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. IPR2017-02150

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

CLAIMS 1, 5, 7, 9

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I. INTRODUCTION

Petitioners Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 1, 5, 7, and 9 (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]

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[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 (EX1051).

3. U.S. Patent No. 5,921,913 to Siess (EX1005, "Siess"), filed June 24, 1997 and issued July 13, 1999, is prior art under 35 U.S.C. § 102(b).

4. WO 97/37696 to Rau (EX1046[Rau]), filed April 2, 1997 and published October 16, 1997, is prior art under 35 U.S.C. § 102(b).[4]

5. Wampler et al., Clinical Experience with the Hemopump Left Ventricular Support Device, Supported Complex and High Risk Coronary Angioplasty, ch. 14, 231-49 (Springer 1st ed. 1991) (EX1008, "Wampler"), published in 1991, is prior art under 35 U.S.C. § 102(b).[5]

B. Grounds for Challenge

Petitioner requests cancellation of Challenged Claims 1, 5, 7, and 9 under the following statutory grounds:

- Ground 1: Claims 1 and 5 are rendered obvious by Aboul-Hosn in view of Siess under 35 U.S.C. § 103(a).
- Ground 2: Claim 7 is rendered obvious by Aboul-Hosn in view of Siess, and further in view of Sammler under 35 U.S.C. § 103(a).

[4] EX1046 is a certified English translation of WO97/37696, which is published in German (EX1057).

[5] Wampler bears a copyright date of 1991 and was publicly available from 1991. *See* EX1008; Declaration of Kiersten Batzli (EX1037); Library of Congress Card Catalog (EX1038).

- Ground 3: Claim 9 is rendered obvious by Aboul-Hosn in view of Siess, and further in view of Wampler under 35 U.S.C. § 103(a).
- Ground 4: Claims 1 and 5 are rendered obvious by Sammler in view of Rau, and further in view of Aboul-Hosn and Siess under 35 U.S.C. § 103(a).
- Ground 5: Claim 9 is rendered obvious by Sammler in view of Rau, and further in view of Aboul-Hosn, Siess, and Wampler under 35 U.S.C. § 103(a).

V. CONVENTIONAL TECHNOLOGY

A. Conventional Intravascular Blood Pumps[6]

The features of the Challenged Claims were well-known and included: a cannula connected to an axial flow pump (Collins ¶61) pumping blood axially along the pump and through the cannula (*id.* ¶¶62-65), a purge fluid system to lubricate and prevent blood from entering the pump motor (*id.* ¶¶66-69), and techniques for monitoring blood pressure near the pump (*id.* ¶¶70-76).

B. Conventional Guide Wire Techniques

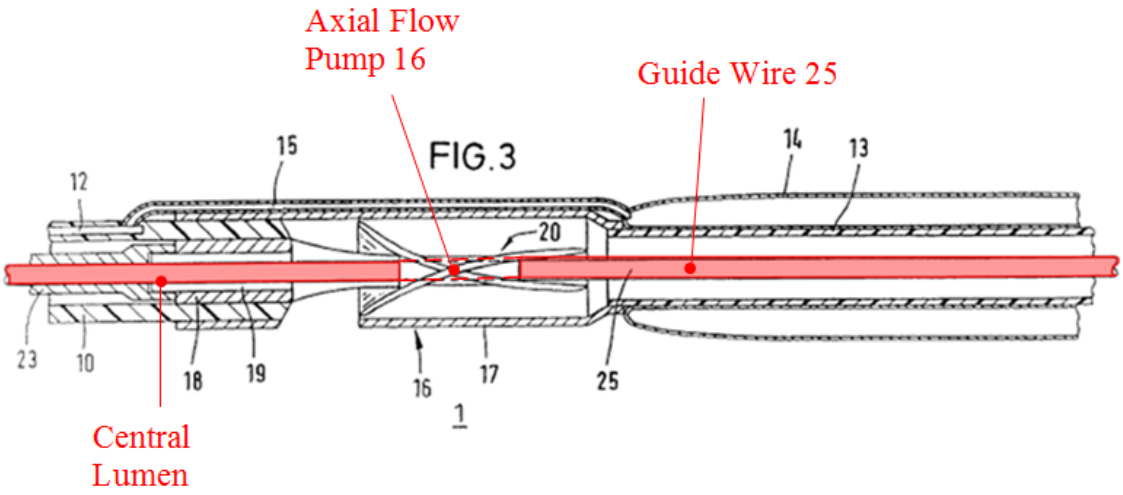
Well-known catheterization techniques included "over-the-wire", "side-rigger" and "guide catheters" and have been used routinely to position blood

[6] For background, Dr. Collins discusses the circulatory anatomy and function, and development of intravascular blood pumps. (Collins ¶¶39-56.)

pumps intravascularly (i.e., within a patient's circulatory system). (Collins ¶¶77-90.)

1. Over-the-Wire

A person of ordinary skill ("POSITA") used "over-the-wire" guide mechanisms to place intravascular blood pumps. (Collins ¶¶80-83.) As shown 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 the pump may be slipped over the guide wire. (Collins ¶82; EX1012[Voelker] 1:46-50, 3:56-60.)

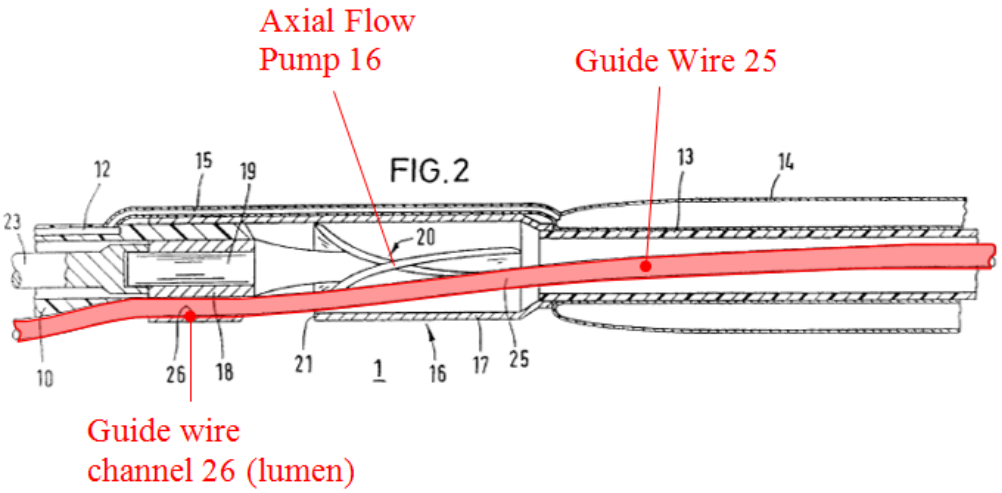


(Collins ¶82; EX1012[Voelker] FIG. 3, annotated.)

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

2. Side-Rigger

"Side-rigger" was a well-known catheterization technique such as in Voelker, as shown in Fig. 2 below, in which a guide wire 25 extends through a side channel 26 of the pump for positioning the pump. (Collins ¶86; EX1012[Voelker] 3:34-43.)



(Collins ¶86; EX1012[Voelker] FIG. 2, annotated.)

3. Guide Catheter

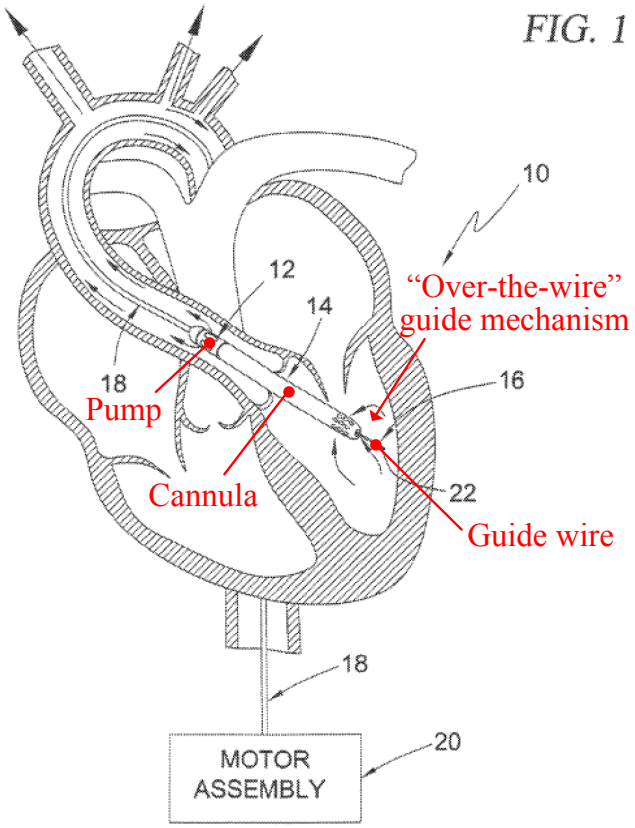
Yock discloses using a guide catheter to position a guide wire and the same technique has been adapted to place intravascular blood pumps. (Collins ¶79; EX1001['068 Patent] 2:26-3; EX1006[Yock] 3:56-4:50.)

VI. OVERVIEW OF THE '068 PATENT

A. Summary of the '068 patent

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]

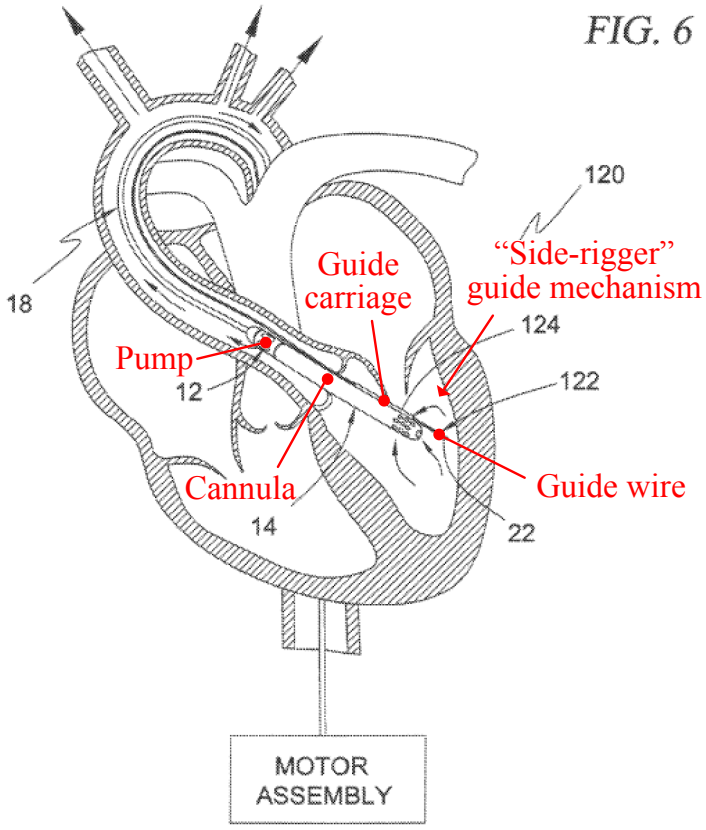
2:26-39.) FIG. 1 of the '068 patent shows a conventional over-the-wire placement technique. (*Id.* 5:7-12.)



(Collins ¶94; EX1001['068 patent] FIG. 1, annotated.)

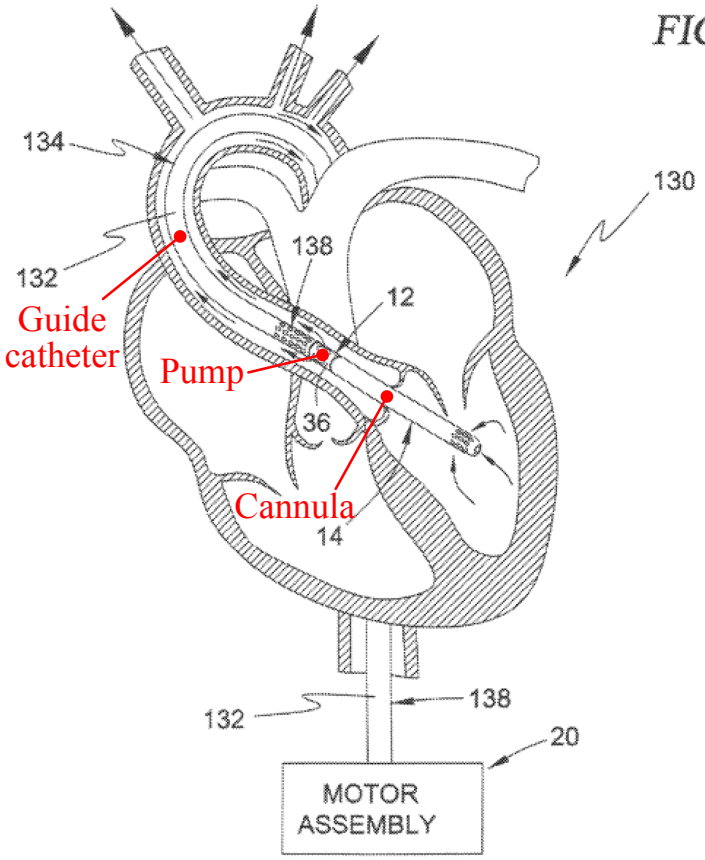
The conventional intravascular blood pump system 10 includes an intravascular blood pump 12, rotor hub, cannula 14, and over-the-wire guide mechanism 16 with a guide wire lumen that passes through the center of the rotor hub and the cannula 14. (*Id.* 7:6-16; Collins ¶94.)

FIG. 6 shows the conventional "side-rigger" guide mechanism. (*Id.* 5:29-34.) The guide mechanism 122 extends through a guide carriage 124 on the side of the cannula 24. (*Id.* 11:60-12:3; Collins ¶96-97.)



(Collins ¶96; 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 ¶99.)



(Collins ¶99; EX1001[’068 patent] FIG. 10, annotated.)

B. The Earliest Possible Priority Date for the '068 Patent

September 1, 2000 is the earliest possible priority date (the "EPD") for the Challenged Claims.[7] 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, "'249 provisional application").

Independent claim 1 requires "a first lumen … operatively arranged to deliver purge fluid to the intravascular blood pump," and "an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface." (EX1001['068 patent] 18:51-53; 18:57-60.) Yet, nowhere in the '249 provisional application is there support for these features. (Collins ¶¶105-109.)

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] 12; Collins ¶106; *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

[7] 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.

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 is September 1, 2000. (Collins ¶105-109.)

VII. OVERVIEW OF THE PRIOR ART

A. Aboul-Hosn[8]

Aboul-Hosn discloses an intravascular 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 the intravascular blood pump system can be positioned using both percutaneous and surgical approaches. (Collins ¶111; EX1004[Aboul-Hosn] FIGS. 21, 23-24, 6:16-29, 11:8-11, 21:19-22:30, 29:17-19, 32:9-13; EX1001['068 patent] 1:56-58, 17:30-42.)

As shown below in FIGS. 1 and 2,[9] the blood pump system has a drive unit 80 (purple) connected to a conventional blood pump having a rotor and blades 70

[8] 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.)

(red) within a housing body 52 (green) and a housing cap 62 (green).[10] (EX1004[Aboul-Hosn] 12:12-13:13.) The blood pump draws blood through an inner cannula 20 (blue) coupled to the housing cap 62 (green) by the rotation of the rotor 70 driven by the drive unit 80. (*Id*.; EX1004[Aboul-Hosn] 13:14-18).

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[9] As noted by Dr. Collins, FIGS. 1 and 2 show an extracorporeal blood pump system, however, Aboul-Hosn discloses 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 Fn. 8; EX1004[Aboul-Hosn] FIGS. 3, 4, and 12.)

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

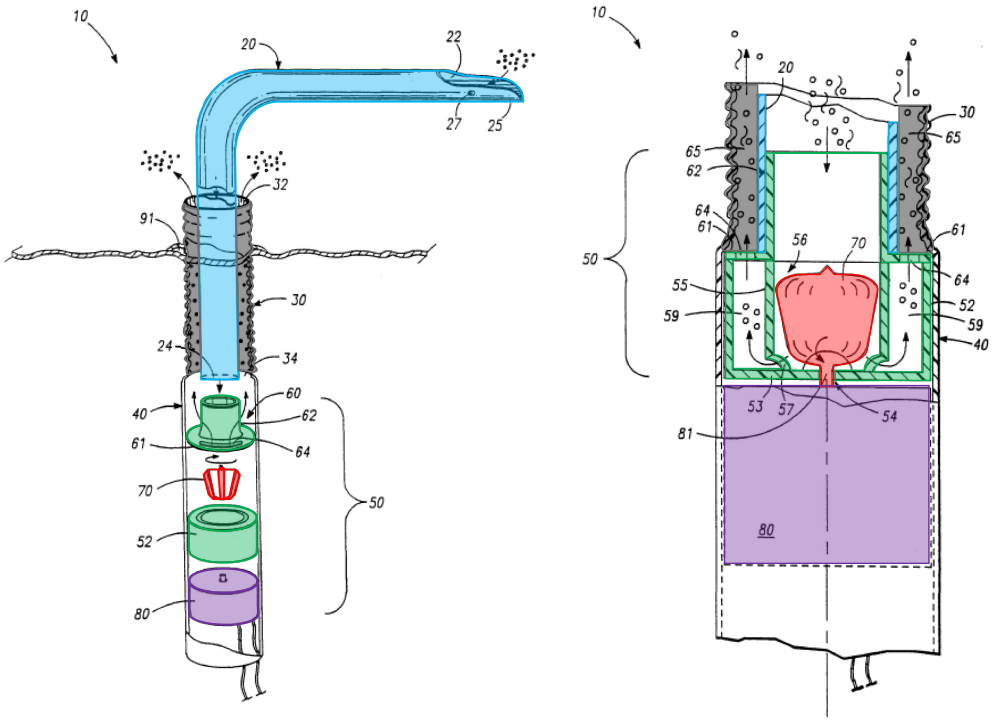


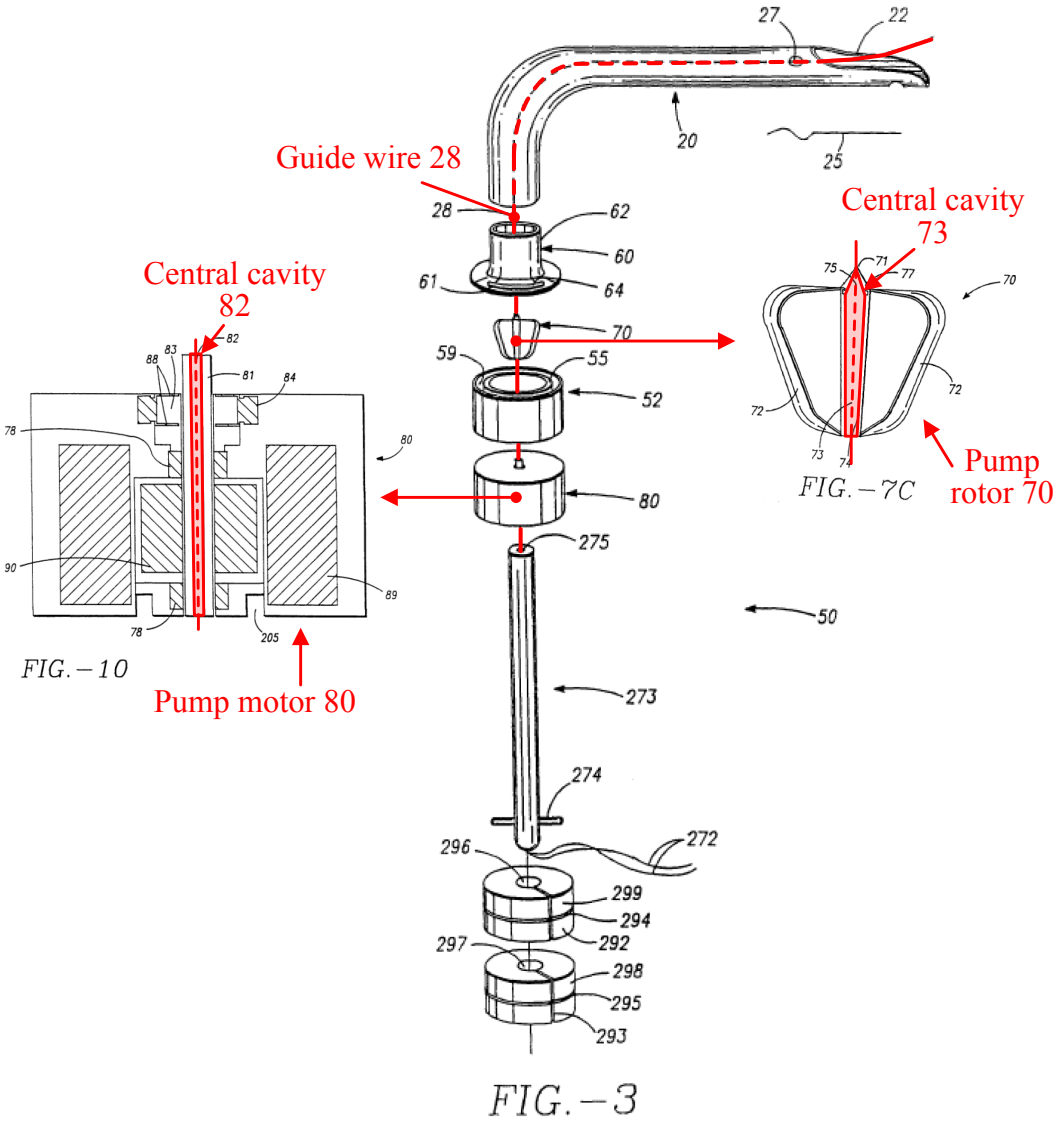
FIG.—1 FIG.—2

(Collins ¶¶112-113; 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 ¶113; 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 a heart chamber or a vessel" using a guide wire. (Collins ¶114; 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 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. (Collins ¶114; EX1004[Aboul-Hosn] 14:17-15:18, 17:19-22, FIG. 12.) 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.* ¶114.)



(Collins ¶114; EX1004[Aboul-Hosn] FIGS. 3, 7C, and 10, annotated.)

As shown in FIGS. 11 and 12, below, to position the pump system inside the patient, 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 ¶115; EX1004[Aboul-Hosn] 6:24-7:5, 12:7-9, 21:11-18.)

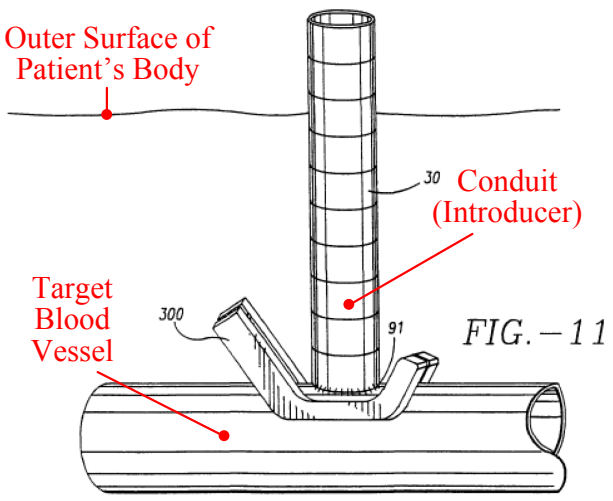


FIG.—11

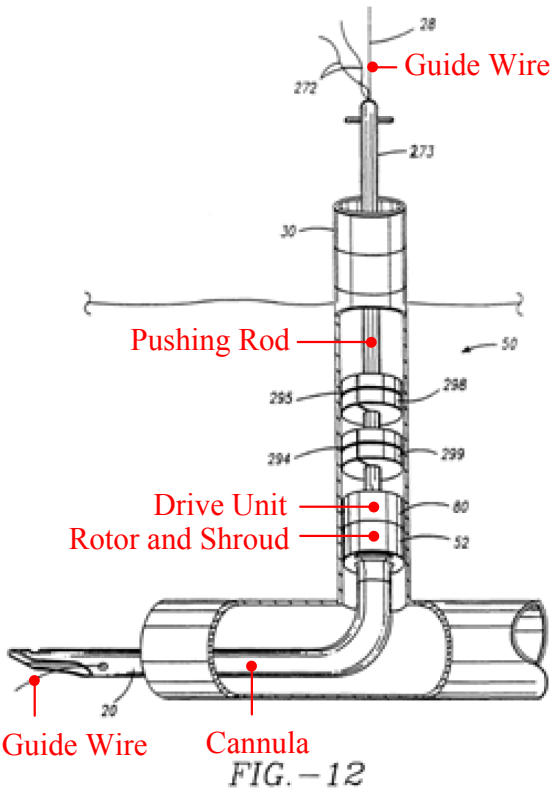


FIG.—12

(Collins ¶116; EX1004[Aboul-Hosn] FIGS. 11 and 12, annotated.)

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 ¶116; EX1004[Aboul-Hosn] 22:10-16.)

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. (Collins ¶¶117-118; EX1004[Aboul-Hosn] 21:27-29, 22:10-25.)

Aboul-Hosn describes the pump system and introduction technique shown in FIGS. 11 and 12 as "an endovascular method and system."[11] (Collins ¶116; EX1004[Aboul-Hosn] 6:24-29.) Using Aboul-Hosn's "endovascular method and system," the blood pump system can be placed in a variety of configurations to provide both left-heart and right-heart support, such as shown in the configurations shown in FIGS. 14-19, 21, and 23. (Collins ¶¶116-120; EX1004[Aboul-Hosn] 9:16-31.)

[11] According to Dr. Collins, in the medical devices field, endovascular has the same meaning as intravascular. (Collins Fn. 14; EX1050[Stedman's Medical Dictionary] 590 ("endo"), 916 ("intra").)

B. Sammler[12]

Sammler discloses an intravascular blood pump system positioned "as a right heart pump, as shown in FIG. 1, below. (Collins ¶129; EX1045[Sammler] 4:15-16.)

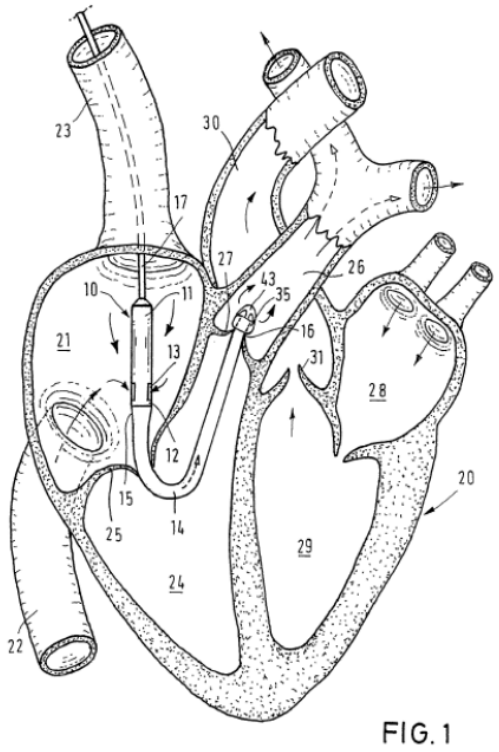


FIG. 1

(EX1045[Sammler] FIG. 1.)

[12] Sammler was included in an IDS submitted by the Patent Owner to the USPTO on November 11, 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.)

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 ¶124; EX1045[Sammler] 4:17-18, 4:21-22.) Sammler discloses the "pump corresponds, e.g., to that of WO 97/37696," referring to Rau which will be described below. (Collins ¶124; EX1045[Sammler] 4:18-19.)

The intravascular blood pump system can be configured 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 ¶125; 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 ¶125; EX1045[Sammler] 3:24-27, 6:3-7.) The lumen 50 can be used to detect blood pressure in the pulmonary artery after the guide wire 51 is removed. (Collins ¶126; EX1045[Sammler] 6:8-12.)

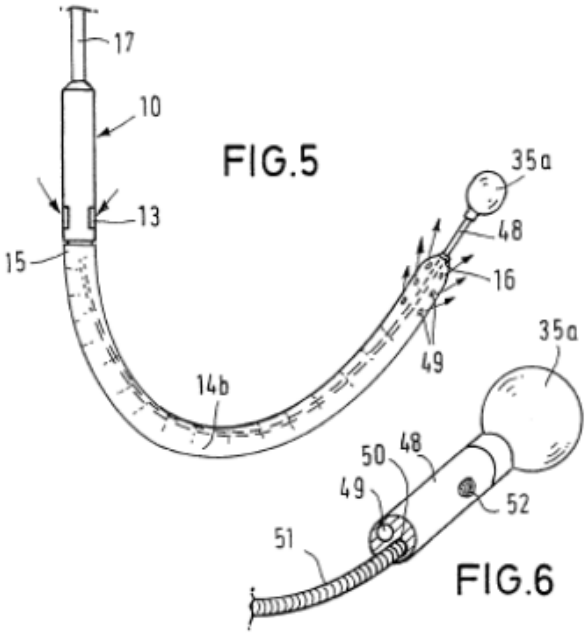


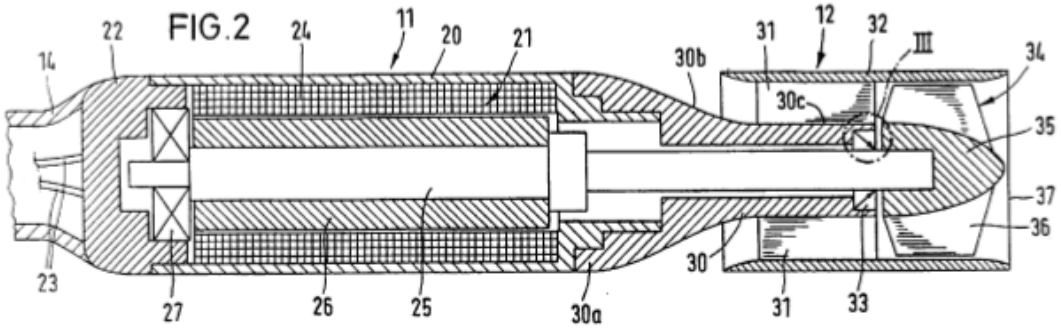
FIG.5

FIG.6

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

C. Rau

As referenced by Sammler, Rau discloses the details of an intravascular blood pump system. (Collins ¶127; EX1046[Rau] 5:17-19, 6:6-16.) Like Sammler, Rau discloses the blood pump 10, shown below in FIG. 2, comprises two distinct parts: (1) a motor part 11 and (2) a pump part 12. (Collins ¶127; EX1046[Rau] 5:17-19.) The blood pump part 12 includes an impeller 34 disposed within a tubular pump housing 32, and "[w]hen the impeller 34 is rotating, blood is suctioned through the front-side suction opening 37 of the pump housing 34 and is driven backward in an axial direction in the pump housing 34." (Collins ¶128; EX1046[Rau] 6:23-7:5.)

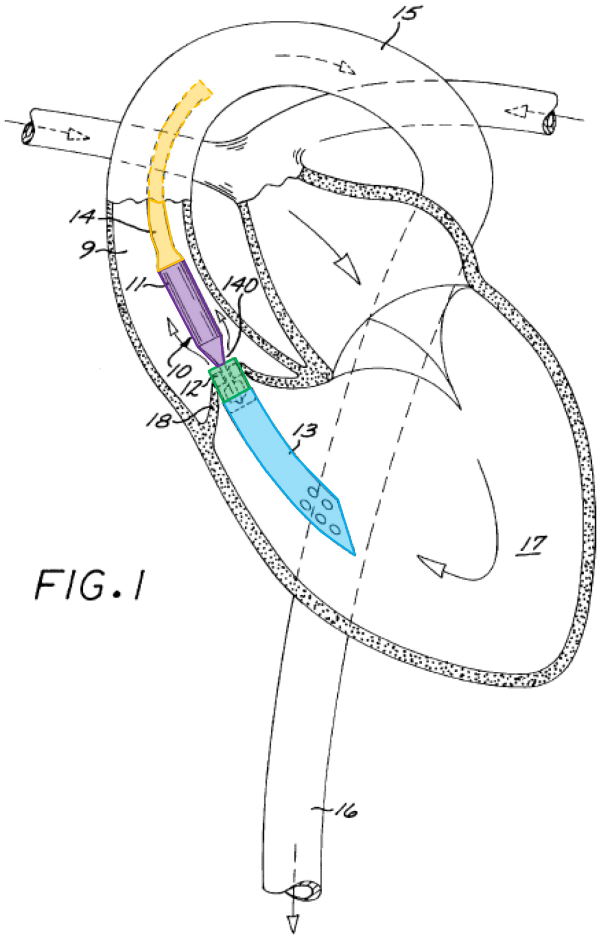


(EX1046[Rau] FIG. 2.)

D. Siess

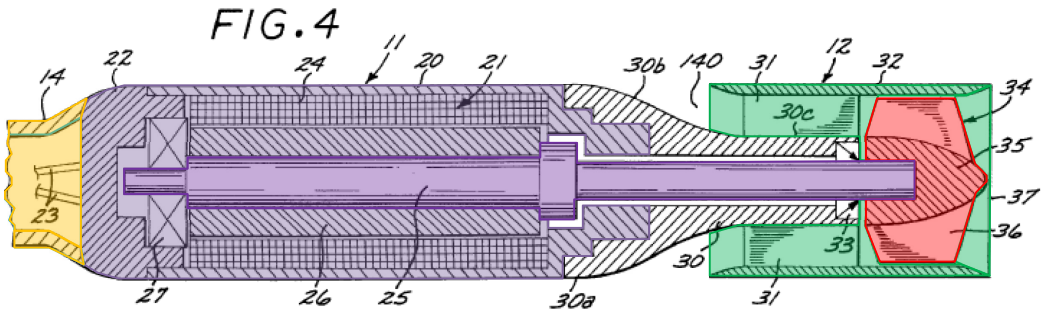
Siess also discloses using a guide wire to place an intravascular blood pump system at a desired location with the patient's vasculature. (Collins ¶129; EX1005[Siess] 5:55-58.) As shown in annotated FIG. 1 below, the microaxial pump 10[13] (green and purple) couples to an inlet cannula 13 (blue) at its distal end, and a catheter 14 (yellow) at its proximal end, and the system is "inserted via the femoral artery through the aortic arch 15 and into the ventricle 17." (*Id.* 5:47-50.)

[13] As noted by Dr. Collins, Siess' blood pump is substantially similar to Rau's, and Thorsten Siess is listed as a co-inventor on the face of both Sammler and Rau. (Collins Fn. 12.)



(Collins ¶129; EX1005[Siess] FIG. 1, annotated.)

As shown below in FIG. 4, the flexible catheter 14 (yellow) is "sealingly connected" to a proximal end of the drive unit 11 (purple) and includes a lumen to deliver a "biocompatible purge fluid[,]…that is pressurized so as to maintain a slow purge rate over the seals of about 1-5ml/hr[,]" to the microaxial pump 10. (*Id.* 8:31-44.)



(Collins ¶130; EX1005[Siess] FIG. 4, annotated.)

E. Wampler

Wampler discloses a system overview of the Hemopump, which was the original catheter-based blood pump used for the treatment of cardiogenic shock. (Collins ¶134; EX1008[Wampler] 232-36.) Wampler provides a schematic of the Hemopump in FIG. 14-2 below showing purge fluid inlet and outlet conduits connected to a purge fluid pump that delivers a continuous infusion of purge fluid to the Hemopump via lumens within the drive cable sheath. (Collins ¶134; EX1008[Wampler] 233-34.)

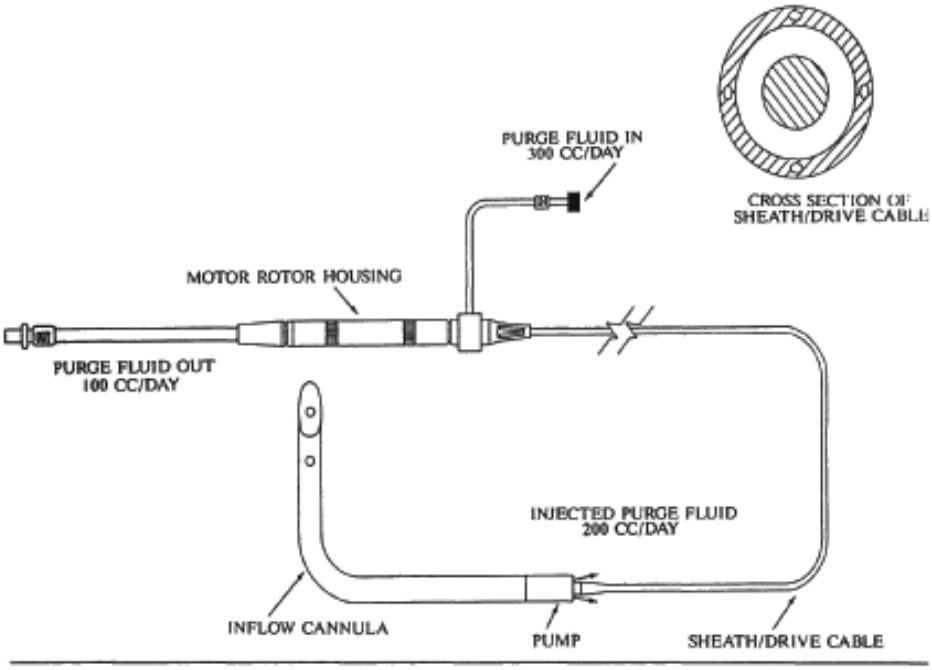


Figure 14-2. Schematic of the Hemopump.

(EX1008[Wampler] FIG. 14-2.)

F. Analogous Art

Aboul-Hosn, Sammler, Rau, Siess, and Wampler are analogous art. *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" or if it "is reasonably pertinent to the particular problem with which the inventor is involved.") As Dr. Collins explains throughout his Declaration, a POSITA would naturally look to analogous art.

First, a POSITA would naturally look to the aforementioned references as they are all directed to axial flow intravascular blood pump systems, and as such are in the same field of endeavor as the '068 patent. (Collins ¶135)

Second, the aforementioned references are also directed to the same problem addressed by the '068 patent, i.e., positioning intravascular blood pump systems within the vascular system to provide left- or right-heart support. (Collins ¶135.)

Accordingly, the references 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.[14] 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 those of ordinary skill in the art.

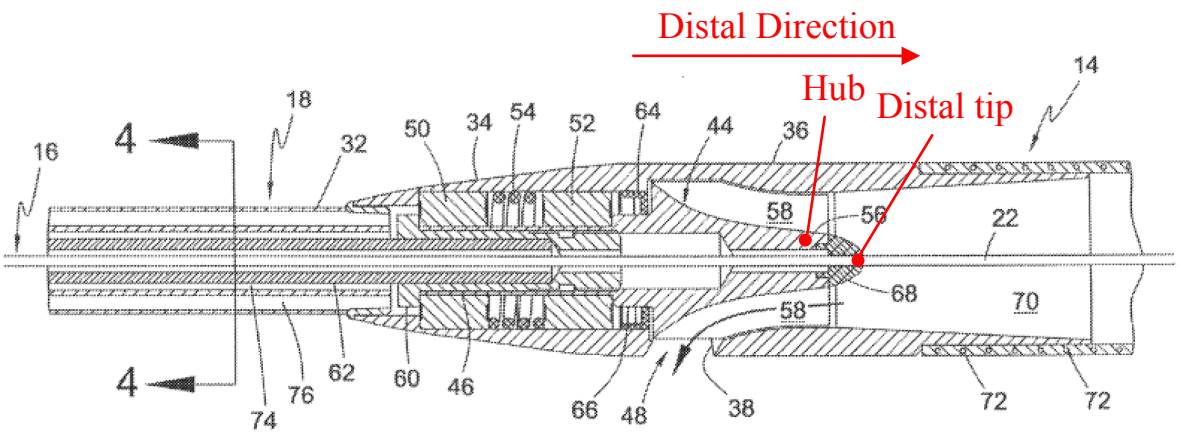
A. "distal"

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 below, the '068 patent provides that "the purge fluid

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

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

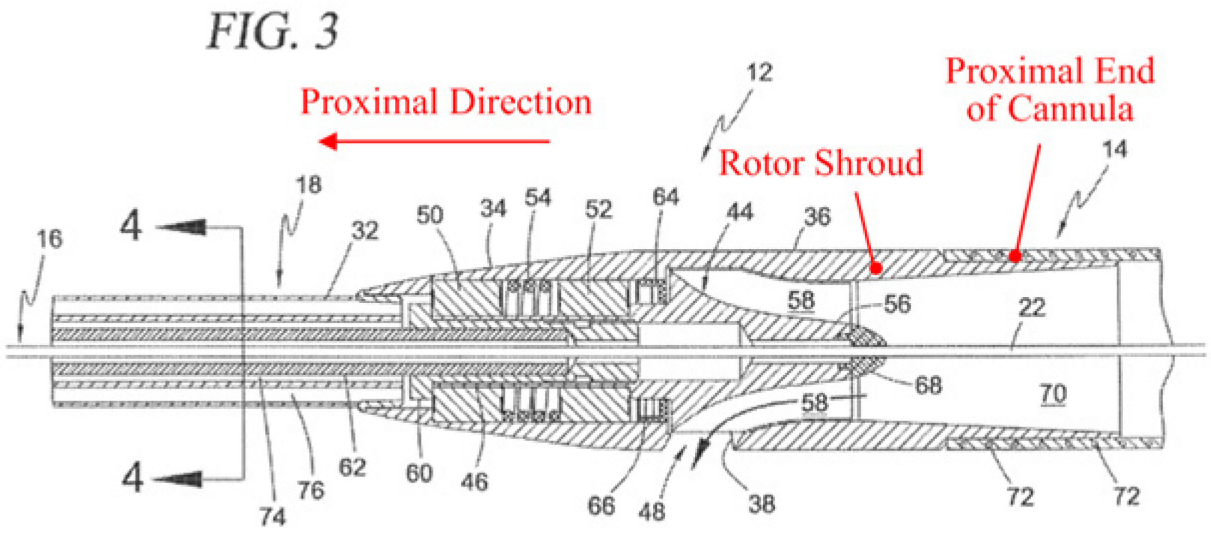


(Collins ¶137; EX1001['068 patent] FIG. 3, annotated.)

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 opening into the patient's heart. (Collins ¶¶137-139.)

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 ¶¶141-143.) 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.* ¶¶141-143; EX1001['068 patent] 8:16-21, 9:47-52.)



(Collins ¶141; EX1001[’068 patent] FIG. 3, annotated.)

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 IPR2017-01028 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. (EX1051[IPR2017-01028 POPR] 75).

Patent Owner overstates the requirement to qualify as a POSITA. (Collins ¶34-35.) Patent Owner provided absolutely no justification for requiring such a stringent "ordinary" level of skill with intravascular heart assist devices. (*Id.* ¶35.) 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).

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 ¶37.) 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.* ¶37.)

Even under Patent Owner's unduly restrictive definition, Dr. Collins is a POSITA for the purposes of the '068 patent. (*Id.* ¶¶34-37.) Dr. Collins received his Ph.D. from MIT in 1988 with a focus on biomedical applications, and from 1998 to 2002,[15] worked as a design engineer helping to form Arthur D. Little Inc's ("ADL") medical devices business including working on the design of numerous

[15] The EPD of the '068 patent is September 1, 2000, 12 years after Dr. Collins began working at ADL.

medical products related to vascular and intravascular medical devices. (*Id.* ¶37.) That experience is more than ample.

X. SPECIFIC GROUNDS FOR PETITION

A. Ground I: Claims 1 and 5 are obvious in view of Aboul-Hosn and Siess

1. Claim 1

a) "*A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system, comprising*:"

Aboul-Hosn discloses an intravascular blood pump system. (Collins ¶146-147; EX1004[Aboul-Hosn] 31:6-9.) 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 ¶146; EX1004[Aboul-Hosn] 21:11-22:30.)

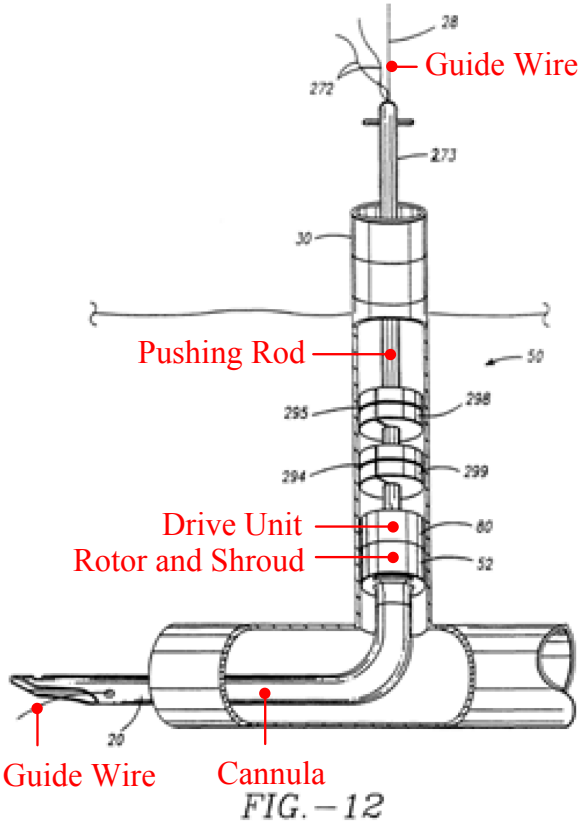


FIG. – 12

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

Aboul-Hosn describes the intravascular blood pump system being introduced into the patient's body and into the vascular system through the conduit 30 as shown in FIG. 12 as an "endovascular method and system."[16] (Collins ¶146; EX1004[Aboul-Hosn] 6:24-7:5.) 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

[16] *See supra,* Fn. 11.

vascular system before being used to unload the left ventricle or aid circulation. (Collins ¶146; EX1004[Aboul-Hosn] 6:22-7:5.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶147.) 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 ¶¶148-164; 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.[17] (Collins ¶149; EX1004[Aboul-Hosn] 8:20-25, 12:22-23).

[17] *See supra,* Fn. 10.

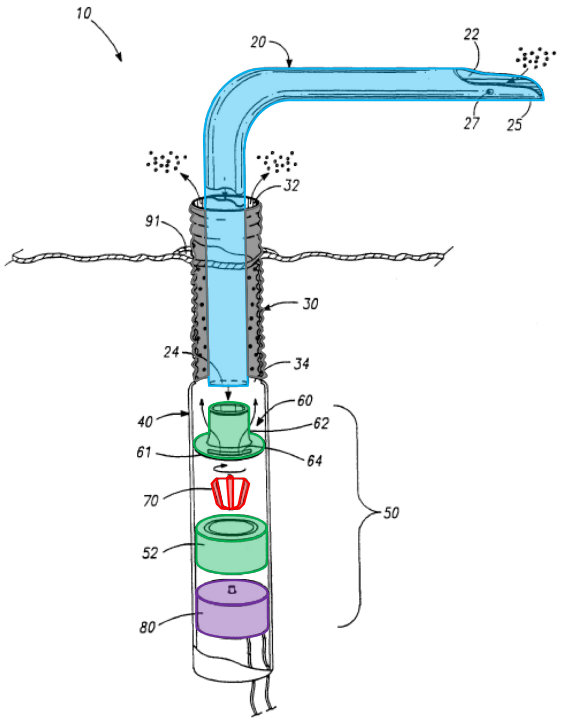


FIG.—1

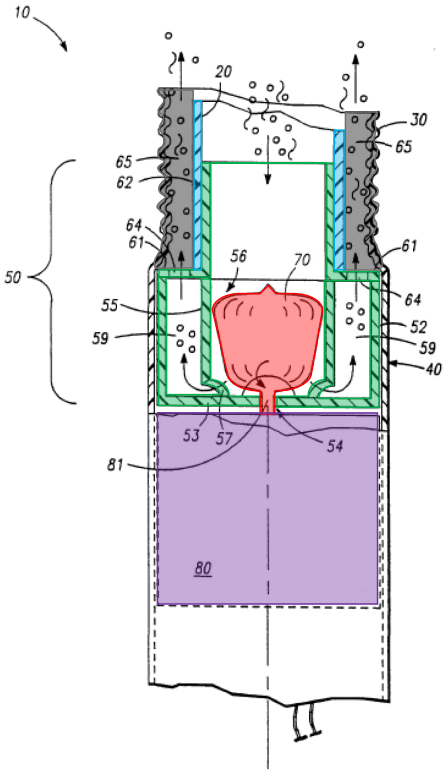


FIG.—2

(Collins ¶150; EX1004[Aboul-Hosn] FIGS. 1 and 2, annotated.)

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 ¶151; 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.)

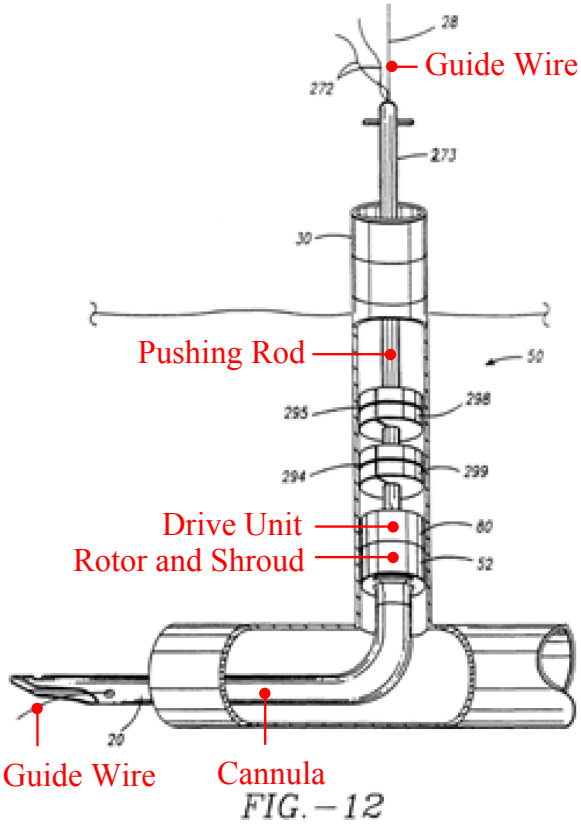


FIG. – 12

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

As shown in FIG. 12, the conduit 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 ¶152; EX1004[Aboul-Hosn] 6:29-7:2.) 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 miniaturized as he contrasts

the intravascular blood pump with the extracorporeal blood pump shown in FIG. 13, which avoids the size constraints of the intravascular blood pump as it is not introduced 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 ¶157.) 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 is not positioned across 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.* ¶157; 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 ¶158; 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 ¶159; 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 ¶159; 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 it may not for the reasons explained above, a POSITA would understand that the blood pump is within the patient's vascular system. (Collins ¶159.)

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.* ¶160; 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, as depicted in FIG. 12 below. (Collins ¶160; EX1029[Guyton] 151.)

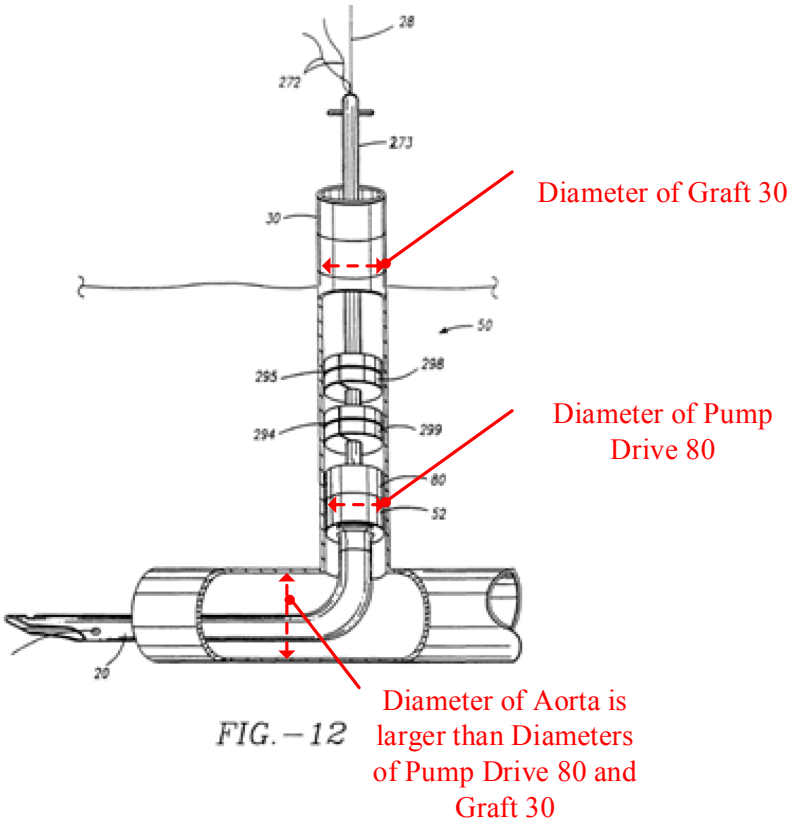


FIG. – 12

(Collins ¶160; EX1004[Aboul-Hosn] FIG. 12, annotated.)

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 ¶160; 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 ¶161.) 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 resulting from frictional head losses associated with a long cannula and requiring a larger pump to offset those losses. (*Id.* ¶162; EX1004[Aboul-Hosn] 14:13-16; EX1032[White] Ch. 6.3; EX1047[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 pump system. (Collins ¶162; EX1004[Aboul-Hosn] 24:26-25:1.)

As such, it would have been preferable to use intravascular blood pumps that can be inserted further distally into the vasculature, closer to the heart, allowing for a shorter cannula while still reaching the desired position across a heart valve. (Collins ¶162.) As shown in FIGS. 21 and 23, Aboul-Hosn expressly contemplated 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.[18] (*Id.* ¶163; EX1004[Aboul-Hosn] 29:17-19, 30:21-24.)

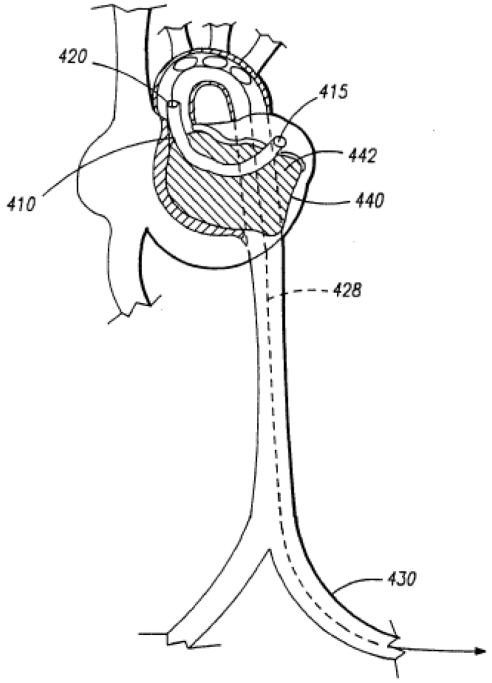


FIG.—21

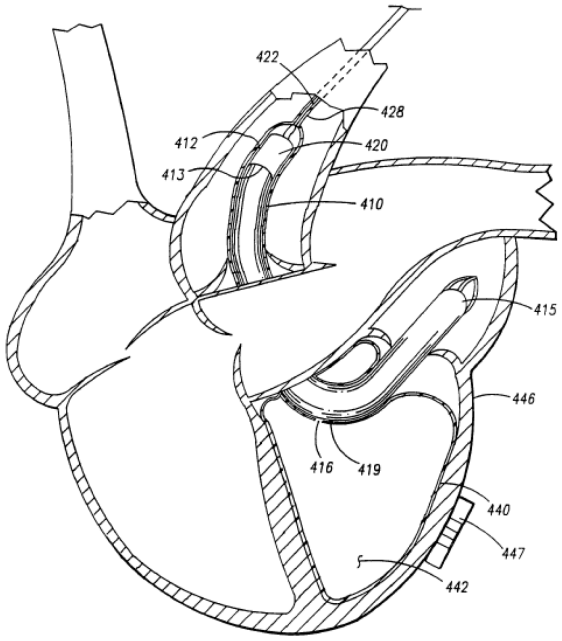


FIG.—23

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

Thus, considered in its entirety, Aboul-Hosn expressly discloses this limitation. (Collins ¶164.)

[18] As Dr. Collins explains, the 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 ¶163.) The multilumen catheter 428 and positioning rod 273 are interchangeable, and can be configured to perform the same functions. (*Id.* ¶163.)

c) "*a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub having a distal end extending distally beyond the most distal portion of the blade*"

The intravascular blood pump of Aboul-Hosn has a rotor having a rotor hub. (Collins ¶¶165-167; EX1004[Aboul-Hosn] FIGS. 7A-7C; 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 extending distally beyond the most distal portion of the blades. (Collins ¶¶165-166.)

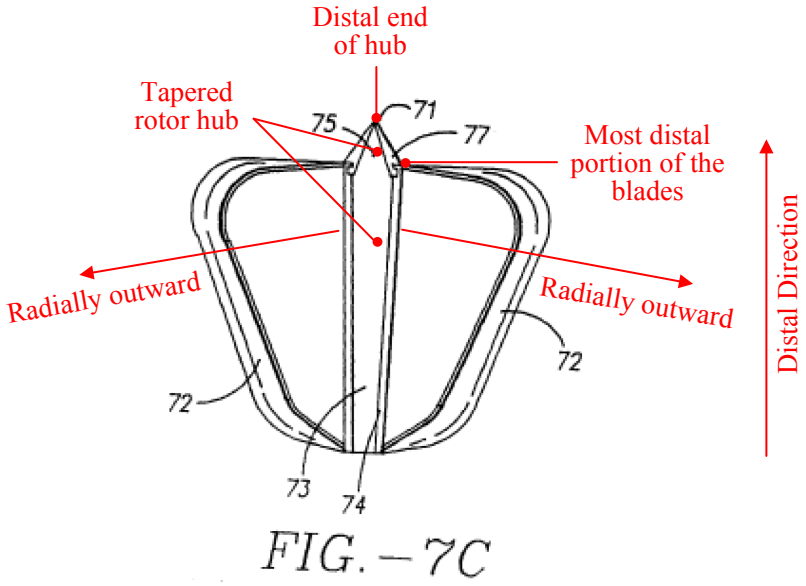


FIG. – 7C

(Collins ¶166; 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.*) 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 ¶165.)

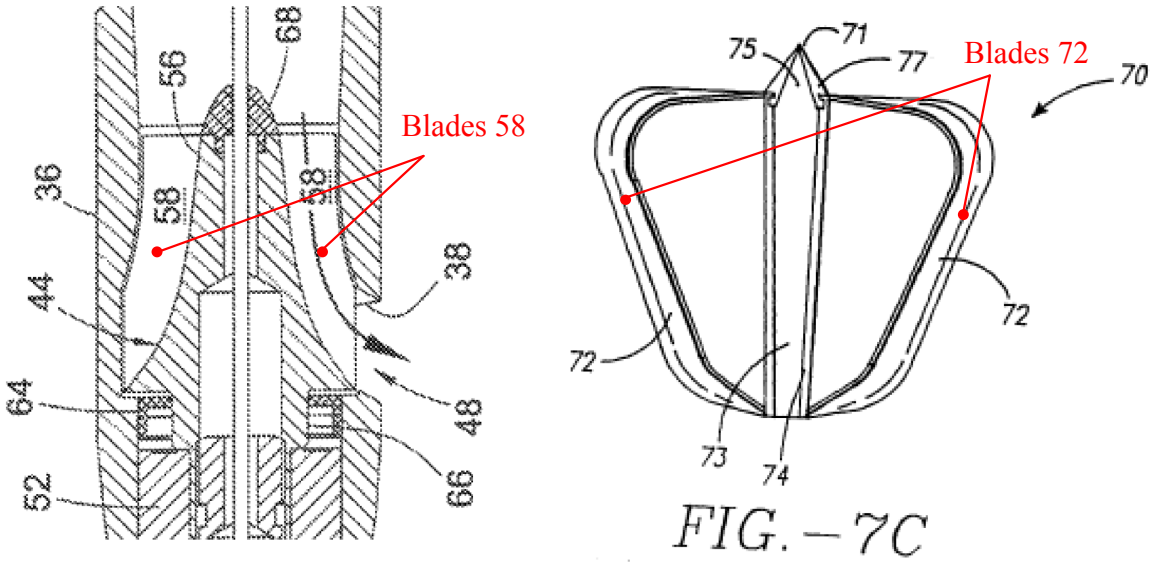


FIG. – 7C

(Collins ¶165; EX1001['068 patent] FIG. 4, annotated (left); EX1004[Aboul-Hosn] FIG. 7C, annotated (right).)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶¶168-169.)

d) *"a shroud within which the rotor is rotatably disposed;"*

As previously discussed in Section VII.A, Aboul-Hosn's blood pump includes a housing body 52 that houses the rotor 70. (Collins ¶170; EX1004[Aboul-Hosn] 12:12-14, 12:31-31:1, 13:7-15.) 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.)

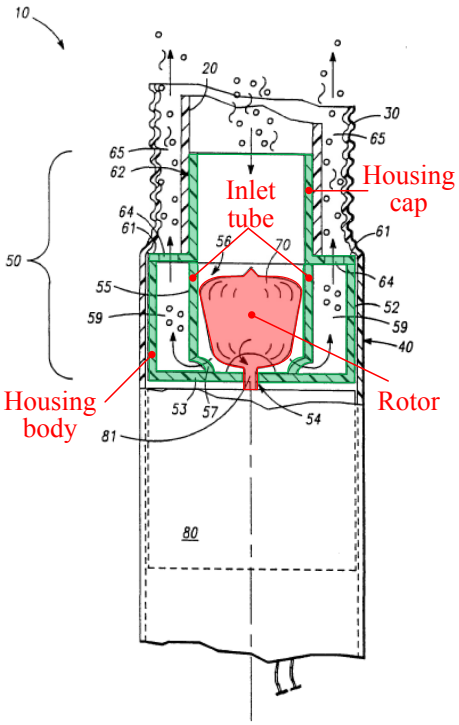


FIG.—2

(Collins ¶171; 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 ¶172.) Moreover, the housing body 52 and housing cap 60 further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "shroud." (Collins ¶173; EX1004[Aboul-Hosn] 13:3-4.)

[19] *See supra,* Fn. 10.

Thus, Aboul-Hosn discloses this limitation. (Collins ¶174.)

e) *"(ii) a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross section along a portion of its length;*"

As shown in annotated FIGS. 1 and 2[20] below, the cannula 20 extends from the inlet neck 62 of the housing cap 60 (green) coupled to the inlet tube 55 (green) (i.e. the "shroud") within the housing body 52. (*Id.* ¶175; EX1004[Aboul-Hosn] 13:2-29.) As discussed in the previous Section, 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, the cannula 20 directly extends from the inlet tube 55 and the inlet neck 62 (i.e. the "shroud"). (Collins ¶176.)

[20] *See supra,* Fn. 10.

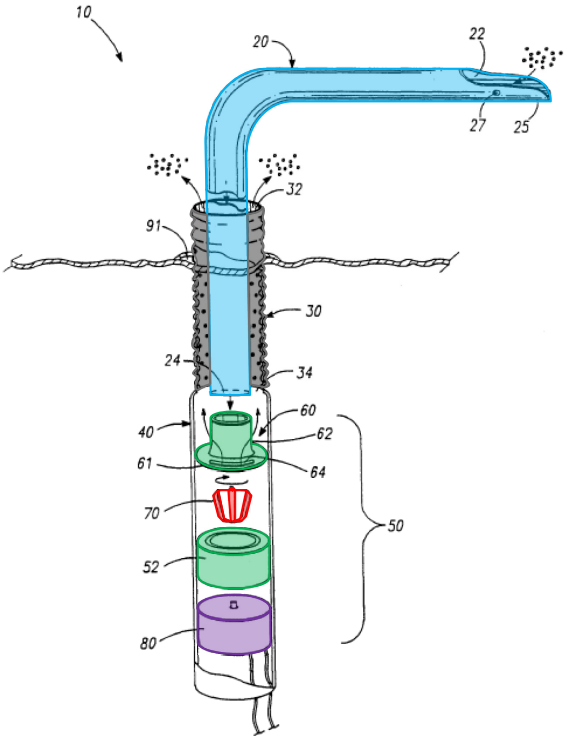


FIG.—1

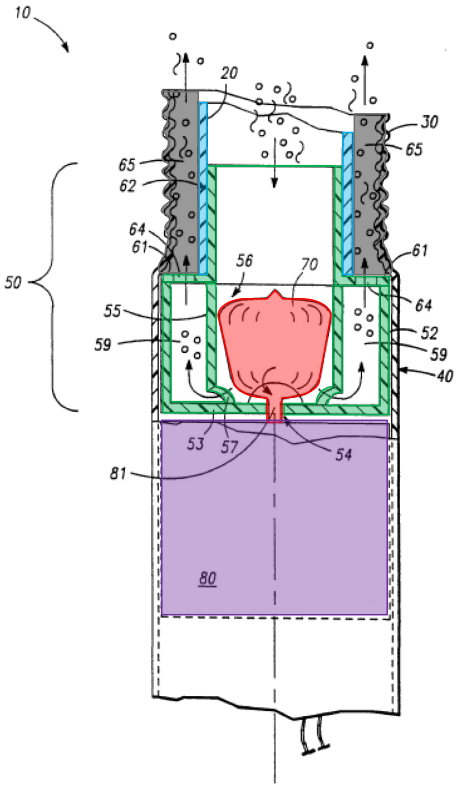


FIG.—2

(Collins ¶175; EX1004[Aboul-Hosn] FIGS. 1 and 2, annotated.)

As also shown in FIG. 3 below, the cannula 20 also has an outer surface and a substantially circular cross section along a portion of its length:

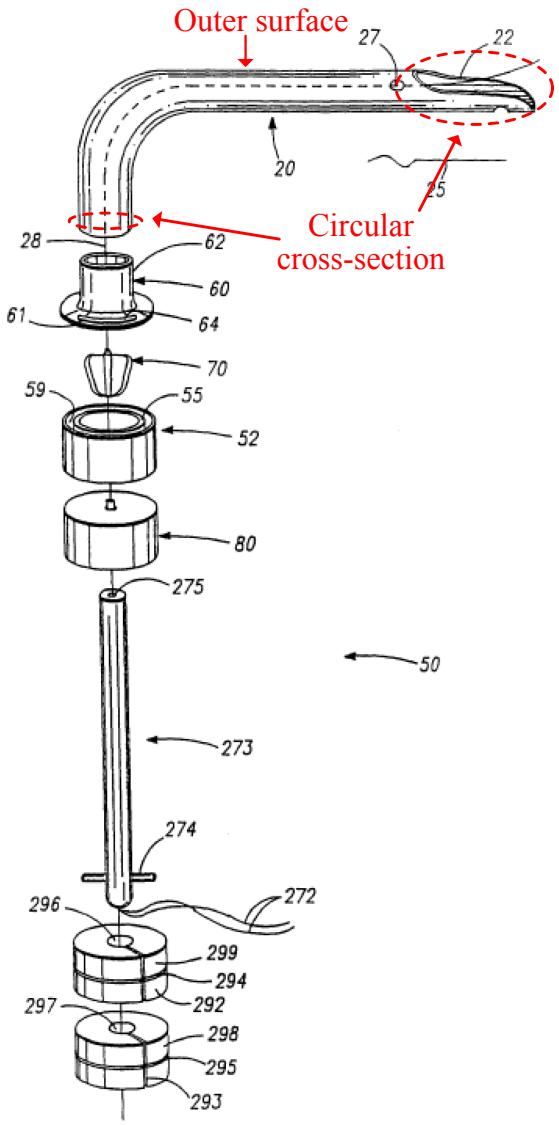


FIG.—3

(Collins ¶177; EX1004[Aboul-Hosn] FIG. 3, annotated.)

FIG. 3 shows a circular opening at the proximal opening 24 and the distal opening 22 of the inner cannula 20 as annotated above, indicating that at least those regions of the inner cannula 20 have a circular cross-section. Aboul-Hosn also discloses that "[a]s with many commercially available cannulas, the inner cannula 20 may be tubular…." (Collins ¶177; EX1004[Aboul-Hosn] 11:14-15.)

Moreover, Aboul-Hosn makes reference to "the outside diameter of cannula 20," making it self-evident that cannula 20 has an outside surface having a substantially circular cross section. (Collins ¶178; EX1004[Aboul-Hosn] 27:20-23.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶179.)

f) *"(iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump*"

As previously discussed in Section V.A, conventional intravascular blood pump systems delivered purge fluid to lubricate a drive unit and keep blood out of the unit. (Collins ¶181.) Aboul-Hosn also discloses using fluid to lubricate the "drive unit 80 that may be used in accordance with the present fluid control and delivery system." (*Id.* ¶182; EX1004[Aboul-Hosn] 20:16-29.) The drive unit 80 has "[a] blood seal 84 [that]…may comprise a central cavity 83 containing a biocompatible lubricating fluid." (*Id*.) The drive unit 80 also includes a groove 205 that attaches to the positioning rod 273, allowing delivery of the biocompatible lubricating fluid to the central cavity 83 of the drive unit 80 through tubes extending through the positing rod 273. (Collins ¶184; EX1004[Aboul-Hosn] 15:6-9, 20:21-23.) FIG. 10, annotated below, is a "simplified sectional side view of the drive unit for a reverse flow blood pump assembly." (*Id.* 9:8-9.)

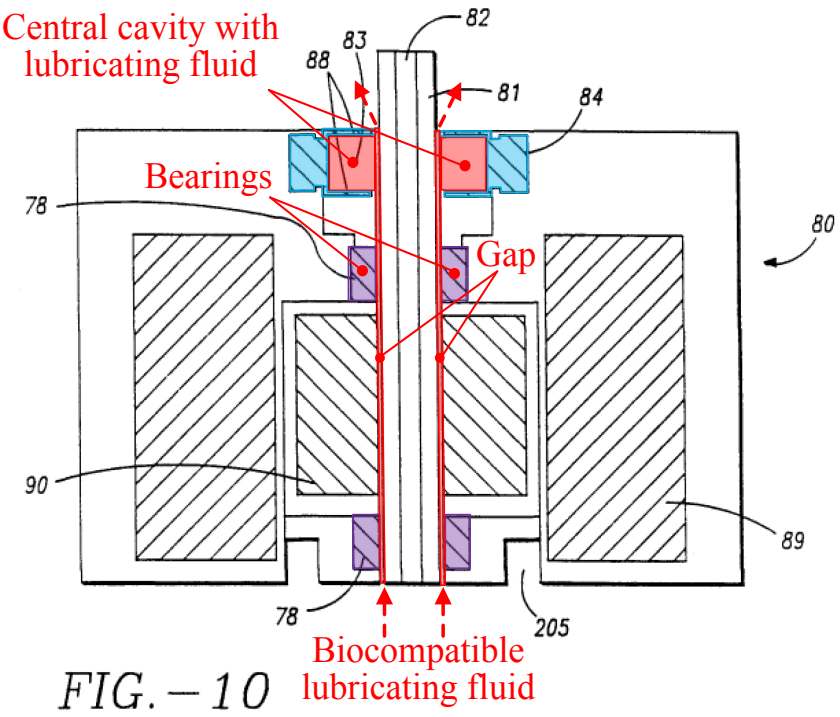


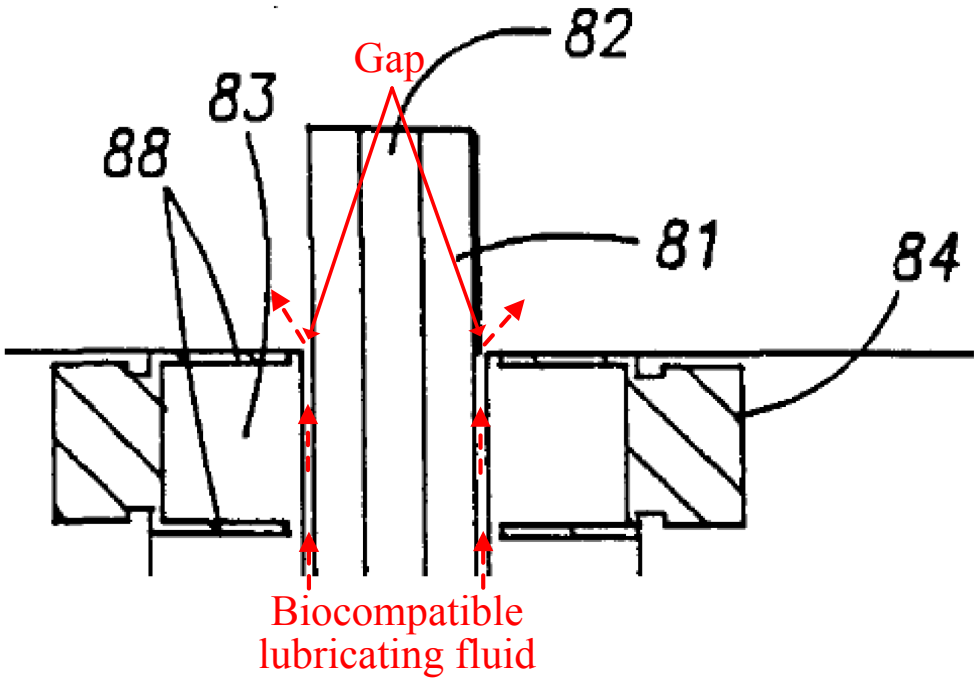
FIG. – 10

(Collins ¶184; EX1004[Aboul-Hosn] FIG. 10, annotated.)

As shown in FIG. 10, the blood seal 84 (blue) includes the central cavity 83 (red), and has "two thin lips 88 that engage the outside diameter of shaft 81 to form a closed chamber to retain the lubricating fluid inside the central cavity 83 during the pump operation." (*Id.* 20:29-31.) The blood seal 84 with two thin lips 88 does not form a perfect seal, and some fluid flows out of the central cavity 83 into a patient's blood stream (through an opening 84 in the rotor shroud which the drive shaft 81 extends to attach to the rotor 70), thereby preventing blood from flowing in the proximal direction into the drive unit. (Collins ¶186.)

Aboul-Hosn further discloses that the fluid is a "biocompatible lubricating fluid," for example a 40% dextrose solution. (EX1004[Aboul-Hosn] 21:1-3.)

Dextrose is a commonly used biocompatible fluid to lubricate mechanical parts of the pump. (Collins ¶187.) Moreover, the fluid needs to be biocompatible because, as described above, there will be some fluid flow out of the central cavity 83 into a patient's blood stream. (*Id.*) As shown in the close-up view of Aboul-Hosn FIG. 10, below, there is a gap between the thin lips 88 of the central cavity 83 and the outside diameter of the shaft 81. (*Id.* ¶187.)



(Collins ¶187; EX1004[Aboul-Hosn] FIG. 10, annotated.)

A POSITA would understand that this gap allows for the biocompatible lubricating fluid to slowly seep outwards from the central cavity 83 and into the blood stream, hence Aboul-Hosn discloses that: 1) the lubricating fluid is biocompatible; and 2) "a continuous infusion of dextrose into the seal area" is desired. (*Id.* ¶189; EX1004[Aboul-Hosn] 21:1-3.) In this manner, the

biocompatible lubricating fluid prevents blood from entering the central cavity 83 adjacent the shaft 81 and clotting, affecting the ability of the shaft 81 to rotate the rotor 70 and harm the patient. (Collins ¶189.)

A POSITA would have readily understood that the biocompatible lubricating fluid is delivered to the central cavity 80 through tubes extending through the central passage 275 of the positioning rod 273. (*Id.* ¶¶190-192; EX1004[Aboul-Hosn] 15:6-9: "the central passage 275 of the positioning rod may … provide for passing wires, tubes or similar accessories needed by the drive unit 80.) Such a configuration was well-known in the art and expressly disclosed by Siess. (Collins ¶190.)

As previously discussed in Section VII.B, like Aboul-Hosn, Siess discloses an intravascular blood pump that "includes a drive unit 11 and a pumping segment 12" coupled to an inlet cannula 13 extending distally from the pumping segment. (EX1005[Siess] 5:41-47.] "The proximal end" of the microaxial pump couples to a catheter 14 "which has been inserted via the femoral artery through the aortic arch 15 and into the ventricle 17." (EX1005[Siess] 5:47-50.) Siess further discloses that "the interior of the drive unit is set into fluid communication with the catheter 14 via duct 78 as is schematically shown in FIG. 8, whereby the void space 76 within the drive unit is continually supplied with a biocompatible purge

fluid such as water sterilized from an extracorporeal source (not shown)." (*Id.* 8:31-36.)

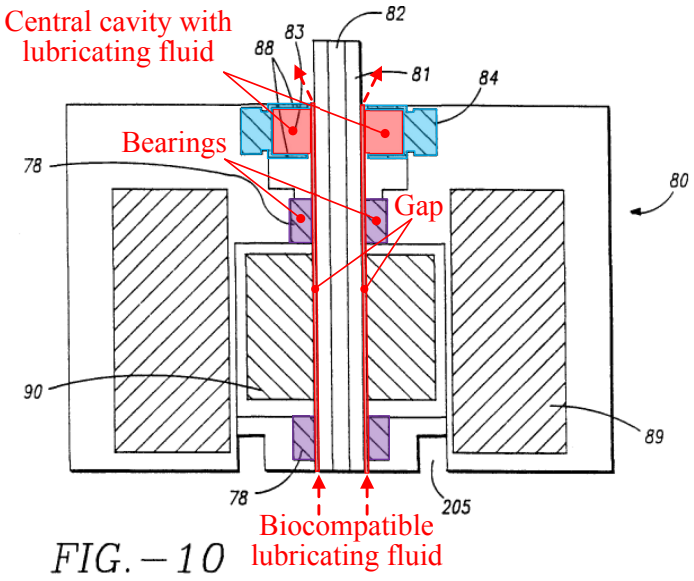
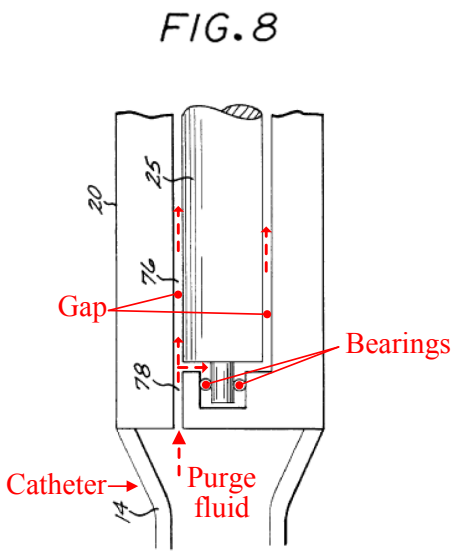


FIG. – 10



(Collins ¶190; EX1004[Aboul-Hosn] FIG. 10, annotated; EX1005[Siess] FIG. 8, annotated.)

Consistent with how a POSITA would understand Aboul-Hosn's disclosure, Siess confirms that "[t]he purge fluid is pressurized so as to maintain a slow purge rate over the seals [of the drive unit 11] of about 1-5 ml/hr." (Collins ¶187; EX1005[Siess] 8:36-38.) This "precludes the incursion of bodily fluid into the drive unit and additionally extends the service life of the seals as the purge fluid continually lubricates the rotating seal interface as it is slowly forced thereacross." (*Id.* 8:36-41.)

A POSITA would have been motivated to "operatively arrange[]" the tubes extending through the central passage 275 of the positioning rod 273 of Aboul-Hosn to provide continuous infusion of biocompatible lubricating fluid to the seal cavity 83 of the drive unit 80 of Aboul-Hosn in the manner disclosed by Siess '913. (Collins ¶192.) Doing so would have been nothing more than routine application of a known technique in the art (connecting the duct of the catheter to the seals within the drive unit to deliver a continuous infusion of purge fluid) to a similar device (intravascular blood pumps) in order to achieve the same results (lubrication of rotating seal interfaces and precluding the incursion of blood into the drive unit). (*Id.* ¶¶192-193.)

Thus, Aboul-Hosn in view of Siess discloses this limitation. (Collins ¶194.)

g) *"(iv) a guide mechanism configured as a second lumen having a proximal end and a distal end,"*

As previously discussed in Section VII.A, Aboul-Hosn discloses placing a blood pump system in a desired location using a guide wire 28. (Collins ¶195; EX1004[Aboul-Hosn] 17:19-20.) As shown in annotated FIG. 3, the guide wire 28 passes through a central passage (i.e. a lumen) running through the motor 80, rotor 70, housing cap 60, and inner cannula 20, and exiting through the distal opening 22 of the cannula. (Collins ¶195.)

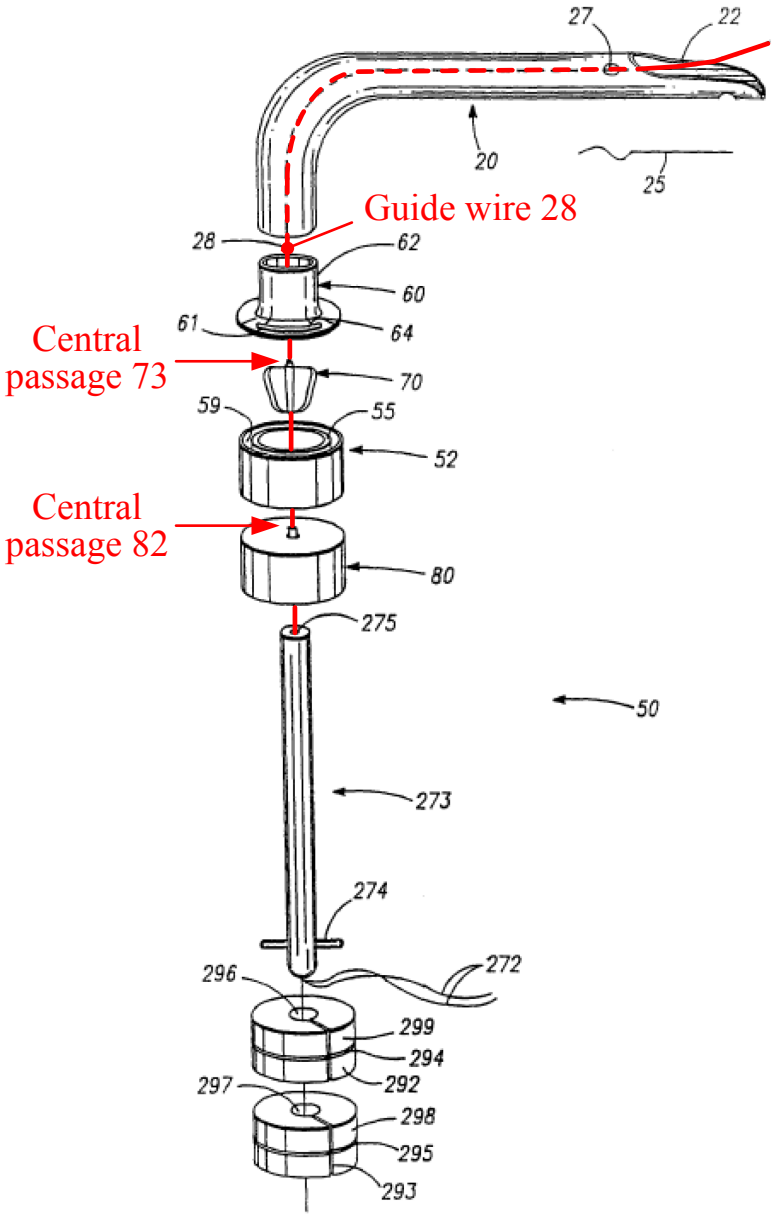
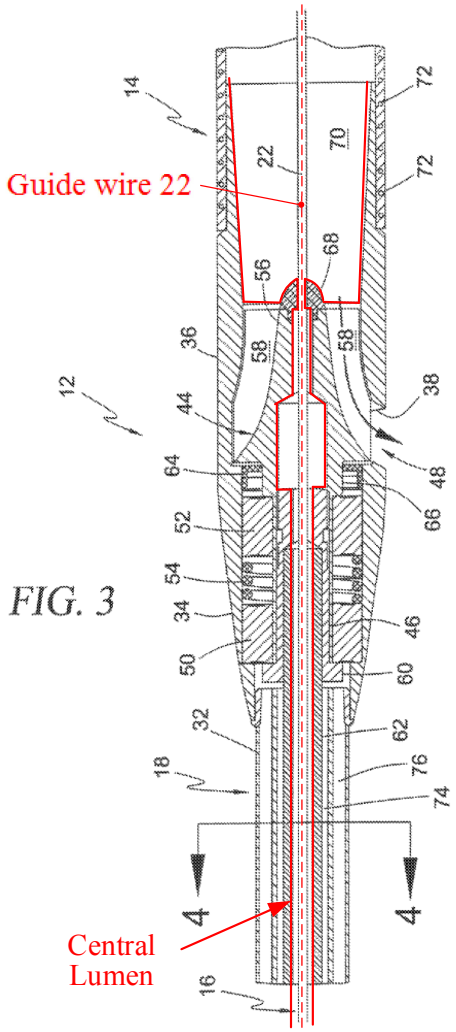


FIG.–3

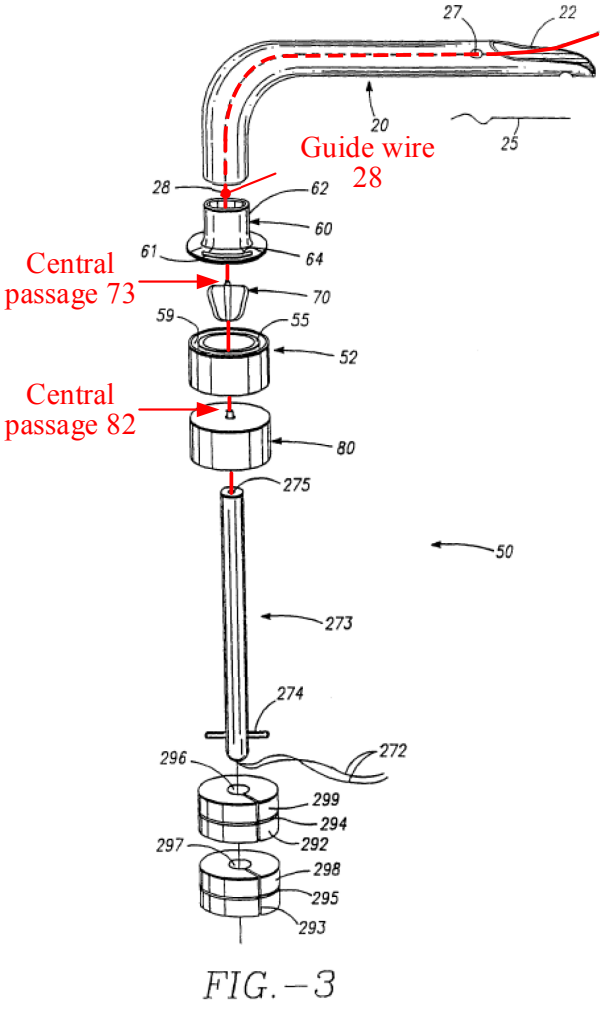
(Collins ¶195; EX1004[Aboul-Hosn] FIG. 3, annotated)

Aboul-Hosn discloses that the central passage "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, Aboul-Hosn's central passage (right) has the same configuration as the guide mechanism in the over-the-wire embodiment of the '068 patent (left). (*Id.* ¶199.)



'728 Patent



Aboul-Hosn

(Collins ¶199; 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 the positioning rod 273, drive unit 80, rotor 70, and inner cannula 20 have respective co-aligned lumens or central passages creating a single continuous lumen through those components—consistent with the “over-the-wire” guide mechanism of the ’068 Patent. (Collins ¶200.)

This central passage/lumen of Aboul-Hosn is a “second lumen” different from the purge fluid lumen (i.e. the “first lumen”), the proximal end of the “second lumen” corresponding to the proximal end of the positioning rod 273 located towards outside of the patient’s body and the distal end of the “second lumen” corresponding to the distal end of the cannula 20. (*Id.* ¶201; EX1004[Aboul-Hosn] FIG. 3.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶202.)

h) “*the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;*”

This limitation only requires a “distal portion” of the intravascular blood pump be guided to a location within the patient’s circulatory system. (Collins ¶203.) 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 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.) In this manner, Aboul-Hosn teaches the guide wire extending through the central passage of the intravascular blood pump (i.e. the "second lumen") positions the distal end of the cannula in any heart chamber or blood vessel, as shown in FIG. 12. (Collins ¶209; EX1004[Aboul-Hosn] 11:8-11, 11:24-28.)

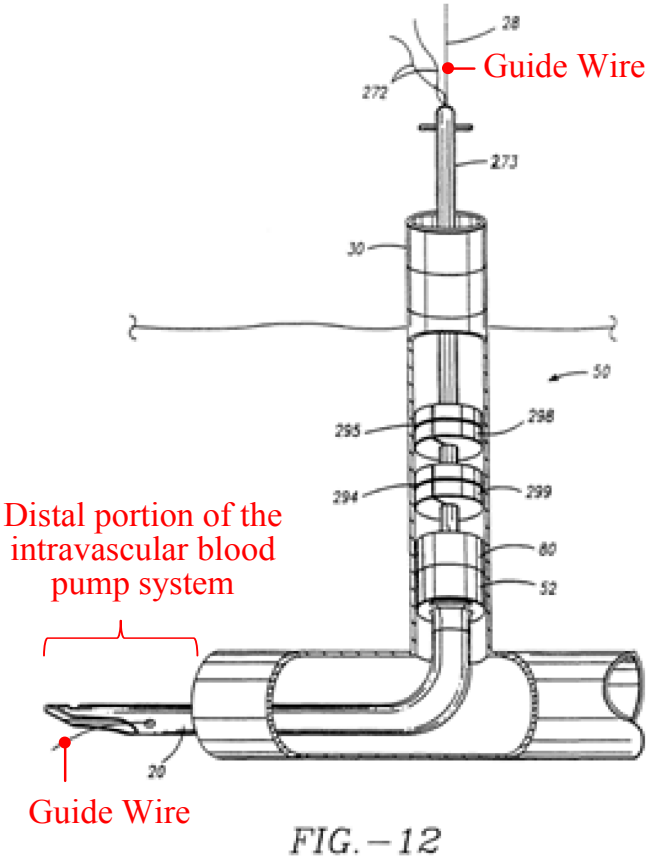


FIG. – 12

(Collins ¶209; EX1004[Aboul-Hosn] FIG. 12, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶210.)

i) "*wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface,*"

The '068 patent does not identify any "region" as being "delimited by the outer cannula surface." Under the USPTO's broadest reasonable interpretation (BRI) standard, the support, if any, must be deduced from the figures. (*SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1348 (Fed. Cir. 2016).) Under the BRI standard, the "region delimited" includes any part of the cannula inside its

outer surface, including the region shown in FIGS. 8 and 9 of the ’068 patent, and any space within the cannula’s inner lumen. (Collins ¶211; EX1001[’068 patent] 12:21-26.)

As shown in annotated FIG. 3, the region delimited by the outer cannula surface corresponds to the region bounded by the outer circumference of the inner cannula 20. (Collins ¶212.) Under the BRI standard, an axis coaxial with a portion of the guide mechanism and extending through a portion of the guide mechanism (i.e., an axis that extends distally through the center of the central passages 82 and 73 of the drive unit 80 and rotor hub 74, respectively, and the housing cap 60) extends through the interior passageway of the inner cannula 20 (i.e. through the region delimited by the outer cannula surface) highlighted in green. (*Id.* ¶213.)

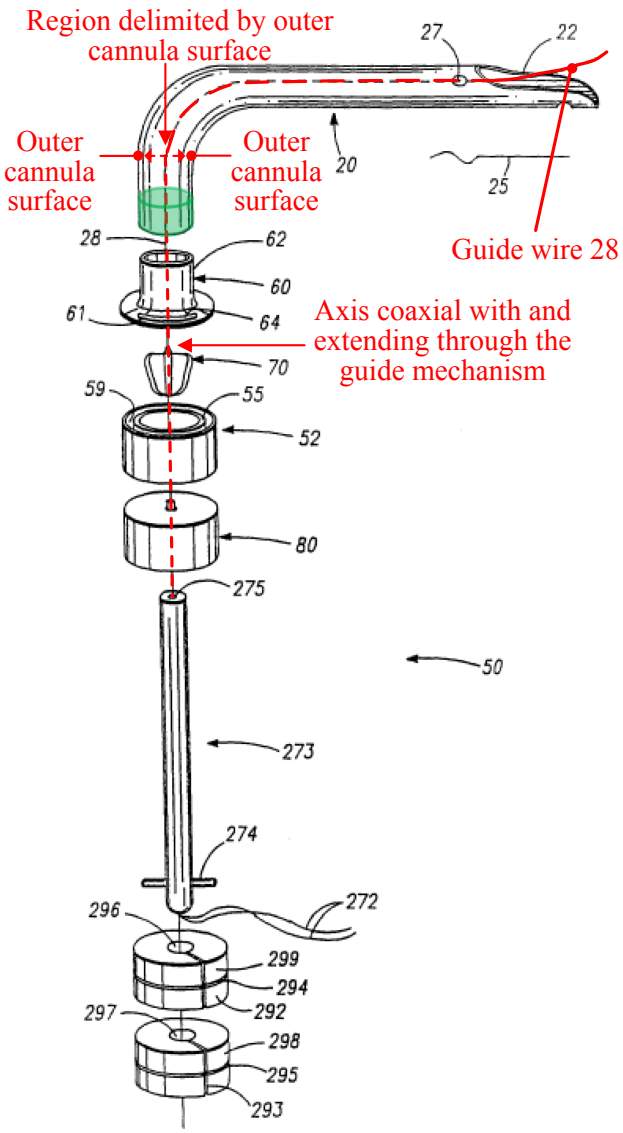


FIG.—3

(Collins ¶212; EX1004[Aboul-Hosn] FIG. 3, annotated.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶216.)

j) "*and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong,*"

Again, as in FIG. 3, Aboul-Hosn discloses the guide wire 28 passes through the central passages of the drive unit 80, rotor hub 74, housing cap 60, and inner cannula 20, and exits out of the distal opening 22. (Collins ¶218; EX1004[Aboul-

Hosn] 24:8-12.) The distal end of the inner cannula 20 is guided to the desired location by sliding the intravascular blood pump system over the guide wire 28. (Collins ¶219; EX1004[Aboul-Hosn] 22:12-16, 24:12-14.)

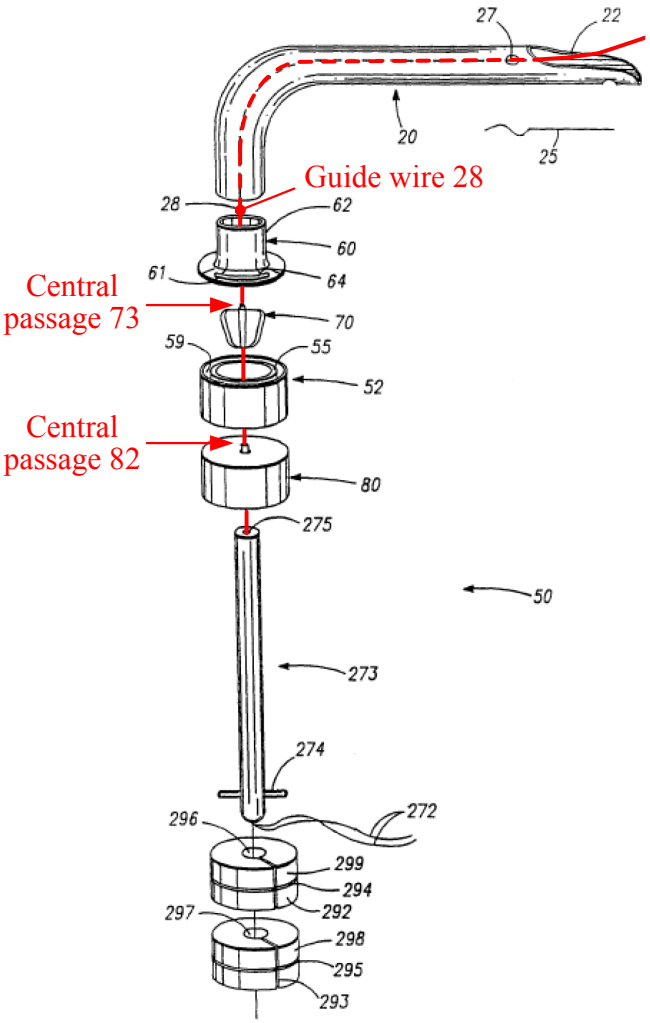


FIG.—3

(Collins ¶219; EX1004[Aboul-Hosn] FIG. 3, annotated)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶220.)

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

As described in Sections VII.A and X.A.1(h), Aboul-Hosn discloses progressing a guide wire to a predetermined location in a particular location in the body, for example in a blood vessel or heart chamber of the patient using imaging techniques. (Collins ¶¶221-222; EX1004[Aboul-Hosn] 22:10-12, 22:12-14.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶223.)

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

As described in Sections VII.A and X.A.1(h), Aboul-Hosn discloses advancing the blood pump system along the guide wire to the predetermined location in the patient's body. (*Id.* ¶¶224-225; EX1004[Aboul-Hosn] 22:12-16.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶226.)

2. Claim 5

Claim 5 depends from claim 1 and recites *"wherein the second lumen has an inner diameter along a portion of its length that is substantially smaller than an outer diameter of the outer cannula surface, and the length of the second lumen is substantially longer than the inner diameter of the second lumen"*

Although the '068 Patent provides no details regarding the meaning of "substantially smaller" or "substantially longer," Aboul-Hosn discloses a lumen much smaller than an outer diameter of the cannula, and much longer in length relative to the lumen inner diameter. (Collins ¶228.) As FIG. 3 of Aboul-Hosn

shows, the guide wire passes through a second lumen formed from the central passages through the pump components. (Collins ¶229.)

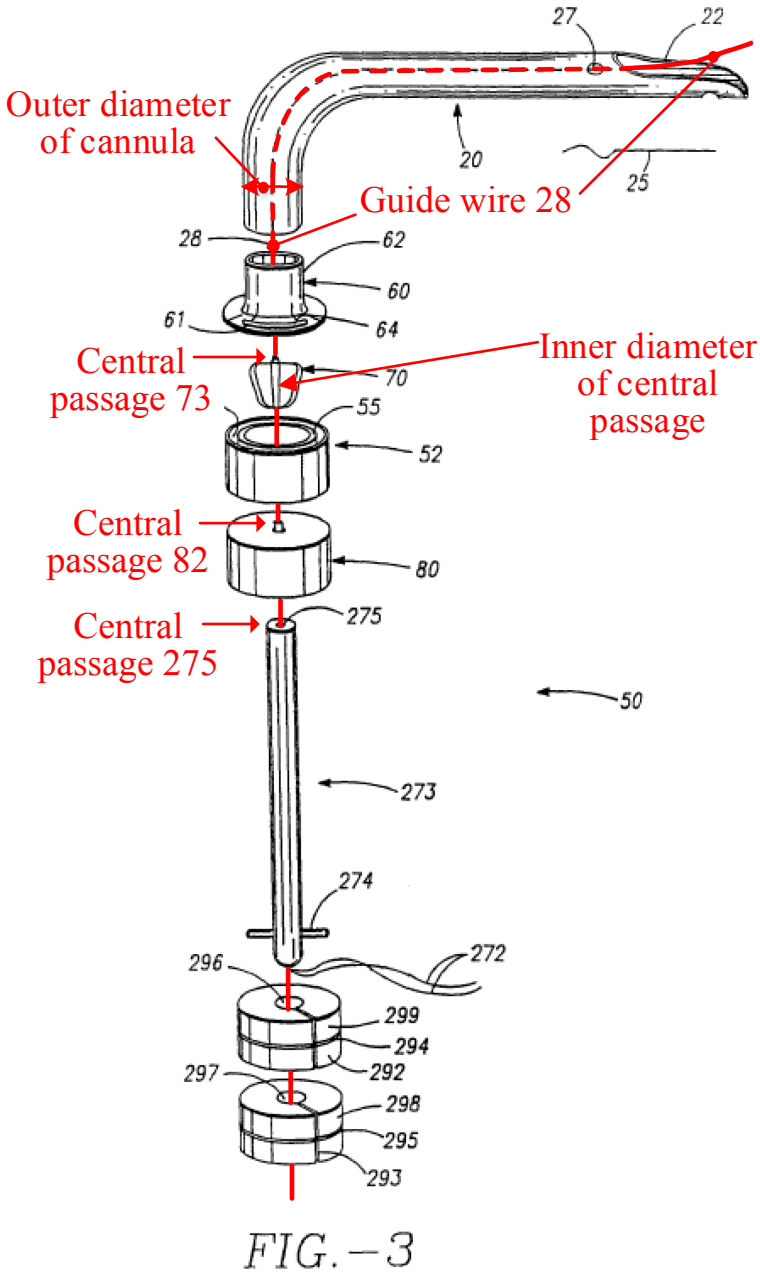


FIG.—3

(Collins ¶230; EX1004[Aboul-Hosn] FIG. 3, annotated)

A POSITA would know that conventional dimensional ranges for the cannula diameter are significantly larger than a diameter of the central passageway shown in FIG. 3. (Collins ¶231.)

Further, the central passageway extends through each of the components of the blood pump, and is clearly many orders of magnitude longer than a width of the central passageway. (Collins ¶233.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶235.)

B. Ground II: Claim 7 is obvious in view of Aboul-Hosn and Siess, and further in view of Sammler.

1. Claim 7

Claim 7 depends from claim 1 and further recites:

a) "*an elongate catheter extending proximally with respect to the intravascular blood pump; and*"

As shown in FIG. 12, Aboul-Hosn discloses the positioning rod coupled to the proximal end of the drive unit 80 to push the intravascular blood pump system into the conduit 30. (Collins ¶237; EX1004[Aboul-Hosn] 20:21-23.) The positioning rod 273 extends in the proximal direction in relation to the blood pump. (Collins ¶238.)

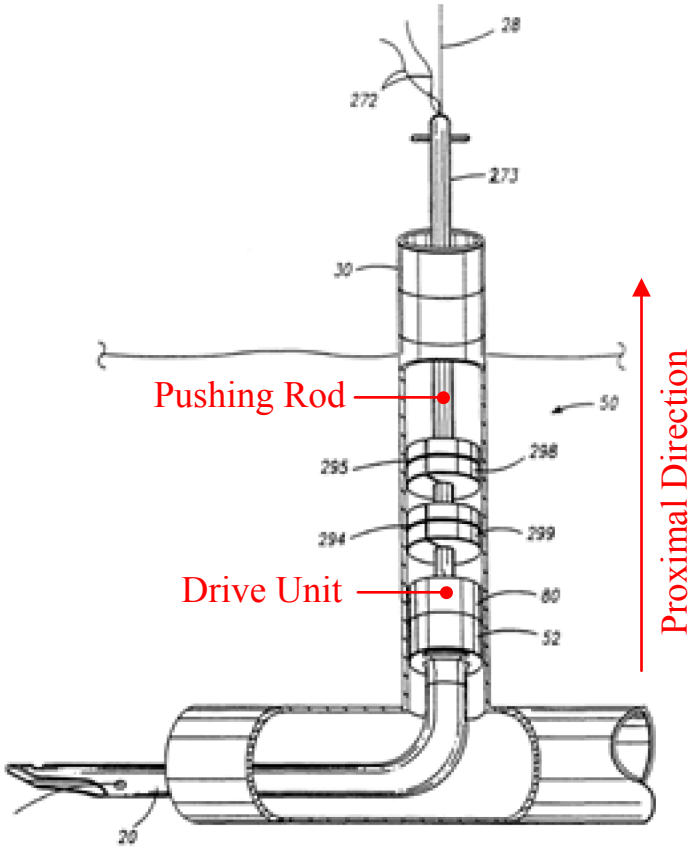


FIG. – 12

(Collins ¶237; EX1004[Aboul-Hosn] FIG. 12, annotated.)

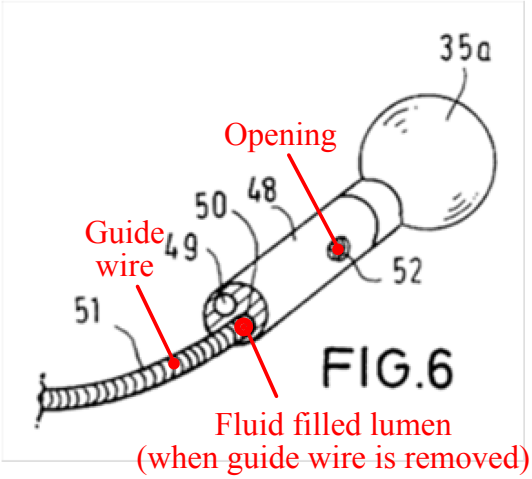
Aboul-Hosn discloses the positioning rod 273 includes a central passageway 275 "for passing wires, tubes or similar accessories needed by the drive unit 80" when the blood pump system is positioned within the vasculature. (Collins ¶238; EX1004[Aboul-Hosn] 15:6-9.) As such, the positioning rod 273 is an elongate catheter that extends proximally with respect to the intravascular blood pump. (Collins ¶238.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶239.)

b) "*a blood pressure detection mechanism comprising a fluid column disposed within the catheter and configured to detect the pressure of the blood proximate the intravascular blood pump.*"

The '068 patent is silent regarding what it means to "detect the pressure of the blood proximate the intravascular blood pump," what constitutes the "fluid column," and how the "fluid column" would be "disposed within the catheter." (Collins ¶240.) Under the BRI standard, we assume this limitation requires the elongate catheter have a fluid column for transmitting blood pressure near the blood pump (*id.*), which Aboul-Hosn in view of Sammler discloses.

As Dr. Collins explains, intravascular blood pump systems using fluid-filled columns to measure blood pressure within or near the pump system were well-known. (Collins ¶241.) Sammler is one such pump system. (*Id.*; EX1045[Sammler] 6:8-12.) As FIG. 6 illustrates, Sammler discloses a lumen 50 for passing a guide wire 51 that extends through a catheter 48 and 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 ¶241; EX1045[Sammler] 3:24-26, 6:5-7.)

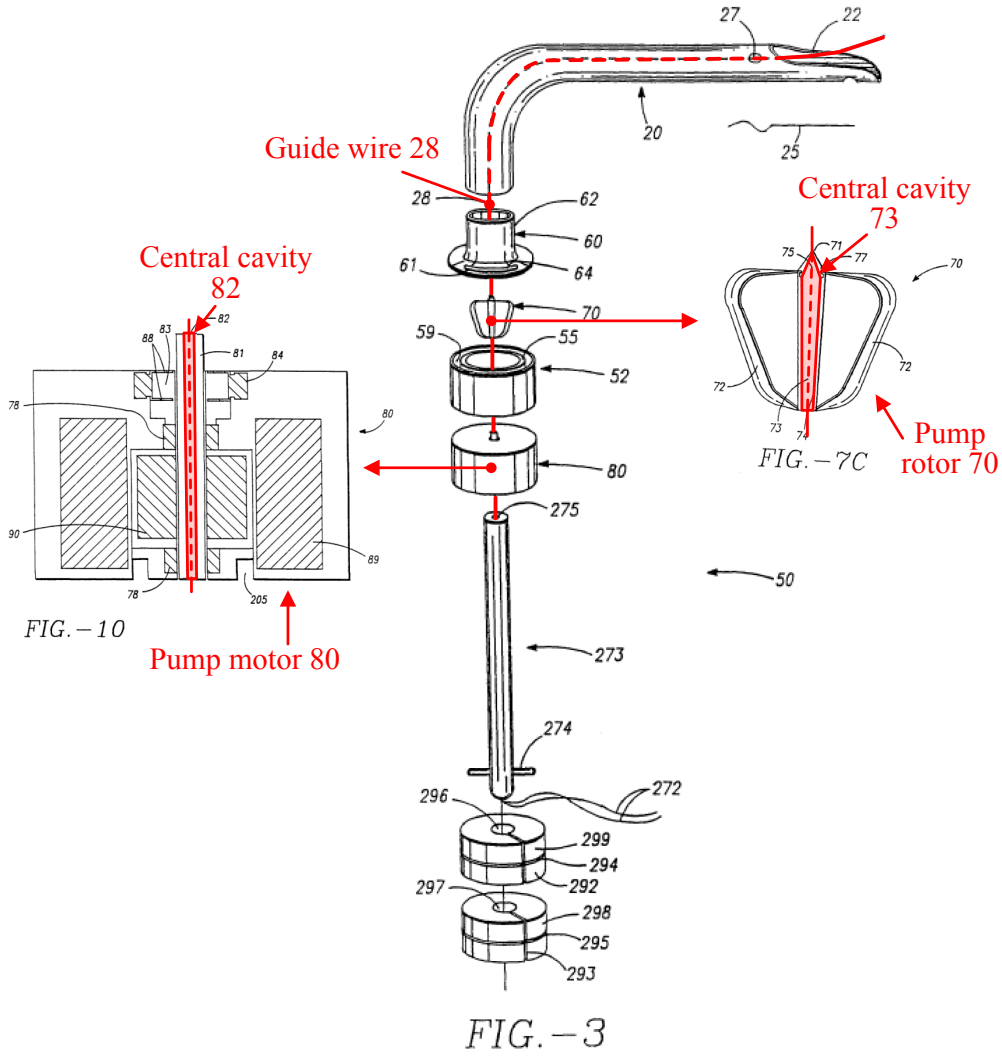


(Collins ¶241; EX1045[Sammler] FIG. 6, annotated.)

Sammler further teaches the lumen 50 can be used "for external pressure measurement" after "removal of the guide wire" by using "an opening 52," shown in FIG. 6, that "can be provided on the catheter 48, which is connected to the lumen 50 and which is blocked by 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 ¶241; EX1045[Sammler] 6:3-10.) The lumen 50 is "connected to a blood pressure measuring instrument" to measure the blood pressure adjacent the opening 52. (*Id.*; EX1045[Sammler] 6:10-12.)

Aboul-Hosn can be configured to detect blood pressure in the same manner as Sammler. (Collins ¶242.) As previously discussed in Sections X.A.1(g)-(l), Aboul-Hosn, like Sammler, discloses using a guide wire extending 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 vasculature

as shown in annotated FIGS. 3, 7C, and 10. (*Id.* ¶242; EX1004[Aboul-Hosn] 17:8-22, 20:23-26, 21:6-10, 24:7-14.)



(Collins ¶242; 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 used as a passageway for a fluid-filled lumen to detect the blood pressure at an opening exposed by removal of the guide wire as

Sammler teaches. (Collins ¶243; EX1004[Aboul-Hosn] 15:4-6, 22:14-16; EX1045[Sammler] 3:26-27, 6:8-12.) As taught by Sammler, blood enters 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 removing the guide wire 28. (Collins ¶244; EX1004[Aboul-Hosn] 17:11-12; EX1045[Sammler] 6:8-12.) Thus, Aboul-Hosn's intravascular blood pump system can be configured to detect 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 ¶244.)

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.* ¶245.) Like Sammler, Aboul-Hosn contemplated 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 ¶245; 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 (i.e., pressure sensors) to Aboul-Hosn's intravascular blood pump system, thereby increasing complexity and cost of the pump system due to the need to attach and route 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 ¶246; EX1004[Aboul-Hosn] 17:11-12.) A POSITA would have been naturally motivated to do so to provide 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 significantly reconfiguring the system or components. (Collins ¶246.)

Thus, Aboul-Hosn in view of Sammler discloses this limitation. (*Id*. ¶247.)

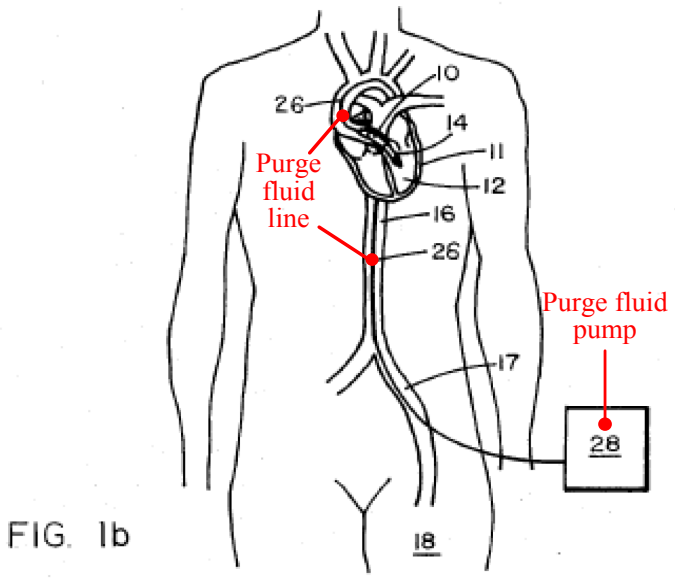
C. Ground III: Claim 9 is obvious in view of Aboul-Hosn and Siess '913, and further in view of Wampler.

1. Claim 9

Claim 9 depends from claim 1, and further recites: "*a first conduit and a second conduit, at least one of the first conduit or the second conduit terminating in a fitting that is configured to be located outside a patient when the intravascular blood pump and cannula are located inside the patient, at least one of the first conduit and second conduit in fluid communication with the first lumen.*"

As previously discussed in Section X.A.1(f), Aboul-Hosn in view of Siess discloses a first lumen in fluid communication with the intravascular blood pump operatively arranged to deliver purge fluid to the pump. (Collins ¶248; EX1004[Aboul-Hosn] 20:16-19, 29:19-25; EX1005[Siess] 8:31-41.)

It was well-known that purge fluid systems included a pump located outside of the patient's body to continuously deliver purge fluid. (Collins ¶250.) As shown in FIG. 1b of Wampler '712, a purge fluid pump 28 connects to a catheter 26 to deliver a "continuous flow of purge fluid 50 … into the pump 10 under pressure through the catheter 26." (EX1009[Wampler '712] 3:40-44.)



(Collins ¶250; EX1009[Wampler '712] FIG. 1b, annotated.)

Figure 14-2 of Wampler shows a schematic of the Hemopump.

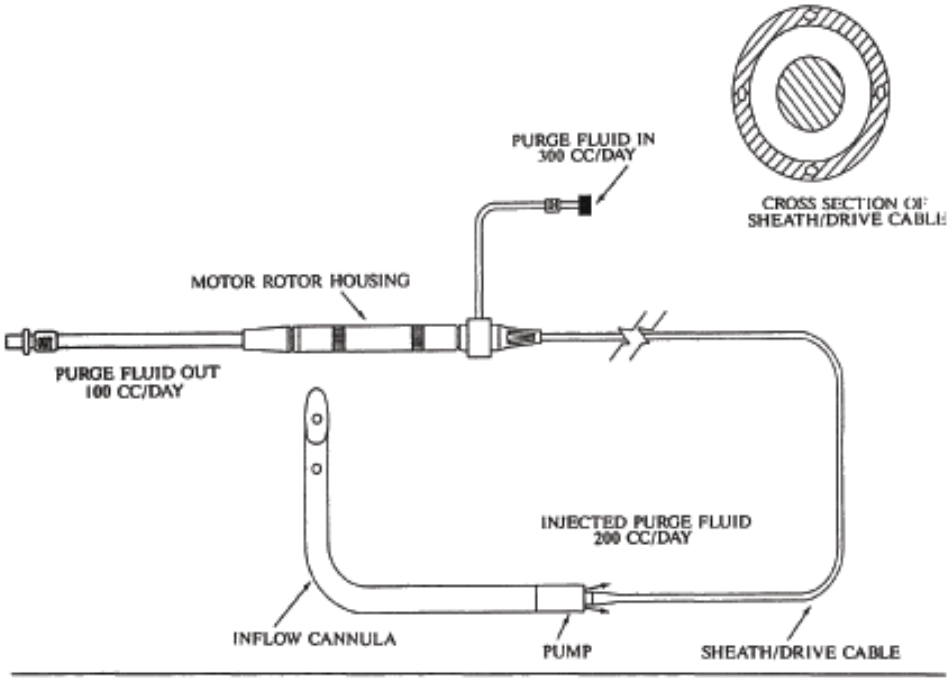


Figure 14-2. Schematic of the Hemopump.

(EX1008[Wampler] Figure 14-2.)

As shown in Figure 14-2 of Wampler, a "roller pump that controls the delivery and collection rates of the purge fluid lubricant" delivers purge fluid via the "Purge Fluid In" and "Purge Fluid Out" conduits fitted to the control console shown in Figure 14-3 using the fittings at the end of the respective conduits. (Collins ¶251; EX1008[Wampler] 233-34.) The roller pump provides continuous infusion of 40% dextrose in water (D40W) purge fluid to the pump via lumens of the sheath, a portion of the fluid flows across the pump seal into the patient and a portion is returned through another lumen of the sheath to a return bag. (Collins ¶254; EX1008[Wampler] 234.) Similar to Wampler, Aboul-Hosn discloses a "40% dextrose solution may also be used as a lubricating fluid with a continuous

infusion of dextrose into the seal area" of the blood pump. (EX1004[Aboul-Hosn] 21:1-3, 29:19-23.)

To provide the "continuous infusion of dextrose into the seal area" taught by Aboul-Hosn, it would have been obvious to a POSITA, and a POSITA would have recognized, that Aboul-Hosn use a purge fluid pump such as the roller pump disclosed by Wampler to provide purge fluid via the "Purge Fluid In" and "Purge Fluid Out" conduits in and out of the blood pump through tubes extending through the positioning rod 273 of Aboul-Hosn. (Collins ¶255.) Both Aboul-Hosn and Wampler used the same purge fluid (40% dextrose solution) delivered in the same manner (continuously via lumens within a catheter or sheath) for the same purpose (lubrication of pump components and to prevent blood from entering the pump). (*Id.* ¶254; EX1004[Aboul-Hosn] 20:16-19, 21:1-3, 29:19-25; EX1008[Wampler] 234.) Moreover, doing so would have been nothing more than an application of a well-known and conventional element originally used in the Hemopump to achieve the "continuous infusion of dextrose into the seal area" taught by Aboul-Hosn. (Collins ¶255.)

Thus, Aboul-Hosn in view of Siess, and further in view of Wampler, discloses this limitation. (*Id.* ¶256.)

D. Ground IV: Claims 1 and 5 are obvious over Sammler in view of Rau, and further in view of Aboul-Hosn and Siess.

1. Claim 1

a) *See* element 1.a, Section X.A.1(a), above.

As shown in FIG. 1, Sammler's intravascular blood pump is "positioned as a heart pump such that it delivers [blood] from the right atrium into the pulmonary artery 26." (Collins ¶257; EX1045[Sammler] 2:6-9, 4:15-16, 4:38-40.)

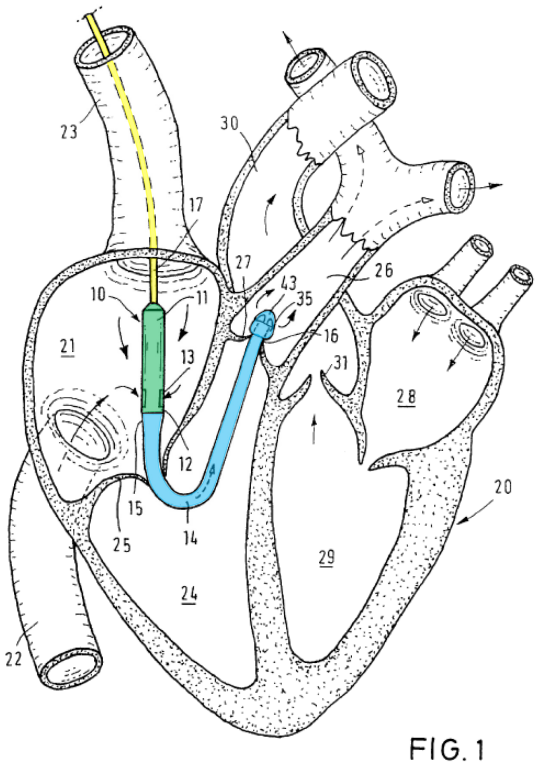


FIG. 1

(Collins ¶257; EX1045[Sammler] FIG. 1.)

Thus, Sammler discloses this limitation. (Collins ¶259.)

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

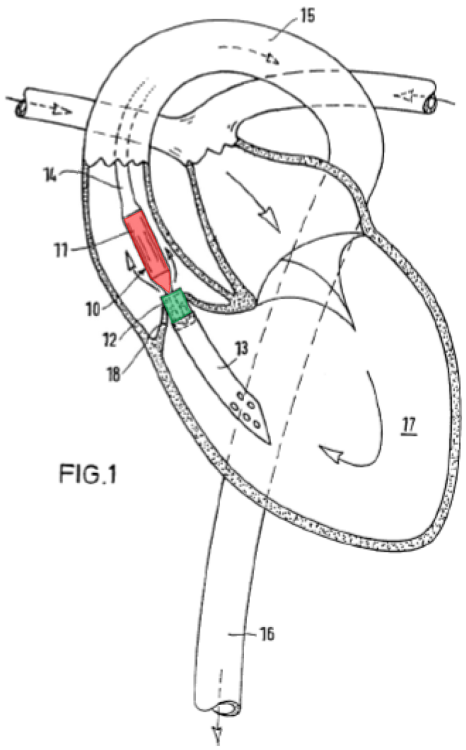
As shown above in annotated FIG. 1, Sammler's intravascular blood pump system includes an intravascular blood pump. (Collins ¶260; EX1045[Sammler] 4:15-16.) As previously discussed in Section VII.B, the "blood pump 10" (green) comprises two distinct components: (1) a drive section 11 and (2) a pump section

12 that "comprises an impeller (not shown), which drives the blood in an axial direction." (Collins ¶260; EX1045[Sammler] 4:21-22.) Sammler discloses the blood pump 10 corresponds to the intravascular blood pump disclosed by Rau, prefaced in Section VII.C. (Collins ¶260; EX1045[Sammler] 4:17-18.)

Thus, Sammler discloses this limitation. (Collins ¶261.)

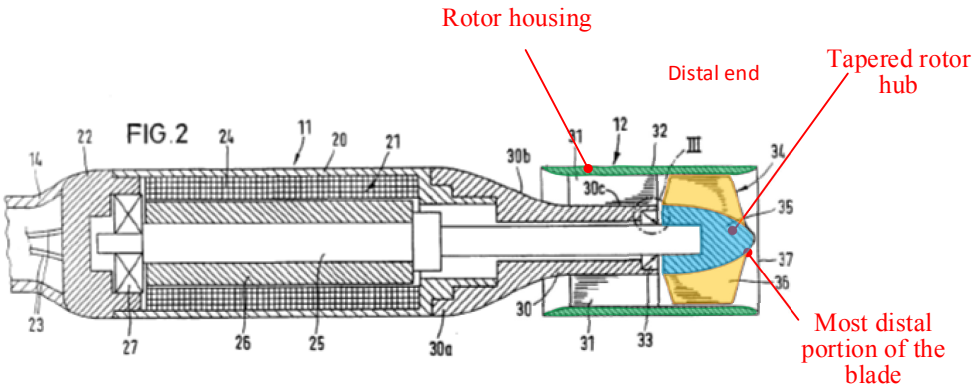
c) *"a rotor having a rotor hub tapering in the distal direction, … the hub has a distal end extending distally beyond the most distal portion of the blade and"*

Sammler explains that because the blood pump 10 corresponds to the pump disclosed by Rau, "its internal structure will not be explained in greater detail here." (Collins ¶262; EX1045[Sammler] 4:18-19.) As previously discussed in Section VII.C, like Sammler, Rau discloses an intravascular "blood pump 10 for left cardiac assistance" which "comprises a motor part 11" (red) and "a pump part 12" (green), and which are "arranged coaxially one after the other" as shown in annotated FIG. 1. (Collins ¶264; EX1046[Rau] 5:17-19.)



(Collins ¶264; EX1046[Rau] FIG. 1, annotated.)

As shown below in FIG. 2, Rau discloses the motor part 11 of the blood pump 10 "comprises an elongate cylindrical housing 20, in which the electric motor 21 is accommodated," and the pump part 12 includes a "cylindrical tubular pump housing 32" in which "[t]he motor shaft 25 protrudes" and "carries an impeller 34 with a hub 35 sitting on the shaft end and with blades 36 or pump blades protruding therefrom." (Collins ¶265; EX1046[Rau] 6:22-24, 7:1-2.)



(Collins ¶265; EX1046[Rau] FIG. 2, annotated.)

As shown above, the impeller 34 (i.e. rotor) has a rotor hub 35 (blue) tapering in the distal direction along the entire length of the hub, and a portion extending beyond the most distal portion of the blades 36 (yellow). (Collins ¶266; EX1046[Rau] 7:1-2.)

Sammler expressly references Rau as disclosing details of the internal structure of Sammler's intravascular blood pump, thereby directing a POSITA to look at Rau's disclosure for those details. (Collins ¶267; EX1045[Sammler] 4:17-18.) Moreover, it would have been natural for a POSITA to look to Rau when looking for other publications and patents by the named inventors of Sammler to discern details of the intravascular blood pump not specifically described, and Thorsten Siess is named as a co-inventor on both Sammler and Rau. (Collins ¶267.)

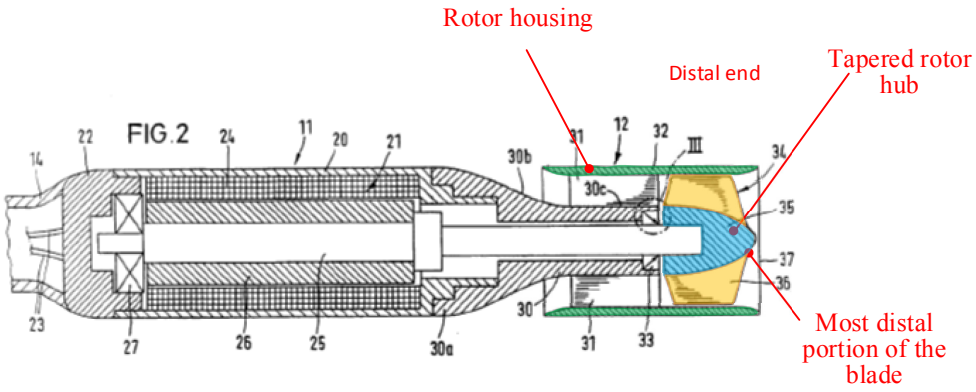
According to Dr. Collins, a POSITA looking at Rau would readily recognize the intravascular blood pump 10 disclosed by Rau would have been compatible

with Sammler's intravascular blood pump system because it can be placed inside the patient's heart to provide support. (*Id.* ¶268; EX1046[Rau] 5:17-18.) Thus, it would have been obvious to, and a POSITA would have been naturally motivated to, use the internal structure of Rau's intravascular blood pump in Sammler's intravascular blood pump system. (Collins ¶268.)

Thus, Sammler in view of Rau discloses this limitation. (*Id.* ¶269.)

d) *"at least one blade extending radially outward from the rotor hub"*

As previously discussed in Section X.A.1(c), the only depiction or description of blades "extending radially outward form the rotor hub" in the '068 patent are in the patent's figures, which depict them as straight fins protruding perpendicularly from the hub. (Collins ¶270; EX1001['068 patent] FIGS. 3, 14, and 18.) As previously discussed in Section X.D.1(c), Rau discloses a pair of blades 36 (yellow) protruding outward from the rotor hub 35 (blue) as shown in FIG. 2.



(Collins ¶270; EX1046[Rau] FIG. 2, annotated.)

Rau does not expressly disclose whether the blades 36 are protruding perpendicularly from the hub 35 as is shown in the '068 patent. (Collins ¶271; EX1001['068 patent] FIGS. 3, 14, and 18.) But, as Dr. Collins explains, such a rotor configuration was well-known, and it would have been obvious to a POSITA to pair a rotor having radially outward extending blades (i.e. protruding perpendicularly from the hub) with Sammler's intravascular blood pump. (Collins ¶272.)

As previously discussed in Sections VII.B and X.D.1(a), Sammler's intravascular blood pump system is "positioned as a right heart pump such that it delivers [blood] from the right atrium 21 into the pulmonary artery 26." (*Id.* ¶272; EX1045[Sammler] 4:38-39.) Sammler acknowledges Rau discloses an intravascular blood pump that is a left-heart pump and effectuates the flow of blood in the opposite direction as Sammler's intravascular blood pump system, i.e. from the distal end of the cannula towards the proximate end of the pump. (Collins ¶272; EX1045[Sammler] 2:18-20.) As such, according to Dr. Collins, a POSITA would have been motivated to consider other conventional blade designs suitable for use in intravascular blood pump systems that provide right-heart support like Sammler's. (Collins ¶273.)

As previously discussed in Section X.A.1(c)., Aboul-Hosn discloses an intravascular blood pump having radially extending blades and providing both left-

and right-heart support, and as such, a POSITA would have naturally looked to Aboul-Hosn in view of Sammler's requirement to provide right-heart support. (*Id.* ¶276; EX1004[Aboul-Hosn] 16:30-31.) A POSITA would have recognized that Aboul-Hosn's pump rotor shown in FIGS. 7A-C is capable of effectuating the blood flow in the right-heart. (Collins ¶276; EX1004[Aboul-Hosn] 16:31-32, 26:21-26.)

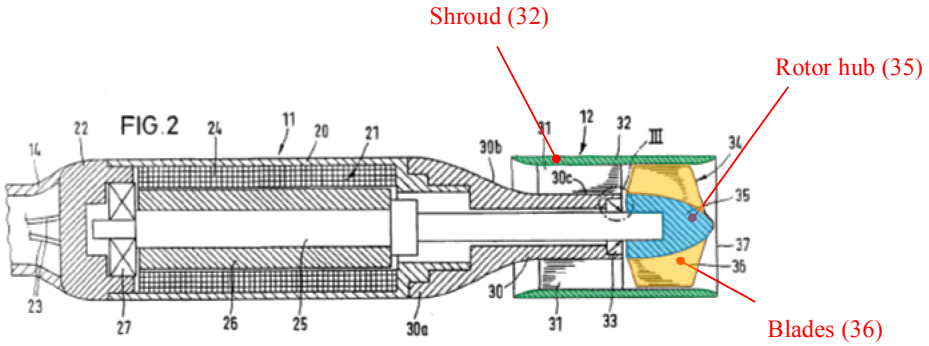
As such, a POSITA would have been motivated to use a rotor configuration like Aboul-Hosn's in Sammler's intravascular blood pump for right-heart support by attaching radially extending blades similar to Aboul-Hosn's blades 72 to Rau's hub 35. Alternatively, Aboul-Hosn's hub 74 could be used in place of Rau's hub 35 to support radially extending blades 72, to provide right-heart support. (Collins ¶276.) Where Aboul-Hosn's hub 74 is used in place of Rau's hub 35 to support radially extending blades, the hub tapers in the distal direction and has a distal end extending beyond the most distal portion of the blades as explained in Section X.A.1(c). (*Id.* ¶276.)

Thus, Sammler in view of Rau and Aboul-Hosn, discloses this limitation. (*Id.* ¶277.)

e) *See* element 1.d, Section X.A.1(d), above.

As shown in annotated FIG. 2, Rau discloses the impeller 34 (i.e. the rotor) comprising hub 35 (blue) and blades 36 (yellow) is disposed within "cylindrical

tubular pump housing 32" (green). (Collins ¶279; EX1046[Rau] 6:22-24, 7:1-2.) Rau discloses that "[w]hen the impeller 34 is rotating, blood is suctioned through the front-side suction opening 37 of the pump housing 32 and is driven backward in an axial direction in the pump housing 34." (*Id.* 7:3-5.)



(Collins ¶279; EX1046[Rau] FIG. 2, annotated.)

Thus, Sammler in view of Rau discloses this limitation. (Collins ¶280.)

f) *See* element 1.e, Section X.A.1(e), above.

As shown in FIG. 1, Sammler discloses the cannula (i.e. the pump hose 14 (blue)) connected to "the outlet of the pump section 12" of the blood pump 10 (green). (Collins ¶281; EX1045[Sammler] 4:22-23.) The pump hose 14 (blue) has an outer surface with a substantially circular cross-section along its length as Sammler discloses that "[t]he pump hose has a length of about 12 cm and an outside diameter of about 8mm." (Collins ¶¶283-284; EX1045[Sammler] 4:29-30.)

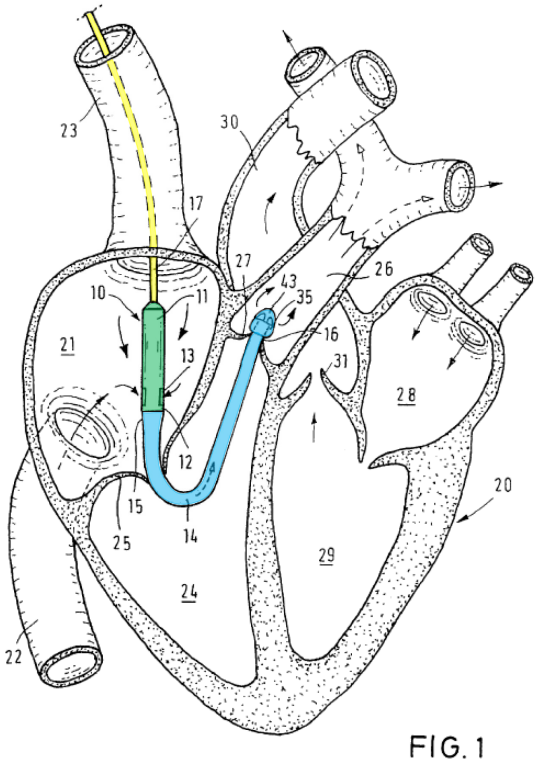
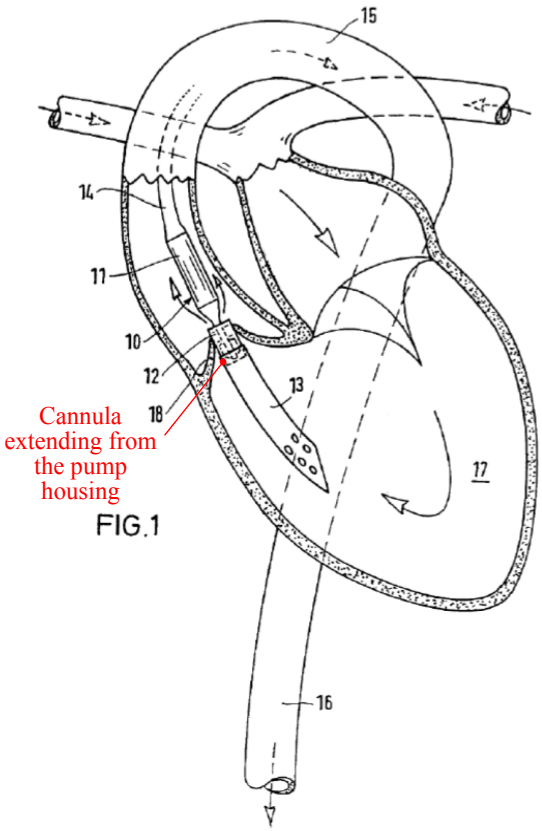


FIG. 1

(Collins ¶281; EX1045[Sammler] FIG. 1.)

The "outlet of the pump section 12" shown in FIG. 1 of Sammler corresponds to the rotor shroud. (Collins ¶282.) As previously discussed in Section X.D.1(c), Sammler expressly identifies the blood pump 10 with an internal structure corresponding to Rau, and it would have been obvious to a POSITA to use Rau's blood pump internal structure with Sammler's intravascular blood pump system. (*Id.* ¶282; EX1045[Sammler] 4:18-19.) As shown in FIG. 1 of Rau, the suction hose 13 (i.e. cannula) is coupled to the distal end of the rotor shroud 32 (discussed above in Section X.D.1(e)) and extends from the rotor shroud 32. (Collins ¶283; EX1046[Rau] 5:19-21.)



(Collins ¶283; EX1046[Rau] FIG. 1, annotated.)

Rau's cannula extends from the intravascular blood pump in the same manner as shown in FIG. 2 of Sammler. (Collins ¶283; EX1045[Sammler] 4:22-23; EX1046[Rau] 5:19-21.) As such, because the internal structure of Sammler's blood pump corresponds to that of Rau, it would have also been obvious to a POSITA to arrange Sammler's pump hose 14 (i.e. cannula) to attach to the rotor shroud of the intravascular blood pump in the manner shown in FIG. 1 of Rau to extend from the rotor shroud. (Collins ¶283.)

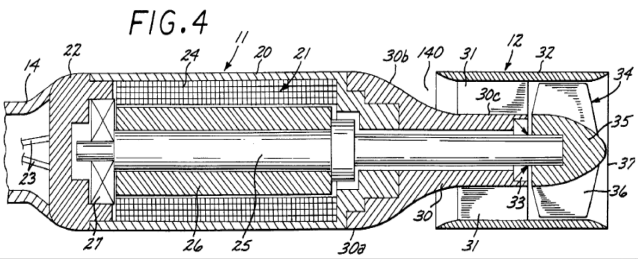
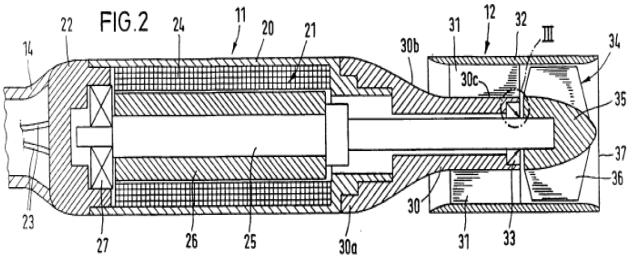
Thus, Sammler in view of Rau discloses this limitation. (*Id.* ¶285.)

g) *See* element 1.f, Section X.A.1(f), above.

While Sammler does not expressly disclose delivering purge fluid to the intravascular blood pump system, Rau acknowledges that purge fluid systems used to lubricate blood pump components were conventional with well-known benefits. (Collins ¶286; EX1046[Rau] 2:13-19.) As previously discussed in Section X.A.1(f), Siess discloses delivering purge fluid through a catheter coupled to an intravascular blood pump system for "positively preventing fluid incursion into the pump and continually lubricat[ing] the seal surfaces to extend service life and minimize risk of thrombi formation related to dissipation in the seal." (Collins ¶286; EX1005[Siess] 8:31-47.)

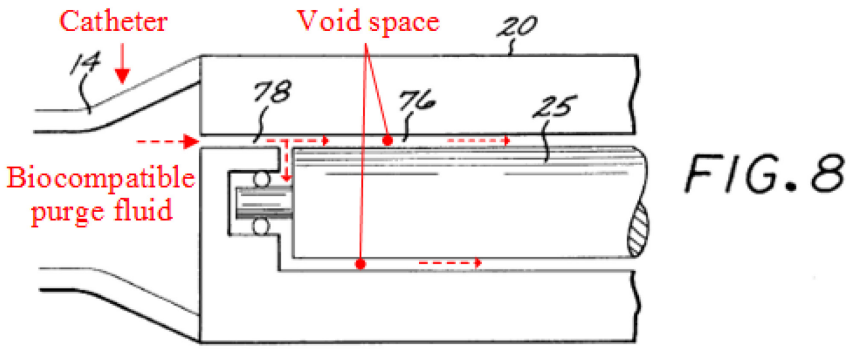
According to Dr. Collins, it would have been obvious to a POSITA to configure Sammler's intravascular blood pump system with a conventional purge fluid system as taught by Siess because of the well-known benefits of doing so (i.e. to "extend service life and minimize risk of thrombi formation" in the pump). (Collins ¶288; EX1005[Siess] 8:31-47.) A POSITA would have naturally looked to Siess because both Siess and Sammler are directed to intravascular blood pump systems, and Siess is also named as a co-inventor of Sammler, so a POSITA looking to improve Sammler's system would have naturally looked to publications and patents by Siess as well. (Collins ¶288; EX1005[Siess] ABSTRACT; EX1045[Sammler] ABSTRACT.) As Dr. Collins notes, Siess' intravascular blood pump is nearly identical to Rau's intravascular blood pump (which Sammler's

intravascular blood pump corresponds to) as shown in the side-by-side comparison below. (Collins ¶288; EX1005[Siess] FIG. 4; EX1055[Rau] FIG. 2.)

EX1005[Siess] FIG. 4	EX1046[Rau] FIG. 2
	

Given the nearly-identical structures of the blood pumps and drive units, it would have been straight-forward for a POSITA to arrange the catheter 17 of Sammler's intravascular blood pump system to include a lumen for delivering purge fluid to the blood pump 10 in the same manner as shown in Siess, which provides a blueprint for doing so using effectively the same blood pump and drive unit. (Collins ¶289.) As shown in annotated FIG. 8 of Siess, the purge fluid would be delivered through Sammler's catheter 17 to the proximal end of the drive unit where "the interior of the drive unit is set into fluid communication with the catheter" via ducts within the drive unit, travel through void spaces between the drive shaft, and flow through the seals of the drive unit into the blood pump to lubricate the bearings 33 (shown in FIG. 2 of Rau to be disposed within the rotor shroud 32) to prevent thrombi formation and extend the service life of the pump. (Collins ¶287; EX1005[Siess] 6:59-65, 8:38-41.) The catheter 17, and the ducts in the drive unit, forms a "first lumen" in fluid communication with Sammler's

intravascular blood pump, operatively arranged to deliver purge fluid to the intravascular blood pump. (Collins ¶287; EX1005[Siess] 6:59-65.)



(Collins ¶287; EX1005[Siess] FIG. 8, annotated.)

Thus, Sammler in view of Rau, and in further view of Siess, discloses this limitation. (Collins ¶290.)

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

As previously discussed in Section VII.B, Sammler discloses using a guide wire 51 (red) within a lumen 50 of the catheter 48 and extending through the catheter 17 (yellow), blood pump 10 (green), and cannula 14b (blue) of the intravascular blood pump system, to position the pump system within the right side of the heart, as shown in annotated FIGS. 5 and 6. (Collins ¶290; EX1045[Sammler] 3:24-27, 6:3-7.)

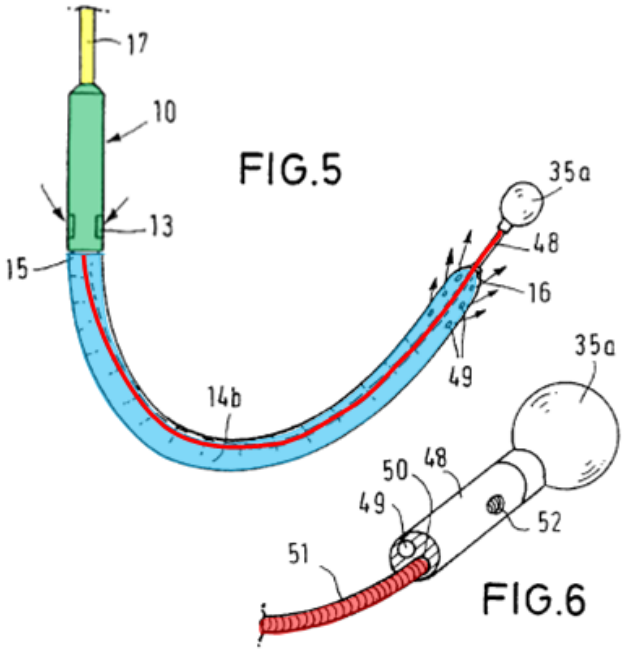


FIG.5

FIG.6

(Collins ¶290; EX1045[Sammler] FIGS. 5 and 6, annotated.)

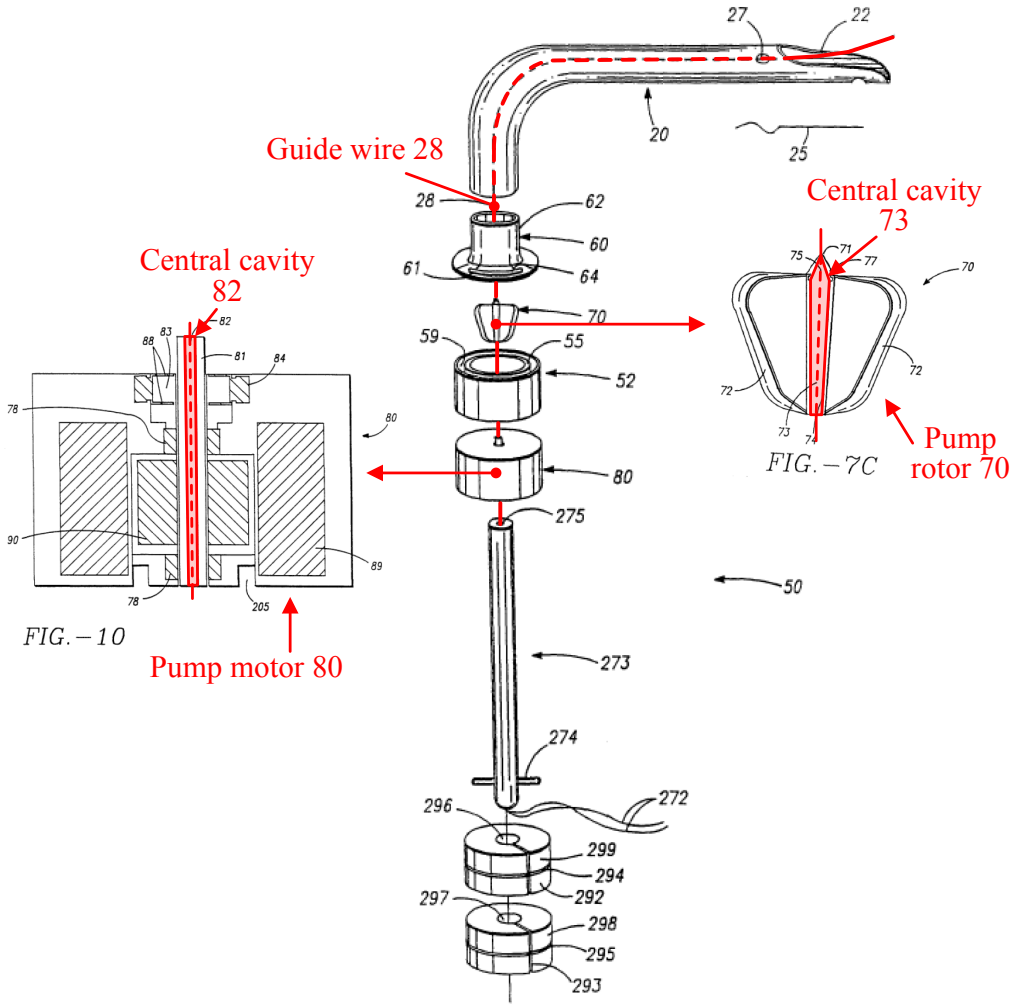
As Dr. Collins explains, the guide wire 51 would be first placed at the desired location in the heart (i.e. with its distal end in the pulmonary artery 26), and then the intravascular blood pump system is advanced over the guide wire through the lumen 50 at the distal end of the catheter 48[21] so the guide wire 51

[21] As Dr. Collins also explains, the balloon 35a is not needed to guide the system when the guide wire 51 is used and would not be inflated (thus allowing the guide wire 51 to enter the distal opening of the lumen 50 within the catheter 48) until the distal end of the pump hose 14 is positioned in the pulmonary artery 26 to keep the pump hose 14b from retracting from the pulmonary valve. (Collins ¶292; EX1045[Sammler] 5:15-19.)

"passes through the catheter 17 and the pump 10." (Collins ¶292; EX1045[Sammler] 6:3-7.)

While Sammler discloses the guide wire 51 "passes through the catheter 17 and the pump 10," Sammler does not detail how this is done, and Rau's intravascular blood pump (corresponding to Sammler's blood pump 10) similarly provides such details. (Collins ¶293; EX1045[Sammler] 6:3-7, 4:18-19; EX1046[Rau] FIG. 2.) As such, a POSITA would have been naturally motivated to look for a conventional intravascular blood pump system with a guide wire extending through the catheter, pump, and cannula consistent with the disclosures of Sammler and Rau to discern these details. (Collins ¶294.) As previously discussed in Section X.A.1(g)-(j), Aboul-Hosn discloses one such intravascular blood pump system. (*Id.* ¶294.)

As shown in annotated FIGS. 3, 7C, and 10 of Aboul-Hosn, the guide wire 28 extends through the intravascular blood pump system via a central lumen extending through the positioning rod 273, the drive unit 80, the rotor 70, and the cannula 20. (*Id.* ¶295; EX1004[Aboul-Hosn] 14:20-26; 22:12-14.)



(Collins ¶296; EX1004[Aboul-Hosn] FIGS. 3, 7C, and 10, annotated.)

As previously discussed in Section X.A.1(b), Aboul-Hosn also uses a miniaturized drive unit 80 to rotate a drive shaft coupled to the rotor hub, and as such, a POSITA would recognize the central lumen can be similarly formed through Rau's blood pump's drive section 11 and pump section 12 (corresponding to Sammler's blood pump) so the guide wire 51 extends through Sammler's blood pump from the catheter 48 to reach catheter 17. (Collins ¶297; EX1004[Aboul-Hosn] 12:30-13:2; EX1045[Sammler] 4:18-19; EX1046[Rau] 7:1-2.) Moreover, a

POSITA would have been motivated to extend the guide wire through Sammler's blood pump 10 via a central lumen providing the most direct path for the guide wire 51 from the catheter 48 in the pump hose 14 to the catheter 17, avoiding unnecessary bends in the guide wire 51 that may increase difficulty of advancing the intravascular blood pump system over the guide wire into the heart. (Collins ¶297; EX1045[Sammler] 6:3-7.)

As taught by Aboul-Hosn, the "second lumen" in Sammler thus extends from the proximal end of the catheter 17 through a central lumen in the pump 10, and through the catheter 48 to its distal end. (Collins ¶298.)

Thus, Sammler in view of Rau, and further in view of Aboul-Hosn, discloses this limitation. (*Id.* ¶299.)

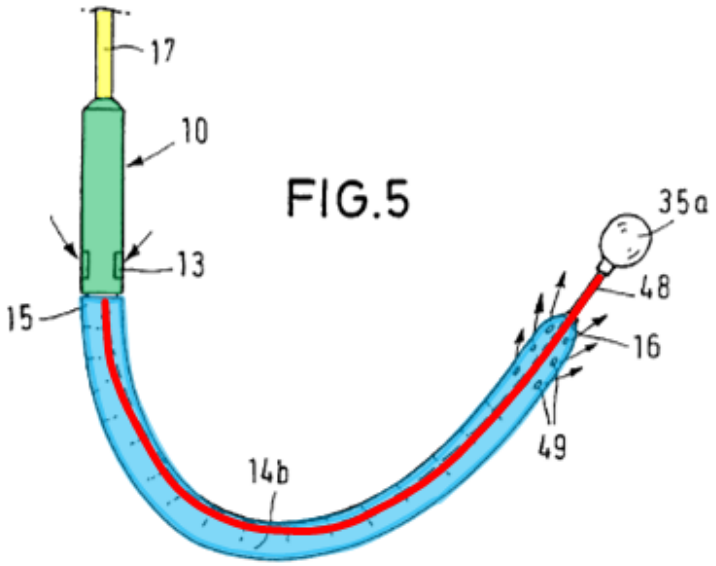
i) *See* element 1.h, Section X.A.1(h), above.

This limitation only requires a "distal portion" of the intravascular blood pump to be guided to a location within the patient's circulatory system. (*Id.* ¶300.) As previously discussed in Section X.D.1(h), Sammler discloses the guide mechanism (i.e. the "second lumen") is used in conjunction with the guide wire 51 to position the distal portion of the intravascular blood pump system in the pulmonary artery 26 of the patient. (*Id.* ¶¶301-302; EX1045[Sammler] 3:24-26, 6:3-7, FIG. 1.)

Thus, Sammler discloses this limitation. (Collins ¶303.)

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

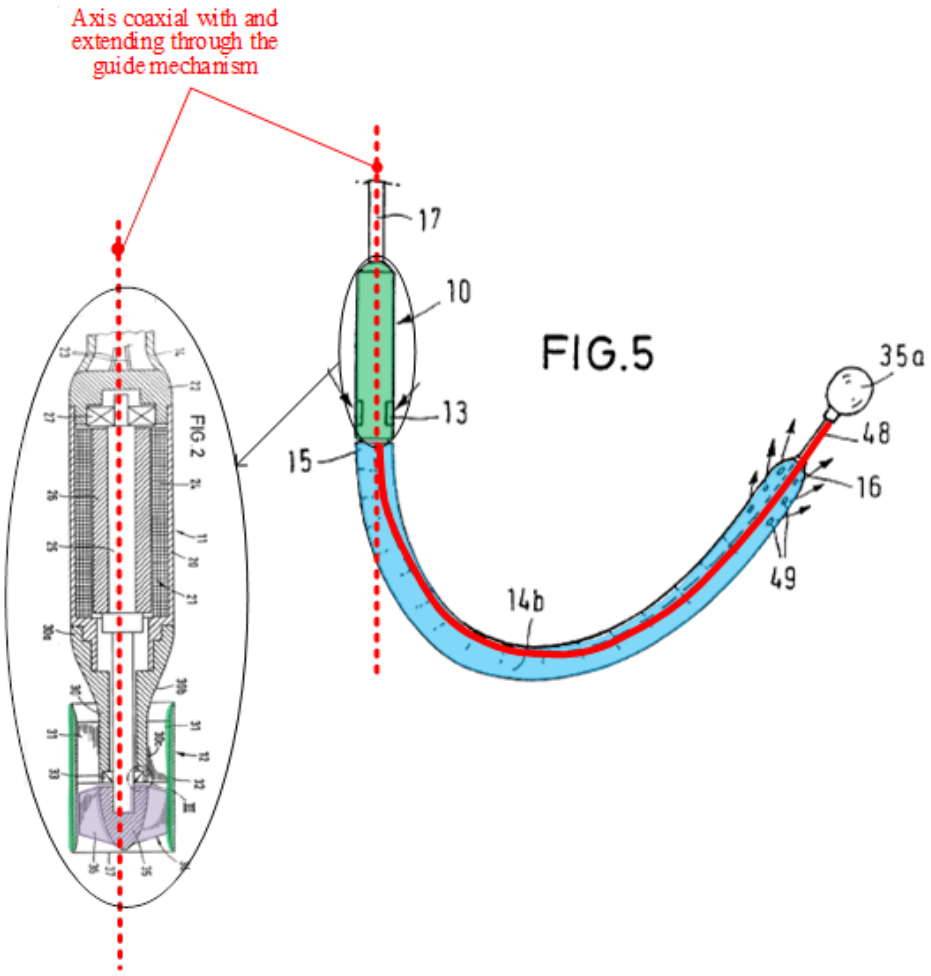
As previously discussed in Section X.D.1(h), a POSITA would understand that Sammler's guide mechanism (i.e. the "second lumen") extends from the proximal end of the catheter 17 through blood pump 10 and catheter 48 (extending through the pump hose 14b). (*Id.* ¶304.) As shown in FIG. 5, the portion of the guide mechanism extending through the catheter 48 (red) extends through "a region delimited by the outer cannula surface" within the inner lumen of the cannula (i.e. pump hose 14b) (blue). (*Id.* ¶304; EX1045[Sammler] 6:3-7.)



(Collins ¶304; EX1045[Sammler] FIG. 5, annotated.)

Moreover, as also discussed in Section X.D.1(h), the guide mechanism also extends through the center of the pump 10 (i.e. through the drive unit and rotor hub as taught by Aboul-Hosn). (Collins ¶305.) As shown in annotated FIG. 5 of Sammler and FIG. 2 of Rau an axis (dashed red line) "coaxial with and extending

through the guide mechanism" (i.e. a central lumen within the pump 10) also extends through the region delimited by the cannula surface (blue) where the proximal end of the cannula couples to the shroud of the pump 10 (green) (as previously discussed in Section X.D.1(e)). (*Id.* ¶306.)



(Collins ¶306; EX1046[Rau] FIG. 2 (left), annotated; EX1045[Sammler] FIG. 5 (right), annotated.)

Thus, Sammler in view of Rau, and further in view of Aboul-Hosn, discloses this limitation. (Collins ¶307.)

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

As previously discussed in Section X.D.1(h), to place Sammler's intravascular blood pump system, the guide wire 51 is first placed at the desired location in the patient's heart (i.e., with its distal end in the pulmonary artery 26), and the intravascular blood pump system is advanced over the guide wire 51 by sliding the guide wire 51 through the lumen 50 at the distal end of the catheter 48 so that the guide wire 51 "passes through the catheter 17 and the pump 10." (Collins ¶308; EX1045[Sammler] 6:3-7.)

Thus, Sammler discloses this limitation. (Collins ¶309.)

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

As previously discussed in Section X.D.1(h), Sammler's intravascular blood pump system includes a second lumen "into which a guide wire is inserted which facilitates advancing of the pump hose through the vascular system." (Collins ¶311; EX1045[Sammler] 2:29-34.) A POSITA would readily understand that it was conventional to advance the guidewire to the desired location in the body. (Collins ¶312.)

Thus, Sammler discloses this limitation. (Collins ¶313.)

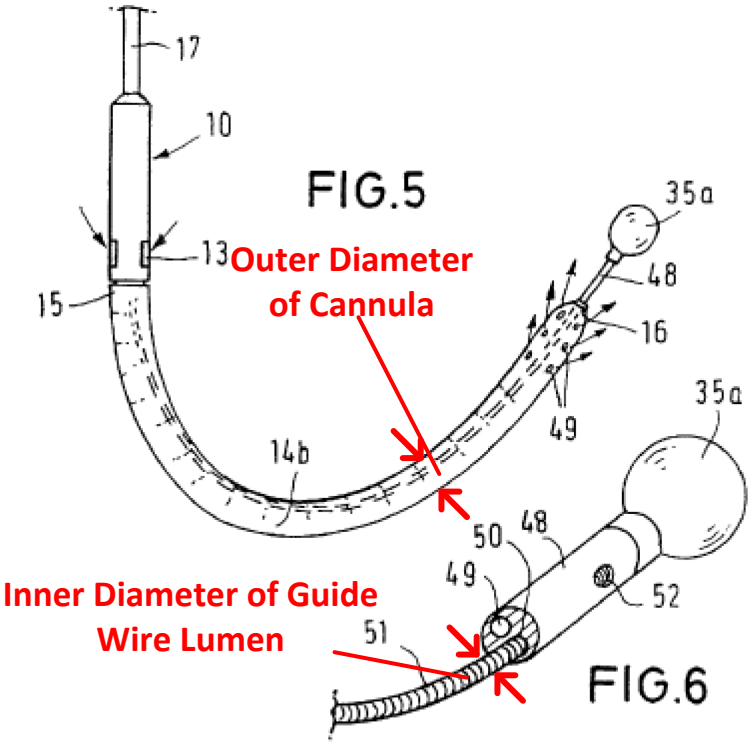
m) *See* element 1.h, Section X.A.1(h), above.

As previously discussed in Section X.D.1(h), Sammler's intravascular blood pump system accommodates the guide wire so that the "guide wire 51…makes it possible for the operating surgeon to controllable influence the laying of the pump hose." (Collins ¶315; EX1045[Sammler] 6:5-7.)

Thus, Sammler discloses this limitation. (Collins ¶316.)

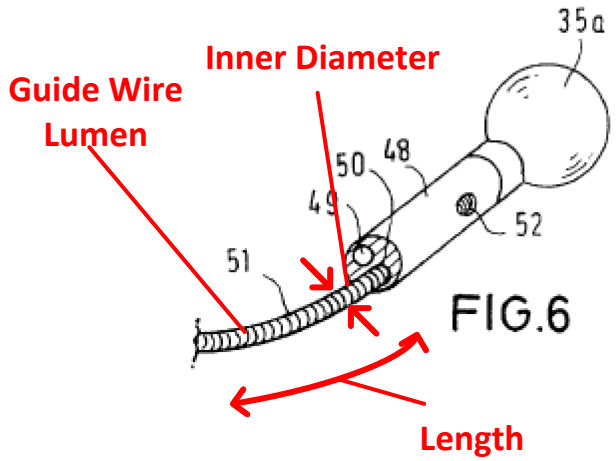
2. Claim 5

First, Sammler discloses the guide wire lumen 50 inner diameter is substantially smaller than an outer diameter of the outer cannula surface, as illustrated in annotated FIGS. 5 and 6 of Sammler. (Collins ¶319; EX1045[Sammler] 5:9-15.)



(Collins ¶320; EX1045[Sammler] FIGS. 5 and 6, Annotated)

Second, Sammler discloses that the length of the guide wire lumen 50 is much longer than the guide wire lumen 50 inner diameter, as shown in Sammler FIG. 6. (Collins ¶322; EX1045[Sammler] 5:15-17.)



(Collins ¶322; EX1045[Sammler] FIG. 6, Annotated)

Thus, Sammler discloses this limitation (Collins ¶323.)

E. Ground V: Claim 9 is obvious over Sammler in view of Rau, and further in view of Aboul-Hosn, Siess, and Wampler.

1. Claim 9

As previously discussed in Section X.D.1(g), it would have been obvious to a POSITA to deliver purge fluid to Sammler's intravascular blood pump system through a purge fluid lumen within the catheter 17 as taught by Siess. (Collins ¶326.) However, Siess does not expressly disclose the details of how purge fluid is provided to the catheter, but as previously discussed in Section X.C.1, it was well-known that the purge fluid system included a pump located outside of the patient's body to continuously deliver purge fluid, as taught by Wampler. (Collins ¶325; EX1008[Wampler] 233-34.) It would have been obvious to a POSITA, and a POSITA would have recognized, that Siess used a purge fluid pump like the roller pump disclosed by Wampler to provide purge fluid via the "Purge Fluid In" and

"Purge Fluid Out" conduits in and out of the blood pump through tubes extending through Siess' catheter. (Collins ¶327; EX1008[Wampler] 234.) Both Siess and Wampler disclose delivering purge fluid in the same manner (continuously via lumens within a catheter or sheath) for the same purpose (lubrication of pump components and to prevent blood from entering the pump). (Collins ¶329; EX1005[Siess] 8:31-47; EX1008[Wampler] 234.) Moreover, doing so would have been nothing more than an application of a well-known and conventional element originally used in the Hemopump to "continually supply" Sammler's blood pump with purge fluid (Collins ¶330; EX1005[Siess] 8:31-47.)

Thus, Sammler in view of Rau, and further in view of Siess, discloses this limitation. (Collins ¶331.)

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 IPR2017-01028[22] (the "'1028 Proceeding") in consideration of the factors recently reiterated by the Board in *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

[22] The Board issued a decision denying institution in IPR2017-01028 on September 20, 2017. Petitioner reserves the right to request rehearing.

asserted in 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 justifiably 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 '1028 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 '1028 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 four claims out of ten claims challenged in the '1028 Proceeding. Thus, this case is distinct from *General Plastic Industrial Co.*, 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,

[23] This Petition is filed merely two days after the Board decision denying institution in IPR2017-01028. As such it has not, and as a practical matter could not have, been prepared using the Board's decision as a roadmap.

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 '1028 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 (PTAB 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'1028 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.

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

[24] For example, the Patent Owner incorrectly represented that the disclosure in Aboul-Hosn is limited to extracorporeal applications. *See* EX1051[IPR2017-01028 POPR] 21-27. Patent Owner also incorrectly represented that Claim 1 requires that the blood pump be placed within the vasculature system. *See Id.* at 44.

district court litigation. *See* EX1052[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. EX1051[Notice Letter]. The intent is clearly to proliferate the litigation and drive up costs. *See* EX1055['669 Notice]; *See* EX1056[Hearing 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 1, 5, 7, and 9 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")
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]
1032	Frank M. White. *Fluid Mechanics*, 2nd edition, 1986 ("White")
1033	O. Jegaden, "Clinical results of Hemopump support in surgical cases," 1991. ("Jegaden")
1034	[RESERVED]
1035	U.S. Patent No. 8,888,728 ("'728 patent")
1036	File History of U.S. Patent No. 8,888,728 ("'728 PH")
1037	Declaration of Pamela Stransbury
1038	Declaration of Kiersten Batzli
1039	Library of Congress, Catalog Record of *Supported Complex and High Risk Coronary Angioplasty*, ch. 14, 231-49 (Springer 1st ed. 1991)
1040	Library of Congress, Catalog Record of Moulopoulos et. al, "Diastolic Balloon Pumping (With Carbon Dioxide) in the

	Aorta – a Mechanical Assistance to the Failing Circulation," in the American Heart Journal, vol. 63, no. 1 (1962) 669-675
1041	Library of Congress, Catalog Record of Konishi et al., "Controller for an axial flow blood pump," in Artificial Organs Journal, vol. 20, no. 6 (Jun. 1996) 618-620
1042	Library of Congress, Catalog Record of *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996)
1043	Library of Congress, Catalog Record of *Fluid Mechanics,* 2nd edition, ed. Frank M. White, (1986)
1044	[Reserved]
1045	D.E. 19821307 ("Sammler")
1046	PCT Pub. No. WO 97/037696 ("Rau")
1047	Systems Analysis and Development of Intravascular Rotation Pumps for Heart Support (Siess 1999)
1048	Colombo, Selection of Coronary Stents, Journal of the American College of Cardiology, 2002. ("Colombo")
1049	Biophysical Measurements, Tektronix, Inc. (1970) ("Tektronix")
1050	Stedman's Medical Dictionary'
1051	IPR2017-01028, Patent Owner's Preliminary Response ("IPR2017-01028 POPR")
1052	Maquet's Infringement Contentions, Abiomed Inc. v. Maquet Cardiovascular LLC, No. 1:16-CV-10914 (D. Mass.) ("Infringement Contentions")
1053	Notice Letters from Maquet Cardiovascular to Abiomed ("Notice Letters")
1054	D.E. 19821307 German Language
1055	Notice of Allowance, Application No. 14/966,669 ("'669 Notice")
1056	Status Conference Transcript, Abiomed Inc. v. Maquet Cardiovascular LLC, No. 1:16-CV-10914 (D. Mass. Jun. 1, 2017) ("Hearing Transcript")
1057	PCT Pub. WO 97/037696 German Language

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 13,879 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/_____

David M. Tennant
Lead Counsel
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 (EX1001-1057)
- Exhibits 1001-1057
- Power of Attorney

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

Getinge US Legal Shared Services

1300 MacArthur Boulevard

Mahwah NJ 07430

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

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Alston & Bird LLP

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101 South Tryon Street, Suite 4000

Charlotte, NC 28280-4000

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