

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH,
Petitioners

v.

Maquet Cardiovascular, LLC
Patent Owner

Case IPR2017-01029
U.S. Patent No. 9,327,068

PATENT OWNER'S PRELIMINARY RESPONSE

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2002	J. Dens et al., <i>First experience with the Impella Recover® LP 2.5 micro axial pump in patients with cardiogenic shock or undergoing high-risk revascularization</i> , 2 <u>EuroIntervention</u> 84 (2006) (“Dens”)
2003	Kenji Araki et al., <i>Hemolysis and Heat Generation in Six Different Types of Centrifugal Blood Pumps</i> , 19 <u>Artificial Organs</u> 928 (1995) (“Araki”)
2004	Yoshitaka Hayashi et al., <i>Percutaneous Cardiopulmonary Support with Heparin-Coated Circuits in Postcardiotomy Cardiogenic Shock</i> , 48 <u>The Japanese J. of Thoracic & Cardiovascular Surgery</u> 274 (2000) (“Hayashi”)
2005	J. Michael Duncan, MD, et al., <i>Implantation Techniques for the Hemopump</i> , 48 <u>Ann Thorac Surg</u> 733 (1989) (“Duncan”)
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2007	A. Michael Lincoff et al., <i>Percutaneous Support Devices for High Risk or Complicated Coronary Angioplasty</i> , 17 <u>JACC</u> 770 (1991) (“Lincoff”)

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2008	Dimitar Mihaylov et al., Development of a New Introduction Technique for the Pulsatile Catheter Pump, 425 <u>Artificial Organs</u> 425 (1997) (“Mihaylov”)
2009	Kevin E. Griffith and Eric Jenkins, <i>Abiomed Impella® 2.5 Patient Transport: Lessons Learned</i> , 25 <u>Perfusion</u> 381 (2010) (“Griffith”)
2010	Devin V. Amin et al., <i>Induction of Ventricular Collapse by an Axial Flow Blood Pump</i> , <u>ASAIO J.</u> M685 (1998) (“Amin”)
2011	Richard K. Wampler et al., <i>The Sternotomy Hemopump: A Second Generation Intraarterial Ventricular Assist Device</i> , <u>ASAIO J.</u> M218 (1993) (“Wampler”)
2012	Steven C. Gundry et al., <i>Percutaneous Cardiopulmonary Bypass to Support Angioplasty and Valvuloplasty: Technical Considerations</i> , <u>Trans Am Soc Artif Intern Organs</u> 725 (1989) (“Gundry”)
2013	Sripal Bangalore and Deepak L. Bhatt, <i>Femoral Arterial Access and Closure</i> , 124 <u>Circulation</u> e147 (2011), available at http://circ.ahajournals.org/content/124/5/e147 (“Bangalore”)
2014	Hirofumi Ide et al., <i>Hemodynamic Evaluation of a New Left Ventricular Assist Device: An Integrated Cardioassist Catheter as a Pulsatile Left Ventricle-Femoral Artery Bypass</i> , 16 <u>Artificial Organs</u> 286 (1992) (“Ide”)
2015	John M. Toomasian and Walid Aboul-Hosn, <i>Coronary Artery Bypass Grafting Using a Miniature Right Ventricular Support System</i> , 15 <u>Perfusion</u> 521 (2000) (“Toomasian”)

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2016	Charanjit S. Rihal et al., <i>2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care</i> , 21 <u>J of Cardiac Failure</u> 499 (2015) (“Rihal”)
2017	Helene Eltchaninoff, MD, et al., <i>Complications Associated with Percutaneous Placement and Use of Intraaortic Balloon Counterpulsation</i> , 71 <u>The Am. J of Cardiology</u> 328 (1993) (“Eltchaninoff”)
2018	<i>Percutaneous</i> , Webster’s II New College Dictionary (3 rd ed. 1999)
2019	T. Sieß et al., <i>Hydraulic Refinement of an Intraarterial Microaxial Blood Pump</i> , 18 <u>The Int’l J of Artificial Organs</u> 273 (1995) (“Siess”)
2020	International Publication No. PCT WO 2017/053361 (“Abiomed PCT”)
2021	Bart Meyns, MD, PhD, et al., <i>Mechanical Support with Microaxial Blood Pumps for Postcardiotomy Left Ventricular Failure: Can Outcome be Predicted?</i> , 120 <u>The J of Thoracic and Cardiovascular Surgery</u> 393 (2000) (“Meyns”)

I. INTRODUCTION

Blood pump systems must be carefully configured to support or even replace the function of a damaged or diseased heart. To achieve these lifesaving goals, designers must balance competing design considerations that are particularly challenging in the case of intravascular pump systems for placement into a patient's circulatory system. In this environment, even the slightest design modifications can mean the difference between life and death. System designers must maintain a delicate balance between a variety of factors including size, shape, stiffness, material composition, and positioning. Moreover, the system and its components must not damage the myriad components in blood.

U.S. Patent No. 9,327,068 ("068 Patent") relates to a method of perfusing a patient with an intravascular blood pump system having a unique combination of features specifically tailored to address the difficulties associated with introducing an intravascular blood pump into a patient's circulatory system and positioning it in a desired location. Prior intravascular pumps did not adequately achieve these goals. The claimed solution provides an intravascular blood pump having a specific impeller design to address challenges associated with the components of blood and sized to fit within a patient's circulatory system. The system includes a guide mechanism physicians can use to safely and reliably position the

intravascular blood pump in a predetermined location within the circulatory system—typically the heart.

The Petition suffers in its entirety from a fundamental error: its reliance on the reverse-flow blood pump in Aboul-Hosn (e.g., Figures 1-13) designed to be located outside a patient's circulatory system, *i.e.*, an **external** pump, as a purported basis for invalidity of the intravascular blood pump system claimed in the '068 Patent. Apparently recognizing the **external** pump of Aboul-Hosn cannot, by itself, provide grounds for unpatentability of the challenged claims, Petitioners attempt to combine Aboul-Hosn's external pump with a broad disclosure elsewhere in the reference of a stabilization balloon catheter having an intravascular pump system (e.g., Figure 23) used when the heart is entirely stopped, even though such disclosure is silent as to the structure and operation of the intravascular pump. Even that is not enough to address the elements of the challenged claims.

Petitioners, untethered from the actual teachings of Aboul-Hosn or other references, propose to manipulate the external pump disclosed in Aboul-Hosn by systematically eliminating or outright redesigning core features of the prior art disclosure in an effort to convince the Board a person of ordinary skill in the art ("POSITA") would understand Aboul-Hosn's external pump could be modified for intravascular use. This transformation finds no support, mischaracterizes the

teachings in the prior art, relies on a wholesale redesign of the disclosed external pump, and ultimately requires the Board to participate in the type of hindsight analysis it routinely and explicitly rejects. What's more, Petitioners embark on their re-design without ever addressing the consequences of removing elements from a particular embodiment, and while remaining completely silent as to how or why distinct embodiments in the Aboul-Hosn reference could (or would) be combined. Once Petitioners' arguments are unpacked, it becomes clear Aboul-Hosn fails to teach or suggest multiple elements of the claims. The numerous secondary references do not make up for these shortcomings, ***nor are they cited for such a purpose.***

The Petition also suffers from numerous procedural flaws. Specifically, Petitioners rely on references either previously considered or redundant of references already considered. Petitioners' primary reference, Published PCT Application WO 99/02204 ("Aboul-Hosn"), shares a common co-inventor with the '068 Patent and was considered during prosecution of the application that led to the '068 Patent. Notably, Petitioners admit Aboul-Hosn is redundant of numerous other references likewise considered during prosecution.

Accordingly, Petitioners have failed to meet their burden under 37 C.F.R. § 42.108(c) of establishing a reasonable likelihood of success that any of Claims

10-22 would be unpatentable. Accordingly, Patent Owner respectfully requests that the Board decline to institute *inter partes* review.

II. BACKGROUND

The inventors of the '068 Patent overcame numerous design challenges to arrive at an innovative intravascular blood pump by balancing conflicting requirements not previously addressed. These devices operate within, and sometimes replace the function of, a patient's heart. Failure can result in severe consequences, even death. Consequently, changes to pump systems are made only after extensive study and testing.

Before discussing the claims in detail, it is helpful first to summarize some (by no means all) design challenges the inventors encountered that had stymied prior artisans.

A. Blood Pump Design Challenges

1. Blood is a Difficult Fluid to Pump

Blood is a non-Newtonian fluid that is a suspension of various living cells and particles. Transporting these cells with a pump must be done delicately to avoid adversely affecting, damaging, or destroying the various cells and particles (Ex. 2001, 193-95; Ex. 2002, 86-88).

Damage to red blood cells and platelet aggregation represent particularly challenging issues (Ex. 2001, 195; Ex. 2003, abstract). For example, rupture of the cell membrane of red blood cells, known as hemolysis, can lead to reduced

oxygenation of vital organs, renal dysfunction, hypertension, and thrombosis, resulting in adverse clinical outcomes and even patient death (Ex. 2002, 89; Ex. 2004, 274). Hemolysis can be caused by shear stress associated with operation of an intravascular pump, as well as excessively turbulent or rapid flow of blood through the cannula or other components of the pump system (Ex. 2002, 86, 89).

Localized temperature elevation during pump operation can also result in blood damage (Ex. 2003, abstract).

Clotting is another concern. Platelet activation as a result of pump operation, or as a result of contact with a non-biocompatible surface, can trigger clot formation (Ex. 2004, 274-75). A clot in the pump can obstruct pump output or even result in pump failure. If a clot breaks free and travels outside the pump system, the patient can suffer a stroke due to obstructed circulation to vital organs, most notably the brain (Ex. 2010, M685).

2. Miniaturizing Technology

In general, the larger a pump, the more blood flow it can safely generate. A large pump may generate flow similar to a healthy heart, but generally at the expense of being more difficult to insert than a smaller pump providing less flow (Ex. 2002, 89). For intravascular blood pump systems this is particularly challenging because of severe space constraints (Ex. 2001, 193-95).

An intravascular pump system must be small enough to be inserted into the circulatory system and flexible enough to advance into the proper location within the heart (Ex. 2006, 769-70). For left ventricle operation, the intravascular pump system may be inserted in the femoral artery in the groin (Ex. 2006, 769). The pump travels up the artery into the descending aorta, around the aortic arch, and towards the aortic valve, while avoiding other major blood vessels (Ex. 2002, 85-86). Once in the aorta, the pump system traverses the aortic valve while the valve is moving and eventually reaches its proper position (Ex. 2002, 85, 89).

These environmental challenges are difficult because once the pump is located in the heart, it still must be sufficiently large to assist the heart with blood circulation (Ex. 2007, 777).

The inventors of the '068 Patent had to design a pump accounting for these conflicting size requirements.

3. Dynamic Environment

Intravascular pump design must account for the dynamic nature of the operating environment. An intravascular pump should not disturb natural contractions of the heart (Ex. 2008, 426-27). The beating of a heart, changes in heart rate or blood pressure, adjustments to pump speed, movement of the patient, and movement of the catheter may all cause dislodgement (Ex. 2009, 383-84).

Further, circulatory demands change over time. For example, changes in blood pressure, metabolic demands of the body, and fluid volume shifts may necessitate adjustments to pump output (Ex. 2010, M685). In addition, changes in native heart output may further require increasing or decreasing pump output (Ex. 2011, M221).

An intravascular pump system must account for these dynamic changes efficiently. Failing to adequately support a patient's heart, even for minutes, can adversely affect a patient (Ex. 2010, M688).

4. Safe Operation

An intravascular pump system must be anatomically appropriate for a broad variety of patients. It must be biocompatible and minimize the risk of traumatizing internal tissues during insertion and operation (Ex. 2006, 769-70). That is, the device should not damage the delicate inner surface of the blood vessels—damage by friction or scraping against a foreign surface may cause erosion to the vessel wall, leading to local clotting and risk of stroke.

This is of particular concern for intravascular systems, which are used in patients suffering from a variety of diseases, including compromised cardiovascular systems (Ex. 2004, 278). In patients with Peripheral Arterial Disease (PAD), care must be taken not to disturb blood vessels and liberate plaque from the vessel wall, which can cause vessel trauma and stroke (Ex. 2012, 725-26).

Certain cancer patients may have tortuous femoral arteries, which complicate the insertion path for these pump systems (Ex. [[2013 – Bangalore]], e149-151).

These are just some challenges the inventors of the '068 Patent encountered. Failure to appropriately balance any of these considerations could damage a patient's heart or other vital organs, cause stroke, and even lead to a patient's death. As a result, changes to intravascular blood pump systems are not performed routinely, but rather as a result of extensive study and testing.

B. Heart Assist Devices

Three main pump designs were developed in the marketplace at the time of the invention. These include external pumps, intra-aortic balloon pumps ("IAB"), and intravascular blood pumps. Each developed independently based on specific design choices unique to that device. At the time of the invention, external pumps and IABs were more developed and available compared to intravascular pumps, which were still in the early stages of development.

1. External Blood Pumps

External blood pumps address the above design concerns by locating the pump external to the circulatory system, often outside the body (extracorporeal pumps). In order to communicate with the circulatory system, these pumps utilize various cannula designs to establish blood flow out of the circulatory system and into the pump (Ex. 2014, 286-87).

There are essentially no space constraints for these pumps, thus more design options are available (Ex. 2008, 425). For example, external designs could include pumps without any impeller, such as roller pumps and scroll pumps. One such external device using a dual cannula configuration with an external pump in order to circulate blood is illustrated below (Ex. 1004, Fig. 24).

Ex. 1004, Figure 24 (Annotations in Red and Blue (Showing Blood Flow))

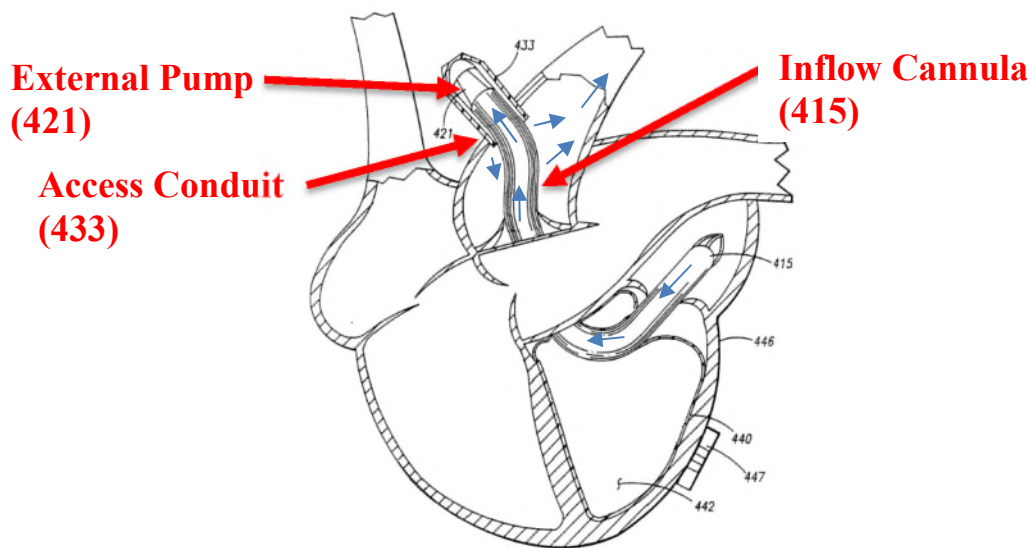
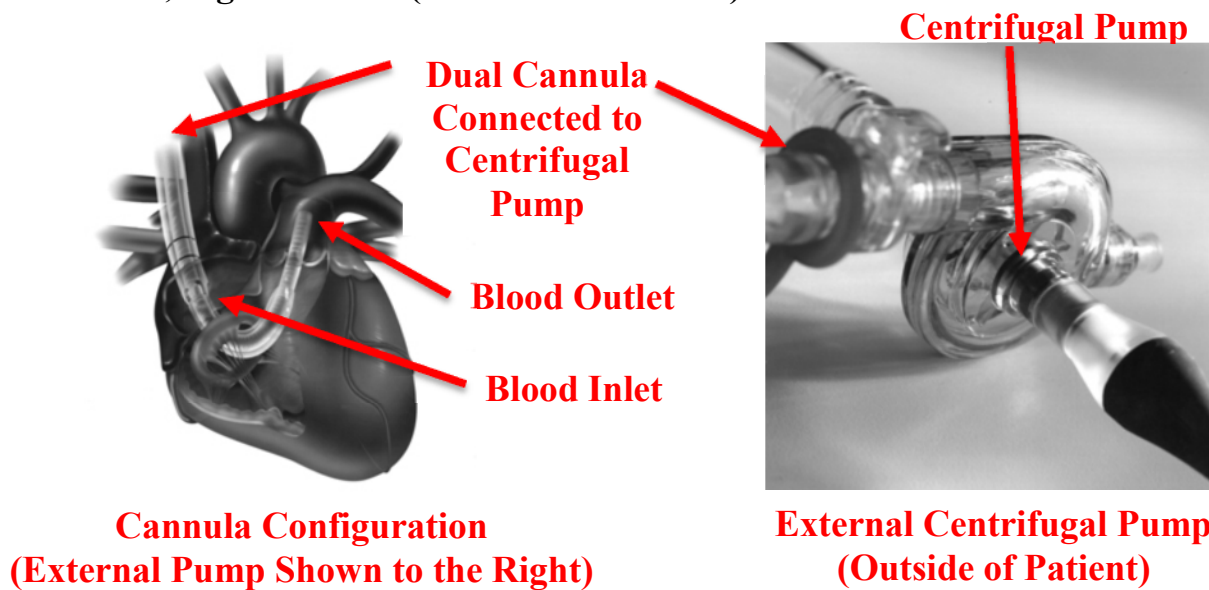


FIG. -24

The above drawing is from Petitioners' primary reference. Below is a picture of a similar system that was actually developed showing an analogous cannula design with an external centrifugal pump (Ex. 2015).

Ex. 2015, Figures 2 & 3 (Annotations in Red).



As shown, external pumps differ significantly from intravascular pumps because only tubular cannulas are inserted into the circulatory system. The pump remains outside the body.

2. Intra-Aortic Balloon Pumps

In addition to external pumps, less invasive devices such as IABs were available at this time. These devices used a balloon located in the descending aorta that inflates and deflates in counter-synchrony with the heart to assist the heart in circulating blood (Ex. 2016, 503).

Although IABs can be inserted into the circulatory system with relative ease, they work differently from other intravascular blood pumps (Ex. 2017, abstract). IABs use a balloon to alter the pressure within the circulatory system instead of an impeller for physically moving blood (Ex. 2007, 771-73). In addition, IABs do not

have cannulas crossing the aortic valve. These factors, and others, allow for a smaller design and a less invasive, less complex insertion procedure.

3. Intravascular Blood Pumps

Unlike external pumps and the IAB pump designs, at the time of the invention intravascular blood pump technology was in its infancy. Only one intravascular blood pump system had been developed, the Hemopump, which was developed in the late 1980s. The lead developer of this device, Dr. Richard Wampler, was the named inventor on many patents relating to these devices (Ex. 1009, Ex. 1010; *see also* Ex. 1008). The Hemopump suffered from a number of drawbacks (Ex. 2001, 196). It was difficult to insert and locate in many patients, particularly in emergency situations (Ex. 1033). In addition, it was a large device ***and could not be percutaneously inserted*** (e.g., by way of needle through the skin without surgery (*See* Ex. 2018, 816)) into a patient (Ex. 2007, 777). As a result, instead of the minimally-invasive percutaneous procedure, the insertion of the Hemopump required a vascular surgeon to cut open a patient's leg and suture a vascular graft to the femoral artery (Ex. 2005, 733-34).

Also at the time of the invention, a company known as Impella, which was a predecessor of Petitioners, was attempting to develop an improved intravascular pump design. Impella's lead developer, Dr. Thorsten Siess, was a named inventor on many patents assigned to this company (Ex. 1005; Ex. 1006; Ex. 1018; Ex.

1019). These designs also failed to disclose the claimed invention (*id.*). Impella focused on using a miniaturized electrical motor to drive the impeller (*id.*; *see also* Ex. 2019, abstract). ***Notably, none of their devices included (or identified a need for) a guide mechanism.***

The only other player at that time in the nascent intravascular blood pump field was A-Med, the developer of the challenged patent and employer of inventor Walid Aboul-Hosn. The fact Petitioners rely primarily on PCT publication WO 99/02204 (“Aboul-Hosn”), a reference from the named inventor of the ’068 patent, rather than a reference directed to the Hemopump or Petitioners’ own Impella, implicitly concedes those other intravascular pump designers had not recognized the advantages of the claimed features at the time of this invention (Petition, 4-5). And while Petitioners’ arguments fail, their positions demonstrate intravascular pump technology was far from “conventional.”

None of these prior intravascular pumps include the claimed guide mechanism. Petitioners concede as much, because they do not even cite the Hemopump, Impella, or A-Med references in their section entitled “Conventional Guide Wire Techniques for Placing Intravascular Blood Pumps” (Petition, 6-9).

Instead, Petitioners’ background section cites two references directed to unrelated devices, Voelker and Yock (*id.*). Voelker discloses a balloon catheter, an angioplasty device designed to remove plaque from blood vessels (Ex. 1012, 1:3-

6). Yock discloses a separate angioplasty device including a catheter and a balloon element but no pump system (Ex. 1007, Title and Abstract). These angioplasty devices are significantly smaller than blood pumps intended to support the heart, are designed to go into coronary blood vessels, and are used for a different purpose. As such, both Voelker and Yock are fundamentally different from the claimed invention. Petitioners apparently recognized this because *neither reference is used by Petitioners as a ground for the “guide mechanism” limitation* in the claims (Petition, 4).

In fact in 2006—over five years after the application that led to the challenged patent was filed—Petitioners were still using devices that did not include guide mechanisms (Ex. 2002). During clinical trials, practitioners were unable to properly locate Impella blood pumps; their first few attempts failed (Ex. 2002, 86-87). As a result, the device was modified to allow for an “over-the-wire” technique and include a “pigtail” feature (Ex. 2002, 87-89).

This article further indicates the need to use this “over-the-wire” technique was only apparent to Petitioners after this 2006 clinical trial:

Initially, investigators, trying to advance the cannula across the *aortic valve directly*, encountered problems of kinking of the cannula. This kinking resulted in failure of crossing the aortic valve (in 2 patients). *Since the introduction of this over-the-wire technique*, no more failures were encountered.

(Ex. 2002, 89) (emphasis added). *Thus, Petitioners’ own products contradict their position that any “conventional” guide mechanisms existed at the time of the invention. It took Petitioners more than five years after the invention date to develop a guide feature and even then, only after clinical trials in which their product failed on LIVE patients did Petitioners incorporate a guide mechanism into its product.*

Moreover, Petitioners themselves asserted an improved guide mechanism was needed as recently as 2015—further contradicting their central argument that a guide mechanism was well-known in 2000 (Ex. 2020, 1:25-2:5 (“But the cannula of the pump assembly can have a tortuous shape, or the cannula can be stiff...This can make backloading and insertion of the pump assembly into a patient particularly difficult....Systems, methods, and devices for an improved guidewire for cannula placement are presented.”)).

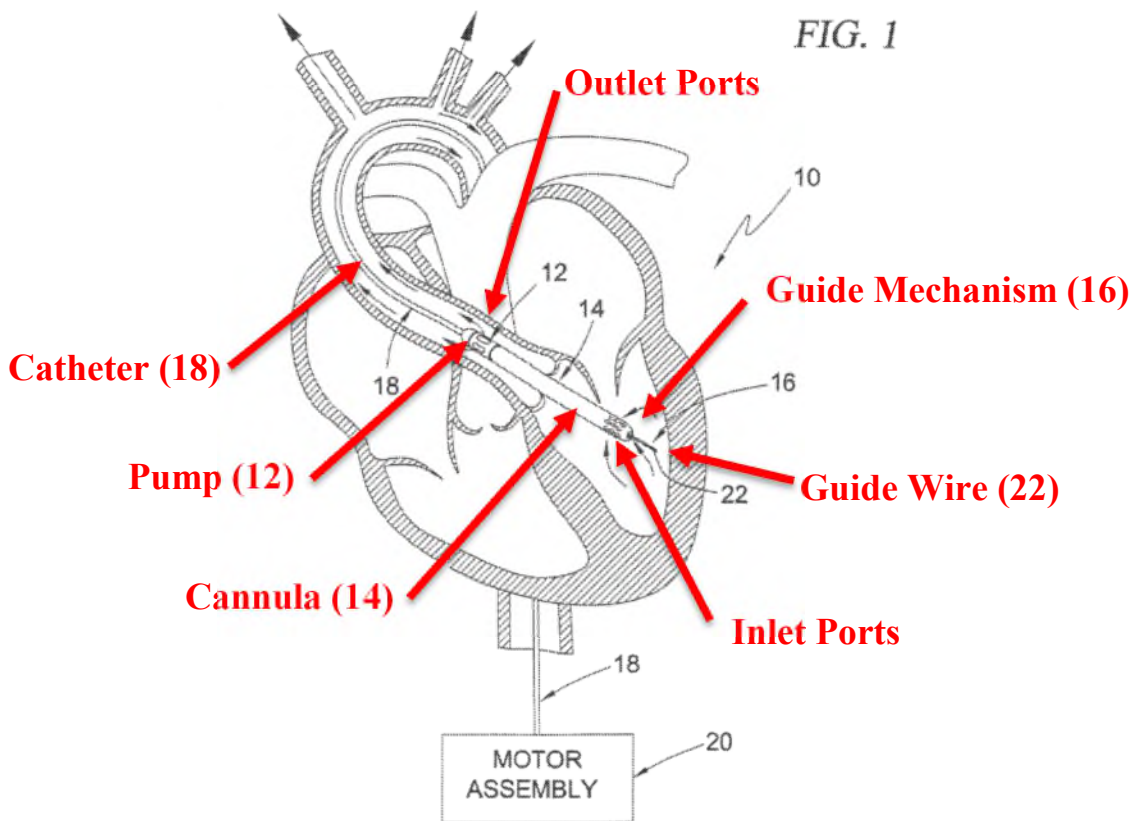
C. U.S. Patent No. 9,327,068

The inventors of the ’068 Patent developed an improved intravascular blood pump system that can be inserted percutaneously (or via other minimally invasive techniques) and located within a patient’s circulatory system, often a patient’s aorta (Ex. 1001, abstract). First, the background confirms the aforementioned shortcomings in intravascular blood pumps, namely the lack of a guide mechanism that could safely and reliably position the pump in the heart without constricting or

otherwise blocking blood flow (Ex. 1001, 2:11-48). In view of this known problem, the '068 Patent provides an advanced design incorporating a guide mechanism, thus addressing the problem that plagued the Hemopump designs and frustrated later-developed Impella designs (Ex. 1001, Abstract). The inventors went further and identified the necessary combination of features to be used in this improved intravascular pump system (Ex. 1001, 2:52–4:67).

Figure 1 illustrates an exemplary embodiment of the present invention, with the guide wire (22) extending out the distal end of the cannula, along with various other features associated with this invention.

Ex. 1001, Figure 1 (Annotations in Red).



This shows the intravascular blood pump, catheter, cannula, and guide mechanism located within a patient's circulatory system. This embodiment is designed to support the function of the left ventricle¹ in circulating blood throughout the body. Once inserted, intravascular pump (12) is located within the aorta (Ex. 1001, 7:6-9, Fig. 1). Cannula (14) traverses the aortic valve, allowing

¹ The disclosed invention can also be used for right ventricle assistance (Ex. 1001, 6:55-57, Fig. 19).

blood to flow into the cannula from the left ventricle (Ex. 1001, 7:20-24, Fig. 1). The cannula then directs blood towards the pump and eventually out the outlet ports located within the aorta (*id.*).

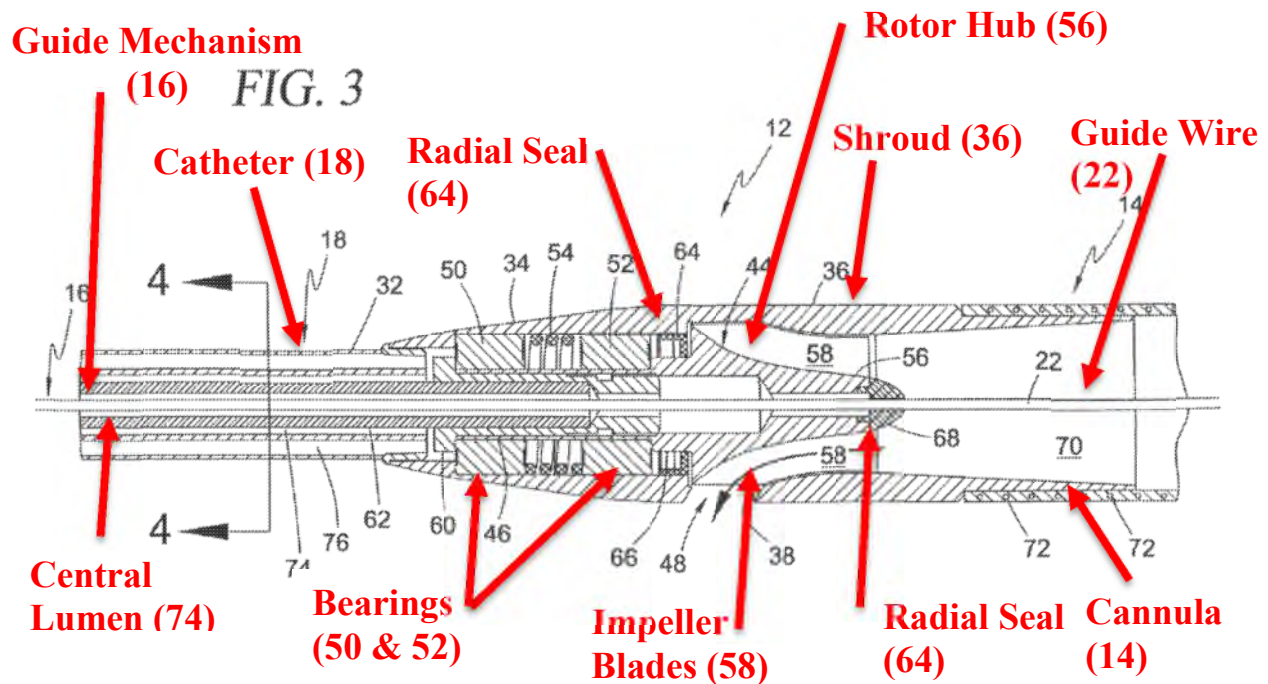
The above embodiment utilizes an “over-the-wire” guide mechanism (16), in which a lumen engages with a guide wire (22) and allows the device to traverse the aortic arch to reach the position shown above (Ex. 1001, 7:9-16). Also, the above figure shows a catheter, which moves the intravascular pump through the circulatory system, maintains the pump and cannula in the proper location, and allows for communication between pump features and devices located outside the body (Ex. 1001, 7:50–8:7).

Each of the features may include additional components. For example, the catheter may include various different elements such as a purge fluid lumen, a fluid-filled lumen for sensing pressure, and potentially other features (Ex. 1001, 8:2-7, 10:16-31, 17:64–18:13). The purge fluid lumen provides a continuous pressurized fluid flow, preventing blood from entering the pump housing and providing lubrication to the impeller shaft (Ex. 1001, 8:2-7, 10:16-31). In one embodiment, to detect pressure, a separate lumen is filled with fluid to communicate pressure near the pump to a transducer outside the body, which converts this pressure into a readable value (Ex. 1001, 17:64–18:13).

In addition, cannula (14) directs the blood being pumped (Ex. 1001, 7:9-11). The size should be sufficient to permit blood flow without creating excessive turbulent flow, which can damage blood components (Ex. 1001, 8:16-35). The cannula must also be flexible enough to allow intravascular insertion, while simultaneously having sufficient rigidity to resist collapsing during pump operation.

Pump (12) includes numerous features to account for challenges of using a miniature pump within the heart (Ex. 1001, 8:65–9:46). The pump must be sufficiently powerful to circulate the desired blood flow, while not destroying blood cells, which can lead to hemolysis, clotting, and even death (Ex. 1001, 1:41-55). Other features, such as the shroud, driveshaft, bearings, seals, and others components, all must be designed to account for the difficulties of operating within a patient's circulatory system while accommodating a guide mechanism (16) (Ex. 1001, 8:65–9:46). An embodiment illustrating in longitudinal cross-section several of these features is shown below.

Ex. 1001, Figure 3 (Annotations in Red).



The '068 Patent includes an innovative guide mechanism used to position these devices within a patient's circulatory system (Ex. 1001, Abstract). The guide mechanism shown above in Figure 3 is an "over-the-wire" type guide mechanism, where a lumen runs through the cannula and engages with a guide wire (Ex. 1001, 7:6-24). The patent further describes multiple additional guide mechanisms that can be used (e.g., Ex. 1001, 2:52–3:54).

III. THE BOARD SHOULD NOT INSTITUTE THE *INTER PARTES* REVIEW

Petitioners rely on the same primary reference in each of their grounds, a published PCT application WO 99/02204 naming Walid Aboul-Hosn as inventor ("Aboul-Hosn"). Unlike the claims of the '068 Patent directed to intravascular

blood pumps placed within a patient's circulatory system by way of a guide mechanism, Aboul-Hosn specifically discloses a reverse flow pump designed to be *external* to a patient's circulatory system (an external pump). This distinction, and the underlying design considerations of Aboul-Hosn, prove fatal to each of Petitioners' grounds.

Two key decision makers already certified the challenged claims are patentable over the cited art. The first is the inventor of the '068 Patent—Dr. Aboul-Hosn. He determined he had invented a unique intravascular blood pump having a guide mechanism by filing the application that led to the '068 Patent some two years after filing the Aboul-Hosn PCT reference. The second is the Examiner who handled the application that led to the '068 Patent and allowed the patent claims to issue. The Examiner had the Aboul-Hosn PCT reference before him while examining the case. The Examiner relied on a total of one hundred sixty-five different references during an extensive and thorough prosecution and apparently found the Aboul-Hosn PCT reference added nothing of note.

Under 35 U.S.C. § 314(a), in order for an IPR to be instituted, Petitioners must establish there is a reasonable likelihood at least one of the challenged claims is unpatentable. As discussed below, Petitioners, even after mischaracterizing Aboul-Hosn, fail to demonstrate that each claim element was in the prior art and fail to make the requisite showing of a motivation to combine the references in the

manner proposed. Petitioners thus fail to show a reasonable likelihood of prevailing. Accordingly, the PTAB should decline to institute the IPR proceeding as requested.

A. Petitioners Fundamentally Misrepresent the Teachings of the Primary Reference.

Petitioners and their purported expert, Dr. Collins, misstate the teachings of Aboul-Hosn by attempting to combine features of different embodiments without pointing to any teaching in Aboul-Hosn, or any other cited prior art, suggesting such a combination. This fundamental error is not surprising given Dr. Collins' lack of experience in blood pump design and the fact he does not qualify as a POSITA.

Aboul-Hosn discloses several distinct fluid transportation systems. One is the reverse-flow pump system shown in Figures 1-13. In this system, a reverse-flow pump, located outside a patient's circulatory system, communicates with blood within a blood vessel via a cannula that enters the blood vessel (Ex. 1004, 10:25–25:5). Separately, Figures 23-24 in Aboul-Hosn illustrate a “stabilization system,” which stabilizes a patient's heart during surgery (Ex. 1004, 28:21–31:9).

Petitioners' foundational premise is these separate embodiments—the reverse flow pump and the stabilization system—are one and the same. They are not. As described more fully below, these are completely separate designs that cannot be combined. Petitioners never address this fundamental fact, choosing

instead to contrive a fictitious combination of these embodiments in a fallacious effort to arrive at the inventive combination of claim elements.

When the separate embodiments disclosed in Aboul-Hosn are appropriately considered, it becomes clear this reference is directed to a fundamentally different design than the claimed invention. As a result, and as discussed more below, Petitioners' arguments fail at a base level. They assume two uncombinable systems are one and the same, and this fundamental mischaracterization of Aboul-Hosn proves fatal to Petitioners' analysis.

1. Petitioners Mischaracterize Multiple Disclosed Embodiments in Aboul-Hosn

In order to combine the separate embodiments in Aboul-Hosn, Petitioners misread the disclosure in Aboul-Hosn directed to both the reverse flow pump (50) and the stabilization system (410).

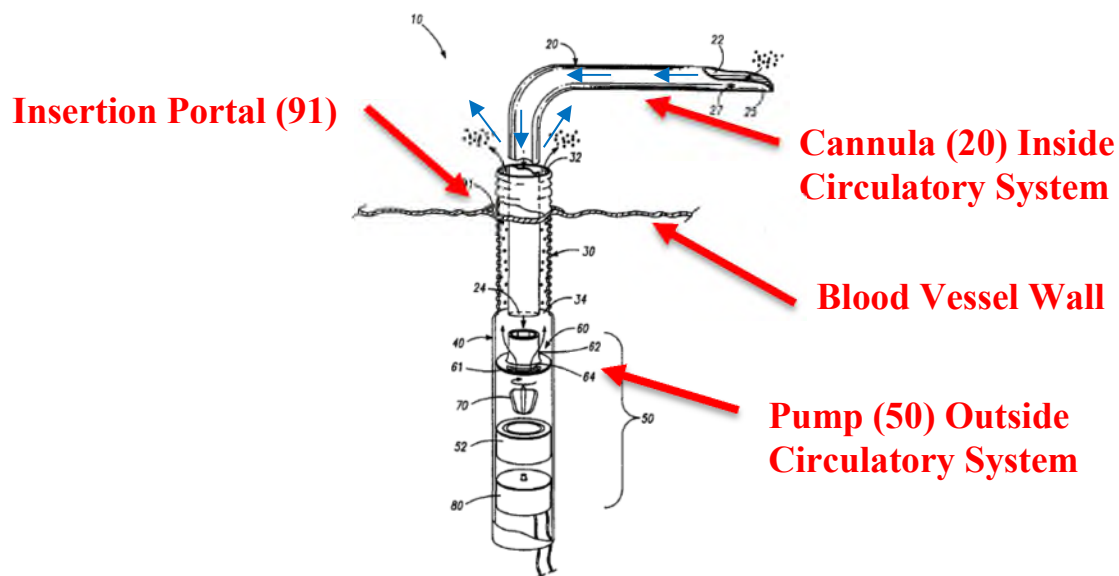
a. Petitioners Improperly Rely on the *External Reverse Flow Pump* of Aboul-Hosn

Petitioners rely on Figures 1-13 of Aboul-Hosn to allegedly render the recitations of the claims obvious. Petitioners do so without ever reconciling the fact that the external reverse flow pump of Figures 1-13 is directed to a pump that must be placed outside of the circulatory system. There is no teaching or suggestion that this pump may be inserted into a patient's circulatory system.

Aboul-Hosn discloses a reverse flow pump configured to be outside of a blood vessel wall (Ex. 1004, Abstract). Aboul-Hosn states: “[b]y using such an arrangement, only one portal 91 may be required to be formed in a blood vessel to support various surgical procedures” (Ex. 1004, 10:30-31).

Petitioners either remove or fail to reference a blood vessel in each of their figures. On page 18, for example, Petitioners attempt to obscure this shortcoming by removing the blood vessel explicitly shown in Figure 1 below:

Ex. 1004, Figure 1 (Annotations in Red and Blue (Showing Blood Flow)).

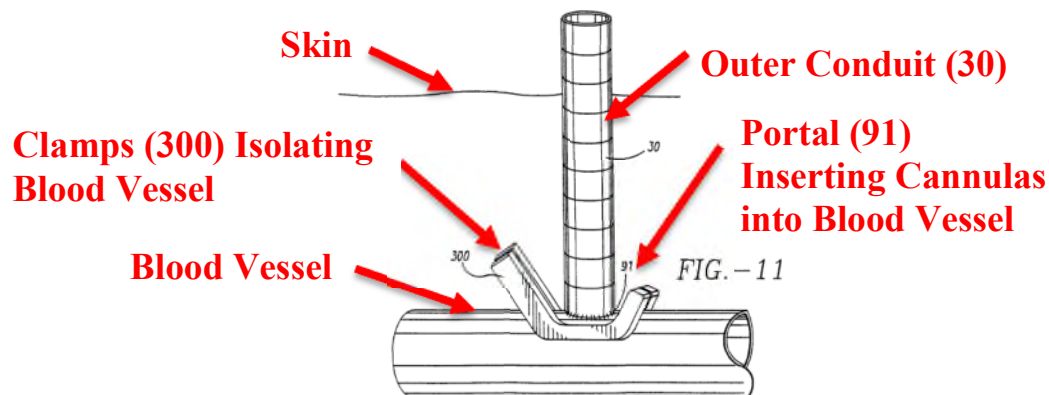


The discussion accompanying Figure 1 confirms the reverse flow pump (50) remains external to the blood vessel with inner cannula (20) and outer conduit (30) extending through the lone portal (91) formed in a blood vessel wall (Ex. 1004, 10:28-31 (“The reverse flow pump 50 may direct bodily fluids such as blood through the inner cannula 20 to the outer conduit 30, and then throughout other

regions of the body. By using such an arrangement, *only one portal 91* may be required to be formed *in a blood vessel* to support various surgical procedures.”) (emphasis added); *id.* at 12:5-7 (“The distal opening 32 of the outer conduit 30 may be extended through *a portal 91* to form a closed circuit between the inner cannula 20 and outer conduit 30.”) (emphasis added); *see also, id.* at 7:11-14)). Figures 3 and 4, which are also cited by Petitioners, do not change the above analysis; rather, the specification establishes these figures are merely “perspective views of the reverse flow pump” (Ex. 1004, 14:17-18).

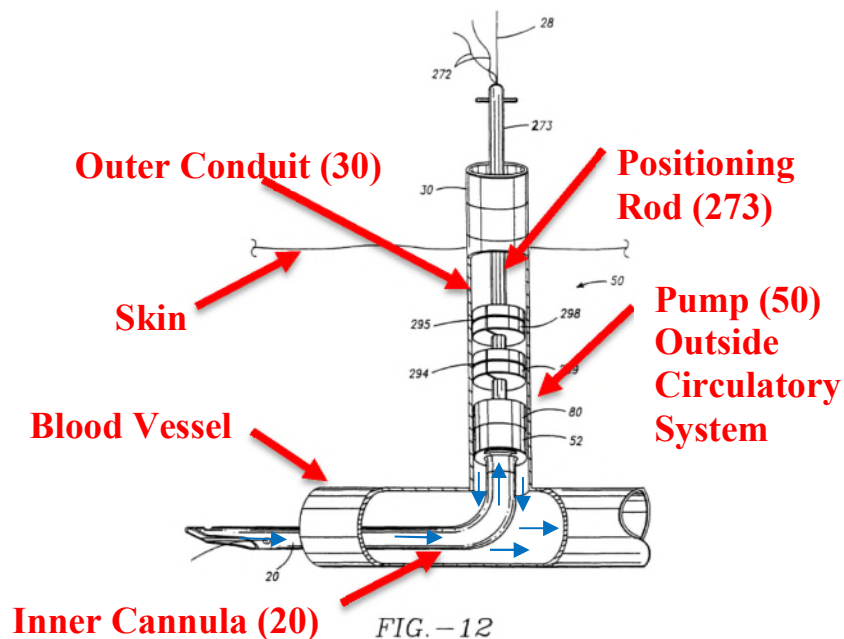
Aboul-Hosn does not stop with this description of the reverse flow pump—it instructs users to locate these devices *outside* of a patient’s circulatory system. On page 21, Aboul-Hosn discusses Figure 11 and that the first step in locating the reverse flow pump is to isolate the blood vessel using clamps (300) (Ex. 1004, 21:14-18). Once these clamps are in place, portal (91) can be created in the blood vessel, and the outer conduit (30) is then inserted into the portal and sutured such that this conduit extends perpendicular to the blood vessel (Ex. 1004, 21:19-22).

Ex. 1004, Figure 11 (Annotations in Red).



(Ex. 1004, Fig. 11). The reference then discusses that the pump assembly should be inserted within the outer conduit (30) and only the inner cannula (20) should be inserted within the blood vessel (Ex. 1004, 21:22-27; 22:10-21; 24:7-14). This is illustrated by Figure 12:

Ex. 1004, Figure 12 (Annotations in Red and Blue (Showing Blood Flow)).



(Ex. 1004, Fig. 12). As Figure 12 shows, reverse flow pump (50) is located outside a patient's circulatory system and **only** inner cannula (20) actually extends inside the blood vessel.

Aboul-Hosn further explains guide wire (28) is **only** used to locate inner cannula (20) inside the blood vessel (Ex. 1004, 21:22-23 (“A commercially available high stiffness guide wire 28 may also be passed through the outer conduit 30 to assist in ***the placement of the inner cannula 20.***”) (emphasis added)). The reference continually repeats these instructions:

A guide wire 28 may be also advanced with the help of imaging techniques ***to dispose the distal end of the inner cannula 20*** in the desired blood vessel, heart chamber or other body cavity. The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the ***distal end of the inner cannula 20*** may be guided to a location before removing the guide wire 28. (Ex. 1004, 22:10-16) (emphasis added).

In contrast, reverse flow pump (50) is located using outer conduit (30) and positioning rod (273) (Ex. 1004, 21:24-26; 22:16-21). The reference confirms, stating that the pump can be located after the guide wire is removed (Ex. 1004, 22:26-28 (“Alternatively, the guide wire 28 may be removed immediately after positioning the inner cannula 20 relative to the outer conduit 30. The pump 50 may ***then*** be secured to the proximal ends of the inner cannula 20 and the outer conduit

30. Accommodations for passage of the guide wire 28 through other components of the fluid transport apparatus may thus be avoided.”)).

The reference never instructs inserting reverse flow pump (50) within the blood vessel; instead it discloses this pump should remain inside outer conduit 30 (or a similar graft) and inserted up to the “clamped section of a vessel” (Ex. 1004, 24:12-14). The clamped section of the vessel is not within the vessel itself. The only alternative design provided shows reverse flow pump (50) located outside the patient entirely (Ex. 1004, 24:15-31, Fig. 13). The reference discloses that a larger design remaining outside of the smaller blood vessel is advantageous because “[t]he outside diameter of the pump rotor and all internal parts dimensions may therefore be larger than earlier described, which may simplify the pump designs, and enable the device capacity to be increased.” (Ex. 1004, 24:29-31). That is, the reference confirms the pump is designed to be so large that it is not able to be inserted into the circulatory system.

Petitioners further rely on Figure 19 in its analysis, but as shown below, this figure also teaches the blood pump should be located **outside** a patient’s circulatory system (Petition, 51; Ex. 1004, Fig. 19). Figure 19 illustrates a separate embodiment of Aboul-Hosn, namely cannula configurations that allow for an alternative to traditional invasive cardiopulmonary bypass procedures (Ex. 1004, 25:6–28:20, Figs. 14-19).

Ex. 1004, Figure 19 (Annotations in Red and Blue (Showing Blood Flow))

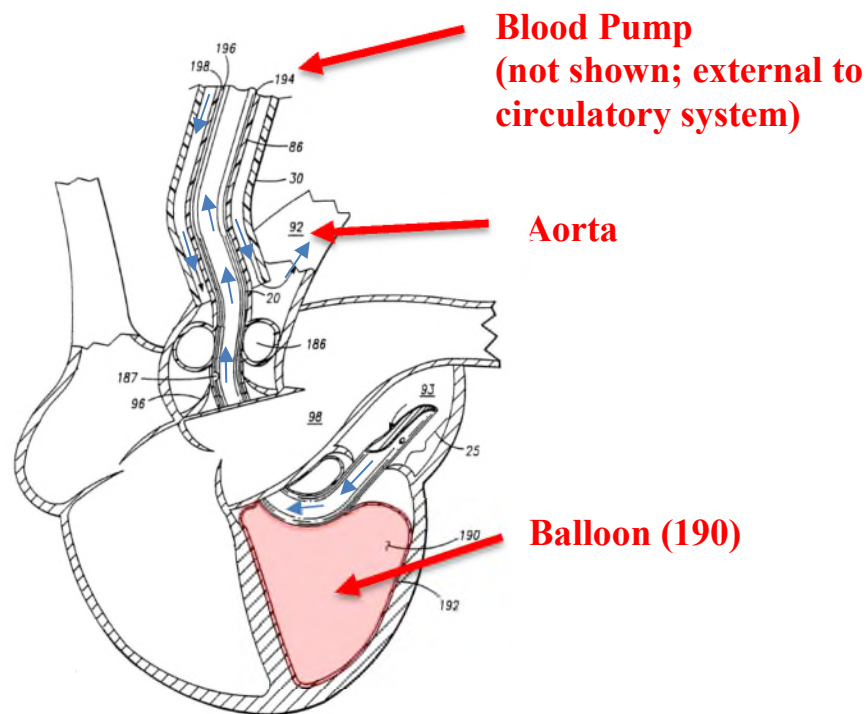


FIG. - 19

Figure 19 is not alone. Figures 1-3, 11-19, and 24 all show cannula designs in which the pump is located outside the patient's circulatory system. For example, Aboul-Hosn states that Figure 24 specifically illustrates the use of the disclosed reverse flow pump. Aboul-Hosn recites:

Fig. 24 similarly illustrates positioning of another stabilization system formed in accordance with the present invention. An access conduit 433 such as a Dacron™ graft may be formed to receive an extracorporeal pump 421, or *a reverse flow pump such as those described above*, at the proximal end of the access conduit 433 and use the stabilization apparatus 410 for its inflow, and access conduit

433 for its outflow to result in a *similar arrangement to the one described above and presented in Fig. 24*.

(Ex. 1004, 30:29–31:4) (emphasis added). As is shown below, the reverse flow pump in Figure 24 is external to the blood vessel.

Ex. 1004, Figure 24 (Annotations in Red and Blue (Showing Blood Flow))

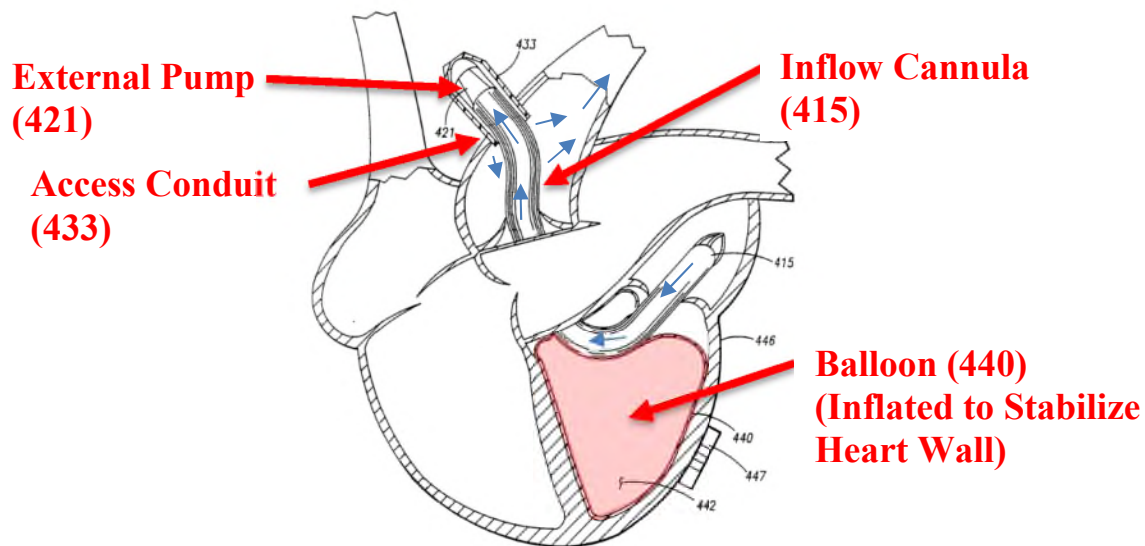


FIG. - 24

In short, all the discussion concerning reverse flow pump (50) instructs the POSITA to locate this device outside the circulatory system—the opposite conclusion that Petitioners assert.

b. Petitioners Mischaracterize the Stabilization System—a Separately Disclosed Embodiment

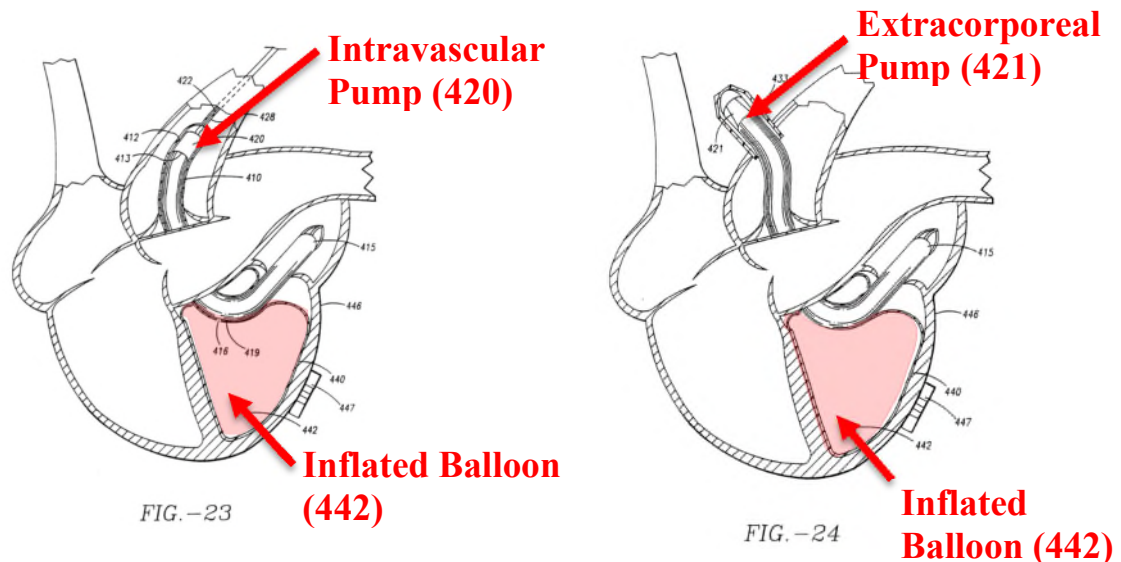
Petitioners also misconstrue their other cited embodiment—Figure 23. This figure, and the accompanying discussion, is directed to stabilization system (410), not a pump design (Ex. 1004, 29:17–31:9). Importantly, the reverse flow pump of

Figures 1-13 *could not work as an intravascular blood pump* with stabilization system (410).

Stabilization system (410) immobilizes the heart wall, allowing a surgeon to operate in a more controlled environment (Ex. 1004, 30:2-19). (A beating heart moves, and this movement provides an additional complication to an already complex process, heart surgery.) Stabilization system (410) addresses this problem by inflating balloon (440) within the left ventricle (Ex. 1004, 30:2-10).

While this discussion in Aboul-Hosn recognizes the need to provide a heart assist device or a heart replacement device to bypass the heart while the heart is stopped by stabilization system 410, the reference provides little detail regarding the intravascular pump to be used (Ex. 1004, 30:20–31:9). The limited discussion provided states that reverse flow pump (50) should be used with the configuration shown in Figure 24 (an external pump configuration), not the configuration shown in Figure 23 (an internal, or intravascular, pump configuration) (Ex. 1004, 30:29–31:4). As shown below, reverse flow pump (50) would not even function in the embodiment of Figure 23.

Ex. 1004, Fig. 23 & 24 (Annotations in Red)



The above two images show different embodiments of stabilization system (410). They each use different element numbers for these features, intravascular pump (420) and extracorporeal pump (421), than the previously disclosed reverse flow pump (50).

This lack of disclosure proves fatal to Petitioners' analysis. Petitioners require the Board to find reverse flow pump (50) shown in Figure 3 could be used as intravascular pump (420) shown in Figure 23. Aboul-Hosn does not make that connection. These devices are different, and Aboul-Hosn's only disclosure of reverse flow pump (50) specifies this device is to remain outside a patient's circulatory system (*supra* § III(A)(1)(a)). In contrast, Aboul-Hosn treats intravascular pump (420) as a "black-box", saying only that a "commercially

available” intravascular pump could be used. *Petitioners never establish and cannot establish that reverse flow pump (50) was commercially available.*

Reverse flow pump (50) would not be used in an intravascular application because an intravascular pump is designed to move blood *away* from the heart. Use of reverse flow pump (50) in an intravascular application would direct blood *toward* the heart instead of *away* from the heart, as needed to circulate a patient’s blood. This is confirmed in Aboul-Hosn, which states stabilization system (410) in Figure 24 may have reverse flow pump (50) located outside the circulatory system (Ex. 1004, 30:30–31:4 (“An access conduit 433 such as a Dacron™ graft may be formed to receive an extracorporeal pump 421, or *a reverse flow pump such as those described above*, at the proximal end of the access conduit 433 and use the stabilization apparatus 410 for its inflow, and access conduit 433 for its outflow to result in a *similar arrangement to the one described above and presented in Fig. 24.*”) (emphasis added)); however, Aboul-Hosn never says reverse flow pump (50) may be used in the embodiment of Figure 23 Showing an intravascular pump placement. Instead, Aboul-Hosn refers only to “black box” pump (420) for which no details are provided (Ex. 1004, 30:21-28). Further, reverse flow pump (50) utilizes a dual cannula configuration, which would result in an overly large device that could not be inserted into a patient’s aorta from a femoral artery (*See* Ex. 1004, 24:29-31). This alone should be sufficient to defeat Petitioners’ analysis.

Aboul-Hosn discloses additional differences between the embodiments in Figure 3 and Figure 23, further demonstrating these devices are incompatible. Reverse flow pump (50) does not include a catheter. Figure 3 never illustrates a catheter, nor do any of the other figures corresponding to the reverse flow pump design (Ex. 1004, 10:25–15:18; Fig. 1-13). Instead, reverse flow pump (50) includes additional features such as positioning rod (273) and sealing plugs (298 & 299), which are not compatible with a catheter. The reverse flow pump further addresses the various uses of a catheter through other mechanisms. For example, this pump can be sutured to outlet conduit (30) in order to maintain its proper location relative to the exterior of the blood vessel of a patient (Ex. 1004, 22:18-21). Similarly, because the reverse flow pump is not within the circulatory system, a catheter is not required to establish communication between the pump and devices outside the body (Ex. 1004, 21:19-31, Fig. 3 & 12).

Similarly, the cannula disclosed in Figure 3 differs from the design provided in Figure 23. The reverse flow pump design utilizes cannula (20), and the cannula used with the stabilization system shown in Figure 23 is identified as cannula (411) (Ex. 1004, 30:20-28). The reference further describes how these cannulas are designed for different purposes. Cannula (411) works in conjunction with balloon (440) and may include various different lumens, openings, and termination points allowing for the insertion and inflation of this balloon (Ex. 1004, 29:17–30:10).

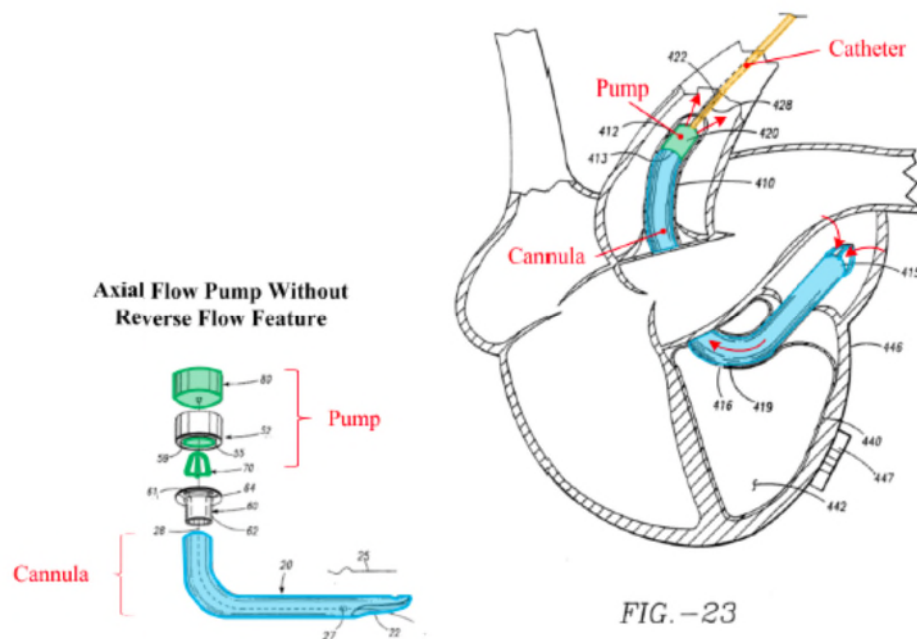
None of these features are discussed in the specification in connection with the reverse flow pump or cannula (20) (Ex. 1004, 11:8-30).

In short, stabilization system (410) is directed to a separate feature, one used to stabilize the heart. The only reference to a reverse flow pump in connection to this stabilization system specifies this pump should be located external to a patient's circulatory system (Ex. 1004, 30:30–31:4). Further, there is no teaching or suggestion that the stabilization system requires transformation of the external reverse flow pump into an intravascular pump or that the external flow pump could ever be used intravascularly. As such, the stabilization system requires some other undisclosed commercially available intravascular blood pump not disclosed in Aboul-Hosn or identified by Petitioners.

2. Petitioners' "Annotations" Distort the Prior Art

Instead of confronting the deficiencies in the disclosure of Aboul-Hosn as discussed above, Petitioners manipulate images from this reference in an attempt to manufacture support for its position. Petitioners summarize their position in the following colorized illustration from p. 23 of the Petition. Petitioners selectively took part of Aboul-Hosn's Figure 3 and modified it in a sleight-of-hand effort to modify and adapt certain components of reverse flow pump (50) for use in stabilization system (410) of Figure 23.

Petition, 23 (Petitioners' Annotations)

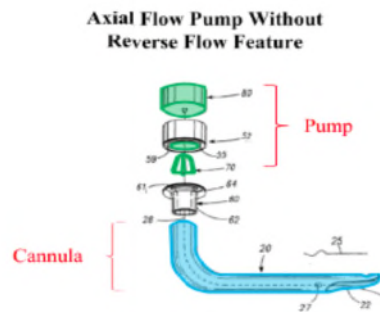


Petitioners fail to justify this modification and redesign of reverse flow pump (50) (Petition, 22-23). Petitioners' argument depends entirely on the premise that critical components of reverse flow pump 50 can be removed, other critical components resized², unnecessary features disclosed in a separate design added, and then after this feature swapping is completed, the pump redesigned such to direct flow in the opposite direction from that taught in the reference.

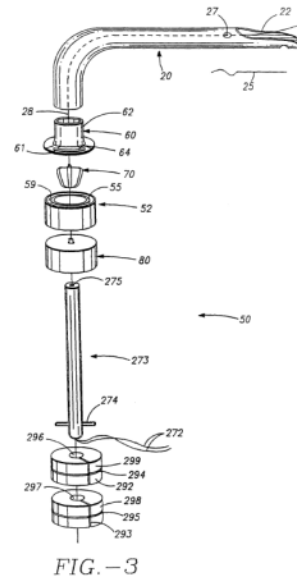
To walk through Petitioners' analysis, below is the actual Figure 3 in Aboul-Hosn alongside Petitioners' "Annotated" design.

² The reference discloses that a larger design that remains outside of the smaller blood vessel is advantageous (Ex. 1004, 24:29-31).

Petition, 23; Ex. 1004, Fig. 3 (Petitioners' Annotations in Green, Blue, and Red; Patent Owner's Annotations in Red Bold)



**Petition's "Annotated"
Fig. 3**



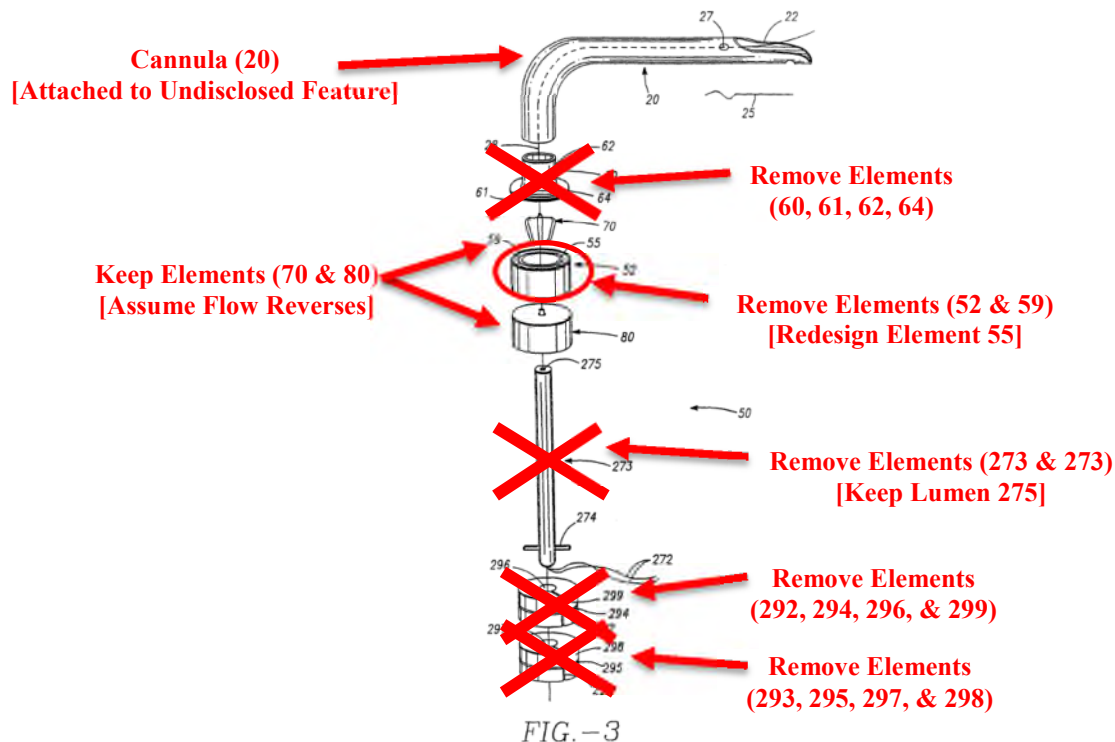
**About-Hosn Fig. 3
(Unannotated)**

By coloring and truncating Figure 3, Petitioners redesign the reverse flow pump in at least the following ways: (1) it removes rigid positioning rod (273) used to locate the device (but the inner lumen of this element must remain, because Petitioners identify that as the “elongate lumen”) (Ex. 1004, 21:31–22:2; Petition, 45, 47); (2) it removes sealing plugs (298 & 299) used to seal the device system and avoid excess bleeding (Ex. 1004, 22:18–24); (3) the outlet port is removed (elements 60, 61, 62, and 64); (4) the pump housing is redesigned by removing both housing body (52) and passage (50), while inlet tube (55) remains; (5) inner cannula (20) must be reattached to an undisclosed feature because housing body (52) has been removed; and (6) finally, the impeller, which in the reference

reverses the flow of blood to outlet ports, would apparently direct blood flow in the opposite direction through drive unit (80) once these modifications were made (Petition, 22-23; Ex. 1002, ¶ 131).

The following illustration shows the features removed or designed by Petitioners' "Annotations."

Petition, 45; Ex. 1004, Fig. 3 (Annotations in Red)



Aboul-Hosn Fig. 3
(Showing Petitioners' Modifications)

This argument is nothing short of a ground up redesign of the reverse flow pump disclosed in Aboul-Hosn without any justification or support from the prior art.

Even this redesign fails to disclose the claimed invention because it does not

include an intravascular blood pump, a guide mechanism, a catheter, or a blood pressure detection mechanism, all as required by various claims of the '068 Patent. These features were of course not present in Aboul-Hosn's reverse flow pump because it is located *external* to a patient's circulatory system.

3. Petitioners Fail to Establish a “Reason Why” a POSITA Would Have Combined Separate Embodiments in Aboul-Hosn to Redesign its Disclosed Blood Pump.

Petitioners' misreading of Aboul-Hosn dooms its Petition. For obviousness grounds, even single reference obviousness, the Board “consider[s] whether a PHOSITA would have been motivated to combine the prior art to achieve the claimed invention.” *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (internal quotation marks, brackets, and citation omitted); *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). “Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000).

Here Petitioners fail to provide any rationale for combining the various different embodiments within Aboul-Hosn, namely reverse flow pump (50) and stabilization system (410), to create an intravascular pump system. Moreover, Petitioners never provide sufficient rationale for its ground-up redesign of the reverse flow pump. As a result, the Petition fails as a matter of law. *In re Kotzab*,

217 F.3d at 1370; Institution Decision at 13, *Cisco Sys., Inc. v. Bockstar Tech. LLC*, IPR2014-01192 (P.T.A.B. Feb. 2, 2015), Paper 10 (denying institution on ground based on single reference obviousness because “[a]lthough both routers are described in a single reference, Petitioner must still articulate a rationale for combining the features of the two devices”); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361–62 (Fed. Cir. 2016) (reversing the Board’s decision that claims were invalid as obvious over a single prior art reference because “common sense—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support....”).

First, Petitioners seamlessly try to interweave disclosures directed to reverse flow pump (50) and stabilization system (410) as though they concern a single intravascular pump system (Petition, 16–17, FN9, 20–22, 31–34, 36–40, 44–49). As discussed above, they do not. Further, Petitioners never provides any rationale as to why a POSITA would combine the teachings in these separate embodiments. Petitioners make a feeble attempt to link these systems by pointing to the following passage from Aboul-Hosn: “[t]he stabilization system shown in FIGS. 23 and 24 illustrate only some of the various types of commercially available intravascular and extracorporeal pumps that are compatible or provided for by the present invention” (Petition, 16-17; Ex. 1004, 31:6-9). Then, in Footnote 9, Petitioners

assert the “present invention” refers to a reverse flow pump with features of the pumps of Figures 1-13 (Petition, FN9).

Petitioners’ convoluted reading of the cited passage to support its combination fails. First, the “present invention” in the cited passage refers to stabilization system (410), not reverse flow pump (50)—as confirmed by the surrounding text (Ex. 1004, 30:20-31:9). Further, Petitioners’ assertion makes no sense because the cited passage is circular if the “commercially available...pumps” are compatible with the “reverse flow pump.” Moreover, Petitioners provide no evidence the reverse flow pump of Aboul-Hosn was a commercially available pump. Next, as discussed above, the reverse flow pump is designed for external use and thus is not compatible with the embodiment shown in Figure 23 (*supra* § III(A)(1)(a)).

Finally, Petitioners’ reading is legally incorrect. The use of the phrase “present invention” is not limited to a particular embodiment or limitation “where the references to a certain limitation as being the ‘invention’ are not uniform....” *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136-37 (Fed. Cir. 2011). Aboul-Hosn uses the phrase “present invention” to refer to numerous aspects and embodiments of its apparatus including, but not limited to, both the reverse flow pump **and** the stabilization system. Accordingly, Aboul-Hosn’s use of the phrase “present invention” is **not uniform** and does not refer to the reverse

flow pump in all cases. For at least these reasons a POSITA would not have combined these separate embodiments.

Petitioners similarly fail to support its ground-up redesign of the Aboul-Hosn reverse flow pump. It simply asserts a “POSITA would...have readily understood that the pump 420 could also be configured without the reverse flow feature of the pump system of FIGS. 1-13...” (Petition, 22; Ex. 1002, ¶ 129; Ex. 1004, 31:6-9). Petitioners then describe the components of the ground-up redesign to distract from its failure to state why the POSITA *would* combine the distinct embodiments of Aboul-Hosn (Petition, 22).

Merely stating why references *may* be combined or redesigned is insufficient. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (rejecting “reasoning [that] seems to say no more than that a skilled artisan, once presented with the two references, would have understood that they could be combined”). More is required than the scant and unsupported arguments put forth by Petitioners. *Id.*

Petitioners further never provide any expectation of success. Petitioners fail to include any commentary or evidence that a POSITA would expect success in making the modifications proposed. Instead, Petitioners describe a complete redesign of the reverse flow pump of Aboul-Hosn such that “the pump 420 would include the components of the pump system of FIGS. 1-13 that generate the axial

flow of blood through the pump..., without the components that cause the blood flow to reverse course...” (Petition, 22). Despite the detailed manipulation of the reverse flow pump of Aboul-Hosn, Petitioners fail to provide any evidence of an expectation of success, which is particularly critical in the present instance due to the complexity of the claimed invention.

Without evidence directed to the expectation of success, there is no way for the Board to determine whether “a person of ordinary skill in the art would have...had a reasonable expectation of success” in combining the embodiments in the matter claimed. *Personal Web Techs.*, 848 F.3d at 991. As such, there is simply insufficient evidence to support an obviousness determination.

B. Petitioners Fail to Carry Their Burden of Proving There Is a Likelihood Any Challenged Claim Is Unpatentable.

Pursuant to 37 C.F.R. § 42.108(c), Petitioners must demonstrate there is a reasonable likelihood each claim is unpatentable to warrant institution of an *inter partes* review for that claim. Petitioners have not carried this burden.

1. Aboul-Hosn and Siess ’913 Fail to Render Obvious Claims 10 and 12-22 (Ground 1)

Petitioners assert Claims 10 and 12-22 are invalid under 35 U.S.C. § 103(a) based on Aboul-Hosn in view of Siess ’913 (Petition, 4). Patent Owner respectfully requests institution be denied with respect to Ground 1. For at least the following several reasons, Petitioners fail to carry their burden with regard to Claims 10 and

20 (and the claims that depend therefrom). Accordingly, institution of this IPR should be denied.

a. Aboul-Hosn in view of Siess '913 Does Not Disclose the Claimed Intravascular Blood Pump.

Petitioners rely on the rotor design of Figure 7B of Aboul-Hosn to allegedly meet the required “an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end” of Claim 10.³ According to Claim 10, the intravascular blood pump must also be sized and shaped to be placed within a circulatory system. Claim 10 also requires “a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump...to a predetermined location within the circulatory system of a patient” (Ex. 1001, Claim 10). As outlined herein, the rotor of Figure 7B is not configured for use as an intravascular blood pump, is not configured to be placed in the circulatory system, is not ever shown as being coupled to a catheter, and has a rotor hub that does not taper in the distal direction.

³ The analysis herein with respect to Claim 10 applies equally to Claim 20.

(i) Petitioners improperly redesign the reverse flow pump to teach certain recitations of the claims.

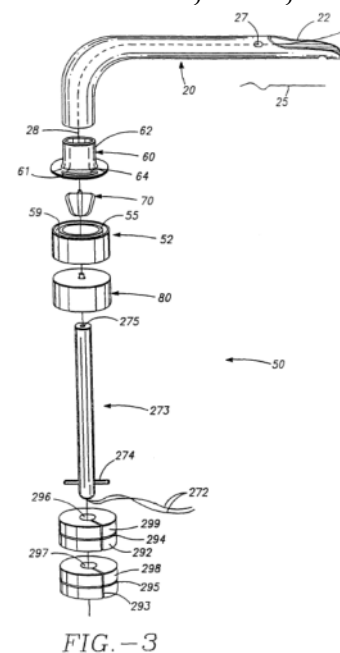
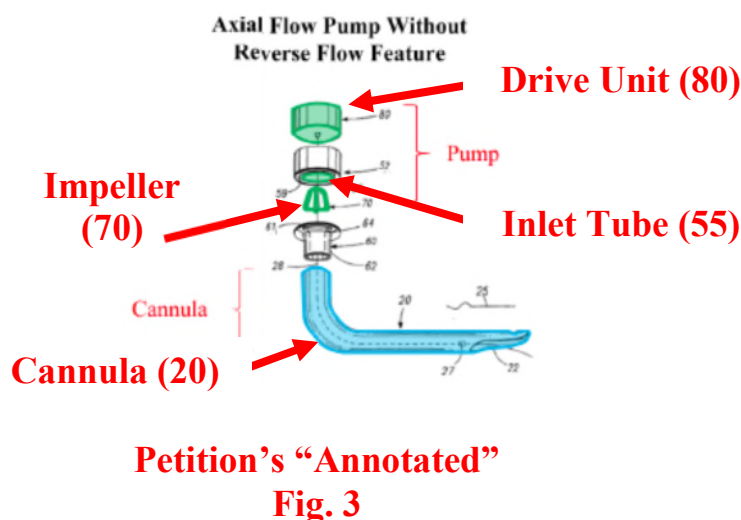
Petitioners analyze the claimed “intravascular blood pump” devoid of its specific claimed requirements. Without the burden of linking the intravascular blood pump to its specific claimed structure, Petitioners bounce back and forth between the reverse flow pump of Figures 1-13 configured to be placed outside the circulatory system and the “black box” intravascular pump of Figure 23 (Petition, 30-34). As described *supra*, Petitioners cannot combine these two distinct embodiments.

Petitioners rely on a bald, unsupported statement that “Aboul-Hosn discloses that the axial flow pump system of FIGS. 1-13 with reverse flow feature can be delivered to the heart percutaneously as shown in FIG. 23...” (Petition, 31). Petitioners continue, theorizing that this transformation is possible by connecting the “pump components illustrated in FIGS. 1-13 with the multilumen catheter 428 and adapting the inner cannula 20 and the outer conduit 30 as the stabilization cannula 411 in FIG 23” (Petition, 31). Petitioners further confirm that “[i]n this configuration, the cannula 20 mates with housing cap 62” (Petition, 32). Nothing in the reference supports this reading.

Going further off script from Aboul-Hosn, Petitioners eliminate key elements of the reverse flow pump. In the stroke of a pen, Petitioners assert the *reverse* flow pump of Figures 1-13 can be modified to no longer provide *reverse*

flow (Petition, 32). No teachings in Aboul-Hosn support this theory. Petitioners simply assert a POSITA would remove the entire pump housing structure (elements 52 and 59) and redesign various other elements to allow the rotor of the reverse flow pump to be used as the hypothetical rotor in the undescribed pump 420. Petitioners' hindsight redesign selected only four of more than twenty features of the reverse flow pump to try to transform it into an intravascular pump.

Petition, 33; Ex. 1004, Fig. 3 (Petitioners' Annotations in Green, Blue, and Red; Patent Owner's Annotations in Red Bold)



Aboul-Hosn Fig. 3 (Unannotated)

Petitioners' theory is wrong. There are at least two pumps in Aboul-Hosn, reverse flow pump (50) of Figures 1-13 and "black box" pump (420) of Figure 23. These pumps are incompatible. This distinction is essential as the following sections illustrate how Petitioners conveniently bounce between the embodiments

and figures in a misguided attempt to render the claims obvious. As a result, Petitioners fail to disclose the claimed features of the challenged patent.

- (ii) Petitioners improperly rely on the rotor design of the reverse flow pump to teach certain recitations of the claims.

To allegedly render claim 10 obvious, specifically “an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub,” Petitioners rely solely on Figure 7B and the related disclosure of Aboul-Hosn. But Figure 7B is directed to a reverse flow pump not configured to be placed in the circulatory system, as required by the claims. Accordingly, Figure 7B and its corresponding description cannot be used to render this limitation obvious.

By relying on Figure 7B, Petitioners mischaracterize Aboul-Hosn. The mischaracterization is clear in the very first sentence of page 34. Petitioners mislead the reader by referring to the pump of Figure 7B as an *intravascular pump*, not a reverse flow pump. Petitioners recite: “[t]he *intravascular blood pump* of Aboul-Hosn has a rotor having a rotor hub” (Petition, 34) (emphasis added). This citation (Ex. 1004, 12:30-31) refers to the external reverse flow pump, not an intravascular blood pump. Nowhere in Aboul-Hosn do Petitioners identify an instance where the reverse flow pump is referred to as an intravascular pump

(Ex. 1004, 12:30-31, 16:30-31). Indeed, the reverse flow pump of Aboul-Hosn cannot be used intravascularly.

Pages 34–36 of the Petition is the only area where Petitioners assert Aboul-Hosn teaches the claimed “rotor hub” limitation. Petitioners only cite to a rotor assembly designed to be used outside the circulatory system. This design cannot be used to render obvious a distinct rotor design used in the distinct intravascular blood pump of the claims.

Irrespective of this error, the rotor design in Figure 7B is not the claimed rotor design. The claims require that the rotor have a “rotor hub tapering in the distal direction.” Aboul-Hosn’s hub illustrated in Figure 7B, while having a pointed tip, has a rotor that tapers in the opposite direction, *i.e.*, it tapers in the proximal direction. For this additional reason, Aboul-Hosn fails to teach or suggest the claim elements.

Petitioners do not cite to Siess ’913 to make up for these shortcomings.

Accordingly, the Petition should be denied.

- (iii) Petitioners improperly rely on Figure 23 to teach an intravascular blood pump coupled to a catheter on a proximal end and a cannula on distal end.

The error in reliance on Figures 3 and 23 compounds as Petitioners continue through the elements of Claim 10. Claim 10 recites: “an intravascular blood pump comprising...the intravascular blood pump coupled to a catheter on a proximal end

and a cannula on a distal end.” (Ex. 1001, Claim 10). It is not just any intravascular blood pump coupled to a catheter and a cannula; it is the intravascular blood pump comprising a rotor having a specific rotor hub. As shown below, Petitioners fail to demonstrate that the reverse flow pump, the pump with the rotor design of Figure 7B as asserted by Petitioners, is configured to be coupled to a catheter.

With regard to this limitation, Petitioners never demonstrate any of the pump designs of Figures 1-13 are configured to be coupled to a catheter. Instead, these designs are explicitly disclosed as being coupled to positioning rod 273. Positioning rod 273 is significant and necessary for the transmission of torque or other force from the positioning rod proximal end to drive unit 80 that is used to drive motor 50 (Ex. 1004, 14:18-20). Petitioners do not assert that positioning rod 273 is a catheter or that it can be replaced by a catheter.

Implicitly understanding that the positioning rod and other key elements of Aboul-Hosn are necessary to the reverse flow pump, Petitioners predictably cite to the intravascular blood pump of Figure 23. Petitioners recite: “[a]s shown in annotated FIG. 23 of Aboul-Hosn, reproduced below, the blood pump 420 (green) connects to the catheter 428 (yellow) and a stabilization cannula 411 (blue) of the blood pump 420” (Petition, 36-37). However, Petitioners provide no credible evidence that the reverse flow blood pump, having a specific rotor design, is the pump that is usable in the “black box” blood pump of Figure 23.

Irrespective of the theory, Petitioners are unable to make their case.

Petitioners either rely on the embodiment of Figures 1-13 that is designed to be external to the body and is *missing a catheter* or on the intravascular system of Figure 23 that does not include any disclosure about the pump and is *missing the particular rotor design*.

- (iv) Petitioners fail to demonstrate that there is a reasonable likelihood that Claim 10 is unpatentable.

In addition to failing to combine the separate embodiments in Aboul-Hosn, Petitioners fail to establish that either the claimed rotor hub or catheter was taught or suggested by Aboul-Hosn. *Petitioners do not cite to Siess '913 to make up for these shortcomings*. Accordingly, Petitioners fail to carry their burden of proving there is a likelihood that Claim 10 is unpatentable.

b. Aboul-Hosn in view of Siess '913 Does Not Disclose the Guide Mechanism of the Challenged Claims.

Petitioners fail to demonstrate that Aboul-Hosn teaches, suggests, or discloses: “a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient” (Ex. 1001, Claims 10 & 22).

- (i) The Aboul-Hosn intravascular pump does not include the guide mechanism as claimed.

Petitioners assert that Figure 3 of Aboul-Hosn renders the claimed “guide mechanism” obvious. Petitioners recite: “the guide wire 28 passes through central passages (*i.e.* a lumen) that run through the motor 80, the rotor hub 74, and the housing cap 60, thus extending through Aboul-Hosn’s intravascular blood pump” (Petition, 44). Again, Figure 3 relates to an embodiment where only the cannula is guided into the circulatory system. That is, the reverse flow pump is not configured to and, due to its size, cannot be guided into the circulatory system (*supra* FN2). Accordingly, Figures 1-13 of Aboul-Hosn cannot teach or suggest the claimed guide mechanism.

Moreover, the claims require that the guide mechanism guide a catheter into the circulatory system of the patient. As noted above, Figure 3 does not include a catheter. Again, the embodiment of Figure 3 is explicitly tied to the positioning rod. Accordingly, the embodiment of the reverse flow pump in Figure 3 cannot render the claims obvious because it does not guide an intravascular blood pump or a catheter to a predetermined location within the circulatory system.

Petitioners then turn to Figure 23. Figure 23 does not illustrate a guide wire and there is no need to include one, given that the stabilization system is designed to be introduced into the vasculature near the heart. That is, the embodiment of Figure 23 is not designed to be inserted percutaneously into the femoral artery and

navigated through the circulatory system by way of a guide wire as is the claimed system. Instead, the embodiment of Figure 23 is designed for direct aortic insertion, *not* percutaneous insertion (Ex. 1004, 30:21-24). This distinction is important as direct aortic insertion requires an invasive cutdown procedure in the aorta (Ex. 2021, 394). This procedure opens up a major blood artery in order to provide a surgeon direct access to a patient's heart to facilitate device location (*id.*). In contrast, percutaneous insertion only involves inserting the device via a needle in the femoral artery (*id.*).

Expert Collins concurs that direct aortic insertion does not require a guide wire. Specifically, Collins states that *either* a guide wire was used to position the pump *or* a surgical method was used, such as direct aortic insertion, to position the pump: “[i]ntravascular blood pump systems were delivered either percutaneously by catheter...or by a surgical approach that introduces the device directly into the vasculature near the heart” (Ex. 1002, ¶ 55). That is, when the surgical method is used, no guide wire is used or needed. Because the text of Aboul-Hosn confirms that the embodiment of Figure 23 relates to a surgical approach that introduces the device directly into the vasculature near the heart, there is no need for a guide wire.

As such, neither the embodiment of Figures 1-13 nor the embodiment of Figure 23 relies on “a guide mechanism adapted *to guide said intravascular blood pump* and cannula *to a predetermined location within the circulatory system.*”

Accordingly, the embodiments of Aboul-Hosn do not teach or suggest the elements of Claim 10 or 22.

- (ii) The central passage disclosed in Aboul-Hosn is distinct from the guide mechanism in the over-the-wire embodiment of the '068 Patent.

Petitioners feign ignorance for a proper description of the term “elongate lumen,” arguing that the specification does not provide sufficient disclosure. In addition to the details in the specification, the claims provide a clear definition for the claimed elongate lumen. Specifically, the elongate lumen is “adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient” and “wherein the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally.”

The claims specifically require that the cannula and the lumen are arranged *in series longitudinally*. However, Petitioners admit that the alleged lumen of Aboul-Hosn is not designed in the same manner. That is, Petitioners admit that the elongate lumen is continuous through the cannula. Petitioners recite:

“[c]orrespondingly, Aboul-Hosn discloses that the catheter 428, motor 80, rotor hub 74, and inner cannula 20 have respective lumens or central passages that are co-aligned to *create a single continuous lumen* through those components—consistent with the “over the wire” guide mechanism of the '068 Patent (Petition,

48) (emphasis added). Because Aboul-Hosn teaches a single continuous lumen through the reverse flow pump of Figures 1-13, the lumen cannot be in series longitudinally with the cannula. Accordingly, for at least this additional reason, Petitioners fail to carry their burden.

- (iii) Petitioners fail to demonstrate that there is a reasonable likelihood that Claim 10 is unpatentable.

Thus, in addition to failing to provide motivation to combine the separate embodiments in Aboul-Hosn, Petitioners fail to demonstrate that the claimed guide mechanism was taught or suggested by Aboul-Hosn. ***Petitioners do not cite to Siess '913 to make up for these shortcomings.*** Accordingly, Petitioners fail to carry their burden of proving there is a likelihood that Claims 10 and 22 are unpatentable.

C. Petitioners' Ground 1 Fails to Disclose a "Blood Pressure Detection Mechanism"

Petitioners continue in their application of unsupported hand waving in an attempt to argue that Aboul-Hosn discloses a blood pressure detection mechanism as disclosed in the claims of the '068 Patent.

For this limitation, Petitioners point to two separate references and multiple different embodiments, but none of these disclosures teach the claimed "blood pressure detection mechanism comprising a fluid column to detect the pressure of the blood proximate the intravascular blood pump" (Ex. 1001, Claim 10). Instead

these disclosures are based on different (and sometimes conflicting) designs, demonstrating that this limitation was non-obvious.

1. Aboul-Hosn Does Not Disclose the Claimed Blood Pressure Detection Mechanism

Petitioners first point to two separate disclosures in Aboul-Hosn and argue that these disclosures teach this limitation, or at least teach a pressure sensor comprising a fluid column. Both of these arguments fail.

Petitioners initially point to a vague disclosure in Aboul-Hosn stating catheter (428) may include a feature “to measure pressure in the vicinity of the catheter along its entire length” (Petition, 50; Ex. 1004, 29:19-24). Petitioners (and their expert) then conclude that based on this disclosure a POSITA would “naturally” understand this sentence to mean that the device includes a fluid column measuring pressure at the intravascular blood pump (Petition, 50; Ex. 1002, ¶ 202.)

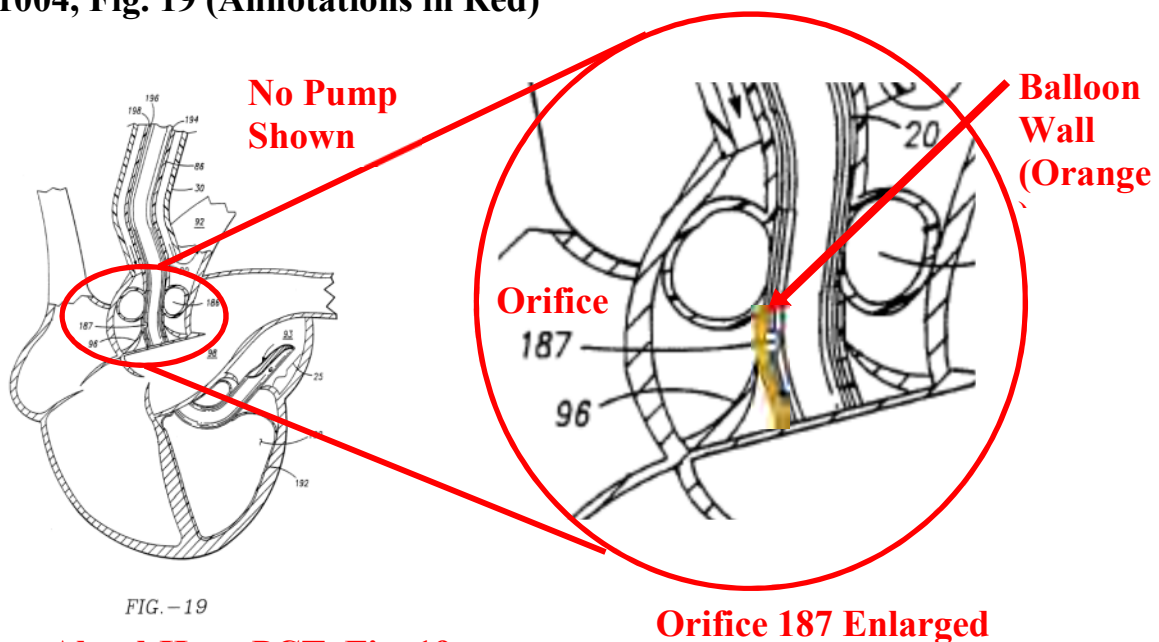
Petitioners and their expert misread this disclosure. There is no discussion in Aboul-Hosn of what is meant by “measure pressure in the vicinity of the catheter along its entire length”—where is the pressure being measured? And what device is performing this measurement? To the extent any specific type of pressure sensor is implied by this disclosure, it would not be a fluid column because, as Petitioners and Dr. Collins concede, a fluid column would have to be hydrostatic (Petition, 52; Ex. 1002, ¶ 201). Said another way, a fluid column must be fluid-tight, and as a

result, it cannot measure pressure continuously along its length. Further, this vague disclosure never states that pressure should be measured near the intravascular blood pump. Thus, it does not disclose either of the two requirements for the claimed pressure sensor.

Petitioners then turn to a *separate embodiment* disclosed in Aboul-Hosn to supplement this general disclosure. They point to “orifice 187” in Fig. 19 of Aboul-Hosn and proposes that this feature connects to a fluid column for measuring pressure (Petition, 51-52). Petitioners manufacture this argument.

Petitioners rely on the embodiment shown in Figure 19 reproduced below with an enlargement added. This image shows that orifice 187 does not communicate with the patient’s blood.

Ex. 1004, Fig. 19 (Annotations in Red)

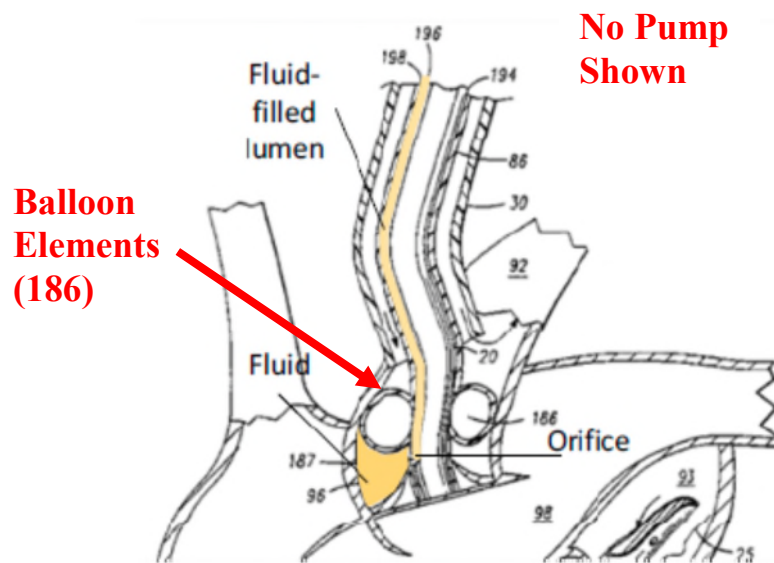


**Aboul-Hosn PCT, Fig. 19
(Directed to Cannula Design)**

As the enlarged image of Figure 19 shows, orifice 187 is covered over by the outer surface of the lumens 190 and 192 communicating with various balloons, and as a result, that feature could not measure blood pressure.

In addition, Petitioners assert, without support, that orifice 187 connects to a fluid column in order to measure pressure. This is not discussed anywhere in Aboul-Hosn, and it exists only in Petitioners' photo-shopped figure shown below:

Petition, 51 (Annotations in Red)



**Aboul-Hosn PCT, Fig. 19
(Directed to Cannula Design)**

Here, Petitioners points to lumens 198 and 196, and colors them both yellow, claiming they serve as a “fluid-filled lumen” for orifice 187 (Petition, 51). This is not disclosed in Aboul-Hosn. The discussion relating to Figure 19 states that lumens 196 and 198 communicate with balloon elements 190 and 192 (Ex. 1004, 27:31-28:3; 28:7-10) Aboul-Hosn does not support Petitioners’ assertions that the lumens 196 and 198 can be combined, as shown in Petitioners’ figure. More importantly, neither of these lumens communicates with orifice 187. Nothing in Aboul-Hosn shows the orifice being connected to a lumen, much less a fluid-filled column, which is a central premise of Petitioners’ argument.

Even assuming for the sake of argument that orifice 187 and Figure 19 disclose a fluid column, Petitioners’ argument still fails because Figure 19 does not

show a pump—much less an intravascular blood pump as required by claim 10. If there a pump, it must be external. Thus, to the extent “orifice 187” measures pressure, it is not measuring pressure “proximate the intravascular blood pump” as set forth in claim 10.

In addition, the discussion in Aboul-Hosn demonstrates that orifice 187 and the accompanying lumen are used for a different purpose than the claimed pressure sensor. This orifice is located “between two balloons,” and thus is located in an area where the blood pressure is isolated by these balloons (Ex. 1004, 28:12-18). As a result, orifice 187 could only measure the pressure in this isolated area and could not assist a practitioner determining pump output (which is the rationale Petitioners provide for combining these separate disclosures) (Petition, 50, 54; Ex. 1002, ¶¶ 202, 209).

Petitioners attempt to remedy these deficiencies by asserting, through their expert, that this disclosure demonstrates that a fluid column *could* be used to measure pressure near an intravascular blood pump (Petition, 51-52; Ex. 1002, ¶¶ 205-207). But the question is not whether this configuration was theoretically possible. It is whether a POSITA would have understood Aboul-Hosn to disclose this feature. The answer to that question is no.

2. Petitioners' Reliance on Siess '913 Does Not Correct the Above-Referenced Deficiencies.

Recognizing the weaknesses in the above arguments, Petitioners turn to a secondary reference, Siess '913. Again, this reference is missing a key element of the pressure sensor limitation, a fluid column. Moreover, Petitioners fail to provide an adequate rationale as to why a POSITA would combine these references. As a result, Petitioners' attempt to rely on both Aboul-Hosn and Siess '913 for this limitation fails.

a. Siess '913 Does Not Disclose the Claimed Fluid Column

First, Petitioners admit that Siess '913 discloses using multiple electrical sensors *not* a fluid column (Petition, 53-54). Petitioners instead use this reference to argue that it teaches a POSITA to locate a pressure sensor near a blood pump and attempt to combine this teaching with the above disclosure in Aboul-Hosn (Petition, 53-54). While Petitioners' assertions are incorrect, as an initial matter none of Petitioners' cited references disclose the claimed fluid column limitation, and as a result, Petitioners' arguments with respect to this limitation fail from the outset.

b. Petitioners Fail to Establish Why a POSITA Would Combine Aboul-Hosn with Siess '913

Petitioners fail to articulate why a POSITA would combine these separate references as required. For obviousness grounds, the Board "consider[s] whether a

PHOSITA would have been motivated to combine the prior art to achieve the claimed invention.” *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (internal quotation marks, brackets, and citation omitted); *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Rather than address this requirement, Petitioners simply assert that a POSITA **would** modify the allegedly complete Aboul-Hosn device with the teachings of Siess ’913 (Petition 50-55). Petitioners provide generic motivations to include a blood pressure detection mechanism uncoupled to the disclosure and teachings of Aboul-Hosn. Specifically, Petitioners note that the “POSITA would understand pressure can be measured ***in any number of ways*** and that ***some of the mechanisms for measuring pressure may be combined*** with the pressure sensors of Aboul-Hosn...” (Petition, 53) (emphasis added). Merely stating why references ***may*** be combined or are compatible is insufficient. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993– 94 (Fed. Cir. 2017). Petitioners state nothing more and as a result this combination fails.

Moreover, the disclosures in both of these references direct a POSITA to the opposite conclusion, *i.e.*, these references teach a POSITA ***not*** to combine their separate teachings. As discussed at length above, the reverse flow pump disclosed in Aboul-Hosn never resides in a patient’s circulatory system. It is not an intravascular blood pump. As a result, it would have no use for the electronic

pressure sensors disclosed in Siess '913. Similarly, there would be no reason to combine the teaching from Siess '913 with the fluid transportation embodiment in Figure 19 containing orifice 187 because, again, this system does not locate a pump in a patient's circulatory system.

Thus, the only embodiment disclosed in Aboul-Hosn where the teachings in Siess '913 may be relevant is the stabilization system, but the disclosure in Aboul-Hosn teaches away from Petitioners' combination. The stabilization system in Aboul-Hosn already includes a feature to measure pressure along the catheter (Ex. 1004, 29:20-25). Thus there would be no need to modify this design to incorporate the electronic pressure sensors disclosed in Siess '913.

In short, all of the embodiments disclosed in Aboul-Hosn teach away from incorporating the teaching in Siess '913. Even if they did not, Petitioners fail to make the requisite showing that a POSITA would combine these separate systems.

Accordingly, in addition to failing to combine the separate embodiments in Aboul-Hosn, Petitioners fail to show unpatentability of the claimed blood pressure detection mechanism.

D. Petitioners' Ground 1 Fails to Disclose the Claimed Method

Petitioners fail to disclose the claimed method of Claims 10 and 22.

Petitioners assert the claimed method steps are "conventional" or "conventionally

taken” in delivering blood pumps to the circulatory system (Petition, 63).

Petitioners again (and improperly) rely on Aboul-Hosn.

First, Aboul-Hosn is fundamentally different from the '068 Patent (*supra* §§ III(A)-(C)). Petitioners refer only to guiding a **cannula** to a desired location using the guide wire, not the pump, because they recognize Aboul-Hosn discloses the reverse flow pump (50) is located outside the circulatory system and **only** the inner cannula (20) actually extends inside the blood vessel wall (Petition, 63-64; Ex. 1004, 21:22-27; 22:10-21; 24:7-14; *supra* § III(A)(1)(a)). Aboul-Hosn further explains the guide wire (28) is **only** used to locate the inner cannula (20) inside the blood vessel (Ex. 1004, 21:22-23). Likewise, nothing in Aboul-Hosn suggests a guide wire is used with regard to Figure 23, nor if one was used, whether it would be used to perform the method as claimed (*supra* § III(B)(1)(b)(i)). Accordingly, Aboul-Hosn fails to teach the claimed *method* steps.

Moreover, Petitioners continue to improperly move between the embodiments of Aboul-Hosn's Figures 1-13 and Figure 23 (Petition, 63-64). Petitioners' theory is simply wrong—there are at least two incompatible pumps in Aboul-Hosn, the reverse flow pump of Figures 1-13 and the undefined intravascular pump of Figure 23 (*supra* § III(C)(1)(a)). Petitioners provide no motivation to combine these embodiments, and a POSITA would not be motivated to combine these embodiments.

As a result, Petitioners fail to demonstrate Aboul-Hosn teaches or suggests the claimed method. ***Petitioners do not cite to Siess '913 to make up for these shortcomings.*** Accordingly, Petitioners fail to show there is a likelihood Claim 10 is unpatentable.

E. The References Relied Upon are Redundant.

Aboul-Hosn represents a well-worn path of references that were previously before the Office during prosecution. Aboul-Hosn was before the Examiner during prosecution, along with many similar and redundant references. For at least these reasons, the Board should exercise its authority to reject the Petition, as the Office has previously considered the same or substantially the same issues. *See* 35 U.S.C. § 325(d); *see also* Institution Decision at 12-13, *Prism Pharma Co., Ltd v. Choongwae Pharma Corp.*, IPR2014-00315 (P.T.A.B. Jul. 8, 2014), Paper 14 (rejecting the Petition because the same prior art and substantially the same arguments were presented to the Office previously during prosecution); Institution Decision at 7-8, *Integrated Global Concepts, Inc. v. Advanced Messaging Techs., Inc.*, IPR2014-01027 (P.T.A.B. Dec. 22, 2014), Paper 16.

Aboul-Hosn was cited by the Applicant in an information disclosure statement considered on August 10, 2015 prior to issuing the first, and only, Office Action (Ex. 1003, 107-117 & 145). In response to the Office Action, a Terminal Disclaimer was filed, and the first Notice of Allowance was issued (Ex. 1003, 153

& 171-180). The Applicant then submitted two additional information disclosure statements citing additional references with a request for continued examination (Ex. 1003, 190-200, 213-221). These new references were considered and a new Notice of Allowance was issued (Ex. 1003, 685-704). Aboul-Hosn was never listed as a reference relevant to the patentability of the claims.

One reference that the Examiner explicitly considered and found the claims patentable over is Voelker.⁴ Petitioners rely on Voelker to establish the so-called state of the art. Petitioners further explain that Voelker and Aboul-Hosn have similar teachings. For example, Petitioners admit that Voelker teaches the same guide mechanism as Aboul-Hosn: “[a]s explained in further detail in Sections VII and X below, Aboul-Hosn disclosed that same well-known ‘over-the-wire’ catheterization technique and used it in delivering intravascular blood pumps into the heart” (Petition, 7). This alleged similarity should provide the Board with sufficient reason to deny the Petition.

Not only do Petitioners admit the redundant nature of Aboul-Hosn and Voelker, but Petitioners’ expert confirms they are redundant (Ex. 1002, ¶¶ 37, 43-44, 63, 70, 84).

⁴ The US Patent that corresponds to the PCT Publication was cited by Petitioners as Ex. 1012.

In short, Petitioners present “old art”—Aboul-Hosn is no different from other art already considered. This is exactly the type of Petition that the Board routinely denies. As such, Patent Owner submits that the Board should defer to Primary Examiner Marcetich’s considered judgment and deny the Petition.

F. Ground 2 Fails to Invalidate Dependent Claim 11

Ground 2 also fails to invalidate any claims in the ’068 Patent. Ground 2 is directed to dependent claim 11 and allegedly discloses the additional features disclosed in this claim. Because Ground 1 fails for the reasons listed above to invalidate the independent claims, this additional ground also fails to invalidate dependent claim 11 (*supra* §§ IV(A)-(E)).

IV. ADDITIONAL ISSUES

This section addresses the hypothetical POSITA, the qualifications of Petitioners’ expert Dr. Collins, and claim construction. The many deficiencies in the Petition described above do not turn on these issues because the references simply do not show what Petitioners allege, and because Petitioners fail to show a basis for their proposed combinations. Nevertheless, as noted below, Petitioners present the wrong level of skill and an incorrect claim construction, and Petitioner’s expert Dr. Collins lacks sufficient qualifications.

A. Person of Ordinary Skill

The hypothetical person of ordinary skill in the art, or POSITA, is not an extraordinarily innovative person, nor a researcher of inexhaustible patience, but is

a person who thinks conventionally in matters affecting the art in which he or she is skilled. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). Factors that may be considered for determining the level of skill include: the educational level of the inventor; types of problems encountered in the art; prior art solutions to these problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citation omitted).

As discussed above, the present invention involves complex technology and numerous design considerations that must be balanced. Many of these are not readily apparent; thus, a POSITA would need practical design experience in the relevant field. A POSITA for the present invention would have to have either: (1) an undergraduate degree in mechanical engineering or bioengineering or similar subject matter and at least 10 years of experience designing intravascular heart assist devices; or (2) have an advanced degree in mechanical engineering or bioengineering (either a masters, Ph.D., or equivalent course work) and at least five years of experience designing intravascular heart assist devices.

Petitioners' definition of a POSITA fails to account for the complexity of the invention and the numerous design considerations the inventors encountered. For example, Petitioners assert that a POSITA may have an advanced degree and "two

to three years of work experience in a medical device or related fields” (Petition, 29). Pointing to the medical device field generally is overbroad and encompasses work in a wide range of irrelevant medical devices, such as prosthetics, grafts, syringes, and other non-vascular devices. This experience would not prepare an engineer to develop intravascular devices generally, much less the intravascular pump systems of the present invention.

Similarly, Petitioners assert that an individual with a Ph.D. “in mechanical or biomedical engineering” and no work experience would be in a position to develop the present invention. This again ignores the complex balancing of design considerations discussed above.

Presumably, Petitioners argue for a broader definition of a POSITA because their expert, Dr. Collins, lacks experience designing intravascular heart assist devices, as evident from the numerous technical deficiencies in the Petition and Dr. Collins’ declaration discussed above.

Dr. Collins’ CV and declaration do not point to any prior work on intravascular heart assist devices. Instead, they list high-level positions at various technology companies, such as his current role of “ensuring CIMIT’s ‘Finding, Funding and Facilitation’ functions are effective and for facilitating teams of clinicians and engineers in the commercialization of technologies in the lab” (Ex. 1002, ¶ 2), and previously serving as president of TIAX LLC “focused on

advancing and developing technologies for commercialization” (Ex. 1002, ¶¶ 7-8), or work in managerial positions at other companies (*id.* ¶¶ 2-3, 6-9). None of these positions are said to have involved intravascular heart assist devices.

Instead, Dr. Collins’ actual design technical experience, again based on his declaration and CV, concerns various mechanical devices such as anti-lock brakes, clean energy technologies, HVAC systems, enhanced security, and automated fryers (Ex. 1002, ¶¶ 6-8, Appendix A). And his experience identified in medical devices does not include any work on intravascular heart assist devices (*id.*).

Because Dr. Collins does not qualify as a POSITA, Patent Owner believes his testimony should be given little weight. *See In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) (“[T]he Board is entitled to weigh the declaration[] and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declaration[]”); Final Written Decision at 17-18, *Schott Gemtron Corp. v. SSW Holding Co., Inc.*, IPR2013-00358 (P.T.A.B. Aug. 20, 2014), Paper 106 (according the testimony of Petitioner’s witness less weight because he was determined to not be a person of ordinary skill in the art at the time of the invention).

B. Claim Construction

When considering whether to institute an *inter partes* review, the Board has indicated it will construe claims by applying the broadest reasonable interpretation

in light of the specification. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48764 (Aug. 14, 2012). There is a “heavy presumption” that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir 2002). However, a “claim term will not receive its ordinary meaning if the patentee acted as his/her own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.” *Id.*

Petitioners’ proposed claim constructions are improper and fail to account for the intrinsic record of the ’068 Patent or the plain and ordinary meaning of the two terms proposed for construction: (1) “distal”; and (2) “proximal.”

The terms “distal” and “proximal” are relative terms that are discussed throughout the patent (e.g., Ex. 1001, 6:9-17; 8:16-35; 9:25-26, 47-67; 10:32-39). The term “distal” refers to locations further from the operator of the devices, and thus it refers to the direction of a feature configured to be located further inside a patient’s body (*id.*). Similarly, the term “proximal” refers to the opposite direction as “distal,” and thus refers to features configured to be located closer to the operator and closer to the point of insertion (*id.*).

Petitioners’ constructions provide an incorrect frame of reference, *i.e.*, the far end of the cannula. Petitioners attempt to define “distal” as the direction

towards the far end of the cannula (Petition, 28) and “proximal” as the direction away from this far end (Petition, 29). This definition does not account for features that may be located past the far end of the cannula, such as those disclosed in the ’068 Patent (Ex. 1001, Fig. 1 (showing guide wire (22) extending beyond the distal end of cannula (14)). Accordingly, Petitioners’ construction should not be adopted, and these terms should be defined based on the relative position of the operator:

- “Distal” means the direction of an element configured to be located further away from the operator of the device.
- “Proximal” means the direction of an element configured to be located closer to the operator of the device.

Patent Owner reserves the right to put forth additional terms for construction should a proceeding be instituted. Moreover, several claim features are not given claim constructions in the Petition. Thus, the Petition should be dismissed because the Petitioners failed to explain how the challenged claims are to be construed as required by 37 C.F.R. § 42.104(b)(3).

V. CONCLUSION

For at least the foregoing reasons, Petitioners have failed to meet the burden under 37 C.F.R. § 42.108(c) of showing a reasonable likelihood of success that any of Claims 10-22 of the '068 Patent would be unpatentable based on its challenges. As such, Patent Owner respectfully requests that the Board deny institution of an *inter partes* review.

Dated: June 30, 2017

Respectfully submitted,

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VI. CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Patent Owner, Patent Owner declares that this Patent Owner's Preliminary Response (Sections I-V) has a total of 13,986 words, according to the word count tool in Microsoft Word™.

Dated: June 30, 2017

Respectfully submitted,

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VII. CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6(e), the undersigned hereby certifies that, on June 30, 2017, a true copy of the foregoing “PATENT OWNER’S PRELIMINARY RESPONSE” and its cited exhibits for this *inter partes* review was served upon the following via email:

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