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Paper 34
Entered: April 21, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioners,

v.

LIFEPORT SCIENCES LLC,
Patent Owner.

Case IPR2014-00288
Patent 7,147,662

Before LORA M. GREEN, SCOTT E. KAMHOLZ, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. *Procedural Posture*

Petitioners, Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Petitioners"), filed a corrected Petition (Paper 6, "Pet.") requesting *inter partes* review of claims 1–16 of U.S. Patent No. 7,147,662 (Ex. 1001, "the '662 patent") on multiple grounds. Patent Owner, Lifeport Sciences LLC ("Lifeport"), did not file a preliminary response.

The Board instituted trial for claims 1–5, 7–13, 15, and 16 on certain grounds raised by Petitioners. Decision to Institute 37–38 (Paper 8, "Dec."). After institution of trial, Lifeport filed a Patent Owner Response (Paper 13, "Resp."), and Petitioners filed a corresponding Reply (Paper 14, "Reply"). Lifeport did not file a Motion to Amend.

Petitioners rely upon the Declaration (Ex. 1026), supplemental Declaration (Ex. 1034), and deposition testimony of Dr. Gary L. Loomis (Ex. 1035). Lifeport relies on the Declaration of Ellen Golds (Ex. 2001) and excerpts from Dr. Loomis's deposition (Paper 21). Petitioners filed a Motion to Exclude portions of Dr. Loomis's testimony (Paper 22 ("Motion to Exclude Evidence"). Lifeport opposes Petitioners' Motion to Exclude Evidence (Paper 23), and Petitioners filed a Response to Lifeport's Opposition (Paper 24).

The Board heard oral argument on February 18, 2015. A transcript is entered as Paper 32 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Upon consideration of the arguments and evidence of record, we determine that Petitioners have not proven by a preponderance of the evidence that claims 1–5, 7–13, 15, and 16 are unpatentable.

Petitioners' Motion to Exclude Evidence is dismissed as moot.

B. *The '662 Patent*

The '662 patent relates to a hook for attaching an endoluminal prosthesis, such as a graft or stent, within an artery, vein, or other type of corporeal lumen. Ex. 1001, 1:14–22. The hook is configured for intraluminal delivery and deployment. *Id.* at Abstract. "The hook is integrally formed with [a] framing structure and is preset into an outward bend, but is resiliently flexible so as to form a substantially straight profile when compressed." *Id.*

Figure 1 of the '662 patent is set forth below:

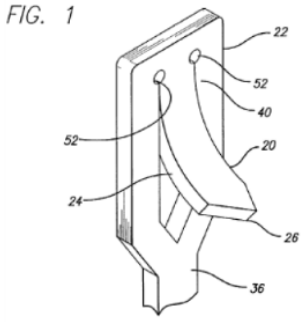


Figure 1 is a perspective view of one embodiment of the disclosed hook and frame combination, showing a hook 20 formed integrally within a frame 22. *Id.* at 2:45–46, 3:11–12. Hook 20 consists of elongated member 24 having a pointed end 26. *Id.* at 3:13–14. Hook 20 "may be bent or curved such that the pointed end 26 extends out of the frame 22." *Id.* at 3:14–15. Hook 20 may be formed in frame 22 by cutting incisions 40 into frame 22, leaving

hook 20 bounded on three sides by incisions 40 and forming elongated member 24 and pointed end 26. *Id.* at 4:55–62.

Figure 2 of the '662 patent is reproduced below:

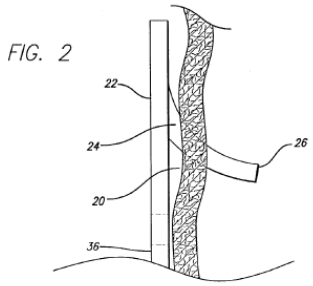


Figure 2 illustrates a side view of frame 22 with a hook 20 in a deployed configuration. *Id.* at 2:47–48. In this embodiment, "force applied downward on the frame 22 causes the hook 20 to embed into the tissue." *Id.* at 3:19–21. "A preferred configuration is sized to be delivered intraluminally and attach to the inside of a blood vessel." *Id.* at 3:21–23.

Figure 3 of the '662 patent is reproduced below:

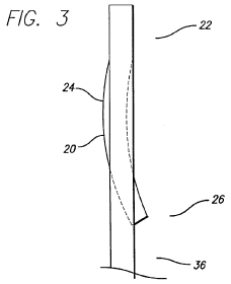
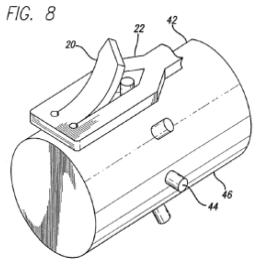


Figure 3 shows a hook 20 in a compressed position that facilitates loading the device into a catheter for delivery. *Id.* at 3:26–37. With respect to Figure 3, "hook 20 is preferably compressed until the hook 20 is within the bounds or circumference of the frame 22." *Id.* at 3:26–28. In this view, "the combination of the hook 20 and frame 22 forms a nearly flat profile.

Because the hook 20 has been deformed into a preset bend, the pointed end 26 may still extend a short distance out from the frame 22." *Id.* at 3:29–33.

Figures 8 and 9 of the '662 patent are reproduced below:



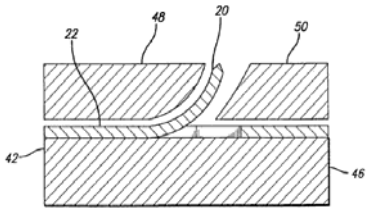


FIG. 9

Figures 8 and 9 illustrate the manufacture of hook 20 on frame 22 using mandrels 42 to force the hook into a predetermined bend. *Id.* at 5:56–67. The bent configuration "can be maintained while the hook 20 is heat set to be permanently predisposed with an outward curve." *Id.* at 5:60–62. "After bending, the hook 20 may be permanently-deformed into the curved configuration by heat setting the material. For a Nitinol hook 20 and frame 22 combination heating at 550° C. for ten minutes is sufficient." *Id.* at 6:1–4.

> With a permanently deformed hook 20, the hook 20 may still be compressed into alignment with the frame 22 without losing the preset curve. Thus, the hook 20 may be compressed into the frame for intraluminal low profile delivery, and then deployed in the curved configuration by releasing.

Id. at 6:7–11.

C. *Illustrative Claim*

Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:
>
> a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;
>
> the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element; and
>
> the elongated member bent away from said frame element wherein the elongate member has a permanent curve.

Id. at 6:22–31.

D. *Grounds of Unpatentability*

This proceeding addresses the following instituted grounds of unpatentability:

1. Whether claims 1–3, 5, 9–13, and 16 are anticipated under 35 U.S.C. § 102 by Lefebvre.[1]
2. Whether claims 7, 8, and 15 are obvious under 35 U.S.C. § 103(a) over the combination of Lefebvre and Lazarus.[2]
3. Whether claims 1–4, 8–12, and 16 are obvious under 35 U.S.C. § 103(a) over the combination of White[3] and Ostrovsky.[4]
4. Whether claims 7 and 15 are obvious under 35 U.S.C. § 103(a) over the combination of White, Ostrovsky, and Lazarus.

[1] US Patent No. 5,108,418, issued Apr. 28, 1992 (Ex. 1003).
[2] US Patent No. 5,562,728, issued Oct. 8, 1996 (Ex. 1006).
[3] PCT International Publication No. WO 00/18322, published Apr. 6, 2000 (Ex. 1004).
[4] US Patent No. 6,447,530 B1, issued Sept. 10, 2002, filed Nov. 25, 1997 (Ex. 1007).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. Feb. 4, 2015). Under this standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citations omitted).

For the purpose of this decision, we focus on the construction of the term "permanent curve." The '662 patent does not provide an express definition of this term. Nor does the patent use the precise term "permanent curve" other than in the claims. During examination of the application upon which the '662 patent issued, however, the Examiner articulated the broadest reasonable construction, in light of the Specification, of "permanent curve" as "a preset curve that . . . maintains a permanent curve regardless of what configuration the device is in." *See* Ex. 1002, 145 (Examiner's Reasons for Allowance). Based on that construction, the Examiner allowed the claims. *See id.* at 144–45.

Citing the testimony of its expert, Gary L. Loomis, Ph.D., Petitioners urged us to adopt the same construction applied by the Examiner. Pet. 9 (citing Ex. 1026 ¶ 60). Dr. Loomis testified that the proffered construction "is supported by the specification and file history and is consistent with that which was applied by the Examiner in his Reasons for Allowance." Ex. 1026 ¶ 60.

For the purposes of instituting *inter partes* review, we agreed with Petitioners and Petitioners' expert that the broadest reasonable interpretation consistent with the Specification of a "permanent curve" is "a preset curve that maintains a permanent curve regardless of what configuration the device is in." Dec. 9 (citing Ex. 1001, 6:1–11). Lifeport and Lifeport's expert, Ellen Golds, also agreed with that construction. Resp. 7; Ex. 2001 ¶ 27. The parties disagree, however, as to whether, under that construction, a permanent curve encompasses a resilient, flexible member that maintains some degree of curvature—even though the arc of the curve may change due to compressive forces—or whether it more narrowly demands a fixed arc that does not vary during use. *See, e.g.*, Reply 7; Tr. 7:24–8:5, 8:16–25, 23:17–24:3.

Petitioners consider the claims unpatentable according to both interpretations. Tr. 9:1–14. With respect to the broader interpretation, Petitioners' expert states that the engagement members of Figure 6b of the White reference, "when made of a resilient spring-aided change material such as nitinol, would maintain a permanent curve in both their compressed and expanded positions . . . such spring aided materials, if curved in their uncompressed orientation, would maintain a curve when compressed." Ex. 1026 ¶ 101; *see also* Pet. 38 (citing Ex. 1026 ¶ 177 ("it is an inherent

property of the heat aided and spring-aided change materials described in White that the curve would be permanent").

Lifeport argues that "Dr. Loomis appears to erroneously conflate materials having shape 'memory' with materials having a permanent curve." Resp. 37; *see* Ex. 2001 ¶ 86. In Lifeport's view, although "a material has 'memory' in that it changes shape when compressed and then returns to its prior shape when not compressed," that is quite different from a "permanent curve," which is "a preset curve that maintains a permanent curve regardless of what configuration the device is in." Resp. 37 (citing Ex. 2001 ¶ 86). Lifeport's expert further emphasizes that engagement members that resiliently return to a memorized shape embody *the opposite* of a permanent curve. Ex. 2001 ¶ 84.

As summarized by Petitioners, Lifeport's broadest reasonable interpretation of permanent curve thus requires that

> the curve of the elongated member/hook/ protrusion must be identical in all configurations of the device, and at all times. Any temporary change to the curvature would mean that it is not permanent, and would fall outside of the scope of the claims. That would exclude a curve that is deformed into a flattened or different curvature during deployment, and that elastically returns to a memorized curvature.

Reply 7 n.5 (internal citations and parenthetical omitted). That definition is consistent with the ordinary meaning of "permanent" as "lasting or continuing for a very long time or forever: not temporary or changing."[5] *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir.

[5] MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/permanent (last accessed Feb. 24, 2015).

1996) ("[We] may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.")

The Specification of the '662 patent references a hook or protrusion as having a "bend" and a "curve." For example, the Specification teaches that in manufacturing an embodiment of the present invention, "hook 20" may be forced into "a predetermined bend" (Ex. 1001, 5:55–67) and then "permanently-deformed into the curved configuration by heat setting the material" (*id*. at 6:1–3). Independent claims 10 and 16, however, make clear that the terms "bend" and "curve" are not necessarily coextensive. In relevant part, these claims recite (emphasis added):

> 10. . . . a hook having two sides and a point . . . said hook having **a permanent bend** that forms **a permanent curve**.
>
> 16. . . . at least one protrusion . . . having **a resiliently flexible bend** formed therein, wherein the at least one protrusion has **a permanent curve** . . . and the at least one protrusion having a pointed end.

In each case, the claims require a hook or protrusion having both a permanent curve and either a permanent bend (claim 10), or a resiliently flexible bend (claim 16). Thus, with respect to the claimed bend, "resiliently flexible" is an express alternative to "permanent."

Considering the teachings of the Specification, we conclude that the curve element must be permanent, as recited in the claims, rather than "resiliently flexible." The Specification teaches that in some embodiments, the hook or protrusion "is resiliently flexible so as to form a substantially straight profile when compressed," (Ex. 1001, Abstract) but "may be

permanently-deformed into the curved configuration by heat setting the material" (*id.* at 6:1–4). As emphasized by Lifeport, the Specification teaches that a permanently deformed hook and frame—and, thus, a permanent curve—can be produced by heating Nitinol hook and frame combinations "at 550° for ten minutes." Resp. 25–26 (citing Ex. 1001, 6:3–4); *see* Ex. 2001 ¶ 77. When thus "permanently deformed," "hook 20 may still be compressed into alignment with the frame 22 *without losing the preset curve*," and subsequently "*deployed in the curved configuration* by releasing." Ex. 1001, 6:7–9 (emphases added).

We further note that the Specification makes clear that the disclosed hooks are incorporated into a variety of devices deployed in the veins of living bodies (*see, e.g.*, Ex. 1001, 3:60–4:8), and subject to various physical forces therein. The '662 patent, thus, discloses an embodiment having "a plurality of hooks 20 from the same incisions 40," which "could form hooks 20 which project in opposing directions" and "provide superior resistance to radial and axial loads from the corporeal lumen and blood flow." Ex. 1001, 5:33–37.

In light of the foregoing, we refine our construction of "permanent curve" to be "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." Insofar as Petitioners, and/or Petitioners' expert, argue that the challenged claims are unpatentable under multiple constructions of this term, we address only those arguments relevant to this construction below.

B. *Patentability Analysis*

To prevail in its challenges to claims 1–5, 7–13, 15, and 16, Petitioners must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

In finding a claim anticipated, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Moreover, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). A finding of inherency "requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present" in the anticipating reference. *Trindec Indus., Inc. v. Top-USA Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

A claim is unpatentable under 35 U.S.C. § 103(a) 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. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

a. *Anticipation of Claims 1–3, 5, 9–13, and 16 by Lefebvre*

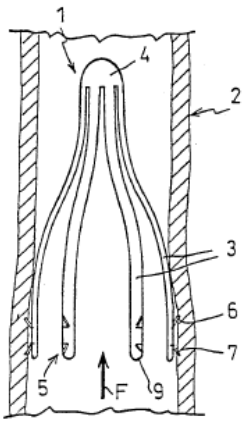
Petitioners contend that claims 1–3, 5, 9–13, and 16 are unpatentable as anticipated by Lefebvre. Pet. 11–18. For the reasons set forth below, we

find that Petitioners have failed to establish that Lefebvre discloses the permanent curve recited in each independent claim at issue.

i. *Overview of Lafebvre*

Lefebvre describes an implantable filter for retaining blood clots in a vein. *See* Ex. 1003, Abstract, 1:7–11. Lefebvre Figure 1 is reproduced below:

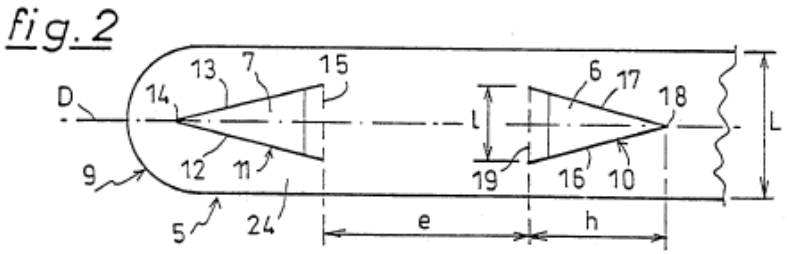
fig.1



Lefebvre Figure 1 illustrates a side view of filter 1 "placed inside a vein **2** in which blood flows in the direction of arrow F." *Id.* at 2:46, 2:52–54. Filter 1 "is generally conical in shape, with lateral legs 3" joined to form head 4 of the filter. *Id.* at 2:55–57. Lefebvre explains that the filter is made "of a material which presents a certain elasticity, with the result that the legs 3 may be brought substantially against one another in a sheath for introduction, of the catheter . . . and [legs 3] open out inside the vein 2 when the filter is pushed out of the sheath." *Id.* at 2:60–65.

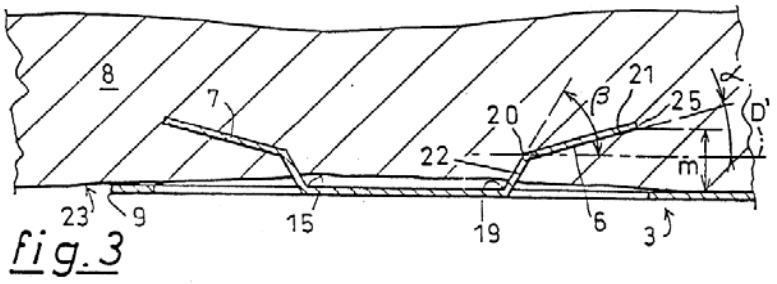
As shown in Figure 1, free end 5 of each leg 3 includes two teeth 6, 7. *Id.* at 2:57–59. In a preferred embodiment, the teeth have the form "of two triangles of which the parallel bases, fast with the leg, are spaced apart by a distance of between 2 and 10 mm." *Id.* at 2:33–36. The "two teeth . . . are

inclined with respect to the surface of the leg, one in the direction of flow of the blood and the other in the opposite direction." *Id.* at 1:64–66. Lefebvre Figure 2, reproduced below, illustrates the manufacture of teeth 6 and 7 from a lateral leg:



Lefebvre Figure 2 illustrates a view of the end of a lateral leg of a filter. *Id.* at 2:46. "To produce teeth 6, 7 two cut-outs are made along solid lines 10, 11." *Id.* at 3:5–9. Tooth 7, for example, is formed by "pushing the triangular part defined by cuts 12, 13, outwardly of leg 3." *Id.* at 3:10–13. The legs of the device, and thus the resulting teeth, can be made from a resilient metal. *See* Ex. 1026 ¶ 70 (citing Ex. 1003, 2:59–68). Lefebvre further discloses that "it is advantageous if the tooth is curved or bent" (Ex. 1003, 2:25–26), such as "by curving the tooth along an arc of circle" (*id.* at 4:16–18). In a deployed configuration, the teeth penetrate the wall of the vessel to hook the filter "without any possibility of subsequent migration." *Id.* at 4:1–4; *see id.* at 2:46–56.

Lefebvre Figure 3 is reproduced below:



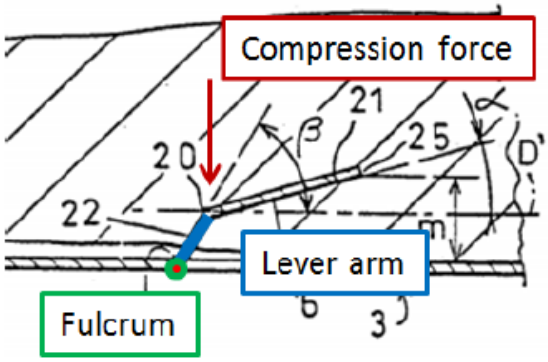
Lefebvre Figure 3 shows a longitudinal section of the end of a leg 3 positioned against the inner surface 23 of a vein, with teeth 6, 7 penetrating into vein wall 8. *Id.* at 2:47–48; 3:45–48; 4:1–3. Teeth 6, 7 are each bent along an axis of bend 20, which separates the triangular end 25 of the tooth from the trapezoidal base portion 22 having base 19 where the tooth joins leg 3. *Id.* at 3:27–33. Lefebvre Figure 3 shows that two angular measurements, α and β, converge at bend 20. "The angle α [is] formed between the triangular end part 21 of the tooth and the direction D' of the plane of the leg 3," and "[t]he angle β [is] formed between the trapezoidal part 22 of the tooth and the direction D' of the plane of the leg 3." *Id.* at 3:34–41.

ii. *Analysis*

Petitioners contend that Lefebvre's device has a permanent curve under Lifeport's construction of the term which, as explained above, is reasonably consistent with our construction (i.e., a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in). *See* Reply 7. In particular, Petitioners rely on Dr. Loomis in asserting that "the geometry disclosed in Lefebvre allows a

tooth made of elastic material to maintain the same curvature at bend 20 despite conformational changes," and "[a]s the device is inserted into the catheter bend 20 remains unchanged when the tooth is compressed within the frame." *Id.* (citing Ex. 1034 ¶¶ 5–9.)

Dr. Loomis models the geometry of tooth 6 in Lefebvre Figure 6 when a catheter sheath or "other force"[6] compresses the Lefebvre device. Ex. 1034 ¶¶ 5–9. Dr. Loomis's first illustration of a modified version of Lefebvre Figure 6 is reproduced below.



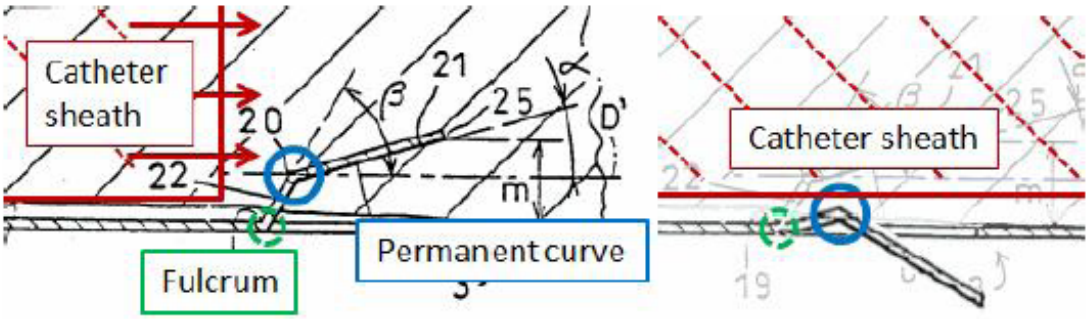
According to Dr. Loomis, this figure shows:

> When the catheter sheath or other force compresses the device, the geometry of the tooth directs the point of contact to bend 20, where the compression force will act. The compression force is transferred along trapezoidal part 22, which acts as a lever arm with a fulcrum where trapezoidal part 22 contacts the base 19.

Ex.1034 ¶ 6.

Dr. Loomis's second and third illustrations are adapted from Lefebvre Figure 6 and are reproduced below.

[6] Although Dr. Loomis indicates that some "other force" may compresses the Lefebvre device (Ex. 1034 ¶ 6), the only force addressed in his opinion comes from the application of a catheter sheath.



According to the adapted illustrations, as the catheter sheath advances from left to right, tooth 6 compresses but bend 20 remains unchanged.[7] *See id.* ¶¶ 7–8. In this model, "the point of contact remains at bend 20, there is no force acting on any portion of end part 21." *Id.* ¶ 8. "Accordingly," Dr. Loomis explains, "there is no force that will change the angle made at bend 20, which remains constant through the conformational change. In this way, bend 20 is a permanent curve as claimed in the '662 patent."[8] *Id.* In sum, Dr. Loomis testifies that as the catheter sheath covers the Lefebvre device, "there will be portions of the curve formed in place of bend 20 that do not experience any force from the catheter. Those portions will remain unchanged and maintain the same curve in either the compressed or expanded configurations." *Id.* ¶ 10.

[7] Dr. Loomis testified that he could have just as easily based his analysis on tooth 7, in which case the catheter sheath would be shown as moving from right to left. Tr. 57:1–10.

[8] Dr. Loomis further states that the '662 patent similarly discloses "elastic deformation at the base of the tooth . . . where the base of the engagement member acts as a fulcrum to allow the engagement member to be compressed within the frame." *Id.* ¶ 9 (referencing Ex. 1001, Figs. 2 and 3, 3:26–28).

Lifeport asserts that Petitioners fail to establish by a preponderance of evidence that Lefebvre teaches a permanent curve. Resp. 22–26. Lifeport's expert argues that nothing in Lefebvre indicates that the teeth have a permanent curve. *Id.* (citing Ex. 2001 ¶¶ 75–78); *see* Ex. 2001 ¶47. To the contrary, because the teeth are cut from leg 3, which is expressly described as elastic, a person of ordinary skill in the art would conclude that teeth do not have a permanent curve. *See id.* ¶ 47.

Lifeport has the more persuasive position. First, we note that endoprostheses such as those disclosed in the '662 patent are deployed and function in a living body (*see, e.g.*, Ex. 1001, 3:60–4:8). Accordingly, our construction of permanent curve as a preset curve that maintains a fixed arc *throughout normal use* regardless of the configuration of the device, is not limited to sheathed and unsheathed configurations taken in isolation.

Thus, whereas Dr. Loomis's analysis of Lefebvre focuses on the force applied by a catheter sheath impinging on a single tooth of the Lefebvre device, "throughout normal use" more broadly encompasses the deployed configuration of Lefebvre Figure 3 in which teeth 6, 7 penetrate into the vein wall "one in the direction of flow of the blood and the other in the opposite direction." *See* Ex. 1003, 1:64–66. Dr. Loomis addressed the compressive effects during the application of a catheter sheath. We find no evidence that Dr. Loomis addressed compressive, hemodynamic, or other forces on the Lefebvre teeth when the device is deployed and functioning in normal use.[9]

[9] Although an analysis of the forces applied to the Lefebvre device when it is deployed in a vein is among the issues raised in Medtronic's Motion to Exclude Evidence, we need not resort to Dr. Loomis's contested testimony as the omission is self-evident. We also are not persuaded by Medtronic's assertion that Figure 3 and column 3, lines 34–42, of Lefebvre demonstrate

The evidence of record is, therefore, insufficient to demonstrate that Lefebvre maintains a permanent curve as properly construed.

Second, with respect to the configurations of Lefebvre that Dr. Loomis does address, we find his analysis speculative and accord it little weight. It is within our discretion to assign the appropriate weight to be accorded to evidence. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (under the Federal Rules of Evidence, which are applicable here,[10] "[o]pinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination.") (citations omitted); *see also In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations . . . and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.").

In weighing Petitioners' expert testimony, we take into account the lack of evidence that Dr. Loomis (1) considered the physical dimensions of the Lefebvre components, such as the distance between teeth, and the

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that the angles of teeth 6, 7 do not change when impaled in the vein. Tr. 12:1–13:18. The specifically recited angles for α (15°) and β (60°) of Lefebvre Figure 3 ("the example" of the referenced passage) refer to the device as shown deployed in the vein. On the record before us, we agree with Lifeport that the cited passage is "not saying that it maintains that shape in all configurations of the device." *Id.* at 25:10–17.

[10] *See* 37 C.F.R. § 42.62 ("the Federal Rules of Evidence shall apply to" an *inter partes* review, except for exclusions not applicable here).

clearance between a catheter sheath and elements of the Lefebvre device—including the second, opposing tooth[11] (*see* Ex. 1035, 21:7–15, 29:2–10; Tr. 48:19–20:4); (2) took into account material properties of the metal used to form the Lefebvre legs and teeth, such as the modulus of elasticity[12] (Ex. 1035, 15:9–24 (Lefebvre "[d]oes not disclose a specific elastic modulus of the metal used."); *see also id.* at 27:14–21 ("For the sake of my analysis, I didn't make any assumptions as to whether [the tooth and leg] were the same material or . . . different materials.")); or (3) employed any computer modeling, physical models, or mockup of any embodiment disclosed in Lefebvre (*id.* at 16:24–17–6; 17:7–18:6; *see* Tr. 13:19–14:2). Those factors point to a lack of rigor and reliability in Dr. Loomis's analysis.

Our concerns are heightened by Dr. Loomis's apparent lack of expertise in the relevant field. Although Dr. Loomis testified that he took "seminars on mechanical behaviors of metals as used in the biomedical device industry" (*id.* at 10:1–6), and as "the director [of] mechanical analysis of materials used in medical devices" (*id.* at 10:19–20), oversaw the "stress/strain analysis testing, radio compression analysis done on

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[11] At best, Dr. Loomis testified that the opposing teeth "would have to be compressed or else they would embed in the catheter," but provided no indication how that would be accomplished according to his model. *See* Tr. 57:11–58:3.

[12] According to Dr. Loomis, modulus of elasticity is "a way of describing the force required to stretch a material. The higher the modulus, the more force is required to stretch [or deform] the material." Ex. 1035, 12:18–25; *see also*, DICTIONARY.COM, http://dictionary.reference.com/browse/modulus+of+elasticity (last accessed 26 February 2015) (Defining modulus of elasticity as "any of several coefficients of elasticity of a body, expressing the ratio between a stress or force per unit area that acts to deform the body and the corresponding fractional deformation caused by the stress.")

instruments such as Instron" (*id.* at 10:13–20), Dr. Loomis is, by training, an organic chemist[13] with extensive experience in polymers, most notably, biopolymers. *See* Ex. 1026 ¶ 3; Ex. 1027. Dr. Loomis's credentials in these areas are notable, but they are not well matched to the mechanical and structural issues of the present matter. By contrast, we find that Lifeport's expert, Ms. Golds, has substantial and highly relevant experience in the design, development, manufacture, and testing of vascular implants, including vena cava filters and self-expanding Nitinol stents. *See* Ex. 2001, ¶¶ 3–13, App.; *see also* Reply at 10 ("[P]ersons of ordinary skill routinely worked simultaneously on both stent and filter design, as Ms. Golds herself did at AlvaMed.").

Third, noting that the '662 patent teaches that "hook 20 may be permanently-deformed into the curved configuration by heat setting the material" (Ex. 1001, 6:1–4), we find no corresponding disclosure in Lefebvre. In accord with this finding, we credit the testimony of Lifeport's expert, Ms. Golds, that there is "no teaching in Lefebvre of 'heating [nitinol] at 550° for ten minutes,' or any other conditions which would cause the curve in the tooth to be 'permanent' such that it maintains a permanent curve regardless of what configuration the device is in." Ex. 2001 ¶ 77.

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[13] Dr. Loomis contends that a person of ordinary skill in the art would, *inter alia*, possess "a degree in biomedical, mechanical, or chemical engineering or material science." Ex. 1026 ¶ 44. Dr. Loomis has undergraduate training in electrical engineering (Ex. 1035, 9:3–21), a master's degree in chemistry and a Ph.D. in Organic Chemistry (Biochemistry minor) (Ex. 1027, 3), and, thus, does not possess the educational background required by his own definition. Ms. Golds, by contrast, does meet Dr. Loomis's educational requirement, holding a bachelor's degree in Biomedical Engineering with a specialty in Mechanical Engineering. Ex. 2001, 1–2, App.

"Certainly, it cannot be said that teeth 7 necessarily have a permanent curve." *Id.* ¶ 75.

For the reasons discussed above, we conclude that Petitioners have not proven by a preponderance of the evidence that Lefebvre renders claims 1–5, 7–13, 15, and 16 unpatentable under 35 U.S.C. § 102.

b. *Obviousness of Claims 7, 8, and 15 in view of Lefebvre and Lazarus*

Petitioners contend that claims 7, 8, and 15 are unpatentable as obvious in view of Lefebvre and Lazarus. Pet. 19–23; Reply 9–10, 14–15; *see* Ex 1026, 40–43. Claims 7 and 8, depending from independent claim 1, and claim 15, depending from independent claim 10, recite a pointed end of the elongated member having at least one barb (claim 7), that the pointed end is "sharpened" (claim 8), and that the point is formed in an "arrowhead configuration" (claim 15). In asserting obviousness, Petitioners rely on Lazarus solely for the use of specially configured pointed ends. At pages 21–22 of the Petition, for example, Petitioners state:

> Lazarus specifically teaches that by modifying hooks like those of Lefebvre to make them sharper, or to configure them as barbs or arrowheads, *more secure anchoring* of the device can be achieved. . . . Thus, a person of skill in the art dealing with the problem of intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of Lefebvre to achieve even stronger anchoring of the device to the lumen wall.

For the reasons discussed above, we find that Lefebvre fails to disclose or suggest the "permanent curve" set forth in independent claims 1 and 10, from which claims 7, 8, and 15 depend. As there is no assertion of

record that the missing element is provided in Lazarus, we conclude that Petitioners have not proven by a preponderance of the evidence that the combination of Lefebvre and Lazarus renders claims 7, 8, and 15 unpatentable under 35 U.S.C. § 103(a).

c. *Obviousness of Claims 1–4, 8–12, and 16 in view of White and Ostrovsky*

Petitioners contend that claims 1–4, 8–12, and 16 are unpatentable as obvious in view of White and Ostrovsky. Pet. 46–56; Reply 11–14; *see* Ex. 1026, 32–35, 70–81; Ex. 1034, 5–8. For the reasons set forth below, we find that Petitioners have failed to establish that the combination of White and Ostrovsky teaches or suggests a "permanent curve" and, thus, has not proven by a preponderance of evidence that the asserted combination renders claims 1–4, 8–12, and 16 obvious.

i. *Overview of White*

White describes an intraluminal device for treating aneurysms and other vascular diseases. Ex. 1004, Abstract. White's device has "a tubular body with two ends" that can expand "from a radially compressed state to a radially expanded state." *Id.* at 2:8–11. White's device includes "engagement members," preferably formed of Nitinol, stainless steel or other "memory" alloy. *Id.* at 8:31–34. Each engagement member is defined by "a small incision in the wall of the device" (*id.* at 17:1–3), is "integral with a wall of the device body" (*id.* at 8:20–23) and "act[s] as an attachment, hook, or anchor to prevent the device from moving longitudinally within the vessel" (*id.* at 7:34–8:2).

White Figures 6a and 6b are reproduced below:

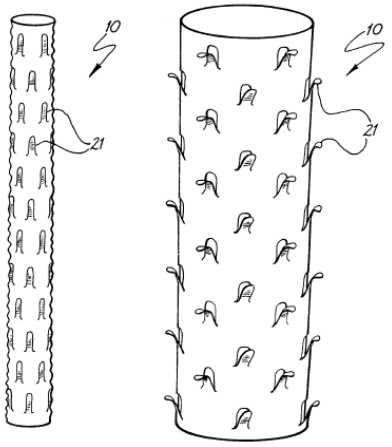

FIG. 6a FIG. 6b

White Figure 6a illustrates device 10 in a compressed state; Figure 6b illustrates the same device in an expanded condition. *Id.* at 14:22–28. The device 10 shown in Figures 6a and 6b includes engagement members 21 in two configurations. *Id.* at 16:34–17:3. White describes that, in the compressed state, the angular relationships of the engagement members to the wall of the device body "may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device body." *Id.* at 9:28–33. According to White, that allows maintaining "the smallest possible diameter along the length of the device body . . . when the device body is in a radially compressed state." *Id.* at 9:33–36. In the expanded state, the engagement members are "splayed out from the wall of the device body into [a different] . . . angular relationship" with the wall of the device body. *Id.* at 14:25–28. White also indicates that the once the device has been positioned in the selected vessel, the engagement members may change from the compressed state to the expanded state "without specific assistance from the surgeon." *Id.* at 10:3–7.

One mechanism by which the White device may change from a compressed state to an expanded state is by "a spring-aided change," which occurs when "the material comprising the engagement members has a 'memory' of [the angular relationship of the engagement members in the expanded position] . . . such that the engagement members may 'spring' into that position upon release from the catheter." *Id.* at 10:18–23. In that embodiment, the device is manufactured from alloys "which have the capacity to 'memorise' their manufactured shape, such that the device, according to this invention, will have a continuous tendency to return to its original shape following any events which cause it to be temporarily deformed." *Id.* at 7:6–11.

In another embodiment, the change from a radially compressed state (Figure 6a) to a radially expanded state (Figure 6b) is mediated by thermal expansion. *Id.* at 16:34–17:15. In that embodiment, engagement members 21 are cut from a Nitinol frame and heat treated such that the engagement members "have the capacity, following a rise in temperature, to splay out from a wall of the device." *Id.* at 17:8–11.

ii. *Analysis*

In asserting that White teaches a permanent curve, Petitioners rely on Figures 6a, 6b, and the following passage from the reference:

> the device body and the engagement members will be such that when the device body is in a radially compressed state, the respective first angular relationships of the engagement members may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device body.

Pet. 50 (citing Ex. 1004, 9:29–33, Figs. 6a, 6b); *see id.* at 55. Petitioners' expert, Dr. Loomis, explains that White discloses "four ways in which an engagement member can change its angular relationship to the device once it is introduced to the vessel," including heat-aided change in response to body temperature and spring aided change in which the member returns to a memorized shape upon the release of a compressive force. Ex. 1026 ¶ 99. The angular relationship of the engagement members to the body wall may be flat "or the engagement members might even project inwardly so the device maintains the smallest profile possible." *Id.* ¶ 100 (citing Ex. 1004, 9:27–10:2.)

Petitioners argue that White's spring expansion embodiment "allows for temporary deformation of the device into a compressed state without altering the curvature of any protrusion." Reply 11. We discern no evidence for this assertion other than Dr. Loomis's statement that, in the White's spring-aided device, "the engagement members that project outwardly when expanded can 'project inwardly, within the lumen of the device' when compressed." Ex. 1034 ¶ 22 (quoting Ex. 1004, 9:27–33). We do not find Dr. Loomis's assertion persuasive. *See Am. Acad. of Sci. Tech Ctr.*, 367 F.3d at 1368 ("[T]he Board is entitled to weigh the declarations [offered in the course of prosecution] and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.").

Dr. Loomis further asserts that expansion of the White device "is analogous to the engagement member disclosed in the '662 patent in Figures 2 and 3, where the engagement member projects inwards from the frame." Ex. 1034 ¶ 22; *see* Reply 11. We are not persuaded that Dr. Loomis's comparison to the embodiments shown in Figures 2 and 3 of the '662 patent is sufficient, as nothing in the Specification requires that those embodiments comprise a permanent curve. To the contrary, the permissive language of the Specification that hook 20 "*may* be permanently-deformed into the curved configuration by heat setting the material" (Ex. 1001, 5:60–62 (emphasis added)), indicates that those embodiments may fall outside the claims ultimately issued. *See also id*. at 6:7–9 ("With a permanently deformed hook 20, the hook 20 may still be compressed into alignment with the frame 22 without losing the preset curve.").

Dr. Loomis further states that

> one skilled in the art would have recognized that the engagement members of Figure 6b, when made of a resilient spring-aided change material such as nitinol, would maintain a permanent curve in both their compressed and expanded positions. Further, it is my opinion that one skilled in the art would have recognized that such spring aided materials, if curved in their uncompressed orientation, would maintain a curve when compressed.

Ex. 1026 ¶ 101; *see also* Reply 11.

We do not discern, nor does Dr. Loomis adequately explain, how the angular relationship of White's engagement members, whether in an expanded, flat, or inwardly-projection configuration, comports with our construction of permanent curve. At best, Dr. Loomis identifies changes in the shape of White's engagement members in response to temperature or

compressive forces. On their face, such changes are incompatible with a permanent curve that is a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in. Dr. Loomis has not convinced us of a contrary interpretation of the White reference. Accordingly, we credit Ms. Gold's testimony that "[n]othing in the disclosure of White indicates that the engagement members 21 have a permanent curve." Ex. 2001 ¶ 59.

iii. *Overview of Ostrovsky*

Ostrovsky describes a "recoverable thrombosis filter that can be implanted and securely positioned within a vein at a desired location, and can be recovered through an endovenous route." Ex. 1007, Abstract. "The various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys." *Id.* at 10:65–11:1. "The selection of materials will also determine the flexibility and resiliency of the various members." *Id.* at 10:63–65.

Ostrovsky's filter comprises "a generally conical structure" having "shaped ends for engaging an inner lumen wall" (*id.* at 3:7–11), as can be seen in Ostrovsky Figure 2, reproduced below:

Fig.2

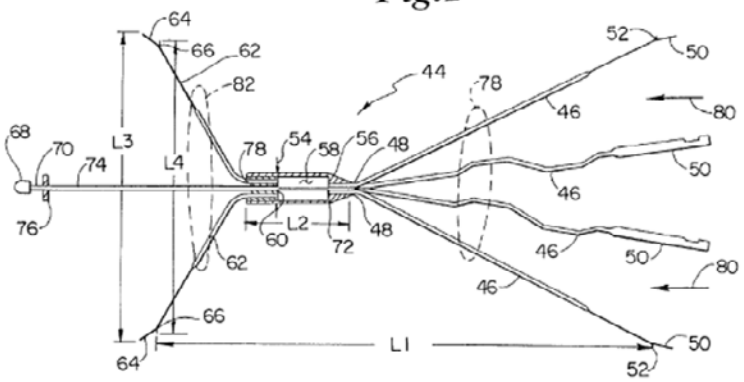

Figure 2 illustrates Ostrovsky's filter 44. *Id.* at 3:66–67. At one end of filter 44, flexible anchoring struts 62 "project outwardly to wall engaging surfaces 64. Projections 66 function to position and hold filter 44 in position when engaged to an inner vein wall." *Id.* at 5:40–43. At the opposite end, filter 44 has "shaped filtering elements 46, each having a mounting end 48 and a wall engaging end 50." *Id.* at 5:31–33. Wall engaging end 50 of element 46 has projections 52 to engage a vein wall. *Id.* at 5:31–34, 6:2–3. Ostrovsky discloses that element 46 may comprise a flat wire having, for example, a thickness of 0.0006 inch and a width of 0.026 inch, and that differences in relative thickness relative to width will affect the flexibility of the element. *Id.* at 6:10–14.

Ostrovsky Figure 3 is reproduced below:

Fig.3

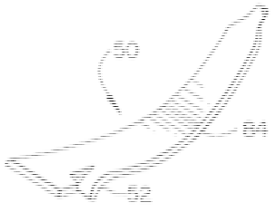

Figure 3 illustrates a wall engaging end 50 of element 48. *Id.* at 4:1–2. Wall engaging end 50, shown in Figure 3, has "a generally curved structure and is flattened to a desired dimension such that the under surface 84 will slidably engage an associated vein wall." *Id.* at 5:65–6:1. "The thickness [of engaging end 50] is selected for the desired flexibility." *Id.* at 6:1–2. Ostrovsky discloses that "[a] similar configuration is utilized for the anchoring elements," such as anchoring struts 62 shown in Figure 2 (previously presented). *Id.* at 6:3–4.

Figures 33 and 34 show an embodiment of Ostrovsky's filter in two stages of being extracted from the vascular system. *Id.* at 4:64–67. Ostrovsky Figure 33 is reproduced below:

Fig.33

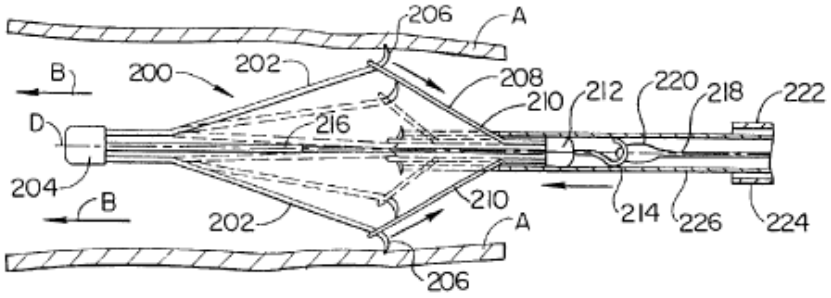

Figure 33 illustrates an early stage of retrieving a filter from blood vessel A. *Id.* at 4:64–65. Ostrovsky's filter includes a flexible anchoring strut 202 with end 206 that is "sharpened and barbed to engage with the wall of vessel A," as shown in Figure 33. *Id.* at 9:65–67. Blood flow is in the direction of arrows B. *See id.* at 9:58–62.

Ostrovsky Figure 34 is reproduced below:

Fig.34

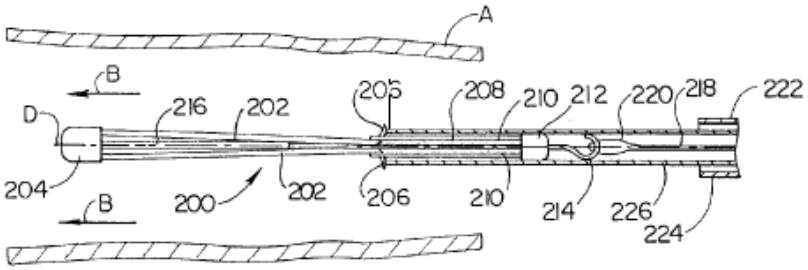

Figure 34 illustrates a later stage of retrieving a filter from a vascular system. *Id.* at 5:1–2. As shown in Figure 34, element 206, the hook-like end of strut 202 has been disengaged from the wall of vessel A, brought to a position adjacent axis D of filter 200, and into contact with inner tube 226. *Id.* at 10:34–43.

iv. *Analysis*

Petitioners contend that Ostrovsky "teaches the use of permanently curved, pointed hooks on a recoverable thrombosis filter for intraluminal implantation" (Pet. 26 (citing Ex. 1007, Abstract, Figs. 3 and 24)); that Ostrovsky Figure 3 "discloses the elongated member (52) bent away from the frame element (50) wherein the elongated member (52) has a permanent curve" (*id.*at 50); and that Ostrovsky Figures 33 and 34 disclose hook-like elements 206 to anchor the device to the lumen wall firmly, wherein these elements "maintain a curve in both their compressed and expanded configurations" (*id.* at 27; *see also* Reply 11 (asserting that hooks 206 "maintain an identical curve in each state")).

Dr. Loomis asserts that Ostrovsky "discloses a curve hook with a curve and materials that would maintain a permanent curve." Ex. 1026 ¶ 136; *see id.* ¶ 109 (noting that "outward projection (52) has a permanent

curve"). Although Ostrovsky discloses the use of "*elastic* materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys" (Ex. 1007, 10:65–11:1 (emphasis added)), Dr. Loomis fails to explain how the reference teaches the generation of a *permanent* curve, as is taught, for example, at column 6, lines 1–4, of the '662 patent (heating a Nitinol hook and frame combination "at 550° C. for ten minutes").

We also take note of Dr. Loomis's failure to address the forces acting on any part of an Ostrovsky device alleged to teach or disclose a permanent curve. For example, as shown in Ostrovsky Figure 33, reproduced above, hook-like elements 206 are anchored in the wall of blood vessel A as blood flows through the filter in the direction of arrows B. Figures 33 and 34 further show that in normal use, the filter may be removed from the vessel in the opposite direction of blood flow. We find no evidence that Dr. Loomis addressed these or any other forces acting upon the hook-like elements 206 when the Ostrovsky device is deployed in normal use. Accordingly, we find the evidence of record insufficient to demonstrate that Ostrovsky maintains a permanent curve as defined herein.

In light of the above, we conclude that Petitioners have not proven by a preponderance of the evidence that the combination of White and Ostrovsky renders claims 1–4, 8–12, and 16 unpatentable under 35 U.S.C. § 103(a).

d. *Obviousness of Claims 7 and 15 in view of White, Ostrovsky, and Lazarus*

Petitioners contend that claims 7 and 15 are unpatentable as obvious in view of White, Ostrovsky, and Lazarus. As discussed above, Petitioners have not shown that any of these references teach or suggest a permanent

curve as construed herein. We, therefore, conclude that Petitioners have not proven by a preponderance of the evidence that the combination of White, Ostrovsky, and Lazarus renders claims 7 and 15 unpatentable under 35 U.S.C. § 103(a).

III. MOTION TO EXCLUDE EVIDENCE

Petitioners move to exclude portions of the deposition transcript of Dr. Gary L. Loomis as exceeding the scope of rebuttal evidence. Paper 22.

We dismiss Petitioners' Motion as moot because we do not rely on any of the objected-to testimony in our final decision.

IV. CONCLUSION

Petitioners have not proven, by a preponderance of evidence, that any of claims 1–5, 7–13, 15, and 16 are unpatentable over the cited prior art.

V. ORDER

After due consideration of the record before us, it is

ORDERED that claims 1–5, 7–13, 15 and 16 of U.S. Patent No. 7,147,662 are not determined to be unpatentable;

FURTHER ORDERED that Medtronic's Motion to Exclude Evidence is dismissed as moot; and

FURTHER ORDED that because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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