DOCKET NO: 429184US

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Edwards Lifesciences Corporation

Petitioner,

v.

Medtronic, Inc.,

Patent Owner.

Case IPR2014-____

U.S. Patent No. 8,623,077

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,623,077
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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Alexandria, VA 22313-1450

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I. OVERVIEW OF PETITION

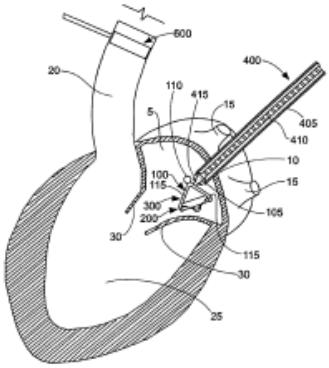
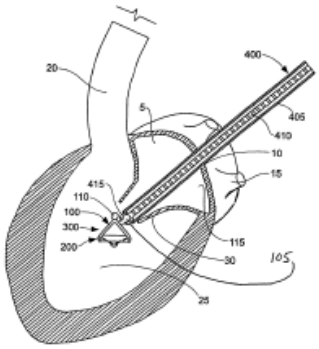
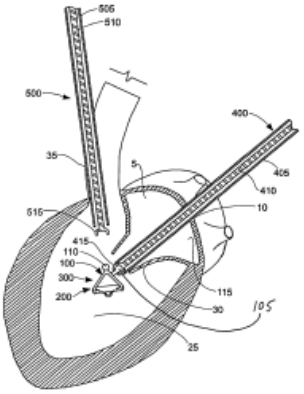
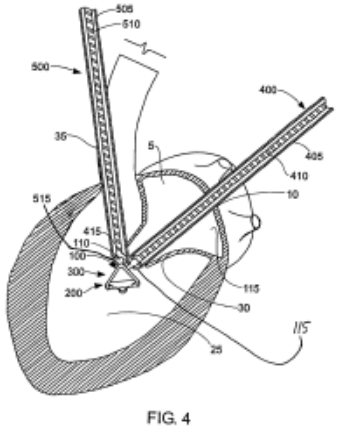
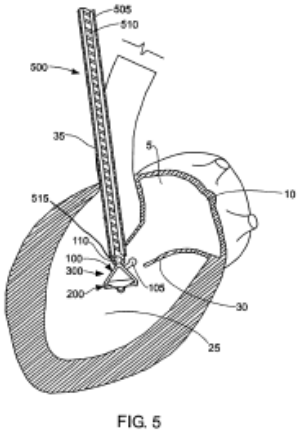
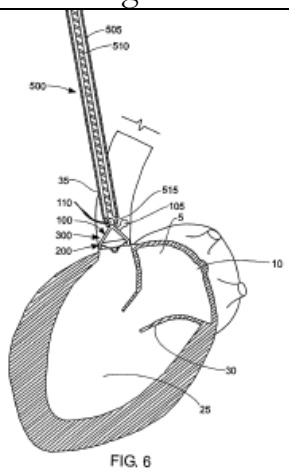
Pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42, the real party-in-interest, Edwards Lifesciences Corporation ("Edwards" or "Petitioner") requests *inter partes* review of claims 1–15 of U.S. Patent No. 8,623,077 (Ex. 1001, "the '077 patent"), filed on December 5, 2011, and issued on January 7, 2014, to William E. Cohn. The '077 patent is assigned to Medtronic, Inc. ("Medtronic" or "the Patent Owner").

A. The Overly Broad Functional Language of the Claims of the '077 Patent is Met by a Wide Range of Prior Art Prosthetic Heart Valve Delivery Devices

The system disclosed in the '077 patent is relatively straightforward – two separate, substantially straight "manipulation instruments" are introduced into the heart through separate incisions to pass a prosthetic heart valve from the low pressure side of the heart to the high pressure side of the heart. According to the '077 patent, this technique allows a surgeon to introduce a full sized, non-collapsible prosthetic heart valve into the heart without: (a) employing a cardiopulmonary bypass; (b) making an incision in the aorta; or (c) using a collapsible and re-expandable prosthetic valve delivered from a remote artery. (Ex. 1001, 1:31-3:7.)

This procedure includes handing-off the prosthetic valve from one manipulation instrument to the other, as shown in Figures 1-6 of the '077 patent, reproduced below. A first manipulation instrument 400 introduces a conventional, non-collapsible prosthetic valve 200 into a low pressure zone in the left atrium, passes the valve 200 through the mitral valve 30, into a high pressure zone in the right

atrium, and then hands off the prosthetic valve 200 to a second manipulation instrument 500 for positioning in the aorta 20.

 FIG. 1	 FIG. 2	 FIG. 3
Entering the left atrium.	Through the mitral valve.	In the right atrium.
 FIG. 4	 FIG. 5	 FIG. 6
The hand-off.	Moving to the aorta.	Implantation in the aorta.

In Figures 1-6, the prosthetic valve handoff requires a positive, ball and socket engagement relationship between grippers on the manipulation instruments and manipulation mounts on a valve holder. The '077 patent emphasizes the importance of such structure on a valve holder, stating: "For the purposes of the present invention, the important point is that some arrangement be provided for releasably

securing the prosthesis holding apparatus (and hence the prosthetic valve) to a manipulation instrument." (Ex. 1001, 7:15-18.)

The claims of the '077 patent are not straightforward. Apparatus claims are typically drafted with the goal of covering what the apparatus is, not what the apparatus does. The Patent Owner has taken a different approach by crafting apparatus claims that are replete with functional and operational language and lack for structural limitations. Independent claim 11 is representative of the independent claims in the '077 patent:

> **11.** A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising:
>
> a first elongate component that is movably disposed to a second elongate component,
>
> the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted, and the second elongate component having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted,
>
> the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location.

The only structural elements recited in claim 11 are first and second elongate components that are "movably disposed" to each other. There is no recitation whatsoever of a valve holder or any structure for releasably securing the valve holder to either one of the elongate components. Instead, claim 11 recites vaguely defined "temporary" and "spaced implantation" locations to which a prosthetic heart valve "can be releasably mounted." The prosthetic heart valve and delivery assembly combination is "configurable" with movement of the first elongate component relative to the second elongate component from one "state" to another "state." These amorphous functional recitations fail to identify what structure, if any, performs the recited function.

The examiner who reviewed the application that ultimately issued as the '077 patent recognized the functional language in the claims as problematic, stating:

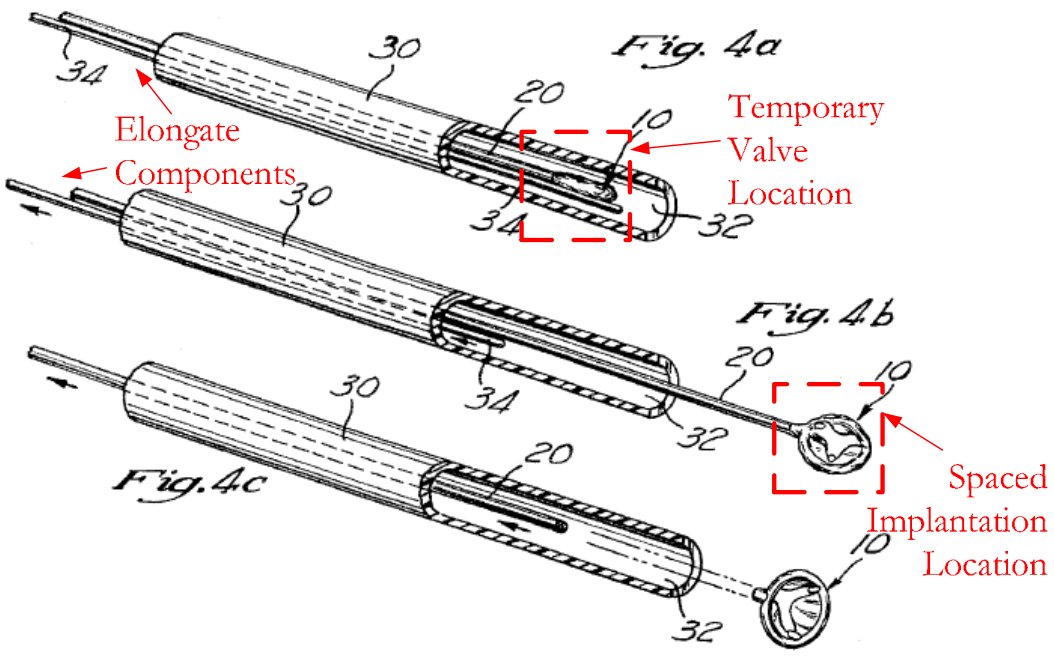
> NOTE: the Examiner wants to point out that multiple parts of the claimed subject matter in the independent claims are referring to location in a particular moment during the deployment of the heart valve within the human body. [T]he location in a particular moment of the delivery assembly and the heart valve are just functional language and have been interpreted broadly. The Examiner is looking for references capable of reading on the functional language.

(Emphasis added. *See* Ex. 1005, 124.)

The examiner's concern is not surprising, given that functional claim language carries a risk that the prior art inherently possesses the physical characteristics that

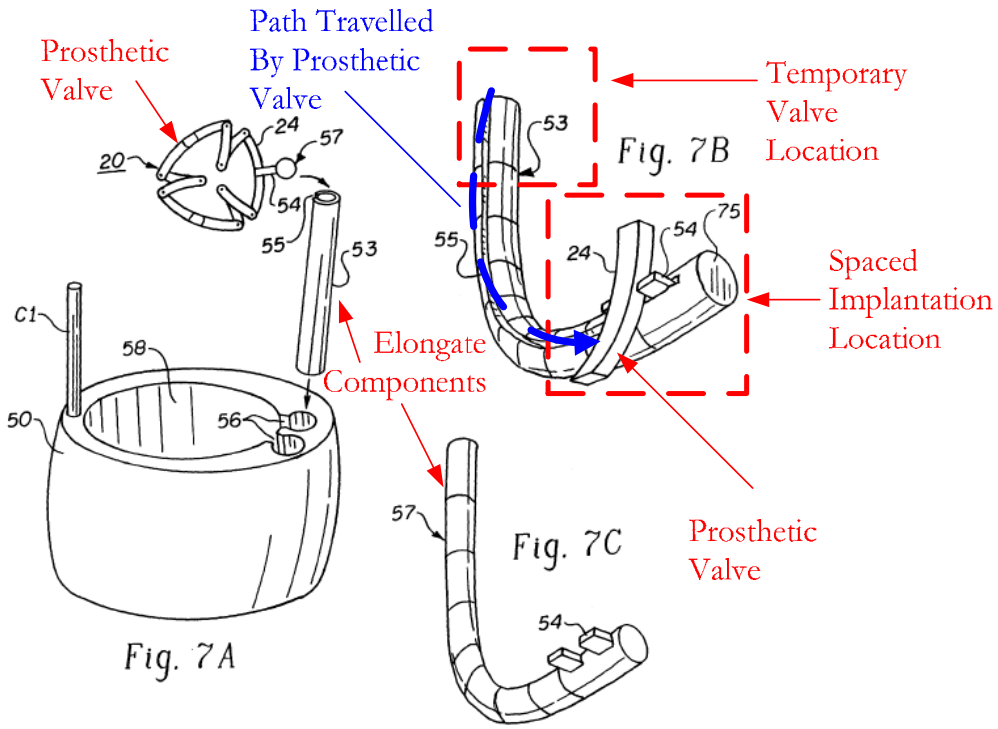
make the device disclosed in the prior art capable of performing the function recited in the claims. *See In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). This Petition includes the exact type of prior art references the examiner was seeking—references that disclose prosthetic heart valve delivery systems that perform all of the functions as recited in the claims of the '077 patent.

For example, U.S. Patent No. 5,554,185 to Block et al. (Ex. 1002, "Block") discloses a valve delivery system that includes two elongate components (elongate inflation tube 20, introducer member 34) that are "moveably disposed" to each other, as shown in Figures 4a-4c of Block, annotated and reproduced below. Figure 4a shows the valve 10 in one of many possible "temporary valve locations" and Figure 4b shows the valve 10 in one of many possible "spaced implantation locations."



Annotated Figures 4a-4c of Block (Ex. 1002)

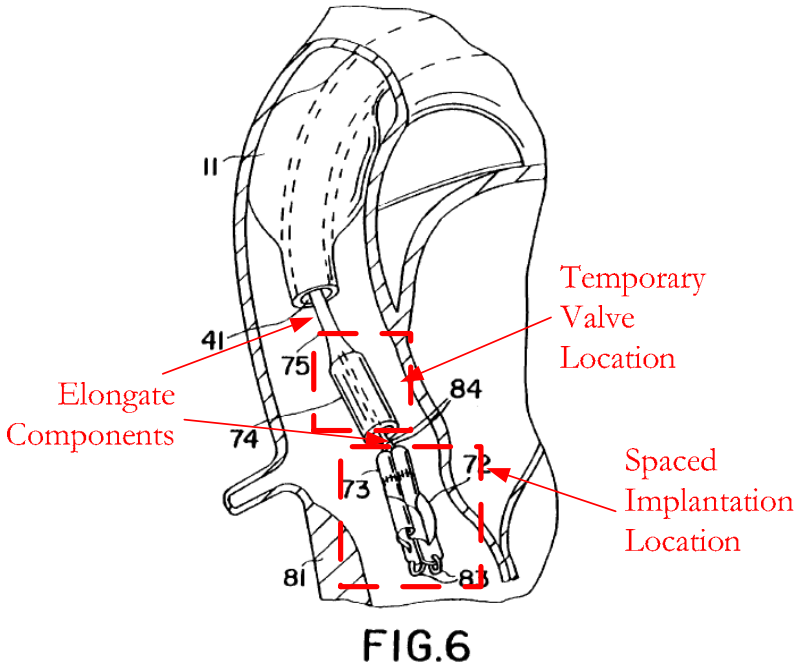
Figures 4a and 4b of Block illustrate that the valve delivery system is configurable with movement of one of the elongate components relative to the other elongate component from a "delivery state" with the prosthetic heart valve 10 mounted to the "temporary valve location" to an "implantation state" with the prosthetic heart valve 10 repositioned from the "temporary valve location" to the "spaced implantation location." In Figure 4c, the prosthetic heart valve 10 is subsequently deployed from the "spaced implantation location."



Annotated Figures 7A-7C of Vesely (Ex. 1003)

International Publication No. WO 99/33414 (Ex. 1003, "Vesely") discloses a catheter-based valve delivery system that includes several catheters or catheter sheaths that can shuttle a prosthetic heart valve in and out of the body to the desired spot. (Ex. 1003, 13:1-15:10.) Figures 7A-7C of Vesely, annotated and reproduced above,

show the valve delivery system includes two elongate components (catheters 53, 57) that are "moveably disposed" to each other to create a "monorail" system that conveniently transports devices in and out of the body by moving the devices along the length of the main guiding catheter 53. (Ex. 1003, 13:19-30.) Annotated Figure 7B identifies one of many "temporary valve locations" and one of many "spaced implantation locations" along the monorail system. As such, the system of Vesely is configurable with movement of one of the elongate components relative to the other elongate component from a "delivery state" with a prosthetic heart valve mounted to the "temporary valve location" to an "implantation state" with the prosthetic heart valve repositioned from the "temporary valve location" to the "spaced implantation location" for subsequent deployment and implantation.



Annotated Figure 6 of Stevens (Ex. 1004)

In another example, Figure 6 of U.S. Patent No. 5,885,238 to Stevens et al. (Ex. 1004, "Stevens"), annotated and reproduced above, illustrates a valve delivery system that includes several elongate components (valve delivery catheter 75, connector cables 84) that are "moveably disposed" to each other. Annotated Figure 6 identifies one of many possible "temporary valve locations" and shows the valve 72 in one of many possible "spaced implantation locations." Figure 6 shows the result of movement of one of the elongate components relative to the other elongate component from a "delivery state" with the prosthetic heart valve 72 mounted to the "temporary valve location" to an "implantation state" with the prosthetic heart valve 72 repositioned from the "temporary valve location" to the "spaced implantation location" for subsequent deployment. (Ex. 1004, 26:44-27:42.)

The actual structure and design of the valve delivery system disclosed in the '077 patent is differs from the systems of valve delivery systems of Block, Stevens, and Vesely in several key aspects. <u>These structural differences are not reflected in the claims of the '077 patent</u>. Instead, the '077 patent discloses a valve delivery system with three basic structural elements: two separate, distinct, and non-coaxial manipulation instruments, each with their own deformable gripper, and a valve holder that includes manipulation mounts that are gripped within the grippers. This structure allegedly enables the system to introduce a non-collapsible prosthetic valve through an incision in the left atrium, pass the prosthetic valve through the mitral valve, and hand-off the valve from one instrument to another in a beating heart. The

claims of the '077 patent do not positively recite any of this structure. Instead, the claims of the '077 patent are so replete with general functional language that they encompass the prior art valve delivery devices disclosed in Block, Stevens, and Vesely.

B. The Broad Functional Language of the Claims of the '077 Patent Reflect the Patent Owner's Attempt to Cover Technology Outside of the Scope of the Disclosure of the '077 Patent.

To the best of Petitioner's knowledge, no one has ever sought FDA approval for the two manipulation instrument system disclosed in the '077 patent. On the other hand, the Petitioner, Edwards Lifesciences, and the Patent Owner, Medtronic, have both applied for and received FDA approval for transcatheter aortic valve replacement systems – systems that include the type of collapsible and expandable replacement heart valves that are disparaged in the '077 patent. (*See* Ex. 1001, 2:48-3:7.) Transcatheter aortic valve replacement systems have been the subject of several patent infringement litigations in the federal courts between Edwards and Medtronic, including one case that resulted in a $73 million judgment in 2010 in favor of Edwards, and another case's recent ruling in January 2014 for nearly $394 million in favor of Edwards. *See Edwards Lifesciences LLC, et al. v. Medtronic CoreValve LLC*, No. 1:08-cv-00091 (D. Del. 2010); and *Edwards Lifesciences LLC, et al. v. Medtronic CoreValve LLC, et al.*, No. 1:12-cv-00023 (D. Del. 2014). Given this backdrop, it is readily apparent why Medtronic pursued claims with broad, functional language in the '077 patent – Medtronic is using functional claim language in an attempt to cover the very

technology that is disparaged in the '077 patent, but has subsequently been adopted by Medtronic.

This tactic is not limited to the '077 patent, as the Patent Owner is following a strategy of trying to 'slip one past' the Office via numerous co-pending applications that share a priority claim with the '077 patent, but are being reviewed by different examiners. Most of these applications stand rejected. For example, pending U.S. Patent Application No. 13/012,466 ("the '466 application") includes claims similar to those in the '077 patent. The Office recently rejected those claims as being outside of the scope of the original disclosure:

> The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. After a thorough review of the specification and drawings, examiner is unable to find support for any part of the claimed catheter system that broadly comprises a first and second support (or mount) which engage the artificial heart valve at respective first and second engagement positions. Throughout the specification, a catheter system comprising first and second manipulation instruments which grasp the valve assembly at first and second mounts is detailed. However, the specification lends no support for the language as broadly claimed. (*See* Ex. 1006, 26, 73-75.)

In other cases the Patent Owner has been more brazen. For example, in U.S. Patent Application No. 12/776,136 ("the '136 application"), the examiner rejected the Patent Owner's attempts to directly claim features that are that are found in

transcatheter aortic valve replacement systems, but that are not disclosed in the '077 patent, such as balloon expandable heart valve assemblies and delivering an artificial heart valve assembly through a peripheral artery (rather than through the left ventricle and mitral valve). (*See* Ex. 1007, 42-43, 87-88.)

The Executive Office of the President of the United States recently issued a report in which it was noted that Patent Assertion Entities (PAEs, also known as "patent trolls") regularly employ overly broad functional language to "take advantage of uncertainty about the scope or validity of patent claims." (*See* Ex. 1008, 1 and 7-9.) In response, the White House Task Force on High-Tech Patent Issues identified "Tightening Functional Claiming" as one five Executive Actions the Administration is taking "to help bring about greater transparency to the patent system and level the playing field for innovators." (*See* Ex. 1009, 1-2.)

Although the President's report emphasizes that these problems are especially acute for software patents, they are by no means limited to claims directed to software or restricted in practice to PAEs. The claims of the '077 patent are an example of problematic functional claim language in the mechanical arts that was prepared by a large medical device company. By design, the vague, functional phrasing in the claims of the '077 patent casts a broad net intended to reach products that were never contemplated by the inventor at the time of the invention.

Properly drafted patent claims serve an important public notice function. As such, the overly broad functional claim language of the claims of the '077 patent does

not only affect Edwards. Ambiguous functional claim language casts a fog that obscures the scope of protection of the '077 patent is properly afforded within the patent landscape of heart valve replacement devices. The resulting uncertainty is a burden on innovation, investment, and job creation within this important medical field. This fog can only be cleared through costly litigation or through action by the Office. When combined with the patent owner estoppel provisions of 37 C.F.R. § 42.73(d)(3)(i), *inter partes* review of the '077 patent is the most resource effective way for the Office to address this problem. Accordingly, it is important that the Board institute *inter partes* review of the '077 patent and force the Patent Owner to amend their claims in a manner that clearly ties the functional language in the claims to the structure that performs the recited function.

II. MANDATORY NOTICES - 37 C.F.R. § 42.8(a)(1)

A. Real Party-in-Interest - 37 C.F.R. § 42.8(b)(1)

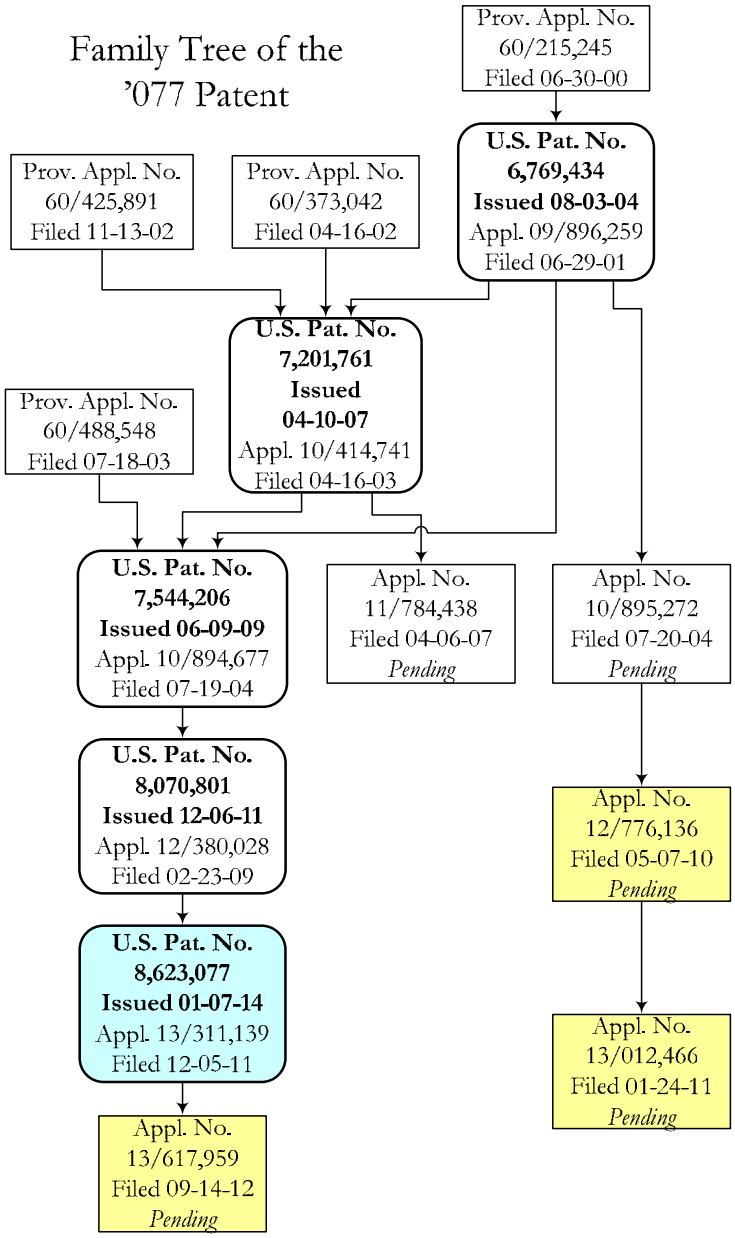
The Petitioner, Edwards Lifesciences Corporation ("Edwards"), is the Real Party-in-Interest.

B. Related Matters - 37 C.F.R. § 42.8(b)(2)

1. Related Pending Patent Applications

The '077 patent is part of an extensive patent family that includes several pending applications with claims that are <u>not</u> patentably distinct from the claims of the '077 patent. The following pending applications may affect or be affected by a decision in this proceeding: U.S. Patent Application Serial Nos. 12/776,136;

13/012,446; and 13/617,959. A family tree of the '077 patent is reproduced below, with the '077 patent highlighted in blue and pending applications that include claims that are not patentably distinct from those of the '077 patent in yellow: The family tree is not an admission of the adequacy of any of the priority claims made in any of the patents or applications included in the family tree.



The examiner determined that the claims that issued as claims 11-15 of the '077 patent are not patentably distinct from claims 1-3 of U.S. Patent No. 8,070,801 ("the '801 patent"), the parent of the '077 patent. (Ex. 1005, 101-102.) Claim 1 of the '801 patent and claim 11 of the '077 patent are nearly identical:

Claim 1 of the '801 Patent	Claim 11 of the '077 Patent
1.a. A prosthetic heart valve in combination with a delivery assembly, the delivery assembly including	**11.a.** A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising:
1.b. a first elongate component that is movably disposed to a second elongate component,	**11.b.** a first elongate component that is movably disposed to a second elongate component,
1.c. the delivery assembly having a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position and	**11.c.** the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted, and
1.d. a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position,	**11.d.** the second elongate component having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted,
1.e. the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted in the temporary location on the delivery assembly to an implantation state with the prosthetic heart valve released from contact with the delivery assembly at the temporary location and relocated to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location.	**11.e.** the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location.

The same examiner recently determined that U.S. Application Serial No. 13/617,959 ("the '959 application"), a child case of the '077 patent, also includes claims that are not patentably distinct from claims 1 and 2 of the '801 patent. (*See* Ex. 1010, 4-5.) Also, a different examiner reviewing the '466 application determined that the '466 application includes claims that are not patentably distinct from claims 1-3 of the '801 patent. (*See* Ex. 1006, 29-31; 77-80.) Given the previous determination that claims 11-15 of the '077 patent and claims 1-3 of the '801 patent are not patentably distinct, it follows that each of the '989 application and the '466 application include claims that are also not patentably distinct from at least claims 11-15 of the '077 patent. Petitioner further submits that at least the '136 application also includes pending claims that are not patentably distinct from several of the claims of the '077 that are challenged in this Petition.

A patent applicant or owner is precluded from taking action inconsistent with an adverse judgment in an IPR, including obtaining in any patent a claim that is not patentably distinct from a finally refused or canceled claim. 37 C.F.R. § 42.73(d)(3)(i). Accordingly, should the Board institute *inter partes* review of the '077 patent, it would serve the interest of preserving Office resources to suspend examination of the '989, '466, and '136 applications pending the outcome of an *inter partes* review of the '077 patent, as these applications all include claims that are not patentably distinct from those that would be subject to review.

The Board has indicated that an examiner can suspend examination of an

application pending the outcome of an *inter partes* review proceeding if the examiner makes a determination that the claims of the application are patentably indistinct from those of the patent subject to *inter partes* review. *See Chi Mei Innolux Corp. v. Semiconductor Energy Lab. Co., Ltd.*, IPR2013-00028, Paper 8 (Nov. 28, 2012); *see also Chi Mei Innolux Corp. v. Semiconductor Energy Lab. Co., Ltd.*, IPR2013-00038, Paper 7 (Nov. 28, 2012). In order to facilitate the examiner's review in this regard, Petitioner respectfully requests that the Board issue a Standing Order in this proceeding, once instituted. The requested Standing Order would require the Patent Owner to provide written notice in at least the '989, '466, and '136 applications of the existence of a related IPR proceeding (within 30 days of institution). The provision of such written notice is particularly important in this case because the '989, '466, and '136 applications are currently being examined by different examiners. Likewise, should the Patent Owner submit claim amendments and/or new claims during the very limited pendency of the related IPR, it is requested that the Standing Order require the Patent Owner to provide for a written reminder to the examiner with each such submission as to the estoppel impact of a finally refused or cancelled claim in this proceeding so that the examiner may suspend further prosecution where appropriate. 37 C.F.R. § 1.103(e).

Alternatively, should the Board require that the above noted relief be requested by motion, pursuant to 37 C.F.R. § 42.20(b), Petitioner hereby requests authorization in this paper to pursue a motion seeking the relief outlined above, and for the judges

assigned to this proceeding to convey such authorization during the first conference call with counsel.

2. Related Reexamination Proceedings

The Office recently ordered *ex parte* reexamination of all of the claims of U.S. Patent No. 8,070,801, the parent case of the '077 patent. (Ex. 1012, Prosecution History of Reexamination Control No. 90/013,064, Order Granting Reexamination of January 13, 2014.)

C. Lead and Backup Counsel - 37 C.F.R. § 42.8(b)(3)

Lead Counsel: Christopher A. Bullard (Registration No. 57,644)

Backup Counsel: Robert C. Mattson (Registration No. 42,850) and W. Todd Baker (Registration No. 45,265)

D. Service Information - 37 C.F.R. § 42.8(b)(4)

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III. PAYMENT OF FEES - 37 C.F.R. § 42.103

The undersigned authorizes the Office to charge the fees set forth in 37 C.F.R. §42.15(a) as required by 37 C.F.R. § 42.103 for this Petition for *Inter Partes* Review to Deposit Account No. 15-0030; any additional fees that might be due are also authorized.

IV. GROUNDS FOR STANDING - 37 C.F.R. § 42.104(a)

Petitioner certifies pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

A. Identification of Claims for Which Review Is Requested and Relief Requested– 37 C.F.R. §§ 42.104(b)(1) and 42.22(a)(1)

Petitioner respectfully requests *inter partes* review of claims 1-15 of the '077 patent, and the cancellation of these claims as unpatentable.

B. Prior Art Patents and Printed Publications

Petitioner relies upon the following patents and printed publications:

Exhibit 1002 – U.S. Patent No. 5,554,185 to Block et al. ("Block"), issued on September 10, 1996. Block is available as prior art under 35 U.S.C. § 102(b).

Exhibit 1003 – International Patent Application Publication No. WO 99/33414 ("Vesely"), published on July 8, 1999. Vesely is available as prior art under 35 U.S.C. § 102(b).

Exhibit 1004 – U.S. Patent No. 5,885,238 to Stevens et al. ("Stevens"), issued on March 23, 1999. Stevens is available as prior art under 35 U.S.C. § 102(b).

C. Statutory Grounds of Challenge – 37 C.F.R. § 42.104(b)(2)

Petitioner requests cancellation of the challenged claims under the following statutory grounds:

A. Claims 1-15 are anticipated by Block (Ex. 1002) under 35 U.S.C. § 102(b).

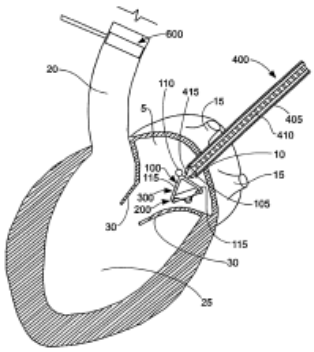
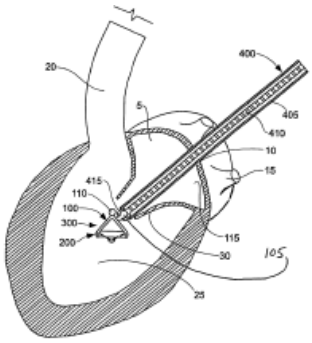
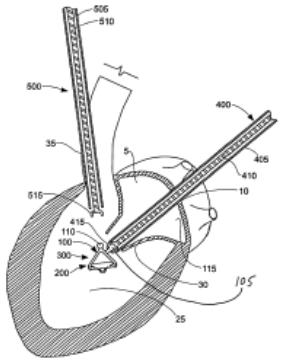
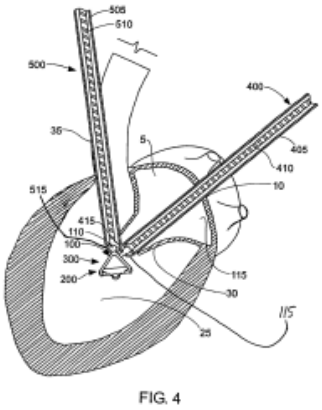
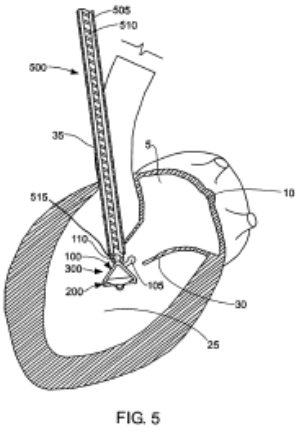
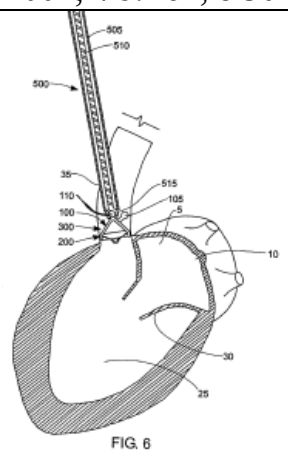
B. Claims 1-15 are anticipated by Vesely (Ex. 1003) under 35 U.S.C. § 102(b).

C. Claims 1-15 are as anticipated by Stevens (Ex. 1004) under 35 U.S.C. § 102(b).

Section VIII below demonstrates, for each of the statutory grounds, that there is a reasonable likelihood that Petitioner will prevail. *See* 35 U.S.C. § 314(a).

VI. OVERVIEW OF THE '077 PATENT

The '077 patent discloses, among other things, a method for the replacement of cardiac valves. The '077 patent notes that "[t]he ideal minimally invasive approach to the treatment of aortic valve disease requires aortic valve replacement without cardiopulmonary bypass and without cardiac arrest." (Ex. 1001, 2: ll. 6-8.) Figures 1-6 of the '077 patent, reproduced below, illustrate a minimally invasive approach in which a first manipulation instrument 400 introduces a conventional prosthetic valve 200 into a low pressure zone in the left atrium, passes the valve 200 through the mitral valve 30, into a high pressure zone in the right atrium, and then hands off the prosthetic valve 200 to a second manipulation instrument 500 for positioning in the aorta 20.

 FIG. 1	 FIG. 2	 FIG. 3
Ex. 1001, 4:52-55; 6:31-48.	Ex. 1001, 4:56-58; 8:21-29.	Ex. 1001, 4:59-61; 8:30-37.
 FIG. 4	 FIG. 5	 FIG. 6
Ex. 1001, 4:62-65; 8:59-67.	Ex. 1001, 4:66-5:3;9:39-47.	Ex. 1001, 5:4-6; 9: 48-52.

The handoff from one manipulation instrument to the other is made possible by the positive engagement relationship between grippers on the manipulation instruments and manipulation mounts on a valve holder. (Ex. 1001, 7:9-15.) Regardless of the configuration of the mount and grippers, the '077 patent emphasizes the importance of a valve holder with some type of structure for releasable engagement, stating: "For the purposes of the present invention, the important point is that some arrangement be provided for releasably securing the prosthesis holding apparatus (and hence the prosthetic valve) to a manipulation instrument." (Ex. 1001, 7:15-18.)

The '077 patent is primarily directed to a minimally invasive technique for replacing a diseased aortic valve without: (a) employing a cardiopulmonary bypass; (b) making an incision in the aorta; or (c) using a collapsible and re-expandable prosthetic valve delivered from a remote artery. (Ex. 1001, 1:31-3:7.)

The '077 patent identifies three challenges with replacing a diseased aortic valve without cardiopulmonary bypass: (1) removing the diseased valve without causing stroke or other ischemic events that might result from the liberation of particulate material while removing the diseased valve; (2) preventing cardiac failure during removal of the diseased valve; and (3) placing a prosthetic valve into the vascular system and affixing it to the wall of the aorta. (Ex. 1001, 2:21-36.)

With respect to the third challenge, the '077 patent notes that it is undesirable to create an incision in the aorta that is large enough to introduce a prosthetic valve while the heart is beating:

> …[D]uring cardiac rhythm, the aortic and arterial pressures are substantially greater than atmospheric pressure. Therefore, any sizable incision made to the aorta in order to insert a standard valve prosthesis into the arterial system creates the potential for uncontrollable bleeding from the incision site. Furthermore, even if bleeding is successfully controlled, pressures within the aorta may result in weakening of the aorta caused by aortic wall dissection. In addition, large incisions on the aorta also increase the potential for liberating plaque from the aortic wall that can lead to embolic complications.
>
> (Ex. 1001, 2, ll. 37-47.)

The background section of the '077 patent acknowledges that one known technique for aortic valve replacement which avoids the need to make an incision in the aorta includes compressing a prosthetic cardiac valve to a relatively small dimension suitable for insertion into the arterial system, advancing the compressed prosthetic valve to the site of the aortic valve, and then expanding the prosthetic valve against the aortic wall. (Ex. 1001, 2:48-55.) However, the background of the '077 patent disparages the use of such collapsible and re-expandable valves:

> …none of these relatively flimsy valve prostheses have proven adequate to endure the repetitive stresses undergone by the aortic valve over the ten to twenty years typically required…(Ex. 1001, 2:55-58.)
>
> …the precise placement of such expandable prosthetic valves in the correct sub-coronary position can be extremely challenging, particularly in view of the high pressure, pulsatile blood flow passing through the aorta…(Ex. 1001, 2:59-63.)
>
> …expandable prosthetic valves would typically be positioned from a remote artery, which would reduce the ability to precisely control the placement and positioning of the device and therefore would increases [sic] the risk of obstructing the coronary arteries…(Ex. 1001, 2:63-67.)
>
> …expandable prosthetic valves are held on the ends of elongate, flexible catheters that are threaded into the aorta, around the aortic arch and then expanded. The pulsatile flow during cardiac rhythm induces a to-and-fro motion of the valve prosthesis relative to the aorta that makes the timing of valve expansion critical for proper placement of the

expandable prosthetic valve and hence the survival of the patient…(Ex. 1001, 2:67-3:7.)

In view of these disparaging remarks, the invention of the '077 patent clearly does not encompass the use of collapsible and re-expandable prosthetic valves delivered from a remote artery. Instead, the '077 patent is instead directed to a system and method that supposedly allows a conventional prosthetic valve (rather than a collapsible and re-expandable prosthetic valve) to be introduced into the heart without the risks associated with making a large incision in the arterial system or the aorta. For example, as shown in Figures 1-4 of the '077 patent, an atriotomy 10 through which non-collapsible prosthetic valve is introduced is made in the lower pressure, left atrium of the heart. The advantages of this technique are discussed in U.S. Provisional Application No. 60/488,548 (Ex. 1012, "the '548 provisional application"), the provisional application to which the '077 patent claims priority. The Patent Owner incorporated the entire contents of the '548 provisional application into the '077 patent by reference. (Ex. 1001, 1:18-20.) The '548 provisional application states:

> The pressure of blood flowing through the left atrium is very low, peaking at a few inches of water during the cardiac cycle. This pressure is a small fraction of that found within the arterial system and thus permits insertion of a conventional valve prosthesis through a relatively large opening formed in the wall of the left atrium without the risk of uncontrollable bleeding. In this respect it will be appreciated that

> various methods are known to those skilled in the art for controlling bleeding from an incision into the left atrium. The left atrium also rarely suffers from atherosclerotic plaque formation or calcification, thus minimizing the risk of embolic debris during such incision.
>
> (Ex. 1012, 13:3-16.)

Not surprisingly, every embodiment of the '077 patent involves introduction of non-collapsible prosthetic valve (not a collapsible and expandable prosthetic valve) from the low pressure, left atrium, through the mitral valve, and then into the right atrium. For example, in an alternative embodiment that requires only a single manipulation instrument, the '077 patent states:

> The use of two separate manipulation instruments, and the method of passing valve prosthesis 200 from one to the other, avoids the complex manipulations of valve prosthesis 200 that would be required to position valve 200 within aorta 20 using only a single manipulation instrument introduced through the left atrium.
>
> (Emphasis added. Ex. 1001, 9:8-13.)

Likewise, in another embodiment in the '077 patent, in which the installation instruments 400 and 500 are replaced with a guidewire and a pusher tool riding on the guidewire, the '077 patent states:

> …in an alternative preferred embodiment, a wire, a catheter, a tube or any other filament can be placed from the left atrium, through the ventricle and into the arterial system, over (or through) which a prosthesis or device can be advanced (pushed or pulled). As an example, a catheter with a balloon can be placed through an incision in the left

atrial wall. The balloon can be inflated and this catheter can then be "floated" along the flow of blood across the mitral valve, into the left ventricle, and out into the arterial system. At that point the catheter can be grasped by an instrument placed through a small incision in the aorta or passed into the aorta by means of a remote vessel such as the femoral artery. At this point, the prosthesis or device can be mounted onto the catheter and either be pushed (or pulled) over the catheter into position. This procedure can be similarly performed by the use of a wire or other filament structure. Also, a tube could be employed, with the prosthesis or device being advanced within the tube.

(Emphasis added. Ex. 1001, 11:28-45.)

As with the previous embodiments in the '077 patent, a non-collapsible prosthetic valve is introduced though an incision in the left atrial wall, and only a receiving instrument is navigated through the femoral artery.

VII. CLAIM CONSTRUCTION - 37 C.F.R. § 42.104(b)(3)

The claim terms are presumed to take on their ordinary and customary meaning. This Petition shows that the challenged claims of the '077 patent are unpatentable when the challenged claims are given their broadest reasonable interpretation in light of the specification. *See* 37 C.F.R. § 42.100(b); see also *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir.1984). It is well established that the Board is not bound by a district court's determination, as a lower standard of proof and a different standard of claim construction apply for unexpired patents in proceedings at the Office. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 (Fed. Cir. 1988); *see also In re*

Swanson, 540 F.3d 1368, 1377 (Fed. Cir. 2008). Likewise, although the Petitioner gives each claim term its plain and ordinary meaning in this proceeding, this is not an admission that the same constructions are appropriate for the concurrent district court litigation, which applies a different claim construction standard than the Office.

"Movably disposed to" This phrase appears in claims 1 and 11, which each recite "a first elongate component that is movably disposed to a second elongate component." This phrase does not appear in the specification, and does not clearly define any structural relationship between the first and second elongate components. As such, under its broadest reasonable interpretation, this phrase should be interpreted broadly to encompass structures in which a first elongate component is movable relative to a second elongate component.

"Temporary valve location" This phrase appears in each of independent claims 1, 8, and 11. Claim 1 recites "the delivery assembly having a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position;" the preamble of claim 8 recites "[a] delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position;" and claim 11 recites "the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted." The recitation of an assembly (claims 1 and 8) or an elongate component of an assembly (claim 11) having a "location" to which something "can be" "releasably mounted" is, on its face, confusing. Under its plain and ordinary meaning,

a location describes a place, not a part of something structural. As such, the phrase "temporary valve location" is not clear on its face as it fails to positively recite any real structural relationships between positively claimed structures. The specification of the '077 patent offers no help in discerning the meets and bounds of the term "temporary valve location" when used with reference to an assembly or an elongate component. Instead, the specification most frequently uses the word "location" to refer to a position inside the human heart, such as seven mentions of "location within the heart," rather than to a specific portion of a device or assembly. (*See* Ex. 1001, 3:44-4:42.) While this usage of "location" is consistent with the plain and ordinary meaning of the word, it does not provide any guidance as to how to interpret a location on an assembly or an elongate component. Accordingly, the phrase "temporary valve location" is interpreted broadly to include any portion of an assembly (claims 1 and 8) or an elongate component of an assembly (claim 11) to which a prosthetic heart valve is capable of being releasably mounted.

"Spaced implantation location" This phrase appears in each of independent claims 1, 8, and 11. Claim 1 recites "the delivery assembly… a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position"; the preamble of claim 8 recites "[a] delivery assembly having … a spaced implantation location to which the prosthetic heart valve can also be releasably mounted in position"; and claim 11 recites "the second elongate component having a spaced implantation location to which the prosthetic heart valve

can also be releasably mounted." As with the phrase "temporary valve location," it is unclear how a structural element can include a "location." Further, the relative phrase "spaced" should not be given any weight as it is not clear what this "location" is "spaced" relative to. Thus, the phrase "spaced valve location" is interpreted broadly to include any portion of an assembly (claims 1 and 8) or an elongate component of an assembly (claim 11) to which a prosthetic heart valve is capable of being releasably mounted.

"Configured to apply an axial force to the prosthetic heart valve in a direction of advancement" Claims 1 and 8 recite "the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement." This phrase is entirely functional in nature and fails to impose any structural limitations on the second elongate component. Further, the directional terms "axial" and "direction of advancement" are not defined relative to any structural element recited in the claims. Accordingly, this phrase is interpreted broadly to encompass any elongate component that is capable of applying any directional force to a prosthetic heart valve, regardless of where the valve is located or when the force is applied.

"Catheter" Under its broadest reasonable interpretation in light of the specification, this phrase in claims 12 and 13 should be construed as a filament similar to a tube or wire. This interpretation is consistent with the specification of the '077 patent, which groups catheters, tubes, and wires together as types of filaments. (Ex.

1001, 11:28-32.)

"Articulable" Claims 7, 10, and 15 recite a distal portion of the first elongate component is articulable, and a distal portion of the second elongate component is articulable. Under its broadest reasonable interpretation in light of the specification, the term "articulable" in claims 7, 10, and 15 should be interpreted as "capable of being articulated." Notably, the claims of the '077 patent do not recite any specific structure, such as a joint, that makes the elongate components "capable of being articulated." Thus, without reading limitations into the claims from the specification, the broadest reasonable interpretation of "articulable" includes elements that are capable of being bent or otherwise manipulated, not just those which include physical joints.

VIII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE - 37 C.F.R. §§ 42.104(b)(4)-(5) and 42.22(a)(2)

A. Statement of Non-redundancy

The grounds raised in the following sections are meaningfully distinct from one another and rely upon fundamentally different types of cited prior art references. Petitioner urges the Board to adopt each ground of unpatentability presented in this Petition at least for the following reasons.

Under the standard that must be applied in this proceeding before the Board, the claims of the '077 patent include far reaching functional language. This overly broad language encompasses the functionality of each of the systems disclosed in

Block, Vesely, and Stevens. However, each of these references discloses valve delivery systems that are structurally different from each other in numerous respects. Given that the Patent Owner is likely, for the first time, to argue that specific structure is required to perform the functions recited in the claims of the '077 patent, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structure of the systems in the cited references. Otherwise the Patent Owner will continue its abusive claiming approach in applications pending before the Office while attempting to obtain patent claims to which it is not entitled

The Board's determination of redundancy also depends, in part, on the claim construction the Board gives to several of the terms discussed in the previous section. For example, the phrase "the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement" in claims 1 and 8 is incredibly broad. Block explicitly discloses a system in which either of the elements the Petitioner has identified as first and second elongate components directly applies such a force to a prosthetic valve during delivery.

On the other hand, Vesely is less explicit. Vesely discloses a valve delivery system that includes two elongate components (catheters 53, 57) that are moveably disposed to each other to create a "monorail" system that conveniently transports devices in and out of the body by moving the devices along the length of a main guiding catheter 53. (Ex. 1003, p. 13, ll. 19-30.) Either of the catheters 53 or 57 in

Vesely is inherently "capable" of applying the type axial force recited in claims 1 and 8 to a prosthetic valve. For example, one could simply place a prosthetic valve on a table and push it along with either of these catheters. Further, as discussed below, Petitioner has identified at least one example where Vesely explicitly discloses how the main guiding catheter 53 at least indirectly applies an axial force on a prosthetic valve during deployment. Likewise, although not explicitly disclosed, the main guiding catheter 53 is inherently capable of applying an axial force to the prosthetic heart valve in a direction of advancement if, for example, a physician adjusts the location of the main guiding catheter 53 while the inner catheter 57 is mounted therein with a prosthetic valve. This scenario is very likely to occur, as a physician may adjust the position of the main guiding catheter 53 to adjust the implantation location Thus, Vesely is less explicit than Block about each of the catheters 53 and 57 directly applying an axial force to a prosthetic valve. However, this distinction between Vesely and Block may be irrelevant if the Board agrees that the phrase "the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement" should be interpreted to encompass any elongate component that is capable of applying any directional force to a prosthetic heart valve, regardless of where or when.

Likewise, the Board's interpretation of the terms "articulable" and "catheter" may be relevant to determining whether the references include redundant teachings. Each of the references discloses different types of manipulations and bending at the

distal tips of the elongate components. If the Board agrees that the proper broadest reasonable interpretation of "articulable" includes elements that are capable of being bent or otherwise manipulated, not just those which include physical joints, all of the references explicitly disclose this feature.

Petitioner proposes the Board interpret the term "catheter" to encompass tubes, wires, and other filaments, consistent with the specification of the '077 patent. If the Board adopts a more narrow interpretation, it may exclude the connector cables 84 disclosed in Stevens, which will affect whether Stevens anticipates claim 13. On the other hand, no reasonable interpretation of "catheters" could exclude the tubes of Block or the catheters of Vesely from meeting this limitation.

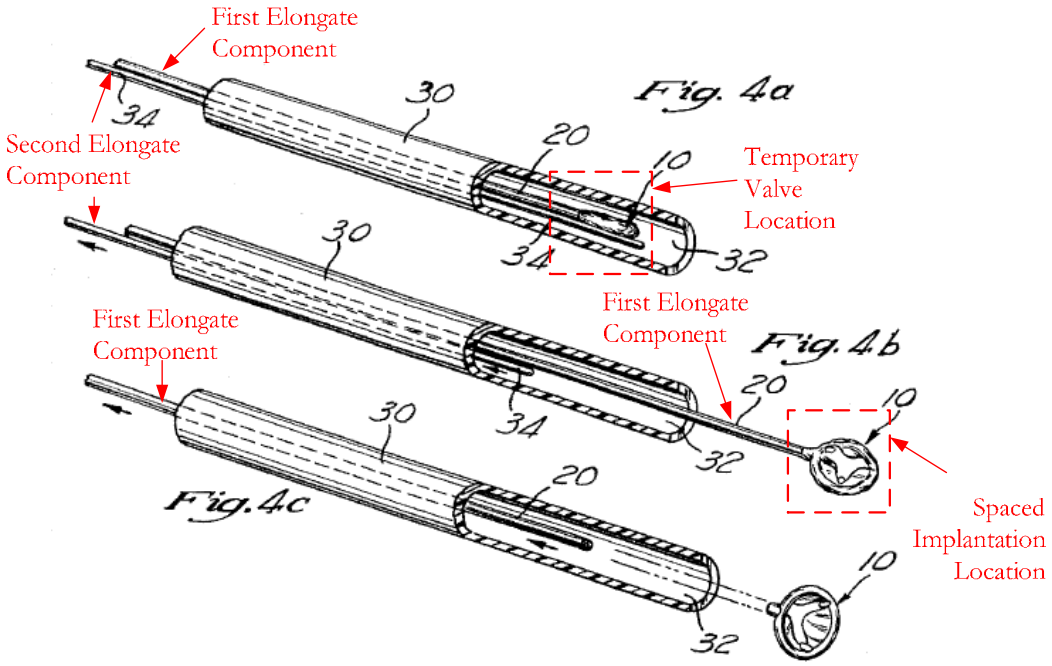
Regardless of claim interpretation, the broad functional language in the claims necessitates application of several references with disparate structures. Accordingly, Petitioner urges the Board to adopt each ground of unpatentability presented in this Petition.

Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is not reasonably possible for Petitioner to submit prior art that may specifically pertain to the many details in the '077 patent specification that are not claimed at this time. For at least this reason, should the Patent Owner amend the claims, the Patent Owner must address all known prior art, not just the applied art. *See Idle Free Systems, Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper 66 (Jan. 7, 2014)

B. Claims 1-15 Are Unpatentable Under 35 U.S.C. § 102(b) as Anticipated by Block

1. Claims 1, 8, and 11

This subsection explains on an element-by-element basis how Block anticipates claims 1, 8, and 11 of the '077 patent.



Analysis of Claims 1 and 8 - Annotated Figures 4a-4c of Block (Ex. 1002)

Claim 1: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate component that is movably disposed to a second elongate component,"

Figures 4a-4c of Block, annotated and reproduced above, show a prosthetic heart valve (10) in combination with a delivery assembly. The delivery assembly includes a first elongate component (elongate inflation tube 20) that is movably disposed to a second elongate component (introducer member 34).

Claim 1: "the delivery assembly having a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position and a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position,"

Figure 4a of Block shows the valve 10 in one of many possible "temporary valve locations," and Figure 4b of Block shows the valve 10 in one of many possible "spaced implantation locations." Block discloses that the valve 10 is releasably mounted in position at both the temporary valve location and the spaced implantation location. (Ex. 1002, 7:24-40.)

Claim 1: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location,"

Figures 4a and 4b of Block illustrate that the prosthetic heart valve (10) and delivery assembly combination is configurable with movement of the first elongate component (elongate inflation tube 20) relative to the second elongate component (elongate inflation tube 20) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that

the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1002, 7:3-61.)

Claim 1: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site,"

Figure 4c shows the first elongate component (elongate inflation tube 20) deploying the prosthetic heart valve at a fixation site. (Ex. 1002, 7:39-41.)

Claim 1: "and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."

Block discloses that the valve 10 is initially mounted to the introducer 34 and advanced through the vasculature. (Ex. 1002, 7:10-38.) As such, Block discloses that the second elongate component (introducer member 34) is configured to apply an axial force to the prosthetic heart valve in a direction of advancement.

Claim 8: "A delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position and a spaced implantation location to which the prosthetic heart valve can also be releasably mounted in position,"

Block discloses a delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position and having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted in position. For example, Figure 4a of Block, annotated and reproduced above, shows the valve 10 in one of many possible "temporary valve locations," and

Figure 4b of Block, also annotated and reproduced above, shows the valve 10 in one of many possible "spaced implantation locations." Block discloses that the valve 10 is releasably mounted in position at both the temporary valve location and the spaced implantation location. (Ex. 1002, 7:24-40.)

Claim 8: "the delivery assembly comprising: a first elongate component; and a second elongate component,"

The delivery assembly of Block includes a first elongate component (elongate inflation tube 20) and a second elongate component (introducer member 34).

Claim 8: "wherein the first elongate component is configured to move relative to the second elongate component from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location,"

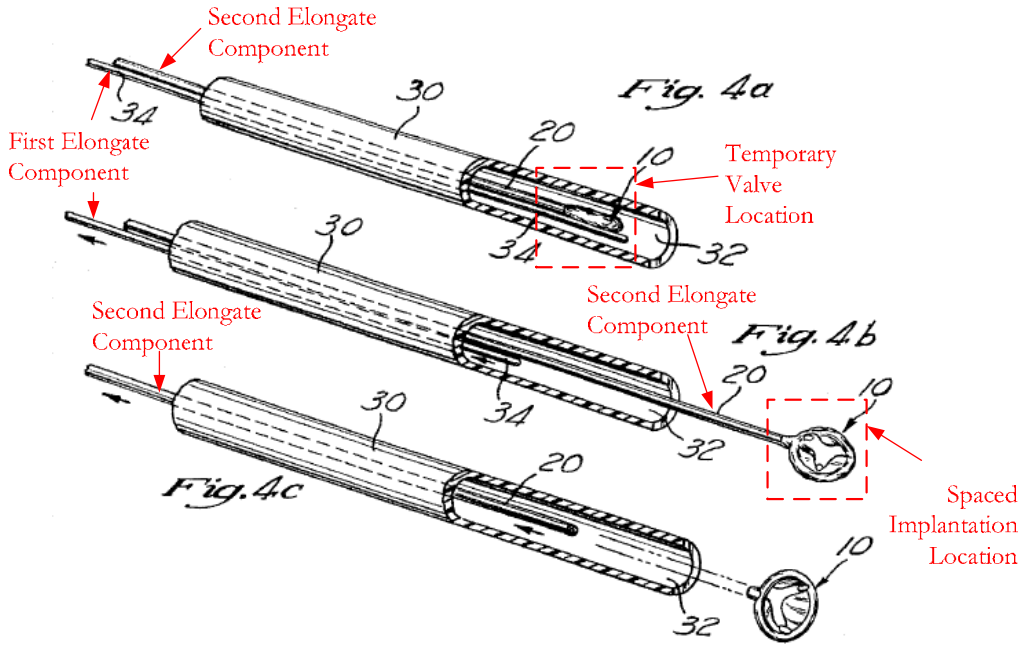
Figures 4a and 4b of Block illustrate that the first elongate component (elongate inflation tube 20) is configured to move relative to the second elongate component (introducer member 34) from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1002, 7:3-61.)

Claim 8: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site,"

Figure 4c shows the first elongate component (elongate inflation tube 20) deploying the prosthetic heart valve at a fixation site. (Ex. 1002, 7:39-41.)

Claim 8: "and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."

Block discloses that the valve 10 is initially mounted to the introducer 34 and advanced through the vasculature. (Ex. 1002, 7:10-38.) In this manner, the second elongate component (introducer member 34) applies an axial force to the prosthetic heart valve in a direction of advancement.



Analysis of Claim 11 - Annotated Figures 4a-4c of Block (Ex. 1002)

Claim 11: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate

component that is movably disposed to a second elongate component,"

Block discloses a prosthetic heart valve in combination with a delivery assembly in which the valve delivery system includes a first elongate component (introducer member 34) that is movably disposed to a second elongate component (elongate inflation tube 20), as shown in Figures 4a-4c of Block, annotated and reproduced above. Note the elements identified as "first" and "second" elongate components are switched relative to the analysis for claims 1 and 8.

Claim 11: "the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted, and the second elongate component having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted,"

Figure 4a shows the valve 10 in one of many possible "temporary valve locations." Block discloses that the valve 10 is releasably mounted to the first elongate component (introducer member 34) at the temporary valve location. (Ex. 1002, 7:24-37.) Figure 4b shows the valve 10 in one of many possible "spaced implantation locations." Block discloses that the valve 10 is releasably mounted to the second elongate component (elongate inflation tube 20) at the spaced implantation location. (Ex. 1002, 7:38-40.)

Claim 11: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first

elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location."

Figures 4a and 4b of Block illustrate that the prosthetic heart valve 10 and delivery assembly combination are configurable with movement of the first elongate component relative (introducer member 34) to the second elongate component (elongate inflation tube 20) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1002, 7:3-61.)

In view of the foregoing, Block discloses all of the elements recited in claims 1, 8, and 11. Accordingly, claims 1, 8, and 11 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Block.

2. Claims 7, 10, and 15

Claims 7, 10, and 15 respectively depend from independent claims 1, 8, and 11. Each of claims 7, 10, and 15 recites a distal portion of the first elongate component is articulable, and a distal portion of the second elongate component is articulable. As discussed above in Section VII, the broadest reasonable interpretation of an elongate

component that is "articulable" includes elements that are capable of being bent or otherwise manipulated. Block describes the introducer member as "as a bendable cardiovascular guidewire or elongate tubular member." (Ex. 1002, 7:17-22.) The inflation tube 20a included manipulation tethers and is illustrated in various stages of bending in Figures 5a-5d. (Ex. 1002, 8:14-39.) Thus, Block discloses that the distal ends of the first and second elongate components are articulable.

Accordingly, Block discloses all of the elements recited in claims 7, 10, and 15. As such, claims 7, 10, and 15 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Block.

3. Claims 12 and 13

Claims 12 and 13 each depend from claim 11. Claim 12 recites the first elongate component is a catheter and claim 13 recites the second elongate component is a catheter. As discussed above in Section VII, the broadest reasonable interpretation of "catheter" in light of the specification is a filament similar to a tube or wire. Block discloses that both the introducer member 34 and the elongate inflation tube 20 can be tubular members. (Ex. 1002, 7:17-38.) Thus, Block discloses that both the first elongate components are catheters.

Accordingly, Block discloses all of the elements recited in claims 12 and 13. As such, claims 12 and 13 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Block.

4. Claims 2-6, 9, and 14

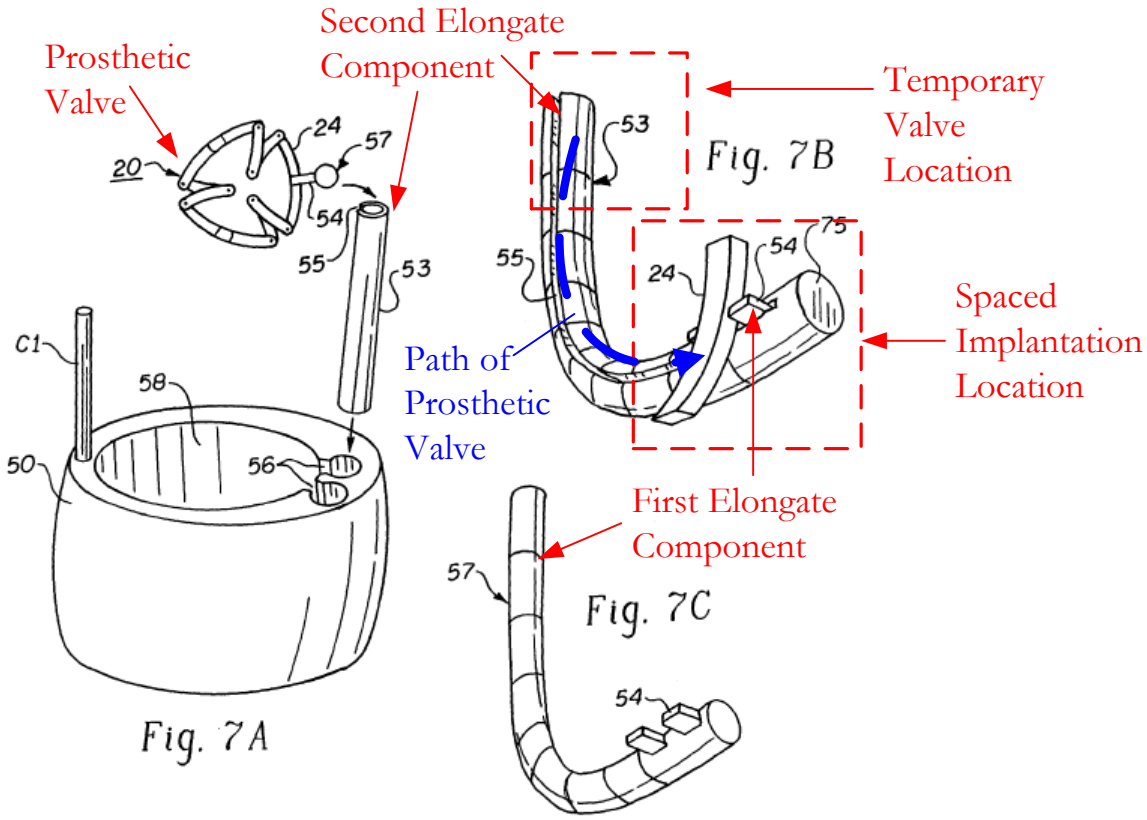
Block discloses all of the elements recited in claims 2-6, 9, and 14. Accordingly, claims 2-6, 9, and 14 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Block. The following claim chart specifies where each element of claims 2-6, 9, and 14 is found in Block:

The '077 Patent	Block (Ex. 1002)
2. The combination of claim 1, wherein the prosthetic heart valve is a replacement aortic valve.	Block states "the valves 10, 10a may be implanted adjacent to or in replacement of a malfunctioning heart valve, as shown in the illustration of the human heart shown in FIG. 3." (Ex. 1002, 5:41-63.) Figure 3 depicts a replacement aortic valve.
3. The combination of claim 1, wherein the prosthetic heart valve comprises tissue leaflets.	Block states "[b]iological leaflets 14 may be formed of chemically fixed mammalian valvular tissue or other biological tissue (e.g., pericardium) which is sufficiently thin and pliable to perform the desired valving function of the leaflets 14." (Ex. 1002, 4:23-27.)
24. The combination of claim 1, wherein the prosthetic heart valve is a replacement mitral valve.	*See* Ex. 1002, 5:41-63; Figure 3.
5. The combination of claim 1, wherein the prosthetic heart valve is a replacement pulmonic valve.	*See* Ex. 1002, 5:41-63; Figure 3.
6. The combination of claim 1, wherein the prosthetic heart valve is a replacement tricuspid valve.	*See* Ex. 1002, 5:41-63; Figure 3.
9. The delivery assembly of claim 8, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1002, 5:41-63; Figure 3.
14. The combination of claim 11, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1002, 5:41-63; Figure 3.

C. Claims 1-15 Are Unpatentable Under 35 U.S.C. § 102(b) as Anticipated by Vesely

1. Claims 1, 8, and 11

This subsection explains on an element-by-element basis how Vesely anticipates claims 1, 8, and 11 of the '077 patent.



Annotated Figures 7A-7C of Vesely (Ex. 1003)

Claim 1: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate component that is movably disposed to a second elongate component,"

Vesely discloses a catheter-based valve delivery system that includes several catheters or catheter sheaths that can shuttle a prosthetic heart valve in and out of the body to the desired spot. (Ex. 1003, 13:l-15:10.) Figures 7A-7C of Vesely, annotated and reproduced above, show the valve delivery system includes two elongate components (catheters 53, 57) that are "moveably disposed" to each other to create a "monorail" system that conveniently transports devices in and out of the body by moving the devices along the length of the main guiding catheter 53. (Ex. 1003, 13:19-30.) Thus, Vesely discloses a prosthetic heart valve (20) in combination with a delivery assembly in which the delivery assembly includes a first elongate component (inner catheter 57) that is movably disposed to a second elongate component (main guiding catheter 53).

> **Claim 1: "the delivery assembly having a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position and a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position,"**

Annotated Figure 7B identifies one of many "temporary valve locations" and one of many "spaced implantation locations" along the monorail system. Thus, the delivery assembly has a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position and a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position.

Claim 1: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location,"

Vesely discloses that prosthetic heart valve (20) and delivery assembly combination are configurable with movement of the first elongate component (inner catheter 57) relative to the second elongate component (main guiding catheter 53) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location.

Claim 1: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site,"

Vesely also discloses that, in one example, the inner catheter 57 and the main guiding catheter 53 cooperate to deploy the prosthetic valve 20. (Ex. 1003, 14:12-17.)

Claim 1: "and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."

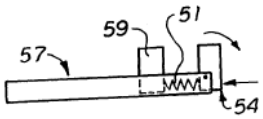


Fig. 7D

Figures 7D of Vesely (Ex. 1003)

The prosthetic valve 20 is releasably held by a gripping means 54 of the inner catheter 57. (Ex. 1003, 13:26-27.) Vesely explains that the gripping means 54 includes a simple, spring-loaded clamp 59 that is held closed by a conventional coil spring 51, shown above in Figure 7D. The spring 51 can be opened remotely simply by pushing the inner catheter 57 against the closed end 75 of the main guiding catheter 53. This generates a pushing force on the clamp 59 and allows one of the jaws to rotate, thus opening the clamp and releasing the device. (Ex. 1003, 14:12-17.) Thus, Vesely discloses that the first elongate component (inner catheter 57) is configured to deploy the prosthetic heart valve (20) at a fixation site. Further, at least through contact with the gripper 54, the second elongate component (main guiding catheter 57) is configured to apply an axial force to the prosthetic heart valve (20) in a direction of advancement.

Claim 8: "A delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position and a spaced implantation location to which the prosthetic heart valve can also be releasably mounted in position,"

Vesely discloses a delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position and a spaced

implantation location to which the prosthetic heart valve can also be releasably mounted in position, as shown in the annotated copy of Figures 7A-7C, above.

> **Claim 8: "the delivery assembly comprising: a first elongate component; and a second elongate component, wherein the first elongate component is configured to move relative to the second elongate component from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location"**

Vesely discloses the delivery assembly includes a first elongate component (inner catheter 57) and a second elongate component (main guiding catheter 53) in which the first elongate component (inner catheter 57) is configured to move relative to the second elongate component (main guiding catheter 53) from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1003, p. 13:1-14:18.)

> **Claim 8: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site, and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."**

As noted above with respect to claim 1, Vesely discloses that that the first elongate component (inner catheter 57) is configured to deploy the prosthetic heart valve (20) at a fixation site, and the second elongate component (main guiding catheter 57) is configured to apply an axial force to the prosthetic heart valve (20) in a direction of advancement.

> **Claim 11: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate component that is movably disposed to a second elongate component,"**

Vesely discloses a prosthetic heart valve in combination with a delivery assembly in which the delivery assembly includes a first elongate component (inner catheter 57) that is movably disposed to a second elongate component (main guiding catheter 53).

> **Claim 11: "the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted, and the second elongate component having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted,"**

As shown in annotated Figure 7b, above, the first elongate component (inner catheter 57) has a temporary valve location to which the prosthetic heart valve can be releasably mounted. The second elongate component (main guiding catheter 53) has

a spaced implantation location to which the prosthetic heart valve can also be releasably mounted.

> **Claim 11: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location."**

Vesely discloses that the prosthetic heart valve and delivery assembly combination are configurable with movement of the first elongate component (inner catheter 57) relative to the second elongate component (main guiding catheter 53) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1003, p. 13:1-14:18.)

In view of the foregoing, Vesely discloses all of the elements recited in claims 1, 8, and 11. Accordingly, claims 1, 8, and 11 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Vesely.

2. Claims 7, 10, and 15

Claims 7, 10, and 15 respectively depend from independent claims 1, 8, and 11.

Each of claims 7, 10, and 15 recites a distal portion of the first elongate component is articulable, and wherein a distal portion of the second elongate component is articulable. As discussed above in Section VII, the broadest reasonable interpretation of an elongate component that is "articulable" includes elements that are capable of being bent or otherwise manipulated.

Vesely states, with reference to the catheters 53 and 57 that "[t]he catheters, themselves act as remote manipulators that can be controlled by pull wires, or by means of small actuators controlled electrically or hydraulically that deflect the catheters or in some way change their shape." (Ex. 1003, 13:14-17.)

Accordingly, Vesely discloses all of the elements recited in claims 7, 10, and 15. As such, claims 7, 10, and 15 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Vesely.

3. Claims 12 and 13

Claims 12 and 13 each depend from claim 11. Claim 12 recites the first elongate component is a catheter and claim 13 recites the second elongate component is a catheter. Vesely discloses a delivery assembly in which the first elongate component is an inner catheter 57, and the second elongate component is a main guiding catheter 53.

Accordingly, Vesely discloses all of the elements recited in claims 12 and 13. As such, claims 12 and 13 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Vesely.

4. Claims 2-6, 9, and 14

Vesely discloses all of the elements recited in claims 2-6, 9, and 14. Accordingly, claims 2-6, 9, and 14 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Vesely. The following claim chart specifies where each element of claims 2-6, 9, and 14 is found in Vesely:

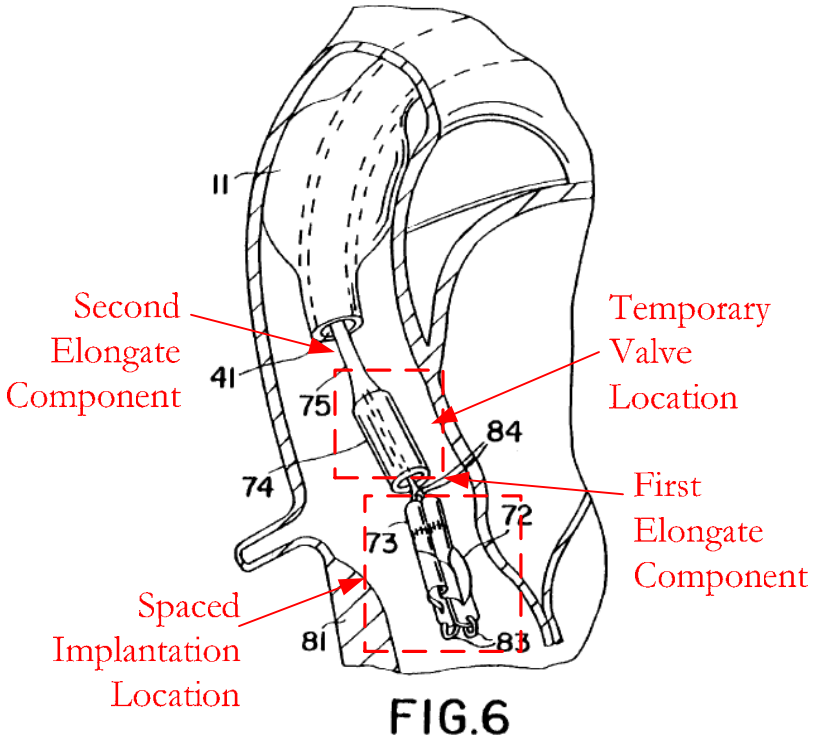
The '077 Patent	Vesely (Ex. 1003)
2. The combination of claim 1, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1003, p. 9, ll. 24-26.
3. The combination of claim 1, wherein the prosthetic heart valve comprises tissue leaflets.	Vesely states "[a]lthough the collapsible valve of the present invention may incorporate a wide range of leaflet materials, such as synthetic leaflets or those constructed from animal tissues, a preferred embodiment of the valve incorporates three (3) valve leaflets constructed from sheets of chemically preserved bovine pericardium." (Ex. 1003, p. 5, ll. 9-13.)
4. The combination of claim 1, wherein the prosthetic heart valve is a replacement mitral valve.	Vesely states "a similar system can be used to insert a similar collapsible valve (e.g., a prosthetic valve or endoprosthesis) into the mitral position, the pulmonary and tricuspid positions of the heart or an other expandable prosthetic device into any other location within the vasculature or an organ of any patient." (Ex. 1003, p. 9, ll. 19-23.)
5. The combination of claim 1, wherein the prosthetic heart valve is a replacement pulmonic valve.	*See* Ex. 1003, p. 9, ll. 19-23.
6. The combination of claim 1, wherein the prosthetic heart valve is a replacement tricuspid valve.	*See* Ex. 1003, p. 9, ll. 19-23.

The '077 Patent	Vesely (Ex. 1003)
9. The delivery assembly of claim 8, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1003, p. 9, ll. 24-26
14. The combination of claim 11, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1003, p. 9, ll. 24-26

D. Claims 1-15 Are Unpatentable Under 35 U.S.C. § 102(b) as Anticipated by Stevens

1. Claims 1, 8, and 11

This subsection explains on an element-by-element basis how Stevens anticipates claims 1, 8, and 11 of the '077 patent.



Analysis of Claims 1 and 8 - Annotated Figure 6 of Stevens (Ex. 1004)

Claim 1: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate

component that is movably disposed to a second elongate component,"

Figures 5-8 of Stevens show a prosthetic heart valve 72 in combination with a delivery assembly. Figure 6 of Stevens, annotated and reproduced above, shows the delivery assembly includes a first elongate component (any of the connector cables 84) that is movably disposed to a second elongate component (valve delivery catheter 75).

Claim 1: "the delivery assembly having a temporary valve location relative to the delivery assembly to which the prosthetic heart valve can be releasably mounted in position and a spaced implantation location relative to the delivery assembly to which the prosthetic heart valve can also be releasably mounted in position,"

Annotated Figure 6 identifies both a temporary valve location and a spaced implantation location. Stevens discloses that the valve 72 is initially disposed within the temporary valve location at the expanded end 74 of valve delivery catheter 75, and then later urged out of the expanded end 74. (Ex. 1004, 26:56-62.) Thus, the valve 74 is releasably mounted in position in the temporary valve location. Stevens further discloses that the valve 72 is released from the connector cables 84 by via releasable means 83 at the spaced implantation location. (Ex. 1004, 27:38-42.) Thus, the valve 74 is releasably mounted in position at the spaced implantation location.

Claim 1: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first

elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location,"

Stevens discloses that the prosthetic heart valve (72) and delivery assembly combination are configurable with movement of the first elongate component (any of the connector cables 84) relative to the second elongate component (valve delivery catheter 75) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1004, 26:56-64.)

Claim 1: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site,"

Stevens further discloses that the first elongate component (any of the connector cables 84) is configured to deploy the prosthetic heart valve at a fixation site. (Ex. 1004, 27:38-42.)

Claim 1: "and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."

Stevens also discloses that the valve 72 is advanced through an occluding catheter 10 by the delivery catheter 75. (Ex. 1004, 26:56-59.) Thus, Stevens discloses that the second elongate component (valve delivery catheter 75) is configured to apply an axial force to the prosthetic heart valve in a direction of advancement.

Claim 8: "A delivery assembly having a temporary valve location to which a prosthetic heart valve can be releasably mounted in position and a spaced implantation location to which the prosthetic heart valve can also be releasably mounted in position,"

Figure 6 of Stevens, annotated and reproduced above, shows a delivery assembly having a temporary valve location to which a prosthetic heart valve 72 can be releasably mounted in position and a spaced implantation location to which the prosthetic heart valve 72 can also be releasably mounted in position. (*See* Ex. 1004, 26:56-62; 27:38-42.)

Claim 8: "the delivery assembly comprising: a first elongate component; and a second elongate component,"

The delivery assembly includes a first elongate component (any of the connector cables 84) and a second elongate component (valve delivery catheter 75).

Claim 8: "wherein the first elongate component is configured to move relative to the second elongate component from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location,"

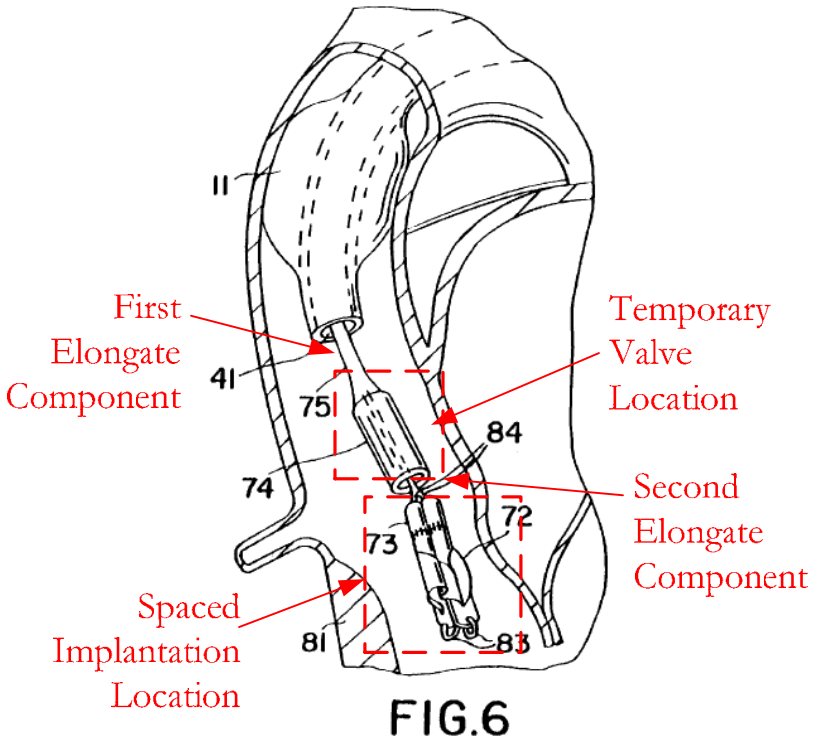
Stevens discloses that the first elongate component (any of the connector cables 84) is configured to move relative to the second elongate component (valve delivery catheter 75) from a delivery state with the prosthetic heart valve mounted at the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location such that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1004, 26:56-64.)

Claim 8: "wherein the first elongate component is configured to deploy the prosthetic heart valve at a fixation site,"

Stevens further discloses that the first elongate component (any of the connector cables 84) is configured to deploy the prosthetic heart valve at a fixation site. (Ex. 1004, 27:38-42.)

Claim 8: "and wherein the second elongate component is configured to apply an axial force to the prosthetic heart valve in a direction of advancement."

Stevens also discloses that the valve 72 is advanced through an occluding catheter 10 by the delivery catheter 75. (Ex. 1004, 26:56-59.) Thus, Stevens discloses that the second elongate component (valve delivery catheter 75) is configured to apply an axial force to the prosthetic heart valve in a direction of advancement.



Analysis of Claim 11 - Annotated Figure 6 of Stevens (Ex. 1004)

Claim 11: "A prosthetic heart valve in combination with a delivery assembly, the delivery assembly comprising: a first elongate component that is movably disposed to a second elongate component,"

Figure 6 of Stevens, annotated and reproduced above, shows a prosthetic heart valve in combination with a delivery assembly in which the delivery assembly includes a first elongate component (valve delivery catheter 75) that is movably disposed to a second elongate component (any of the connector cables 84). Note the elements identified as "first" and "second" elongate components are switched relative to the analysis for claims 1 and 8.

Claim 11: "the first elongate component having a temporary valve location to which the prosthetic heart valve can be releasably mounted, and the second elongate component having a spaced implantation location to which the prosthetic heart valve can also be releasably mounted,"

As shown in Figure 6, the first elongate component (valve delivery catheter 75) has a temporary valve location to which the prosthetic heart valve can be releasably mounted. (Ex. 1004, 26:56-62.) Likewise, the second elongate component (any of the connector cables 84) has a spaced implantation location to which the prosthetic heart valve can also be releasably mounted. (Ex. 1004, 27:38-42.)

Claim 11: "the prosthetic heart valve and delivery assembly combination being configurable with movement of the first elongate component relative to the second elongate component from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location."

Stevens discloses that the prosthetic heart valve and delivery assembly combination is configurable with movement of the first elongate component (valve delivery catheter 75) relative to the second elongate component (any of the connector cables 84) from a delivery state with the prosthetic heart valve mounted to the temporary location to an implantation state with the prosthetic heart valve

repositioned from the temporary location to the implantation location so that the prosthetic heart valve can subsequently be deployed from the implantation location. (Ex. 1004, 26:56-64.)

In view of the foregoing, Stevens discloses all of the elements recited in claims 1, 8, and 11. Accordingly, claims 1, 8, and 11 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Stevens.

2. Claims 7, 10, and 15

Claims 7, 10, and 15 respectively depend from independent claims 1, 8, and 11. Each of claims 7, 10, and 15 recites a distal portion of the first elongate component is articulable, and wherein a distal portion of the second elongate component is articulable. As discussed above in Section VII, the broadest reasonable interpretation of an elongate component that is "articulable" includes elements that are capable of being bent or otherwise manipulated. Stevens discloses both the bending and manipulation of both the valve delivery catheter 75 and the connector cables 84. (*See* Ex. 1004, 26:56-62; 27:38-42.)

Accordingly, Stevens discloses all of the elements recited in claims 7, 10, and 15. As such, claims 7, 10, and 15 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Stevens.

3. Claims 12 and 13

Claims 12 and 13 each depend from claim 11. Claim 12 recites the first elongate component is a catheter and claim 13 recites the second elongate component

is a catheter. As discussed above in Section VII, the broadest reasonable interpretation of "catheter" in light of the specification is a filament similar to a tube or wire. Both the valve delivery catheter 75 and the connector cables 84 meet this definition.

Accordingly, Stevens discloses all of the elements recited in claims 12 and 13. As such, claims 12 and 13 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Stevens.

4. Claims 2-6, 9, and 14

Stevens discloses all of the elements recited in claims 2-6, 9, and 14. Accordingly, claims 2-6, 9, and 14 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Stevens. The following claim chart specifies where each element of claims 2-6, 9, and 14 is found in Stevens:

The '077 Patent	Stevens (Ex. 1004)
2. The combination of claim 1, wherein the prosthetic heart valve is a replacement aortic valve.	Stevens states "[t]he procedures with which the invention will find use include repair or replacement of aortic, mitral, and other heart valves…" (Ex. 1004, 20:32-34.)
3. The combination of claim 1, wherein the prosthetic heart valve comprises tissue leaflets.	Stevens states "[t]he valve 72 is preferably a bioprosthetic valve such as xenograft valve. Porcine glutaraldehyde preserved valves are quite suitable because, as previously mentioned, they are readily accessible, they are storable, and they are available in a variety of sizes." (Ex. 1004, 26:46-51.)
4. The combination of claim 1, wherein the prosthetic heart valve is a replacement mitral valve.	*See* Ex. 1004, 20:32-34.

The '077 Patent	Stevens (Ex. 1004)
5. The combination of claim 1, wherein the prosthetic heart valve is a replacement pulmonic valve.	*See* Ex. 1004, 20:32-34.
6. The combination of claim 1, wherein the prosthetic heart valve is a replacement tricuspid valve.	*See* Ex. 1004, 20:32-34.
9. The delivery assembly of claim 8, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1004, 20:32-34.
14. The combination of claim 11, wherein the prosthetic heart valve is a replacement aortic valve.	*See* Ex. 1004, 20:32-34.

IX. CONCLUSION

For the foregoing reasons, claims 1-15 of the '077 patent are unpatentable. Petitioner therefore requests that an *inter partes* review of these claims be instituted pursuant to 35 U.S.C. § 314, and that claims 1-15 be cancelled.

Respectfully submitted,

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EXHIBIT APPENDIX

Ex.	Description
1001	U.S. Patent No. 8,623,077 (for *inter partes* review)
1002	U.S. Patent No. 5,554,185 to Block et al., issued on September 10, 1996
1003	International Patent Application Publication No. WO 99/33414, published on July 8, 1999
1004	U.S. Patent No. 5,885,238 to Stevens et al., issued on March 23, 1999
1005	Prosecution History of U.S. Patent No. 8,623,077
1006	Prosecution History of U.S. Patent Application No. 13/012,466
1007	Prosecution History of U.S. Patent Application No. 12/776,136
1008	Office of the President, *Patent Assertion and U.S. Innovation,* June 2013
1009	*FACT SHEET: White House Task Force on High-Tech Patent Issues*, June 4, 2013
1010	Prosecution History of U.S. Application Serial No. 13/617,959
1011	Prosecution History of Reexamination Control No. 90/013,064
1012	U.S. Provisional Application No. 60/488,548

CERTIFICATE OF SERVICE

I hereby certify that, on February 20, 2014, I caused a true and correct copy of the foregoing Petition for *inter partes* review of U.S. Patent No. 8,623,077 ("the '077 patent") and all associated supporting materials to be served via UPS Overnight Delivery at the correspondence address of record for the '077 patent:

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