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Paper No. 21
October 31, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-01281
Patent 7,828,767 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and STACY B. MARGOLIES, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Edwards Lifesciences Corporation ("Petitioner") challenges the patentability of claims 1–12, 14, 16, and 17 of U.S. Patent No. 7,828,767 B2 (Ex. 1001, "the '767 patent"), owned by Boston Scientific Scimed, Inc. ("Patent Owner"). We have jurisdiction under 35 U.S.C. § 6(c) to hear this *inter partes* review instituted pursuant to 35 U.S.C. § 314. In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we find on the record before us that Petitioner has shown by a preponderance of the evidence that claims 5, 6, 8–12, 14, 16 and 17 of the '767 patent are unpatentable for the reasons discussed below. *See* 35 U.S.C. § 316(e).

A. PROCEDURAL HISTORY

Petitioner filed a Petition requesting institution of *inter partes* review of claims 1–12, 14, 16, and 17 of the '767 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We initially instituted review only of challenged claims 5, 6, 8–12, 14, 16, and 17, because we determined the Petition showed a reasonable likelihood that Petitioner would prevail as to those challenged claims on the following grounds (the "First Set of Grounds"):

Reference(s)	Basis	Claim(s) Challenged
Dlugos[1]	§ 102	5
Dlugos and Eskaros[2]	§ 103	5
Dlugos, Eskaros, and Hijlkema[3]	§ 103	8
Dlugos, Eskaros, and Forman[4]	§ 103	6, 14, and 16
Dlugos, Eskaros, and Traxler[5]	§ 103	9, 10, and 12
Dlugos, Eskaros, Traxler, and Forman	§ 103	11
Dlugos, Eskaros, Forman, and Becker[6]	§ 103	17

Paper 9 ("Inst. Dec."); *see also* 35 U.S.C. § 314. Our Case Management and Scheduling Order set a deadline for Patent Owner to file a response to the instituted grounds of the Petition and cautioned Patent Owner that "any arguments for patentability not raised in the response will be deemed waived." Paper 10, 6. Patent Owner did not file a response. We subsequently confirmed during a conference call with the parties on February 21, 2018, that, by not filing a response, Patent Owner waived any arguments for patentability with regard to the grounds instituted. Paper 13, 3.

Prior to the scheduled oral argument in this case, the Supreme Court held in *SAS Inst., Inc. v. Iancu* that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the

[1] WO 2007/020087 A1, pub. Feb. 22, 2007 (Ex. 1008, "Dlugos").
[2] U.S. Patent App. Pub. No. 2008/0097300 A1, pub. Apr. 24, 2008 (Ex. 1011, "Eskaros").
[3] U.S. Patent No. 5,853,389, iss. Dec. 29, 1998 (Ex. 1009, "Hijlkema").
[4] U.S. Patent No. 5,501,759, iss. Mar. 26, 1996 (Ex. 1012, "Forman").
[5] U.S. Patent App. Pub. No. 2001/0047149 A1, pub. Nov. 29, 2001 (Ex. 1013, "Traxler").
[6] U.S. Patent No. 4,251,305, iss. Feb. 17, 1981 (Ex. 1014, "Becker").

petition. 138 S. Ct. 1348, 1359–60 (2018). As explained above, prior to *SAS Inst.*, we had not instituted review on all of the challenged claims in this case. *See* Inst. Dec. 31. In accordance with *SAS Inst.*, we modified the Institution Decision to include review of all challenged claims on all grounds asserted in the Petition. Paper 15, 3–4. In particular, we further instituted review on the following additional grounds asserted in the Petition (the "Second Set of Grounds"):

Reference(s)	Basis	Claim(s) Challenged
Dlugos and Hijlkema	§ 103	1, 2, 4, 5, and 8
Dlugos, Hijlkema, and Konstantino[7]	§ 103	3
Dlugos, Hijlkema, and Forman	§ 103	6, 14, and 16
Dlugos	§ 103	5
Dlugos, Eskaros, and Konstantino	§ 103	7
Dlugos and Bampos[8]	§ 103	1

Id. at 4. We also permitted the parties to seek additional briefing with regard to the Second Set of Grounds. *Id.* Based upon the parties' requests, we authorized Patent Owner to rely on the arguments it raised in its Preliminary Response as to the Second Set of Grounds in place of filing a Patent Owner response and we authorized Petitioner to file a reply only to issues raised in either the Institution Decision or Patent Owner's Preliminary Response and only with respect to the Second Set of Grounds. Paper 16, 3. Petitioner filed a Reply in accordance with our prior authorization. Paper 17 ("Reply"). Oral argument was held before the Board on August 7, 2018. Paper 20 ("Tr.").

[7] U.S. Patent App. Pub. No. 2005/0177130 A1, pub. Aug. 11, 2005 (Ex. 1010, "Konstantino").
[8] U.S. Patent No. 6,013,055, iss. Jan. 11, 2000 (Ex. 1015, "Bampos").

B. RELATED MATTERS

According to the parties, the '767 patent is asserted in the United States District Court for the Central District of California, in a case captioned *Boston Scientific Corp. and Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corp.*, Civil Action No. 8:16-cv-0730 (C.D. Cal.). Pet. 72; Paper 3, 2.

C. REAL PARTIES IN INTEREST

Petitioner identifies only itself as a real party in interest. Pet. 72. Patent Owner identifies itself and Boston Scientific Corp. as real parties in interest. Paper 3, 2.

II. BACKGROUND

The '767 patent, titled "Balloon Design and Weld Design to Increase Ease of Re-Wrapping and Decrease Withdrawal Force," issued November 9, 2010, from U.S. Application No. 12/129,380, filed May 29, 2008. Ex. 1001. As background information, below we provide a summary of the '767 patent and two illustrative claims from the '767 patent and we identify the proffered expert testimony.

A. SUMMARY OF THE '767 PATENT

The '767 patent generally relates "to a balloon catheter where a balloon cylinder is folded to form pleats and then is welded directly to the catheter," and a method of making the same. *Id.* at 2:18–24.

The '767 patent illustrates a portion of a prior art balloon catheter in Figure 1, reproduced below.

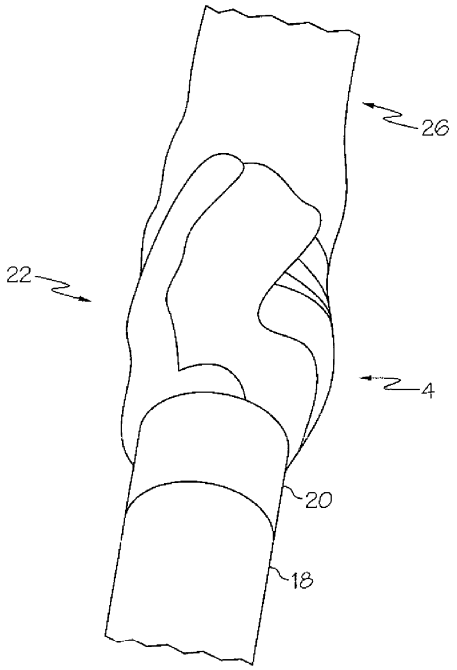


FIG. 1
(PRIOR ART)

Figure 1 illustrates prior art balloon catheter 22, including a preformed balloon with center region 26, cone 4, and weld 20 at which the waist of the balloon is welded to shaft 18. Ex. 1001, 1:46–51. Similar structures are present at both the proximal end (closest to the operator of the catheter) and the distal end (furthest from the operator) of the balloon catheter. *See* Ex. 1001, 1:46 (referring to Figure 21 as an "end view"); Prelim. Resp. 2. According to the '767 patent, Figure 1 shows center region 26 folded to a smaller outer diameter after being welded to shaft 18, but cone 4 is not folded, creating a bulky transition region. Ex. 1001, 1:54–65.

Figures 9 and 11 of the ’767 patent are reproduced below.

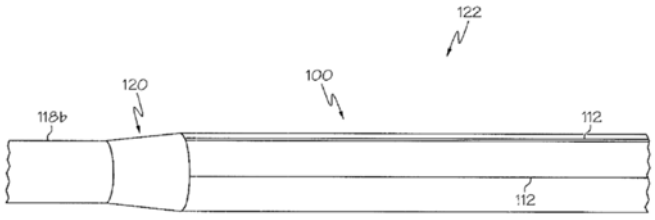


FIG. 9

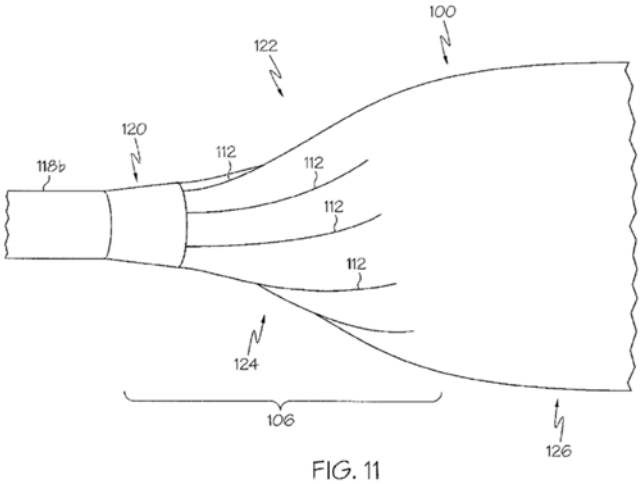


FIG. 11

Partial side views of an embodiment of the claimed balloon catheter 122 after balloon 100 has been welded to outer shaft 118b illustrate the balloon in a deflated state in Figure 9 and in an inflated state in Figure 11. Ex. 1001, 2:54–56, 2:60–61, 5:25–32. Balloon 100 has smooth middle region 126 and pleated cone regions 124. *Id.* at 5:32–35. “[T]he folds 112 of the pleated cone regions 124 facilitate re-wrapping along the original folds 112.” *Id.* at 5:35–37. According to Petitioner, the “extension of the folds through the cone regions and into the welds is the sole invention of the ’767 patent.” Pet. 3. Patent Owner states that the ’767 patent is “directed to a unique balloon design and a method of manufacturing a balloon,” but offers no substantive description of the invention of the ’767 patent. Prelim. Resp. 2–4.

B. ILLUSTRATIVE CLAIMS

Challenged claims 1 and 5 are independent. Challenged claims 2–4 depend from claim 1, and challenged claims 6–12, 14, 16, and 17 depend from claim 5. Claims 1 and 5 are illustrative of the claimed subject matter and are reproduced below:

> 1. A balloon catheter, the balloon catheter comprising:
> at least one shaft; and
> a balloon, the balloon comprising a first weld region, a first cone region, a middle region, a second cone region and a second weld region, the first weld region engaging the balloon to the at least one shaft, the first cone region adjacent to the first weld region, the middle region between the first cone region and the second cone region, the second cone region adjacent to the second weld region, the second weld region engaging the balloon to the at least one shaft, the balloon having an uninflated state and an inflated state, the balloon having at least one fold extending from the first weld region to the second weld region in the uninflated state and the first and second cone regions of the balloon having at least one fold in the fully inflated state.

Ex. 1001, 6:40–55.

> 5. A method for making a balloon catheter comprising:
> providing a balloon cylinder, the balloon cylinder having a first end and a second end, the first end and the second end separated by a longitudinal length;
> providing a catheter comprising at least one shaft;
> incorporating at least one fold, the at least one fold extending from the first end to the second end of the balloon cylinder; and
> welding the balloon cylinder with the at least one fold to the at least one shaft of the catheter.

Ex. 1001, 7:1–10.

C. PROFFERED EXPERT DECLARATION

Petitioner supports its challenge with a Declaration of Thomas Trotta, dated April 17, 2017. Ex. 1005. Mr. Trotta is an "independent consultant" and states that he has more than thirty years of experience involving the processes used to manufacture percutaneous transluminal coronary angioplasty (PTCA) catheters and stent delivery systems. *Id.* ¶¶ 1, 6; *see also* Ex. 1006 (curriculum vitae of Mr. Trotta). Mr. Trotta further states that he is "a named inventor of thirty-three patents, of which twenty-eight address discoveries and improvements pertaining to balloon catheters." *Id.* ¶ 7); *see also* Ex. 1007 (list of patents on which Mr. Trotta is a named inventor). Patent Owner did not proffer an expert declaration in this case.

III. ANALYSIS

In our analysis of Petitioner's unpatentability contentions with respect to the challenged claims of the '767 patent over the asserted prior art, we next address the applicable principles of law; the level of ordinary skill in the art; the construction of the claim terms "fold" and "balloon cylinder"; and the scope and content of the asserted prior art of Dlugos, Eskaros, Hijlkema, Forman, Traxler, Becker, Konstantino, and Bampos. We then discuss the First Set of Grounds for which there is no Patent Owner response and then we turn to the Second Set of Grounds for which Patent Owner was authorized to rely on its Preliminary Response in opposition to Petitioner's contentions.

A. PRINCIPLES OF LAW

To prevail in its challenge to the patentability of claims 1–12, 14, 16, and 17 of the '767 patent, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

In an *inter partes* review, "[a] claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc.*

v. Apotex Inc., 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable as obvious under 35 U.S.C. § 103(a) if "the differences between" the claimed subject matter "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 said subject matter pertains." 35 U.S.C. § 103(a). An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

An obviousness determination "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham,* 383

U.S. at 17. "The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.* Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.").

B. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art at the time of the claimed invention would have had either of the following qualifications: (1) "an undergraduate degree in mechanical manufacturing or material science engineering, as well as at least five years of experience in the industry working with catheters and balloons and the manufacturing of those devices; or without an undergraduate degree," or (2) "ten years of working experience designing, manufacturing and/or overseeing the processes for designing and/or manufacturing the tools and/or the devices." Pet. 14. Mr. Trotta supports Petitioner's contention with regard to the level of ordinary skill in the art. Ex. 1005 ¶ 57. Patent Owner does not contest Petitioner's asserted level of ordinary skill in the art. *See* Prelim.

Resp. 6 n.3. Based on the evidence provided, including the prior art of record, we agree with Petitioner's proposed level of ordinary skill and also find that the prior art of record further reflects the level of ordinary skill in the art. *See also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (noting that the prior art of record may reflect the level of ordinary skill in the art).

C. CLAIM CONSTRUCTION

1. "fold"

Claims 1 and 5 each recite "at least one fold." Ex. 1001, 6:52, 7:6. Petitioner contends that "fold" includes "folds, pleats, wings, lobes, wraps, wrappings, or protrusions." Pet. 13. In support, Petitioner states that, according to the '767 patent, "the term 'fold' includes pleats, wings, and any similar structure." *Id.* (quoting Ex. 1001, 3:62–63). Petitioner further asserts that "[t]he specification provides several 'non-limiting examples of methods of balloon folding' that include reference to 'lobes,' 'wraps,' 'wrappings,' and 'protrusions.'" *Id.* In this statement, the Petition cites "3:63–4:2" of Exhibit 1001, implying it is quoting the '767 patent. It is not. The Specification of the '767 patent instead states the following:

> As used in this application, the term "fold" includes pleats, wings, and any similar structure. Non-limiting examples of methods of balloon folding are discussed in commonly Assigned U.S. Patent Application Publication No. 2003/0163157, entitled Balloon Folding Apparatus, Methods and Products and U.S. Patent Application Publication No. 2005/0251194, entitled Curved Wing Balloon and Manufacture Thereof, each of which are hereby incorporated by reference in their entirety.

Ex. 1001, 3:62–4:3. Thus, by citing in the Petition only to the '767 patent Petitioner did not identify what particular document incorporated by reference to the '767 patent Specification refers to 'lobes,' 'wraps,'

'wrappings,' and 'protrusions,' or where in the record of this proceeding there is any teaching of 'lobes,' 'wraps,' 'wrappings,' and 'protrusions' that constitute a "fold," as that term is used in the '767 patent. Mr. Trotta provides no additional substantive support for Petitioner's broadest reasonable interpretation of "fold." *See* Ex. 1005 ¶¶ 64–65 (citing Ex. 1001 2:5–7, 3:63–4:3).

Patent Owner, however, does not contest Petitioner's assertion that "fold" encompasses "folds, pleats, wings, lobes, wraps, wrappings, or protrusions." *See* Prelim. Resp. 6 n.3. The Institution Decision, in the absence of any opposition by Patent Owner to Petitioner's proposed construction, stated that for purposes of that decision there was no need to expressly construe "fold." Inst. Dec. 9. Nevertheless, the burden remains on Petitioner at all times to show the unpatentability of the challenged claims, including the proper claim construction.

For the following reasons, we find insufficiently supported and unreasonably broad Petitioner's contention that "fold" broadly includes all "lobes," "wraps," "wrappings," and "protrusions," even if those terms appear in some context in patent applications incorporated by reference to the '767 patent. Petitioner neither identifies precisely where that context can be found in the record of this proceeding nor offers any explanation of that context to demonstrate by a preponderance of the evidence that the term, reasonably construed in light of the Specification of the '767 patent, defines "fold" as including all "lobes," "wraps," "wrappings," and "protrusions." The mere incorporation by reference of other applications into the Specification of the '767, absent further persuasive explanation, does not sufficiently support the proposition that the term "fold" broadly

encompasses, for example, any "protrusion." Moreover, Petitioner provides no explanation for why "examples of methods of balloon folding" that "reference" the terms "lobes," "wraps," "wrappings," and "protrusions" demonstrate that the meaning of "fold" encompasses those terms. Finally, the '767 patent expressly states that the term "fold"' includes "pleats, wings, and any similar structure." Ex. 1001, 3:62–63. Petitioner, however, makes no persuasive showing supported by more than conclusory assertions that all "lobes," "wraps," "wrappings," and "protrusions" constitute "similar structure" to folds, pleats, or wings. Accordingly, we find the term "fold" in the '767 patent encompasses "pleats, wings, and any similar structure." Thus, "fold" also encompasses lobes, wraps, wrappings, or protrusions (or any other feature) only to the extent such feature constitutes "similar structure" to folds, pleats, or wings.

2. "balloon cylinder"

Claim 5 of the '767 patent, as well as each of challenged claims 6, 9–12, 14, and 16–17, recites the term "balloon cylinder." *See*, *e.g.*, Ex. 1001, 7:2. Petitioner contends that a person of ordinary skill would have understood "balloon cylinder" to encompass "a preformed balloon shaped to include necks." Pet. 13. In support, Petitioner argues that during prosecution of the '767 patent the examiner characterized a balloon with a rounded transition to a neck on each end as meeting the "balloon cylinder" limitation. Pet. 12 (citing Ex. 1002, 137–138). Mr. Trotta supports Petitioner's broadest reasonable interpretation of "balloon cylinder." Ex. 1005 ¶¶ 67–71. In particular, we credit Mr. Trotta's explanation that a person of ordinary skill in the art "would have understood that the term 'balloon cylinder' under the broadest reasonable interpretation standard

applicable to inter partes review [includes] a tubular structure as well as preformed balloons with necks." *Id.* at ¶ 67.

Patent Owner does not contest Petitioner's assertion that "balloon cylinder" encompasses a balloon with necks. *See* Prelim. Resp. 6 n.3. Moreover, we find no evidence in the record to suggest that that the broadest reasonable interpretation of "balloon cylinder," as used in the '767 patent, is limited to a structure that lacks necks. Accordingly, Petitioner has persuasively shown that "balloon cylinder," as used in the '767 patent, encompasses "a preformed balloon shaped to include necks."

D. Scope and Content of the Prior Art

1. Summary of Dlugos

Dlugos, titled "Method of Producing a Balloon of a Balloon Catheter," published February 22, 2007. Ex. 1008, [54], [43]. Dlugos generally describes "a method of producing a balloon of a balloon catheter having improved folding characteristics." Ex. 1008, 1–2.[9]

The method of Dlugos includes first preparing a balloon body "free of any kinds of folds." *Id.* at 2. Figure 1 of Dlugos is reproduced below.

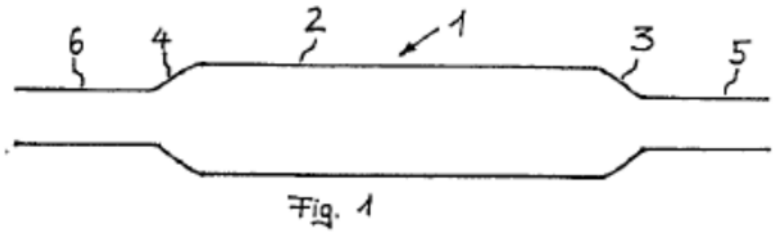


Fig. 1

To show the first step of Dlugos, Figure 1 illustrates balloon 1 with balloon body 2, transitional sections 3 and 4, proximal sleeve 5, and distal sleeve 6. *Id.* at 4, 6.

[9] The original pagination is used in all citations to Dlugos.

Next, Dlugos teaches that "folds are created at least in the distal sleeve." *Id.* at 2. According to Dlugos, "it is also possible to create folds in the proximal sleeve, and it is preferred that the folds are created only in the sleeves, i.e.[,] that no folds are created in the transition section and/or the body," but Dlugos further states that "the folding must reach into the cone (transition section), otherwise a refolding of the balloon is not possible." *Id.* Dlugos also explains that it is possible to "fold the entire balloon . . . so that the folds extend from the sleeves into the transitional section and the body of the balloon with the folds being fixed, e.g.[,] by welding, in the distal end or proximal balloon sleeve." *Id.* at 2–3.

Figure 2 of Dlugos is reproduced below.

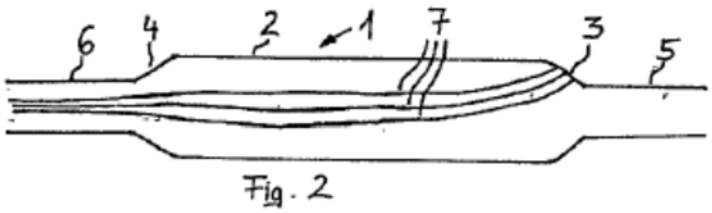


Fig. 2

To show the second step of Dlugos, Figure 2 illustrates balloon 1 folded creating folds 7 "that, in this case, run from the distal sleeve 6, the transitional section 4, the balloon body 2, the transitional section 3 to the proximal sleeve 5." *Id.* at 4. Not shown in Figure 2, a protector can be pulled over at least the distal sleeve 6 to pre-fix folds 7. *Id.* In the final step of Dlugos, at least a distal section or portion of the folds of the distal sleeve are fixed. *Id.* at 2.

Figure 3 of Dlugos is reproduced below.

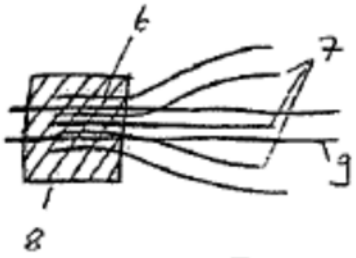


Fig. 3

To show the third step of Dlugos, Figure 3 illustrates folds 7 that are fixed at least in the distal section of distal sleeve 6 by welding at the welding/fixing portion 8. *Id.* at 5–6. Dlugos states that it is also possible to fix the folds extending into distal sleeve 6 over the entire length of distal sleeve 6. *Id.* at 5. Additionally, Figure 3 illustrates guide wire tube 9, also referred to in Dlugos as an "inner tube." *Id.* at 3, 6. Dlugos explains that "[t]he inner tube is always fixed with the distal sleeve," and that "the balloon could not be inflated" if it were fixed with the proximal sleeve. *Id.* at 3. Dlugos further states that "it is also possible to fix the folds 7 running into proximal sleeve 5 in the same manner" as they are shown to be fixed at distal sleeve 6. *Id.* at 5.

2. Summary of Eskaros

Eskaros, titled "Catheter Balloon with Multiple Micropleats," published April 24, 2008. Ex. 1011, [54], [43]. Eskaros describes "a catheter balloon formed of at least one balloon material having a longitudinal axis with micropleats distributed about the circumference of the balloon resulting in a low profile and an essential symmetry upon inflation." Ex. 1011 ¶ 4.

Figures 3 and 4 of Eskaros are reproduced below.

FIG. 3

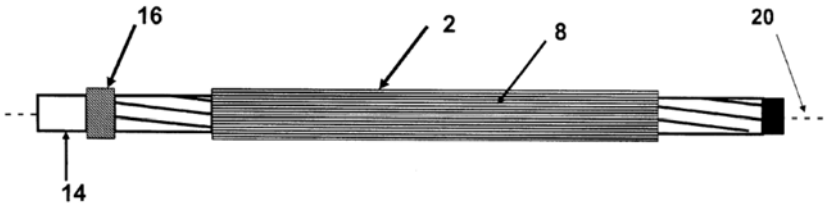
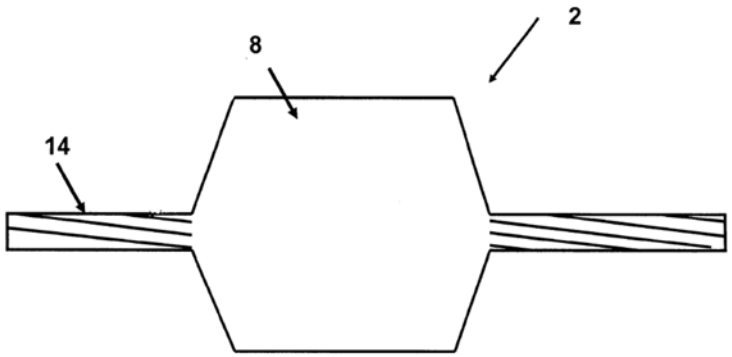


FIG. 4



A micropleated catheter is illustrated in an uninflated state in Figure 3 and in an inflated stated in Figure 4. Ex. 1011 ¶¶ 8–9. Balloon 2 includes micropleats 8 oriented longitudinally over the working length of the balloon. *Id.* ¶ 18. Balloon seal 16, distinct from the inflatable balloon portion, may be present on catheter shaft 14. In an inflated state, micropleats 8 pull taut such that they are not visible. *Id.* "The micropleats may be arranged on a formed balloon 2 or on a tubular structure of balloon material." *Id.*

3. Summary of Hijlkema

Hijlkema, titled "Balloon Catheter and Method for Manufacturing," issued December 29, 1998. Ex. 1009, [54], [45]. Hijlkema generally relates

to manufacturing a balloon catheter, and particularly to a balloon that can be properly folded into a small diameter. Ex. 1009, 1:36–39.

Figures 2 and 3 of Hijlkema are reproduced below.

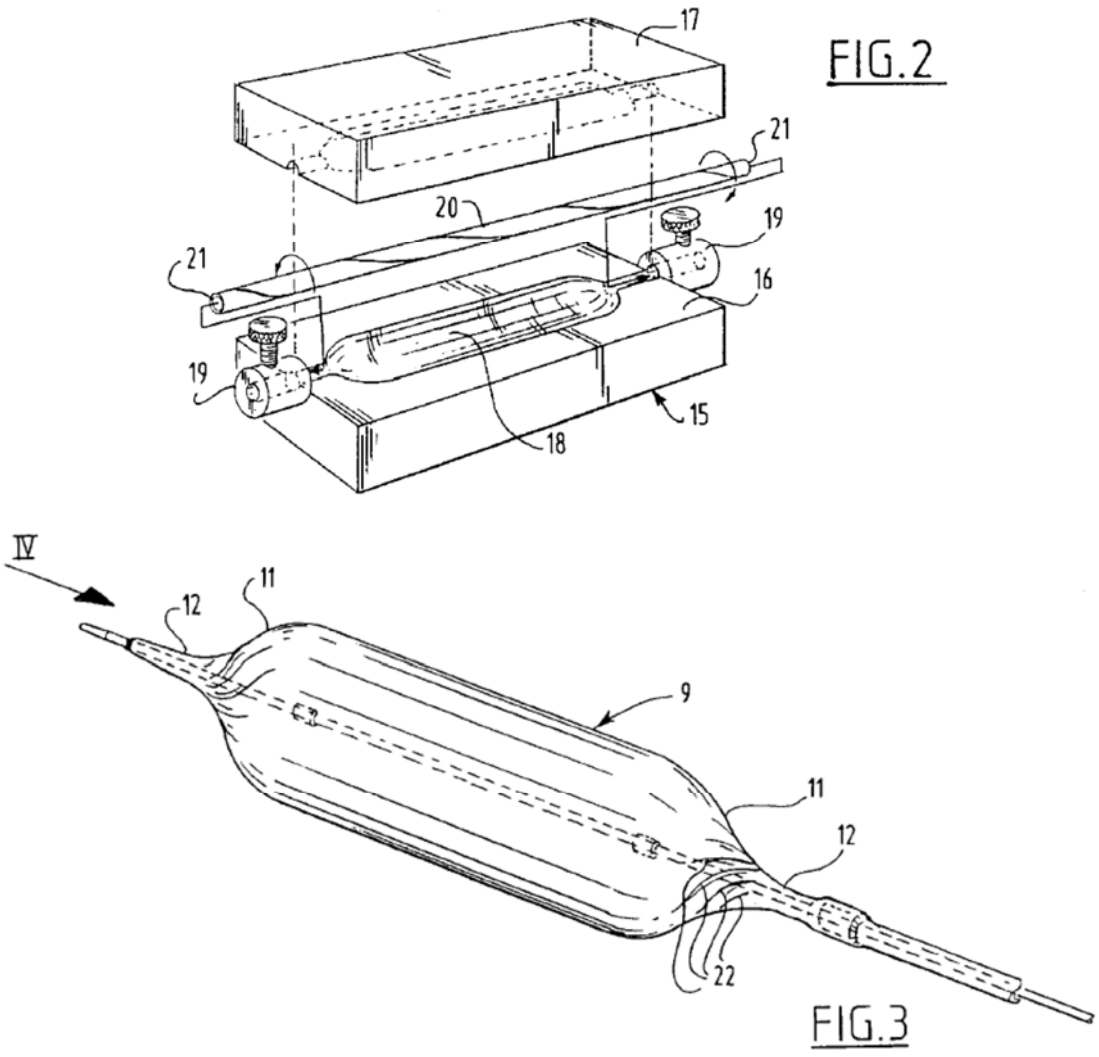


FIG.2

FIG.3

Figure 2 illustrates mold 15 into which tube-like parison or semi-manufacture 20 is secured by securing elements 19. Ex. 1009, 3:25–32. The semi-manufacture 20 is twisted before being placed in mold 15 and expanded under pressure and heat in a blow-molding process to form balloon member 9 illustrated in Figure 3. *Id.* at 3:33–48. The resulting balloon member 9 includes ridges of material 22 formed in transition

sections 11 extending spirally inwardly from end sections 12. *Id.* at 3:56–61. According to Hijlkema, ridges of material 22 "can fold against each other, whereby the thinner material in between is folded into pleats," in a manner similar to an umbrella. *Id.* at 3:65–4:3.

Hijlkema also explains the operation of the balloon catheter. Figures 5 and 6 of Hijlkema are reproduced below.

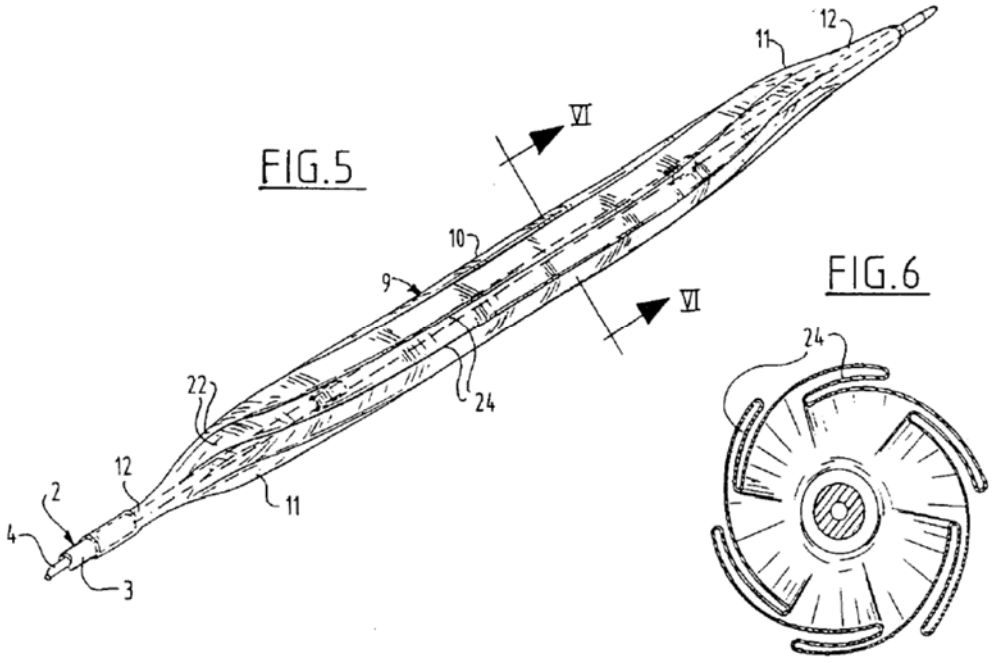


Figure 5 illustrates a perspective view of balloon member 9 in the folded state and Figure 6 illustrates a cross-section of balloon member 9 of Figure 5 along the line VI–VI. Ex. 1009, 2:58–61. Hijlkema states that "[t]he folds 24 fit closely together and substantially coincide with the fan-shaped ridges of material 22." *Id.* at 4:8–10. In Figure 5, proximal end section 12 (at the left of the figure) is connected with outer tube-like element 3. Distal end section 12 (at the right of the figure) is connected to inner tube-like element 4. Outer tube-like element 3 is shorter than inner tube-like element 4. As a result, the inside of balloon member 9 is connected to a channel between outer tube-like element 3 and inner tube-like element 4,

through which a gas or liquid under pressure may be supplied to unfold balloon member 9 into its expanded form. *Id.* at 4:11–24. Petitioner refers to such a configuration with inner and outer tube elements as a "coaxial balloon catheter." Pet. 33.

4. Summary of Forman

Forman, titled "Laser Bonding of Angioplasty Balloon Catheters," generally teaches a process for assembling a balloon catheter involving selectively concentrating laser energy. Ex. 1012, Abstract. According to Petitioner, "Forman describes using a laser beam 46 or 98 focused at the interface between the balloon 90 and catheter tubing 88, with some embodiments using heat shrink tubing 92, to weld the balloon to the catheter shaft." Pet. 55–56 (citing Ex. 1012, 7:4–10, 8:18–30, Fig 10).

5. Summary of Traxler

Traxler, titled "Balloon Wrap Device and Method," generally teaches a method and apparatus for sequentially forming, wrapping, and compressing a catheter balloon. Ex. 1013, Abstract. With respect to Traxler, Petitioner explains as follows:

> Traxler teaches methods for folding the balloons of angioplasty balloon catheters using a balloon wrapping tool having bores or channels that progressively compress folds in the balloon. Ex. 1013, ¶0015. As illustrated in figure 1 of Traxler, a mandrel or guide wire is placed through the balloon wrapping tool 10 and the catheter of a balloon catheter is "back loaded" onto the mandrel. A sequence of steps involving inflating and deflating the balloon mounted to the catheter and advancing the catheter through the tool results in the formation of folds in the balloon that are then tightly compressed. *Id.* at ¶0042. The result is a more compressed balloon and a reduced profile for the balloon catheter than would otherwise be possible. *Id.* at ¶0001.

Pet. 60–61.

6. Summary of Becker

Becker, titled "Method of Radiant Heat Sealing of a Balloon onto a Catheter Employing Tinted Shrink Tubing," generally relates "to providing seals along shafts of medical devices by means of radiant energy." Ex. 1014, 1:8–11. The method steps taught by Becker include "the use of shrink tubing to hold the balloon in place and simultaneously assist in shaping smooth seals, which method includes preshrinking the shrink tubing into place." *Id.* at 2:18–22; *see also* Pet. 66–68 (discussing the teachings of Becker).

7. Summary of Konstantino

Konstantino, titled "Balloon Catheter With Spiral Folds," generally teaches a balloon for use in catheters that incorporates "one or more permanent helical fold lines so that the balloon can be spirally folded." Ex. 1010, Abstract. With respect to Konstantino, Petitioner explains as follows:

> Konstantino teaches two to five helical fold lines. *Id.* at ¶¶0013, 0071. The material of the balloon is folded along each fold line to form a flap. Accordingly, any cross-section along the balloon will show multiple flaps. [Ex. 1010] at ¶0053. Figure 6 of Konstantino shows these flaps 24, each formed at a fold line 22. Konstantino illustrates that the end of each flap radially overlaps the start of the next flap. *Id.* at, Fig. 6.

Pet. 46.

8. Summary of Bampos

Bampos, titled "Catheter Balloon Having Selected Folding Characteristics," generally teaches a balloon for use in catheters that incorporates an inflatable membrane having a number of perpendicular ribs. Ex. 1015, Abstract. The catheter of Bampos features a balloon with "a

number of perpendicular ribs which have a high resistance to collapse during deflation." *Id.* at 2:30–34. The longitudinal ribs extend "between a proximal and distal end of the balloon." *Id.* at 2:34–37. Triangular indentations are provided between adjacent longitudinal ribs and extend "along a portion of the balloon between the proximal and distal ends." *Id.* at 2:37–41. The triangular indentations "enhance the collapse of the balloon from an expanded configuration to a folded configuration because the triangular indentations along the rib weaken or lessen the resistance to folding along that rib." *Id.* at 2:44–48.

E. FIRST SET OF GROUNDS

As stated above, Patent Owner did not file a Patent Owner response, and, as a result, waived any arguments for patentability with regard to the First Set of Grounds. *See* Paper 13, 3. The burden, however, remains on Petitioner to demonstrate by a preponderance of the evidence that the claims challenged under the First Set of Grounds are unpatentable. 35 U.S.C. § 316(e); *Dynamic Drinkware*, 800 F.3d at 1378.

We have reviewed Petitioner's arguments in the Petition as well as the evidence discussed in the Petition, including the declaration of Mr. Trotta. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claim 5 is anticipated by Dlugos and would have been obvious over Dlugos and Eskaros; that claim 8 would have been obvious over Dlugos, Eskaros, and Hijlkema; that claims 6, 14, and 16 would have been obvious over Dlugos, Eskaros, and Forman; that claims 9, 10, and 12 would have been obvious over Dlugos, Eskaros, and Traxler; that claim 11 would have been obvious over Dlugos, Eskaros, Traxler, and

Forman; and that claim 17 would have been obvious over Dlugos, Eskaros, Forman, and Becker.

1. Anticipation of Claim 5 by Dlugos

Petitioner provides a claim chart identifying how Dlugos discloses every element of claim 5 of the '767 patent. Pet. 50–54. In particular, Petitioner has shown that under the construction of "balloon cylinder" we adopt above, which encompasses a preformed balloon shaped to include necks, balloon body 2 of balloon 1 of Dlugos corresponds to the claimed "balloon cylinder." Pet. 48, 50–52; Ex. 1008, 2–6; *see also* Pet. 18–22 (explaining the teachings of Dlugos). Dlugos also discloses folds 7 that extend from the first end to the second end of the balloon cylinder, as required by claim 5. Ex. 1008, 2–3. Mr. Trotta supports Petitioner's contentions and explains the features of Dlugos which correspond to the limitations of claim 5. Ex. 1005 ¶¶ 75, 115–123, 145, 151. We are persuaded that Petitioner has shown by a preponderance of the evidence that Dlugos discloses every limitation of claim 5 for the reasons provided in the Petition (pages 48–54), which we adopt as our own findings.

2. Obviousness of Claim 5 over Dlugos and Eskaros

Petitioner contends the subject matter of claim 5 would have been obvious over Dlugos and Eskaros. Pet. 48–54. In particular, Petitioner contends that if "balloon cylinder" is construed to require a "constant diameter balloon," then claim 5 would have been obvious over Dlugos and Eskaros. *Id.* at 48–49. Petitioner provides a claim chart identifying how it contends the combination of Dlugos and Eskaros teaches each limitation of claim 5. Pet. 51–54. Of particular note with regard to the "balloon cylinder" limitation, Petitioner states that Eskaros teaches the use of "a tubular

structure of balloon material." Pet. 52 (quoting Ex. 1011 ¶ 18). Further, Petitioner contends that Figures 5 and 7 of Eskaros illustrate a balloon made of a tubular structure with no formed cone regions. Pet. 52–53. Figure 2 of the '767 patent depicts a balloon cylinder that is consistent with Petitioner's assertion that Eskaros discloses a balloon cylinder. *See* Ex. 1001.

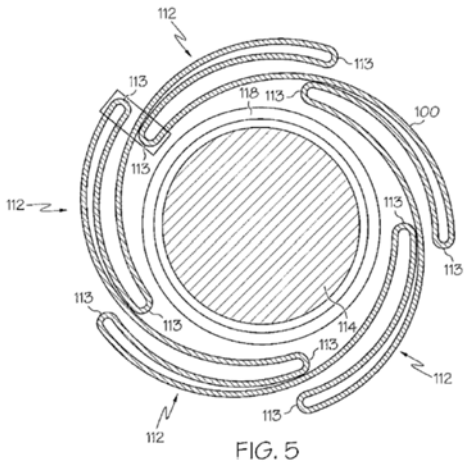
Petitioner also contends that a person of ordinary skill in the art would have recognized that the balloon disclosed by Eskaros would fold easily along its entire length as compared to the balloon of Dlugos, motivating the use of the constant diameter balloon cylinder of Eskaros with Dlugos to fold the entire balloon as suggested by Dlugos. Pet. 50 (also contending that the "predictable outcome of combining Dlugos and Eskaros would be a balloon that folds consistently through the body, transition regions, and end regions, resulting in fewer bulges and a reduced diameter of the uninflated balloon catheter for transiting through a body lumen to the treatment site").
Mr. Trotta supports Petitioner's contentions and explains the features of Dlugos and Eskaros that correspond to the limitations of claim 5.
Ex. 1005 ¶¶ 115–123, 145–150. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos and Eskaros teaches every limitation of claim 5 and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 48–54), which we adopt as our own findings.

3. Obviousness of Claim 8 over Dlugos, Eskaros, and Hijlkema

Claim 8 recites "[t]he method of claim 5, the at least one fold being a plurality of folds, the plurality of folds having even material thickness."
Ex. 1001, 7:17–19. Under either construction of "balloon cylinder,"
Petitioner has shown by a preponderance of the evidence that the additional

limitations of claim 8 are taught by Hijlkema. *See* Pet. 44–45 (addressing claim 4, which also recites "the at least one fold being a plurality of folds, the plurality of folds having even material thickness"), 55.

Figure 5 of the '767 patent is reproduced below on the left and Figure 6 of Hijlkema is reproduced below on the right.



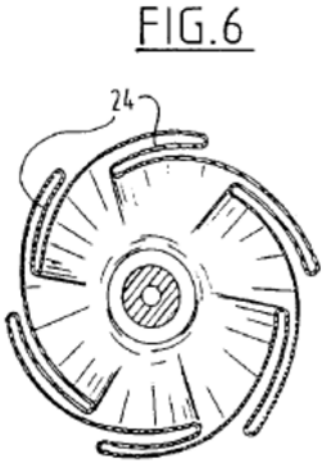


Figure 5 of the '767 patent illustrates a cross-sectional view of a balloon cylinder showing a fold overlap embodiment (Ex. 1001, 2:42–46), and Figure 6 of Hijlkema illustrates a cross-sectional view of a balloon cylinder in the folded state (Ex. 1009, 2:58–61). Petitioner explains that Figure 6 of Hijlkema "teaches multiple folds 24, in which the material that comprises each fold has an even thickness." Pet. 44. Petitioner also explains why a person of ordinary skill would have been motivated to apply the even thickness of the balloon folds taught by Hijlkema to the method for forming a balloon catheter of Dlugos to achieve the same low profile benefit. *Id.* at 44–45, 55. We understand Petitioner to contend that the same rationale for applying Hijlkema to Dlugos would also apply to the combination of Hijlkema with Dlugos and Eskaros. *Id.* at 55. Mr. Trotta supports Petitioner's contentions. Ex. 1005 ¶¶ 28–31, 124–128, 136–138, 153–54.

We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos, Eskaros, and Hijlkema teaches every limitation of claim 8 and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 44, 45, and 48–55), which we adopt as our own findings.

4. Obviousness of Claims 6, 14, and 16 over Dlugos, Eskaros, and Forman

Petitioner contends the subject matter of claims 6, 14, and 16 would have been obvious over Dlugos, Eskaros, and Forman. Pet. 55–60. Claim 6, which depends from claim 5, relates to the use of a laser to weld the balloon to the catheter. Ex. 1001, 7:11–12. Claim 14, which depends from claim 5, and claim 16, which depends from claim 14, each relate to the use of heat shrink material about a portion of the balloon cylinder. *Id.* at 8:10–14, 18–24. Petitioner contends that Dlugos describes welding, but not in the level of detail provided by Forman, and that Forman also teaches the use of shrink corresponding to the additional limitations of claims 6, 14, and 16. Pet. 55–60. Petitioner also contends a person of ordinary skill in the art would have applied the teachings of Forman to Dlugos and Eskaros to produce robust seals between the balloon and catheter. *Id.* Mr. Trotta supports Petitioner's contentions and discusses the use of both welding and heat shrink tubing in balloon catheter applications. Ex. 1005 ¶¶ 32, 37, 38, 40, 99–109, 155–165. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos, Eskaros, and Forman teaches every limitation of claims 6, 14, and 16, and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 48–60), which we adopt as our own findings.

5. Obviousness of Claims 9, 10, and 12 over Dlugos, Eskaros, and Traxler

Petitioner contends the subject matter of claims 9, 10, and 12 would have been obvious over Dlugos, Eskaros, and Traxler. Pet. 60–63. Claims 9 and 12, which depend from claim 5, and claim 10, which depends from claim 9, generally refer to disposing the balloon around the catheter shaft, a mandrel, or both. *Id.* at 60; *see also* Ex. 1001, 7:20–26, 8:3–5. Petitioner describes how Traxler teaches the additional limitations of claims 9, 10, and 12. Pet. 62–63. Petitioner also contends a person of ordinary skill in the art would have applied the teachings of Traxler to Dlugos and Eskaros to produce a balloon catheter with a less bulky profile in its unexpanded configuration. *Id.* at 61. Mr. Trotta supports Petitioner's contentions and discusses the use of a mandrel in balloon catheter applications. Ex. 1005 ¶¶ 33–34, 166–176. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos, Eskaros, and Traxler teaches every limitation of claims 9, 10, and 12, and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 48–54, 60–63), which we adopt as our own findings.

6. Obviousness of Claim 11 over Dlugos, Eskaros, Traxler, and Forman

Petitioner contends claim 11 would have been obvious over Dlugos, Eskaros, Traxler, and Forman. Pet. 64–66. Claim 11 recites "[t]he method of claim 10 wherein the balloon cylinder is disposed about the at least one shaft which is disposed about the mandrel when the balloon cylinder is welded to the at least one shaft of the catheter." Ex. 1001, 7:27–8:2.

Expanding upon its contentions with respect to claim 10, Petitioner contends the additional limitations of claim 11 related to welding are taught

by Forman, and that such teachings would be relied upon in combination with the other asserted references to produce robust seals between the balloon and the catheter shaft. Pet. 65–66. Mr. Trotta supports Petitioner's contentions and discusses the use of a mandrel in balloon catheter applications. Ex. 1005 ¶¶ 34–35, 177–179. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos, Eskaros, Traxler, and Forman teaches every limitation of claim 11 (as well as claims 10, 9, and 5 from which it depends) and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 48–54, 60–66), which we adopt as our own findings.

7. Obviousness of Claim 17 over Dlugos, Eskaros, Forman, and Becker

Petitioner contends claim 17 would have been obvious over Dlugos, Eskaros, Forman, and Becker. Pet. 66–69. Claim 17, which depends from claim 14, further requires "wherein pre-shrinking the section of heat shrink material presses the balloon cylinder onto the at least one shaft of the catheter." Ex. 1001, 8:25–27.

Expanding upon its contentions with respect to claim 14, Petitioner contends the additional limitations of claim 17 related to heat shrink material are taught by Becker, and that such teachings would be relied upon to compress the balloon to the shaft to eliminate air pockets before welding and to compress the folds along the balloon to reduce the profile of the balloon. Pet. 66–69. Mr. Trotta supports Petitioner's contentions and discusses the use of heat shrink tubing in balloon catheter applications. Ex. 1005 ¶¶ 37–40, 103–109, 180–186. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Dlugos, Eskaros,

Forman, and Becker teaches every limitation of claim 17 (as well as claims 14 and 5 from which it depends) and has articulated reasoning with rational underpinning to support the legal conclusion of obviousness in the Petition (pages 48–59, 66–69), which we adopt as our own findings.

F. SECOND SET OF GROUNDS

As explained above, the Second Set of Grounds were added to this *inter partes* review when we modified the Institution Decision in light of the determination in *SAS Inst*. (138 S. Ct. at 1359–60) that under 35 U.S.C. § 314 we may not institute on fewer than all claims challenged in the petition. *See* Paper 15, 3–4. Patent Owner, with our prior authorization, chose to rely on the arguments it raised in its Preliminary Response in opposition to the Second Set of Grounds in lieu of filing a Patent Owner response. Paper 16, 3. Petitioner filed a Reply to the Second Set of Grounds addressing issues raised in either the Institution Decision or Patent Owner's Preliminary Response. Paper 17.

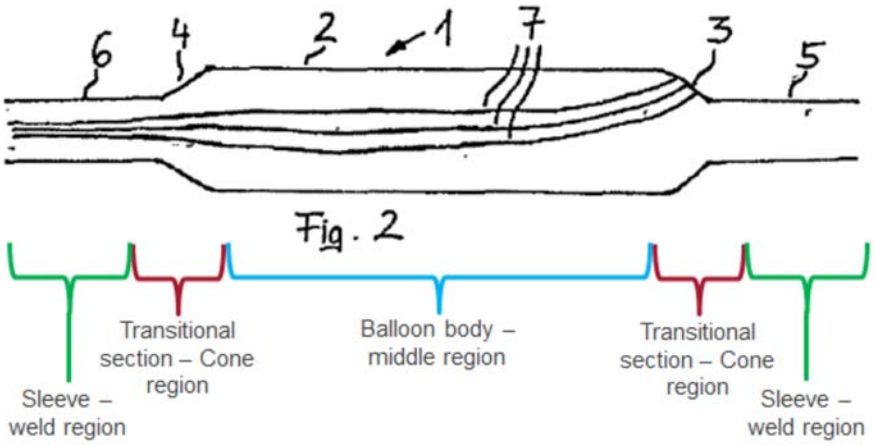
We have reviewed Petitioner's arguments in the Petition and Reply, as well as the evidence discussed in the Petition and Reply, including the declaration of Mr. Trotta. For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claim 1, 2, or 4 would have been obvious over Dlugos and Hijlkema; that claim 3 would have been obvious over Dlugos, Hijlkema, and Konstantino; that claim 5 would have been obvious over Dlugos, alone or in combination with Hijlkema; that claim 8 would have been obvious over Dlugos and Hijlkema; that claim 6, 14, or 16 would have been obvious over Dlugos, Hijlkema, and Forman; that claim 7 would have been obvious over Dlugos, Eskaros, and

Konstantino; or that claim 1 would have been obvious over Dlugos and Bampos.

1. Obviousness of Claims 1, 2, and 4over Dlugos and Hijlkema

a. Claim 1

Petitioner provides a claim chart identifying how it contends the combination of Dlugos and Hijlkema teaches each limitation of claim 1. Pet. 27–40. Dlugos teaches a balloon catheter with "a shaft" ("guide wire tube (9)," also identified as "an inner tube" (Ex. 1008 3, 6–7)) and "a balloon" ("balloon 1" (*id.* at 4)), as recited by claim 1. Petitioner provides the following annotated version of Figure 2 of Dlugos to show additional features of balloon 1 that correspond to recited limitations of claim 1:



Pet. 32 (reproducing Figure 2 of Dlugos with labeling identifying the features corresponding to claim 1 of the '767 patent). In particular, the annotated version of Figure 2 of Dlugos shows that Dlugos teaches a balloon comprising a first weld region, a first cone region, a middle region, a second cone region, and a second weld region, with the first cone region adjacent to the first weld region, the middle region between the first cone region and the

second cone region, and the second cone region adjacent to the second weld region, as recited by claim 1.

Claim 1 further requires "the first weld region engaging the balloon to the at least one shaft" and "the second weld region engaging the balloon to the at least one shaft." Although claim 1 requires that both welding regions engage the balloon to "the at least one shaft," the '767 patent provides that "the at least one shaft comprising an outer shaft and an inner shaft." Ex. 1001, 6:56–60 (claim 2).

First, we find for the following reasons that Petitioner has not shown by a preponderance of the evidence that Dlugos teaches first and second weld regions (i.e., regions that are welded, not merely alternative regions that could be welded) engaging the balloon to at least one shaft. Petitioner identifies only one element in the Petition from Dlugos as corresponding to the claimed "at least one shaft" and that is "guide wire tube 9." Pet. 30 (stating "Dlugos discloses a catheter with an inner 'guide wire tube 9,' shown in figure 3," and "[t]his inner tube constitutes a shaft") (citing Ex. 1008, 3, 6). However, there is no dispute that inner guide wire tube 9, the "at least one shaft" of Dlugos, is not engaged to a first weld region and a second weld region. *See* Ex. 1008, 3 (stating that "[t]he inner tube is always fixed with the distal sleeve," and that "[i]f it, [i.e., the inner tube] would be fixed with the proximal sleeve, the balloon could not be inflated"); *see also* Reply 3 (stating that "[i]f both sleeves of the balloon were welded to the inner tube, it would not be possible to inflate the balloon with fluid").

In its Reply, Petitioner seeks to expand upon the arguments provided in the Petition and contends that Mr. Trotta explained that because Dlugos identifies an "inner tube," a person of ordinary skill in the art would have

understood the disclosed catheter is a conventional coaxial design with both an outer tube and an inner tube. Reply 3 (citing Ex. 1005 ¶¶ 93, 132–133). However, to the extent the Petition suggests that Dlugos teaches welding both the proximal sleeve and the distal sleeve, the Petition does not argue that Dlugos inherently discloses a coaxial catheter or that an outer tube is necessarily present such that one sleeve is welded to the inner guide wire tube 9 and the other sleeve is welded to an outer tube not shown in any of the figures provided by Dlugos. *See* Pet. 21; *see also* Ex. 1005 ¶ 123 (stating that "Dlugos does not expressly teach a catheter shaft with an outer and inner shaft").[10] Accordingly, we find Petitioner's argument that Dlugos teaches an outer sleeve to have been improperly raised for the first time in the Reply. Moreover, Petitioner fails to show persuasively in the Reply that an outer sleeve is inherently taught by Dlugos. Thus, Petitioner has not shown that Dlugos, alone, teaches a "first weld region" and a "second weld region," both of which engage the balloon to the shaft, as required by claim 1 of the '767 patent.

Second, we find for the following reasons that Petitioner has shown by a preponderance of the evidence that Dlugos in combination with Hijlkema teaches a "first weld region" and a "second weld region," both of which engage the balloon to the shaft. As explained above, Hijlkema details a coaxial balloon catheter with connecting regions at the proximal and distal

[10] Petitioner also argues in the Reply, without citation, that "Dlugos carefully distinguishes between the 'inner tube' and 'shaft.'" Reply 4. To the contrary, Petitioner directs us to no portion of Dlugos that uses the term "shaft," and it is Petitioner who expressly contends in the Petition that "[t]he inner tube constitutes a shaft." Pet. 30. Petitioner fails to reconcile its argument that Dlugos purportedly distinguishes the inner tube from the shaft with its argument that the inner tube is the "at least one shaft" of claim 1.

ends of balloon member 9, respectively fixed to an outer tube and an inner tube. Ex. 1009, 4:11–24. Petitioner also demonstrates that welding was a conventional means of connecting a balloon to a shaft, as shown in Dlugos. Pet. 34. Petitioner's contentions are supported by Mr. Trotta. Ex. 1005 ¶¶ 132–133. Thus, Petitioner has shown that the combination of the teaching in Dlugos of folding and welding the balloon to a shaft and the teaching in Hijlkema of a coaxial catheter with a shaft comprised of an inner tube and an outer tube to which the balloon is affixed teaches, in combination, a "first weld region" and a "second weld region," both of which engage the balloon to the shaft as required by claim 1. Pet. 33–37.

Claim 1 also recites "the balloon having an uninflated state and an inflated state." Petitioner has shown that Hijlkema discloses and illustrates both the uninflated and inflated state of the balloon catheter. Pet. 37 (citing Ex. 1009, 3:66–4:24, Figs. 3, 5). We also find that Dlugos necessarily discloses a balloon with both an uninflated and an inflated state. *See* Ex. 1008, 3 (stating that "the balloon could not be inflated" if the inner tube were fixed to the proximal sleeve of the balloon); *see also* Ex. 1005 ¶ 121 (explaining that the balloon of a balloon catheter such as Dlugos necessarily has an uninflated and an inflated state).

Claim 1 further requires that the balloon have "at least one fold extending from the first weld region to the second weld region in the uninflated state."[11] *Id.* at 6:50–52. Petitioner argues that Dlugos and

[11] In the Institution Decision we were not persuaded that Petitioner had shown a reasonable likelihood of prevailing in showing that Dlugos teaches this limitation. Inst. Dec. 15–16 (stating that "[s]ince Dlugos fails to teach two separate weld regions that engage the balloon, we are not persuaded that Dlugos, alone, teaches a fold that extends from the first weld region to the

Hijlkema each separately teach the claimed feature, but we find that Petitioner has shown by a preponderance of the evidence only that the feature is taught by the combination of both references. *See* Pet. 38–39.

First, Dlugos states as follows:

> According to step 2 of the method according to the present invention (shown in an also schematically simplified depiction of Fig. 2), the balloon 1 is folded thus creating folds 7 that, in this case, run from the distal sleeve 6, the transition section 4, the balloon body 2, the transitional section 3 to the proximal sleeve 5.

Ex. 1008, 4. Although folds 7 in Figure 2 of Dlugos are not illustrated as reaching proximal sleeve 5 because the ends of folds 7 are not visible, Dlugos expressly states that folds 7 "run from distal sleeve 6 . . . to the proximal sleeve 5." *Id*. Dlugos further states that the folds extending into distal sleeve 6 may be fixed by welding and that the folds may be fixed "over the entire length of the distal sleeve 6." *Id.* at 5. Moreover, according to Dlugos, "[a]lthough not depicted in the drawings, it is also possible to fix the folds 7 running into proximal sleeve 5 in the same manner as described here-in before." *Id.* at 5. Petitioner's contentions are supported by Mr. Trotta, who explains as follows:

> Figure 2 of Dlugos depicts folds 7 that begin in the distal sleeve 6, continue through distal transition 4 and the working length 2 and disappear from view in the proximal transition 3. From the drawing one cannot determine whether the folds curl around the balloon helically and continue or whether they end in the transition section. But the language of Dlugos is unambiguous. The folds extend the length of the entire balloon: through "the

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second weld region"). Having subsequently added the ground of obviousness over Dlugos and Hijlkema to this review, we revisit the issue in light of the full record as developed through the trial.

> distal sleeve 6, the transitional section 4, the balloon body 2, the transitional section 3 to the proximal sleeve 5." (*Id.*)

Ex. 1005 ¶ 118.

Patent Owner argues that Figure 2 of Dlugos "unquestionably shows that the folds do not reach the proximal sleeve." *Id.* at 9; *see also id.* at 11–12 (asserting that it is possible none of the folds of Dlugos extend from one sleeve to the other). We disagree with Patent Owner's contention that Figure 2 definitively shows folds 7 do not reach the proximal sleeve as the figure is, at best, ambiguous as to where folds 7 end. Instead, we look to the description of Figure 2 of Dlugos, which unambiguously states "the balloon 1 is folded thus creating folds 7 that, in this case, run from the distal sleeve 6, the transition section 4, the balloon body 2, the transitional section 3 to the proximal sleeve 5." Ex. 1008, 4. Nevertheless, what Petitioner has not shown sufficiently is that Dlugos teaches two separate weld regions (i.e., regions that are welded) that engage the balloon, as explained above. Therefore, Petitioner has not shown by a preponderance of the evidence that Dlugos, alone, teaches a fold that extends from the first weld region to the second weld region even if Dlugos teaches a fold that extends the entire length of the balloon.

Second, Petitioner asserts in the Petition that "Hijlkema explicitly discloses that each of the folds 24 of figure 5 extends continuously from end to end." Pet. 39. Patent Owner disagrees, arguing that "[c]learly, folds 22 in Figure 5 of Hijlkema do not even come close to extending from one weld region to another weld region." Prelim. Resp. 12. We noted in the Institution Decision that "[i]t is not readily apparent how Figure 5 of Hijlkema discloses a fold from one weld region to another, and Petitioner directs us to no support for its contentions from its expert." Inst. Dec. 16.

Petitioner attempts to remedy this deficiency in its Reply by making arguments that do not appear in the Petition, and, therefore, are not properly before us. *See* Reply 6–8. Nevertheless, we have considered Mr. Trotta's testimony and find it insufficient to support Petitioner's contention that Hijlkema teaches "at least one fold extending from the first weld region to the second weld region in the uninflated state." *See* Ex. 1005 ¶ 125 (stating with regard to Hijlkema that "[t]he balloon is pre-formed with helical fold ridges 22 that start in the 'end sections' and extend into the 'transition sections' of the balloon, as illustrated in figure 4") (citing Ex. 1009, 3:57–61). Petitioner and Mr. Trotta provide no persuasive showing that end sections 12 of Hijlkema constitute weld regions or that end sections 12 would correspond to weld regions in combination with the welding technique of Dlugos. *See*, *e.g.*, Pet. 26 (suggesting a person of ordinary skill would have applied the technique of twisting the ends of the balloon of Hijlkema to Dlugos). Thus, Hijlkema, alone, does not teach a fold that extends from the first weld region to the second weld region even if the fold extends the entire length of the balloon.

Third, in consideration of Dlugos and Hijlkema in combination, Petitioner has shown the following: (1) Dlugos teaches folds that extend from a first region available to be welded to a second region available to be welded, and (2) Hijlkema teaches welding at both a first and a second region of attachment to the shaft. Thus, we are persuaded that Petitioner has shown by a preponderance of the evidence that Dlugos and Hijlkema, in combination, teach all of the elements of "at least one fold extending from the first weld region to the second weld region in the uninflated state," as required by claim 1.

Finally, claim 1 recites "the first and second cone regions of the balloon having at least one fold in the fully inflated state." First, Petitioner argues that by teaching welding the folds Dlugos inherently discloses this feature because a person of ordinary skill "would have understood that if the fold is welded into place, then the fold must necessarily extend beyond the weld region, even when the balloon is expanded." Pet. 40 (citing Ex. 1005 ¶¶ 119–120).

The Federal Circuit has explained that the concept of inherency in the patentability analysis was originally rooted in anticipation and "must be limited when applied to obviousness." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014); *see also Honeywell Int'l Inc. v. Mexichem Amanco Holdings S.A. DE C.V.*, 865 F.3d 1348, 1354–55 (Fed. Cir. 2017) (cautioning that "the use of inherency in the context of obviousness must be carefully circumscribed"). The Federal Circuit has further explained that:

> A party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue must necessarily be present, or the natural result of the combination of elements explicitly disclosed by the prior art.

PAR Pharm., 773 F.3d at 1195–96. Thus, inherency "may not be established by probabilities or possibilities." *Id.* at 1195 (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)). "'The mere fact that a certain thing may result from a given set of circumstances is not sufficient' to render the result inherent." *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) (quoting *Oelrich*, 666 F.2d at 581).

Because Petitioner has not shown sufficiently that Dlugos teaches two weld regions that both engage the balloon to the shaft, Petitioner has not

shown that Dlugos necessarily teaches first and second cone regions of the balloon having at least one fold in the fully inflated state. Moreover, we find Mr. Trotta's testimony in support of Petitioner's contention insufficient. According to Mr. Trotta:

> When folds are welded down, as shown in the figure 3, it would necessarily result in folds remaining in the transition/cone regions of the balloon when the balloon is inflated, and even when fully inflated to the specifications on the label. Because the folds are captured within the welded region, even when the balloon is fully inflated, the pressure will distribute such that there is more pressure in the working region and less pressure at the transition regions. Thus, there is insufficient pressure in the transition cone regions for the folds to be completely removed.

Ex. 1005 ¶ 119. Mr. Trotta cites no support for his opinions and offers no plausible explanation for why "pressure will distribute such that there is more pressure in the working region and less pressure at the transition regions," rather than equal pressure throughout the interior space of a balloon. Nor are we persuaded that statements by the Examiner during prosecution identified by Petitioner, which Patent Owner contends were later abandoned by the Examiner, are sufficient to establish the inherency of the claimed feature. *See* Pet. 39–40; Prelim. Resp. 14–15. Petitioner has not shown by a preponderance of the evidence that Dlugos teaches "first and second cone regions of the balloon having at least one fold in the fully inflated state" because Petitioner has not shown that Dlugos necessarily teaches any cone region having at least one fold in the fully inflated state, much less both a first and a second cone region, in the absence of a persuasive showing that Dlugos teaches welding both ends of the balloon to the shaft.

Petitioner also contends that Hijlkema teaches folds in first and second cone regions in the fully inflated state, as recited by claim 1. Pet. 40. (stating that "Hijlkema plainly shows that the folding ridges 22 in the material of the balloon remain even in the inflated state") (citing Ex. 1009, Fig. 3). Mr. Trotta also explains the following:

> The balloon [of Hijlkema] is pre-formed with helical fold ridges 22 that start in the "end sections" and extend into the "transition sections" of the balloon, as illustrated in figure 4. ([Ex. 1009] at 3:57–61.) The balloon folds along the fold ridges, in a manner similar to the folding of the pleats of an umbrella over the spokes, forming folds of even thickness that extend fully from one end of the balloon to the other. (*Id.* at 3:66–4:3, FIGS 5, 6.) When inflated, the folds disappear through the central portion of the balloon, although the folding ridges remain plainly visible in the transition sections. (*See*, *id.* at FIGS 1, 3.)

Ex. 1005 ¶ 125. We note that Hijlkema does not identify element 22 as "helical fold ridges" or "folding ridges" as suggested by Petitioner, but instead identifies the feature as "ridges of material 22." Ex. 1009, 3:60. Mr. Trotta states that "folding ridges" remain visible in transition sections, but does not state that the "folding ridges" are "folds," as recited by claim 1. Moreover, the Petition is virtually silent as to how "ridges of material 22" constitute "folds" within the broadest reasonable meaning of that term.

Patent Owner argues that ridges of material 22 are not "folds" because they operate like the spokes of an umbrella and "while the spokes can be folded, the spokes themselves are not folds." Prelim. Resp. 16. Indeed, as Patent Owner notes, Hijlkema distinguishes ridges 22 from folds 24. In the Reply, Petitioner offers no persuasive rebuttal to Patent Owner's argument, stating the following:

> Hijlkema's manufacturing process creates folds that run along the entire length of the balloon, including into the ends. Hence,

> Mr. Trotta explained that folds remain in the cone regions even after inflation, and cited to figures 1 and 3 of Hijlkema showing plainly the folding ridges in the inflated state, which in turn means the folds would exist as well.

Reply 9 (citing Ex. 1005 ¶¶ 125–26).

Petitioner's arguments in the Reply appear to suggest that because ridges of material 22 remain in the cone regions after inflation, "the folds" would also remain. That is not the argument raised by Petitioner in the Petition ("the folding ridges 22 in the material of the balloon remain even in the inflated state"), and the argument is not persuasively supported by the cited portions of Mr. Trotta's declaration. *See* Pet. 40; Ex. 1005 ¶¶125–26. To the extent Mr. Trotta's statement that "the folds disappear through the central portion of the balloon" when inflated implies the folds remain outside of the central portion, we find insufficient support for such a conclusion. It is akin to arguing that the folds are inherently present, but there is insufficient support to establish such inherency. In sum, even under Petitioner's proposed construction of "folds" as including "protrusions," the Petition and Mr. Trotta fail to persuasively explain how "ridges of material 22" are structures similar to folds, pleats, or wings.

For the foregoing reasons, we find that Petitioner has not shown that either Dlugos or Hijlkema teach "first and second cone regions of the balloon having at least one fold in the fully inflated state," as required by claim 1.

Because Petitioner has not shown that every limitation of claim 1 is taught by the combination of Dlugos and Hijlkema, Petitioner has not shown by a preponderance of the evidence that claim 1 would have been obvious over Dlugos and Hijlkema.

b. Claims 2 and 4

Petitioner provides claim charts and argument identifying how it contends the subject matter of claims 2 and 4 would have been obvious over Dlugos and Hijlkema. Pet. 41–45. Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 2 and 4, which depend from claim 1, would have been obvious over Dlugos and Hijlkema for the same reasons provided with respect to claim 1.

2. Obviousness of Claim 3 over Dlugos, Hijlkema, and Konstantino

Petitioner contends the subject matter of claim 3 would have been obvious over Dlugos, Hijlkema, and Konstantino. Pet. 45–48. Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 1 of the '767 patent would have been obvious over Dlugos and Hijlkema for the reasons provided above. Petitioner also does not suggest that Konstantino resolves the deficiencies in its contentions with regard to claim 1. Accordingly, Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 3, which depends from claim 1, would have been obvious over Dlugos, Hijlkema, and Konstantino for the same reasons provided above with respect to the alleged obviousness of claim 1 over Dlugos and Hijlkema.

3. Obviousness of Claim 5 over Dlugos, Alone or in Combination with Hijlkema

Petitioner states that "Claim 5 is Unpatentable over Dlugos." Pet. 48. Because this could be understood to be both an obviousness and anticipation argument, we instituted on both grounds. Under our construction of "balloon cylinder" as including a balloon with necks, we determine above that Dlugos anticipates claim 5. Additionally, we determine above that,

even if "balloon cylinder" excludes a balloon with necks, Petitioner has demonstrated that the subject matter of claim 5 would have been obvious over Dlugos and Eskaros because Eskaros discloses a balloon cylinder without necks and Petitioner provides a sufficient rationale for the combination of Dlugos and Eskaros. *See id.* at 48–54.

By contrast, Petitioner provides virtually no argument to show that claim 5 would have been obvious over Dlugos alone. In particular, Petitioner has not shown that if the construction of "balloon cylinder" excludes a balloon with necks, claim 5 nonetheless would have been obvious over Dlugos alone. Nor has Petitioner identified any other feature of claim 5 absent from Dlugos that nonetheless would have been obvious over Dlugos alone. We recognize that it has been stated that a disclosure that anticipates under 35 U.S.C. § 102 also renders the claim unpatentable under 35 U.S.C. § 103, for anticipation is the epitome of obviousness, *See In re Pearson*, 494 F.2d 1399, 1402 (CCPA 1974); *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982). Nevertheless, in this case we are not persuaded that the record supports such a finding in the absence of persuasive argument of differences between the asserted reference and the claim or a rationale for obviousness over a single reference.

Petitioner also includes claim 5 under its discussion of obviousness over Dlugos and Hijlkema. Pet. 18. Petitioner, however, fails to provide an analysis to show that claim 5 would have been obvious over Dlugos and Hijlkema and does not include a claim chart showing how the features of claim 5 are taught by the asserted references. *See* Pet. 18–45. Petitioner also does not address the obviousness of claim 5 over Dlugos and Hijlkema in its Reply. Accordingly, we find that Petitioner has not shown by a

preponderance of the evidence that the subject matter of claim 5 would have been obvious over Dlugos, alone or in combination with Hijlkema.

4. Obviousness of Claim 8 over Dlugos and Hijlkema

Petitioner includes claim 8 under its discussion of obviousness over Dlugos and Hijlkema. Pet. 18. Petitioner, however, fails to provide an analysis to show that claim 8 would have been obvious over Dlugos and Hijlkema and does not include a claim chart showing how the features of claim 8 are taught by the asserted references. *See* Pet. 18–45. Petitioner also does not address the obviousness of claim over Dlugos and Hijlkema in its Reply. Accordingly, we find that Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 8, which depends from claim 5, would have been obvious over Dlugos and Hijlkema.

5. Obviousness of Claims 6, 14, and 16 over Dlugos, Hijlkema, and Forman

Petitioner contends the subject matter of claims 6, 14, and 16, which depend from claim 5, would have been obvious over Dlugos, Hijlkema, and Forman. Pet. 55–60. Petitioner does not address claims 6, 14, and 16 in its Reply. Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 5 of the '767 patent would have been obvious over Dlugos and Hijlkema for the reasons provided above. Petitioner also does not suggest that Forman resolves the deficiencies in its contentions with regard to claim 5. Accordingly, Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 6, 14, and 16, which depend from claim 5, would have been obvious over Dlugos, Hijlkema, and Forman for the same reasons provided above with respect to the alleged obviousness of claim 1 over Dlugos and Hijlkema.

Accordingly, we find that Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 6, 14, and 16, which depend from claim 5, would have been obvious over Dlugos, Hijlkema, and Forman.

6. Obviousness of Claim 7 over Dlugos, Eskaros, and Konstantino

Petitioner contends the subject matter of claim 7 would have been obvious over Dlugos, Eskaros, and Konstantino. Pet. 54–55. Petitioner asserts claim 7 is "virtually identical to claim 3." *Id.* at 54–55. Although the additional limitations of claim 7 mirror claim 3, claim 3 depends from claim 1, whereas claim 7 depends from claim 5. Thus, Petitioner's contention that claim 7 is virtually identical to claim 3 is incorrect.

Petitioner further relies on its analysis of claim 3 as obvious over Dlugos, Hijlkema, and Konstantino to purportedly show that the subject matter of claim 7 would have been obvious over Dlugos, Eskaros, and Konstantino. *Id.* at 55. We are not persuaded by Petitioner's cursory analysis of claim 7 based on its discussion of claim 3, particularly because Petitioner's analysis of claim 3 was not limited to Dlugos and Konstantino, but included Hijlkema, a reference not applied to claim 7. *See* Pet. 47–48 (stating, for example, that a person of ordinary skill in the art "would have found it desirable to combine the teachings Dlugos, Hijlkema and Konstantino in order to minimize the profile of the balloon and provide the balloon catheter with better performance"). Petitioner fails to identify a sufficient reason for combining the teachings of Dlugos, Eskaros, and Konstantino. *See* Pet. 54–55. As a result, Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 7 of the '767 patent would have been obvious over Dlugos, Eskaros, and Konstantino.

7. Obviousness of Claim 1 over Dlugos and Bampos

Petitioner contends claim 1 would have been obvious over Dlugos and Bampos. Pet. 69–71. Petitioner first argues that "[a]s discussed above [in the Petition], Dlugos teaches every element of claim 1." *Id.* at 69. Contrary to Petitioner's assertion, there is no developed argument in the Petition that claim 1 is anticipated by Dlugos or would have been obvious over Dlugos alone. *See id.* at 17–18 (identifying Petitioner's only contentions with respect to claim 1 as alleged obviousness over "Dlugos in light of Hijlkema" and "Dlugos in view of Bampos"). Further, as discussed above, claim 1 requires, among other things, "at least one fold extending from the first weld region to the second weld region in the uninflated state" and "first and second cone regions of the balloon having at least one fold in the fully inflated state." Ex. 1001, 6:40–55. Petitioner has not persuasively shown, for the reasons provided above, that Dlugos teaches either of these limitations.

Petitioner also contends that, to the extent lacking from the teachings of Dlugos, Bampos teaches at least one fold extending from the first weld region to the second weld region. *Id.* at 69.

Figure 16 of Bampos, as annotated by Petitioner, is reproduced below:

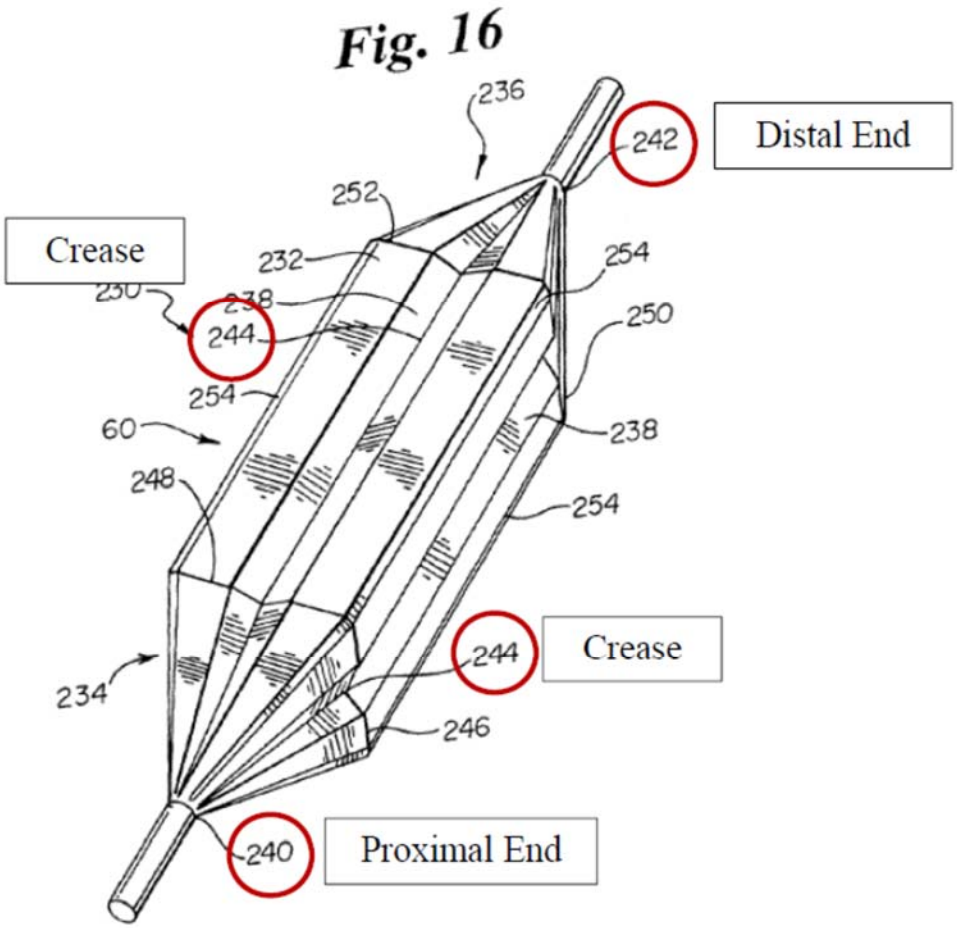

Figure 16 of Bampos illustrates balloon 230 in a non-pressurized state with body 232, proximal transition region 234, and distal transition region 236. Ex. 1015, 10:24–28. As noted by Petitioner, Bampos states that "[t]riangular indentations 238 extend from proximal end 240 to distal end 242" and "[t]riangular indentations 238 each have one of creases 244." Pet. 70 (quoting Ex. 1015, 10:28–30). Petitioner argues that a person of ordinary skill would see "that Bampos teaches the advantages of multiple folds or creases, each of which extends continuously in the uninflated state from the

proximal end of the balloon to the distal end, as shown in figure 16." *Id.* at 71.

Patent Owner contends in response that Petitioner fails to identify any weld region in Bampos, and that even if the distal and proximal ends "have something to do with weld regions, Figure 16 shows a gap between the crease 244 and the proximal end 240 and a gap between the crease 244 and the distal end 242," and therefore does not teach a fold from one weld region to the other. Prelim. Resp. 34. Patent Owner also asserts that Petitioner makes no attempt to show that Bampos teaches "the first and second cone regions of the balloon having at least one fold in the fully inflated state," as required by claim 1. *Id.* at 35.

Petitioner argues in reply as follows:

> Bampos teaches folds that extend from the proximal end to the distal end, where these two ends are affixed. In describing figure 16, Bampos states: "Triangular indentations 238 extend from proximal end 240 to distal end 242. Triangular indentations 238 each have one of creases 244. … Longitudinal ribs 254 extend from the proximal end 240 to distal end 242 of balloon 230. … Creases 244 of triangular indentations 238 extending from proximal end 240 to distal end 242…." Ex. 1005 ¶190; Ex. 1015 at 10:24–36. Bampos further provides that these creases assist in the deflation of the balloon from the expanded state to the deflated state. Ex. 1005 ¶190; Ex. 1015 at 10:39–45. Thus, while figure 16 may show small gaps between the creases and the ends of the balloon, the language is clear that creases do extend from the proximal end to the distal end. Moreover, it is at these ends that Bampos teaches that the balloon is affixed to the inner and outer shafts: "Distal tip 16 [of the inner shaft] is affixed at distal end 14. Shaft 18 couples to proximal end 12 of balloon 10." Ex. 1015 at 5:52–62. While this language describes figure 1, comparison of figures 1 and 16 show the distal and proximal ends in the same location with respect to the shaft.

Reply 14–15.

Petitioner offers no persuasive reply to Patent Owner's assertion that Bampos fails to disclose first and second cone regions of the balloon having at least one fold in the fully inflated state, as required by claim 1. It is undisputed that Figure 16 of Bampos illustrates balloon 230 in the "non-pressurized" state, not a fully inflated state. Ex. 1015, 10:27–28. With regard to the combination of Dlugos and Bampos, the Petition, Mr. Trotta's declaration, and the Reply all fail to discuss this requirement in the context of this asserted combination, much less demonstrate by a preponderance of the evidence how it is satisfied. *See* Pet. 69–71; Ex. 1005 ¶¶ 187–91; Reply 14–15.

Accordingly, Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 1 of the '767 patent would have been obvious over Dlugos and Bampos.

IV. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated by a preponderance of the evidence that claim 5 is anticipated by Dlugos and would have been obvious over Dlugos and Eskaros; that claim 8 would have been obvious over Dlugos, Eskaros, and Hijlkema; that claims 6, 14, and 16 would have been obvious over Dlugos, Eskaros, and Forman; that claims 9, 10, and 12 would have been obvious over Dlugos, Eskaros, and Traxler; that claim 11 would have been obvious over Dlugos, Eskaros, Traxler, and Forman; and that claim 17 would have been obvious over Dlugos, Eskaros, Forman, and Becker.

Petitioner has not shown by a preponderance of the evidence that claim 1, 2, or 4 would have been obvious over Dlugos and Hijlkema; that claim 3 would have been obvious over Dlugos, Hijlkema, and Konstantino;

that claim 5 would have been obvious over Dlugos, alone or in combination with Hijlkema; that claim 8 would have been obvious over Dlugos and Hijlkema; that claim 6, 14, or 16 would have been obvious over Dlugos, Hijlkema, and Forman; that claim 7 would have been obvious over Dlugos, Eskaros, and Konstantino; or that claim 1 would have been obvious over Dlugos and Bampos.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 5, 6, 8–12, 14, 16 and 17 of U.S. Patent No. 7,828,767 B2 have been shown to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written 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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