UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Maquet Cardiovascular, LLC
Patent Owner

Case No. IPR2017-02151

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,327,068

CLAIMS 10, 13-15, AND 20

TABLE OF CONTENTS

Table of Authorities

Page(s)

CASES

STATUTES AND RULES

I. INTRODUCTION

Petitioners Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 10, 13-15, and 20 (the "Challenged Claims") of U.S. Patent No. 9,327,068 (the "'068 patent"). The Challenged Claims add nothing new to the art and should be found unpatentable and canceled.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real parties in interest are Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH.

B. Related Matters

Abiomed Inc. filed a declaratory judgment action against Maquet Cardiovascular LLC ("Maquet" or "Patent Owner") for non-infringement of the '068 patent in the District of Massachusetts. Case No. 1:16-cv-10914 ("Litigation"). Petitioner will file concurrently with the present Petition petitions challenging certain additional claims of the '068 patent, certain claims of U.S. Patent No. 8,888, 728 (the "'728 patent"), and certain claims of U.S. Patent No. 7,022,100 (the "'100 patent"). Petitioner has previously filed: (1) petitions for IPR of the '728 patent (IPR2017-01026 and IPR2017-01027); (2) petitions for IPR of the '068 patent (IPR2017-01028 and IPR2017-01029); (3) petition for IPR of the '100 patent (IPR2017-01025); (4) petitions for IPR of U.S. Patent No. 9,545,468

(the "'468 patent") (IPR2017-01201, IPR2017-01202, and IPR2017-01203); (5) petitions for IPR of U.S. Patent No. 9,561,314 (the "'314 patent") (IPR2017-01204 and IPR2017-01205); and (6) petitions for IPR of U.S. Patent No. 9,597,437 (the "'437 patent") (IPR2017-01207, IPR2017-01208, IPR2017-01209, and IPR2017-01253). The '728, '100, '469, '314, and '437 patents are related to the '068 patent.

C. Counsel

Lead Counsel: David M. Tennant (Reg. No. 48,362)

Backup Counsel: Charles D. Larsen (Reg. No. 48,533); Nathan Y. Zhang (Reg. No. 71,401)

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), papers concerning this matter should be served on the following. Petitioner consents to electronic service.

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III. GROUNDS FOR STANDING

Petitioner certifies the '068 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR of the Challenged Claims. Patent

Owner served Abiomed, Inc. and Abiomed R&D, Inc. with a counter claim asserting infringement of the '068 patent on September 22, 2016 and November 1, 2016, respectively. Patent Owner named Abiomed Europe GmbH on the counterclaim as well and served Abiomed Europe GmbH through the Hague convention.[1]

IV. RELIEF REQUESTED

Petitioner requests review of the Challenged Claims and a ruling that the Challenged Claims are unpatentable.

A. The Challenged Claims Are Invalid in View of the Following Prior Art[2]:

1. WO 99/02204 to Aboul-Hosn (EX1004, "Aboul-Hosn"), published January 21, 1999, is prior art under 35 U.S.C. § 102(b).

2. DE 19821307 to Sammler (EX1045[Sammler]), published October 21, 1999, is prior art under 35 U.S.C. § 102(a).[3]

[1] Abiomed Europe GmbH is only a petitioner because it was so named and served; it disputes that it is properly named as a party.

[2] The pre-AIA statutory framework applies to the '068 patent.

[3] EX1045 is a certified English translation of DE 19821307, which is published in German (EX1056).

B. Grounds for Challenge

Petitioner requests cancellation of the Challenged Claims under the following statutory grounds:

- Ground 1: Claims 10 and 13-15 are rendered obvious by Aboul-Hosn in view of Sammler under 35 U.S.C. § 103(a).
- Ground 2: Claim 20 is anticipated by Aboul-Hosn under 35 U.S.C. § 102(b).

V. CONVENTIONAL TECHNOLOGY

A. Conventional Intravascular Blood Pumps[4]

The features of the Challenged Claims were well-known and included: a cannula connected to an axial flow pump (Collins ¶¶61-64) pumping blood axially along the pump and through the cannula (*id.* ¶¶65-67), and techniques for monitoring blood pressure near the pump (*id.* ¶¶72-78).

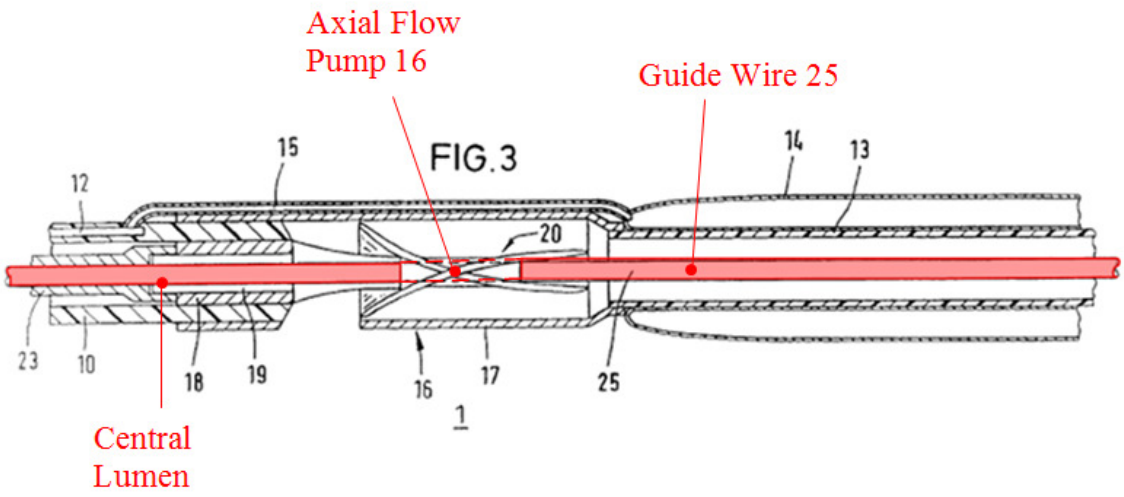
B. Conventional Guide Wire Techniques

Well-known catheterization techniques included "over-the-wire", "side-rigger" and "guide catheters" and have been used routinely to position blood pump intravascularly (i.e. within a patient's circulatory system). (Collins ¶¶79-92.)

[4] For background, Dr. Collins discusses the circulatory anatomy and function, and development of intravascular blood pumps. (Collins ¶¶40-52.)

1. Over-the-Wire

A person of ordinary skill in the art ("POSITA") used "over-the-wire" guide mechanisms to place intravascular blood pumps. (Collins ¶¶82-85.) As shown below in FIG. 3, Voelker applied the "over-the-wire" guide mechanism to an axial flow intravascular blood pump with the guide wire extending coaxially through the shaft 19 and other pump components so that the pump may be slipped over the guide wire. (Collins ¶84; EX1012[Voelker] 1:46-50, 3:56-60.)



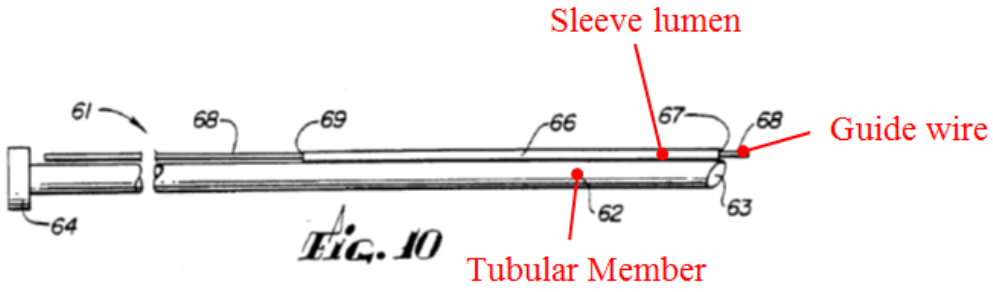
(Collins ¶85; EX1012[Voelker] FIG. 3, annotated.)

As explained in further detail in Sections VII and X below, Aboul-Hosn and Sammler both used the same well-known "over-the-wire" technique in delivering intravascular blood pumps into the heart. (Collins ¶¶82-85.)

2. Side-Rigger

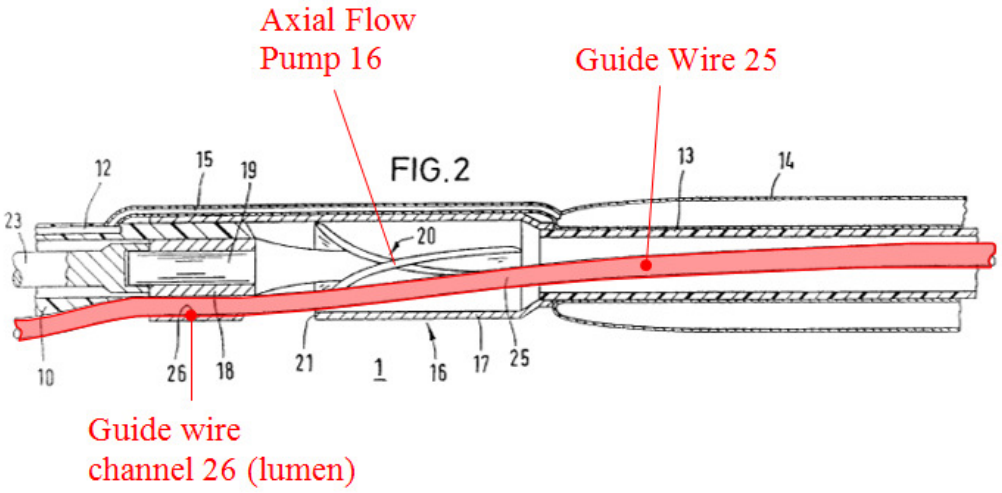
"Side-rigger" was a well-known catheterization technique. (Collins ¶89.) Yock disclosed placing a conventional "side-rigger" catheter by sliding it along a

guide wire extending through a sleeve secured to the exterior of the cannula or embedded within the cannula wall itself. (*Id.* ¶87; EX1007[Yock] FIG. 10, 7:64-68.)



(Collins ¶86; EX1007[Yock] FIG. 10, annotated.)

Voelker, at Fig. 2 (below) applied this "side-rigger" approach to an intravascular blood pump -- a guide wire 25 extending through a side channel 26 of a pump for positioning the pump, as illustrated below. (Collins ¶88; EX1012[Voelker] 3:34-43.)



(Collins ¶88; EX1012[Voelker] FIG. 2, annotated.)

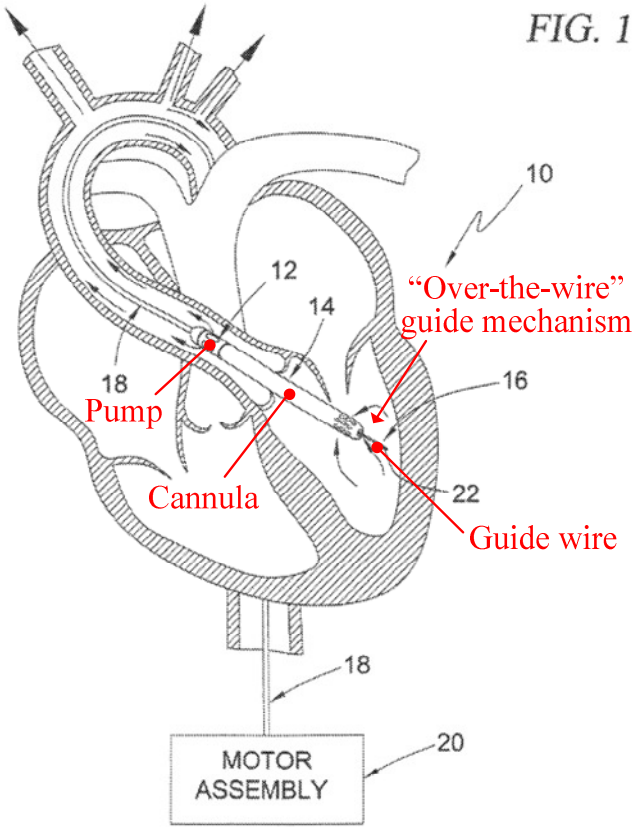
3. Guide Catheter

Yock also discloses using a guide catheter to position to position a guide wire. (Collins ¶¶80-81; EX1007[Yock] 3:56-4:50.) The same technique as disclosed by Yock has been adapted to place intravascular blood pumps. (Collins ¶81; EX1001['068 Patent] 2:26-36.)

VI. OVERVIEW OF THE '068 PATENT

A. Summary

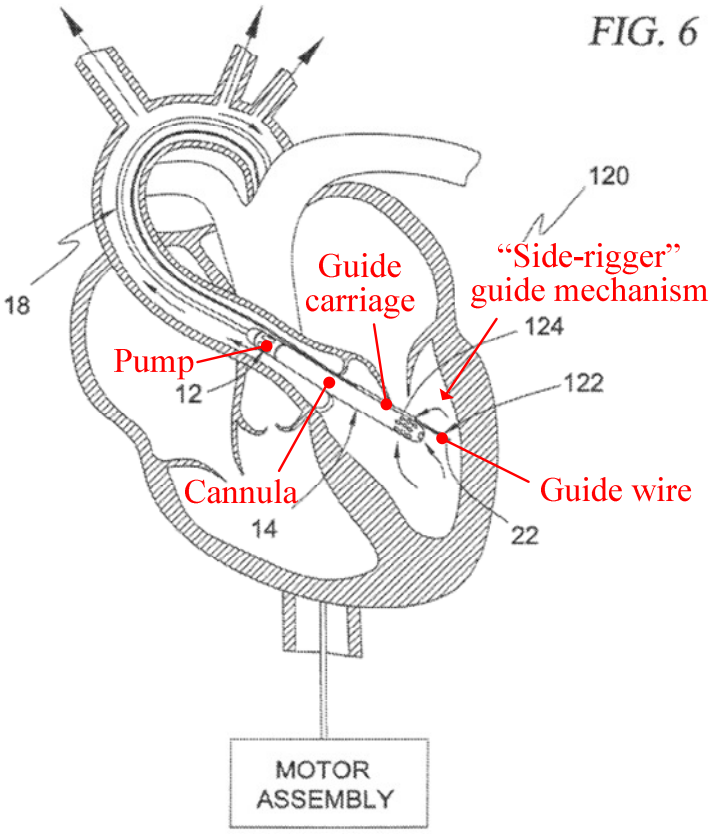
The background of the '068 patent openly admits that it is not the first to use "guide mechanism[s]" to place an intravascular pump. (EX1001['068 patent] 2:26-39.) FIG. 1 of the '068 patent shows a conventional over-the-wire placement technique. (*Id.* 5:7-12.)



(Collins ¶96; EX1001['068 patent] FIG. 1, annotated.)

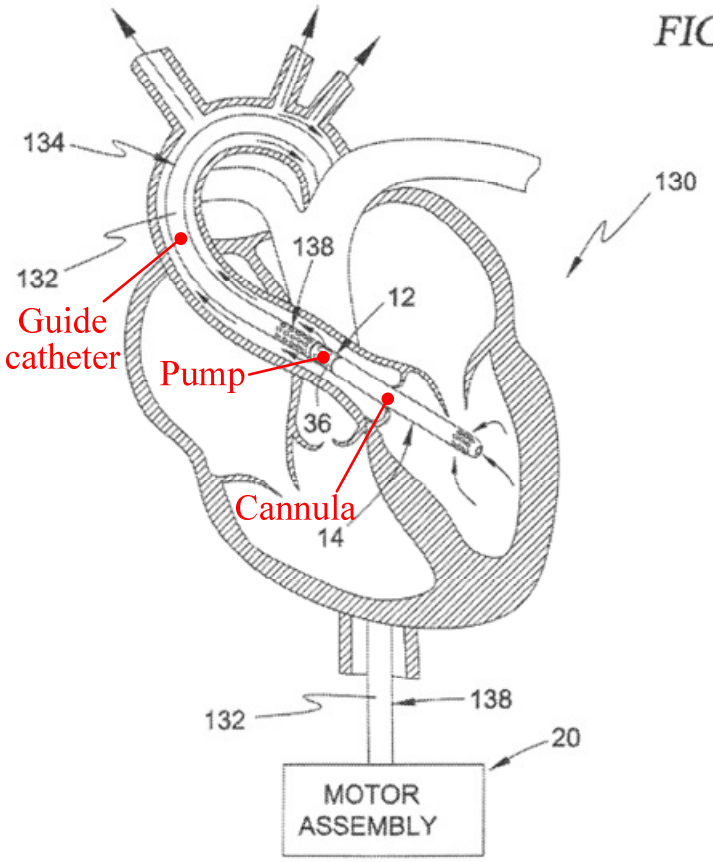
The conventional intravascular blood pump system 10 includes an intravascular blood pump 12, rotor hub, cannula 14, and over-the-wire guide mechanism 16 with a guide wire lumen that passes through the center of the rotor hub and the cannula 14. (*Id.* 7:6-16; Collins ¶¶95-97.)

FIG. 6 shows the conventional "side-rigger" guide mechanism of the prior art. (*Id.* 5:29-34.) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a … guide wire 22 … dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (*Id.* 11:60-12:3; Collins ¶¶98-100.)



(Collins ¶98; EX1001['068 patent] FIG. 6, annotated.)

Finally, the '068 patent at FIG. 10 shows a "guide catheter" mechanism 132 as in the prior art where the rotor and shroud are placed in two different steps. (EX1001['068 patent] 13:4-9; Collins ¶101.)



(Collins ¶101; EX1001[’068 patent] FIG. 10, annotated.)

B. The Earliest Possible Priority Date

The September 1, 2000 priority date of the ’068 patent is the earliest possible priority date (the “EPD”) for the Challenged Claims.[5] The subject matter of the Challenged Claims is not supported by an earlier-filed provisional application, Provisional U.S. Application No. 60/152,249 (EX1013, the “’249 provisional application”).

[5] The ’068 Patent was filed November 17, 2014 and claims priority to PCT Application No. PCT/US00/24515, which was filed on September 1, 2000.

Independent claims 10 and 20 require a lumen "arranged coaxially with at least one of a distal end or a proximal end of the cannula," and claim 10 further requires "a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump." (EX1001['068 patent] at 19: 54-57; 19:59-60.) Yet nowhere in the '249 provisional application is there support for a lumen "arranged coaxially" with an end of the cannula, or "a blood pressure detection mechanism." (Collins ¶¶108-110.)

The '249 provisional application fails to provide written description support for, and is non-enabling with respect to, each of the aforementioned claimed features. (EX1013['249 provisional application] at 12; Collins ¶112; *Dynamic Drinkware, LLC. v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("the specification of the *provisional* must 'contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.") (quoting *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002) (emphasis in original).)

Accordingly, the EPD for the Challenged Claims is September 1, 2000. (Collins ¶112.)

VII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Aboul-Hosn[6]

Aboul-Hosn discloses anintravascular blood pump system incorporating an over-the-wire guide mechanism to position the pump system "in a heart chamber or a vessel to completely or partially stop the heart in order to operate on the organ." (Collins ¶114; EX1004[Aboul-Hosn] 6:24-29, 11:9-14, 30:1-2, 31:6-9.) Like the '068 patent, Aboul-Hosn discloses that the intravascular blood pump system can be positioned using both percutaneous and surgical approaches. (Collins ¶114; EX1004[Aboul-Hosn] FIGS. 21, 23-24, 6:16-29, 11:8-11, 21:19-22:30, 29:17-19, 32:9-13; EX001['068 patent] 1:56-58, 17:30-42.)

As shown below in FIGS. 1 and 2,[7] and similar to the '068 patent, the blood pump has a drive unit 80 (purple) connected to a conventional blood pump having

[6] Aboul-Hosn was included in an Information Disclosure Statement ("IDS") submitted by the Patent Owner to the USPTO on November 17, 2014 but was not relied upon by the Examiner during prosecution of the '068 patent nor were any arguments made in relation to it. (EX1003['068PH] 75-86.)

a rotor and associated blades 70 (red), within a housing body 52 (green) and a housing cap 62 (green).[8] (EX1004[Aboul-Hosn] 12:12-13:13.) An inner cannula 20 (blue) is coupled to the housing cap 62 (green), and extends beyond the distal opening 32 of the outer conduit 30 (dark grey.) (*Id*.)

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[7] As noted by Dr. Collins, FIGS. 1 and 2 show an extracorporeal blood pump system, however, Aboul-Hosn discloses that the intravascular blood pump system can comprise the same components which are properly sized in order to fit into an introducer for positioning within the vascular system of the patient. (Collins ¶115 n. 7; EX1004[Aboul-Hosn] FIGS. 3, 4, and 12.)

[8] The housing body 52 and the housing cap 60 may form "a unitary body." (EX1004[Aboul-Hosn] 12:22-23.)

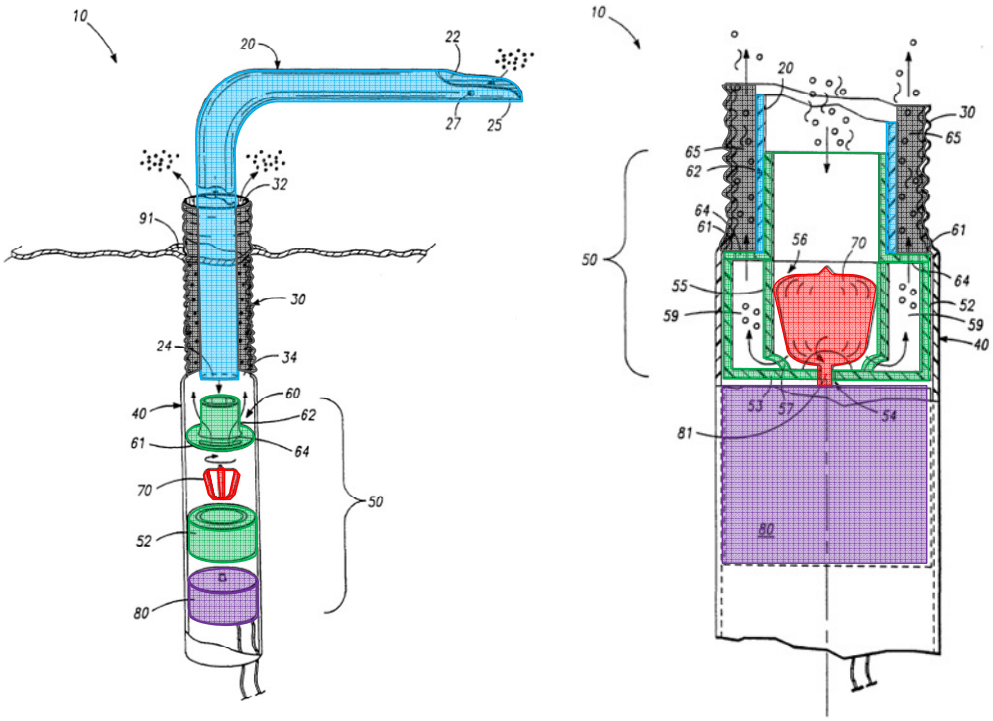


FIG.–1 FIG.–2

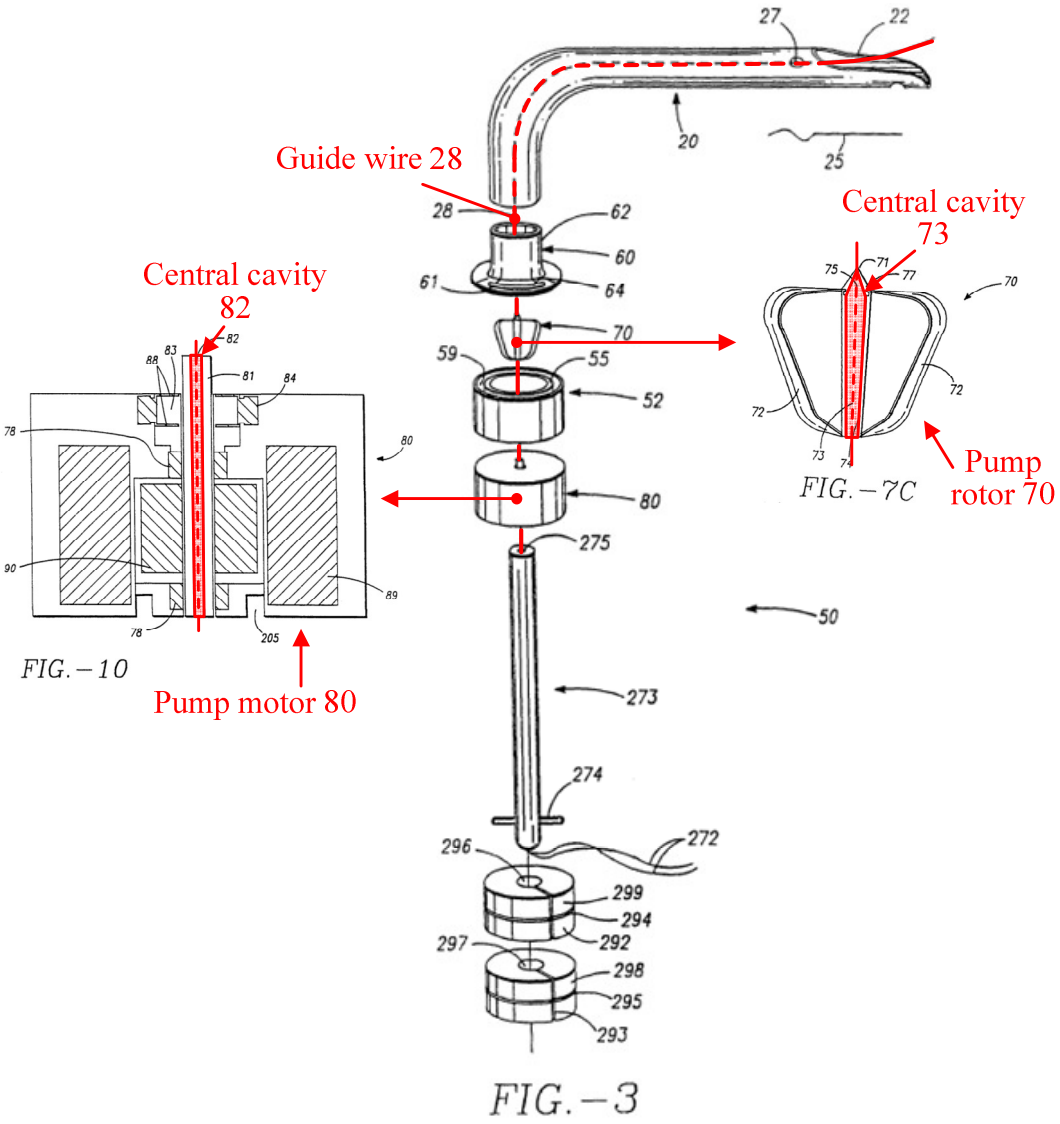
(Collins ¶115; EX1004[Aboul-Hosn] FIGS. 1 and 2, annotated.)

The rotor 70 and associated blades (red) generate an axial flow of blood (that also has a radial component), which is then "reversed" when the blood exits the inlet tube 55, as shown in FIG. 2 by the directional arrows. (Collins ¶116; EX1004[Aboul-Hosn] 13:25-18, 18:15-19.)

Like the '068 patent, the design of Aboul-Hosn's intravascular pump system allows it to be positioned in "in a heart chamber or a vessel" using a guide wire. (Collins ¶117; EX1004[Aboul-Hosn] 11:26-28, 14:13-16, 14:20-24, 21:22-24, 22:10-16.) FIGS. 3, 7C, and 10 show the integration of the conventional over-the-wire technique in Aboul-Hosn's intravascular blood pump system in detail, where

the guide wire 28 (red) passes through a central lumen extending through the center of the positioning rod 273, drive unit 80, the rotor 70, and the inner cannula 20.[9] (Collins ¶117; EX1004[Aboul-Hosn] 14:17-15:18, 17:19-22, FIG. 12.) In addition, as shown in FIG. 3 the intravascular blood pump system comprises the same pump components as the extracorporeal pump system shown in FIGS. 1 and 2, along with the addition of a pushing rod 273 to push the intravascular blood pump system into the patient's body. (*Id.* ¶117.)

[9] A POSITA could also readily adapt the Aboul-Hosn's pump system to be positioned using the conventional "side-rigger" technique. (Collins ¶117, n. 9.)



(Collins ¶117; EX1004[Aboul-Hosn] FIGS. 3, 7C, and 10, annotated.)

FIGS. 11 and 12 below illustrate the process of positioning Aboul-Hosn's intravascular blood pump system using the over-the-wire technique. (Collins ¶¶118-119; EX1004[Aboul-Hosn] 21:11-22:30.)

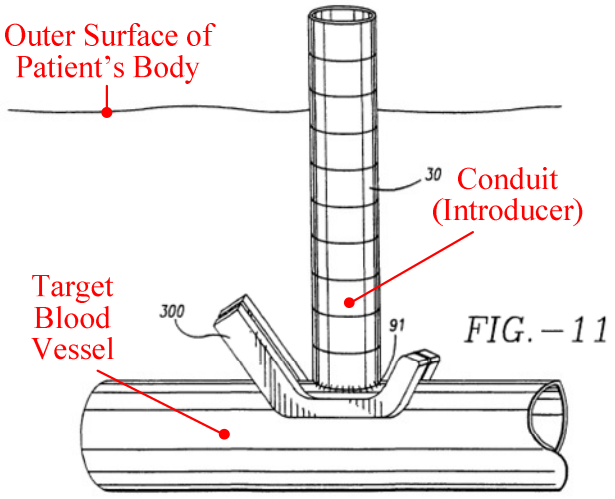


FIG.–11

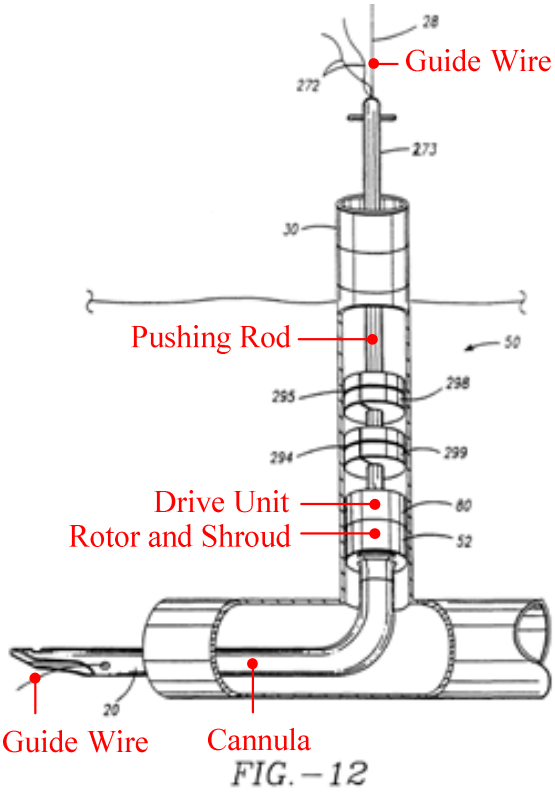


FIG.–12

(Collins ¶118; EX1004[Aboul-Hosn] FIGS. 11 and 12, annotated.)

As shown in FIG. 11, an outer conduit 30 is first inserted through a small incision in the patient's body and attached to "a targeted blood vessel or [heart] chamber using thorascopic suturing or microstapling." (Collins ¶119; EX1004[Aboul-Hosn] 21:11-18.) As Dr. Collins explains, attaching the conduit 30 to a target blood vessel as shown in FIG. 11 allows the intravascular blood pump system to be introduced through the vasculature, whereas attaching the conduit to a heart chamber allows the pump system to be introduced directly into the heart. (Collins ¶120; EX1004[Aboul-Hosn] 6:24-7:5, 12:7-9.) After the outer conduit 30 is attached to the target blood vessel or heart chamber, "a commercially available

high stiffness guide wire" is inserted through the outer conduit 30 and "positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20." (Collins ¶121; EX1004[Aboul-Hosn] 22:10-16.)

The pump system is then advanced over the guide wire 28, which as shown above in FIGS. 3, 7C, and 10 the guide wire 28 extends through the central lumen extending through the rotor 70, drive unit 80, and positioning rod 273, and introduced into the patient's body through the outer conduit 30. (Collins ¶121; EX1004[Aboul-Hosn] 21:27-29.) Using the positioning rod 273, the surgeon pushes the pump system over the guide wire 28 through the outer conduit 30 and to the desired position within the patient's vasculature, after which the guide wire 28 may be removed and the blood pump is activated. (Collins ¶121; EX1004[Aboul-Hosn] 22:10-25.)

Aboul-Hosn describes the intravascular blood pump system introduced through the conduit and positioned within the patient's vasculature in the manner shown in FIGS. 11 and 12 as "an endovascular method and system."[10] (Collins ¶119; EX1004[Aboul-Hosn] 6:24-29.) Using Aboul-Hosn's "endovascular method

[10] According to Dr. Collins, in the medical devices field, endovascular has the same meaning as intravascular. (Collins ¶141 n. 11; EX1049[Stedman's Medical Dictionary] 590("Endo"), 916 ("intra").)

and system," the intravascular blood pump system can be placed in a variety of configurations to provide both left-heart and right-heart support, such as in the configurations shown in FIGS. 14-19, 21, and 23. (Collins ¶¶122-124; EX1004[Aboul-Hosn] 9:16-31.) For example, FIG. 17, below, shows a configuration using two of Aboul-Hosn's intravascular blood pump systems that are positioned surgically to provide left-heart and right-heart support simultaneously. (Collins ¶122; EX1004[Aboul-Hosn] 26:21-23.)

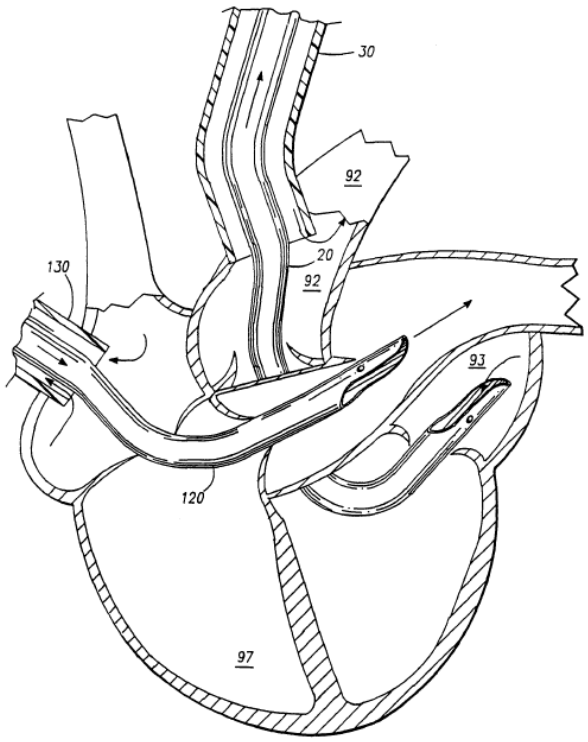


FIG.—17

(EX1004[Aboul-Hosn] FIG. 17.)

B. Sammler[11]

Sammler discloses an intravascular blood pump system positioned "as a right heart pump such that it delivers [blood] from the right atrium 21 into the pulmonary artery 26." (Collins ¶126; EX1045[Sammler] 4:15-16, 4:38-40.) As shown in FIG. 1, below, the intravascular blood pump system is inserted through either the upper or lower vena cava and into the right atrium of the heart. (Collins ¶126; EX1045[Sammler] 4:15-18, 4:38-40).

[11] Sammler was included in an IDS submitted by the Patent Owner to the USPTO on November 17, 2014, but was not relied upon by the Examiner during prosecution of the '068 patent nor were any arguments made in relation to it. (EX1003['068PH] 75-86.)

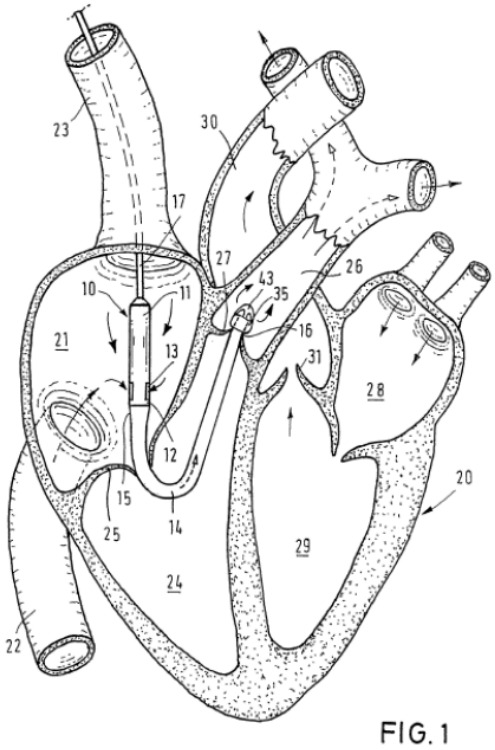


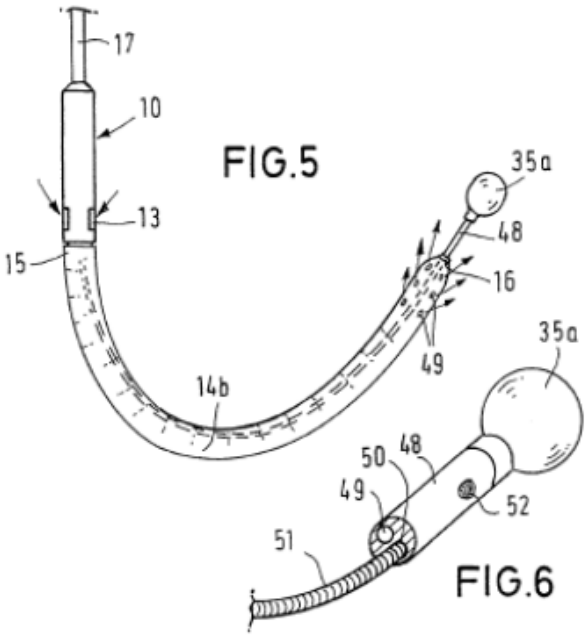
FIG. 1

(EX1045[Sammler] FIG. 1.)

Sammler discloses that the blood pump 10 comprises two distinct parts: (1) a drive section 11 and (2) a pump section 12 that "comprises an impeller … which drives the blood in an axial direction." (Collins ¶127; EX1045[Sammler] 4:17-18, 4:21-22.)

Sammler further discloses configuring the intravascular blood pump system with an integrated guide mechanism comprising a guide wire and lumen to position the intravascular blood pump system within the right side of the patient's heart. (Collins ¶128; EX1045[Sammler] 6:3-12.) As shown in FIGS. 5 and 6 below, a guide wire 51 extends through a lumen 50 within the catheter 48 and pump hose 14b, the pump 10, and the catheter 17. (Collins ¶128; EX1045[Sammler] 3:24-27,

6:3-7.) Once the intravascular blood pump system has been positioned, the guide wire 51 can be removed and the lumen 50 can be used to detect blood pressure in the pulmonary artery to help control the operation of the pump system. (Collins ¶129; EX1045[Sammler] 6:8-12.)



(EX1045[Sammler] FIGS. 5 and 6.)

C. Analogous Art

Aboul-Hosn and Sammler are analogous art. As Dr. Collins explains throughout his Declaration, a POSITA would naturally look to analogous art.

First, a POSITA would naturally look to Aboul-Hosn and Sammler, as they are both directed to axial flow intravascular blood pump systems, and as such are in the same field of endeavor as the '728 patent. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (a reference is analogous art to the claimed invention if it is

in "the same field of endeavor, regardless of the problem addressed").) (Collins ¶130.)

Second, both Aboul-Hosn and Sammler are directed to the same problem addressed by the '728 patent, i.e., positioning intravascular blood pump systems within the vascular system to provide left or right heart support. *See In re Bigio*, 381 F.3d at 1325 (a reference is also analogous art to the claimed invention if it "is reasonably pertinent to the particular problem with which the inventor is involved.") (*Id.*)

Accordingly, Aboul-Hosn and Sammler are analogous art.

VIII. CLAIM CONSTRUCTION

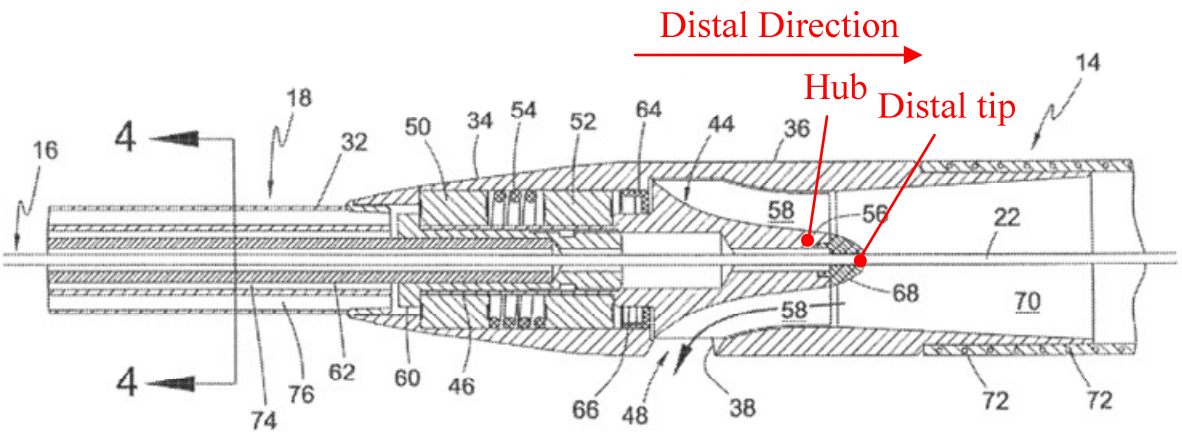
A claim in IPR is given the "broadest reasonable construction in light of the specification." (37 C.F.R. § 42.100(b).) Any claim term that lacks a definition in the specification is therefore also given a broad interpretation. (*In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).) Consistent with 37 C.F.R. § 42.100(b), Petitioner submits the following claim term constructions.[12] Any claim terms not included in the following discussion are to be given their broadest reasonable construction in light of the specification as commonly understood by a POSITA.

[12] Petitioner reserves the right to pursue different constructions in a district court, where a different standard applies.

A. "distal"

The Challenged Claims recite the term "distal," which refers to being directed toward the far end of the cannula relative to the position of the pump. (*Id.* ¶143-45.) Referring to FIG. 3, as reproduced below, the '068 patent provides that "the purge fluid flows distally around the cable adapter, through the ball bearing assemblies 50, 52, and onward past the radial seal 64." (EX1001['068 patent] 10:20-23.)

FIG. 3

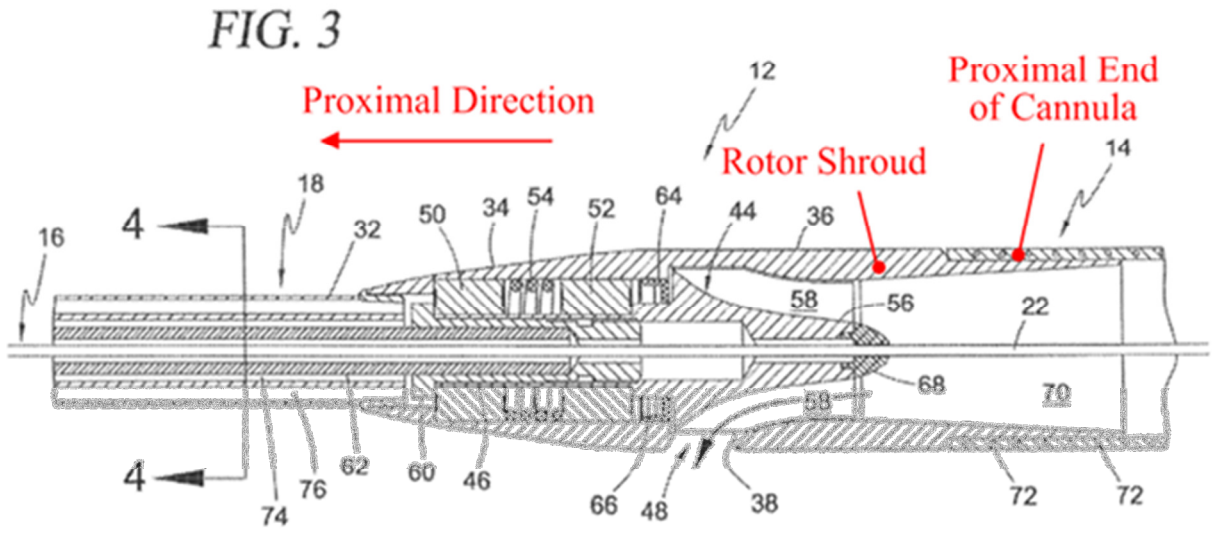


(Collins ¶132; EX1001['068 patent] at FIG. 3, annotated.)

As shown in FIG. 3, the "distal flow" travels through the blood pump in a direction towards the cannula indicating that the distal direction runs from left-to-right moving away from the pump body towards the opening of the cannula into the patient's heart. (Collins ¶¶132-135.) Thus, distal refers to "towards the far end of the cannula relative to the position of the pump." (Collins ¶135.)

B. "proximal"

The Challenged Claims also recite the term "proximal," which refers to being directed away from the far end of the cannula relative to the position of the pump (i.e., opposite of "distal"). (Collins ¶¶136-137.) For example, the '068 patent provides that "[t]he cannula 14 is coupled at its proximal end to the rotor shroud 36," which is the end opposite the "distal region" of the cannula. (*Id.*; EX1001['068 patent] 8:16-21, 9:47-52.)



(Collins ¶136; EX1001['068 patent] FIG. 3, annotated.)

Thus, proximal refers to "away from the far end of the cannula relative to the position of the pump." (Collins ¶138.)

IX. PERSON HAVING ORDINARY SKILL IN THE ART

A POSITA as of the EPD would have had (i) a Bachelor's degree in mechanical or biomedical engineering, or a similar field, and two to three years of

work experience with intravascular cardiac assist devices, (ii) a Master's degree in mechanical or biomedical engineering, or a similar field, and two to three years of work experience in medical device or related fields, or (iii) a Ph.D. in mechanical or biomedical engineering, or a similar field. (Collins ¶33.)

In IPR2017-01029 challenging certain claims of the '068 patent, Patent Owner takes a position that a POSITA must have either 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 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. (EX1050[IPR2017-01029 POPR] 66).

Patent Owner overstates the requirement to qualify as a POSITA. (Collins ¶35.) Patent Owner provided absolutely no justification for requiring such a stringent "ordinary" level of skill with intravascular heart assist devices. (*Id.*) As the Board previously acknowledged, both experience and education should be factored in the level of skill of the POSITA. *See Symantec Corp. vs. Finjan Inc.*, IPR2015-01552, Paper 9 (P.T.A.B. January 14, 2016) (holding that "additional graduate education might substitute for experience, while significant experience in the field … might substitute for formal education."); *see also Samsung Electronics*

Co. Ltd. v. Queen's University at Kingston, IPR2015-00583, Paper 54 (P.T.A.B. July 27, 2016) (same).

Moreover, the Board has found that "a person of ordinary skill in the art *designs* devices, and, thus, actively monitors the relevant technical literature, rather than is merely familiar with devices (e.g., an operator or a manufacturer)." *See Dynamic Air Inc. v. M-I Drilling Fluids UK Ltd.*, IPR2016-00259, Paper 54 at 17 (P.T.A.B. May 23, 2017) (emphasis in original); *see also Stryker Corp. v. Zimmer, Inc.,* 2012 U.S. Dist. LEXIS 12329, *39 (W.D. Mich. Feb. 1, 2012) (defining a POSITA for patents directed to "pulsed lavage irrigation systems … commonly used in orthopedic surgeries" to possess "a bachelor's degree in mechanical engineering and 2-3 years of industry experience relating to the design of medical devices."); *Cook Grp. Inc. v. Boston Scientific Scimed, Inc.,* IPR2017-00133, Paper 7 at 7 (P.T.A.B. May, 3, 2017) (adopting Petitioner's definition of a POSITA to be "an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices" for patents directed to compression clips used to cause hemostasis of blood vessels along the gastrointestinal tract).

Dr. Collins was not "merely familiar with devices" but was involved in the design of a variety of medical devices, including intravascular heart assist devices, as detailed in his Declaration and accompanying CV. (Collins ¶7.) As Dr. Collins

explains, his skill level meets or exceeds that of a POSITA due to his necessary familiarity with the relevant design challenges and Federal safety regulations associated with his work designing such intravascular heart assist devices. (*Id.* ¶35.)

Even under Patent Owner's unduly restrictive definition, Dr. Collins is a POSITA for the purposes of the '068 patent. (*Id.* ¶37.) Dr. Collins received his Ph.D. from MIT in 1988 with a focus on biomedical applications, and from 1998 to 2002, he worked as a design engineer helping to form Arthur D. Little Inc's ("ADL") medical devices business including working on the design of numerous medical products related to vascular and intravascular medical devices. (*Id.*) That experience is more than ample.

X. SPECIFIC GROUNDS FOR PETITION

The below sections demonstrate in detail how the prior art discloses each and every limitation of the Challenged Claims and how those claims are rendered obvious by the prior art. The declaration by Dr. Collins (EX1002) confirms these analyses and conclusions.

A. Ground I: Claims 10 and 13-15 are obvious in view of Aboul-Hosn and Sammler

1. Claim 10

a) "*A method for perfusion a patent [sic]with an intravascular blood pump system, the intravascular blood pump system comprising:*"

As previously discussed in Section VII.A, Aboul-Hosn's intravascular blood pump system can be "positioned in a heart chamber or a vessel" either percutaneously or surgically by advancing the blood pump system over a guide wire and through a conduit attached to a blood vessel or heart chamber, which is shown in annotated FIG. 12 below. (Collins ¶141; EX1004[Aboul-Hosn] 31:6-9, 21:11-22:30.)

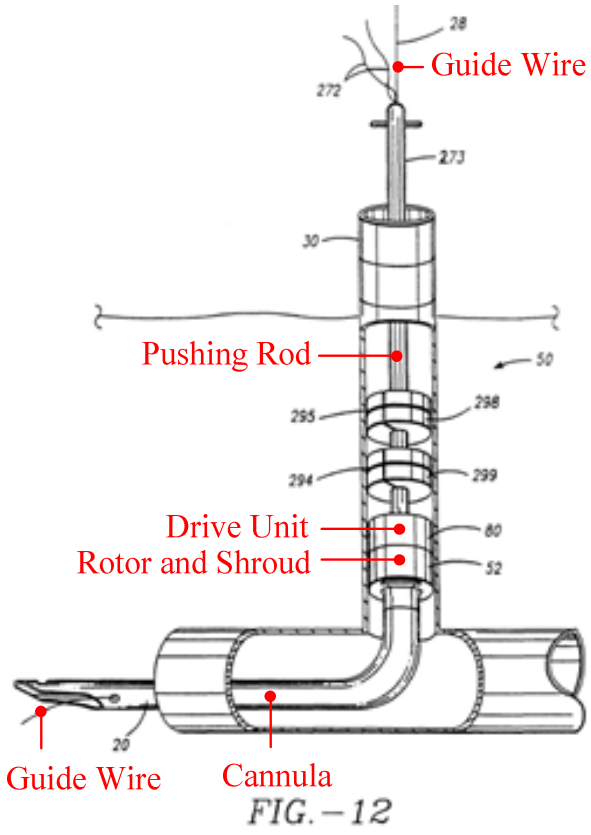


FIG. – 12

(Collins ¶147; EX1004[Aboul-Hosn] at FIG. 12, annotated.)

Aboul-Hosn describes the introduction of the intravascular blood pump system being introduced into the patient's body and into the vascular system through the conduit 30 as shown above in FIG. 12 as an "endovascular method and

system."[13] (Collins ¶141; EX1004[Aboul-Hosn] 6:24-7:5: "[a] **reverse flow bood pump system may be passed through the conduit** and positioned in a heart chamber or vessel in preparation to completely or partially stop the heart in order to operate on the organ." (emphasis added).) Aboul-Hosn confirms the blood pump system is intravascular as it is "passed through a conduit and positioned in a heart chamber or vessel in preparation to completely or partially stop the heart in order to operate on the organ," indicating that the pump system is positioned within the patient's vascular system. (Collins ¶141; EX1004[Aboul-Hosn] 6:24-7:5.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶142.) Petitioner provides further details below.

b) *"(i) an intravascular blood pump comprising*"

As previously discussed in Section VII.A, Aboul-Hosn's intravascular blood pump system includes an intravascular blood pump. (Collins ¶143; EX1004[Aboul-Hosn] 1:10-14, 6:6-9, 6:11-14.) The blood pump includes the rotor 70 (red) disposed within an inlet tube 55 of the housing body 52 (green), and connected to the drive unit 80 (purple) as shown in annotated FIGS. 1 and 2, below. (Collins ¶¶144-145; EX1004[Aboul-Hosn] 8:20-25, 12:22-23). Again, as explained in Section VII.A, while FIGS. 1 and 2 show Aboul-Hosn's

[13] *See supra* Fn. 10.

extracorporeal pump system,[14] FIG. 3, which shows an intrvascular blood pump system, confirms that Aboul-Hosn's intravascular blood pump comprises the same components as the extracorporeal blood pump as they are denoted with the same element labels. (Collins ¶144; *c.f.* EX1004[Aboul-Hosn] FIG. 3 *with* EX1004[Aboul-Hosn] FIGS. 1 and 2.)

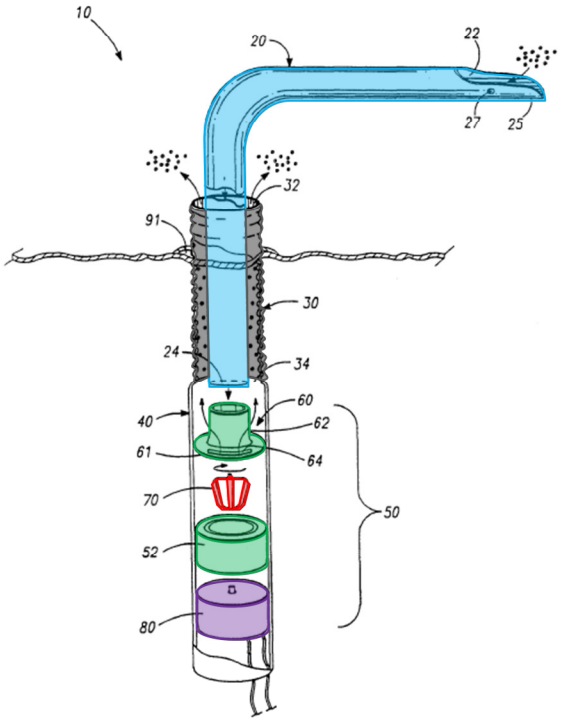


FIG.—1

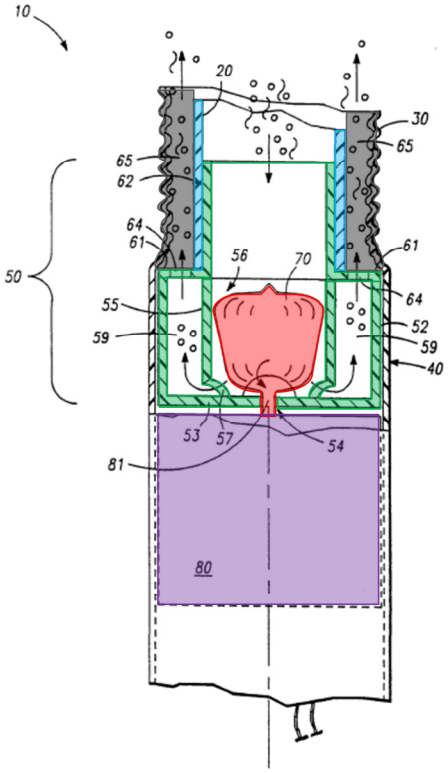


FIG.—2

(Collins ¶145; EX1004[Aboul-Hosn] FIGS. 1 and 2, annotated.)

[14] *See supra* Fn. 7.

Aboul-Hosn's blood pump is intravascular as it is both (1) a miniaturized blood pump and (2) capable of being percutaneously or surgically introduced into the vascular system of the patient. (Collins ¶146; EX1001['068 patent] 1:56-59.)

As previously discussed in Sections VII.A and X.A.1(a), Aboul-Hosn's intravascular blood pump system is "positioned in a heart chamber or a vessel" either percutaneously or surgically by advancing the blood pump system over a guide wire and through a conduit attached to a blood vessel or heart chamber, which is shown in annotated FIG. 12 below. (Collins ¶152; EX1004[Aboul-Hosn] 21:11-22:30.)

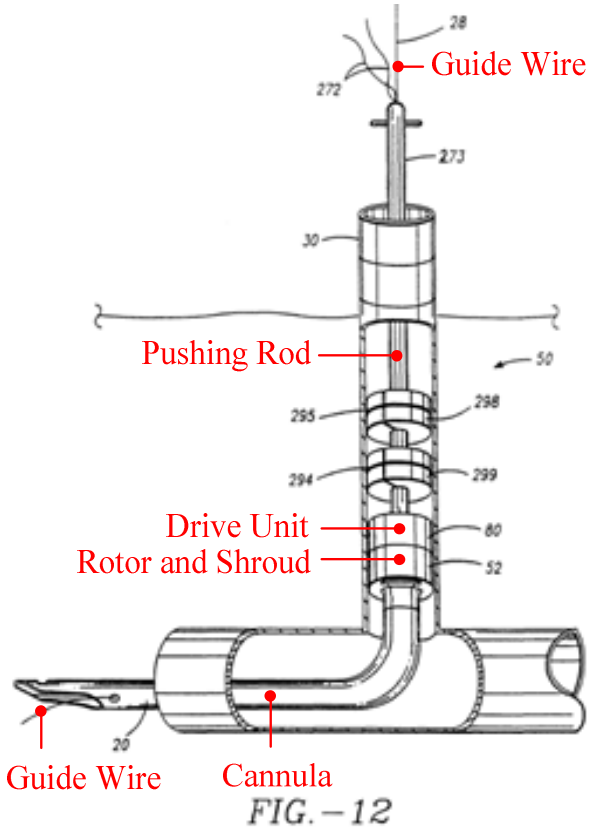


FIG. – 12

(Collins ¶152; EX1004[Aboul-Hosn] FIG. 12, annotated.)

As shown in FIG. 12, the conduit 30 acts as an "introducer" through which the intravascular blood pump is advanced is "inserted into the [patient's] body through a portal of minimal size formed in tissue of a body wall, and engaging an external surface of a vessel or the heart to limit any significant bleeding." (Collins ¶155; EX1004[Aboul-Hosn] 6:29-7:2, 12:7-9.) Correspondingly, the intravascular blood pump must be miniaturized in order to fit into, and advance through, the minimally sized conduit 30 for positioning within the vascular system of the patient, as shown above in FIG. 12. (Collins ¶155; EX1004[Aboul-Hosn] 6:27-7:2, 22:10-12, 22:16-18.) Aboul-Hosn confirms the intravascular blood pump is a miniaturized pump for insertion into the patient's body as he contrasts the intravascular blood pump with the extracorporeal blood pump shown in FIG. 13, below, which avoids the size constraints of the intravascular blood pump as it is not inserted into the minimally sized conduit for introduction into the patient's body and so can be made larger than the intravascular blood pump, thereby simplifying the pump design and "enable[s] the blood capacity to be increased significantly without increase in pump design sophistication." (Collins ¶155; EX1004[Aboul-Hosn] 6:29-7:2, 24:24-25:1.)

As Dr. Collins explains, Aboul-Hosn's intravascular blood pump is also capable of being percutaneously and surgically introduced into the vascular system of the patient. (Collins ¶152.) As shown in FIG. 12, above, the intravascular

blood pump is in the process of being advanced through the conduit 30 as the distal end of the cannula 20 because the distal opening of the cannula and the outflow windows of the intravascular blood pump are not separated by a structure such as a heart valve, and if operated in this condition will draw in blood and pump out blood, respectively, into the same blood vessel, defeating the stated purpose of Aboul-Hosn's blood pump system for "unloading the heart" and transporting "fluids between different regions within the body." (*Id.* ¶152; EX1004[Aboul-Hosn] 6:6-8, 6:19-7:5, 21:11-22:30.) The blood pump would need to be advanced further through the conduit 30 until the distal end of the cannula is positioned, for example, across a heart valve in order to transport blood from one heart chamber to another, or to the blood vessel. (Collins ¶153; EX1004[Aboul-Hosn] FIGS. 14-19.)

Aboul-Hosn also discloses that "[i]n a preferred embodiment," the outer conduit 30 can be "an introducer, or a vascular graft, such as a Dacron™ graft" that is typically used to extend or replace a portion of the vascular system. (Collins ¶154; EX1004[Aboul-Hosn] 12:7-9.) Once attached to a target vessel or heart chamber, the conduit 30 forms an extension of the patient's vascular system akin to a branching blood vessel. (Collins ¶154; EX1004[Aboul-Hosn] 21:31-22:1.) As such, even if the intravascular blood pump were to remain within the conduit 30 as shown in FIG. 12, which may not for the reasons explained above, a POSITA

would understand that the blood pump is within the patient's vascular system. (Collins ¶154.)

A POSITA would also understand that commercially available Dacron grafts can have stated diameters that are consistent and compatible for use as introducers for intravascular blood pumps that are "inserted in the body through a portal of minimal size." (*Id.* ¶155; EX1004[Aboul-Hosn] 6:29-7:2.) The Dacron graft used to introduce the intravascular blood pump would be much smaller in size compared to the aorta or an even larger heart chamber, and which is depicted in FIG. 12 below. (Collins ¶155; EX1029[Guyton] 151.)

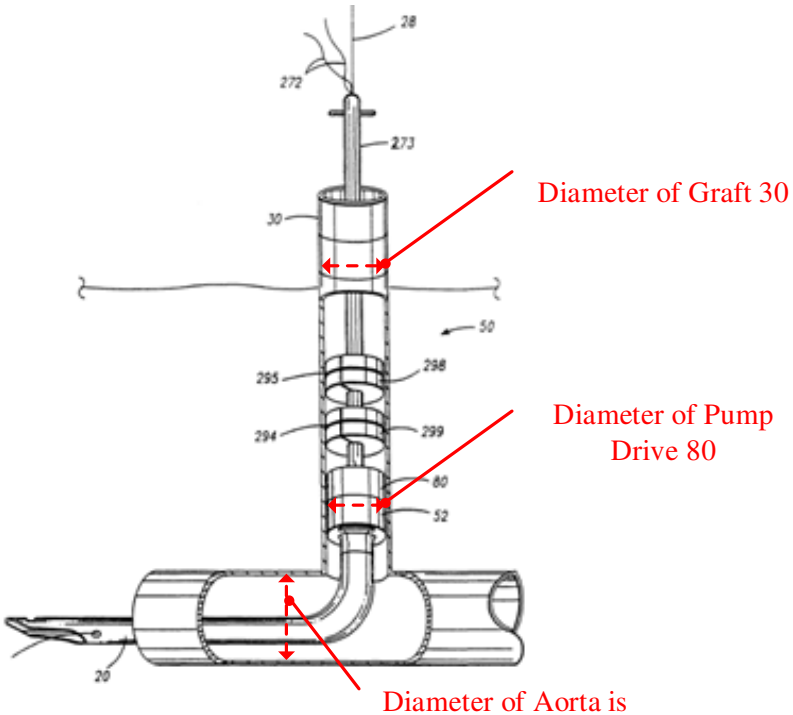


FIG.–12

While Aboul-Hosn does not indicate that FIG. 12 is drawn to scale, a POSITA would understand that FIG. 12 shows the correct relative size comparison between the Dacron graft (and by association the intravascular blood pump inside the graft) and the blood vessel, indicating that the pump is capable of being pushed further into the blood vessel. (Collins ¶155; EX1004[Aboul-Hosn] 6:31-7:2, 24:26-29.)

While the intravascular blood pump only needs to be capable of being introduced into the circulatory system (so as to be indicative of the miniature size), indeed, there are advantages to inserting the intravascular blood pump into the vascular system of the patient, rather than keeping the blood pump in the conduit 30. (Collins ¶156.) As shown in FIG. 12, to achieve the desired blood transport between chambers without displacing the blood pump in the conduit 30, the inner cannula would have to be extended in order for the distal end of the cannula to be positioned across a heart valve, thereby increasing hydrodynamic losses in the system are a result of frictional head loses associated with a long cannula and requiring a larger pump to offset those losses. (*Id.* ¶¶156-157; EX1004[Aboul-Hosn] 14:13-16; EX1032[White] Ch. 6.3; EX1044[SiessThesis] Ch. 5.8.4.) Aboul-Hosn appreciated this in connection with the extracorporeal pump system shown in FIG. 13, which naturally would have a longer cannula as compared to an

intravascular blood pump system, thereby requiring a larger pump with increased capacity. (Collins ¶156; EX1004[Aboul-Hosn] 24:26-25:1.)

As such, for intravascular blood pump systems which, due to space constraints, cannot use a larger pump with increased capacity, in order to maintain sufficient blood pumping capacity to provide heart support, it would have been preferable to use intravascular blood pumps that can be inserted further distally into the vasculature, closer to the heart, which allows for a shorter cannula (thereby reducing hydrodynamic losses associated with the cannula) while still reaching the desired position across a heart valve. (Collins ¶157.) This is particularly true where the graft (i.e. conduit 30 or introducer) is attached to a target blood vessel at a position away from the heart, such as the femoral artery. (*Id.* ¶¶157-158; EX1004[Aboul-Hosn] 21:11-18.) As shown in FIGS. 21 and 23 below, Aboul-Hosn expressly disclosed that the intravascular blood pump is capable of being introduced into the vascular system of the patient through the conduit attached to the femoral artery.[15] (*Id.* ¶158; EX1004[Aboul-Hosn] 29:17-19, 30:21-24, 31:6-9:

[15] As Dr. Collins explains, a multilumen catheter 428 would be used in place of the positioning rod 273 due to the distance the intravascular blood pump system travels through the artery to reach the heart. (Collins ¶158.) The multiluemn catheter 428 is interchangeable with the positioning rod 273, and can be configured to perform the same functions as the positing rod 273. (*Id.* ¶124 n. 10)

"[t]he stabilization systems 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**." (emphasis added).) The positioning of Aboul-Hosn's intravascular blood pump system is discussed in greater detail in Section X.A.1(g), below

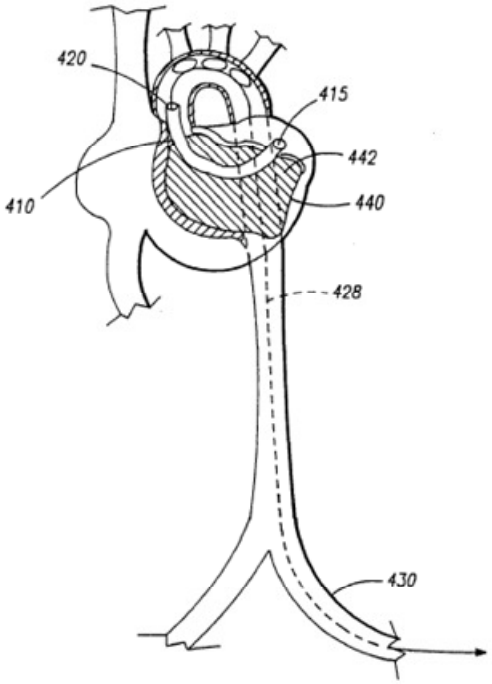


FIG.–21

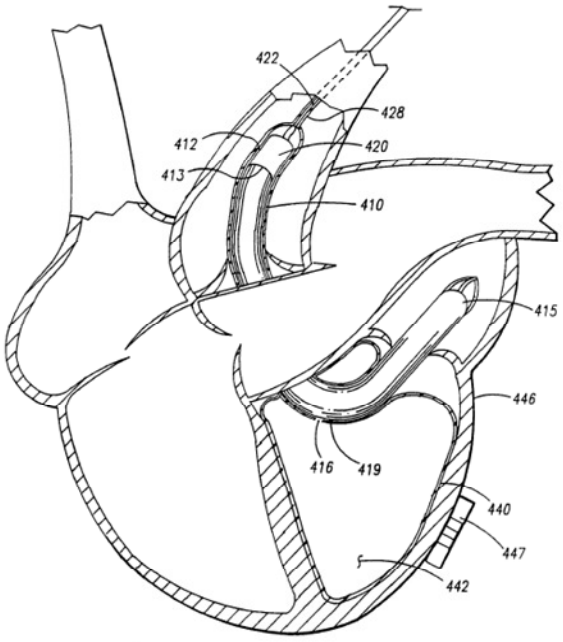


FIG.–23

(EX1004[Aboul-Hosn] FIGS. 21 and 23.)

Thus, considered in its entirety, Aboul-Hosn expressly discloses this limitation. (Collins ¶159.)

c) "*a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub,*"

The intravascular blood pump of Aboul-Hosn has a rotor having a rotor hub. (Collins ¶¶160-163; EX1004[Aboul-Hosn] at 12:30-1.) FIGS. 7A-7C "illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus." (*Id.* 16:30-31.) For example, FIG. 7C, reproduced below, shows a rotor 70 having a central hub 74 tapering in the distal direction and a distal end that extends distally beyond the most distal portion of the blades. (Collins ¶161.)

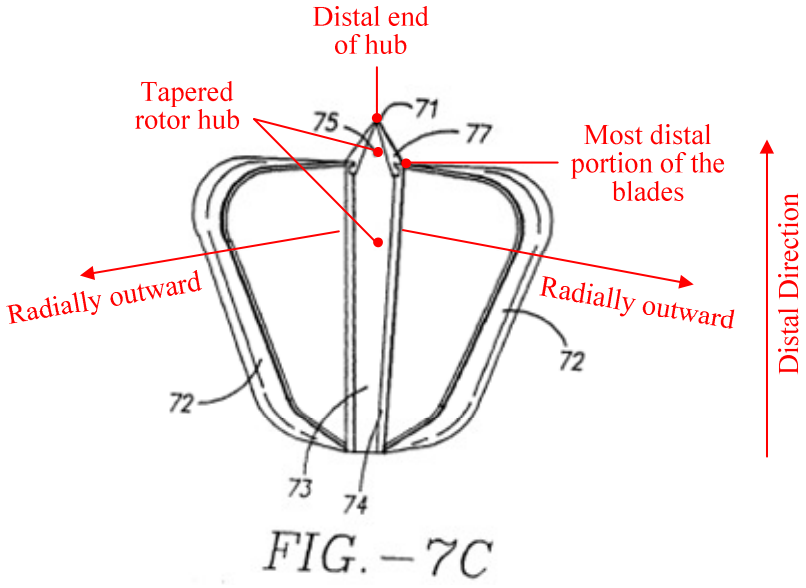
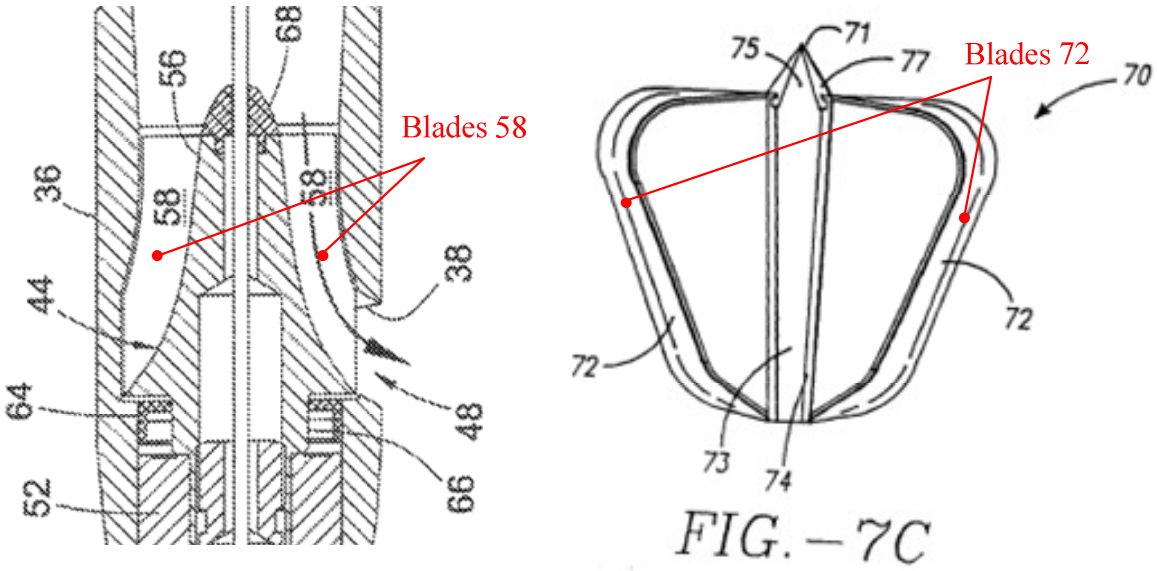


FIG.—7C

(Collins ¶161; EX1004[Aboul-Hosn] FIG. 7C, annotated.)

As applied to FIG. 7C of Aboul-Hosn, the distal direction is the direction towards the far end of the cannula relative to the position of the pump. (*Id.*) As seen in FIGS. 1, 2, and 7C of Aboul-Hosn, the hub of the rotor 70 tapers in the

distal direction. (*Id.* ¶161.) As also shown in annotated FIG. 7C, above, the rotor 70 has blades 72 each extending radially outward from the central hub 74. (EX1004[Aboul-Hosn] 17:1-2.) In fact, the blades 72 extend "radially outward" from the hub 74 in the same manner as the blades 58 of hub 56 shown in FIG. 3 of the '068 patent. (Collins ¶161.)



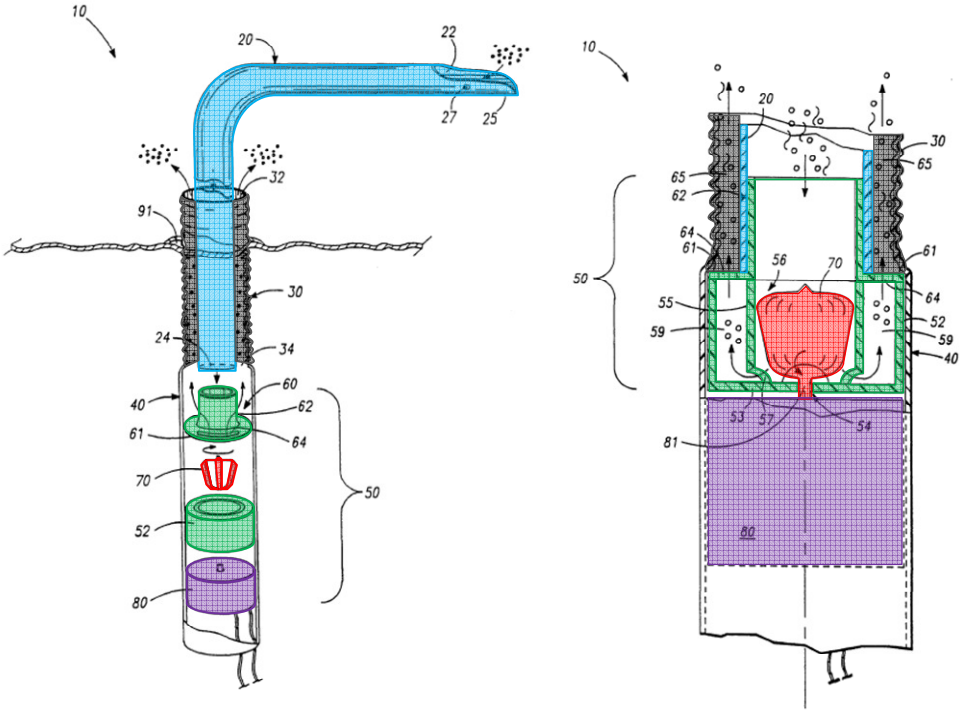
(Collins ¶160; EX1001['068 patent] FIG. 4, annotated (left); EX1004[Aboul-Hosn] FIG. 7C, annotated (right).)

Thus, Aboul-Hosn discloses this limtiation. (Collins ¶¶160-163.)

d) *"the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;"*

The '068 patent does not disclose the phrase "the intravascular blood pump coupled to a catheter on a proximal end," nor does it identify what it means for the intravascular blood pump to be "coupled to a catheter." (Collins ¶164.) Under the BRI standard, we assume this limitation requires the catheter to be connected to a proximal end of the intravascular blood pump (*id.*), which Aboul-Hosn discloses.

As shown in FIGS. 1 and 2[16] annotated below, the cannula 20 is connected to, and extends from, the inlet neck 62 of the housing cap 60 (green) that is coupled to the inlet tube 55 (green) within the housing body 52 that forms the shroud of the intravascular blood pump. (*Id.* ¶165; EX1004[Aboul-Hosn] 13:2-29.) As discussed in the Section VII.A, Aboul-Hosn discloses that "[t]he housing body 52 and the housing cap 60 may also form a unitary body." (EX1004[Aboul-Hosn] 13:3-4.) In such a formation, there is a direct connection between the cannula 20 and the shroud of the intravascular blood pump. (Collins ¶166.)



(Collins ¶165; EX1004[Aboul-Hosn] FIGS. 1 and 2, annotated.)

[16] *See supra* Fn. 7.

As also shown in FIG. 12 below, the positioning rod 273 interfaces with the proximal end of the drive unit 80, which in turn connects to the proximal end of the intravascular blood pump rotor and shroud 52. (Collins ¶167; EX1004[Aboul-Hosn] 16:11-12, 20:21-26.)

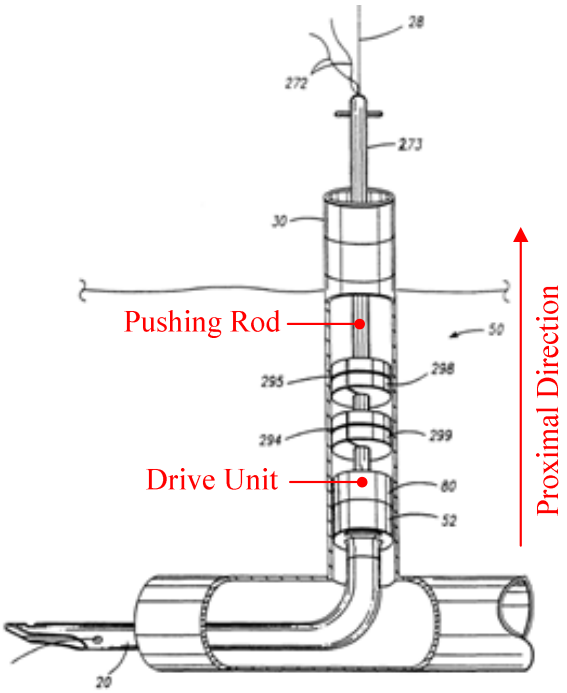


FIG.–12

(Collins ¶167; EX1004[Aboul-Hosn] FIG. 3, annotated.)

Aboul-Hosn also discloses that the positioning rod 273 includes a central passageway 275 "for passing wires, tubes or similar accessories needed by the drive unit 80" when the blood pump system is positioned within the vasculature. (Collins ¶168; EX1004[Aboul-Hosn] 15:6-9.) As such, the positioning rod 273

corresponds to a catheter connected to the proximal end of the intravascular blood pump through the drive unit 80. (Collins ¶168.)

Moreover, as discussed in Section X.A.1(b), where Aboul-Hosn introduces the intravascular blood pump system as shown in FIG. 12, above, through the graft attached to a target blood vessel at a position away from the heart, such as in the femoral artery as shown in FIGS. 21 and 23 below, for placement in the heart, the multilumen catheter 428 is necessarily used in place of the positioning rod 273 due to the distance the intravascular blood pump system travels through the artery to reach the heart. (*Id.* ¶169; EX1004[Aboul-Hosn] 29:17-19, 30:21-24.)

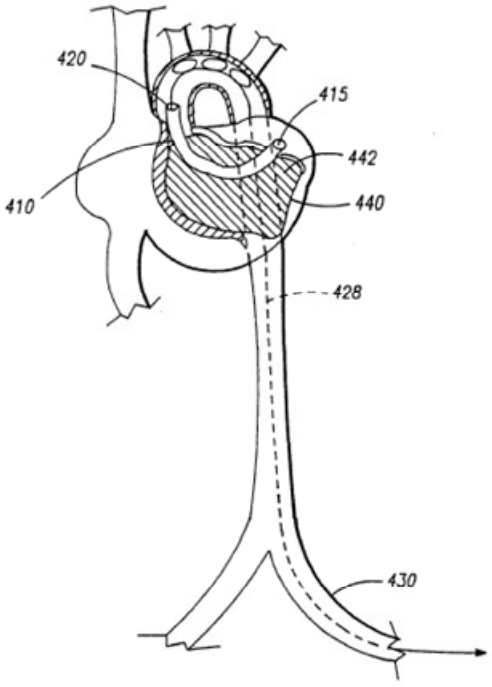


FIG.–21

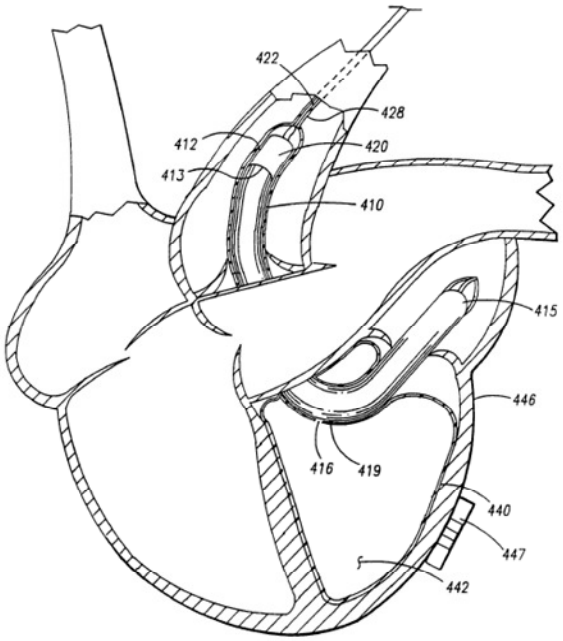


FIG.–23

(EX1004[Aboul-Hosn] FIGS. 21 and 23.)

As Dr. Collins explains, the multilumen catheter 428 and positioning rod 273 are interchangeable, and the catheter 428 can be configured to perform the same functions as the positioning rod 273. (Collins ¶124 n. 10.) In such applications, the multilumen catheter 428 couples to the proximal face of the drive unit 80 (as with the positioning rod 273), and thus also connects to the proximal end of the intravascular blood pump through the drive unit 80. (*Id.* ¶170; EX1004[Aboul-Hosn] 16:11-12, 20:21-26.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶¶164-170.)

e) *"(ii) a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;*"

As shown in FIG. 2,[17] below, Aboul-Hosn discloses that the inlet tube 55 of the housing body 52 (green) of the blood pump includes cut-outs 57 that allow the blood (red arrows) pumped by the rotor 70 (red) through the inner cannula 20 (blue) to flow out of the pump. (Collins ¶174; EX1004[Aboul-Hosn] 13:6-13, 13:15-18, 15:22-26, 16:13-22.) As further shown in FIG. 2, the cut-outs 57 are in close proximity to the rotor 70. (Collins ¶¶173-175.) Blood enters through the holes 22 and 27 of the distal end of the cannula 20 and exits through the cutouts 57

[17] *See supra* Fn. 7.

into passageway 59, then out the outlet windows 64 and into the blood stream. (*Id.* ¶177.) Thus, the cut-outs 57 and/or the outflow windows 64 are the "first set of apertures" as recited by claim 10. (*Id.* ¶178.)

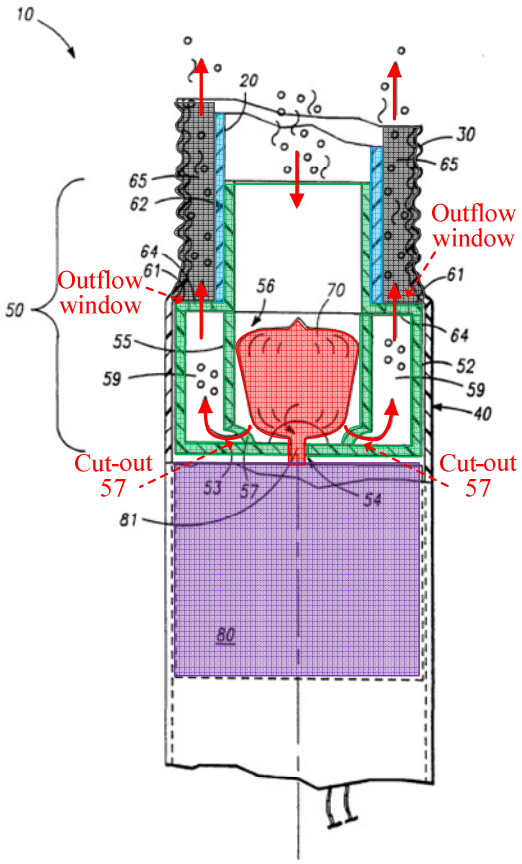


FIG.—2

(Collins ¶173; EX1004[Aboul-Hosn] FIG. 2, annotated.)

Aboul-Hosn also discloses that the inner cannula 20 has "a plurality of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise obstructed." (EX1004[Aboul-Hosn] 11:21-24.) As shown in the close-up view of FIG. 4, below, the plurality of openings 27 at the distal tip of the inner cannula 22

work in conjunction with the distal opening 22 to allow blood to flow (red arrows) into the inner cannula 20 from outside the inner cannula 20 to the blood pump, where it is then directed out through the cut-outs 57 (not shown) and outflow windows 64. (Collins ¶176.) The one or more of the openings 27 are the "second set of apertures" as recited by claim 10. (*Id.* ¶176.)

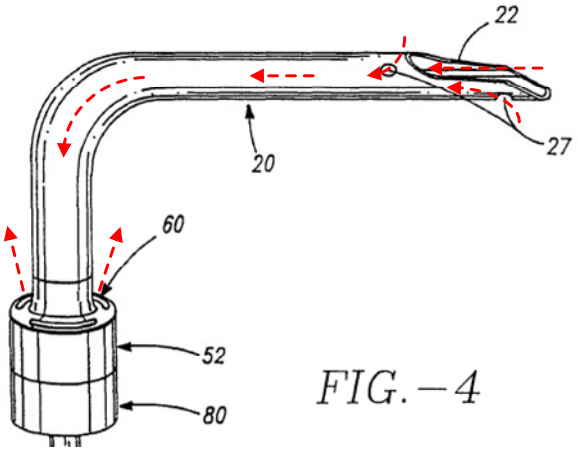


FIG.—4

(Collins ¶176; EX1004[Aboul-Hosn] FIG. 4, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶181.)

f) *"(iii) a guide mechanism configured as an elongate lumen and"*

As previously discussed in Section VII.A, Aboul-Hosn discloses how a blood pump system may be placed in a desired location within a patient, such as within the left side of the heart, by using a guide wire 28. (Collins ¶182; EX1004[Aboul-Hosn] 17:19-20.) As shown in FIG. 3 annotated below, the guide wire 28 passes through a central passage (i.e. a lumen) that runs through the motor

80, the rotor 70, the housing cap 60, and the inner cannula 20, and then exits out of the distal opening 22 of the cannula. (Collins ¶182.)

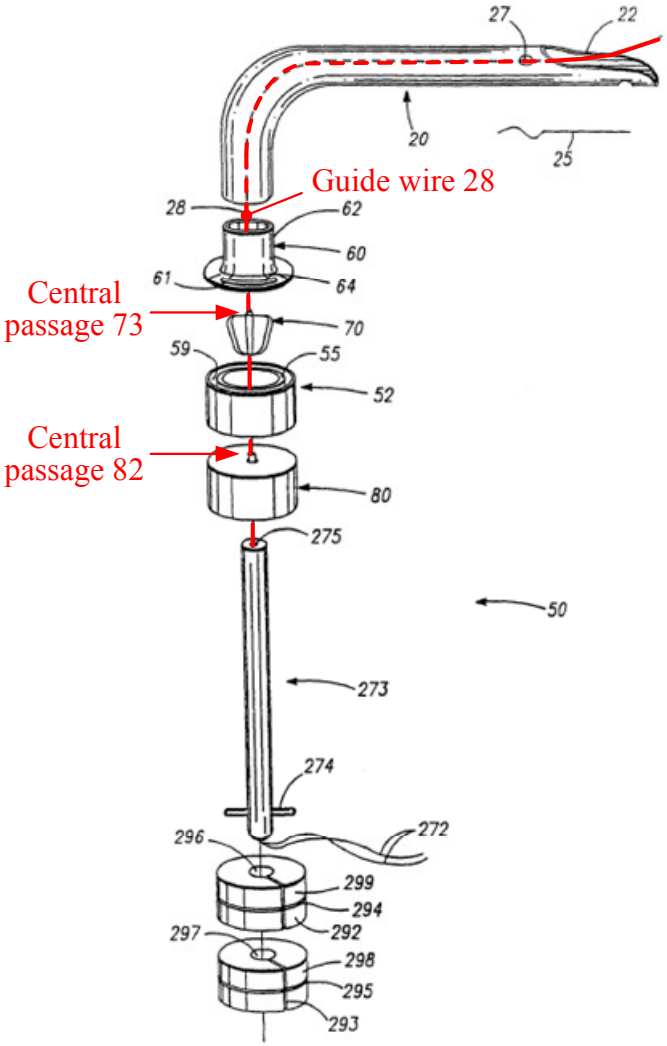
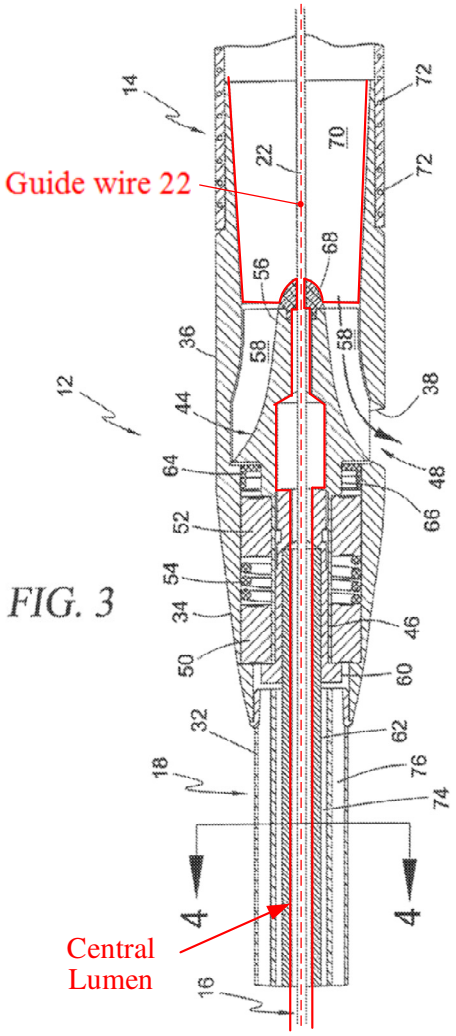


FIG.—3

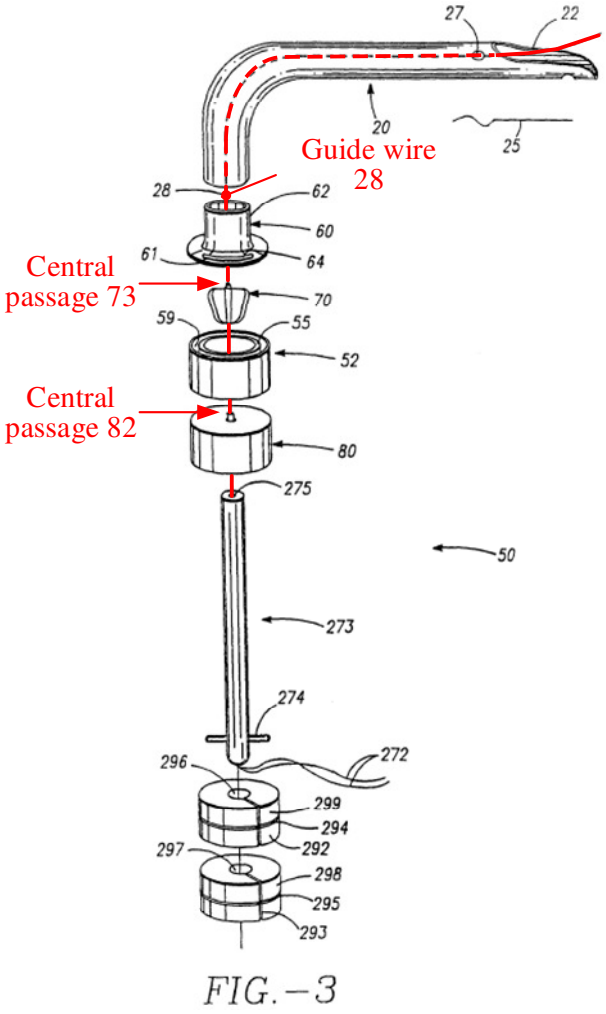
(Collins ¶182; EX1004[Aboul-Hosn] FIG. 3, annotated)

Aboul-Hosn discloses that "a central rotor passage 73 may extend the entire length of the rotor 70 and preferably forms a continuation of central passage 82 of drive unit 80." (EX1004[Aboul-Hosn] 17:8-10.) As shown in the side-by-side comparison below, this central passage disclosed in Aboul-Hosn (right) has the

same configuration as the guide mechanism in the over-the-wire embodiment of the '068 patent (left). (*Id.* ¶186.)



'728 Patent



Aboul-Hosn

(Collins ¶186; EX1001['068 patent] FIG. 3, annotated (left); EX1004[Aboul-Hosn] FIG. 3, annotated (right).)

As the '068 Patent explains, "[t]his central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the

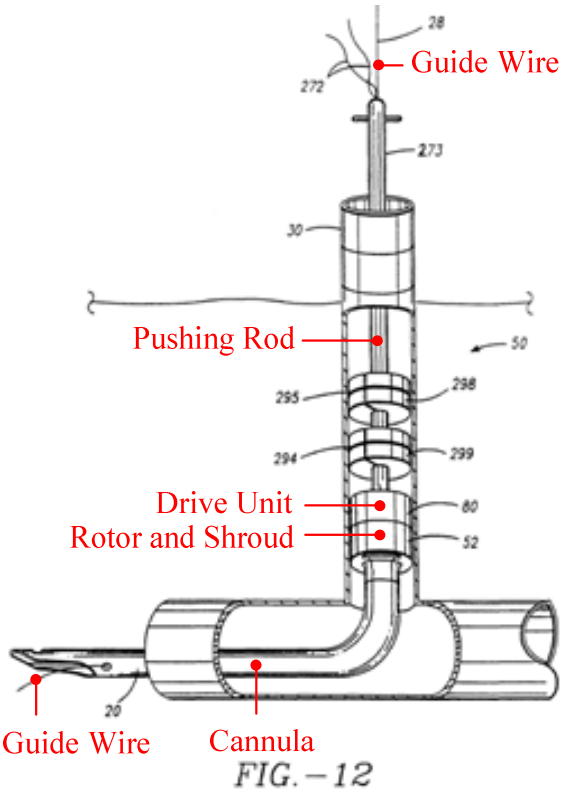
cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14." (EX1001['068 patent] 10:36-39.) Correspondingly, Aboul-Hosn discloses that the positioning rod 273 or catheter 428 (as i.e., for percutaneous insertion through the femoral artery as shown in FIGS. 21 and 23 as discussed in Sections X.A.1(b) and (d)), drive unit 80, rotor 70, 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. (Collins ¶188.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶190.)

g) "*adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of the patient; and"*

Aboul-Hosn discloses that "[i]n preparation for insertion of a fluid transport system into a patient, a commercially available high stiffness guide wire 28 may be used and passed through the central passage of the positioning rod 273 proximal end, to the distal end of the rotor 70, passing through the gland valve 77, and through the cannula 20." (EX1004[Aboul-Hosn] 24:8-12.) Aboul-Hosn further discloses that the "guide wire 28 may be also advanced with the help of imaging techniques to dispose the distal end of the cannula 20 in the desired blood vessel, heart chamber, or other body." (*Id.* 22:10-12.)

As discussed in Section X.A.1(b), Aboul-Hosn's FIG. 12, reproduced below, illustrates the introduction and positioning of Aboul-Hosn's intravascular blood pump system in the patient's circulatory system. (Collins ¶195; EX1004[Aboul-Hosn] 21:11-22:30.)



(Collins ¶195; EX1004[Aboul-Hosn] FIG. 12, annotated.)

Again, as shown above, FIG. 12 illustrates the intravascular blood pump is being advanced through the conduit 30 and into the heart. (Collins ¶195; EX1004[Aboul-Hosn] 12:7-9.) It is clearly evident because the distal opening of the cannula and the outflow windows of the intravascular blood pump are not separated by a structure such as a heart valve, and if operated in the placement illustrated, the pump will draw in and pump out blood, respectively, into the same

blood vessel, defeating the stated purpose of Aboul-Hosn's blood pump system for "unloading the heart" and transporting "fluids between different regions within the body." (*Id.* ¶195; EX1004[Aboul-Hosn] 6:6-8, 6:19-7:5, 21:11-22:30.) Accordingly, the blood pump would need to be advanced further through the conduit 30 until the distal end of the cannula is positioned, for example, across a heart valve in order to transport blood from one heart chamber to another, such that the intravascular blood pump and the positioning rod 273 or a multilumen catheter 428 (depending on the position of the graft and the distance the intravascular blood pump system needs to travel to reach the patient's heart as discussed in Section X.A.1(b)) are also positioned within the circulatory system. (Collins ¶196; EX1004[Aboul-Hosn] FIGS. 14-19.) Moreover, Aboul-Hosn expressly confirms that the intravascular blood pump system will be advanced through the graft and into the circulatory system. (Collins ¶196; EX1004[Aboul-Hosn] 6:26-29: "**[a] reverse flow blood pump system may be passed through a conduit and positioned in a heart chamber or vessel** in preparation to completely or partially stop the heart in order to operate on the organ." (emphasis added).)

Aboul-Hosn also discloses that "[i]n a preferred embodiment," the outer conduit 30 can be "an introducer, or a vascular graft, such as a Dacron™ graft" that is typically used to extend or replace a portion of the vascular system. (Collins ¶197; EX1004[Aboul-Hosn] 12:7-9.) Once attached to a target vessel or heart

chamber, the conduit 30 forms an extension of the patient's vascular system akin to a branching blood vessel. (Collins ¶197; EX1004[Aboul-Hosn] 21:31-22:1.) As such, even if the intravascular blood pump were to remain within the conduit 30 as shown in FIG. 12 and the distal end of the cannula is positioned across a heart valve or other structure, which is not shown in FIG. 12, a POSITA would understand that the blood pump and positioning rod 273 are positioned within the patient's vascular system. (Collins ¶197.)

A POSITA would also understand that commercially available Dacron grafts can have stated diameters that are consistent and compatible for use as introducers for intravascular blood pumps that are "inserted in the body through a portal of minimal size." (*Id.* ¶198; EX1004[Aboul-Hosn] 6:29-7:2.) The Dacron graft used to introduce the intravascular blood pump would be much smaller in size compared to the aorta or an even larger heart chamber, and which is depicted in FIG. 12. (Collins ¶198; EX1029[Guyton] 151.) As such, a POSITA would understand that the pump is capable of being pushed further into the blood vessel such that the blood pump and the positioning rod 273 or multilumen catheter 428 are positioned in the circulatory system. (Collins ¶198; EX1004[Aboul-Hosn] 6:31-7:2, 24:26-29.)

As also discussed in Section X.A.1(b), there are advantages to inserting the intravascular blood pump system into the vascular system of the patient, rather

than keeping the blood pump in the conduit 30. (Collins ¶199.) As shown in FIG. 12, to achieve the desired blood transport between chambers without displacing the blood pump in the conduit 30, the inner cannula would have to be extended in order for the distal end of the cannula to be positioned across a heart valve, thereby increasing hydrodynamic losses in the system are a result of frictional head loses associated with a long cannula and requiring a larger pump to offset those losses. (*Id.* ¶200; EX1004[Aboul-Hosn] 14:13-16; EX1032[White] Ch. 6.3; EX1044[SiessThesis] Ch. 5.8.4.) Aboul-Hosn appreciated this in connection with the extracorporeal pump system shown in FIG. 13, which naturally would have a longer cannula as compared to an intravascular blood pump system, thereby requiring a larger pump with increase pumping capacity to compensate for those losses. (Collins ¶200; EX1004[Aboul-Hosn] 24:26-25:1.)

As such, for Aboul-Hosn's intravascular blood pump system that it introduced into the patient's body as shown in FIG. 12 which, due to space constraints, cannot use a larger pump with increased capacity, in order to maintain sufficient blood pumping capacity to provide heart support, it would have been preferable to insert the blood pump system further distally into the vasculature, closer to the heart, which allows for a shorter cannula (thereby reducing hydrodynamic losses associated with the cannula) while still reaching the desired position across a heart valve. (Collins ¶200.) Again, this is particularly true where

the graft (conduit 30) is attached to a target blood vessel at a position away from the heart, such as the femoral artery. (*Id.* ¶200; EX1004[Aboul-Hosn] 21:11-18.)

As shown in FIGS. 21 and 23 below, as discussed in Section X.A.1(b), Aboul-Hosn expressly disclosed the intravascular blood pump system (i.e. the blood pump, cannula, and catheter) is introduced into the vascular system of the patient through the conduit attached to the femoral artery such that the blood pump and the catheter are positioned in the circulatory system of the patient.[18] (*Id.* ¶201; EX1004[Aboul-Hosn] 29:17-19, 30:21-24.)

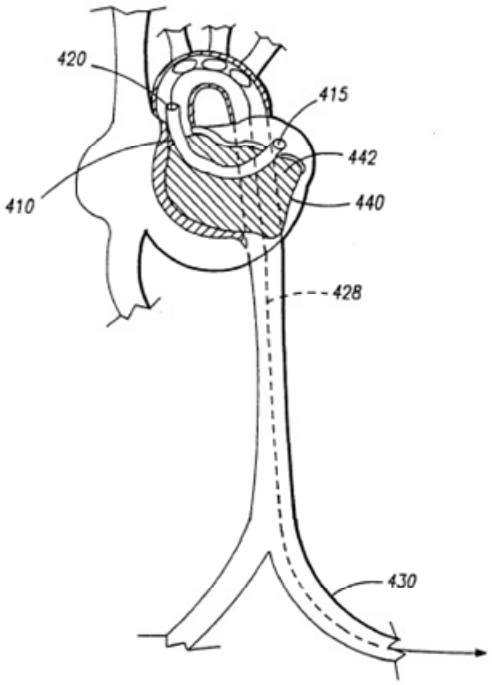


FIG.–21

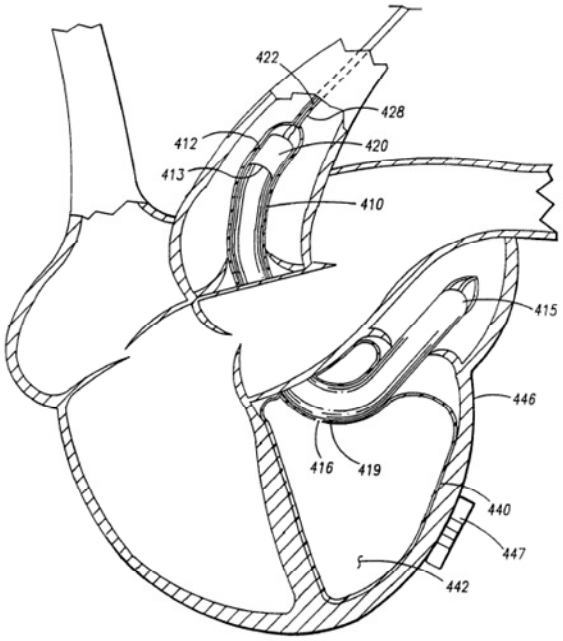


FIG.–23

(EX1004[Aboul-Hosn] FIGS. 21 and 23.)

[18] *See supra,* Fn. 17.

Notably, with respect to FIGS. 21 and 23, Aboul-Hosn discloses that "Fig. 21 is a stabilization system provided **in accordance with the present invention** that is introduced through a femoral artery," and "[t]he stabilization systems 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**." (Collins ¶202; EX1004[Aboul-Hosn] 10:6-7, 31:6-9 (emphasis added).) Aboul-Hosn discloses "the present invention provides a reverse flow pump system that transports fluid between different regions within the body in order to support a wide variety of surgical procedures" (EX1004[Aboul-Hosn] 6:6-8) which, as discussed in this Section as well as Sections VII.A and X.A.1(b), includes the intravascular blood pump system as shown in FIGS. 3, 4, and 12 that is inserted into the patient's vasculature through a graft and shares the same components as the extracorporeal blood pump system shown in FIGS. 1, 2, and 13 (i.e. rotor 70, housing 52 and cap 60, drive unit 80, etc.), that are sized accordingly (i.e. miniaturized) for introduction into the patient's body. (Collins ¶202; EX1004[Aboul-Hosn] 6:6-8, 6:24-29, 21:9-22:18, 24:26-25:1.) Accordingly, Aboul-Hosn expressly discloses that the "stabilization system" shown in FIGS. 21 and 23 as "provided by the present invention" uses the intravascular blood pump of FIGS. 3, 4, and 12.

Thus, considered in its entirety, Aboul-Hosn expressly discloses this limitation. (Collins ¶203.)

Notwithstanding Aboul-Hosn's express disclosures, as Dr. Collins explains, it would have also been obvious to a POSITA to use Aboul-Hosn's intravascular blood pump system to provide the "stabilization system" shown in FIGS. 21 and 23. (Collins ¶204.)

As excerpted above, Aboul-Hosn discloses that the "stabilization system" shown in FIGS. 21 and 23 are "provided in accordance with the present invention" and "provided for by the present invention," respectively. (*Id.* ¶205; EX1004[Aboul-Hosn] 10:6-7, 31:6-9.) This would have motivated a POSITA to look at the blood pump systems expressly disclosed by Aboul-Hosn in the preceding pages of his published PCT application to discern what the "present invention" is that provides for the "stabilization system" shown in FIGS. 21 and 23. (Collins ¶205.) There, a POSITA would have encountered Aboul-Hosn's extracorporeal blood pump system as shown in FIGS. 1, 2, and 13, and Aboul-Hosn's intravascular blood pump system as shown in FIGS. 3, 4, and 12. (*Id.* ¶205; EX1004[Aboul-Hosn] 10:25-15:18, 21:11-22:18, 24:15-25:1.)

A POSITA would have readily understood that the extracorporeal blood pump system would not have been used as an intravascular blood pump system shown in FIGS 21 and 23. However, it would have been imminently clear to and

understood by a POSITA that Aboul-Hosn's intravascular blood pump shown in FIGS. 3, 4, and 12 (i.e. "the present invention") would provide for the "stabilization system" shown in FIGS. 21 and 23 because, as previously discussed in this Section and Sections VII.A and X.A.1(b), the blood pump of Aboul-Hosn's intravascular blood pump system is miniaturized so that it can be introduced through a graft that is attached to a target blood vessel (such as the femoral artery in FIG. 21), and inserted into the patient's circulatory system. (Collins ¶206; EX1004[Aboul-Hosn] 21:11-22:18, 24:26-25:1.)

This is further reinforced by Aboul-Hosn's disclosure of the rotor in FIGS. 7A-7C, which is used in Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12. (Collins ¶207.) Aboul-Hosn expressly states that "Figs. 7A-C and 8 illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus," which indicates to a POSITA that the rotor 70 of Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12 can be used in "**any other type of fluid transport apparatus**." (*Id*. ¶207; EX1004[Aboul-Hosn] 16:30-31 (emphasis added).) The "stabilization system" shown in FIGS. 21 and 23 qualifies as "any other type of fluid transport apparatus." (Collins ¶207.)

Aboul-Hosn's express teaching would directly motivate a POSITA to use rotor of FIGS. 7A-7C in the stabilization system of FIGS. 21 and 23. (*Id.*) As the

rotor 70 would not be able to generate the flow of blood without its corresponding shroud (i.e. housing 52, cap 60, etc) as it provides the axial flow of blood for the blood pump as explained above in Section X.A.1(e), a POSITA would logically find it straightforward to use the corresponding shroud (i.e. housing 52, cap 60, etc.) along with the rotor 70 in the stabilization system of FIGS. 21 and 23. (Collins ¶208; EX1004[Aboul-Hosn] 16:30-31.) As the shroud and the rotor make up the blood pump portion of Aboul-Hosn's intravascular blood pump system (and in fact, in relation to the "intravascular blood pump" of the claim, the claim only requires the "intravascular blood pump comprising a rotor"), a POSITA would readily be motivated to use Aboul-Hosn's intravascular blood pump shown in FIGS. 3, 4, and 12 in the "stabilization system" shown in FIGS. 21 and 23. (Collins ¶209; EX1004[Aboul-Hosn] 10:6-7, 31:6-9.) Indeed, Aboul-Hosn provides no specific details of the pump 420 used in FIGS. 21 and 23, which signals to a POSITA to look elsewhere in the specification to discern the details of the pump 420, which would lead them to Aboul-Hosn's express teachings to use the rotor 70 (that can be used in "any type of fluid transport apparatus") and the corresponding shroud of the intravascular blood pump of FIGS. 3, 4, and 12, which are miniaturized so as to be capable of being inserted into the vasculature as discussed in Section X.A.1(b), and use them for the "stabilization system" shown in FIGS. 21 and 23 for the reasons detailed above. (Collins ¶209.)

Moreover, as Dr. Collins further explains, Aboul-Hosn does not expressly limit or constrain the location in which the graft to introduce the intravascular blood pump system in the patient can be sutured or attached, broadly stating that the graft can be attached to a portal that "is created in the desired blood vessel or body cavity." (*Id.* ¶210; EX1004[Aboul-Hosn] 21:19-23.) Aboul-Hosn expressly discloses that intravascular blood pumps can be introduced percutaneously through the femoral artery, as shown in FIG. 21. (*Id.* ¶210; EX1004[Aboul-Hosn] 29:17-19.) As such, where Aboul-Hosn's intravascular blood pump system is introduced into the patient's femoral artery through the graft, a POSITA would have been motivated to advance the intravascular blood pump system (i.e. cannula, blood pump, and positioning rod 273 or multilumen catheter 428 depending on the distance the pump system needs to travel within the vasculature) through the graft and into the patient's circulatory system for to obtain the same advantages discussed above in this Section and Section X.A.1(b), including a shorter cannula length to reduce hydrodynamic losses and to maintain sufficient pumping capacity with the miniaturized pump components of the intravascular pump. (Collins ¶210.)

Indeed, as discussed in Sections V.B and VII.B, these teachings and techniques were already well-known in the art – to percutaneously insert and position intravascular blood pumps within the patient's vasculature such that the pump system is inserted closer to the patient's heart – as evidenced by, *inter alia*,

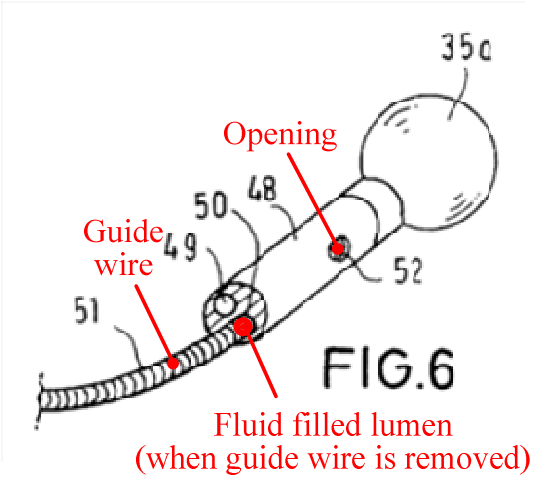
Sammler which discloses positioning an intravascular blood pump system through the upper vena cava and into the right side of the heart over a guide wire. (Collins ¶211; EX1045[Sammler] 4:38-40, 6:5-7, FIGS. 1, 5, and 6; EX1005[Siess] FIG. 1, 5:55-58; EX1008[Wampler '712] FIG. 1a.) Positioning Aboul-Hosn's intravascular blood pump, catheter, and cannula in the manner shown in FIGS. 21 and 23 (i.e. through the femoral artery and into the heart) in the manner as shown in FIG. 12 (i.e. via a conduit 30 attached to the femoral artery and pushing the blood pump over the guide wire into the patient's femoral artery) is, therefore, not only consistent with Aboul-Hosn's teachings and disclosures, it is also generally consistent with the teachings and techniques that were already well-known in the art. (Collins ¶211.)

Thus, Aboul-Hosn, either expressly or in view of its teachings to a POSITA, considered in its entirety, discloses this limitation. (*Id.* ¶212.)

h) *"(iv) a blood pressure detection mechanism comprising a fluid column configured to detect the blood pressure of the blood proximate the intravascular blood pump;"*

The '068 patent is silent as to what it means to "detect the pressure of the blood proximate the intravascular blood pump" or what constitutes the "fluid column." (Collins ¶213.) Under the BRI standard, we assume this limitation requires the a fluid column for transmitting blood pressure near the blood pump (*id.*), which Aboul-Hosn in view of Sammler discloses.

As Dr. Collins explains, it was well-known for intravascular blood pump systems to use fluid-filled columns to measure the blood pressure within or near the pump system. (Collins ¶214.) Sammler is one such pump system. (*Id.*; EX1045[Sammler] 6:8-12.) As shown in FIG. 6 below, Sammler discloses a lumen 50 for passing a guide wire 51 that extends through a catheter 48 and the cannula (pump hose 14b), as well as through the pump system and the catheter out of the patient's body, to help position the blood pump system in the vasculature. (Collins ¶214; EX1045[Sammler] 3:24-26, 6:5-7.)

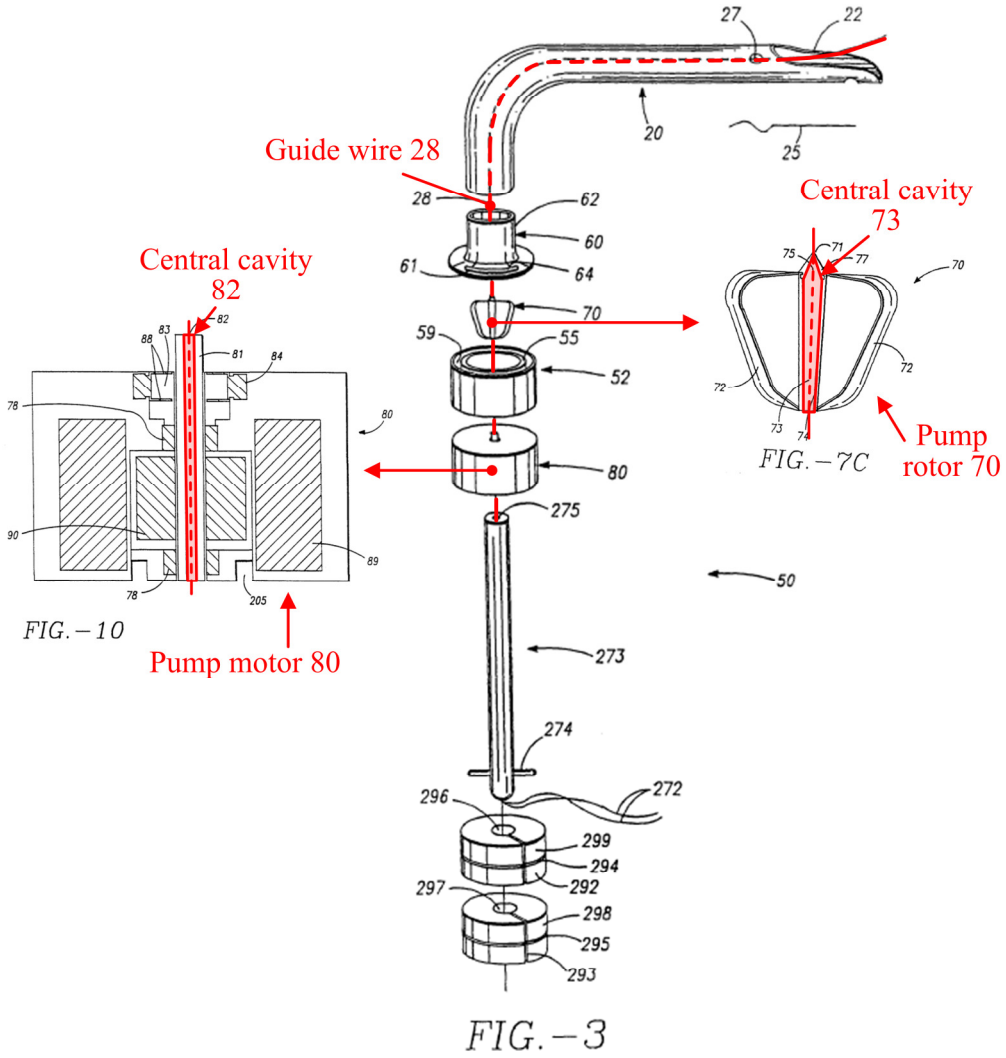


(Collins ¶214; EX1045[Sammler] FIG. 6, annotated.)

Sammler further teaches that the lumen 50 can be used "for external pressure measurement" after "removal of the guide wire." (Collins ¶214; EX1045[Sammler] 6:3-5.) This is accomplished by using "an opening 52," shown above in FIG. 6, that "can be provided on the catheter 48, which is connected to the lumen 50 and which is blocked by the the guide wire 51," and "[a]fter the guide wire 51 is withdrawn from the lumen 50, blood enters the lumen 50 through the

opening 52." (Collins ¶214; EX1045[Sammler] 6:8-10.) The lumen 50 is "connected to a blood pressure measuring instrument" to measure the blood pressure adjacent the opening 52. (Collins ¶214; EX1045[Sammler] 6:10-12.)

Aboul-Hosn can be configured to detect blood pressure in the same manner as Sammler. (Collins ¶215.) As previously discussed in Sections X.A.1(g)-(j), Aboul-Hosn, like Sammler, similarly discloses using a guide wire that extends through a central passage of the intravascular blood pump system (co-aligned central passageways 73, 82, and 275) to position the pump system within the patient's vasculature as shown below in annotated FIGS. 3, 7C, and 10. (*Id.* ¶215; EX1004[Aboul-Hosn] 17:8-22, 20:23-26, 21:6-10, 24:7-14.)



(Collins ¶215; EX1004[Aboul-Hosn] FIGS. 3, 7C, and 10, annotated.)

Once Aboul-Hosn's intravascular blood pump system is positioned, the guide wire 28 may be removed and the central passageway extending through the pump system's components can be similarly used as a passageway for a fluid-filled lumen to detect the blood pressure at an opening that is exposed by the removal of the guide wire as taught by Sammler. (Collins ¶216; EX1004[Aboul-Hosn] 15:4-6, 22:14-16; EX1045[Sammler] 3:26-27, 6:8-12.) As taught by Sammler, blood can enter the central passageway of Aboul-Hosn's intravascular pump system through

the opening at the distal end of the passage 73 through the pump rotor 70 (shown above in FIG. 7C, right), which Aboul-Hosn discloses "may be left open" after the guide wire 28 is removed. (Collins ¶217; EX1004[Aboul-Hosn] 17:11-12; EX1045[Sammler] 6:8-12.) Thus, Aboul-Hosn's intravascular blood pump system can be configured to detect the blood pressure proximate the intravascular blood pump, at the distal end of the rotor 70, using a fluid-filled lumen extending through the pump system's components and connected to a blood pressure measuring instrument as taught by Sammler. (Collins ¶217.)

According to Dr. Collins, it would have been obvious to a POSITA, and a POSITA would have been motivated to configure Aboul-Hosn's intravascular blood pump system to detect blood pressure in the manner taught by Sammler. (*Id.* ¶218.) Like Sammler, Aboul-Hosn contemplated that the "pump 50 may also be equipped for sensing devices (not shown) for measuring various body conditions such as the blood pressure, the presence of blood, or other parameters that would suggest the need for altering the flow rate of the fluid transport apparatus 10," for example the pump "may include pressure sensors along the inner cannula 20." (Collins ¶218; EX1004[Aboul-Hosn] 23:4-10; EX1045[Sammler] 6:10-12.)

In view of Sammler's teachings, a POSITA would have appreciated that rather than add additional components such as pressure sensors to Aboul-Hosn's intravascular blood pump system which would increase the complexity and the

cost of the pump system due to the need to attach and rout the sensors through the pump system, the preexisting central passageway extending through the pump system can be used to pass a fluid-filled lumen for the same purpose – to detect the pressure of the blood in the inner cannula at the distal opening of central passageway 73 of the pump rotor 70. (Collins ¶219; EX1004[Aboul-Hosn] 17:11-12.) A POSITA would have been naturally motivated to do so because it provides a more efficient way of measuring blood pressure within the inner cannula using the preexisting structure of Aboul-Hosn's intravascular blood pump system without the need to significantly reconfigure the system or its components. (Collins ¶219.)

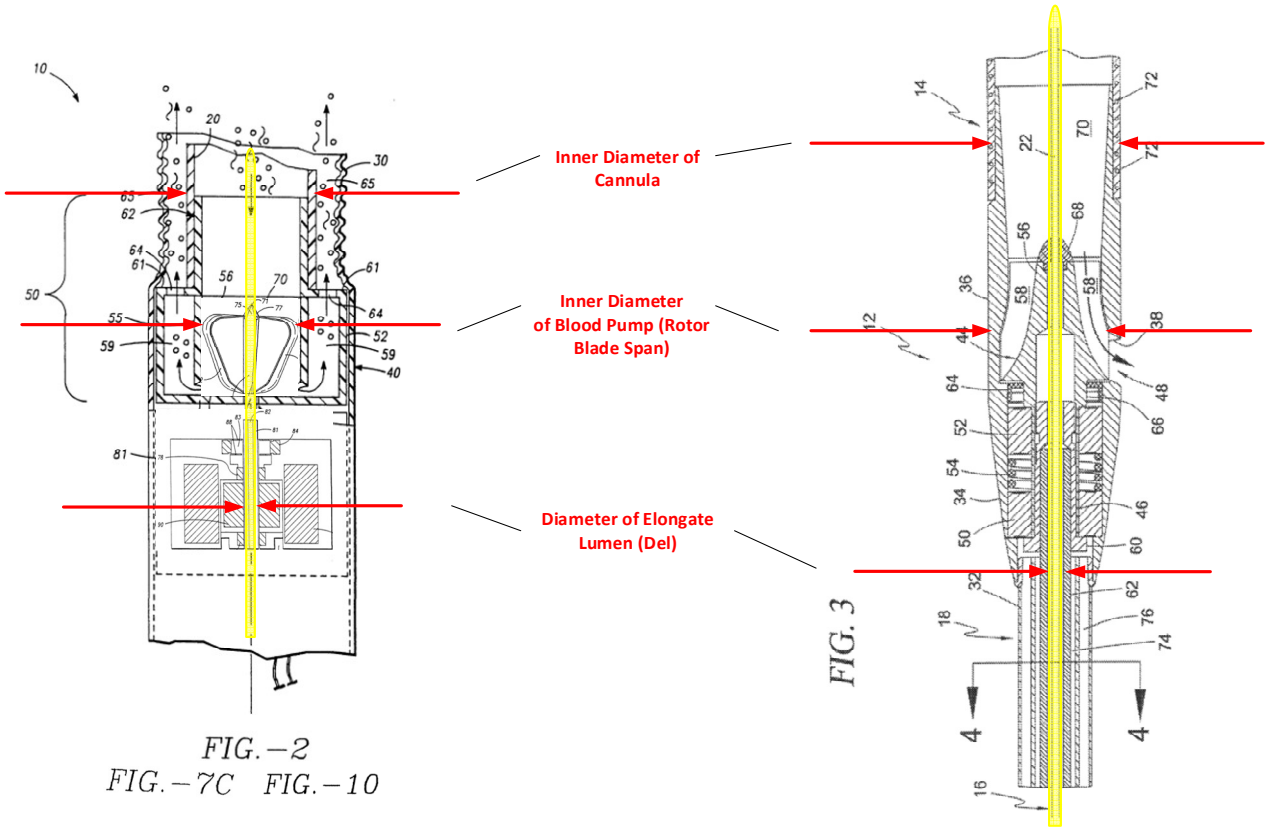
Thus, Aboul-Hosn in view of Sammler discloses this limitation. (*Id*. ¶220.)

i) *"wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump;"*

This element requires two comparisons involving the elongate lumen--a first comparison to the inner diameter of the cannula and a second comparison to the inner diameter of the intravascular blood pump. (Collins ¶221.)

The '068 patent does not identify or disclose what it means for the elongate lumen to be sized "substantially smaller" than an inner diameter of the cannula and intravascular blood pump. (Collins ¶222.) The '068 patent does not define "substantially smaller," but regardless of how the '068 patent would define

"substantially smaller", at any point along the pump and cannula, Aboul-Hosn discloses the same relative size shown in the '068 patent between the elongate lumen diameter and the pump inner diameter and the cannula inner diameter. (Collins ¶222.)



(Collins ¶223; EX1004[Aboul-Hosn] FIG. 2 (left), annotated; EX1001['068 Patent] FIG. 3 (right), annotated;.)

Moreover, the elongate lumen in Aboul-Hosn is sized substantially smaller than these conventional dimensional ranges for the diameter of the cannula. (Collins ¶225.) Aboul-Hosn indicates that the guide wire passage has a diameter of "approximately 0.040 inches," or about one millimeter, which is substantially

smaller than the conventional dimensional ranges for the diameter of the cannula, which is on the order of 6-9mm. (Collins ¶¶226-227; EX1004[Aboul-Hosn] 20:23-25, 17:16-18; EX1001['068 patent] 8:30-35; EX1045[Sammler] 3:40-43.)

As illustrated in Fig. 7C below, the central passage 73 (which forms a part of the elongate lumen, along with the co-aligned central passage 82 of the drive unit 80 and the central passage 275 of the positioning rod 273 as discussed in Section X.A.1(f)) fits within the rotor hub 74 and is smaller than the rotor hub diameter. (Collins ¶230; EX1004[Aboul-Hosn] 17:8-19.) The outer diameter of the rotor hub is substantially smaller than the outer diameter of the blades (equivalent to the inner diameter of the pump) in order for the blades to pump the blood. (Collins ¶231; EX1004[Aboul-Hosn] 15:26-16:1.) As shown in annotated FIG. 7C below, the elongate lumen size is substantially smaller than the inner diameter of the intravascular blood pump (corresponding to the diameter of the pump blades, along with a small clearance needed for the rotor to rotate). (Collins ¶231.)

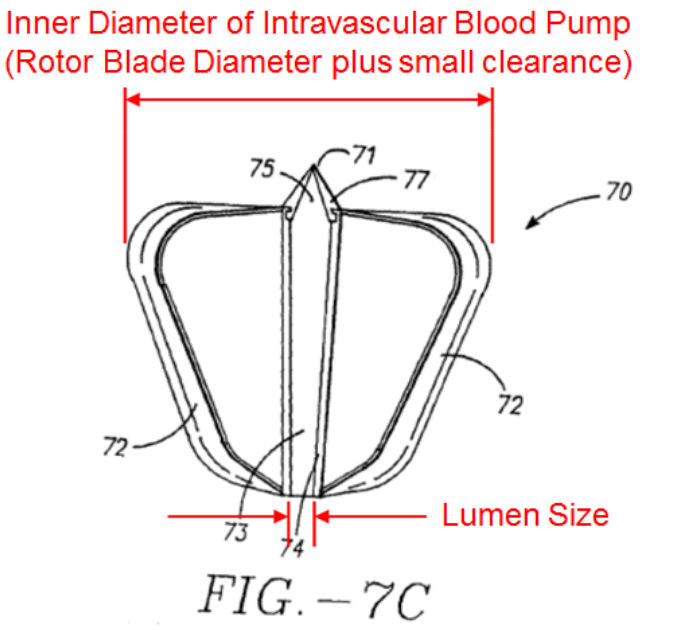


FIG. – 7C

(Collins ¶231; EX1004[Aboul-Hosn] FIG. 7C, annotated.)

Thus, Aboul-Hosn discloses the elongate lumen is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump. (Collins ¶224.)

> j) *"(b) is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and (c) is arranged in series longitudinally with the cannula:"*

As further illustrated below, Aboul-Hosn also discloses that 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. (Collins ¶233.) As the central passage 73 of the rotor 70 extends through its center (hence "central passage 73"), and the rotor 70 aligns within the inlet tube 55. Accordingly, the lumen through which the guide wire 28 passes will be coaxial

with the proximal opening 24 of the inner cannula 20 by virtue of the concentrically aligned inlet neck 62 and inlet tube 55. (Collins ¶229.) Moreover, Aboul-Hosn discloses that the rotor 70 is disposed "longitudinally inside the inlet tube 55," and as such, the elongate lumen that extends through the central passage 73 of the rotor 70 is also arranged longitudinally and in series with respect to the inner cannula 20. (*Id.* ¶239; EX1004[Aboul-Hosn] 13:14-15.)

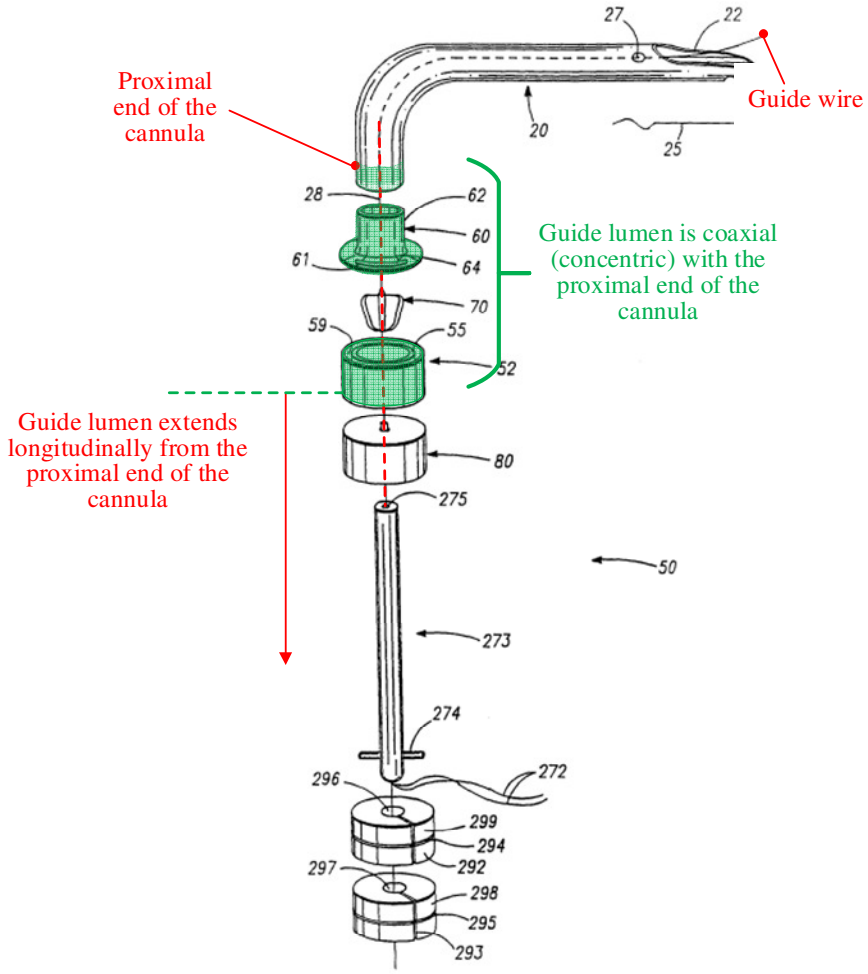


FIG.–3

(Collins ¶235; EX1004[Aboul-Hosn] at FIG. 3, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶¶233-240.)

k) *"the method comprising: advancing a guide wire to a predetermined location in the circulatory system of the patient; and"*

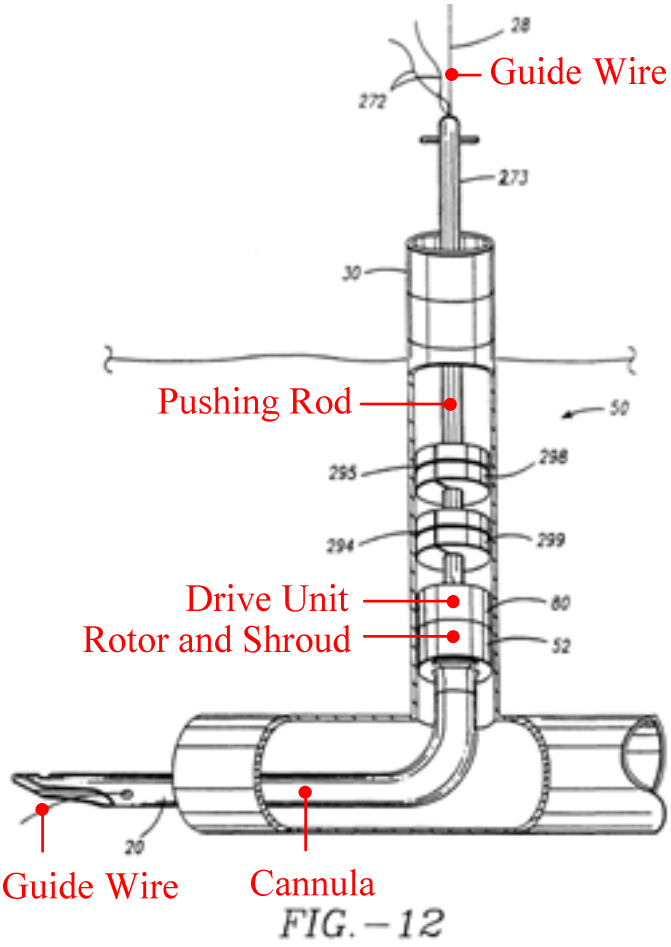
As previously discussed in Section VII.A, Aboul-Hosn discloses that first the guide wire is inserted into a desired location in the body before advancing the cannula 20 over the guide wire into a position in the body. *See* EX1004 [Aboul-Hosn] at 22:12-14 ("The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20."). Aboul-Hosn also discloses that the guide wire may be advanced to a particular location in the vasculature of a patient using imaging techniques to place the guide wire. *See* EX1004 [Aboul-Hosn] 22:10-16. (Collins ¶¶241-243.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶243.)

l) *"advancing the blood pump system along the guide wire to the predetermined location."*

Aboul-Hosn teaches that after the guide wire has been positioned in the vasculature, the cannula 20 can be guided into a position over the guide wire. *See* EX1004 [Aboul-Hosn] at 22:12-16 ("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."). (Collins ¶244.) Aboul-Hosn teaches that the guide wire can position the cannula

in any location within the vasculature of the patient. (Collins ¶246; EX1004[Aboul-Hosn] 11:9-11, 11:24-28.) Annotated FIG. 12 of Aboul-Hosn, below, shows the blood pump being advanced into the vasculature. (Collins ¶246.)



(Collins ¶246; EX1004[Aboul-Hosn] FIG. 12, annotated)

Further, as discussed in X.A.1.(g), Aboul-Hosn expressly contemplated that intravascular blood pumps are capable of being introduced into the vascular system of the patient. (Collins ¶247.) FIGS. 21 and 23 of Aboul-Hosn, below, show an example of a percutaneous placement of an intravascular blood pump with the distal end of the cannula in the left atrium. EX1004[Aboul-Hosn] 29:17-19, 30:21-24.

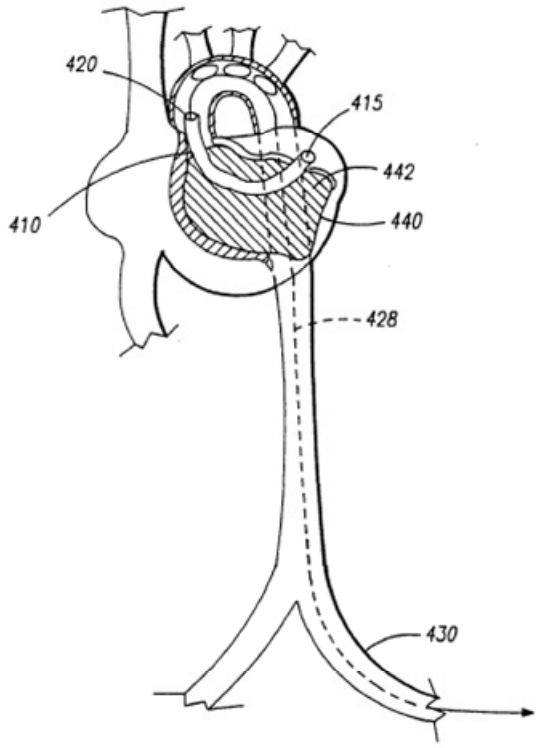


FIG.–21

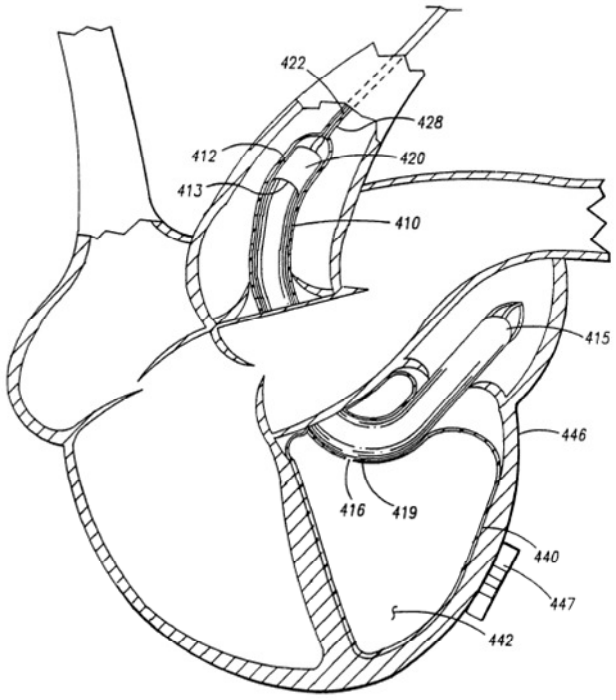


FIG.–23

Thus, Aboul-Hosn discloses this limitation. (Collins ¶248.)

2. Claim 13

Claim 13 depends from claim 10 and recites *"further comprising a plurality of egress flow ports disposed in a shroud of the intravascular blood pump, and a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports."*

Aboul-Hosn further discloses that "[t]he housing body 52 illustrated in this embodiment of the present invention is generally cylindrical-shaped and includes a longitudinally and concentrically aligned inlet tube 55" where "[a] rotor 70 may be

disposed longitudinally inside the inlet tube 55 as shown in FIG. 2."[19]

(EX1004[Aboul-Hosn] 13:7-15.)

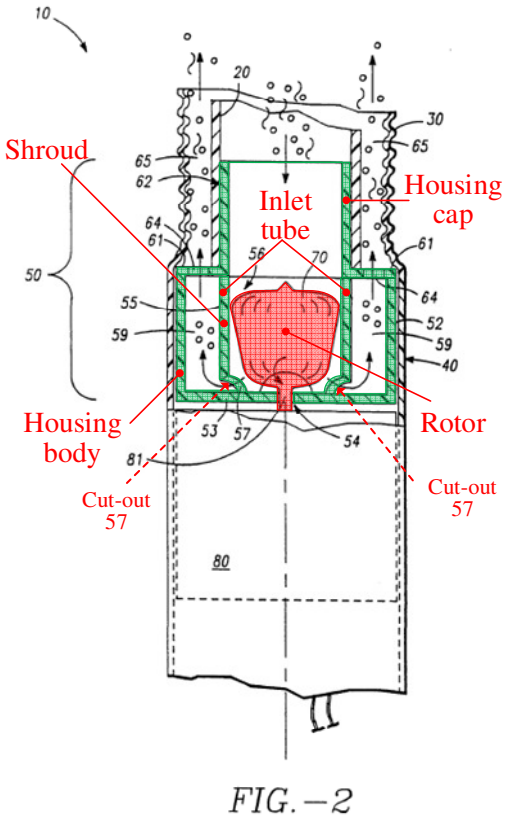


FIG.—2

(Collins ¶252; EX1004[Aboul-Hosn] FIG. 2, annotated.)

Aboul-Hosn requires "[a] clearance between the inlet tube 55 profile and the rotor 70 should exist to permit the rotor 70 to rotate without contacting the walls of the inlet tube 55." (*Id.* 15:26-16:1.) Thus, the inlet tube 55 forms the "shroud." (Collins ¶253.) Moreover, the housing body 52 and the housing cap 60 further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "shroud." (Collins ¶254; EX1004[Aboul-Hosn] 13:3-4.)

[19] *See supra,* Fn. 7.

As previously discussed in Section X.A.1(e), Aboul-Hosn further discloses that the inlet tube 55 of the housing body 52 "may comprise multiple cut-outs 57 at its proximal end" to "permit the passage of fluid" out of the inlet tube 55 and out of the housing body 52 via the outflow ports 64. (EX1004[Aboul-Hosn] 13:11-13, 13:15-18, 15:22-26.) As shown in FIG. 2, below, the multiple cut-outs 57 of the inlet tube 55 are egress flow ports as the blood (red arrows) flows out of the inlet tube 55 through the multiple cut-outs 57 and out the distal opening 32 of the blood pump.[20] (Collins ¶256.)

[20] For the purposes of claim 15, Petitioner considers the "first set of apertures" recited by claim 10, from which claim 15 depends, to be the outflow windows 64 as discussed in Section X.A.1(e).

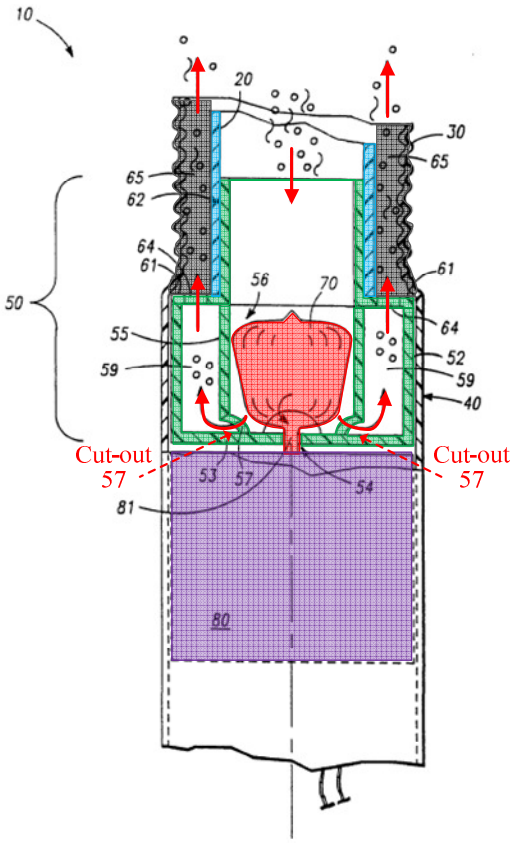


FIG.—2

(Collins ¶173; EX1004[Aboul-Hosn] FIG. 2, annotated.)

As also previously discussed in Section X.A.1(e), Aboul-Hosn discloses a plurality of openings 27 formed near the distal tip 25 of the inner cannula 20 "to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise obstructed." (Collins ¶256; EX1004[Aboul-Hosn] 11:21-24.) These plurality of openings 27 along with the distal opening 22 are ingress flow ports because they "allow blood to flow into the inner cannula 20," and they are spaced apart from the egress flow ports (cut-outs 57) because they are located "near the distal tip 25." (Collins ¶256;

EX1004[Aboul-Hosn] 11:21-24.) As such, the plurality of openings 27 and the distal opening 22 are also the ingress flow ports. (Collins ¶256.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶257.)

3. Claim 14

Claim 14 depends from claim 13 and recites *"wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port."*

As discussed in Section X.A.2, directly above, Aboul-Hosn discloses the distal opening 22 which is an ingress flow port formed as an end port and a plurality of openings 27 (ingress flow ports) near the distal tip 25 of the inner cannula 20. (Collins ¶258; EX1004[Aboul-Hosn] 11:21-24.) Moreover, the inner cannula 20 has a distal opening 22 that also allows blood to flow into the inner cannula, and as such, can also be considered to be an ingress flow port. (Collins ¶259.) As shown in the close-up view of FIG. 4 of Aboul-Hosn, the plurality of openings 27 are proximal to the distal opening 22 of the inner cannula 20, where the distal opening 22 is an end port of the inner cannula 20. (Collins ¶259.)

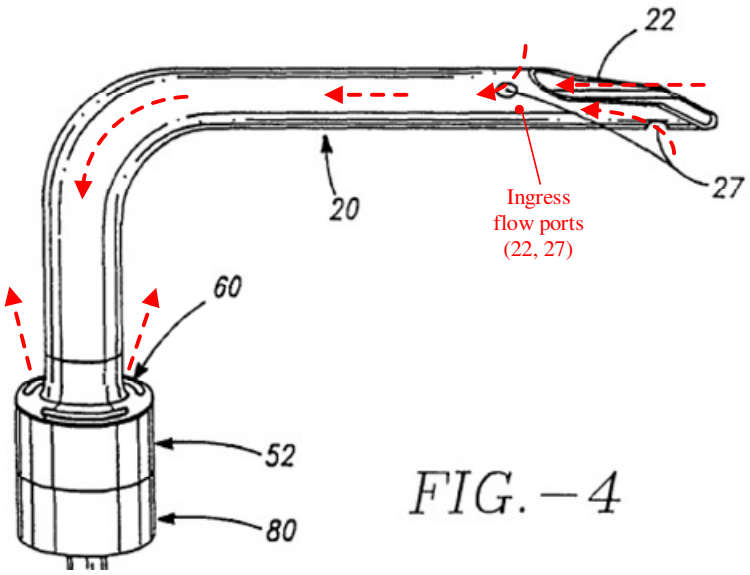


FIG.—4

(Collins ¶259; EX1004[Aboul-Hosn] at FIG. 4, annotated.)

While FIG. 4 only shows two openings 27, a POSITA would recognize that because the inner cannula 20 is tubular, there would be another opening 27 opposite the opening 27 formed inwards of the distal opening 22. (Collins ¶261.) Moreover, Aboul-Hosn's use of the phrase "a plurality of openings 27" means at least two or more openings, and a POSITA would understand that in order to maintain a sufficient flow of blood into the inner cannula 20 "when the distal opening 22 may become occluded or otherwise obstructed," more than two openings 27 as shown in FIG. 4 are required. (Collins ¶261; EX1004[Aboul-Hosn] 11:21-24.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶262.)

4. Claim 15

Claim 15 depends from claim 10 and recites *"wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub."*

As discussed in Sections X.A.1(e) and X.A.2, Aboul-Hosn discloses a first set of apertures that are egress ports (multiple cut-outs 57 of the inlet tube 55 that directs pumped blood out of the pump via the outflow windows 64) and a second set of apertures that are ingress ports (plurality of openings 27 near the distal tip 25 and the distal opening 22 that allows blood to flow into the inner cannula 20). (Collins ¶263: EX1004[Aboul-Hosn] 11:21-24, 13:11-13, 13:15-18, 15:22-26.)

As shown in FIGS. 2[21] and 5C, below, the multiple cut-outs 57 of the inlet tube 55 are also configured to direct blood passing through the interior of the inner cannula 20 towards the rotor 70 in a direction that is both proximal and radially outward with respect to the rotor hub 74. (Collins ¶263.)

[21] *See supra,* Fn. 7.

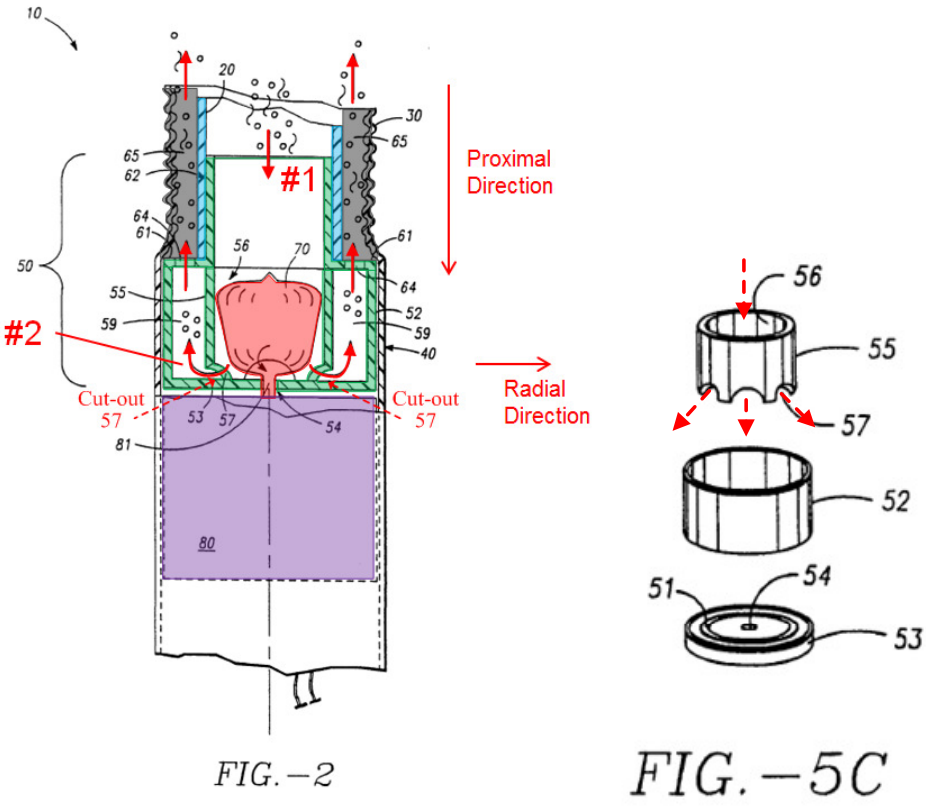


FIG.–2 FIG.–5C

(Collins ¶263; EX1004[Aboul-Hosn] FIGS. 2 and 5C, annotated.)

As shown above in FIGS. 2 and 5C, the cut-outs 57 at the bottom of inlet tube 55 provide a flow path for the blood that is being pumped through the rotor 70 and out of the inlet tube 55, as indicated by the red arrows in the annotated figure. (Collins ¶264; EX1004[Aboul-Hosn] 13:15-18.) Thus, the cut-outs 57 allow the blood to flow in a proximal direction towards the rotor 70. (*Id.* ¶264.) As indicated by the directional arrows in FIG. 5C, the blood flow has both a proximal (downwards toward the rotor 70) and radial component, with the blood exiting radially outward from the hub 74 (center of the rotor 70, not shown) at the bottom of the inlet tube 55 through the cut-outs 57. (*Id.* ¶264.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶265.)

B. Ground II: Claim 20 is anticipated or rendered obvious by Aboul-Hosn.

1. Claim 20

a) "*A method for perfusion a patent [sic]with an intravascular blood pump system, the intravascular blood pump system is configured to be advanced to a predetermined location in a patient's circulatory system and comprises: (i) an intravascular blood pump,*"

As previously discussed in Sections X.A.1(a) and X.A.1(f), Aboul-Hosn discloses an intravascular blood pump system that is configured to be advanced to a predetermined location in a patient's circulatory system comprising an intravascular blood pump. (Collins ¶266.)

b) "*a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;*"

As previously discussed in Section X.A.1(c), the intravascular blood pump of Aboul-Hosn has a rotor having a rotor hub. (Collins ¶267; EX1004[Aboul-Hosn] at 12:30-1, 16:30-31.) For example, FIG. 7C, reproduced below, shows a rotor 70 having a central hub 74 tapering in the distal direction and a distal end that extends distally beyond the most distal portion of the blades. (Collins ¶269.)

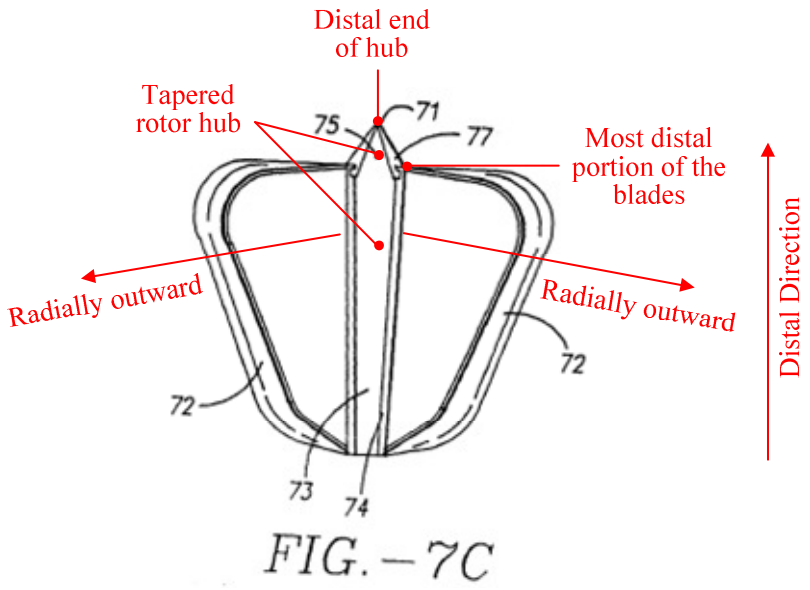


FIG. – 7C

(Collins ¶269; EX1004[Aboul-Hosn] FIG. 7C, annotated.)

As applied to FIG. 7C of Aboul-Hosn, the distal direction is the direction towards the far end of the cannula relative to the position of the pump. (*Id.*) As seen in FIGS. 1, 2, and 7C of Aboul-Hosn, the hub of the rotor 70 tapers in the distal direction, and the rotor 70 has at least two blades 72 each extending radially outward from the central hub 74 in the same manner as the bladed 58 of hub 56 shown in FIG. 3 of the '068 patent. (*Id.* ¶268; EX1004[Aboul-Hosn] 17:1-2.)

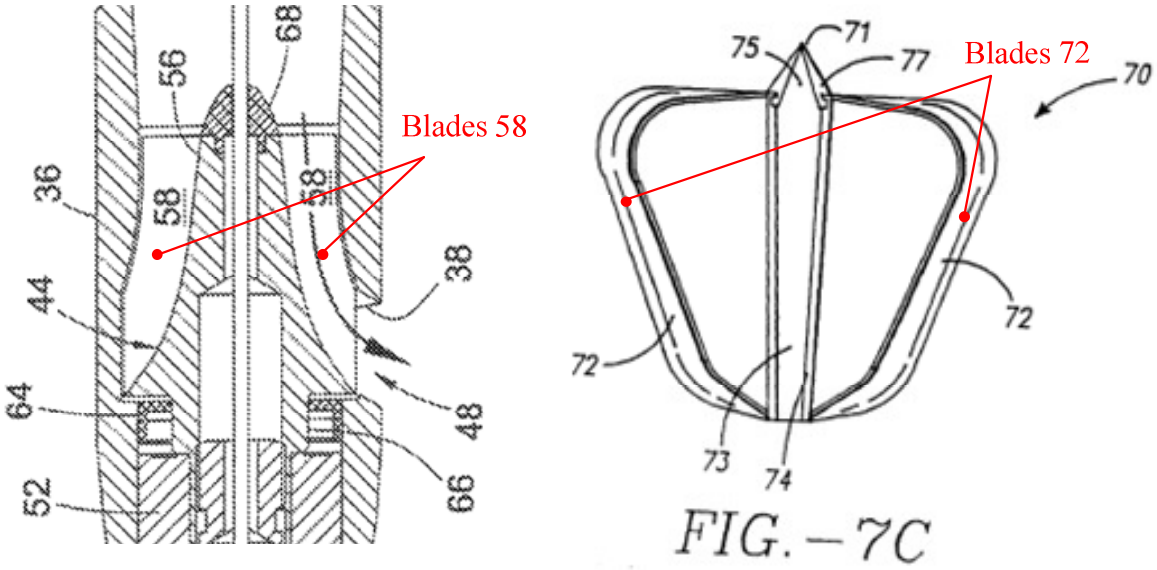


FIG. – 7C

(Collins ¶268; EX1001[’068 patent] FIG. 4, annotated (left); EX1004[Aboul-Hosn] FIG. 7C, annotated (right).)

The rotor hub 70 of Aboul-Hosn also has a generally conical shape. (Collins ¶270.) As shown below in annotated FIG. 7B, below, both the gland valve 77 of the central hub 74, as well as the lower portion of the central hub 74 below (proximal) the gland valve 77 are generally conical. (*Id.* ¶281; EX1004[Aboul-Hosn] at 17:11-26.)

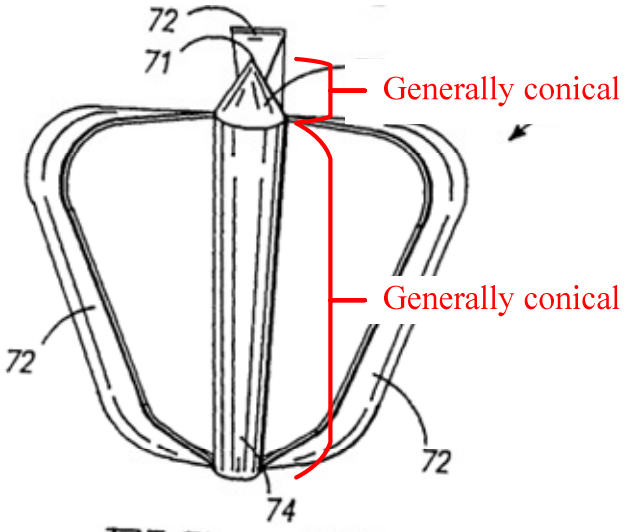


FIG. – 7B

(Collins ¶270; EX1004[Aboul-Hosn] FIG. 7C, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶272.)

c) *"(ii) a cannula extending distally from the intravascular blood pump;"*

As previously discussed in Section X.A.1(c), Aboul-Hosn discloses a cannula extending distally from the intravascular blood pump. (Collins ¶273.)

d) *"(iii) a plurality of ingress ports located towards a distal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;*

As shown in FIG. 2, below, Aboul-Hosn discloses that the inlet tube 55 of the housing body 52 (green) of the blood pump includes cut-outs 57 that allow the blood (red arrows) pumped by the rotor 70 (red) through the inner cannula 20 (blue) to flow out of the pump. (Collins ¶277; EX1004[Aboul-Hosn] 13:6-13,

13:15-18, 15:22-26, 16:13-22.) Blood enters through the holes 22 and 27 of the distal end of the cannula 20 and exits through the cutouts 57 into passageway 59, then out the outlet windows 64 and into the blood stream. (*Id.* ¶277.) Thus, the cut-outs 57 and/or the outflow windows 64 are the "plurality of egress ports located in proximity to the blood pump" as recited by claim 20. (*Id.*.)

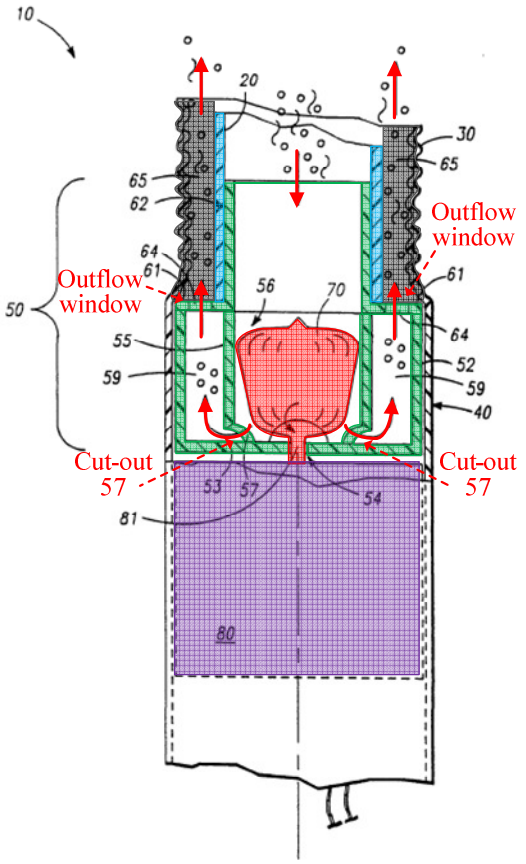
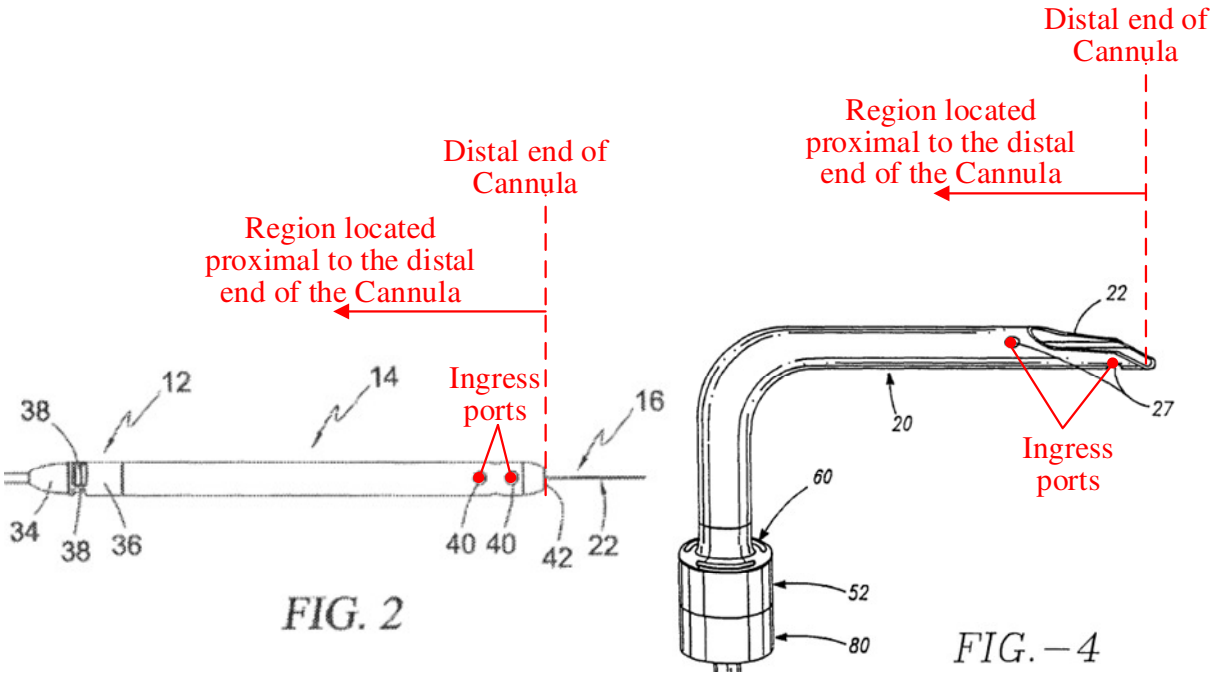


FIG.—2

(Collins ¶277; EX1004[Aboul-Hosn] FIG. 2, annotated.)

Aboul-Hosn also discloses that the inner cannula 20 has "a plurality of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20, particularly when the distal opening 22 may become occluded or otherwise

obstructed." (EX1004[Aboul-Hosn] 11:21-24.) As shown in the close-up view of FIG. 4, below, the plurality of openings 27 at the distal tip of the inner cannula 22 work in conjunction with the distal opening 22 to allow blood to flow (red arrows) into the inner cannula 20 from outside the inner cannula 20 to the blood pump, where it is then directed out through the cut-outs 57 (not shown) and outflow windows 64. (Collins ¶176.) The one or more of the openings 27 are the "plurality of ingress ports located towards a distal region of the cannula" as recited by claim 10. (*Id.* ¶176.) Further, as Dr. Collins describes, Aboul-Hosn discloses that blood enters the cannula through the plurality of openings 27 at the distal end of the cannula and moves through the cannula and out the cut-outs 57 and outflow windows 64. (Collins ¶176.)



(Collins ¶276; EX1001['068 patent] FIG.2 (left); EX1004[Aboul-Hosn] FIG. 4

(right), annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶278.)

e) *"(iv) a guide wire having a cross-section substantially smaller than the cannula; and"*

As previously discussed in Section X.A.1(i), Aboul-Hosn discloses the elongate lumen advanced along the guidewire is significantly smaller than the diameter of the inner cannula and therefore the guidewire must also have a cross-section substantially smaller than the cannula. (Collins ¶279.)

f) *"(v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong,"*

As explained in Section X.A.1.(f), Aboul-Hosn discloses an elongate lumen that accommodates the guide wire and extends through the catheter lumen (or the positioning rod lumen 273), and the central passage of the drive unit 80, through the rotor hub 74 and through the cannula 20. (Collins ¶280.) As explained in Section X.A.1.(i), the elongate lumen has a diameter significantly smaller than the inner diameter of the catheter. (Collins ¶¶280-281.). The elongate lumen must have a sufficiently large diameter to accommodate the guide wire when the guide wire is advanced along the elongate lumen, as shown for example in Aboul-Hosn's FIG. 3. (Collins ¶281.) Thus, Aboul-Hosn discloses this claim element. (*Id.*)

g) *"(b) arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and (c) arranged in series longitudinally with the cannula,"*

As previously discussed in Section X.A.1(j), Aboul-Hosn also discloses that 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. (Collins ¶282.)

h) *See element 1.b, Section X.A.1(k), above.*

As previously discussed in Section X.A.1(k), Aboul-Hosn discloses progressing a guide wire to a predetermined location in the circulatory system of the patient. (*Id.* ¶283.)

i) *See element 1.b, Section X.A.1(l), above.*

As previously discussed in Section X.A.1(l), Aboul-Hosn discloses advancing the blood pump system along the guide wire to the predetermined location in the patient's body. (*Id.* ¶284.).

XI. INSTITUTION IS PROPER UNDER 35 U.S.C. § 325

Institution of this Petition is proper under 35 U.S.C. § 325(d). This is true notwithstanding the denial of institution of IPR2017-01029[22] (the "'1029 Proceeding") in consideration of the factors recently reiterated by the Board in

[22] The Board issued a decision denying institution in IPR2017-01029 on September 20, 2017. Petitioner reserves the right to request rehearing.

General Plastic Industrial Co., Ltd., v. Canon Kabushiki Kaisha, IPR2016-01357, Paper No. 19 at 15-16 (P.T.A.B. Sept. 6, 2017). The instant petition presents specific and targeted additional arguments focusing on a subset of the claims asserted in the Litigation. The fairness factors weigh heavily against the exercise of discretion to deny institution under § 325(d). *See, e.g.*, *Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2013-00250, Paper 25 at 11-12 (P.T.A.B. Sept. 3, 2013) (declining to exercise discretion not to institute IPR of later-filed petition involving "the same parties, the same patent, and much of the same prior art" when later filed petition corrected "oversight" from the first petition). Institution of trial for a limited number of challenged claims is fair and not prejudicial to Patent Owner.

First, trial should be instituted to include the new grounds, relying on new prior art (Sammler), that was neither pursued nor the "same or substantially the same prior art or arguments" pursued in the '1029 Proceeding. The Board's discretion, whether or not to institute under Section 325(d), is not applicable to timely filed *new grounds*. *See* 35 U.S.C. § 325(d) (the Board only has discretion as to whether to (i) "stay, transfer, consolidate[e], or terminat[e]" trial or (ii) institute proceedings based on "the same or substantially the same prior art or arguments" as previously presented). Indeed, Petitioner is merely exercising its statutory right pursuant to 35 U.S.C. § 311 to petition for IPR not "more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served

with a complaint alleging infringement of the patent" 35 U.S.C. § 315(b). As such one-year bar has yet to expire, this Petition is proper and timely.

Second, Petitioner filed the instant petition without undue delay and without regard to the Board's recent September 20, 2017 decision for the '1029 Proceeding.[23] Petitioner received service of Patent Owner's infringement contentions on May 25, 2017 and needed sufficient time to review, digest and formulate its views with respect to those positions that bear directly on the application of the language of the claims. Petitioner is also required to operate under a litigation schedule set by the court, which set a deadline of September 8, 2017 for invalidity contentions. Meanwhile, Patent Owner continues to file and prosecute patent applications with specifications common to this patent, which influence the potential construction and application of the '068 patent. Moreover, Petitioner has filed the instant petition only after denial of a request for a reply to address the Patent Owner's misrepresentations, discussed below.

The instant petition seeks to conserve the limited resources of the Board by challenging only five claims out of thirteen claims challenged in the '1029 Proceeding. Thus, this case is distinct from *General Plastic Industrial Co.*,

[23] This Petition is filed merely two days after the Board decision denying institution in IPR2017-01029. As such it has not, and as a practical matter could not have, been prepared using the Board's decision as a roadmap.

IPR2016-01357, *NVIDIA Corp. v. Samsung Electronics Co.*, IPR2016-00134 (P.T.A.B. May 4, 2016) and *Alarm.com Inc. v. Vivint, Inc.*, IPR2016-01110, (P.T.A.B. Nov. 28, 2016) where the petitioners filed serial petitions to expand the scope of the review. To further conserve the Board's resources, Petitioner has sought to join this Petition with the '1029 Proceeding.

Institution, especially in this limited manner, is not fundamentally unfair to Patent Owner. Indeed, any alleged prejudice to the Patent Owner is mitigated in light of its own tactics and long history of delay. *See SK Hynix v. Netlist, Inc*, IPR2017-00561 (P.T.A.B. July 7, 2017), Paper 7 at 4 (finding period of three years between first and second petitions did not weigh against institution when "mitigating factors" existed). Patent Owner made significant misrepresentations[24] in its preliminary responses in the '1029 Proceeding that Petitioners could not have addressed following the Board's denial of Petitioner's requested reply, and those misrepresentations seem to have influenced the Board's decision to deny institution.

[24] For example, the Patent Owner incorrectly represented that the disclosure in Aboul-Hosn is limited to extracorporeal applications. *See* Ex1050[IPR2017-01029, POPR] 22-28. Patent Owner also incorrectly represented that Claim 1 requires that the blood pump be placed within the vasculature system. *Id.*, 44-45.

As another mitigating factor, Patent Owner asserted 98 claims from the '068 patent and 5 other patents from its patent family, many of them repetitive, in the district court litigation. EX1051[Infringement Contentions]. Patent Owner continues to seek further continuations, again with much repetition, by extracting old abandoned prior art and incorporating it into its specification, submitting all of Petitioners' prior art and petitions to the USPTO and conducting non-public examiner interviews, all in an effort to obtain additional claims to assert against the same products, but without having to take a position on the record regarding their bases of patentability. EX10554[Notice Letters]. The intent is clearly to proliferate the litigation and drive up costs. EX1054['669 NOA]; EX1055[Status Conference Transcript]. That practice, although not subject to the Board's authority, is far more abusive than Petitioner's submission of one more petition focused solely on claims asserted in the Litigation. Exercising the Board's discretion to not institute trial would fundamentally prejudice Petitioner, as it would deny Petitioner's use of a statutory right provided specifically to aid Petitioner in patent litigation. *See, e.g.* 157 Cong. Rec. H. 4495 (daily ed. June 23, 2011) (statement of Rep. Smith).

For the reasons above, institution of trial on all grounds is fundamentally and justifiably fair.

XII. CONCLUSION

Based on the foregoing, claims 10, 13-15, and 20 of the '068 patent recite subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel these claims.

Respectfully Submitted,

___/David M. Tennant/_____

David M. Tennant
Registration No. 48,362

Table of Exhibits for U.S. Patent 9,327,068 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 9,327,068 ("'068 patent")
1002	Collins Declaration ("Collins")
1003	File History of U.S. Patent No. 9,327,068 ("'068 PH")
1004	WO 99/02204 ("Aboul-Hosn")
1005	U.S. Patent No. 5,921,913 ("Siess")
1006	E.P. Publication No. 0916359 ("Siess '359")
1007	U.S. Patent No. 5,061,273 ("Yock")
1008	Wampler et al., *Clinical Experience with the Hemopump Left Ventricular Support Device*, published in *Supported Complex and High Risk Coronary Angioplasty*, ch. 14, 231-49 (Springer 1st ed. 1991) ("Wampler")
1009	U.S. Patent No. 4,625,712 ("Wampler '712")
1010	U.S. Patent No. 4,846,152 ("Wampler '152")
1011	U.S. Patent No. 4,479,497 ("Fogarty")
1012	U.S. Patent No. 6,248,091 ("Voelker")
1013	U.S. Provisional Application No. 60/152,249 ("the '249 provisional application")
1014	[RESERVED]
1015	[RESERVED]
1016	[RESERVED]
1017	[RESERVED]
1018	U.S. Patent No. 6,544,216 ("Sammler '216")
1019	U.S. Patent 6,176,822 ("Nix")
1020	U.S. Patent No. 6,849,068 ("Bagaoisan")
1021	Diastolic Balloon Pumping (With Carbon Dioxide) in the Aorta – a Mechanical Assistance to the Failing Circulation by S.D. Moulopoulos (1962) ("Moulopoulos")
1022	Pierce, W. S. et al., *Portable artificial heart systems*, ASAIO Journal 29.1: 757-59 (Apr. 1983) ("Pierce")

1023	Practical Angioplasty (David P. Faxon, M.D. ed., Raven Press 1993) ("Faxon")
1024	Abou-Awdi N.L., et al., *Hemopump Left Ventricular Support in the Peripartum Cardiomyopathy Patient*, 8 J. Cardiovascular Nursing, Issue 2 (Jan. 1994) ("Abou-Awdi")
1025	Lynn R. Williams, *Reference Values for Total Blood Volume and Cardiac Output in Humans*, Oak Ridge Nat'l Lab. (Sept. 1994) ("Williams")
1026	E.E. Kunst, J.A. van Alste, T. Arts, and H. B. K. Boom, *Integrated Unit for Programmable Control of the 21F Hemopump and Registration of Physiological Signals*, Med. & 32 Biol. Eng. & Comput. 694-95 (Nov. 1994) ("Kunst")
1027	Konishi, H. et al., *Controller for an Axial Flow Blood Pump*, 20 Artificial Organs 20(6): 618–20 (Jun. 1996) ("Konishi")
1028	Andre F. Cournand, Control of the pulmonary circulation in man with some remarks on methodology, Nobel Lecture, December 11, 1956, page 531 and page 533.
1029	Textbook of Medical Physiology by Arthur C. Guyton and John E. Hall, 9th Edition (1996) ("Guyton")
1030	Lawrence K. Altman, *A Tiny Heart Pump Saves Its First Life, Researchers Report*, N.Y. Times, May 5, 1988. ("Wampler Article")
1031	[RESERVED]
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CERTIFICATE OF WORD COUNT UNDER 37 CFR § 42.24(d)

Pursuant to 37 C.F.R. §§ 42.24(d) and 42.24(a)(1), I hereby certify that the number of words in this Petition is 13,999 excluding the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, and the listing of exhibits.

Respectfully Submitted,

___/David M. Tennant/_____

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Registration No. 48,362

CERTIFICATE OF SERVICE

I, Daniel Shults, hereby certify that I am a resident of the State of Maryland and over the age of eighteen years, and not a party to the within action; my business address is 701 13th Street NW, #600, Washington, DC, 20005. On September 22, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 9,327,068 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- List of Exhibits for Petition for Inter Partes Review of U.S. Patent No. 9,327,068 (EX1001-1056)
- Exhibits 1001-1056
- Power of Attorney

to be served via FedEx on the attorney of record with the following correspondence address as listed on PAIR:

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and to be served via FedEx on the designated representative of patent owner with the following correspondence address:

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I declare that I am employed in the office the above captioned attorney at whose direction the service was made.

__/s/ *Daniel Shults*
Daniel Shults