis to a smaller tubular diameter to fit within an outer catheter to hold the stent compressed. Ex. 1005, col. 1, ll. 5–15. The stent can be made of radiopaque material, such as platinum or platinum iridium to permit locating the stent at the stenosis site using fluoroscope techniques. *Id.* at col. 3, ll. 35–39, col. 5, ll. 3–8.

According to Petitioner, it would have been obvious to combine one or more of the radiopaque stent materials of Wolff with the covered stent of Cragg as modified by Schaer "for the purpose of enhancing visibility, and thus ability to properly locate and align, overlapped covered stents in vessels of a patient." Pet. 38 (*citing* Ex. 1013 ¶¶ 126, 127). Specifically, Petitioner asserts it would have been obvious to include one or more of the "V" shaped stent sections from Wolff's stent to determine more specifically the rotational orientation of the first and second prosthesis segments thereby to further facilitate alignment and positioning. *Id.* at 38–39; *see also*, Ex. 1013 ¶ 126 (stating the same position).

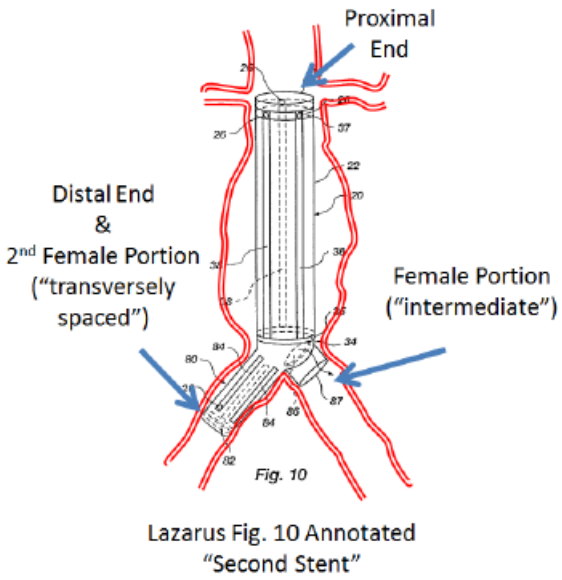
Based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 21–23, 32, 41–43 and 61–63 would have been obvious over Cragg, Schaer, and Wolff.

4. Obviousness Based on Cragg, Schaer, and Lazarus

Petitioner asserts that claims 5–12, 29, 49, 69, and 72–79 would have been obvious based on the disclosures in Cragg, Schaer, and Lazarus. Pet. 39. These claims require various limitations relating to a bifurcated stent or a stent having two transversely spaced female portions.

Lazarus discloses a bifurcated intraluminal vascular graft including self-expanding, circumferential and longitudinal support structures that operate to expand the device against a vessel wall, such as bifurcated blood vessels. Ex. 1006, col. 2, ll. 43–62; *see also*, Ex. 1006, Fig. 10 (illustrating a vascular graft with a single leg portion), Fig. 11 (illustrating a vascular graft having two leg portions, positioned within an abdominal aorta and bifurcating iliac arteries). Petitioner provides the following annotated version of Figure 10 in Lazarus illustrating a bifurcated prosthesis that is adapted to extend across a bifurcation in a

blood vessel.



Petitioner's annotation of Ex. 1006, Fig. 10. Pet. 42

Lazarus also discloses that longitudinal support structures 38 for the vascular graft may be adjustable in length, with one member telescopically positioned relative to the other. Ex. 1006, col. 10, ll.28–41. 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 provide the limitations of the challenged claims. Pet. 43 (*citing* Ex. 1013 ¶¶ 128, 129).

Dr. Criado states his opinion that it would have been obvious to combine the covered continuous stent design and overlapping methodology disclosed by the Cragg-Schaer combination with the bifurcated structure as taught by Lazarus to provide a system for the treatment of bifurcated vessels in order to achieve a desired leg length following implantation. Ex. 1013 ¶ 129. Dr. Criado also opines that, by September 1994, a person of ordinary skill would have understood that bifurcated stents and stent grafts would provide an important treatment option for

certain conditions in branching vessels and sites of bifurcation. *Id.* ¶ 132. Dr. Criado also relies on the following annotated Figure 10 from Lazarus.[6] Dr. Criado relies on this annotated illustration to illustrate and support his opinion that a person of ordinary skill would be motivated 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.* ¶ 133.

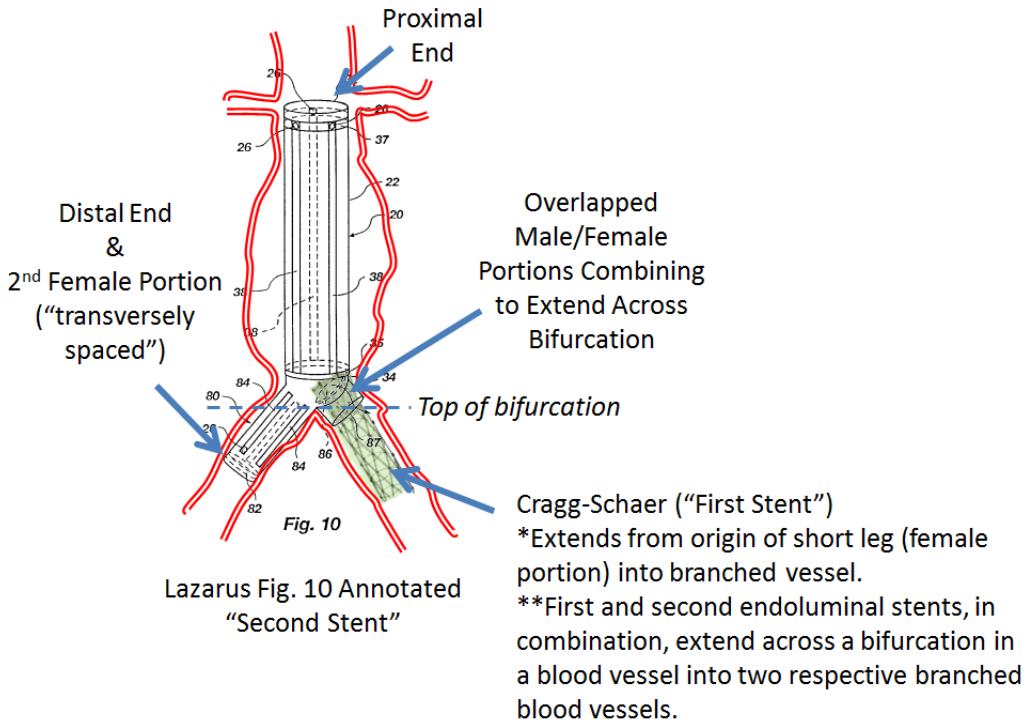


Figure 10 from Lazarus annotated in Ex. 1013 ¶ 133.

Based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 5–12, 29, 49, 69, and 72–79 would have been obvious over Cragg, Schaer, and Lazarus.

[6] The Petition relies on this same illustration. Pet. 46.

5. Obviousness Based on Cragg, Schaer, Lazarus, and Wolff

Petitioner asserts that claims 80–82 would have been obvious based on the disclosures in Cragg, Schaer, Lazarus, and Wolff. Pet. 47. Claims 80–82, depend, directly or indirectly, from independent claim 72. Claim 80 requires a marker "imageable" from outside a body in which a stent is located. Claim 81 requires the image of the marker to differ depending on the rotational orientation of the stent. Claim 82 states the marker is adapted to facilitate alignment with a second stent.

The disclosures of the cited references are discussed above. Petitioner asserts it would have been obvious to combine one or more of the radiopaque stent materials of Wolff with the covered stents of Cragg as modified by Schaer and Lazarus for the purpose of enhancing visibility, and thus the ability to locate and align overlapped, covered stents in vessels of a patient. Pet. 48. As an example of the proposed combination of elements from the various references, Petitioner also asserts it would have been obvious to include one or more of the "V" shaped stent sections from Wolff's stent to determine more specifically the rotational orientation of the first and second prosthesis segments to further facilitate alignment and positioning. Pet. 48 (*citing* Ex. 1013 ¶¶ 134, 135). According to Petitioner, the fluoroscopic image of Wolff's radiopaque, "V" shaped section would differ depending on the rotational orientation of the stent, thus allowing rotational orientation to be determined during delivery. *Id.*

As discussed above, Wolff discloses that the stent can be made of radiopaque material, such as platinum or platinum iridium to permit locating the stent at the stenosis site using fluoroscope techniques. Ex. 1005, col. 3, ll. 35–39, col. 5, ll. 3–8 ("Radiopaque markers 22 at the ends of both inner catheter 20 and outer catheter 16 provides a capability of determining the location of these catheters by using X-ray excitation and a fluoroscope monitoring device external to

the body.").

Dr. Criado opines that a person of ordinary skill would have understood that "the resulting fluoroscopic image of Wolff's radiopaque, V-shaped stent ends would differ depending on the rotational orientation of the stent, thus allowing rotational orientation to be determined during delivery." Ex. 1013 ¶ 135.

Based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 80–82 would have been obvious over Cragg, Schaer, Lazarus, and Wolff.

6. Obviousness Based on Cragg, Schaer, and Dumon

Petitioner asserts that claims 5–12, 29, 49, 69, and 72–79 would have been obvious based on the disclosures in Cragg, Schaer, and Dumon. Pet. 49. As discussed above in connection with the asserted ground of obviousness over Cragg, Schaer, and Lazarus, these challenged claims require various limitations relating to a bifurcated stent or a stent having two transversely spaced female portions.

Dumon discloses a tubular endoprosthesis for anatomical conduits or channels, such as the trachea or bronchus. Ex. 1007, col. 1, ll. 8–14. Petitioner asserts that one of ordinary skill in the art would understand that problems addressed by tracheal bronchus endoprostheses in Dumon, esophageal endoprostheses in Schaer, vascular endoprostheses of Cragg and the endoluminal prostheses of the '167 patent are in the same field of endeavor. Pet. 50 (*citing* Ex. 1013 ¶ 94).

As shown in Figure 5 of Dumon, the tubular endoprosthesis may have a principal tube extending into two divergent tubular branches. Ex. 1007, col. 2, ll. 38–40. 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 col. 2, ll. 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 col. 2, ll. 44–47.

Petitioner provides the following two annotated figures from Dumon illustrating the installation of a second independent tubular branch hereby creating a bifurcated endoprosthesis, as required by the challenged claims.

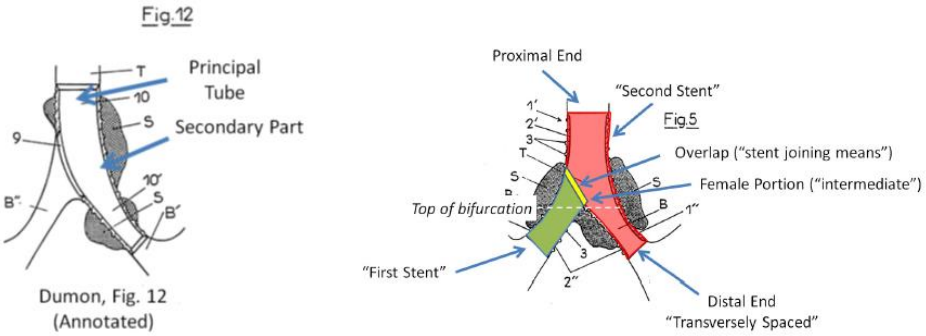


Fig. 12 (Pet. 51) and Fig. 5 (Pet. 53) of Ex. 1007 annotated by Petitioner.

Petitioner acknowledges that neither Cragg nor Schaer disclose a bifurcated stent or a stent having two transversely spaced female portions. Pet. 51. Petitioner asserts, however, it would have been obvious to modify the endoprosthesis system of the Cragg-Schaer combination to reflect the structure taught by Dumon for the treatment of bifurcated vessels. *Id.* at 52 (*citing* Ex. 1013 ¶ 137). The rationale for the proposed combination of elements is that the combination would achieve the benefits of Dumon relating to treatment of a bifurcated structure, while also achieving the benefits of the Cragg-Schaer covered stent, such as being self-expandable, deployable by catheter, and incorporating a flexible, supported structure that follows the curvature of the vessel in which it is implanted. *Id.*

Dr. Criado opines that a rationale for combining Dumon with Cragg and Schaer is that when implanted at a site of bifurcation, straight stents and stent

grafts may block bloodflow to healthy branching vessels. Ex. 1013 ¶ 139. 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 evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 5–12, 29, 49, 69, and 72–79 would have been obvious over Cragg, Schaer, and Dumon.

7. Obviousness Based on Cragg, Schaer, Dumon, and Wolff

Petitioner asserts that claims 80–82 would have been obvious based on the disclosures in Cragg, Schaer, Dumon, and Wolff. Pet. 55. The challenged claims are the same group of claims included in Ground 5, discussed above. In this asserted ground, however, Dumon is cited as a reference in place of Lazarus, which is relied on in Ground 5. Dumon is asserted as a reference under § 102(b); Lazarus is asserted as a reference under § 102(e). As discussed above, these challenged claims require various limitations relating to a bifurcated stent or a stent having two transversely spaced female portions.

Based on our analysis above, and further based on the evidence and arguments in the Petition, and for purposes of this Decision, we are persuaded that there is a reasonable likelihood that the Petitioner will prevail in establishing that claims 80–82 would have been obvious over Cragg, Schaer, Dumon, and Wolff.

III. CONCLUSION

Upon consideration of the Petition, as discussed in this Decision, we are persuaded that the record before us demonstrates a reasonable likelihood that Petitioner will prevail in establishing that claims 1–82 of the '167 patent are not patentable based on the references asserted in the Petition.

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. The Board has not made a final determination on the patentability of the challenged claims.

IV. ORDER

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review hereby is instituted as to the following claims and grounds:

1. that claims 1, 3, 13–20, 24–28, 30, 31, 33–40, 44–48, 50, 52–60, 64–68, 70, and 71 would have been obvious based on the disclosures in Cragg and Schaer;

2. that claims 2, 4, and 51 would have been obvious based on the disclosures in Cragg, Schaer and Pinchuk;

3. that claims 21–23, 32, 41–43, and 61–63 would have been obvious based on the disclosures in Cragg, Schaer, and Wolff;

4. that claims 5–12, 29, 49, 69, and 72–79 would have been obvious based on the disclosures in Cragg, Schaer, and Lazarus;

5. that claims 8082 would have been obvious based on the disclosures in Cragg, Schaer, Lazarus, and Wolff;

6. that claims 5–12, 29, 49, 69, and 72–79 would have been obvious based on the disclosures in Cragg, Schaer, and Dumon; and

7. that claims 80–82 would have been obvious based on the disclosures in Cragg, Schaer, Dumon, and Wolff;

FURTHER ORDERED that no ground other than that specifically granted above is authorized for the *inter partes* review; 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 commencing on the entry date of this decision.

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