UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION

Petitioner

v.

BOSTON SCIENTIFIC SCIMED, INC.

Patent Owner

IPR2017-
Patent No. 7,828,767
Filing Date: May 29, 2008
Issue Date: November 9, 2010

Title: BALLOON DESIGN AND WELD DESIGN TO INCREASE EASE OF RE-WRAPPING AND DECREASE WITHDRAWAL FORCE

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 7,828,767

TABLE OF CONTENTS

Page

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 7,828,767 (Patent at Issue)
1002	File History of U.S. Patent 7,828,767
1003	U.S. Publication 2007/0167973 (Stupecky)
1004	U.S. Patent 6,740,191 (Clarke)
1005	Declaration of Thomas Trotta (Ex. 1005)
1006	CV of Thomas Trotta
1007	List of Patents Naming Thomas Trotta as an Inventor
1008	WO 2007/020087 A1 (Dlugos)
1009	U.S. Patent 5,853,389 (Hijlkema)
1010	U.S. Patent Publication 2005/0177130 (Konstantino)
1011	U.S. Patent Publication 2008/0097300 (Eskaros)
1012	U.S. Patent 5,501,759 (Forman)
1013	U.S. Patent Publication 2001/0047149 (Traxler)
1014	U.S. Patent 4,251,305 (Becker)
1015	U.S. Patent 6,013,055 (Bampos)
1016	U.S. Patent 5,041,125 (Montano)
1017	U.S. Patent 6,696,121 (Jung)
1018	U.S. Patent 5,049,131 (Deuss)

I. INTRODUCTION

Petitioner Edwards Lifesciences Corporation ("Edwards" or "Petitioner") respectfully petitions for *inter partes* review of claims 1 through 12, 14, 16, and 17 of U.S. Patent No. 7,828,767 ("the '767 patent") in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 et seq. ("Petition").

The '767 patent is "directed to making a balloon catheter with a folded/pleated balloon welded to the balloon catheter." 2:22-24.[1] The '767 patent does not, however, disclose or claim anything new. Balloon catheters have been in widespread use in the treatment of cardiovascular disease for decades. One of the requirements of a balloon catheter is that it have a compact unexpanded shape so that it can safely traverse the vascular system to the point where it is to be expanded. Practitioners in the field have been using pleats and folds to create compact unexpanded balloons since long before the filing date of the '767 patent: May 29, 2008. The '767 patent adds nothing to the art and its claims should be found unpatentable as anticipated and/or obvious.

[1] Citations to figures or in the form xx:yy are to the column and line of the '767 patent unless stated otherwise.

II. OVERVIEW OF THE '767 PATENT

A. Background and Summary of the '767 Patent

As the '767 patent acknowledges, balloon catheters have been known for decades. In fact, the '767 patent illustrates a portion of one such prior art balloon catheter 22 in figure 1. This device has a balloon with a center region 26 and a cone region 4 on either end of the center region. Each cone region narrows to a waist region at the proximal and distal ends of the balloon. A weld 20 at the waist region affixes that end of the balloon onto the shaft 18 of the catheter. 1:46-54, Fig. 1.

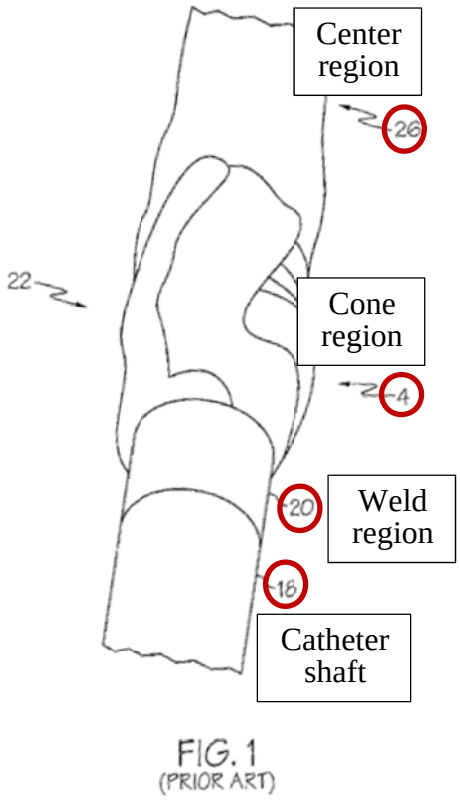


FIG. 1
(PRIOR ART)

According to the '767 patent, the center region of the prior art balloon 26 is folded in the unexpanded state but the folds do not extend into the cone. Rather, the cone regions are simply bunched up, creating "a bulky transition between the center region 26 and the cone 4 that has an increased outer diameter." 1:54-65.

The purported invention of the '767 patent is a balloon catheter in which the balloon is folded to form pleats that extend along the entire length of the balloon and then welded to the catheter. 3:10-13, 45-49, 4:55-63; see also 112 of Fig. 3.

Extending the folds the entire length of the balloon purportedly eliminates bunching of material in the cone. 2:17-24, 3:6-10, 31-35; Figs. 3, 9, 11.

Because the ends of the balloon are welded to the shaft after the balloon is folded, the folds are captured in the welds. Thus, even when the balloon is inflated, vestigial folds 112 remain in the end region 106, i.e., in the cone region 124 and extending into the waist or weld region 120 as shown in figure 11.

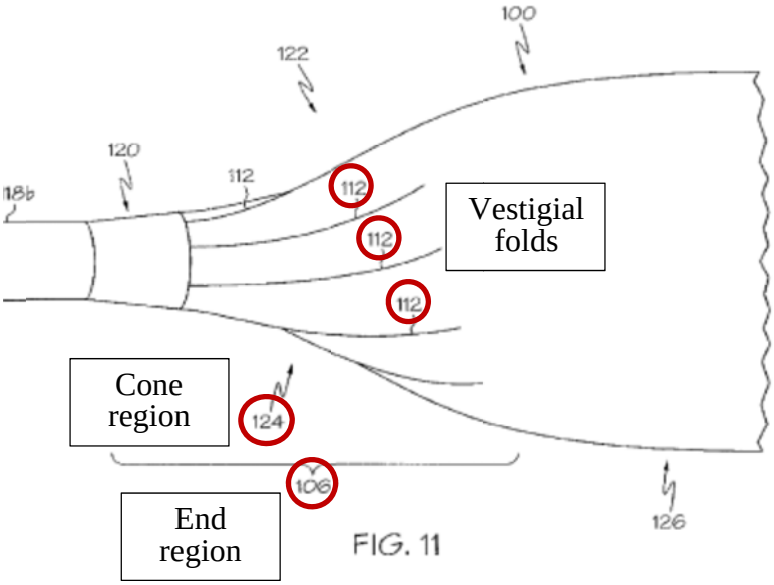


FIG. 11

This extension of the folds through the cone regions and into the welds is the sole invention of the '767 patent. There is no secret to the folds themselves. As the patent states: "the term 'fold' includes pleats, wings, and any similar structure." 3:62-4:2 (also incorporated by reference lobes, wraps, wrappings, protrusions). Nor is there magic in the weld. The '767 patent specifies that "[w]elds 120 are formed by any mechanism desired, for example, but not limited to, through transmission laser welding and direct or indirect application of heat to the weld site by any conventional method." 4:65-5:1 (emphasis added).

1. Independent Claims

Only claims 1 and 5 of the ’767 patent are independent. These claims state (numbering added for clarity):

1.0 A balloon catheter, the balloon catheter comprising:

1.1 at least one shaft; and

1.2 a balloon,

(a) the balloon comprising a first weld region, a first cone region, a middle region, a second cone region and a second weld region,

(b) the first weld region engaging the balloon to the at least one shaft,

(c) 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,

(d) the second weld region engaging the balloon to the at least one shaft,

1.3 the balloon having an uninflated state and an inflated state,

1.4 the balloon having at least one fold extending from the first weld region to the second weld region in the uninflated state and

1.5 the first and second cone regions of the balloon having at least one fold in the fully inflated state.

5.0 A method for making a balloon catheter comprising:

5.1 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;

5.2 providing a catheter comprising at least one shaft;

5.3 incorporating at least one fold, the at least one fold extending from the first end to the second end of the balloon cylinder; and

5.4 welding the balloon cylinder with the at least one fold to the at least one shaft of the catheter.

2. Dependent Claims

The dependent claims of the ’767 patent merely add conventional features. Claim 2 requires the catheter shaft to have an outer shaft and an inner shaft. The first weld region engages the balloon to a portion of the outer shaft; the second

weld region engages the balloon to a portion of the inner shaft.[2] Claims 3 and 7 require a plurality of folds with "radially adjacent ends overlapping." Claims 4 and 8 require a plurality of folds having "even material thickness." Claim 6 specifies that the welding be by laser. Claims 9 through 17 involve the use of a mandrel or heat shrinking at different steps when making the claimed balloon catheter.

B. Summary of Relevant Prosecution File History

The application that issued as the '767 patent was filed on May 29, 2008, with 17 claims. Claims 1, 5, 7 and 8 were slightly amended during prosecution. Otherwise, the claims were allowed as filed. The relevant portions of the file history can be found at Exhibit 1002.

The examiner initially rejected all 17 pending claims. The examiner determined that claims 1, 3, and 4 were anticipated by U.S. Publication No. 2007/0167973 ("Stupecky"), submitted as Exhibit 1003. Stupecky discloses a balloon catheter with a shaft 3 and a balloon 2 with weld regions, cone regions and a middle region. Ex. 1002, pp. 136-137 (9/4/09 Office Action).

---

[2] In a typical balloon catheter prior to 2008, the catheter would include an outer sheath used to inflate the balloon and an inner sheath that fits over the guide wire. Ex. 1005, ¶92.

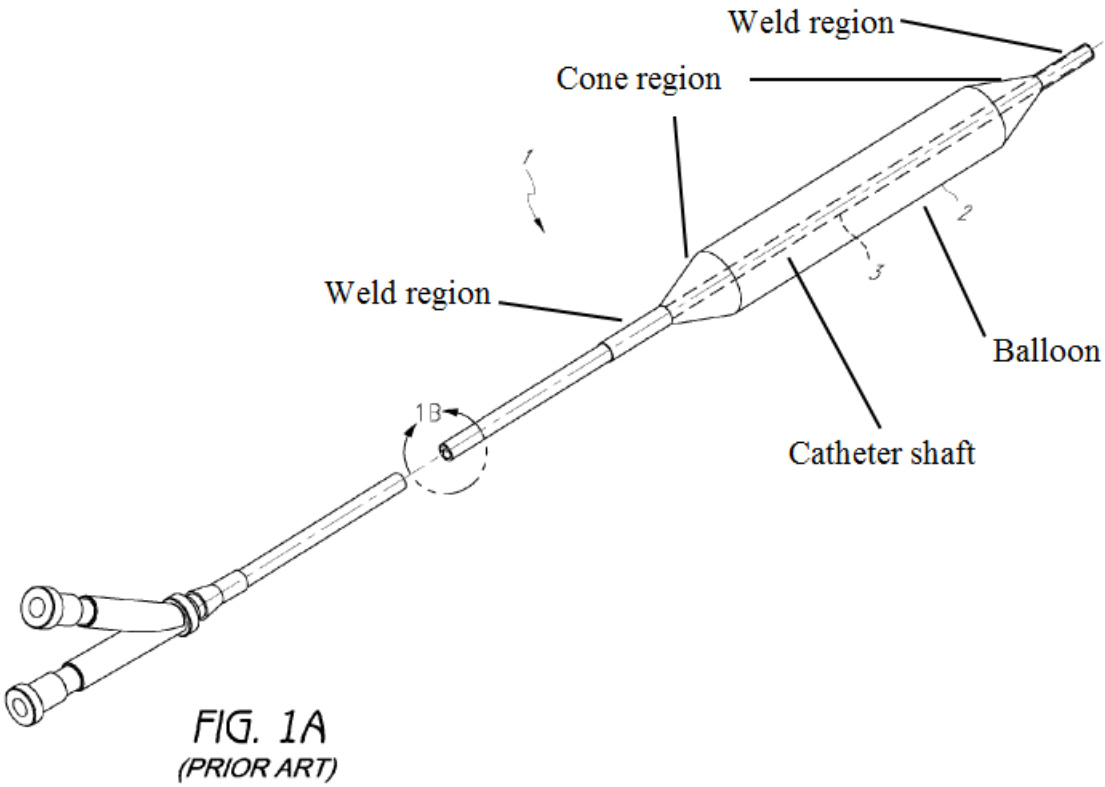


FIG. 1A
(PRIOR ART)

The examiner further describes the Stupecky balloon catheter as having:

> an uninflated state ([0080]) with a fold extending from the first weld region [40 on the left side of Fig. 22E] to the second [40 on the right side of Fig 22E] in the uninflated state (See Fig 22E) and as seen in (Fig 2) the conical regions are folded and appear to be connected to the welded region in the folded manner which shows that the folds a [sic] capable of being maintained in the conical portions upon inflation.

Id. The examiner clearly understood the flutes 6 shown in figure 2 to extend well into the distal and proximal "necks" 50 and 51, which are sized for "optimal welding and/or attachment to the catheter." Ex. 1003 (Stupecky), ¶0022.

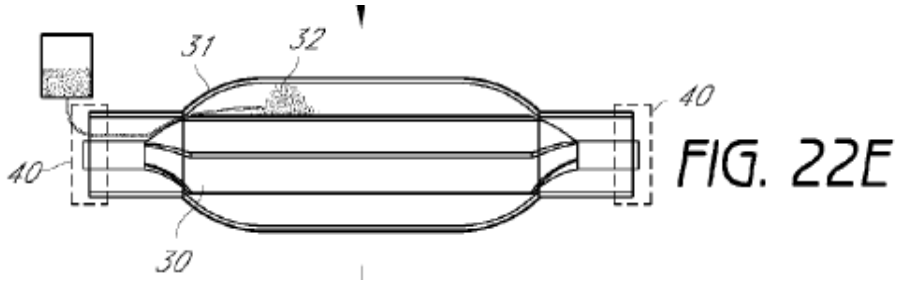


FIG. 22E

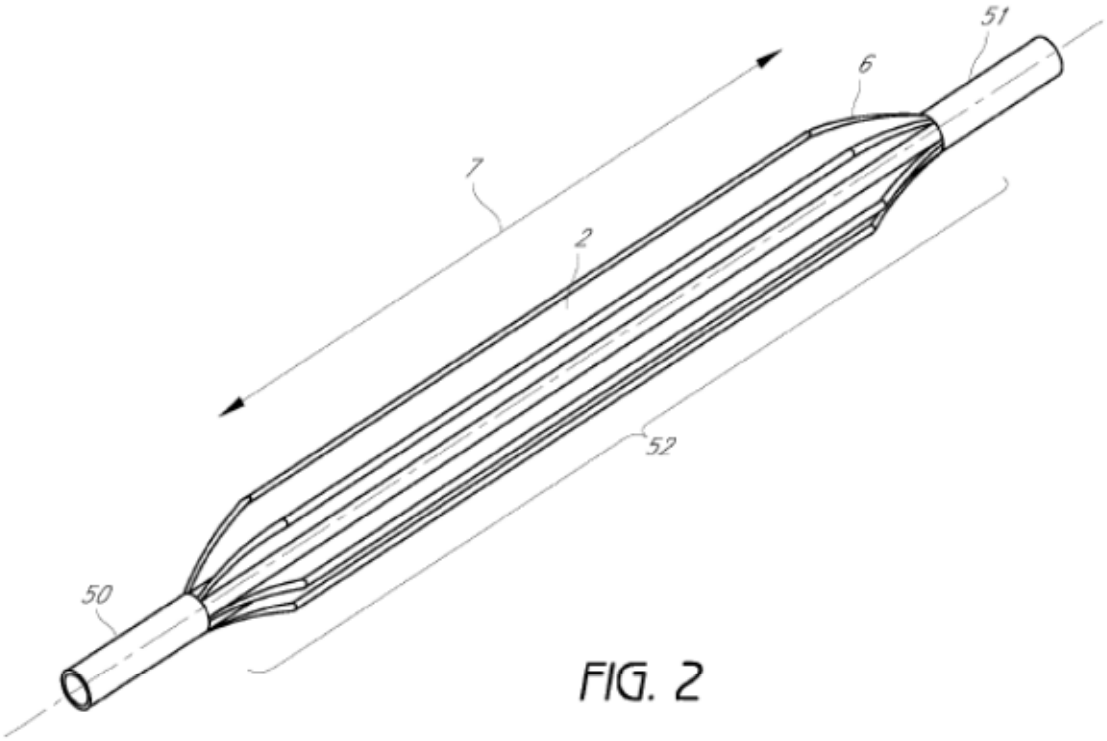
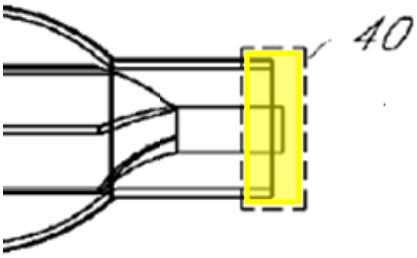


FIG. 2

The examiner rejected all other claims as obvious due to Stupecky in combination with U.S. Pat. No. 6,740,191 ("Clarke"). Ex. 1002, pp. at 137-138 (9/4/09 Office Action). While Stupecky teaches making a balloon catheter with folds, Clarke discloses welding the ends of the balloon to a catheter having outer and inner shafts. Finally, the examiner concluded that claims 12 and 13, requiring use of a mandrel, and claims 14 through 17, requiring the use of heat shrink

material, would have been obvious to a person of ordinary skill in the art ("POSITA") in view of Stupecky. *Id.* at 138.

In response, the applicant attempted to distinguish Stupecky as having folds that did not extend all the way to the weld areas shown by the dotted boxes 40 in figure 22E above. Ex. 1002, pp. 69-70 (12/4/09 Remarks). The applicant noted that the folds of Stupecky "extend between the proximal neck 50A to the distal neck 51A," but that the weld regions of Stupecky (the dashed boxes 40, highlighted in the portion of figure 22E reproduced at right) are found only in the outermost portions of each neck, resulting in a weld region that is longitudinally separated from the flutes (folds). Thus, the folds do not extend from one weld region to the other. *Id.* at 73.



The examiner found applicant's position unpersuasive and issued a final rejection of all claims. The examiner explained that the "folds need not be directly connected to weld region according to the claim as presented," which merely required that the balloon have at least one fold extending from the first weld region to the second weld region in the uninflated state. The examiner reiterated that in Stupecky, the "folds still extend from one region to the other without being directly connected [to the weld region]." *Id.* at 51 (3/25/10 Final Rejection). Further, the examiner reiterated that Stupecky disclosed folds in the conical region of the

balloon while the balloon is inflated "since upon inflation the ends are still connected to the catheter and therefore cannot expand in a manner in which no folds would exist in an inflated state." *Id.* at 51-52. The examiner provided additional arguments for rejecting all of the dependent claims.

The applicant chose not to respond to the examiner on the dependent claims, but rather, in a further response, focused on just the two independent claims. With respect to both claims, the applicant reiterated that the folds of the claimed balloon catheter extend the entire length of the balloon cylinder. The balloon is only welded to the catheter shaft after the folds are formed. Thus, "the folds extend from the first weld region to the second weld region in the uninflated state and do not begin a distance away from the weld region." *Id.* at 38 (5/25/10 Response). Indeed, the applicant argued, the only way to understand the claim language consistent with the dictionary definitions of "from" and "to" is to read "extending from the first weld region to the second weld region" to mean "the starting point of the fold as recited in claim 1 is the first weld region and the ending point of the fold as recited in claim 1 is the second weld region." *Id.* at 40.

Furthermore, pointing to figure 22E of Stupecky, the applicant argued that Stupecky fails to disclose that the folds in the cone region are welded to the catheter. Thus, expansion of those unwelded portions of the neck "would affect

the unfolding of the folds adjacent to these neck portions when the balloon is expanded." *Id.* at 41.

After considering these arguments, the examiner issued a notice of allowance for claims 1 through 17, stating:

> The claims in this application have been allowed because the prior art of record fails to disclose … [that] the balloon has a fold extending from the first weld region to the second weld region which is maintained within the cone regions upon inflation of the balloon.

Id. at 23 (7/9/10 Notice of Allowance).

III. PROPOSED CLAIM CONSTRUCTION

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purpose of this Petition, Edwards affords the claim terms their broadest reasonable construction in light of the specification. See In re Cuozzo Speed Techs., LLC, 793 F. 3d 1268, 1278-79 (Fed. Cir. 2015), aff'd 136 S. Ct. 2131 (2016). [3]

[3] Edwards here addresses only the question of the correct construction of those terms relevant to this Petition. Edwards makes no admission as to the interpretation to be given any term in district court litigation. Edwards makes no admission that the claims conform to the requirements of 35 U.S.C. § 112 and preserves all such arguments.

A. "Balloon Cylinder"

Independent claim 5 refers to a "balloon cylinder." Edwards submits that, under its broadest reasonable interpretation, this term includes a pre-formed balloon shaped to have tapered portions or necks.

The specification refers to "a balloon cylinder 100, as shown in FIG. 2. The balloon cylinder 100 has a proximal end region 106, a middle region 126 and a distal end region 108. The proximal end region 106 includes a weld region 120 and a cone region 124, as shown in FIG. 11. Similarly, the distal end region 108 includes a weld region 120 and a cone region 124. " 3:23-29.

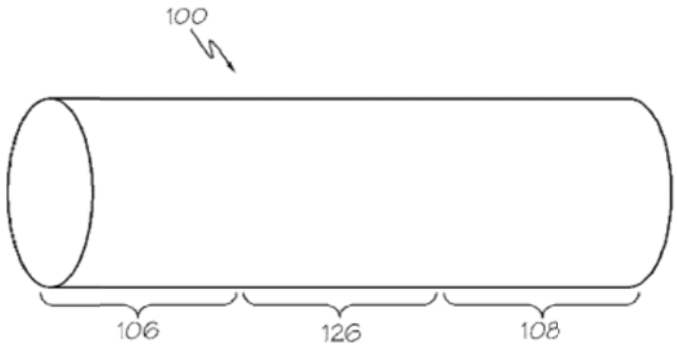


FIG. 2

The balloon cylinder of the claims is not necessarily a tube with a constant diameter, however. During prosecution, the examiner characterized the preformed balloon of Stupecky, with a rounded transition to a neck on each end, as meeting the balloon cylinder limitation. See e.g., Ex. 1002, pp. 137-138 (9/4/2009 Office Action).

Accordingly, a person of ordinary skill, giving the term "balloon cylinder" its broadest reasonable interpretation, would have understood that term to include a preformed balloon shaped to include necks.

B. "Fold"

Independent claim 1 recites a "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." (emphases added). Independent claim 5 recites "incorporating at least one fold, the at least one fold extending from the first end to the second end of the balloon cylinder." (emphases added). The applicant broadly defined the term "fold" in the specification, stating: "As used in this application, the term 'fold' includes pleats, wings, and any similar structure." 3:62-63; see also 2:17-20 ("a balloon cylinder is folded to form pleats"). The specification provides several "non-limiting examples of methods of balloon folding" that include reference to "lobes," "wraps," "wrappings," and "protrusions." 3:63-4:2.

There is no reason to apply any other definition here. Accordingly, for the purposes of this Petition, and applying the broadest reasonable interpretation, a POSITA would have understood the term "fold" to include folds, pleats, wings, lobes, wraps, wrappings, or protrusions.

IV. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art is a hypothetical person presumed to know the relevant prior art. Gnosis S.p.A. v. South Alabama Med. Sci. Found., IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person is of ordinary creativity, and not an automaton, and is capable of making inferences and combining teachings in the prior art. See *id.* (citing KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420-21 (2007)).

A POSITA at the time of the claimed invention would have had 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, a POSITA would have ten years of working experience designing, manufacturing and/or overseeing the processes for designing and/or manufacturing the tools and/or the devices.

V. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS FOR CANCELLATION (37 C.F.R. §§ 42.22(a) AND 42.104(b))

The Board is requested to find that there is a reasonable likelihood that Edwards will establish that each of claims 1 through 12, 14, 16 and 17 of the '767 patent are invalid in light of the teachings of the following references, alone or in combination with each other:

- WO Publication 2007/020087 A1, published on February 22, 2007 ("Dlugos"), Ex. 1008.
- U.S. Patent 5,853,389, issued on December 29, 1998 ("Hijlkema"), Ex. 1009.
- U.S. Publication 2005/0177130 A1, published on August 11, 2005 ("Konstantino"), Ex. 1010.
- U.S. Patent Publication 2008/0097300, published on April 24, 2008 (hereinafter referred to as "Eskaros"), Ex. 1011.
- U.S. Patent 5,501,759, issued on March 26, 1996 ("Forman"), Ex. 1012.
- U.S. Patent Publication 2001/0047149, issued on November 29, 2001 ("Traxler"), Ex. 1013.
- U.S. Patent 4,251,305, issued on February 17, 1981 ("Becker"), Ex. 1014.
- U.S. Patent 6,013,055, issued on January 11, 2000 ("Bampos"), Ex. 1015.

Each of the listed references except Eskaros was published more than one year before the '767 patent's priority date of May 29, 2008, and is therefore prior art under pre-AIA 35 U.S.C. section 102(b). Eskaros is a patent application filed prior to the priority date of the '767 patent and is therefore prior art under pre-AIA

sections 102(a) and (e). With the exception of Hijlkema, none of these references were before the examiner during prosecution of the '767 patent.

A person of skill in the art would be motivated to combine these references in ways that would produce the claimed inventions of the '767 patent. The '767 patent is directed generally to a balloon catheter in which the balloon has been folded and then welded to at least one shaft of the catheter in order to have a more compact uninflated shape. Ex. 1001 ('767 patent), Abstract. Each listed reference similarly addresses improvements to balloon catheters and methods of manufacturing an improved balloon catheter. Dlugos, Hijlkema, Bampos, Konstantino, Eskaros, and Traxler are directed to improved ways to fold a balloon catheter, primarily in order that the profile of the unexpanded balloon can be reduced.[4] Forman and Becker disclose well-known balloon catheter welding

[4] The object of the invention in Dlugos is to "provide a method of producing a balloon of a balloon catheter having improved folding characteristics." Ex. 1008 (Dlugos), pp. 1-2. Hijlkema, Bampos, Konstantino, Eskaros, and Traxler seek to provide improved balloon folding characteristics to achieve a lower profile balloon. Ex. 1009 (Hijlkema), 1:36-39; Ex. 1015 (Bampos), 1:10-13; Ex. 1010 (Konstantino) ¶¶0007, 0009; Ex. 1011 (Eskaros), ¶0004; Ex. 1013 (Traxler), ¶0001.

techniques using lasers and heat shrink material, relevant to certain dependent claims.[5] Petitioner therefore respectfully requests that the Board cancel the challenged claims of the ’767 patent based on the following grounds:

- Ground 1: Claims 1, 2, 4, 5 and 8 are unpatentable as obvious over Dlugos in light of Hijlkema.
- Ground 2: Claim 3 is unpatentable as obvious over Dlugos in view of Hijlkema and Konstantino.
- Ground 3: Claim 5 is unpatentable over Dlugos or over Dlugos in light of Eskaros.
- Ground 4: Claim 7 is unpatentable as obvious over Dlugos in view of Eskaros and Konstantino.
- Ground 5: Claim 8 is unpatentable as obvious over Dlugos in view of Eskaros and Hijlkema.
- Ground 6: Claims 6, 14, and 16 are unpatentable as obvious over Dlugos and Hijlkema or Dlugos and Eskaros in view of Forman.
- Ground 7: Claims 9, 10 and 12 are unpatentable as obvious over Dlugos in view of Eskaros and Traxler.

[5] Ex. 1012 (Forman), 1:12-67, 2:38-40; Ex. 1014 (Becker), 1:8-11.

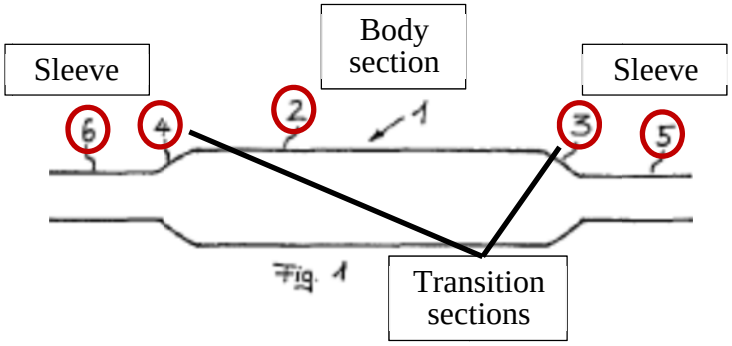
- Ground 8: Claim 11 Is unpatentable as obvious over Dlugos and Eskaros in light of Traxler and Forman.
- Ground 9: Claim 17 is unpatentable as obvious over Dlugos and Eskaros in view of Forman and Becker.
- Ground 10: Claim 1 is unpatentable as obvious over Dlugos in view of Bampos.

The scope and content of the references and their application to the claims are more specifically discussed below under the separate grounds for unpatentability.

A. Ground 1: Claims 1, 2, 4, 5 and 8 are Unpatentable as Obvious Over Dlugos in Light of Hijlkema

1. Dlugos

Dlugos (WO Publication 2007/020087) discloses a method of producing a balloon catheter that can be easily folded into a more compact configuration. It involves three steps. In the first step, a preformed balloon is made, typically in a mold. The balloon has a body section 2, bonded on either side by transition sections 3, 4, that narrow down to sleeves 5, 6, at either end. Ex. 1008, p. 4.



In the second step, folds 7 are created. In the embodiment depicted in figure 2, the folds begin in the distal sleeve 6 and continue through the distal transition section and the balloon body and pass out of sight in the proximal transition section. It is not possible to tell from the figure whether the folds continue out of view or terminate. But the language of Dlugos is unambiguous. The folds go from one end right to the other, through "the distal sleeve 6, the transitional section 4, the balloon body 2, the transitional section 3 to the proximal sleeve 5." *Id.*

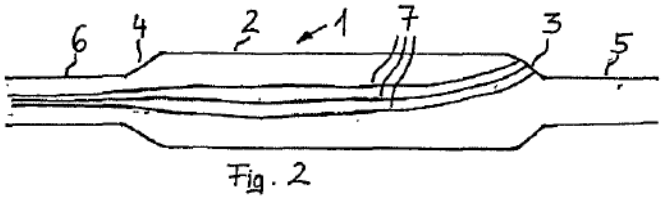


Fig. 2

Finally, the folds are fixed by welding in the sleeves. *Id.* at 5.

As noted above, the applicant strenuously argued during prosecution that the prior art did not show a fold extending under the weld. No such point of distinction can be made with respect to Dlugos. Figure 3 of Dlugos depicts the distal end of the balloon over the inner guide wire tube 9 (highlighted in yellow). A weld region 8 is shown as a cross-hatch block over the balloon distal sleeve 6. Three folds 7 extend well into the weld region 8. Dlugos teaches that these folds will be fixed in the welding to the inner tube 9. As the examiner noted during prosecution of the '767 patent, such a configuration will result in folds in the cone regions,

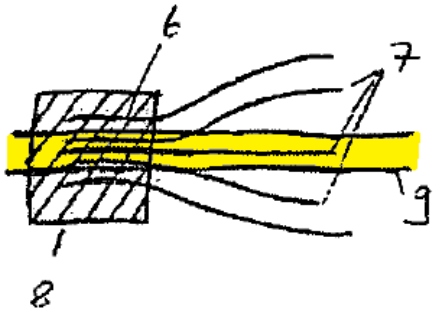


Fig. 3

even when the balloon is fully inflated. Ex. 1002, pp. 51-52 (3/25/2010 Final Rejection) ("since upon inflation the ends are still connected to the catheter [the balloon] … cannot expand in a manner in which no folds would exist in an inflated state."). The applicant never disputed this position, and indeed, logically cannot.

Although Dlugos does not expressly refer to the balloon as having an inflated and an uninflated state (an express requirement of claim 1), these two states are inherent. Dlugos describes a balloon catheter. The American Heritage College Dictionary defines 'balloon' to be "a flexible bag designed to be inflated." A bag that is designed to be inflated is necessarily uninflated until that occurs. Furthermore, a person of ordinary skill at the time would have understood the term 'balloon catheter' to refer to a catheter on which a balloon has been mounted for use in a particular manner: the catheter is inserted through a body lumen until the uninflated balloon is positioned at a treatment site, the balloon is then inflated to perform the necessary procedure, and the balloon is deflated in order that it be removed. Ex. 1005, ¶121. Dlugos's use of the term "balloon catheter," alone, suggests a device that had an uninflated and an inflated state. Finally, Dlugos describes itself as a method of making a balloon catheter with improved folding characteristics compared to identified prior art. That prior art, of course, teaches balloon catheters having an uninflated, folded configuration and an inflated, unfolded configuration. Ex. 1008, pp. 1-2. A person of skill in the art, therefore,

would have plainly understood that the balloon catheter of Dlugos necessarily had two states: an uninflated (folded) configuration and an inflated (unfolded) configuration. Ex. 1005, ¶121.

Similarly, the POSITA would understand Dlugos to disclose at least one embodiment in which the balloon is welded to the catheter at both the distal and proximate ends, as required by claim 1 and its dependents. Dlugos describes and illustrates an "inner tube (guide wire tube)" to which the distal sleeve of the balloon of the balloon catheter is fixed. *Id.* at 3, see also element 9 of Fig. 3. Dlugos also teaches, however, that folds can be welded into the distal sleeve, the proximal sleeve, or both. *Id.* at 3 ("with the folds being fixed, e.g. by welding, in the distal end or proximal balloon sleeve"); *id.* at 5 ("the folds 7 are fixed at least in the distal section of distal sleeve 6, e.g., by welding, …. [I]t is also possible to fix the folds 7 running into the proximal sleeve 5 in the same manner as described hereinbefore."); see also, Ex. 1005, ¶¶118, 131.

Finally, Dlugos also teaches that at least one fold extends continuously from the weld region at one end of the balloon to the weld region at the other. Dlugos describes one embodiment, illustrated in figure 2, in which folds begin in the distal sleeve and continue to the proximal sleeve and the folds are fixed only in the distal sleeve. But Dlugos also teaches an alternative embodiment in which those same

folds are fixed in place in the proximal sleeve too. The relevant passage of Dlugos, with intermediate steps deleted, reads:

> 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 transitional section 4, the balloon body 2 the transitional section 3 to the proximal sleeve 5.
>
> * * *
>
> In the last method step, depicted in Fig. 3, the folds 7 are fixed at least in the distal section of distal sleeve 6, e.g. by welding.
>
> * * *
>
> Although 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 herein before.

Ex. 1008, pp. 4-5. Thus, the folds 7 are welded at one end in the distal sleeve, and continue through the distal transition section, the central region and the proximal transition section to be welded at their other end at the proximal sleeve.

2. Hijlkema

Hijlkema (U.S. Patent No. 5,853,389) teaches a balloon catheter and a method of manufacturing the balloon. The balloon 9 is made in a blow molding process. As the balloon is being formed, the ends are twisted to produce 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, 3:57-61.

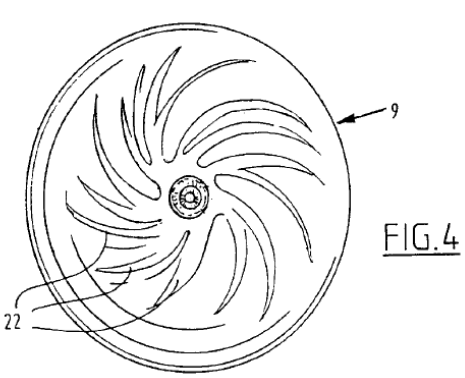


FIG.4

As shown in figure 5, a portion of which is reproduced here, the catheter 2 of Hijlkema consists of two coaxial tubes. The outer tube 3 is shorter than the inner tube 4. The end of the outer tube 3 is mounted to ("connected with") the proximal end section 12 of the balloon. The inner tube 4 extends past the end of the outer tube 3, through the balloon, and out the distal end of the balloon. The distal

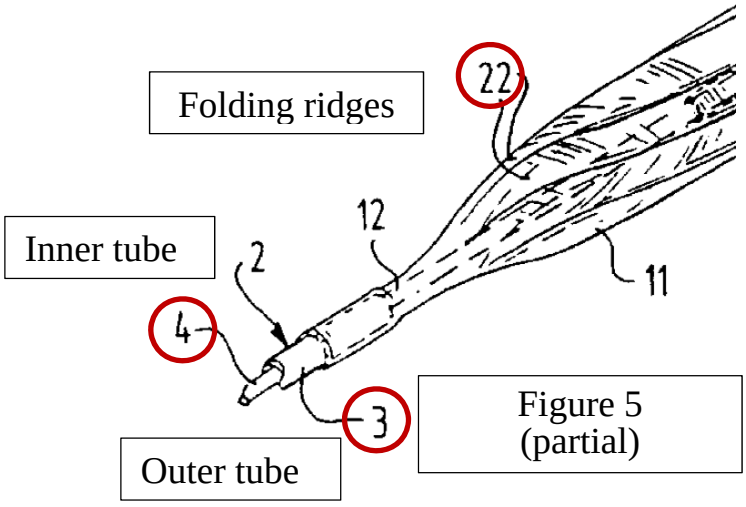


Figure 5 (partial)

end of the balloon is mounted to inner tube 4. Tube 3 therefore provides an annular passageway into the interior of the balloon and allows the balloon to be inflated and uninflated. *Id.* at 3:6-12, 4:11-24.

When the balloon of Hijlkema is inflated, the folds disappear through the central portion of the balloon. The folding ridges 22 remain plainly visible in the transition sections, as shown in figure 3 below. See also *id.* at Fig. 1.

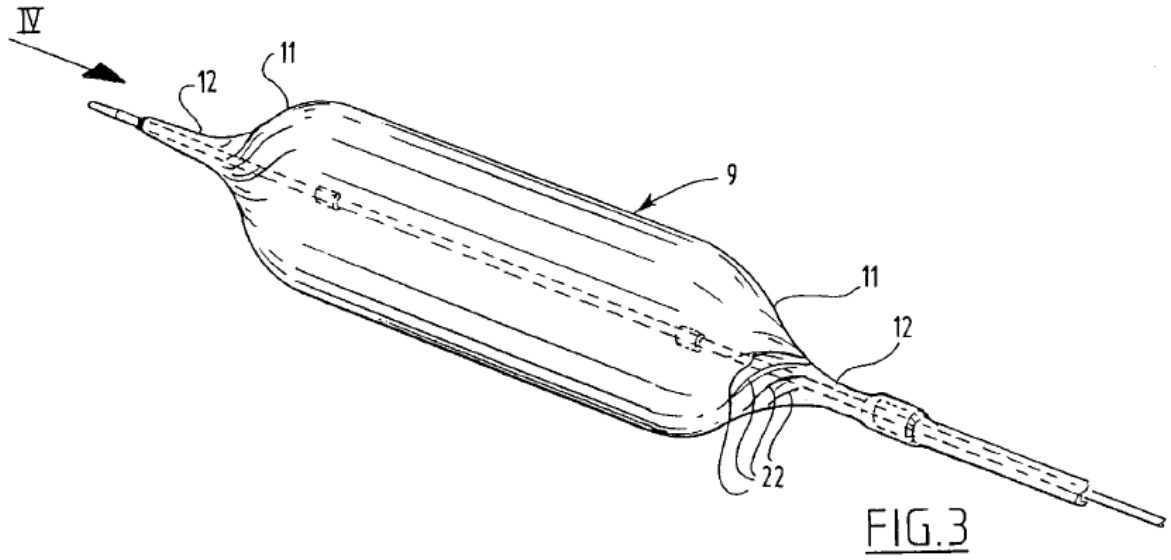
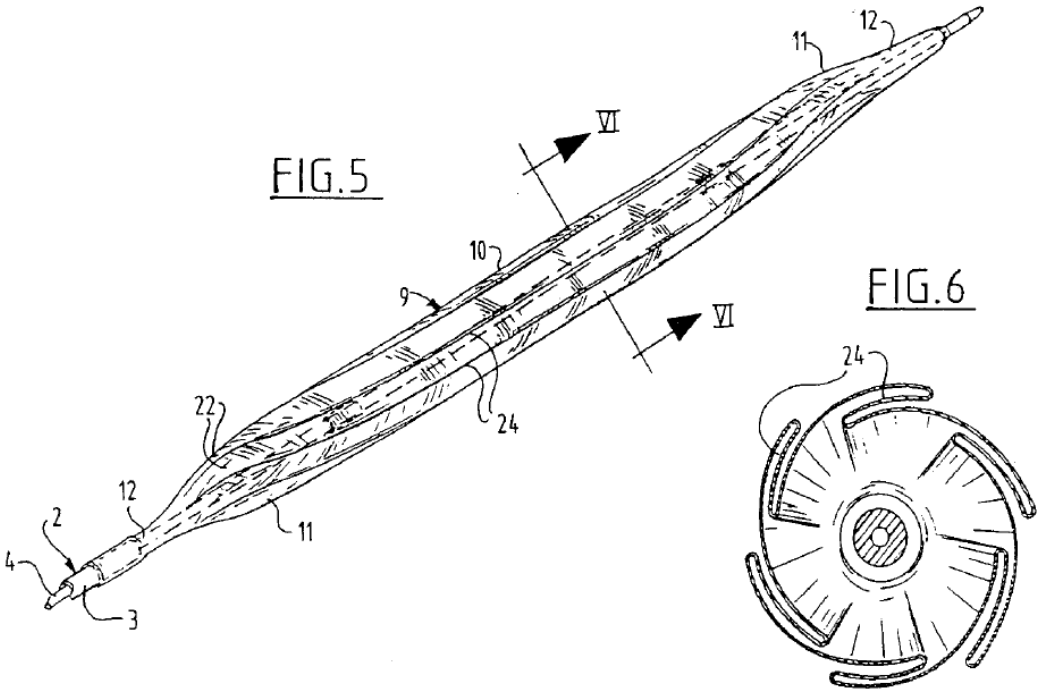


FIG.3

When the balloon is deflated, it 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, as shown in figures 5 and 6. *Id.* at 3:66-4:3, Figs 5, 6.



3. The Combination of Dlugos and Hijlkema

One of skill in the art would have been motivated to combine Dlugos and Hijlkema for several reasons. Both references address the problem purportedly solved by the ’767 patent: bulky bulges in the cone regions of the uninflated balloon. Specifically, the object of the invention in Dlugos is to “provide a method of producing a balloon of a balloon catheter having improved folding characteristics” over prior art balloon catheters, including angioplasty balloon

catheters such as disclosed in U.S. Patent No. 5,041,125. Ex. 1008 (Dlugos), pp. 1-2 (citing U.S. Pat. No. 5,041,125, Ex. 1016). Dlugos does not discuss the folding procedure in detail beyond specifying that the folds are fixed to the catheter. This would have led the skilled reader to consider suitable folding methods for use with the Dlugos invention. Ex. 1005, ¶191. Hijlkema discloses one suitable method. Hijlkema states that its object "is to provide a balloon catheter and a method for manufacturing such a balloon catheter, resulting in a balloon which can be properly folded into a small diameter." Ex. 1009 (Hijlkema), 1:36-39. Furthermore, Dlugos itself describes Hijlkema as relevant background. See Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc., 713 F.3d 1369, 1375 (Fed. Cir. 2013) (finding motivation to combine prior art references due, in part, to express identification in one of the references to the other reference).

A person of skill in the art would also have considered the combination of Dlugos and Hijlkema because of the overlap in the manufacturing techniques. Both references begin with a blow molded balloon. A POSITA would understand that blow molding would result in relatively thicker material in the end and cone sections, where the material was not as distended. Further, a POSITA would anticipate that this thicker material might impair folding. Ex 1005, ¶¶127, 149. A person attempting to apply the teachings of Dlugos would have needed to find a solution to this challenge. Hijlkema expressly teaches that twisting the ends of the

balloon during the blow molding will create helical ridges that will assist orderly folding. A POSITA would therefore have attempted to modify the teachings of Dlugos with Hijlkema.

Not only is there a motivation to combine, but doing so would be highly feasible. In both references the balloon starts as a parison in a first mold and is then expanded through blow molding into the final balloon shape. Compare, Ex. 1009 (Hijlkema), 3:25-31 and Ex. 1017 (U.S. Patent No. 6,696,121 (cited by Dlugos at p. 2)), 2:36-44. The opportunity therefore existed for the person making the Dlugos balloon to apply the manufacturing technique of Hijlkema. Ex. 1005, ¶127.

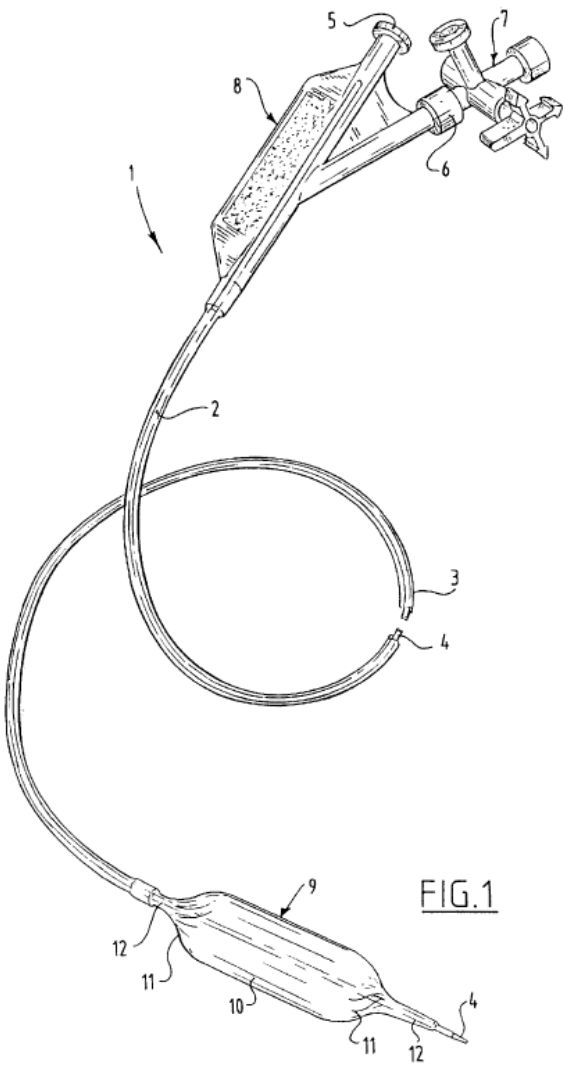
The predictable outcome of combining Dlugos and Hijlkema would be a balloon catheter with folds through the cone regions and thereby, fewer bulges and a reduced diameter of the uninflated balloon catheter, for transiting through a body lumen to the treatment site. Ex. 1005, ¶¶126, 149.

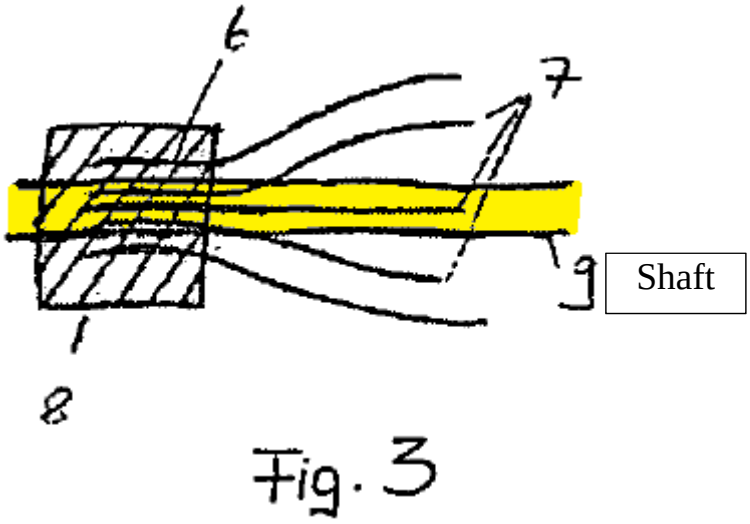
4. Applying Dlugos and Hijlkema to the Claims

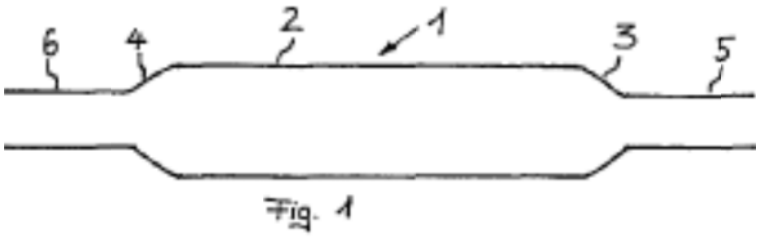
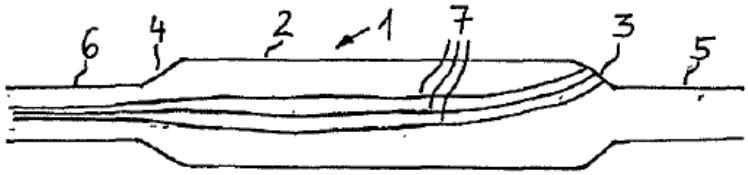
The combination of Dlugos and Hijlkema teaches every limitation of claims 1, 2, 4, 5 and 8 of the ’767 patent, as set forth in greater detail in the following charts.

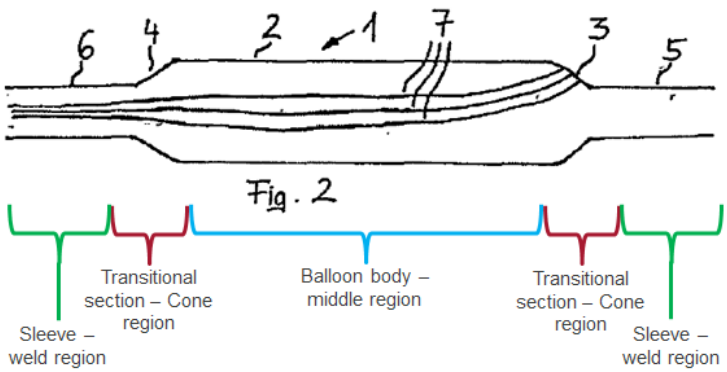
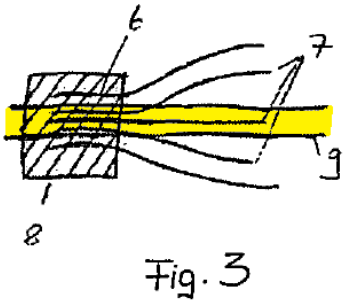
	Claim Language	Dlugos and Hijlkema
1.0	A balloon	Dlugos is directed to a “method of producing a

	Claim Language	Dlugos and Hijlkema
	catheter, the balloon catheter comprising:	balloon of a balloon catheter." It specifically discloses just such a balloon catheter. Ex. 1008, pp. 2, 4, claims 1, 8.) "It is an object of the present invention to provide a method of producing a balloon of a balloon catheter having improved folding characteristics." *Id.* at 2:1-3. Hijlkema similarly addresses a balloon catheter, as shown in figure 1.

	Claim Language	Dlugos and Hijlkema
		 FIG.1 Ex. 1009, Fig. 1.

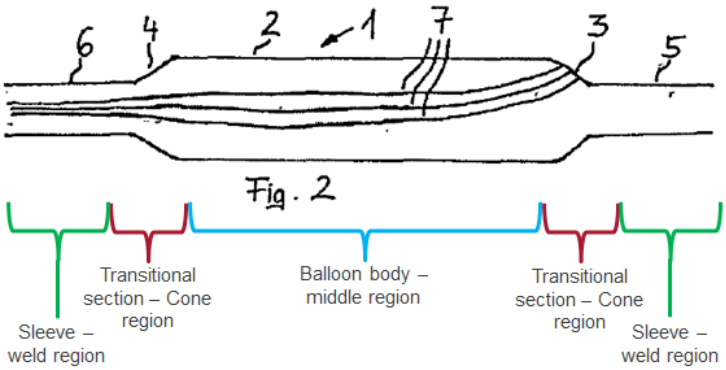
	Claim Language	Dlugos and Hijlkema
1.1	at least one shaft; and	Dlugos discloses a catheter with an inner "guide wire tube 9," shown in figure 3 (highlighting added). Ex. 1008, pp. 3, 6.) This inner tube constitutes a shaft.  Fig. 3 "Usually, a balloon manufactured according to the method of the present invention is provided with an inner tube (guide wire tube), the distal section of the distal sleeve is fixed to." *Id.* at Fig. 3, 3:5-7.

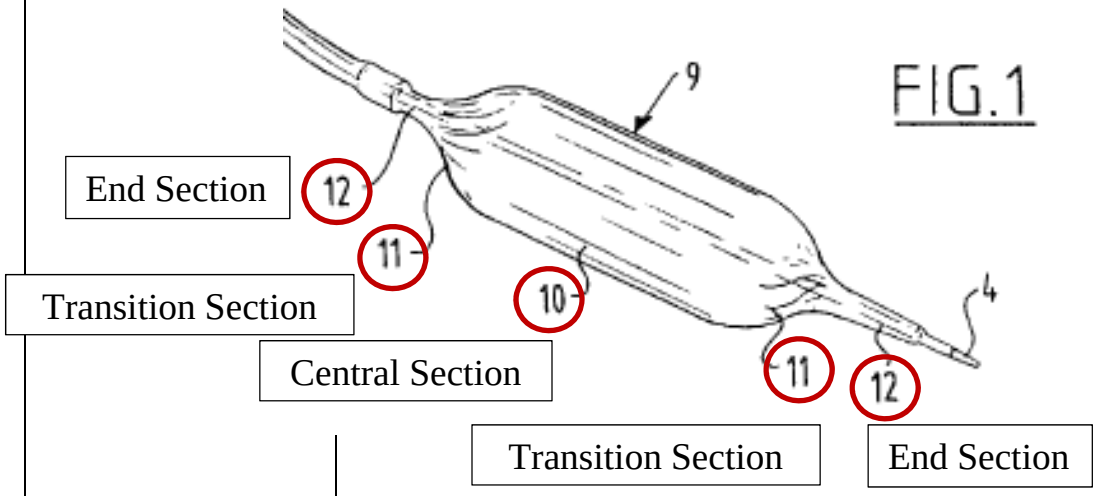
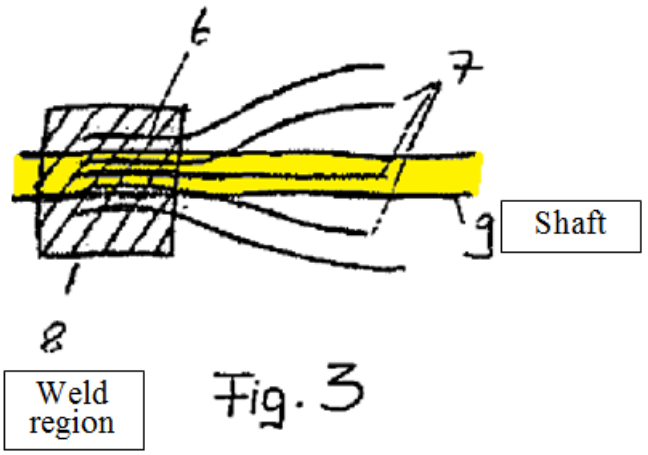
	Claim Language	Dlugos and Hijlkema
1.2	a balloon,	Figures 1 and 2 of Dlugos depict a balloon 1.  Fig. 1  Fig. 2 *Id.* at Figs 1, 2.
1.2(a)	the balloon comprising a first weld region, a first cone region, a middle region, a second cone region and a second weld region,	Referring to figure 2, Dlugos states that the balloon 2 includes "a balloon body 2 of a usual cylindrical shape, two transitional sections 3 and 4, a proximal sleeve 5 and a distal sleeve 6 being connected to the respective transitional sections 3 and 4, respectively." *Id.* at 4. The annotated figure 2, below, shows the relative locations of the various regions required by this limitation.

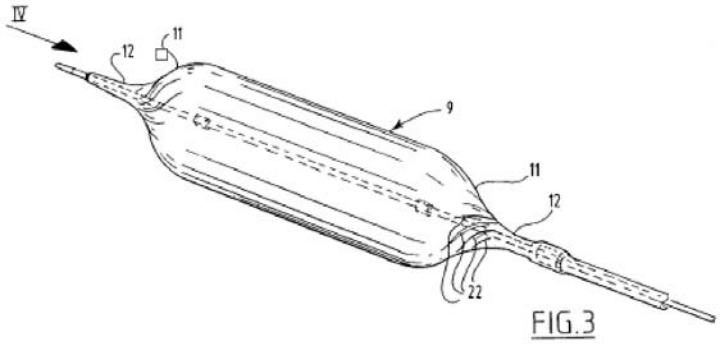
	Claim Language	Dlugos and Hijlkema
		
1.2(b)	the first weld region engaging the balloon to the at least one shaft,	For the purposes of this claim chart, the "welding portion" of the proximal sleeve of the Dlugos balloon corresponds to the first weld region of the claims and the welding portion of the distal sleeve of Dlugos corresponds to the second weld region of the claims. Dlugos suggests that a distal section of the distal sleeve of the balloon is "usually" fixed to the inner tube at a "welding/fixing portion" 8, as shown in figure 3. *Id.* at 3.  But Dlugos also refers several times to fixing the proximal sleeve. See, e.g., *id.* at 2-3 ("with the folds being fixed, e.g., by welding, in the distal end or proximal balloon sleeve."); *id.* at 5 ("it is also possible to fix the folds 7 running into the proximal sleeve 5 …"). The fixing in the distal sleeve is done by

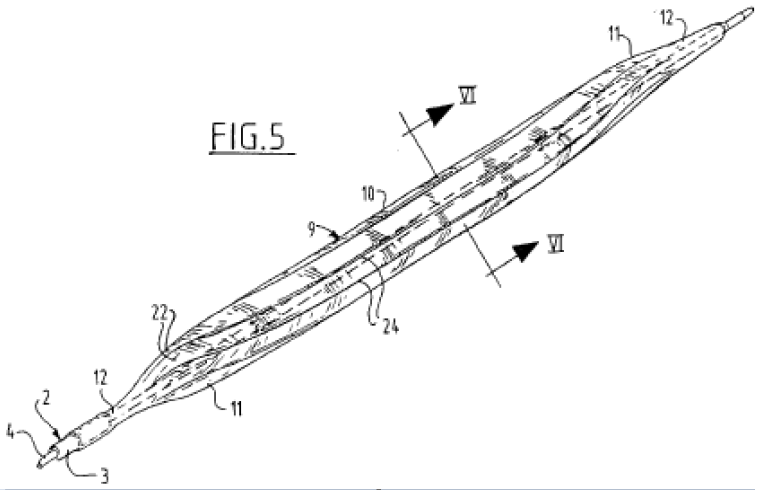
	Claim Language	Dlugos and Hijlkema
		welding, as shown by the "welding/fixing portion" 8 of figure 3. *Id.* at 3 ("fixed, e.g., by welding"); *id.* at 5 (same). See the discussion of welding the distal sleeve to the inner tube, at claim element 1.2(d), below, for further details. Dlugos notes that in the alternative embodiment, in which the proximal sleeve is fixed too, the fixing is done in the proximal sleeve "in the same manner," i.e., by welding. *Id.* at 5. Thus, the weld portion of the proximal sleeve forms a weld region at which the balloon is engaged to the catheter shaft. Ex. 1005, ¶118. In addition, a person of ordinary skill would have combined Dlugos with Hijlkema to meet this limitation. Dlugos refers to only a single catheter shaft but describes this shaft as an "inner tube." *Id.* at 3. A person of ordinary skill would understand from this phraseology that Dlugos contemplates that the catheter would also have an "outer tube." Ex. 1005, ¶ 132, 135. Indeed, coaxial balloon catheters in which an inner tube provides the lumen for a guide wire and an outer tube provides an annular passage for the fluid used to inflate the balloon not only were well known in the art, but well known to the authors of Dlugos. Dlugos expressly discussed Hijlkema, a reference that depicts just such a system. Ex. 1005, ¶133; Ex. 1008, p. 1 (referring to "US-A-5 853 389,"

	Claim Language	Dlugos and Hijlkema
		the Hijlkema patent). Accordingly, one of ordinary skill in the art seeking to apply the Dlugos folding and welding techniques in the context of a coaxial catheter would have looked to the teachings of Hijlkema. Ex. 1005, ¶¶132, 134, 135. Hijlkema specifically discloses "connecting" the proximal end section of the balloon to the outer tube 3 of the coaxial lumen catheter, in order to create a passageway into the interior of the balloon at the proximal end of the balloon through the annular space inside tube 3. "The relatively proximal section 12 of the balloon member 9 is connected with the end of the outer tube-like element 3, …." Ex. 1009 (Hijlkema), 4:11-16 (emphasis added). Dlugos plainly teaches welding and a POSITA would have considered welding to be a conventional approach to "connecting" the proximal end of the balloon in Hijlkema to the outer catheter shaft. Ex. 1005, ¶132. Thus a first weld region engaging the balloon to the catheter at the proximal end of the balloon would have been obvious to one of skill in the art in light of Hijlkema and Dlugos.
1.2(c)	the first cone region adjacent to	Figure 2 of Dlugos plainly shows the first cone region (proximal transition region 3) adjacent the first weld

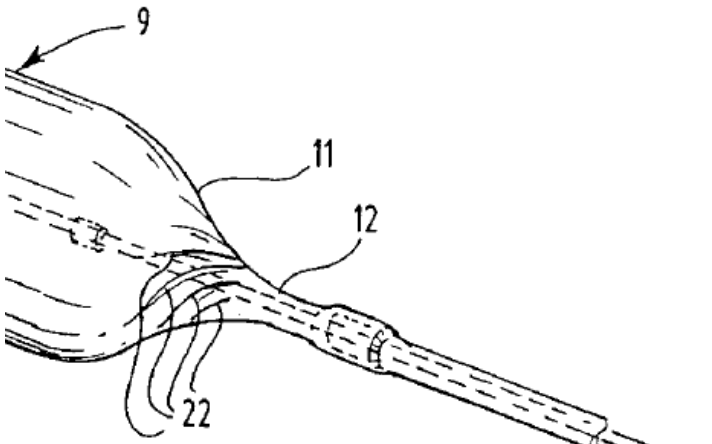
	Claim Language	Dlugos and Hijlkema
	the first weld region, the middle region between the first cone region and the second cone region, the second cone region adjacent to the second weld region,	region (proximal sleeve 5), the intervening middle region (balloon body 2), and the second cone region (distal transition region 4) adjacent the second weld region (distal sleeve 6). Ex. 1008 (Dlugos), p. 4.  Figure 1 of Hijlkema similarly illustrates first and second cone regions (transition sections 11) adjacent first and second connecting regions (end sections 12), and the middle region (central section 10) between the two. Ex. 1009 (Hijlkema), 3:18-20. As discussed above, it would have been obvious to one of skill in the art to connect the balloon to the catheter in the connecting regions using welding.

	Claim Language	Dlugos and Hijlkema
		
1.2(d)	the second weld region engaging the balloon to the at least one shaft,	Dlugos figure 3 shows a "welding portion" of the distal sleeve of the balloon, at which the balloon is fixed to the inner tube (shaft) of the catheter. For the purposes of this claim chart, the welding portion of the distal sleeve of Dlugos corresponds to the second weld region of the claim.  Dlugos notes that the distal sleeve of the balloon is welded to the inner tube 9 (shaft) of the catheter: "the

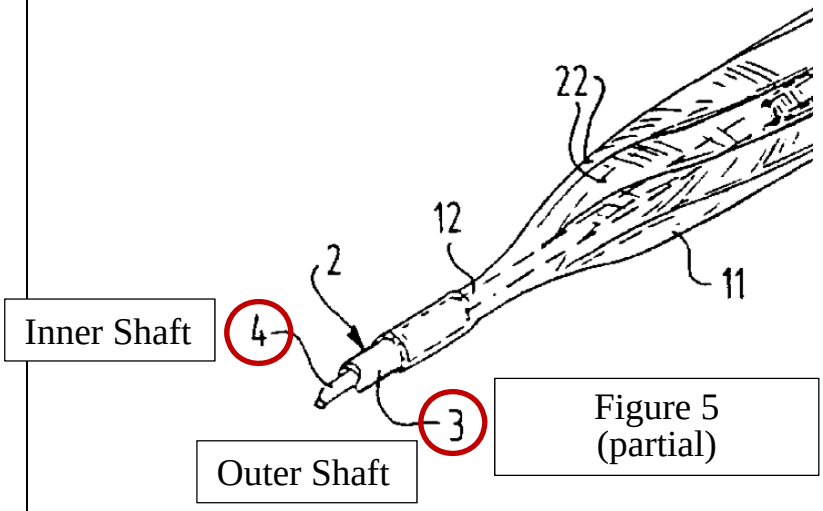
	Claim Language	Dlugos and Hijlkema
		folds 7 are fixed at least in the distal section of distal sleeve 6, e.g. by welding ….” Ex. 1008, p. 5, (emphasis added). Hence, Dlugos explicitly teaches engaging the balloon to the shaft by welding at a second region.
1.3	the balloon having an uninflated state and an inflated state,	As discussed above, an uninflated, folded state and an inflated, unfolded state are inherent in the balloon catheter of Dlugos. In addition, to the extent an express disclosure is deemed necessary, Hijlkema expressly references and illustrates the uninflated, folded state and the inflated state of the balloon catheter. Ex. 1009, 3:66-4:24, compare Figs. 3 (inflated) and 5 (uninflated).  FIG.3

	Claim Language	Dlugos and Hijlkema
		
1.4	the balloon having at least one fold extending from the first weld region to the second weld region in the uninflated state and	Dlugos teaches that folds 7 run from the distal sleeve 6 to a proximal sleeve 5: "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 (Dlugos), p. 4. As discussed above, the proximal sleeve of Dlugos includes a first weld region (see claim element 1.2(b), above) and the distal sleeve of Dlugos includes a second weld region (see claim element 1.2(d), above). Note that this is not the embodiment of Dlugos figure 2, in which the ends of the folds are not visible. Rather, this is the alternative embodiment in which Dlugos expressly teaches that the proximal ends of the folds are welded in the proximal sleeve area: "Although 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 herein-

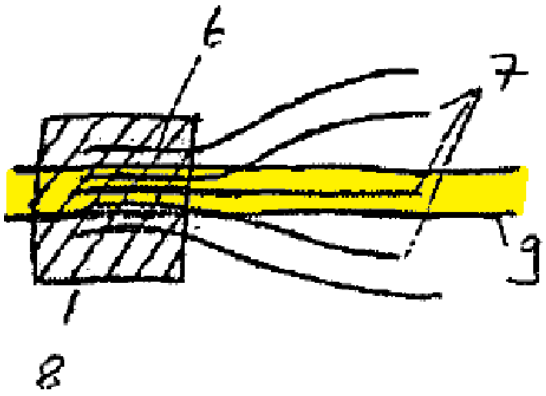
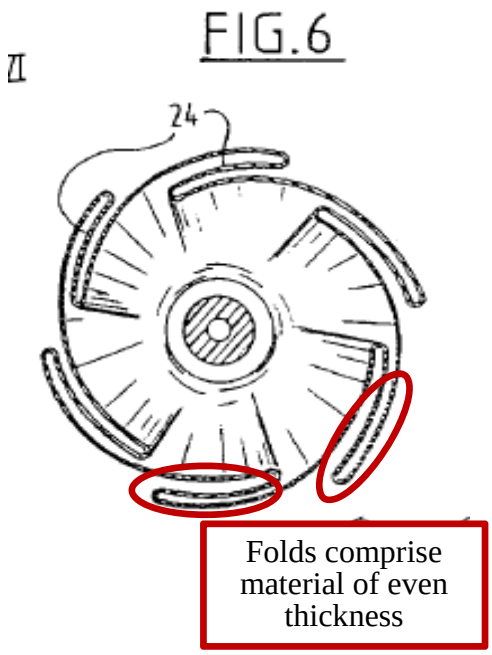
	Claim Language	Dlugos and Hijlkema
		before." *Id.* at 5. Dlugos further describes that "it is also possible to fold the entire balloon after having formed the balloon body, the transitional sections and the sleeves, so that the folds extend from the sleeves into the transitional section and body of the balloon." *Id.* at 2 (emphasis added). A person of skill in the art would have understood Dlugos here to disclose folds running the entire length of the balloon from the first end—the distal sleeve—to the second end—the proximal sleeve. Ex. 1005, ¶118, 191. In addition, to the extent a further disclosure is deemed necessary, Hijlkema explicitly discloses that each of the folds 24 of figure 5 extends continuously from end to end.
1.5	the first and second cone regions of the balloon having at least one fold in the fully inflated state.	Dlugos teaches and shows in figure 3 that the folds 7 are "fixed at least in the distal section of the distal sleeve 6" (Ex. 1008, p. 5) and that "it is also possible to fix the [same] folds 7 running into proximal sleeve 5 in the same manner as described herein-before" for the distal section (*id.*). In other words, Dlugos teaches pinning down the folds with welds at each end of the balloon. During prosecution, the examiner noted that if a fold existed under a weld at one end of the balloon, then necessarily that fold would persist in the

	Claim Language	Dlugos and Hijlkema
		transition or cone region to some degree even when the balloon was fully inflated. Ex. 1002, pp. 51-52 (3/25/2010 Final Rejection). Applicant never disputed the point. U.S. Patent 5,049,131, cited in Dlugos, illustrates the exact same phenomenon. Ex. 1018, 2:29-49; Ex. 1008, Fig. 2. Indeed, the POSITA 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. Ex. 1005, ¶¶119, 120. To the extent an additional express disclosure is deemed necessary, Hijlkema plainly shows that the folding ridges 22 in the material of the balloon remain even in the inflated state. Ex. 1009, Fig. 3.  FIG.3

	Claim Language	Dlugos and Hijlkema
2.0	The balloon catheter of claim 1,	As discussed above, Dlugos and Hijlkema each disclose a balloon catheter. Dlugos in combination with Hijlkema renders claim 1 obvious.
2.1	the at least one shaft comprising an outer shaft and an inner shaft,	Dlugos expressly discloses an "inner tube (guide wire tube)." Ex. 1008, p. 3. The POSITA, reading a description of a balloon catheter having an "inner tube" would understand that Dlugos was referring to a common balloon catheter design in which the catheter is a coaxial catheter. Ex. 1005, ¶132. In a coaxial catheter, the catheter includes at least two tubes, an inner tube and an outer tube. The inner tube is typically threaded over the guide wire used to direct the catheter to the treatment site. The outer tube provides a passage for the fluid used to inflate the balloon. *Id.* Not only was this design well known in the field, it is exactly the balloon catheter described in references Dlugos discusses as background. U.S. Patent No. 5,049,131, for example, describes the typical catheter as having a first tubular body for inflating the balloon, and a second tubular body, the "coaxial inner tube," that serves as the passage for a flexible guide wire. Ex. 1018, 2:13-32; 3:17. Thus, the person of skill in the art would understand that Dlugos, with its express references to the "inner tube (guide tube)," incorporated a coaxial catheter having an outer tube in addition to the inner tube.

	Claim Language	Dlugos and Hijlkema
		To the extent an additional express disclosure is deemed necessary, Hijlkema expressly teaches an outer tube and an inner tube, referred to as "outer shaft 3" and "inner shaft 4," plainly visible in figure 5. Ex. 1009, 3:4-11; Fig. 1.  Figure 5 (partial)
2.2	the first weld region engaging the balloon to a portion of the outer shaft and	As discussed above, the welding/fixing portion of the proximal sleeve of Dlugos constitutes a first weld region (see claim element 1.2(b), above). Dlugos does not discuss engaging the proximal sleeve to an outer shaft of the catheter, expressly. Rather, Dlugos simply states that the inner tube should always be fixed to the distal sleeve, i.e., the second weld region, and that the inner tube should not be fixed to the proximal sleeve, as this would prevent inflation of the balloon. If the proximal sleeve, i.e., the first weld region, cannot be engaged to the inner tube, then in the alternative embodiment in which both the distal

	Claim Language	Dlugos and Hijlkema
		and proximal ends of the balloon are fixed, the proximal sleeve must be fixed to the outer tube. Ex. 1005, ¶118. To the extent an additional express disclosure is deemed necessary, Hijlkema expressly teaches "[t]he relatively proximal end section 12 of the balloon member 9 is connected with the end of the outer tube-like element 3." Ex. 1009, 4:13-17. Hijlkema does not expressly disclose welding, but rather, simply leaves the manner of engaging the balloon to the catheter to the reader's discretion. As noted above, Dlugos teaches using welding for such connections and one of skill in the art would consider this the conventional approach for such a connection. Ex. 1005, ¶118. It would therefore have been obvious to a person of skill in the art to engage the distal end of the balloon of Hijlkema to the inner tube of Hijlkema by welding.
2.3	the second weld region engaging the balloon to a portion of the inner shaft.	As discussed above (see claim element 1.2(d)), the welding/fixing portion of the distal sleeve of Dlugos constitutes a second weld region. Dlugos expressly teaches welding the distal sleeve 6 to the inner tube 9 of the catheter at the welding/fixing portion 8. Ex. 1008, p. 3, Fig. 3.

	Claim Language	Dlugos and Hijlkema
		 Fig. 3
4.0	The balloon catheter of claim 1,	As discussed above, Dlugos and Hijlkema each disclose a balloon catheter. Dlugos and Hijlkema render claim 1 obvious.
	the at least one fold being a plurality of folds, the plurality of folds having even material thickness.	Hijlkema teaches multiple folds 24, in which the material that comprises each fold has an even thickness, as shown in figure 6 of that patent. Ex. 1009, Fig. 6.  A POSITA would have been motivated to construct the balloon catheter of Dlugos with folds of even material thickness as taught by

	Claim Language	Dlugos and Hijlkema
		Hijlkema. Ex. 1005, ¶¶126, 138. Both Dlugos and Hijlkema are concerned with folding the balloon to reduce the profile. Ex. 1008 (Dlugos), pp. 1-2; Ex. 1009 (Hijlkema), 1:36-39. The even material thickness of Hijlkema provides a consistent diameter at different rotations about the balloon, without bumps or bulges, contributing to a smaller profile. Ex. 1005, ¶127, 149. A POSITA would have been motivated to use the even material thickness disclosed in Hijlkema with Dlugos to achieve the same low profile benefit. *Id.*

B. Ground 2: Claim 3 is Unpatentable as Obvious over Dlugos in View of Hijlkema and Konstantino

Claim 3, dependent upon claim 1, recites the added element: "the at least one fold being a plurality of folds, each of the plurality of folds having a first end and a second end, radially adjacent ends being overlapping." The '767 patent identifies "radially adjacent ends being overlapping" as the boxed area in figure 5 of the patent, in which the ends 113 of the two folds 112 overlap. 10:12-15.

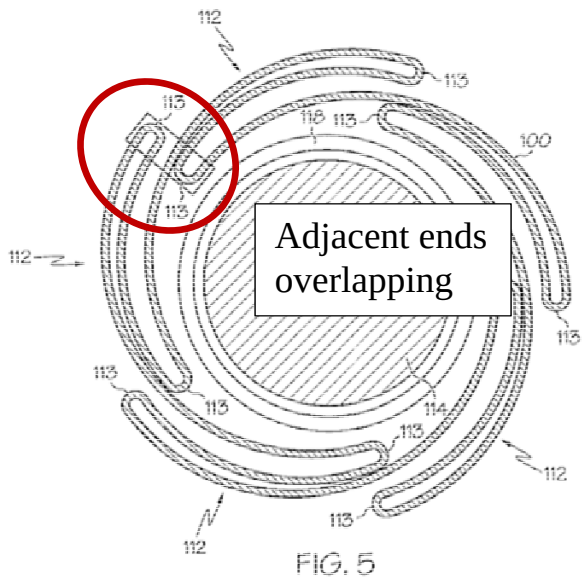


FIG. 5

Like Dlugos and Hijlkema, Konstantino (US 2005/177130) discloses a balloon catheter for use in the vascular system. The balloon has a compressed or folded configuration and an expanded configuration. To minimize the profile of the balloon in the compressed configuration, Konstantino teaches folding the balloon along helical fold lines that run the full length of the balloon, as shown in Figure 4. Ex. 1010, ¶0009, Abstract.

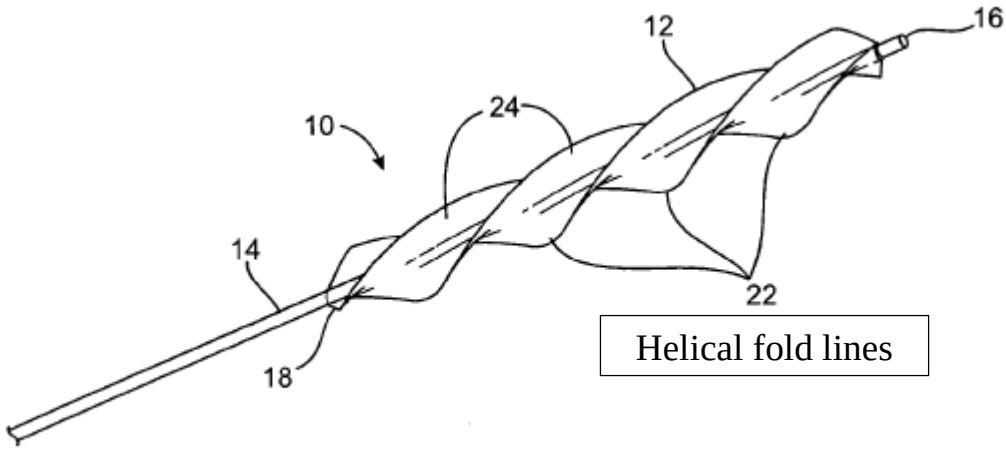


FIG. 4

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. *Id.* 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. Figure 6 of Konstantino, in other words, depicts exactly the same feature as shown in figure 5 of the ’767 patent and recited in claim 3.

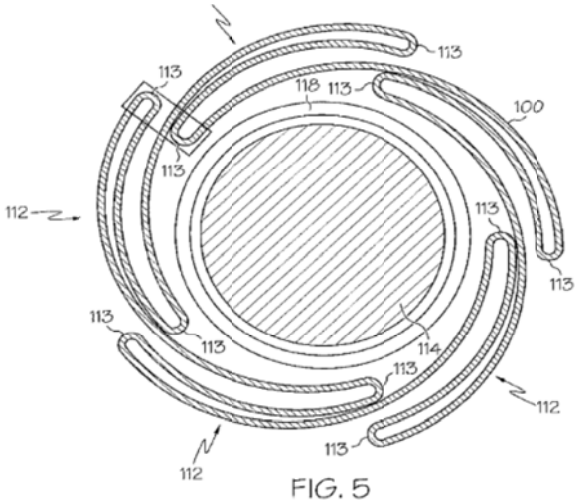


FIG. 5

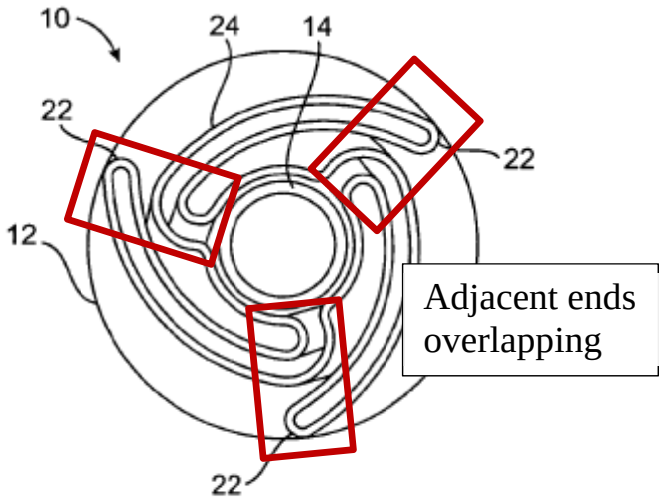


FIG. 6

One of skill in the art would have considered constructing the balloon catheter taught by Dlugos and Hijlkema with folds configured as shown by Konstantino. Hijlkema and Dlugos describe similar balloon catheters in which the balloon is designed to be folded so as to have a low profile. Compare, Ex. 1008 (Dlugos), p. 2 (describing balloon catheter) and Ex. 1009 (Hijlkema), 1:36-38; Ex. 1005, ¶144. Konstantino describes a balloon catheter with a balloon designed to be folded so as to minimize the balloon profile in its uninflated state. Ex. 1010, ¶¶0054-0055. Hijlkema specifically seeks to obtain helical folds through the use of the helical folding ridges in the transition sections of the balloon. Ex. 1009, 4:32-35. Konstantino suggests helical folds (or flaps) formed along helical fold lines that transit the entire length of the balloon. Ex. 1010, ¶¶0054-0055. All three

references describe balloon catheters that are also designed to be inflated within stenotic regions of the body, and therefore, are designed to expand at specified times in a predictable and safe manner. Ex. 1008 (Dlugos), pp. 1-2; Ex. 1009 (Hijlkema), 1:35-38; 2:20-26; Ex. 1010 (Konstantino), ¶0061. A POSITA therefore 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. Ex. 1005 at ¶144. Accordingly, claim 3 is obvious.

C. Ground 3: Claim 5 is Unpatentable over Dlugos or over Dlugos in Light of Eskaros

The second independent claim of the ’767 patent, claim 5, is directed to a method of making a balloon catheter. The method involves forming a fold in a balloon cylinder that extends from one end of the balloon to the other and then welding the folded balloon to a catheter shaft.

Claim 5 requires a “balloon cylinder.” As discussed above, one of skill in the art would understand “balloon cylinder” in the context of the ’767 patent to include balloons preformed with transitions between wider portions and narrower sleeves or necks. Interpreting “balloon cylinder” in this fashion, Dlugos meets every limitation of claim 5 and renders claim 5 invalid. If, however, the Board reads “balloon cylinder” as implying a constant diameter balloon, rather than one

in which the balloon narrows to necks or sleeves on each end, claim 5 is invalid as obvious over Dlugos in combination with Eskaros.

Eskaros (US 2008/0097300) discloses a method of making balloon catheters starting from a "tubular structure of balloon material," i.e., a tube of essentially constant diameter. Ex. 1011, ¶¶0018, 0033 (balloon is a tube measuring 4 mm x 40 mm). Longitudinal or helical "Micropleats" are formed in the surface of the balloon, each micropleat having at least one fold. The micropleats reduce the balloon profile and store the balloon material until the balloon is inflated. *Id.* at ¶0016.

One of skill in the art would be motivated to apply the teachings of Dlugos with the tubular structure balloon of Eskaros. Like the '767 patent and Dlugos, Eskaros is directed to techniques for creating a balloon catheter that has a low profile, permitting it to be inserted through a smaller diameter introducer sheath. *Id.* at ¶¶0002-0003, 0017-0018.) And like both the '767 patent and Dlugos, Eskaros pursues that goal through precise folding of the balloon followed by affixing the balloon to a catheter shaft. *Id.* at ¶¶0021, 0033.

Dlugos discloses that the balloon is molded to have a balloon body, transition sections, and sleeves. Ex. 1008, p. 2. Dlugos also discloses one embodiment in which folds extend for the entire length of the balloon, including the transition sections and sleeves. *Id.*

A POSITA would have been aware that to blow mold a balloon to a preformed shape with narrower sleeves on either end, it would be necessary to stretch the material in the central region of the balloon more than in the transition and sleeve regions and that this will result in the transition sections and sleeves retaining thicker material. Ex. 1005, ¶¶127, 149. The relatively thicker material made it difficult to fold the transition region and end region. *Id.* Eskaros discloses that it is possible to start with a balloon formed to have transition sections and sleeves, or start with a cylindrical tube with no transition region and end region. See Ex. 1011, ¶0018. A POSITA would have recognized that starting with a balloon molded to a constant diameter, such as the one disclosed in Eskaros, would provide a balloon that could fold easily along its entire length. Ex. 1005, ¶149. A POSITA would therefore have been motivated to begin with the constant diameter cylinder disclosed in Eskaros to more easily "fold the entire balloon," as suggested in Dlugos. *Id.* (emphasis added). 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. *Id.*

As shown below, Dlugos alone or Dlugos in combination with Eskaros teaches the method of claim 5 of the '767 patent.

	Claim Language	Dlugos in view of Eskaros
5.0	A method for making a balloon catheter comprising:	Dlugos teaches a method of producing the balloon of a balloon catheter and mounting that balloon to the catheter. Ex. 1008, pp. 1, 2, 4. Eskaros' Example 1 teaches manufacturing a balloon and mounting that balloon to a catheter to form a balloon catheter. Ex. 1011, ¶¶0029-0036.
5.1	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;	Dlugos discloses providing a balloon cylinder with a first (proximal) end and a second (distal) end separated by the longitudinal length of the balloon body 2: > According to the first step of the method … represented by the schematically simplified depiction of Fig. 1, a balloon 1 of a catheter according to the present invention is produced … usually carried out in a forming mould forming a balloon body 2 of a usual cylindrical shape, the two transitional sections 3 and 4, a proximal sleeve 5 [first end] and a distal sleeve 6 [second end] being connected to the respective transitional sections 3 and 4, respectively. Ex 1008, pp 2, 4.

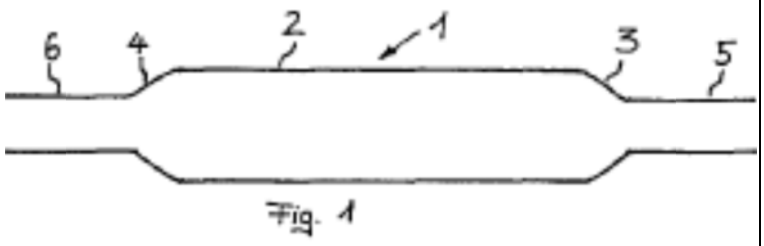


Fig. 1

Id., at Fig. 1.

Eskaros teaches that "micropleats may be arranged on a formed balloon 2 or on a tubular structure of balloon material" having a first end separated by a longitudinal length from the second end. Ex. 1011, ¶0018 (emphasis added); see also, *id.*, Figs. 5, 7.

> As shown in FIG. 5, an uninflated balloon may be adhered to a catheter shaft 14…. A compressive radial force is then applied to the inflated outer diameter of the balloon to cause deflation of the balloon and create longitudinal folds in the balloon material 4."

Id. at ¶0019. Further, Eskaros figures 5 and 7 show balloon material 4 and 2 respectively that is a tubular structure with no formed cone regions.

Fig. 5:

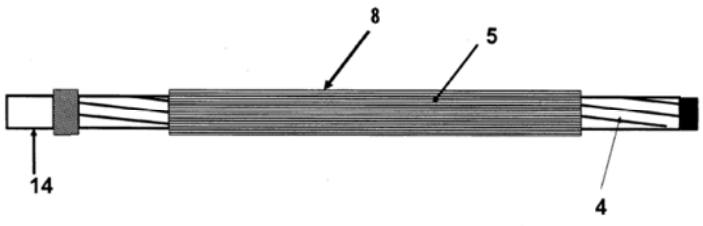
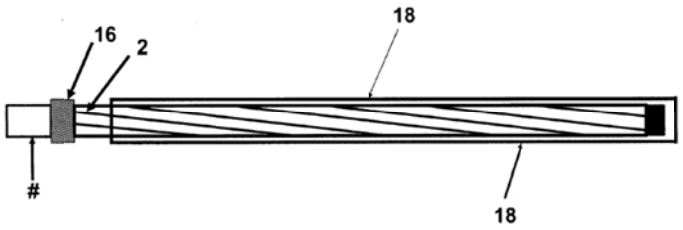
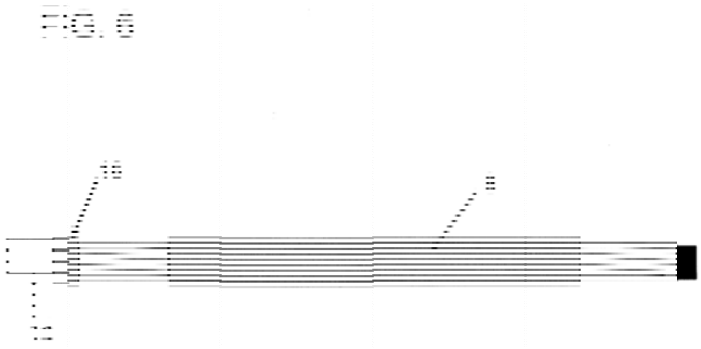
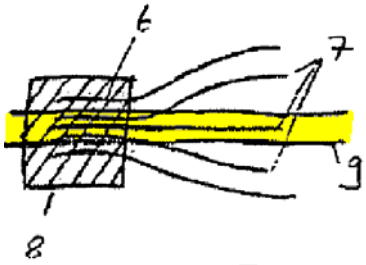


		Fig. 7: 
5.2	providing a catheter comprising at least one shaft;	Dlugos teaches a catheter having an "inner tube (guide tube)," as shown in figure 3. Ex. 1008, p. 3. Eskaros teaches providing a catheter shaft 14 and balloon is sealed on the shaft at 16. Ex. 1011, ¶0019, Fig. 6. 
5.3	incorporating at least one fold, the at least one fold extending from the first end to the second end of the balloon cylinder; and	Dlugos teaches folds that run the full length of the balloon, from the distal sleeve to proximal sleeve: "balloon 1 is folded thus 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." Ex. 1008, p. 4; see Ground 1, claim element 1.4, above.

5.4	welding the balloon cylinder with the at least one fold to the at least one shaft of the catheter.	Dlugos teaches that in the third step of manufacturing the disclosed balloon catheter, the distal sleeve of the balloon, containing the folds created in the second step, is fixed to the inner tube of the catheter by welding. Úsually, a balloon manufactured according to the method of the present invention is provided with an inner tube (guide wire tube), the distal section of the distal sleeve is fixed to. Ex. 1008, p. 3. In the last method step, depicted in Fig. 3, the folds 7 are fixed at least in the distal section of distal sleeve 6, e.g., by welding … *Id.* at 5. Figure 3 shows the balloon with folds 7 under a welding/fixing portion 8 that fixes the balloon to the shaft 9.  Fig. 3

D. Ground 4: Claim 7 is Unpatentable as Obvious over Dlugos in View of Eskaros and Konstantino

Claim 7 depends from claim 5 and adds the limitation that there be a plurality of folds, "each of the plurality of folds having a first end and a second end, radially adjacent ends being overlapping." Claim 7 is thus virtually identical

to claim 3. As discussed above under Ground 2, a POSITA would have been motivated to apply the radially overlapping ends of the balloon folds taught by Konstantino to the balloon catheter forming method of Dlugos. Dlugos in view of Eskaros and Konstantino therefore renders claim 7 obvious.

E. Ground 5: Claim 8 is Unpatentable as Obvious over Dlugos in View of Eskaros and Hijlkema

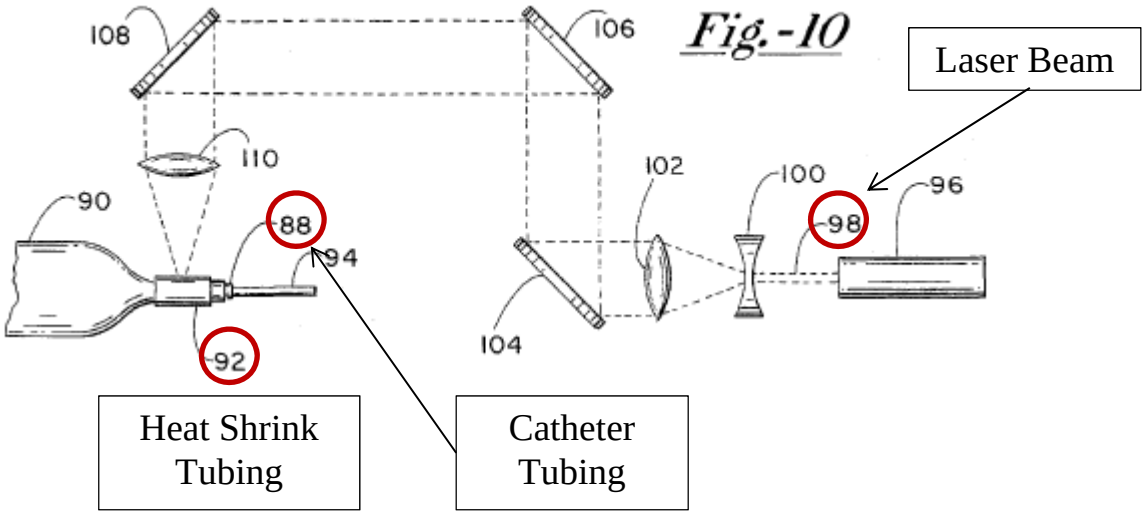
Claim 8 depends from claim 5 and adds the limitation that there be a "plurality of folds having even material thickness." Claim 8 is therefore virtually identical to claim 4. As discussed above under Ground 1, a POSITA would have been motivated to apply the even thickness of the balloon folds taught by Hijlkema to the balloon catheter forming method of Dlugos. See pp. 45-46, above.

F. Ground 6: Claims 6, 14, and 16 are Unpatentable as Obvious over Dlugos and Hijlkema or Dlugos and Eskaros in View of Forman

1. Forman

Claims 6, 14, and 16 depend from claim 5 and relate generally to the use of heat shrink material and a laser to weld a balloon to a catheter shaft. Forman (U.S. Patent No. 5,501,759) teaches methods for manufacturing balloon catheters, such as those of Dlugos, Hijlkema, and Eskaros, using laser welding to affix the ends of the balloon to the catheter. Specifically, 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. Ex. 1012, 7:4-10, 8:18-30 (discussing alternative means for concentrating laser energy to the bonding site), Fig. 10.



The balloon catheters described in Forman are similar in design and application to those of Dlugos, Hijlkema, and Eskaros, as well as the '767 patent. Further, Forman shares goals with the cited prior art and the '767 patent. The '767 patent, Dlugos, Hijlkema and Eskaros all refer to minimizing the profile or diameter of the uninflated balloon catheter, in order that it can more readily pass through the constricted space of a vascular lumen to the treatment location. Forman is directed to making "a balloon catheter more maneuverable along arteries." *Id.* at 2:38-43. Among the goals of the '767 patent, in particular, was the formation of robust seals between the catheter and the balloon. 1:37-43, 61-66. Foreman also wanted to solve this problem; "[a] further object is to provide balloon catheters with proximal and distal fusion bonds [that is laser welding] that

are narrow, yet able to withstand high burst pressures. 1:12-67, 2:38-40. As noted above, Dlugos specifically refers to welding as one technique for securing the folds of the balloon and such an approach would be equally appropriate for Hijlkema or Eskaros. Dlugos does not, however, describe the welding process in detail. This would have led the POSITA to identify suitable welding techniques and therefore, to consider the laser welding techniques of Forman. As Forman disclosed an improved means for forming a fluid tight seal between balloon and catheter (Ex. 1012, 1:12-67, 2:38-40), the POSITA would have been motivated to apply the Forman laser welding to the balloon catheter designs of Dlugos, Hijlkema and Eskaros to obtain a reduced profile balloon catheter with robust seals between the balloon and the catheter. Ex. 1005, ¶¶157, 179.

Moreover, Forman himself is considered one of the leading authorities on laser welding. His patents for laser welding are often cited by people in the industry making balloon catheters and a POSITA would have been well aware of Forman's techniques before 2008. Ex. 1005, ¶158. Thus, it would have been common sense for a POSITA to try applying Forman's laser welding approach to the balloon catheter of Dlugos.

2. Claim 6

Claim 6 specifically requires that "a laser is used to weld the balloon cylinder to the catheter." As discussed above, independent claim 5 is invalid over

Dlugos or the combination of Dlugos with Eskaros. Because Forman teaches laser welding of the balloon to the catheter, Forman, in combination with the art that invalidates claim 5, renders claim 6 obvious.

3. Claim 14

Claim 14 reads:

> 14. The method of claim 5, further comprising
>
> providing at least one section of heat shrink material;
>
> disposing the at least one section of heat shrink material about at least a portion of the balloon cylinder; and
>
> pre-shrinking the section of heat shrink material.

It is clear from Forman that the limitations of claim 14 were well known in the art. In discussing the background to his own invention, Forman states:

> For example, U.S. Pat. No. 4,251,305 (Becker et al) discloses a non-contact method for sealing a balloon onto a catheter. A length of thin tubing [the balloon] is slid over an elongated shaft of the catheter. Shrink tubing is installed over the thin walled tubing at its ends, and overlapping the shaft, and partially shrunk. Then lamps provide further radiant energy to form gradually tapering thermoplastic joints that bond the tubing and shaft.

Ex. 1012 (Forman), 2:11-14. Here, Forman discloses a section of heat shrink material that is placed about a portion of the balloon cylinder (the thin tubing) and pre-shrunk, exactly meeting the limitations of claim 14. Accordingly, Forman in combination with the art that invalidates claim 5 renders claim 14 obvious.

4. Claim 16

Claim 16 depends on claim 14 and further requires:

> the at least one section of heat shrink material comprising a first section and a second section, the balloon cylinder comprising a first weld region and a second weld region, the first section of heat shrink material being disposed about the first weld region and the second section of heat shrink material being disposed about the second weld region.

In other words, claim 16 requires that both ends of the balloon be treated with the heat shrink tubing.

In its summary of the Becker patent, Forman refers to installing heat shrink tubing over the thin walled tubing "at its ends," i.e., at both the first and second end of the balloon. These areas are then first partially shrunk and then further heated to form thermoplastic bonds—i.e., the ends become weld regions.

The disclosure of Forman's work (as opposed to discussions of background) similarly confirm that heat shrink tubing will be used over weld regions at each end of the balloon. Forman discusses the use of heat shrink material around the

distal shaft in detail. See, e.g., *id.* at 6:51-54 ("As seen from FIG. 7, heat shrink tubing 64 surrounds distal shaft 68 ..."); see also Fig. 7. Forman explains that the same process can be used to form the proximal bond as well. Forman at 9:13-16 ("While only the distal bond is discussed in detail, it is to be appreciated that forming a proximal bond between the proximal shaft of the dilatation balloon and catheter tubing is substantially the same.")

A POSITA would have been motivated to use heat shrink material on both ends of the balloon. Accordingly, claim 16 adds nothing patentable and should also be found obvious.

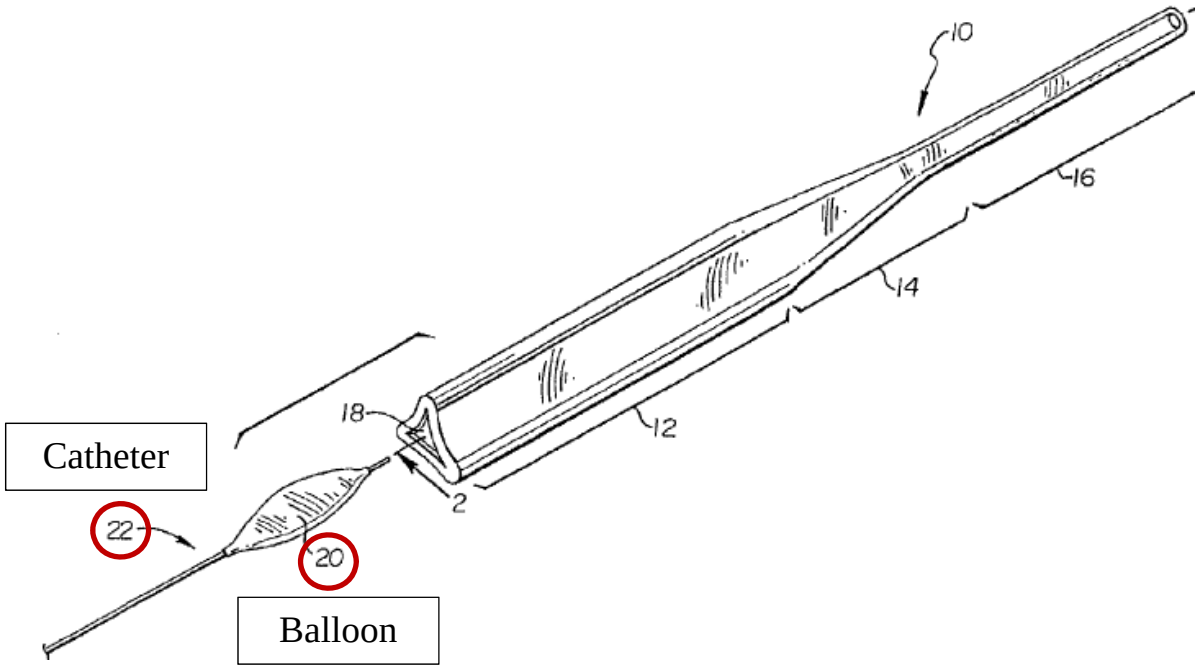
G. Ground 7: Claims 9, 10 and 12 are Unpatentable as Obvious over Dlugos in View of Eskaros and Traxler

1. Traxler

Claims 9, 10, and 12 depend from claim 5 and generally refer to disposing the balloon around the catheter shaft, a mandrel, or both. The additional limitations of these dependent claims, however, are taught by Traxler (U.S. 2001/0047149) and therefore add nothing to patentability.

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.



A person of ordinary skill would have been motivated to apply the balloon wrapping tool and methodology taught by Traxler to the balloon catheters of Dlugos and Eskaros to result in a balloon catheter that, in its unexpanded configuration, has a less bulky profile. Attaining a more compressed, smaller uninflated balloon is an express goal of all three references; it is also an express goal of the '767 patent. Furthermore, the Traxler tool and methodology is universal in its application: it applies equally to any foldable balloon on a catheter

shaft. One would therefore expect the combination of the Traxler balloon wrapping tool and methodology with the balloon catheters of Dlugos and Eskaros not only to be feasible, but to be successful. Ex. 1005, ¶174.

2. Claim 9

Claim 9 provides:

> The method of claim 5, wherein the balloon cylinder is disposed about the at least one shaft when incorporating the at least one fold.

Dlugos or the combination of Dlugos and Eskaros meet the limitations of claim 5. Traxler specifically teaches that the balloon is disposed about the catheter shaft while the balloon is folded, as it is the advancement of the catheter through the balloon wrapping tool that causes the increased compression of the folds. Ex. 1013, ¶0042 ("To facilitate advancement of the catheter through the balloon wrapping tool …."), ¶0043 ("The balloon wrapping tool is advanced proximally, relative to the catheter 20 [sic 22], until the balloon 20 is in the final wrapping section …"). Traxler therefore meets the limitations of claim 9, and in combination with Dlugos or Dlugos and Eskaros, renders claim 9 obvious.

3. Claims 10 and 12

Claim 10 adds to claim 9 the use of a mandrel:

> 10. The method of claim 9, further comprising providing a mandrel, the balloon cylinder being disposed about the

> at least one shaft which is disposed about the mandrel when incorporating the at least one fold.

Claim 12 similarly requires the use of a mandrel but only as a dependent claim to claim 5.

> 12. The method of claim 5, further comprising providing a mandrel, the balloon cylinder being disposed about the mandrel while incorporating the at least one fold.

As noted above, Traxler expressly teaches loading the catheter shaft onto a mandrel or guide wire in preparation for the folding operation.

> [T]o facilitate the advancement of the catheter through the balloon wrapping tool 10, it is contemplated that a mandrel or guidewire may first be positioned through the balloon wrapping tool 10, and the catheter may be back-loaded over the mandrel. The mandrel provides additional column support to the catheter thereby increasing pushability of the catheter.

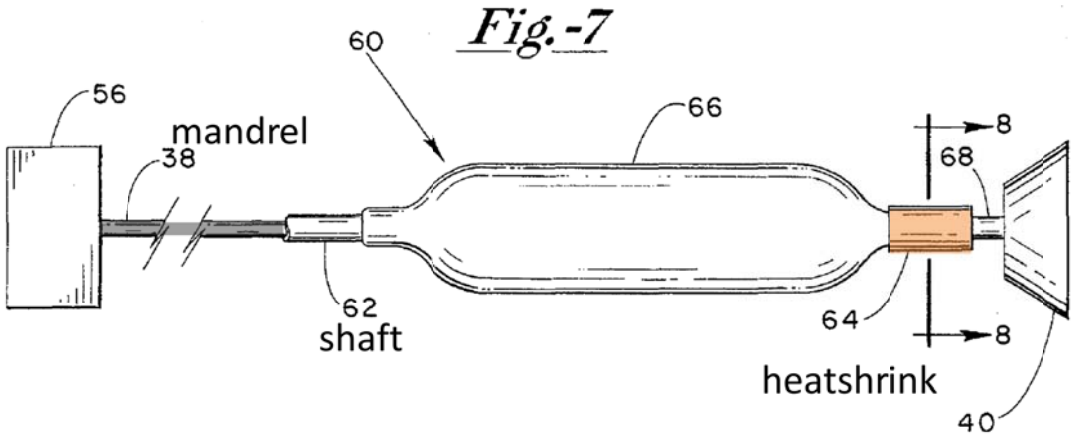
Id. at ¶0042; see also *id.* at ¶0043 ("The balloon wrapping tool is advanced proximally, relative to the catheter 20 [sic 22], until the balloon 20 is in the final wrapping section …"). Neither claim 10 nor claim 12, therefore, adds anything to the prior art. Both should be found obvious.

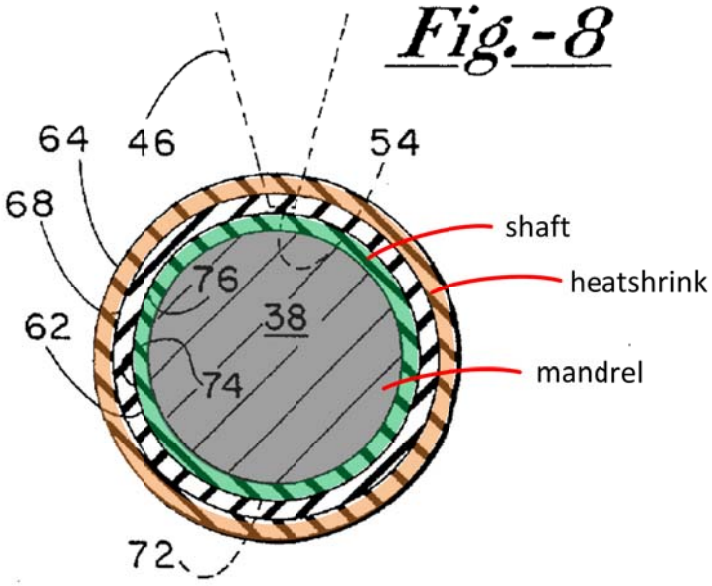
H. Ground 8: Claim 11 Is Unpatentable as Obvious over Dlugos and Eskaros in Light of Traxler and Forman

Claim 11 reads: "The 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." As noted above, the parent independent claim, claim 5, is unpatentable over Dlugos and Eskaros and the additional limitations of claim 10 are met by Traxler. The use of a mandrel in the catheter shaft while the balloon cylinder is being welded to the shaft is plainly disclosed in Forman. Claim 11 is therefore obvious.

As discussed above, Forman teaches laser welding in the manufacturing of a balloon catheter. In particular, Forman describes inserting a mandrel inside a shaft of a balloon catheter when welding the balloon cylinder to the catheter shaft, stating, "[t]he assembly of a balloon catheter 60 begins with the placement of a length of catheter tubing 62 onto the mandril, … Then, a dilatation balloon 66 is fit onto and about the catheter tubing…." Ex. 1012, 6:37-51 (emphasis added). "With the catheter tubing, dilatation balloon and heat shrink tubing properly positioned and with the laser system properly aligned, laser source 44 is fired to generate beam 46 while mandril 38 is rotated." *Id.* 7:1-9.

Annotated figures 7 and 8 illustrate the process.





Ex. 1012 (Forman), Figs. 7, 8.

As noted above (Ground 6), a person of skill in the art would have been motivated to use the laser welding manufacturing process of Forman in the fabrication of the balloon catheters of Dlugos and Eskaros to result in a balloon catheter that could be folded into a small uninflated state while having robust seals

between the balloon and the catheter shaft. The Traxler balloon wrapping tool could just as easily be applied to a balloon catheter manufactured as described in Forman as any other balloon catheter. The person of skill in the art would, therefore, readily combine these references to solve the problem of creating a robust balloon catheter with a small uninflated state.

I. Ground 9: Claim 17 is Unpatentable as Obvious over Dlugos and Eskaros in View of Forman and Becker

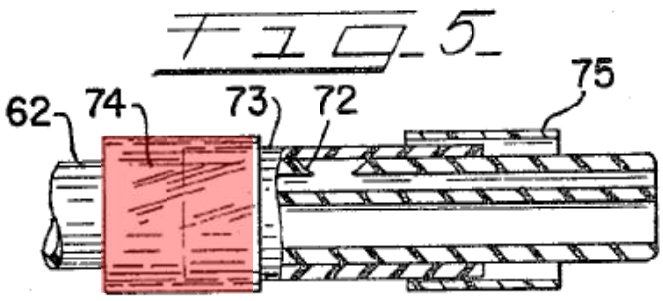
Claim 17 depends from claim 14. As discussed in Ground 6, above, claim 14 is obvious over Dlugos or Dlugos and Eskaros, in view of Forman. Claim 14 provides:

> 14. The method of claim 5, further comprising
> providing at least one section of heat shrink material;
> disposing the at least one section of heat shrink material about at least a portion of the balloon cylinder; and
> pre-shrinking the section of heat shrink material.

Claim 17 adds to claim 14 the limitation that "pre-shrinking the section of heat shrink material presses the balloon cylinder onto the at least one shaft of the catheter."

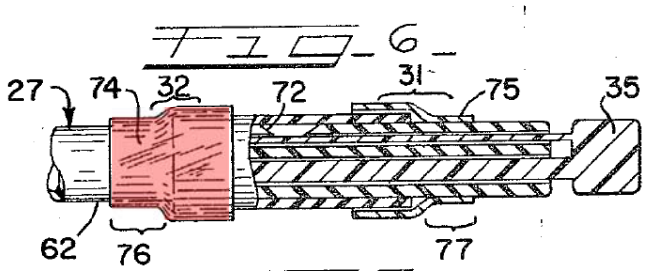
Becker (U.S. Patent 4,251,305) described—in 1981!—a problem in the prior art with seals and other weak points on the catheter balloon due to various welding and sealing methods. Becker's solution was "the use of shrink tubing to hold the balloon in place and simultaneously assist in shaping smooth seals, which method

includes preshrinking the shrink tubing into place." Ex. 1014, 2:16-23. Figure 5 shows the heat shrink tubing 74 and 75 placed on the two ends of the balloon 65 disposed about the catheter 62.



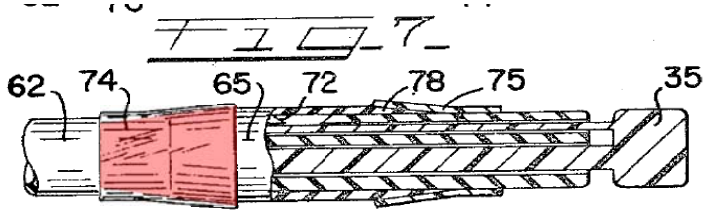
Id. at Fig. 5.

> FIG. 6 illustrates the step of preshrinking the shrink tubing 74, 75, …. Basically, each length of tubing 74, 75 is subjected to an environment including an elevated temperature at which tubing 74, 75 will partially shrink in diameter, …. This preshrinking step has a major objective of removing these gaps between the elongated shaft 62 and the shrink tubing 74, 75.



Id. at 5:40-68, Fig. 6.

Then, the heat shrink tubing is further shrunk and "the tubing 73 and shaft 62 are subjected to a temperature in their thermoplastic melting ranges whereby the tubing 73 is softened, shaped, and thermoplastically bonded to the softened shaft 62 into a smooth and gradually tapering …." *Id.* at 6:1-21. The result is shown in figure 7.



By the 2008 filing date of the '767 patent, the concepts set forth in Becker were well known manufacturing techniques. Ex. 1005, ¶¶103, 182. A person of skill in the art would frequently deploy heat shrink material around at least a portion of the balloon cylinder during the process in which the balloon cylinder was welded to the catheter shaft. A POSITA would have the used this heat shrink material to: 1) compress the balloon against the shaft and eliminate unwanted air pockets before joining the ends of the balloon to the shaft through methods such as welding, and/or 2) compress the folds along the balloon in order to reduce the profile of the balloon and facilitate insertion and removal of the balloon into vasculature. Ex. 1005 ¶¶ 185, 186. A POSITA would have been motivated to use

the pre-shrinking method Becker disclosed to achieve the same benefit when constructing the balloon catheter of Dlugos. *Id.*

Becker demonstrates that the pre-shrinking step required by claim 17 is not new with the '767 patent, but rather, pre-dates the '767 patent by a quarter century. Claim 17 is therefore obvious.

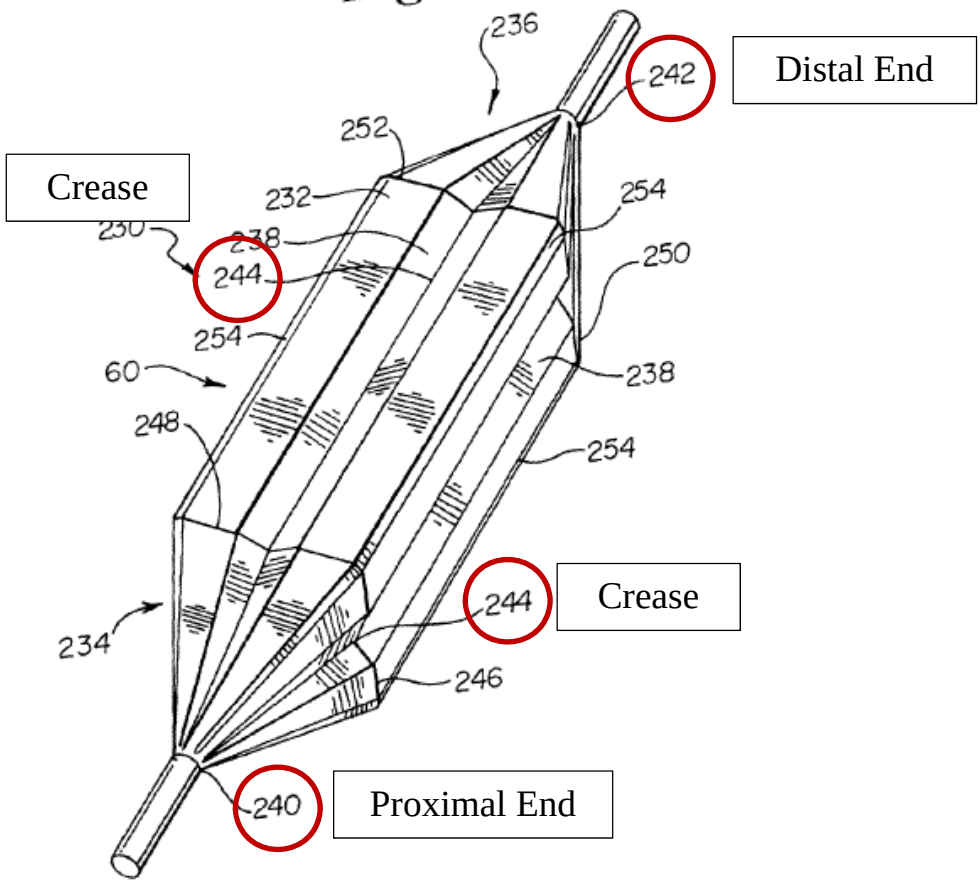
J. Ground 10: Claim 1 is Unpatentable as Obvious over Dlugos in View of Bampos

As discussed above, Dlugos teaches every element of claim 1. To the extent, however, that the Board concludes that Dlugos fails adequately to teach "the balloon having at least one fold extending from the first weld region to the second weld region in the uninflated state" (element 1.4), Petitioner submits that the combination of Dlugos with Bampos (U.S. Patent No. 6,013,055) plainly teaches one of skill in the art exactly this feature. Dlugos in view of Bampos therefore renders claim 1 obvious.

Bampos discloses "a balloon catheter and method of manufacture." The balloon catheter in Bampos has the same structure as virtually every reference discussed above: a balloon 10; a shaft 18; the shaft ends in a distal tip 16; the distal end 14 of the balloon is mounted to the shaft at the distal tip 16; the proximal end 12 of the balloon is mounted to the shaft 18; the balloon has an inflated and an uninflated configuration. Ex. 1015, 5:50-65.

Bampos offers several embodiments. Perhaps the most relevant is the fourth alternative embodiment, shown in figure 16. In this figure, the balloon 230, has proximal and distal transition regions. "Triangular indentations 238 extend from proximal end 240 to distal end 242. Triangular indentations 238 each have one of creases 244." The creases "extend[] from proximal end 240 to distal end 242." *Id.* at 10:24-36. These creases assist in the deflation of the balloon from the expanded state to the deflated state.

Fig. 16



A POSITA would have been motivated to modify the balloon catheter Dlugos with the folding scheme of Bampos. Both references are directed to the same problem the '767 patent confronts: how best to minimize the profile of a balloon catheter that must be navigated to a particular point in the circulatory system. Ex. 1005, ¶191; Ex. 1008 (Dlugos), p. 2; Ex. 1015 (Bampos), 2:34-51. Both Dlugos and Bampos describe preforming the balloon, using molds. Ex. 1008, p. 4; Ex. 1015, 8:6-38; 9:8-30. Moreover, while a POSITA would recognize that Dlugos describes folds that can extend from the weld in the distal sleeve to a weld in the proximal sleeve, Dlugos does not mandate any particular technique for forming the folds. The balloon walls of the transition portion of a blow molded balloon are likely to be thicker and therefore stiffer than the central portion balloon walls. Ex. 1005, ¶191. This stiffer material is more challenging to fold. *Id.* A POSITA implementing the design of Dlugos would therefore be motivated to look for and apply folding teachings from references such as Bampos. That person would then 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. Bampos therefore teaches the longitudinal folds extending from one weld region to the other, as required by element 1.4 of claim 1.

VI. REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Ground for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that (1) the ’767 patent is available for IPR; (2) Petitioner is not barred or estopped from requesting IPR of the ’767 patent on the grounds identified herein; and (3) Petitioner has not filed a complaint relating to the ’767 patent.

VII. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(b)

A. Real Parties in Interest

Petitioner certifies that Edwards is the real party-in-interest.

B. Related Matters

The ’767 patent has been asserted in litigation by Boston Scientific Corporation and Boston Scientific SciMed Inc. v. Edwards Lifesciences Corporation, Central District of California case number 16-CV-730.

C. Payment of Fees

Petitioner requests review of 15 claims of the ’767 patent. This Petition is accompanied by an *inter partes* review request fee payment of $9,000 and an *inter partes* review post-institution fee of $14,000, which meet the fee requirements under 35 U.S.C. § 312(a)(1). The USPTO is authorized to charge any fees or credit any overpayments to Deposit Account No. 20-1430.

D. Designation of Lead and Back-Up Counsel

Lead Counsel for Petitioner is A. James Isbester (Reg. No. 36,315) of Kilpatrick Townsend & Stockton LLP, and back-up counsel for Petitioner are Craig S. Summers (Reg. No. 31,430) and Cheryl T. Burgess (Reg. No. 55,030) of Knobbe, Martens, Olson & Bear, LLP, at contact information provided below.

E. Power of Attorney

Powers of attorney are filed herewith in accordance with 37 C.F.R. § 42.10(b).

F. Service Information

Edwards serves this Petition and all exhibits to the address of the attorney or agent of record in the Patent Office for the ’767 patent. Edwards may be served at mailing addresses below, and also consents to service at the e-mail addresses below.

Respectfully submitted,
By: /s/ A. James Isbester
A. James Isbester
Registration No. 36,315
Lead Counsel for Petitioner

Lead Counsel	Back-Up Counsel
A. James Isbester, Reg. No. 36,315 jisbester@kilpatricktownsend.com Kilpatrick Townsend & Stockton LLP Postal and Hand-Delivery Address: Two Embarcadero Center, Suite 1900 San Francisco, CA 94111 Telephone: (415) 576-0200 Facsimile: (415) 576-0300	Craig S. Summers (Reg. No. 31,430) Email: 2css@knobbe.com Cheryl T. Burgess (Reg. No. 55,030) Email: 2ctb@knobbe.com Knobbe, Martens, Olson & Bear, LLP Postal and Hand-Delivery Address 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

CERTIFICATE OF WORD COUNT

The undersigned certifies pursuant to 37 C.F.R. § 42.24(d) that the foregoing Petition for *Inter partes* Review excluding any table of contents, table of authorities, certificates of service or word count, or appendix of exhibits or claim listing, contains 12,848 words according to the word-processing program used to prepare this paper (Microsoft Word). Including annotations in figures, Petitioner certifies that this Petition for *Inter partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(a).

Dated: April 18, 2017

/s/ A. James Isbester
Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Petition for *Inter Partes* Review of U.S. Patent No. 7,828,767, including its supporting Exhibits (1001-1018) and Power of Attorney has been served via Express Mail on April 18, 2017, upon the following:

SEAGER, TUFTE & WICKHEM, LLP
100 SOUTH 5TH STREET
SUITE 600
MINNEAPOLIS, MN 55402

BOSTON SCIENTIFIC SCIMED, INC.
ONE SCIMED PLACE
MAPLE GROVE, MN 55311

JENNIFER L. BUSS
6640 SHADY OAK ROAD
SUITE 400
EDEN PRAIRIE, MN 55344

Respectfully,

Dated: April 18, 2017

By: /s/ A. James Isbester
A. James Isbester
Registration No. 36,315
Counsel for Petitioner