UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Maquet Cardiovascular, LLC
Patent Owner

Case No. IPR2017-01204

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,561,314

CLAIMS 1-8, 10-23, and 25-26

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I. INTRODUCTION

Petitioners Abiomed, Inc. and Abiomed R&D, Inc. (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 1-8, 10-23, and 25-26 (the "Challenged Claims") of U.S. Patent No. 9,561,314 (the "'314 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. and Abiomed R&D, Inc.

B. Related Matters

Petitioner has filed, or will file, concurrently with the present Petition: (1) a second petition for *inter partes* review of claims 27 and 29-30 of the '314 patent; (2) petitions for *IPR* of U.S. Patent Nos. 9,545,468 and 9,597,437; and (3) petitions for *IPR* of U.S. Patent Nos. 7,022,100 (IPR2017-01025), 8,888,728 (IPR2017-01026 and IPR2017-01027), and 9,327,068 (IPR2017-01028 and IPR2017-01029) (the "related patents") which are related to the '314 patent.

C. Counsel

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

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

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[1]:

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. 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).

[1] The pre-AIA statutory framework applies to the '314 Patent.

3. Jegaden, Clinical results of Hemopump support in surgical cases, Published in Temporary Cardiac Assist with an Axial Pump System, p.61-65 (Springer 1991) (EX1033,"Jegaden"), is prior art under 35 U.S.C. § 102(b).[2]

4. 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) (EX1007,"Wampler"), published in 1991, is prior art under 35 U.S.C. § 102(b).[3]

5. U.S. Patent No. 5,421,338 to Crowley (EX1047,"Crowley"), filed June 3, 1994 and issued June 6, 1995, is prior art under 35 U.S.C. § 102(b).

6. U.S. Patent No. 4,625,712 to Wampler (EX1008, "Wampler_712"). Filed September 28, 1983 and issued December 2, 1986, is prior art under 35 U.S.C. § 102(b).

B. Grounds for Challenge

Petitioner respectfully requests review of the Challenged Claims and cancellation of those claims under the following statutory grounds:

[2] Jegaden bears a copyright date of 1991 and was publicly available from 1992. EX1033; Declaration of Leupold (EX1046).

[3] Wampler bears a copyright date of 1991 and was publicly available from 1991. *See* EX1007; Declaration of Kiersten Batzli (EX1035); Library of Congress Card Catalog (EX1036).

- Ground 1: Claims 1-8, 14, 16-20, and 25-26 are rendered obvious by Aboul-Hosn in view of Siess and Wampler, under 35 U.S.C. § 103(a).
- Ground 2: Claims 10-11, 13, 21, and 23 are rendered obvious by Aboul-Hosn in view of Siess and Wampler, and further in view of Jegaden under 35 U.S.C. § 103(a).
- Ground 3: Claims 12 and 22 are rendered obvious by Aboul-Hosn in view of Siess and Wampler, and further in view of Crowley under 35 U.S.C. § 103(a).
- Ground 4: Claims 15 is rendered obvious by Aboul-Hosn in view of Siess and Wampler, and further in view of Wampler_712 under 35 U.S.C. § 103(a).

V. CONVENTIONAL TECHNOLOGY

A. Conventional Intravascular Blood Pumps

The blood pump features of the Challenged Claims were well known: (1) a cannula formed as a tube, connected at its proximal end to an axial flow pump and with a distal end to be disposed in a heart chamber (Collins ¶¶52, 55-59; EX1004[Aboul-Hosn] 30:20-28; U.S. Patent No. 4,625,712 to Wampler (EX1008[Wampler_712] 3:40-51); EX1013[Siess] 5:28-61); (2) a pump having a tapered rotor with a distally extending tip and multiple blades disposed within a shroud, to pump blood axially along the pump and through the cannula (Collins

¶¶61-65; EX1004[Aboul-Hosn] 12:28-13:31, 16:30-17:26; EX1008[Wampler_712] 3:26-39; U.S. Patent No. 4,846,152 to Wampler et al. (EX1009,[Wampler_152] 2:63-3:23); EX1005[Siess] 6:26-7:21); (3) a purge fluid system to prevent blood from entering the pump motor and to lubricate the pump motor (Collins ¶¶66-72; EX1004[Aboul-Hosn] 20:16-21:3; EX1008[Wampler_712] 3:40-51; EX1005[Seiss913] 8:31-44); and (4) techniques for monitoring blood pressure near the pump (Collins ¶¶73-79; EX1004[Aboul-Hosn] 29:16-25; EX1005[Siess] 11:25-56). The few other minor details of the Challenged Claims were also well-known in intravascular blood pumps in the prior art—I.e., purge fluid pump and fittings (in Wampler), or pressure sensor configurations (in Aboul-Hosn or Siess). (Collins ¶¶70-72, 76-78.)

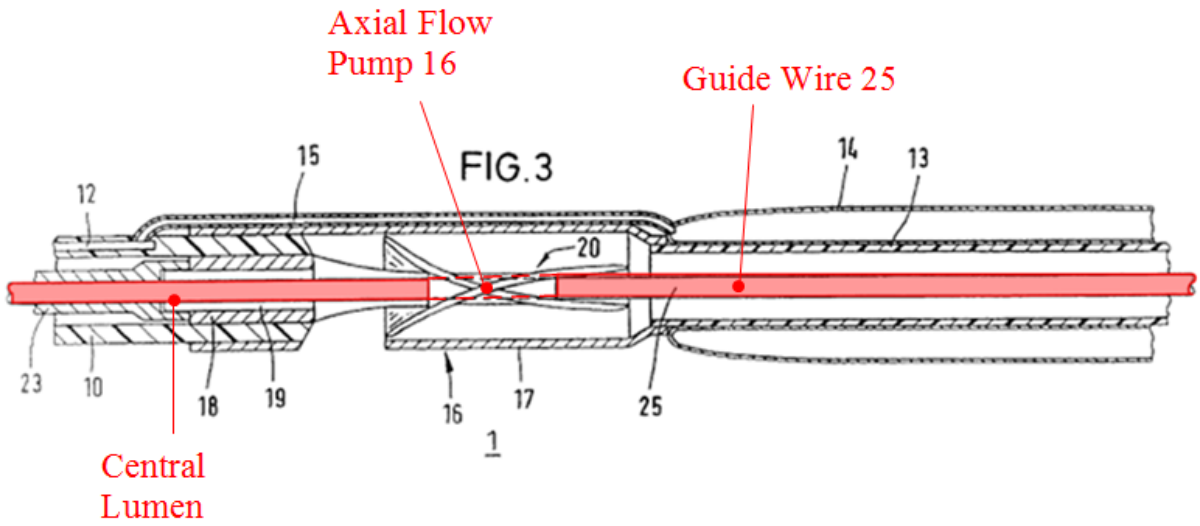
B. Placing Intravascular Blood Pumps

The guide wire mechanism of the Challenged Claims was well-known in catheterization as the "over-the-wire" technique. Along with "rapid-exchange" and "guide catheters," over-the-wire was used routinely to position blood pumps intravascularly. (Collins ¶¶81-82.)

1. Over-the-Wire

POSITAs used "over-the-wire" guide mechanism to place intravascular blood pumps. (Collins ¶¶86-88.) For example, as shown below in FIG. 3, U.S.

Patent No. 6,248,091 to Voelker[4] (EX1011,"Voelker") applied the "over-the-wire" guide mechanism to an axial flow intravascular blood pump with the guide wire extending coaxially through the flexible shaft 23, the shaft 19, and the impeller wheel 20 so that the pump may be slipped over the guide wire. (Collins ¶88; EX1011[Voelker] 3:56-60; EX1004[Aboul-Hosn] 22:10-16, FIG. 3.)



(Collins ¶88; EX1011[Voelker] FIG. 3, annotated.)

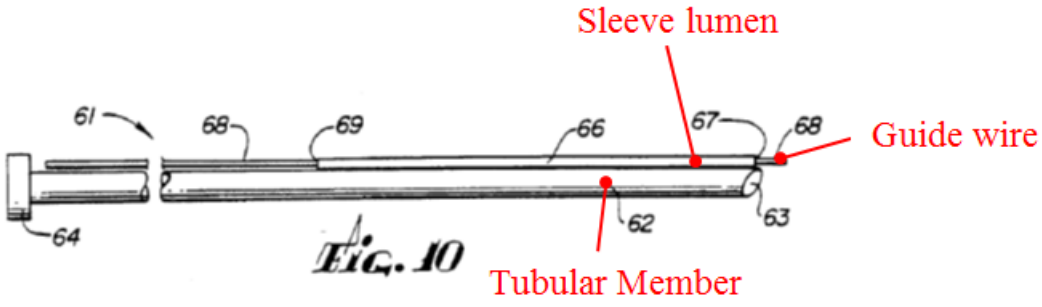
As explained in further detail in Sections VII.A and X below, Aboul-Hosn disclosed that same well-known "over-the-wire" catheterization technique and used it in delivering intravascular blood pumps into the heart.

2. Rapid-Exchange

"Rapid-exchange" was a well-known catheterization technique. (Collins ¶90.) Yock disclosed placing a conventional "rapid-exchange" catheter by sliding

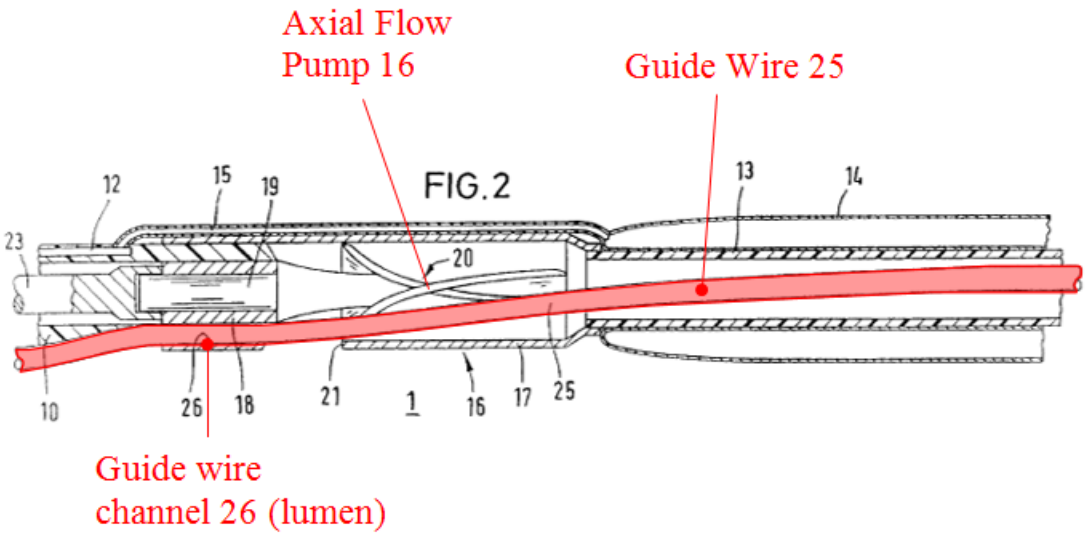
[4] Voelker is also published as PCT Publication WO97/46270 on Dec. 11, 1997.

it along a guide wire extending through a sleeve secured to the exterior of the cannula or embedded within the cannula wall itself. (*Id.* ¶91; EX1006[Yock] FIG. 10;7:64-8:2.)



(Collins ¶91; EX1006[Yock] FIG. 10, annotated.)

Voelker, at Fig. 2 (below) applied this rapid exchange approach to an intravascular blood pump—a guide wire 25 extended through a side channel for positioning a blood pump as illustrated below. (Collins ¶93; EX1011[Voelker] 3:34-43.)



(Collins ¶93; EX1011[Voelker] FIG. 2, annotated.)

3. Guide Catheter

Yock also discloses using a guide catheter to position a guide wire. (Collins ¶83; EX1006[Yock] 3:56-4:50.) The same technique as disclosed by Yock has had been adapted to place axial flow intravascular blood pumps. (Collins ¶84.) In fact, the '314 Patent acknowledges this conventional technique. (EX1001['314 Patent] 2:34-55.)

4. Interchangeability of Over-the-Wire and Rapid Exchange

Over-the-wire and rapid-exchange techniques have long been used interchangeably, with minimal differences in design, to deliver cardiac assist devices, including blood pumps. (Collins ¶96; EX1023[Faxon] 58-59; EX1006[Yock] 8:16-25; EX1011[Voelker] FIGS. 2 and 3.) Over-the-wire and rapid-exchange were part of a limited set of delivery techniques. (Collins ¶97.) For example, U.S. Patent No. 5,928,181 to Coleman et al. (EX1042, "Coleman") discloses that catheters coupled to a cardiopulmonary bypass pump may be suitably guided into position using either technique. (EX1042[Coleman] 34:14-39.)

The interchangeability of over-the-wire and rapid-exchange was also well understood for intravascular blood pump applications. (Collins ¶98.) For example, Voelker's blood pump could be configured to use either technique. (*Id.*; EX1011[Voelker] FIG. 2 (over-the-wire), and FIG. 3 (rapid-exchange).) Of

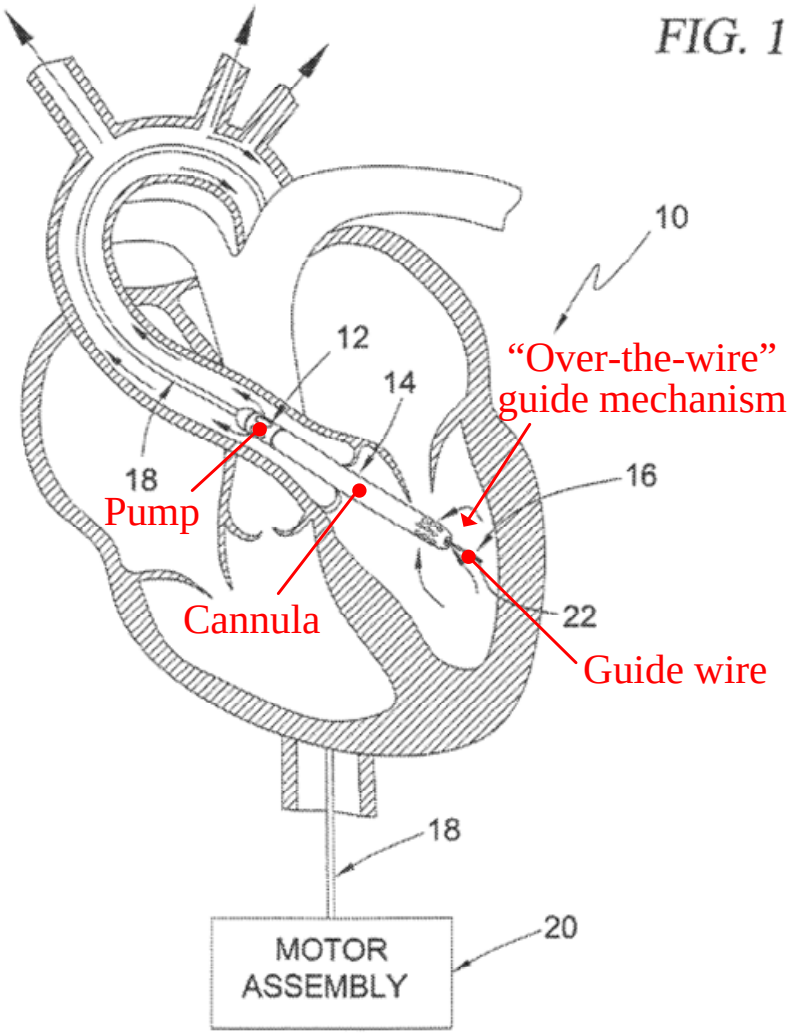
course, deploying an intravascular blood pump to use over-the-wire or rapid-exchange involves certain design choices, but such design choices were also well-known within the prior art. (Collins ¶99; EX1001[Voelker] 3:34-55.)

VI. OVERVIEW OF THE '314 PATENT

A. Summary of the '314 Patent

The '314 patent describes placement of a conventional intravascular blood pump system using the same three conventional guide wire delivery techniques discussed above. (EX1001['314 patent] 9:13-32, 13:62-14:10, 15:5-21; Collins ¶102-104.) The background of the '314 patent openly admits that it is not the first to use "guide mechanism[s]" to place an intravascular pump. (EX1001['314 patent] 2:35-45.)

FIG. 1 of the '314 patent illustrates a conventional over-the-wire placement technique. (*Id.* 5:25-30.)

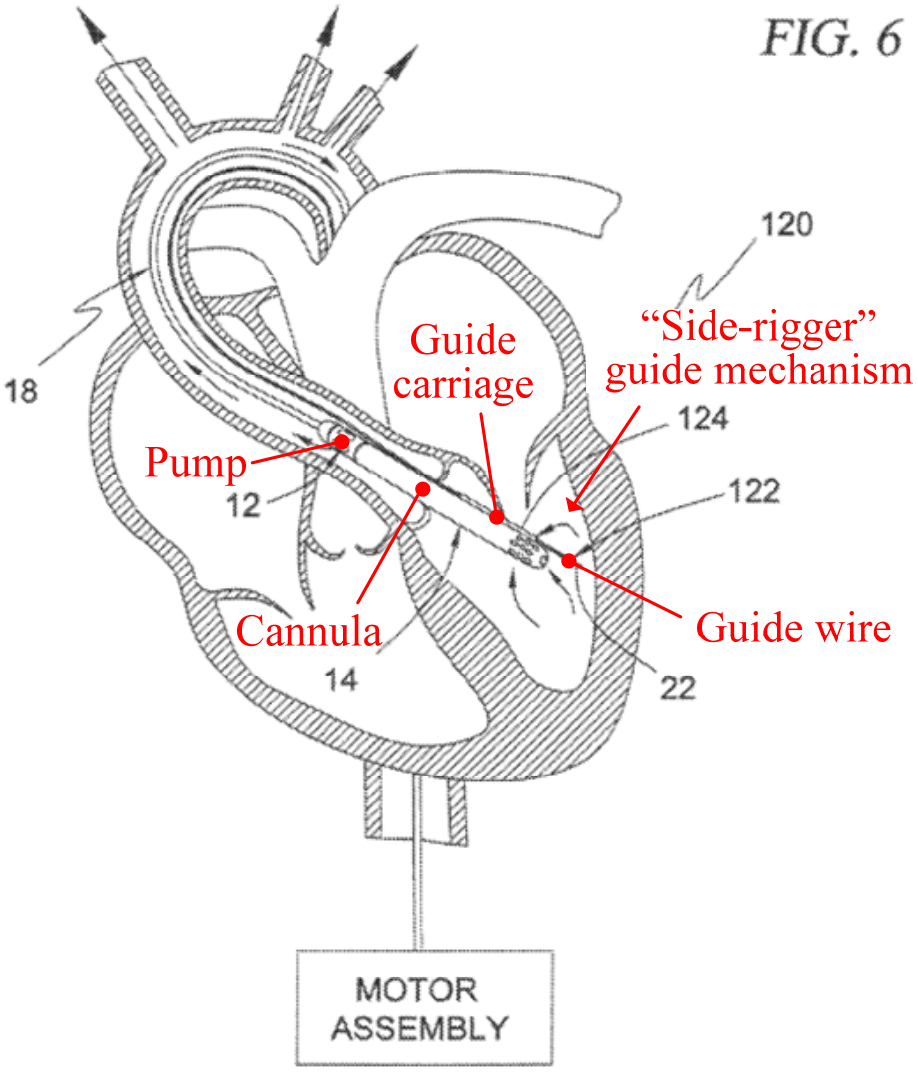


(Collins ¶105; EX1001['314 patent] FIG. 1, annotated.)

The conventional intravascular blood pump system 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.* 9:13-24; Collins ¶105.) The blood pump 12 provides heart support in the same manner as conventional axial-flow intravascular blood pumps – by "deliberately re-rout[ing] through and past the right and/or left ventricle in an

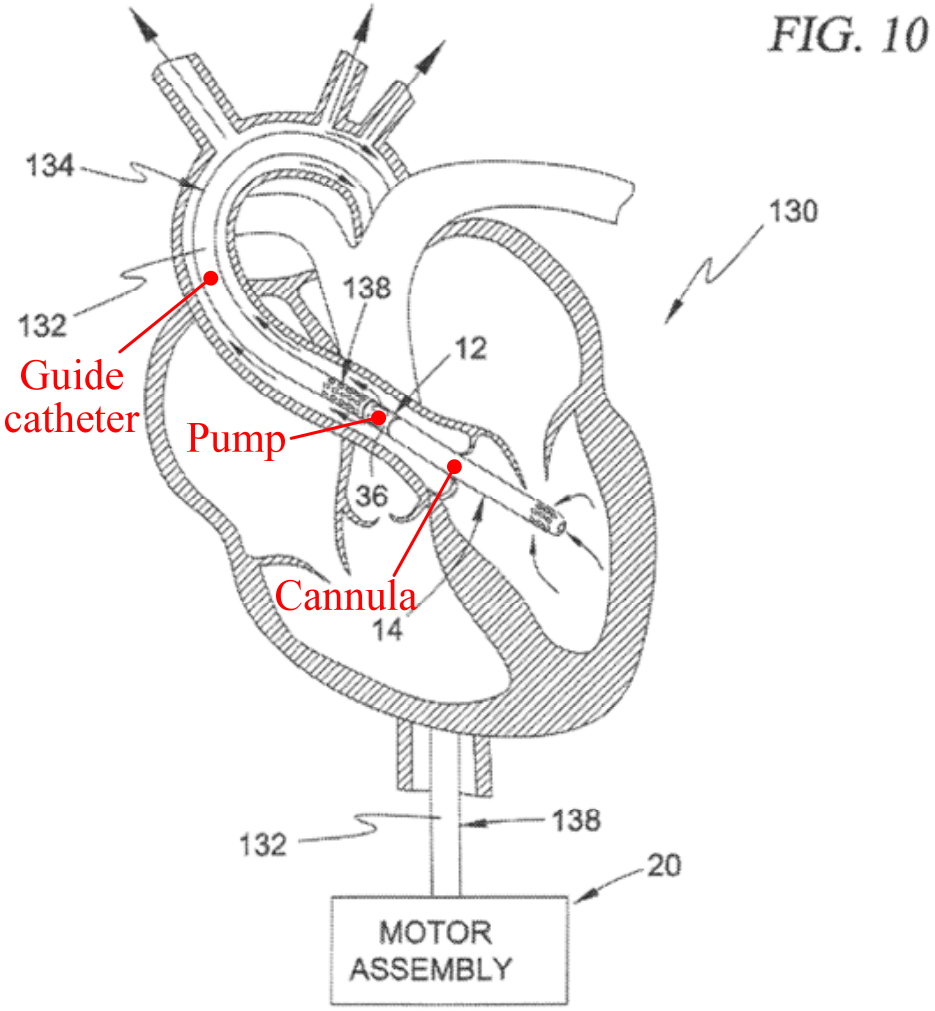
effort to reduce the volume of blood to be pumped by the particular ventricle." (*Compare* EX1001['314 patent] 20:43-48 *with id.* 2:16-19; Collins ¶103.)

FIG. 6 shows the conventional "rapid-exchange" or "side-rigger" guide mechanism of the prior art. (*Id.* 5:25-30.) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable … guide wire 22 … dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (*Id*. 14:15-21; Collins ¶107-108.) As with the prior art (Collins ¶108), the guide carriage 124 may be formed as "an integral extension of the wall of the cannula 14." (EX1001['437 patent] 14:37-39.)



(Collins ¶107; EX1001['314 patent] FIG. 6, annotated.)

Finally, the '314 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['314 patent] 5:65-6:3; Collins ¶110)



(Collins ¶110; EX1001[’314 patent] FIG. 10, annotated.)

B. Prosecution History

During prosecution of the ’314 patent, in the sole office action the Examiner indicated that eight co-pending and patented applications were relevant to the Challenged Claims, but found the Challenged Claims to be patentably distinct—not because of a specific combination of elements, but because “a guide wire *not* passing through the rotor hub and a housing and catheter with a purge lumen” were not disclosed in those applications. (EX1003[’314 PH] 238.) There is no

patentable synergy between the recited guide wire configuration and the purge system feature that the Examiner found missing. (Collins ¶112.) As with the other conventional features of the Challenged Claims, a "guide wire not passing through the rotor hub" and a "housing and catheter with a purge lumen" were conventional elements that were well-known and disclosed by prior art references not relied on by the Examiner. (*Id.* ¶113.)

C. The Earliest Possible Priority Date for the '314 Patent is September 1, 2000

The earliest possible priority date (as defined above, the "EPD") for the Challenged Claims is September 1, 2000, which is the date of PCT Application No. PCT/US00/24515, to which the '314 patent claims priority. The subject matter of the Challenged Claims is not supported by its claimed earlier-filed provisional application. (EX1012, the "'249 provisional application").

Independent claims 1 and 20 require, for example, "a purge lumen extending through the catheter and operatively arranged to deliver purge fluid," "a pressure sensing element", "an elongate lumen arranged coaxially with at least a portion of the cannula," "an end of the elongate lumen is adjacent an end of the cannula," and "the elongate lumen sized to slidably receive the guide wire." (EX1001['314 patent] 34:11-14; 34:22; 34:17-18; 34:15-21; 34:18-21; 36:2-3; 36:12, 36:5-9.)

None of these limitations are supported in the '249 provisional application.[5] (Collins ¶124-125; *Dynamic Drinkware, LLC. v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("[T]he specification of the *provisional* must contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms, 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.") (emphasis in original).)

Accordingly, the EPD for the Challenged Claims is September 1, 2000.[6] (Collins ¶127.)

VII. OVERVIEW OF THE PRIOR ART

[5] During prosecution of the related '728 Patent, the Examiner found that the claims directed to "a blood pressure detection mechanism," and "a guide wire and an elongate lumen" were not entitled to the priority date of the '249 provisional application, and the Patent Owner never challenged in any subsequent response. (EX1043['728 PH] 259-280.)

[6] If the Board finds that one or more Challenged Claims is entitled to the September 3, 1999 filing date of the '249 provisional application, the cited prior art would still qualify as prior art under 35 U.S.C. § 102(a) or 102(b).

A. Overview of Aboul-Hosn[7]

Aboul-Hosn discloses an axial flow intravascular blood pump for heart support, that is delivered intravascularly to a desired location within the heart using the same well-known guide mechanisms as noted in the '314 patent. (Collins ¶128; EX1004[Aboul-Hosn] 11:9-14; 30:1-2.) Aboul-Hosn further discloses both percutaneous and surgical approaches for delivering the blood pump. (Collins ¶147-151; EX1004[Aboul-Hosn] FIG. 21; 21:19-22:30; 11:8-12.)

Annotated FIGS. 21 and 23, below, show a percutaneous approach for delivering the pump using a guide wire. (Collins ¶148; EX1004[Aboul-Hosn] 30:1-2, 20-27.) FIG. 21 shows how the blood pump (green) passes along the guide wire up the femoral artery, so the cannula 411[8] (blue) goes through the aorta and into the left ventricle. In FIG. 23, the cannula then also continues into the left

[7] Aboul-Hosn and Siess were cited in an Information Disclosure Statement dated August 19, 2016 but there is no record the Examiner relied upon them. (EX1003['314 PH] 271, 280). There is no record of Jegaden, Yock, or Wampler being disclosed during prosecution of the '314 patent. (EX1003['314 PH] 552-558.)

[8] FIG. 20 is a zoomed-in view of the stabilization system 410 of FIG. 23; it identifies element 411 as the stabilization cannula that passes through the stabilization balloon 440 (red). (EX1004[Aboul-Hosn] 28:23-27.)

atrium, where it is positioned to pump blood from the left atrium to the aorta. (Collins ¶¶148-149; EX1004[Aboul-Hosn] 29:17-28, 30:1-2, 30:20-27.) In addition, the cannula's inflow tip may also be placed in "the left ventricle, … or any of the left heart vessels" to provide left heart support. (*Id.* 26:10-13.)

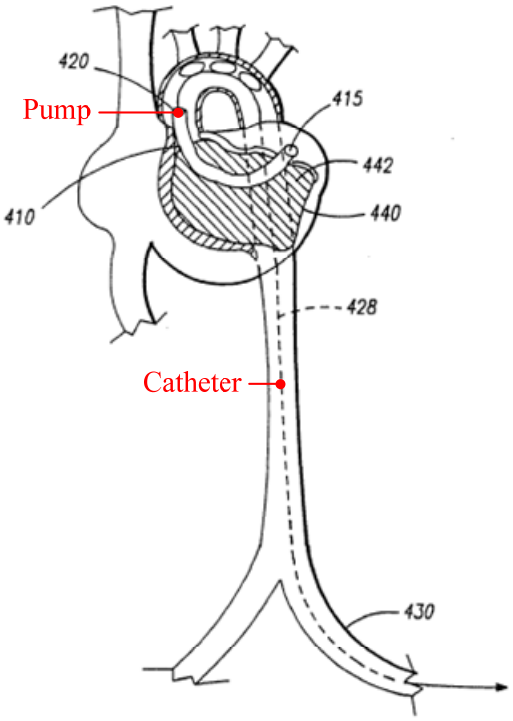


FIG.–21

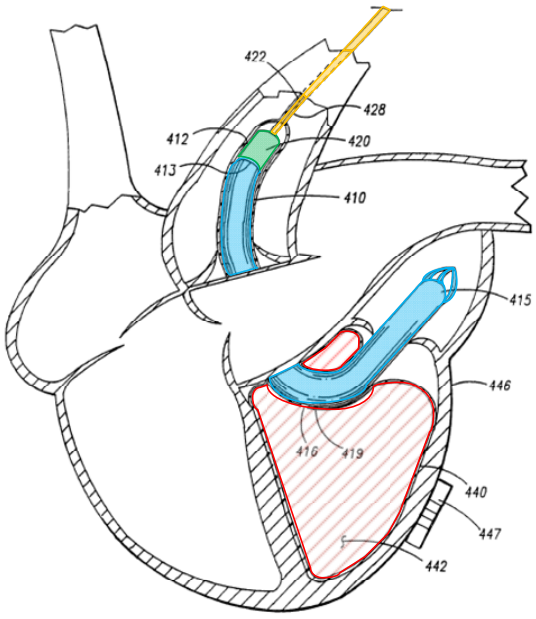
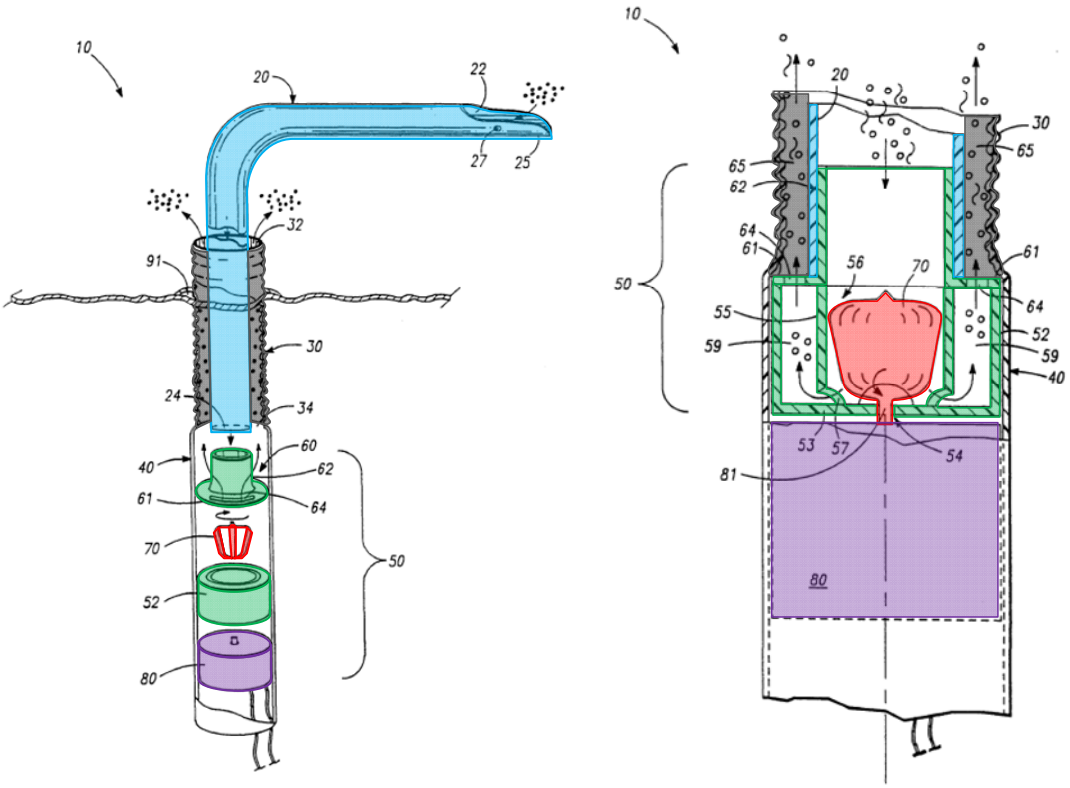


FIG.–23

(Collins ¶148; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

FIGS. 1-13 show a surgical approach with details about the interior of the pump and cannula. Numerous conventional features of intravascular blood pumps are disclosed, including a "commercially available" cannula (EX1004[Aboul-Hosn] 11:14, together with a "reverse flow" feature that reverses the direction of blood flow as it exits the pump. (Collins ¶¶135-137.)

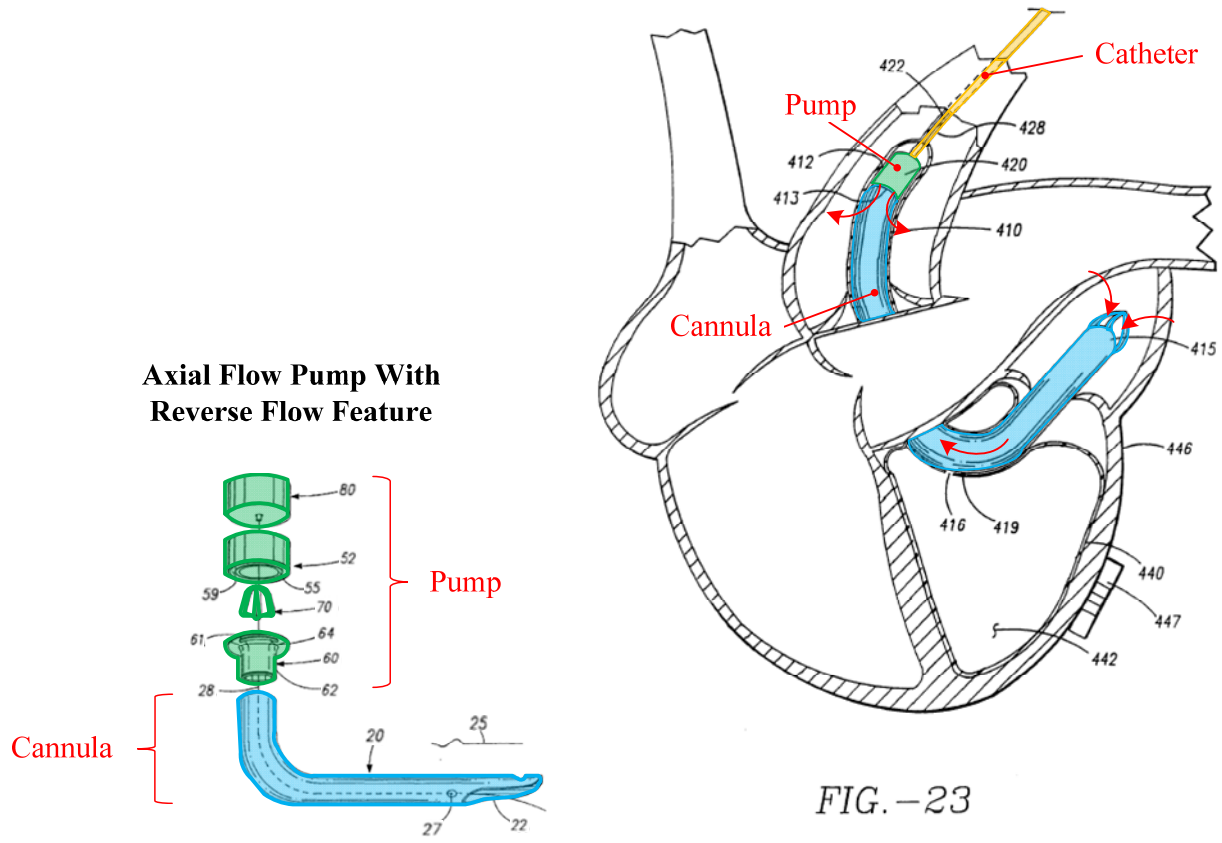
As shown below in FIGS. 1 and 2, and similar to the '314 patent, the pump system has a conventional drive motor 80 (purple) connected to a rotor and associated blades 70 (red), within a housing body 52 (green) and a housing cap 60 (green)[9]. (EX1004[Aboul-Hosn] 12:12-13:13.) The inner cannula 20 (blue) is coupled to the housing cap 60 (green), and extends beyond the distal opening 32 of the outer conduit 30 (dark grey). (*Id.*)



(Collins ¶135; EX1004[Aboul-Hosn] FIGS. 1, 2, annotated.)

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

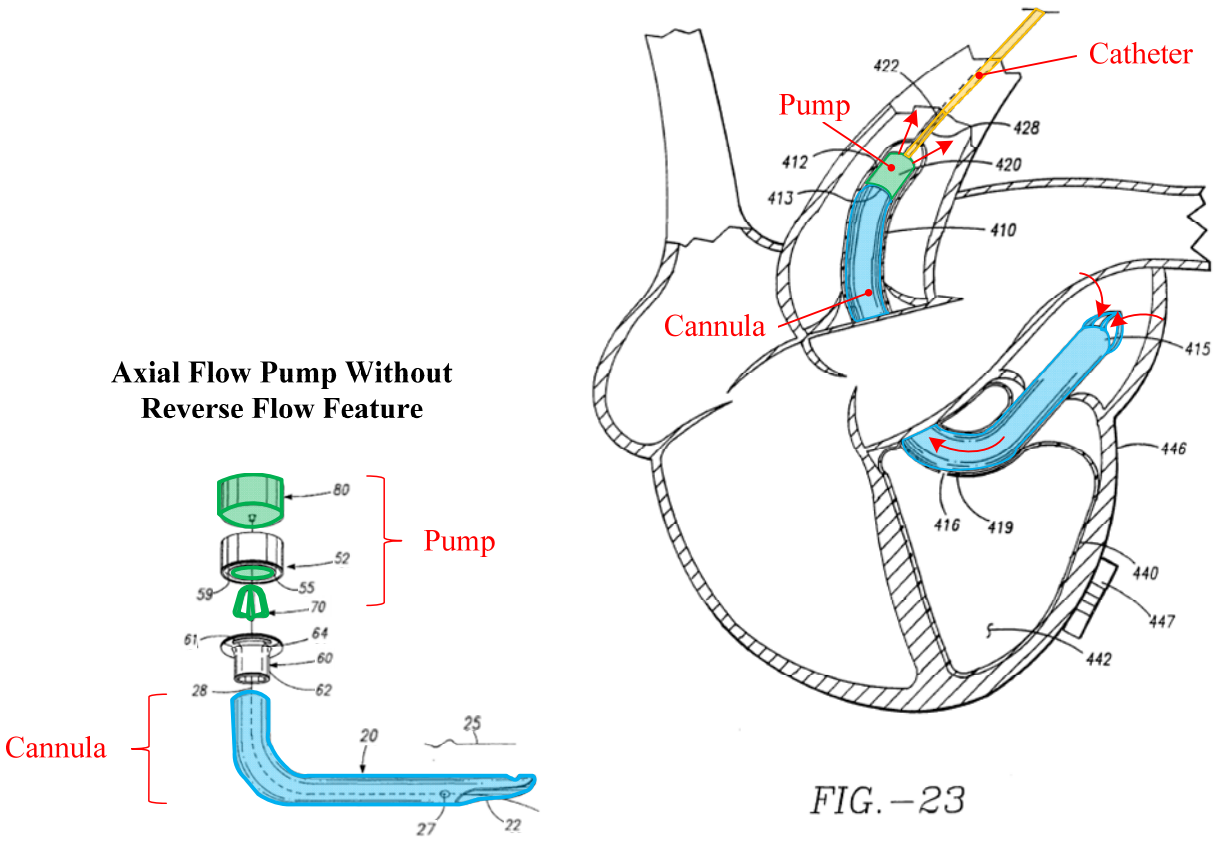
As shown below, to apply the percutaneous approach in the reverse flow configuration, the pump (green) in the system of FIGS. 1-13 (i.e. an intravascular pump "provided for by the present invention") would be readily connected to the multilumen catheter 428 (yellow). (Collins ¶¶144-145.) In this configuration, the catheter 428 would be used to advance the pump 420 and stabilization cannula 411 over a guide wire to the desired location within the patient's heart through the femoral artery. (Collins ¶145; EX1004[Aboul-Hosn] 29:18-25.)



(Collins ¶138; EX1004[Aboul-Hosn] FIGS. 1, 23, annotated.)

The pump 420 could also be configured without the reverse flow feature of the pump system of FIGS. 1-13. (Collins ¶139-141; *see also* EX1004[Aboul-

Hosn] 31:6-9.) In this configuration, the pump 420 would include the components of the pump system of FIGS. 1-13 that generate the axial flow of blood through the pump (i.e. rotor 70 and inlet tube 55, connected to drive unit 80), without the components that cause the blood flow to reverse course (i.e. housing body 52, housing cap 60, and outer cannula 30). (Collins ¶139.) Instead, the blood (represented by the red arrows) discharges axially over the drive unit and out the pump 420 (green). (*Id.*)



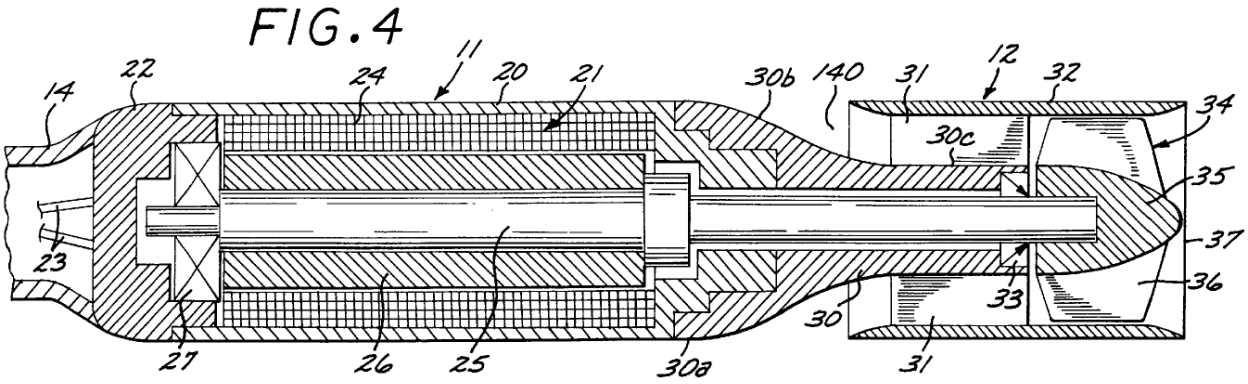
(Collins ¶139; EX1004[Aboul-Hosn] FIGS. 1, 23, annotated.)

As explained in greater detail in Section X.A.1(i) below, Aboul-Hosn uses a guide wire to deploy the pumps intravascularly using the over-the-wire technique.

(Collins ¶129; EX1004[Aboul-Hosn] 11:26-28, 14:13-16, 14:20-24, 21:22-24, 22:10-16.) FIG. 3 shows the conventional over-the-wire technique. (Collins ¶129; EX1004[Aboul-Hosn] 14:17-15:18, 17:19-22, FIG. 12.)

B. Overview of Siess

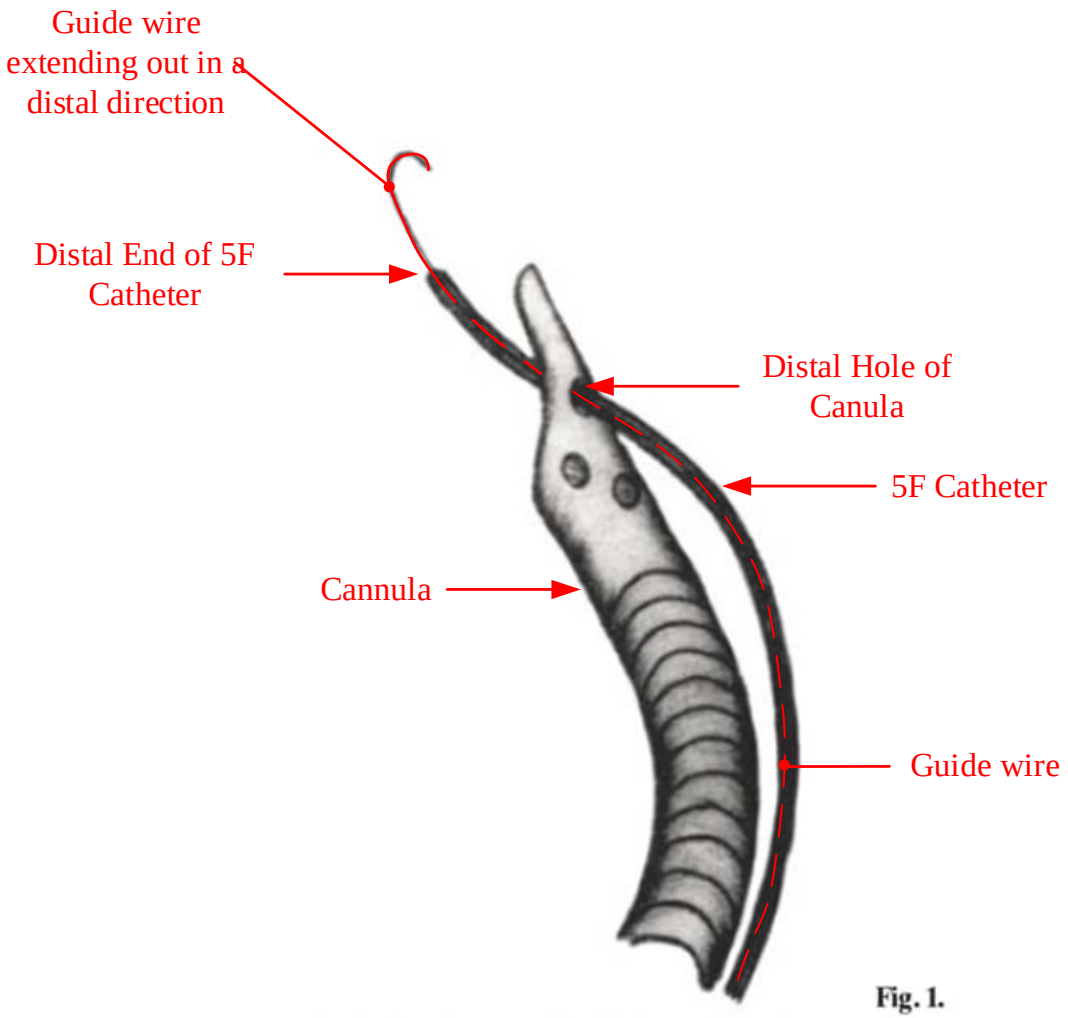
Siess also discloses an intravascular blood pump configured to be delivered to a desired location within the patient's vasculature using a guide wire. (Collins ¶¶168-172; EX1005[Siess] 5:55-58.) The pump is connected to a catheter that includes a lumen to deliver a "biocompatible purge fluid[,] … that 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.). Additionally, it can have "electrical conduits extending therethrough to allow the operation of the drive unit to be monitored and controlled." (*Id.* 3:15-18, 11:23-40.)



(EX1005[Siess] FIG. 4, annotated.)

C. Overview of Jegaden

Jegaden discloses placing a conventional axial flow intravascular pump system (i.e. the Hemopump) to a desired location using the conventional rapid-exchange technique. (Collins ¶¶152-157; EX1033[Jegaden] 61-62.) As shown in FIG. 2, the five French ("5F") catheter having a guide wire extending coaxially through its lumen and exiting its distal end is "passed through the distal hole of the cannula and introduced into the femoral artery up to the aorta," and "[t]hen the cannula is introduced into the femoral artery and is pushed into the aorta, guided by the vasculature catheter" (i.e. the 5F catheter). (Collins ¶153; EX1033[Jegaden] 62.) The 5F catheter and cannula's distal hole function as a rapid-exchange guide mechanism for the pump. (Collins ¶154-156.)



(Collins ¶154; EX1033[Jegaden] FIG. 1, annotated.)

D. Overview of Wampler

Wampler discloses the Hemopump, introduced in Jegaden, which was the original catheter-based blood pump used for the treatment of cardiogenic shock. (Collins ¶¶163-167; EX1007[Wampler] 232-36.) FIG. 14-2 of Wampler provides a schematic of the Hemopump, 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 ¶165-167; EX1007[Wampler] 233-34.)

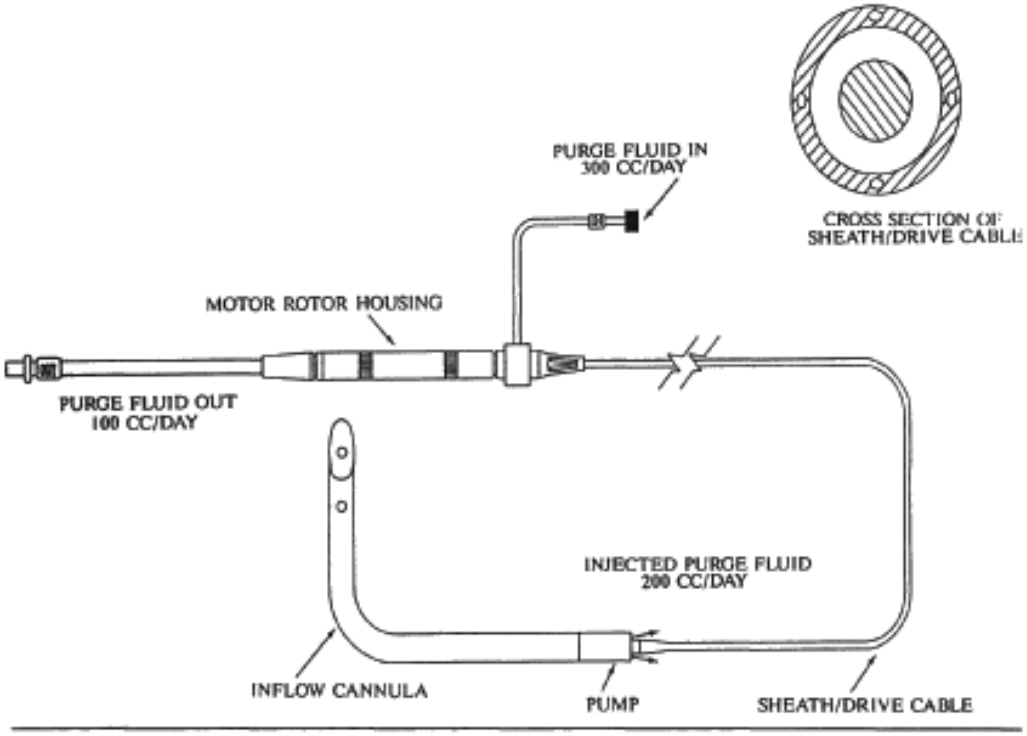


Figure 14-2. Schematic of the Hemopump.

(EX1007[Wampler] FIG. 14-2.)

E. Overview of Wampler_712

Wampler_712 also describes the Hemopump, disclosing an axial flow intravascular blood pump connected to the cannula at the cannula's proximal end. The blood pump includes a rotatable rotor within a shroud to push blood axially along the pump. The Hemopump's cannula is connected to a rotor within a generally cylindrical housing.

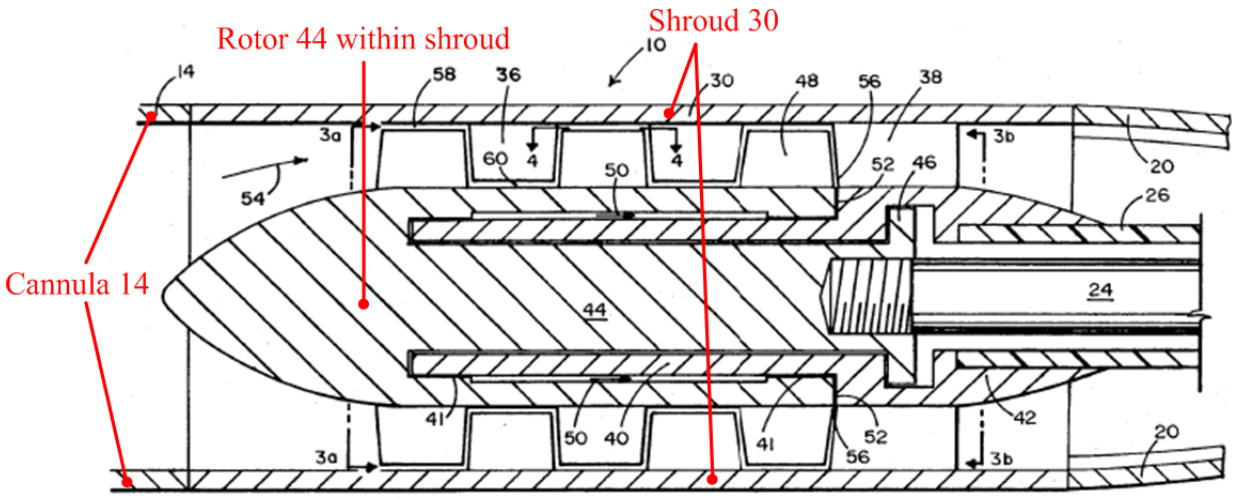
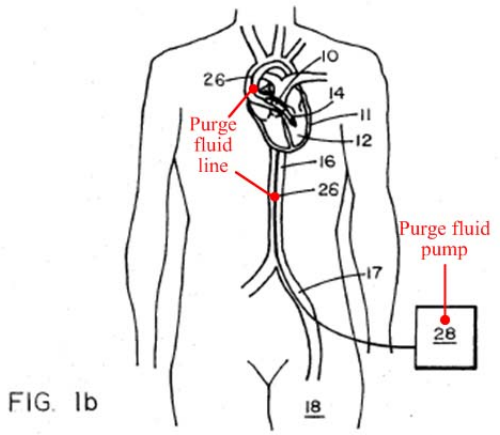


FIG. 2

(Collins ¶174; EX1008[Wampler_712] FIG. 2, annotated.)

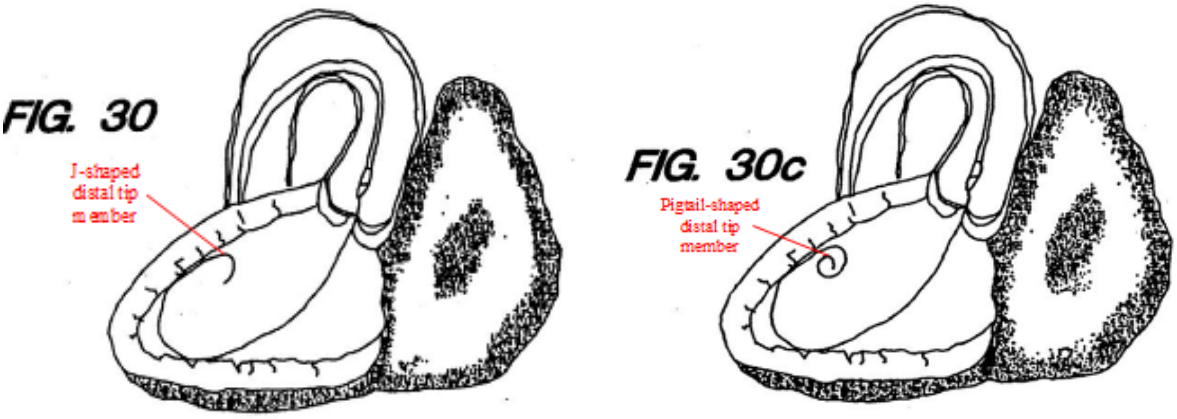
Wampler_712 also discloses additional purge fluid features, including a support unit 28, with a purge fluid pump providing purge fluid through a catheter 26 to the blood pump 10. (EX1008[Wampler_712] 3:40-42.) As shown in FIG. 1b below, purge fluid pump 28 connects to catheter 26 to deliver a "continuous flow of purge fluid 50 … into the pump 10 under pressure through the catheter 26." (EX1008[Wampler_712] 3:40-44.) Wampler_712 discloses that the "catheter also provides a conduit to supply the pump bearings with a blood-compatible purge fluid at a rate and pressure sufficient to prevent thrombus formation and introduction of blood elements between rotating and stationary elements of the pump." (*Id.* Abstract.)



(Collins ¶175; EX1008[Wampler_712] FIG. 1b, annotated.)

F. Overview of Crowley

The use of a distal tip member to improve the placement of intravascular devices in the heart was well known before the EPD. (Collins ¶173) For example, Crowley describes the use of a guide wire 80 to "guid[e] the ultrasound device through a valve such as the heart." (*Id.*; EX1047[Crowley] 16:41-43.) The guide wire "support[s] and stead[ies] the free end of the ultrasound device during axial movement of the catheter to improve its imaging capability; see FIGS. 30-30c." (EX1047[Crowley] 16:50-55.) The guide wire has a curved distal tip member (a J-tip member in FIG. 30, a pigtail member in FIG. 30C).



(Collins ¶173; EX1047[Crowley] FIGS. 30, 30c.)

VIII. CLAIM CONSTRUCTION

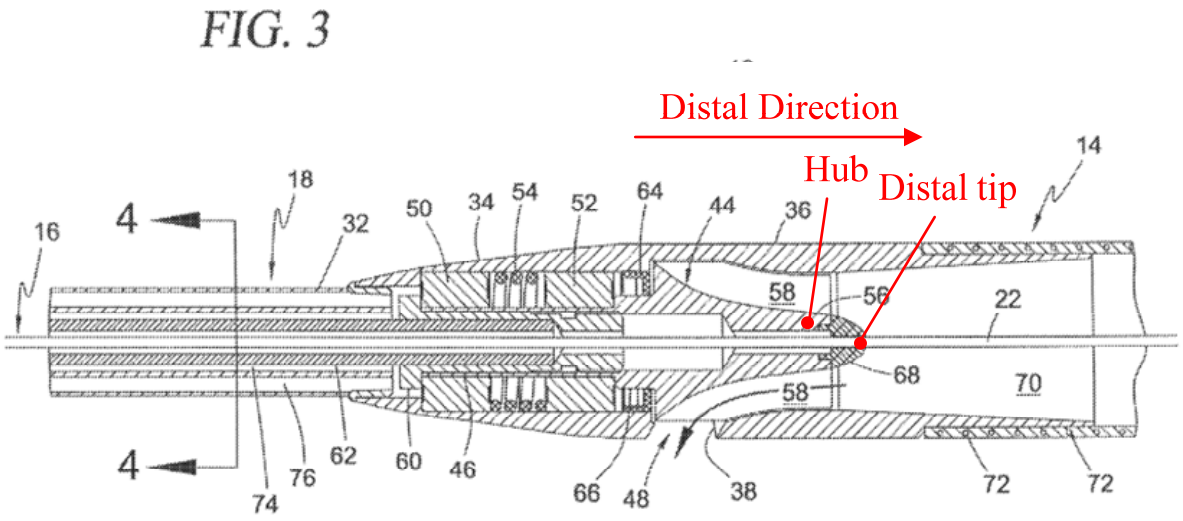
A claim in *IPR* is given the "broadest reasonable construction in light of the specification." (37 C.F.R. § 42.100(b).) Any claim term that lacks a definition in the specification is therefore also given a broad interpretation. (*In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).) Petitioner submits the following claim term constructions.[10] Any claim terms not included in the following discussion are to be given their broadest reasonable construction in light of the specification as commonly understood by a POSITA.

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.*

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

¶¶116-119.) The '314 patent provides that "the purge fluid flows distally around the cable adapter, through the ball bearing assemblies 50, 52, and onward past the radial seal 64." (EX1001['314 patent] 12:34-37.)

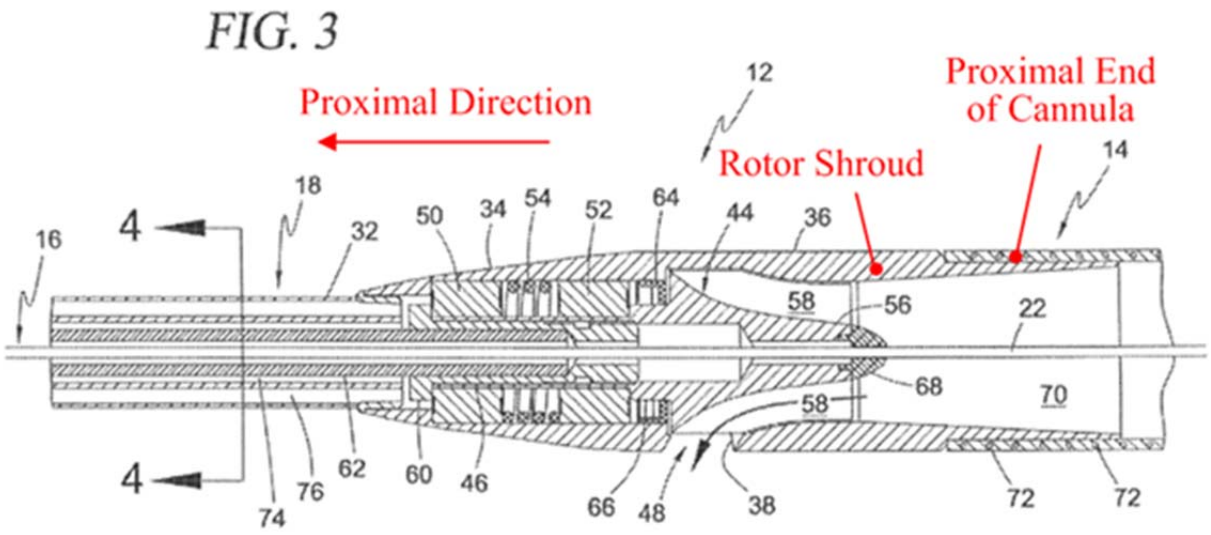


(Collins ¶116; EX1001['314 patent] FIG. 3, annotated.)

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 towards the opening of the cannula into the patient's heart. (Collins ¶¶117-119.)

B. "proximal"

The Challenged Claims also recite the term "proximal." This term refers to the opposite of "distal." (Collins ¶¶120-122.) For example, the '314 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.* ¶120; EX1001['314 patent] 10:27-30, 11:60-61.)



(Collins ¶120; EX1001[’314 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.)

X. SPECIFIC GROUNDS FOR PETITION

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

A. Ground I: Claims 1-8, 14-20, and 25-26 are obvious over Aboul-Hosn in view of Siess and Wampler

1. Claim 1

a) "*An intravascular blood pump system comprising:*"

Aboul-Hosn discloses an intravascular blood pump system. (Collins ¶¶201-211; EX1004[Aboul-Hosn] 6:6-7("[A] reverse flow pump system that transports fluid between different regions within the body," 6:26-28: "A reverse flow blood pump system may be passed through a conduit and positioned in a heart chamber or a vessel.") FIG. 23 of Aboul-Hosn, annotated below, shows "a partial sectional view of the heart and a stabilization system used in cooperation with an intravascular pump" that was delivered percutaneously into the heart through the femoral artery. (*Id.* 10:10-11, 29:17-19.)

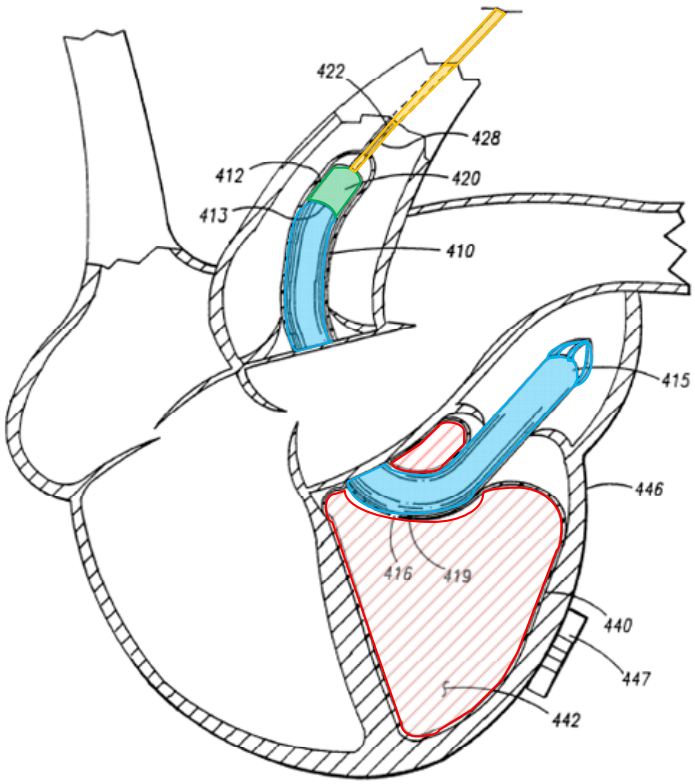


FIG.–23

(Collins ¶204; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As discussed in Section VII.A, Aboul-Hosn discloses that the axial flow pump system of FIGS. 1-13 with or without the reverse flow feature can be delivered to the heart percutaneously by connecting the pump components illustrated in FIGS. 1-13 with the multilumen catheter 428 and adapting the inner cannula 20 and the outer conduit 30 as the stabilization cannula 411 in FIG. 23. (Collins ¶205-206 EX1004[Aboul-Hosn] 8:20-9:13, 29:18-30:28, 14:13-16.) Petitioner explains further details below.

b) "*an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a*

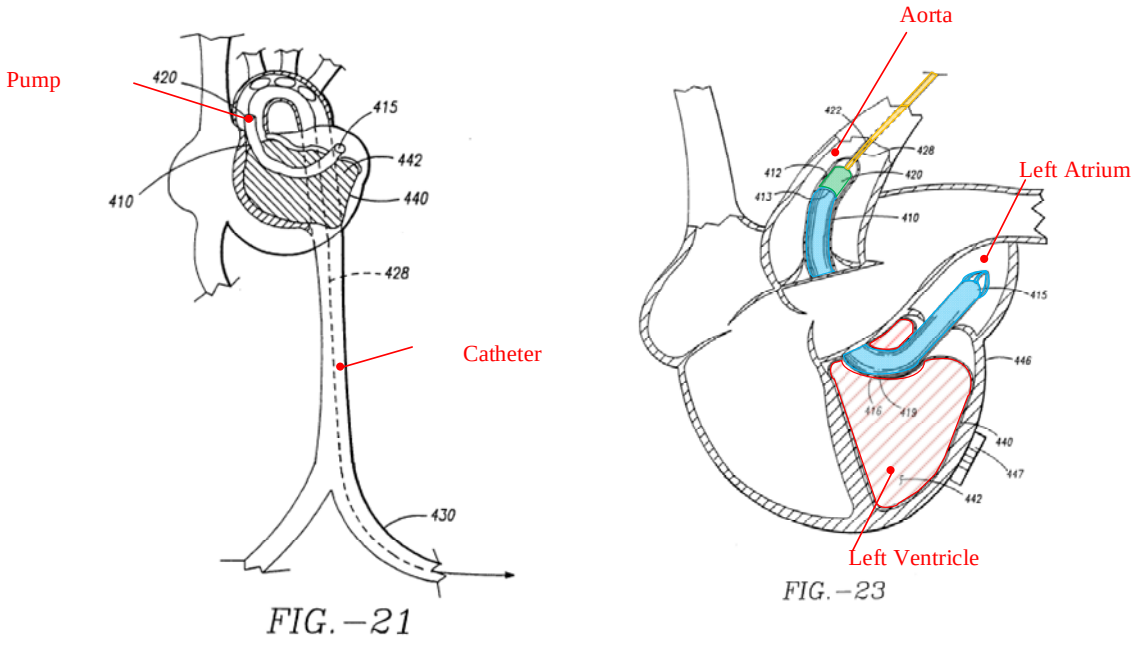
> *patient by a guide wire and the intravascular blood pump configured to provide left-heart support,*"

Aboul-Hosn discloses that the axial flow blood pump system of FIGS. 1-13 (i.e. an intravascular blood pump), either with or without the reverse flow feature, can be delivered to the heart percutaneously as shown in FIG. 23. (Collins ¶¶212-216; EX1004[Aboul-Hosn] 8:20-9:13, 29:18-30:28, 14-16.) Aboul-Hosn discloses extending a guide wire through a lumen to place the blood pump in a desired location within the patient. (Collins ¶212; EX1004[Aboul-Hosn] 11: 24-26, 17:19-23, 22:10-16, 24:7-14, 29:23-25.)

Specifically, the guide wire is first placed in the desired location, and then the distal end of the inner cannula 20 and the pump 50 are guided to the desired location within the patient's vasculature by sliding the inner cannula 20 and pump 50 over the guide wire. (Collins ¶213; EX1004[Aboul-Hosn] 22:12-16: "[t]he guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28.") The guide wire can guide the cannula coupled to the pump to any location in the body, including any "blood vessel, heart chamber or other body cavity." (Collins ¶213; EX1004[Aboul-Hosn] 11:8-11, 11:24-28, 22:10-12.) This includes the left ventricle or atrium to provide left-heart support in the same conventional manner as disclosed by the '314 patent. (Collins

¶215; EX1004[Aboul-Hosn] 26:10-13, 29:31-30:2: "[a]fter proper positioning, a pump may be activated to take over the left ventricle function."; EX1001['314 patent] 20:43-48: "[v]arious pump and cannula arrangements have been described and show above for providing … left heart support wherein blood is deliberately re-routed through and past the … left ventricle in an effort to reduce the volume of blood to be pumped by the [left] ventricle.")

As shown in FIGS. 21 and 23 of Aboul-Hosn below, "to take over the left ventricle function," the pump is positioned in the patient's aorta and the cannula extends through the left ventricle and into the left atrium, bypassing the left ventricle. (Collins ¶216.)



(Collins ¶216; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

Aboul-Hosn also provides other examples using the axial flow blood pump to provide left-heart support, right-heart support, or both. (Collins ¶218-219; EX1004[Aboul-Hosn] FIGS. 15-17, 19.)

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

c) "*the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub;*"

The intravascular blood pump of Aboul-Hosn has a rotor having a rotor hub. (Collins ¶¶221-223; EX1004[Aboul-Hosn] 12:30-1: "[t]he reverse flow pump 50 … includes a rotor 70 axially aligned inside a cylindrical shaped housing body 52.") FIGS. 7A-7C "illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus." (*Id.* 16:30-31.) For example, FIG. 7B, reproduced below, shows a rotor 70 having a central hub 74 tapering in the distal direction. (Collins ¶221.) As applied to FIG. 7B of Aboul-Hosn, the distal direction is the direction towards the far end of the cannula relative to the position of the pump. (*Id.*)

Aboul-Hosn discloses at least one blade extending radially outward from the rotor hub. (*Id*.) FIG. 7B illustrates the rotor 70 having three blades 72 each extending radially outward from the central hub 74. (*Id.*; EX1004[Aboul-Hosn] 17:1-2)

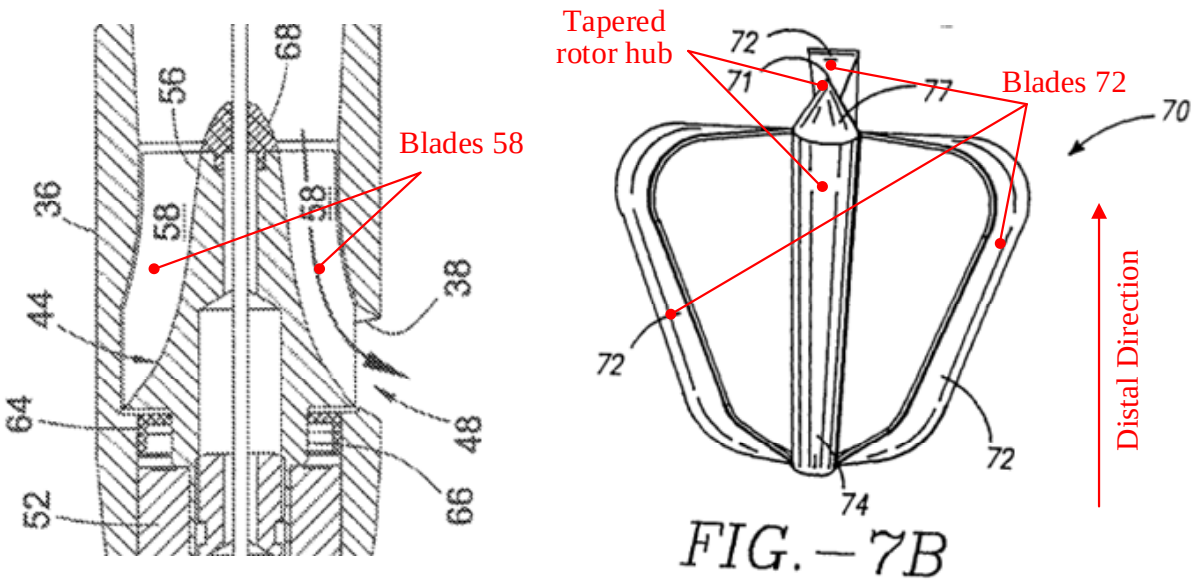


FIG. – 7B

(Collins ¶221; EX1001['314 patent] FIG. 3, annotated (left); EX1004[Aboul-Hosn] FIG. 7B, annotated (right).)

Aboul-Hosn discloses this limitation. (Collins ¶¶224-225.)

d) "*a cannula coupled to a distal end of the intravascular blood pump, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port, and*"

Aboul-Hosn discloses an intravascular blood pump 420 (green) coupled to a catheter 428 (yellow) on its proximal end and a cannula 411 (blue) on its distal end. (Collins ¶226-229; EX1004[Aboul-Hosn] 30:27-28.)

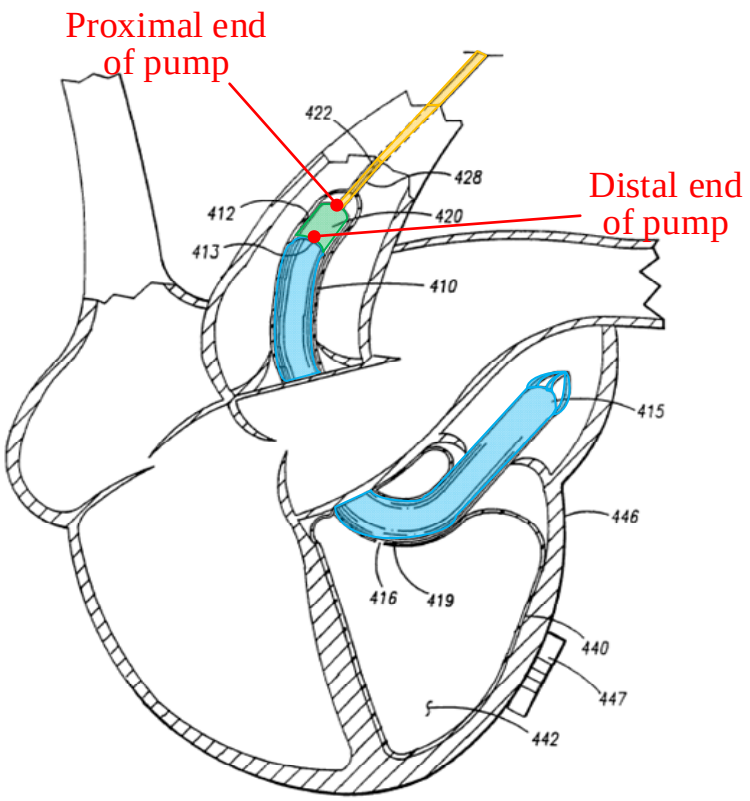
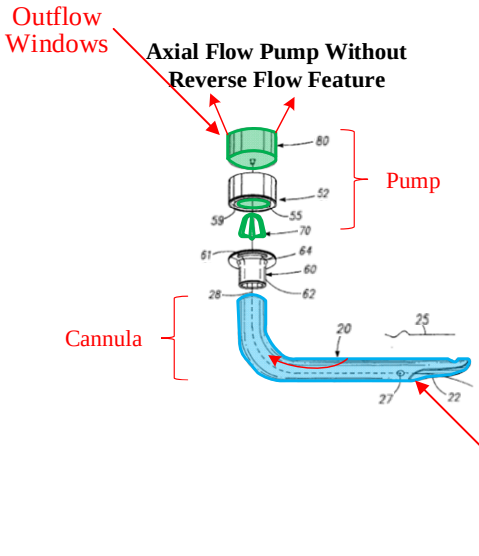


FIG.–23

(Collins ¶228; EX1004[Aboul-Hosn] FIG. 23, annotated.)

The axial blood pump components of FIGS. 1-13 with or without the reverse flow feature can be used for the blood pump 420. (Collins ¶230-231.) As shown in FIGS. 3 and 23 below, in operation, for either the axial flow pump with or without the reverse flow feature, blood enters the cannula through openings at its distal end 415, and is pushed by the rotor of the pump 420 through outflow windows of the pump housing and exits the proximal end of the pump 420. (Collins ¶¶232-241; EX1004[Aboul-Hosn] 11:21-24: "a plurality of openings 27 formed near its tip 25 to allow blood to flow into the inner cannula 20", 13:6-13,

13:15-18: "[d]uring operation of the fluid control apparatus in this configuration, the rotor 70 is rotated by the driving unit 80 through an opening or hole 54 in order to direct fluids such as blood".)



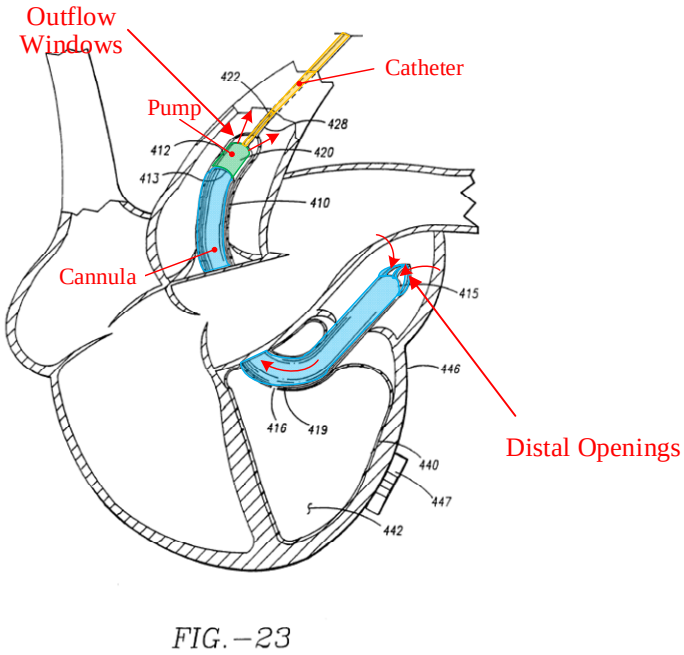


FIG.–23

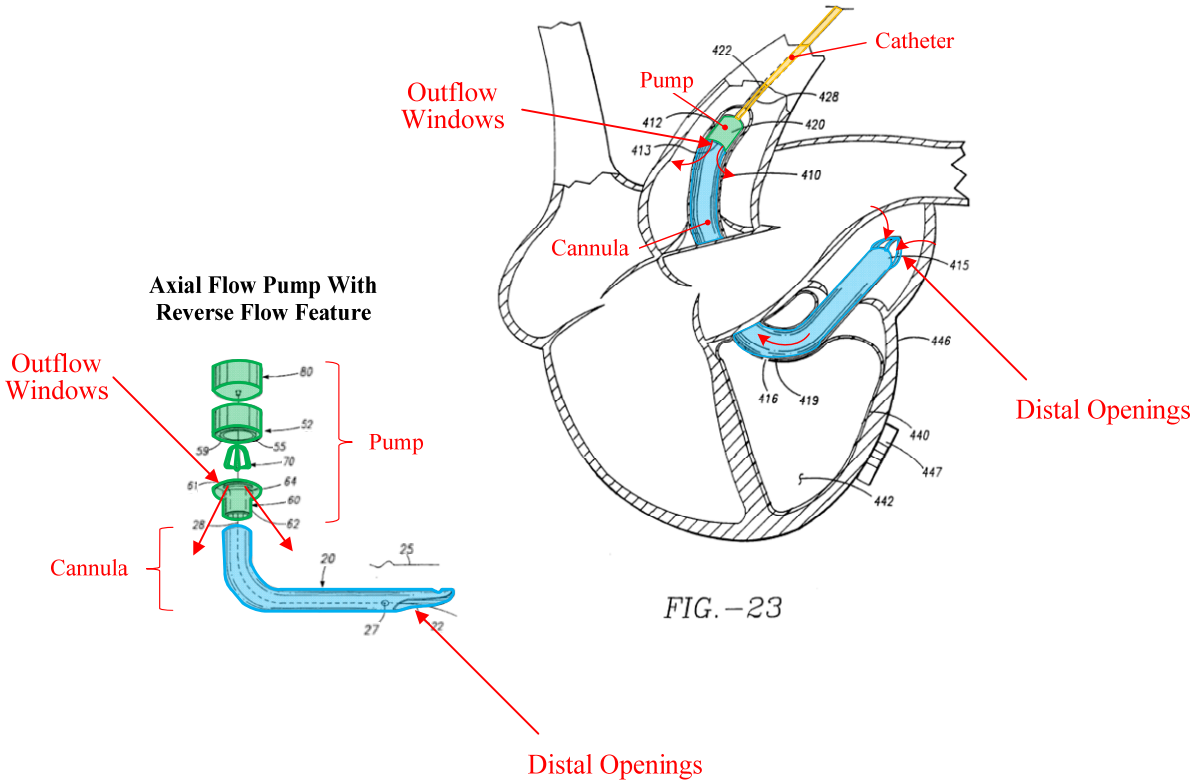


FIG.–23

(Collins ¶230; EX1004[Aboul-Hosn] FIGS. 3, 23, annotated.)

When the pump 420 is activated, blood flows through the distal opening 22, openings 27, and outflow windows in the pump housing establish fluid communication between a lumen of the inner cannula 20 and an exterior region of the inner cannula 20 during operation of the blood pump 420. (Collins ¶¶237-238.) Moreover, FIGS. 3 and 23show, for both the axial flow pump with or without the reverse flow feature, the distal opening 22 and openings 27 are located at the distal region of the cannula, whereas the outflow windows are located at the opposite end of the blood pump 420 adjacent the rotor 70 within the housing body 62. (*Id.* ¶¶235-239.)

Thus, when the pump is actuated, the distal opening 22 along with openings 27 are the "one or more second ports," and the outflow windows would be the "one or more first ports," where the one or more first ports and the one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, and at least one first port is in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port. (Collins ¶¶237-242.)

e) "*wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient,*"

Aboul-Hosn discloses the intravascular blood pump may be positioned in any "blood vessel, heart chamber or other body cavity," including the left ventricle (EX1004[Aboul-Hosn] 11:8-11, 11:24-28, 22:10-12, 26:10-13.) Aboul-Hosn discloses the distal end 415 of the cannula extends through the aortic valve into the left ventricle, and through the left ventricle into the left atrium to provide left-heart support. (Collins ¶¶245-246, 253.) "After proper positioning, a pump may be activated to take over the left ventricle function." (EX1004[Aboul-Hosn] 29:31-30:2.)

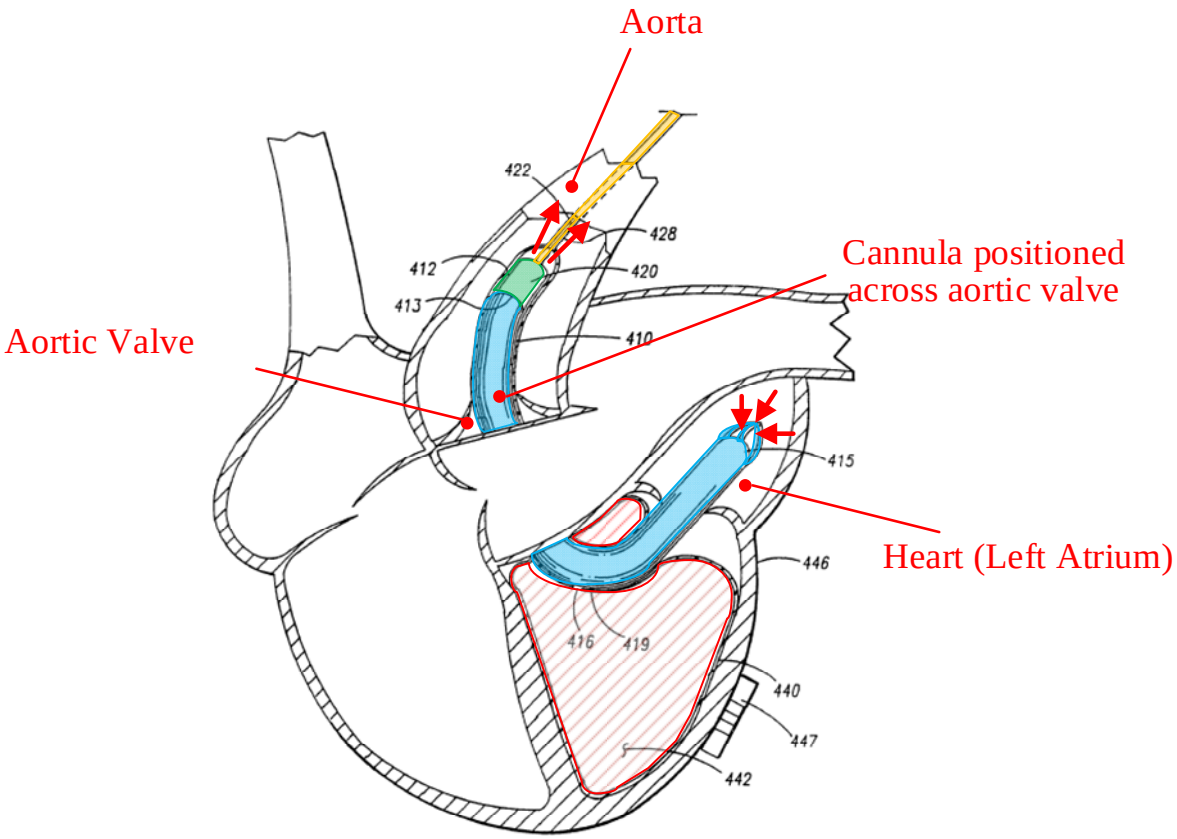


FIG.–23

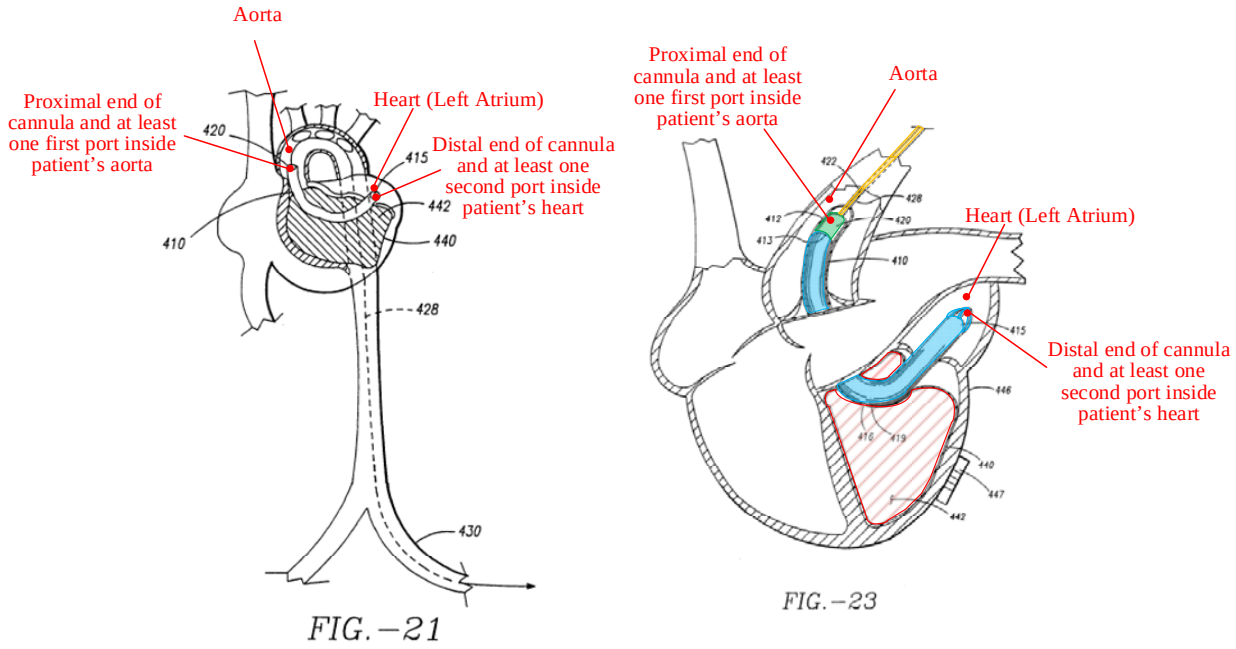
(Collins ¶253; EX1004[Aboul-Hosn] FIG. 23, annotated.)

In operation, blood flows (indicated by the red arrows) from the left atrium of the patient's heart through the distal openings 22 and openings 27 at the distal end 415 of the cannula, through the cannula, and is pumped into the aorta. (*Id.*) Thus, Aboul-Hosn discloses this limitation. (*Id.*¶254)

f) "*the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and*

the at least one first port are positioned in the patient's aorta;"

Aboul-Hosn discloses an intravascular blood pump configured for left-heart support, meeting this limitation. (Collins ¶¶243-247; EX1004[Aboul-Hosn] 29:31-30:2.) As shown in FIGS. 21 and 23, reproduced below, when providing left heart support the pump 420 is positioned in the patient's aorta and the cannula extends through the left ventricle and into the left atrium, bypassing the left ventricle. (Collins ¶245.)



(Collins ¶245; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

In this configuration, the distal opening 22 and openings 27 (i.e. the "at least one second port") located at the distal region of the cannula are positioned inside of the patient's heart along with the distal end 415. (Collins ¶246-247.) The outflow windows formed in the pump 420 housing (i.e. the "at least one first port")

along with the proximal end of the cannula which is connected to the pump 420 are positioned in the aorta. (*Id*.) Thus, Aboul-Hosn discloses this limitation. (*Id.*)

g) "*a catheter connected to a proximal end of the intravascular blood pump*,"

Aboul-Hosn discloses this limitation in the same manner as the '314 patent. (*Id.*) As shown in FIG. 23, below, Aboul-Hosn discloses an intravascular blood pump 420 (green) coupled to a catheter 428 (yellow) on its proximal end and a cannula 411 (blue) on its distal end. (Collins ¶257.)

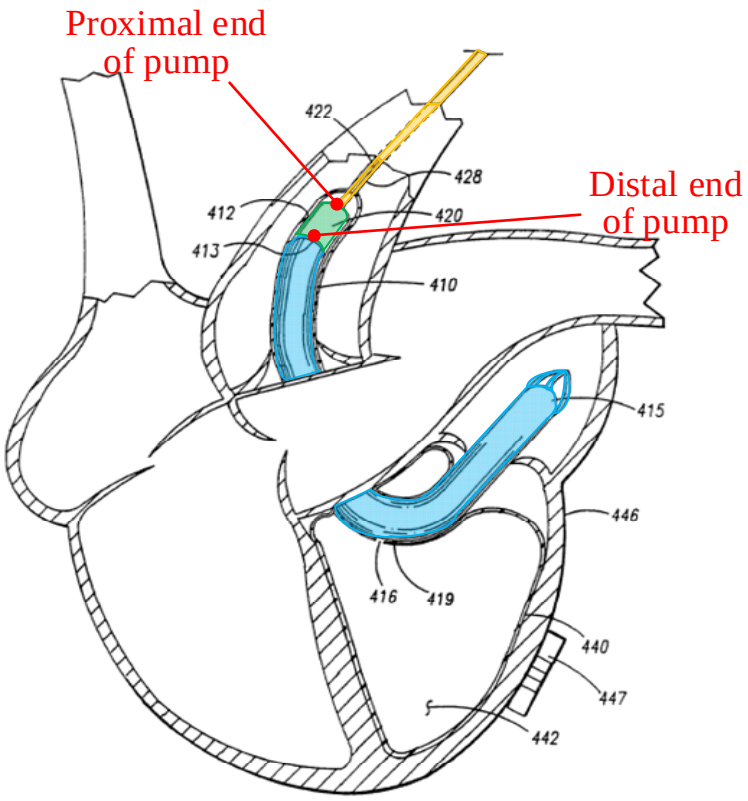


FIG.–23

(Collins ¶257; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As applied to FIG. 23 of Aboul-Hosn, the distal end of the blood pump 420 is the end closest to the distal end 415 of the cannula, and the proximal end of the blood pump is the end away from the distal end 415. (*Id.*) Aboul-Hosn shows the catheter 428 directly connected to the proximal end of the pump 420 in FIG. 23. (*Id.* ¶258.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶259.)

h) "*a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump;*"

Aboul-Hosn in view of Siess discloses a purge lumen in fluid communication with the intravascular blood pump. (Collins ¶¶260-272.) As shown in annotated FIG. 23 below, Aboul-Hosn discloses a catheter 428 (yellow) attached to the intravascular blood pump 420 (green), the catheter 428 "linking the device to the exterior of the body." (EX1004[Aboul-Hosn] 29:17-19.)

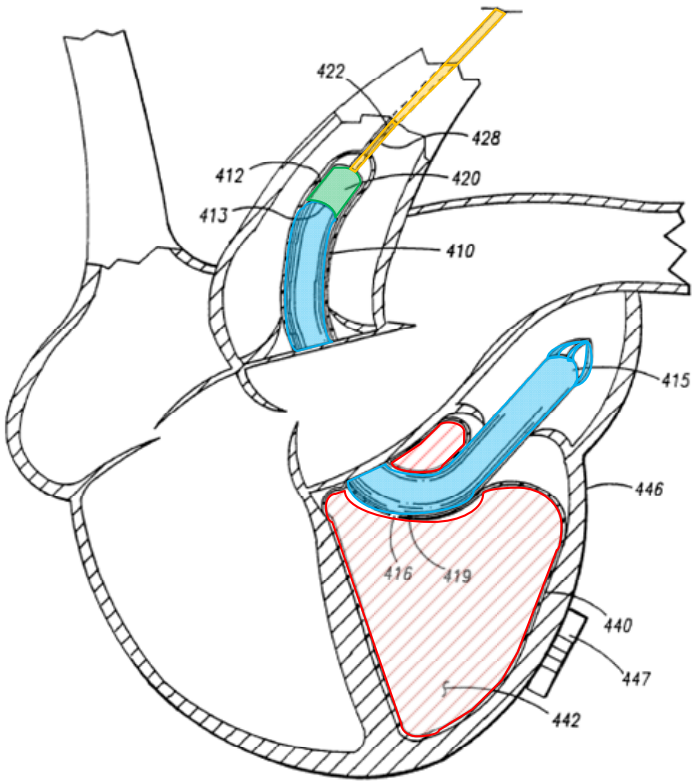


FIG.–23

(Collins ¶257; EX1004[Aboul-Hosn] FIG. 23, annotated.)

Aboul-Hosn further discloses that "[t]he catheter 428 may be a multilumen catheter with separate lumens to drive the pump 420, to measure pressure in the vicinity of the catheter along its entire length, ***to deliver or remove fluid***, to enable the passage of small diameter guides or leads, or to perform other similar functions." (*Id.* 29:19-25, emphasis added.)

Moreover, Aboul-Hosn discloses delivering purge fluid to the intravascular blood pump using fluid to lubricate the "drive unit 80 that may be used in accordance with the present fluid control and delivery system." (Collins ¶¶261-

263; 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, such as … dextrose solution …" (*Id.*) The drive unit 80 also includes a groove 205 that attaches to either the positioning rod 274 or the multi-lumen catheter, allowing the biocompatible lubricating fluid to flow into the two bearings (purple) and the blood seal 84 (blue). (Collins ¶264; Aboul-Hosn at 20:21-23, 29:19-24.) 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.)

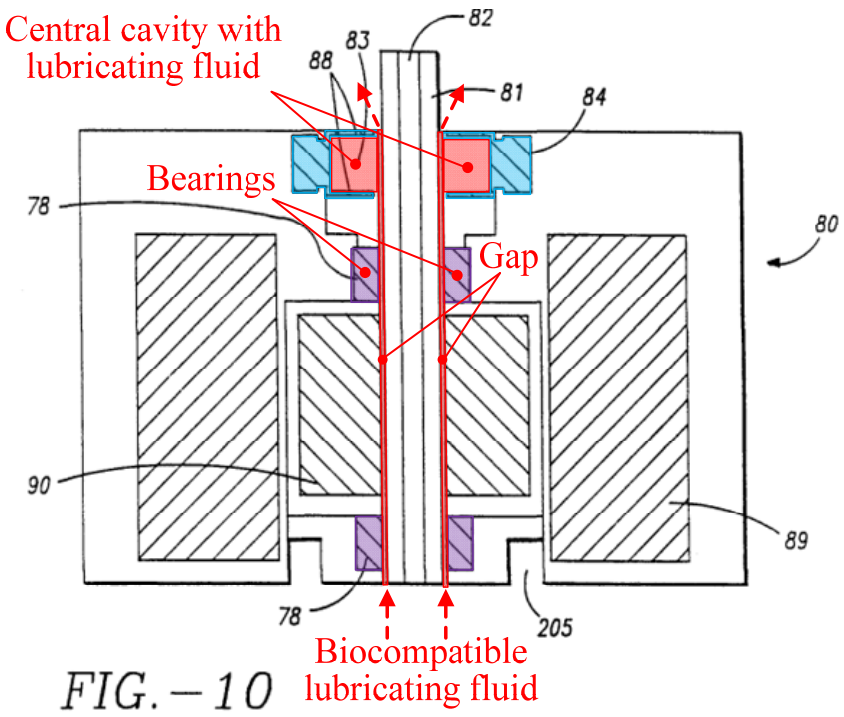


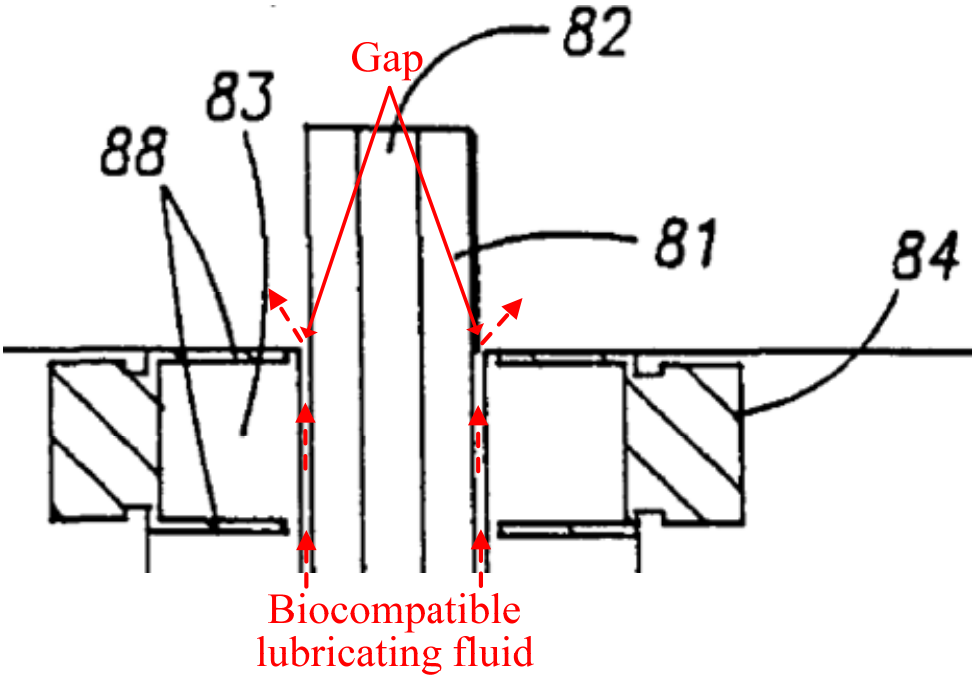
FIG. – 10

(Collins ¶263; EX1004[Aboul-Hosn] FIG. 10, annotated.)

Aboul-Hosn discloses "purge fluid" as a "biocompatible lubricating fluid," for example a 40% dextrose solution. (EX1004[Aboul-Hosn] 21:1-3.) Dextrose is a commonly used biocompatible purge fluid to lubricate mechanical parts of the pump. (Collins ¶262.)

The '314 patent discusses that the "purge fluid" serves the dual purpose of "thwart[ing] the ingress of blood past the radial seal 65, which might otherwise cause clotting and/or pump damage," and "reduces frictional heating within the pump 12 and/or central lumen 74 of the sheath 32 during pump operation." (EX1001['314 patent] 12:30-46.) The biocompatible lubricating fluid of Aboul-Hosn serves the same purpose. (Collins ¶¶263-266.) First, it is self-evident that the biocompatible lubricating fluid acts as a lubricant for the bearings and shaft 81, reducing friction and heat associated with friction, which is why Aboul-Hosn refers to the fluid as a biocompatible lubricating fluid. (*Id*. ¶¶261-265)

Second, as shown in the close-up view of FIG. 10, below, in Aboul-Hosn, the drive shaft is structured to permit purge fluid to flow out of the pump and there is a gap between the thin lips 88 of the central cavity 83 and the outside diameter of the shaft 81. (*Id.* ¶¶265-266)

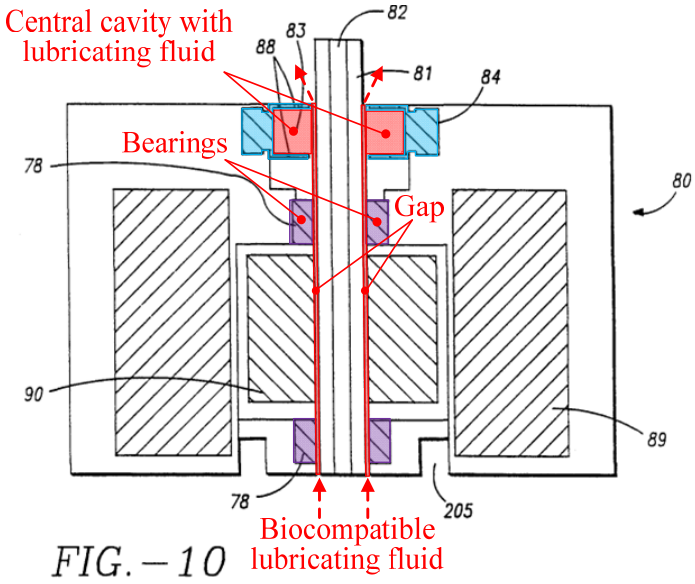


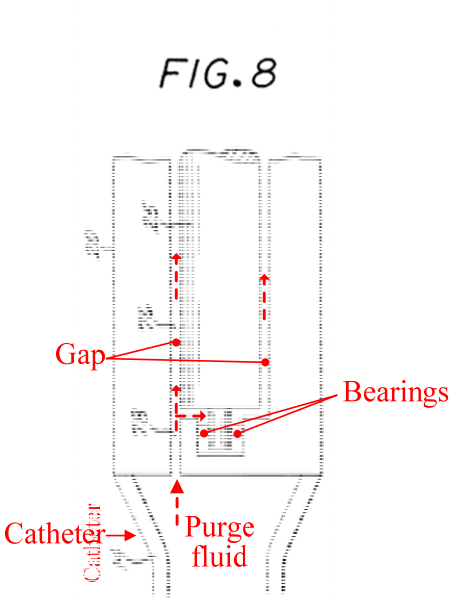
(Collins ¶265; EX1004[Aboul-Hosn] FIG. 10, annotated.)

This gap allows for the biocompatible lubricating fluid to slowly seep outwards from the central cavity 83, 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.* ¶266; 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 ¶266.)

A POSITA would have readily understood that the purge lumen within the multilumen catheter 248 would be "operatively arranged" to deliver purge fluid towards the intravascular blood pump by the continuous infusion of dextrose solution to the central cavity 83. (*Id.* ¶¶267-268; EX1004[Aboul-Hosn] 29:19-25.)

Such a configuration was well known in the art and expressly disclosed by Siess. (Collins ¶268.) Siess 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)." (EX1005[Siess] 8:31-36.)





(Collins ¶268; EX1004[Aboul-Hosn] FIG. 10, annotated (left); EX1005[Siess] FIG. 8, annotated (right).)

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 ¶268; 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.)

Thus, to provide a continuous infusion of purge fluid as disclosed in Aboul-Hosn, it would have been obvious to a POSITA to connect one or more lumens of the multi-lumen catheter 428 and the drive unit 80 in the manner disclosed in Siess (as shown above in annotated FIG. 10 of Aboul-Hosn and FIG. 8 of Siess), such that there is fluid communication between the catheter 428 and the central cavity 83 within the drive unit 80, and then to pressurize the purge fluid to maintain infusion. (Collins ¶269.)

A POSITA would have been motivated to "operatively arrange[]" the multilumen catheter 428 and the drive unit 80 in that manner based on Aboul-Hosn's express teachings of (1) "a multilumen catheter with separate lumens … to deliver or remove fluid" (EX1004[Aboul-Hosn] 29:19-23), (2) "[a] blood seal 84 may be attached to the drive unit 80 and may comprise a central cavity 83 containing a biocompatible lubricating fluid, such as nutrilipid, dextrose solution, glycerin, or alike" (*Id.* 20:26-29), and (3) to provide "a continuous infusion of dextrose into the seal area" (*Id.* 21:1-3). (Collins ¶270.)

Doing so would have been a 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.* ¶271.) Indeed, the use of a purge fluid delivery system to prevent undesirable "thrombus formation in the pump" was already well-known in the art before the EPD. (*Id*. ¶¶68-71; EX1008[Wampler_712] 3:40-51.)

Thus, Aboul-Hosn in view of Siess discloses this limitation. (Collins ¶272.)

> i) **"***an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula, and an end of the elongate lumen is adjacent an end of the cannula, the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen;***"**

The '314 Patent does not define *elongate* lumen, however Aboul-Hosn discloses this element in the same manner as disclosed in the '314 Patent in an over-the-wire configuration. (Collins ¶¶273-285)

Aboul-Hosn discloses an elongate lumen arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally. (Collins ¶273) Aboul-Hosn's over-the-wire guide mechanism includes a lumen extending through the length of the multi-lumen catheter 428, the central passages within the drive unit 80 and the pump components (including the rotor hub 74), and the length of the cannula 411. (Collins ¶274) Cannula 411 includes the inner cannula 20 (and outer conduit 30 in

the reverse flow mode) adapted for percutaneous access. (Collins ¶274; EX1004[Aboul-Hosn] 14:13-16.) The guide mechanism has an axis through the central passages of the components of the intravascular blood pump system because the various components of the intravascular blood pump system align to form the lumen, as shown in annotated FIG. 3 below. (Collins ¶274; EX1004[Aboul-Hosn] 12:28-13:1; 13:7-9; 13:23-24.)

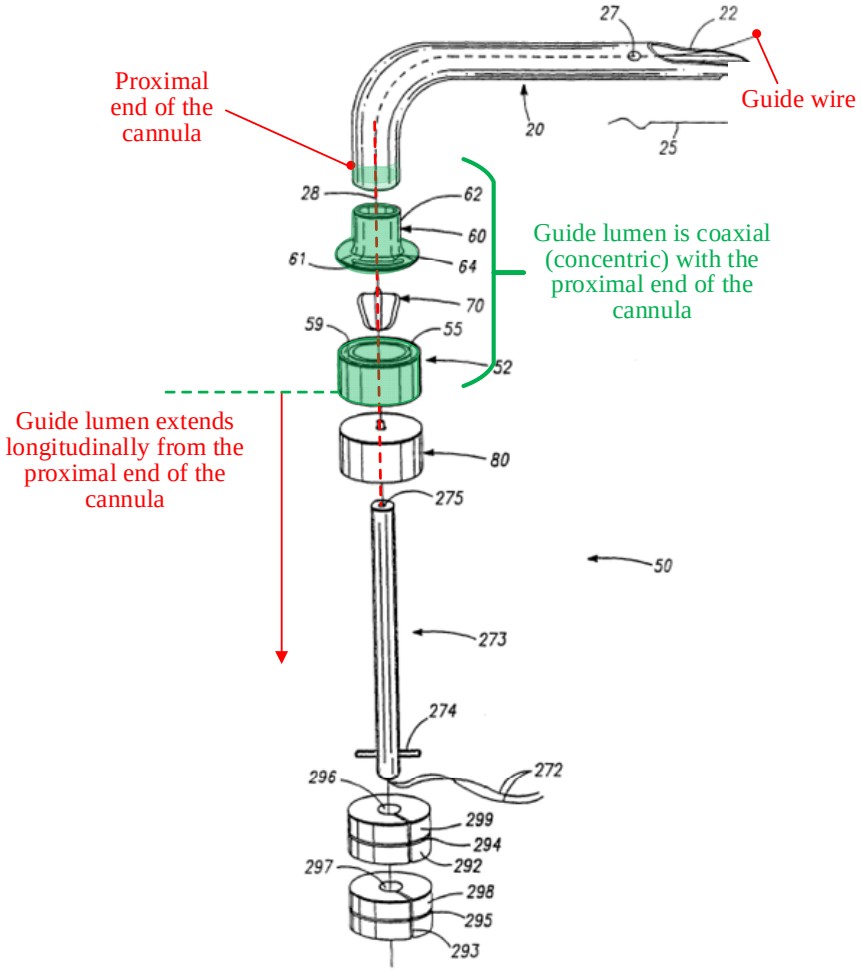


FIG.—3

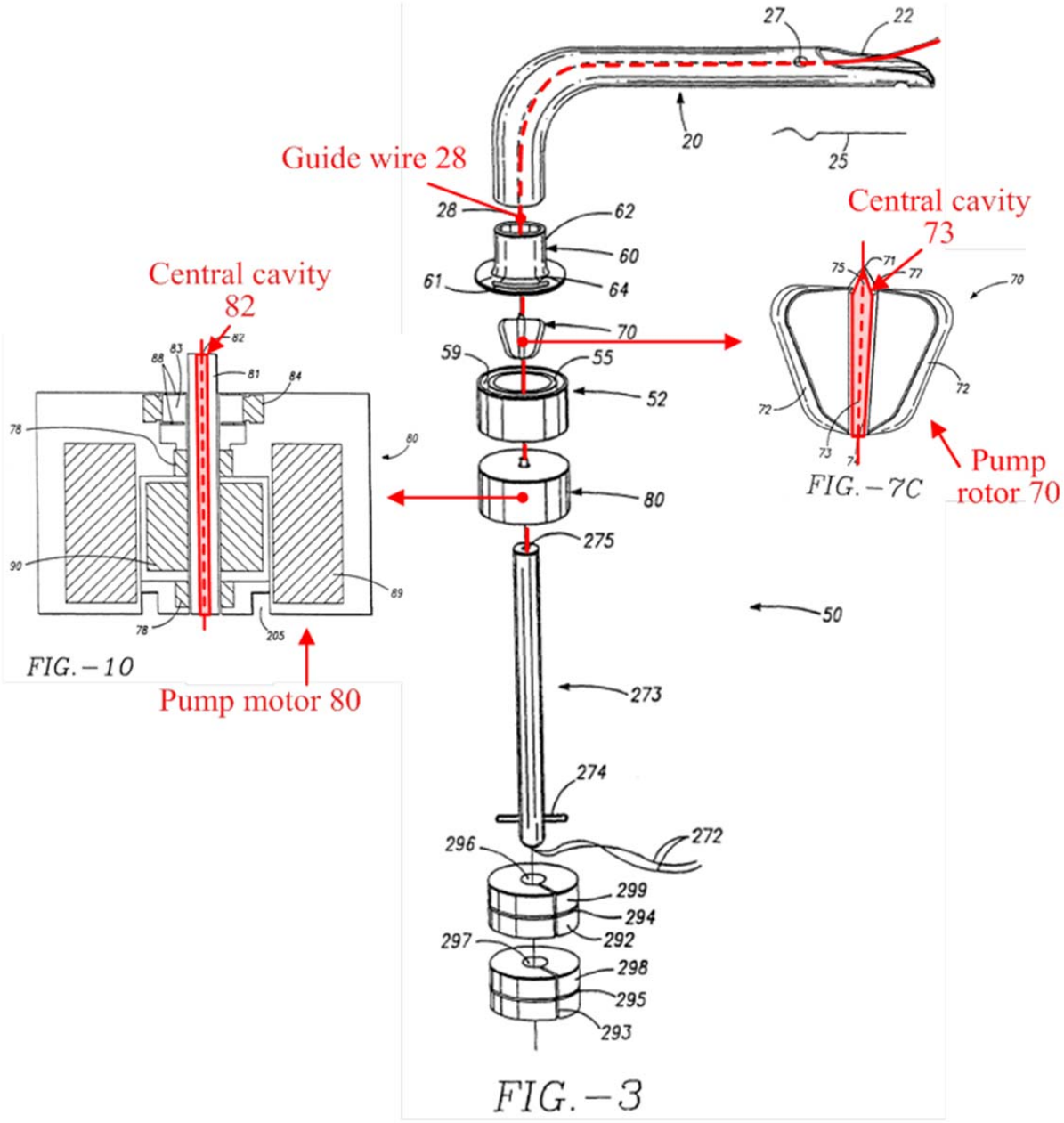
(Collins ¶279; EX1004[Aboul-Hosn] FIG. 3 (annotated))

As shown above, the elongate guide lumen is coaxial (concentric) with the proximal end of the cannula over this portion (indicated with a green bracket). (Collins ¶281) Accordingly, the proximal end of the cannula is concentric with the components of the pump in the region of the housing cap 60 (i.e., the housing cap 60 fits within the distal end of the cannula 20 (or cannula 411)) and shares a common axis within that region. (*Id.*)

Annotated FIG. 3 above also includes a red arrow below the portion of the pump (indicated with green bracket) showing the elongate guide lumen extending longitudinally away from the proximal end of the cannula. (*Id.*) In FIG. 3, the cannula is aligned in series longitudinally with the lumen, as the various components of the intravascular blood pump system align to form a lumen that extends from the cannula through the drive unit and the pump components and through the rod 273. (Collins ¶281; EX1004[Aboul-Hosn] 14:20-26, 30:20-27.)

Aboul-Hosn also discloses that "an end of the elongate lumen is adjacent an end of the cannula." (Collins ¶¶282-284) As shown in FIGS. 3, 7C and 10, below, the central lumen extends through the drive unit 80 and the pump components, such as the rotor 70, the housing cap 60, and the inner cannula 20; the guide wire (red) passes through that lumen (i.e. through central cavities 73 and 82), allowing the blood pump to advance along the guide wire into the desired location in the heart using a positioning rod 273. (Collins ¶282; EX1004[Aboul-Hosn] 14:20-24,

17:8-22, 22:10-21; 24:7-14.) The positioning rod 273 has "a central passage 275 extending the entire length of the positioning rod 273 and [is] used for passing a guiding element 28, such as a guide wire or a catheter or like devices, through its center." (Collins ¶282; EX1004[Aboul-Hosn] 14:20-24.)



(Collins ¶282; EX1004[Aboul-Hosn] FIGS. 3, 7C, 10 annotated.)

The central lumen (elongate lumen) extends distally through the end of the pump rotor 70 via central cavity 73 where the housing cap 60 fits within the distal end of the cannula 20. (Collins ¶283) Thus, the distal end of the central lumen is adjacent to the proximal end of the cannula 20. (*Id.*

Aboul-Hosn also discloses that the guide mechanism is configured to allow a guide wire to slideably advance along the lumen, as "the guide wire 28 may be inserted and positioned to a desired location" and "the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28." (Collins ¶274; EX1004[Aboul-Hosn] 22:12-16.)

Furthermore, as illustrated in annotated FIG. 3 above, in a configuration where the elongate lumen is coaxial (concentric) with the cannula while residing within a portion of the cannula, the elongate lumen must have a diameter that is smaller than the diameter of the cannula. (Collins ¶284)

j) *"a pressure sensing element configured to sense pressure proximate the intravascular blood pump;"*

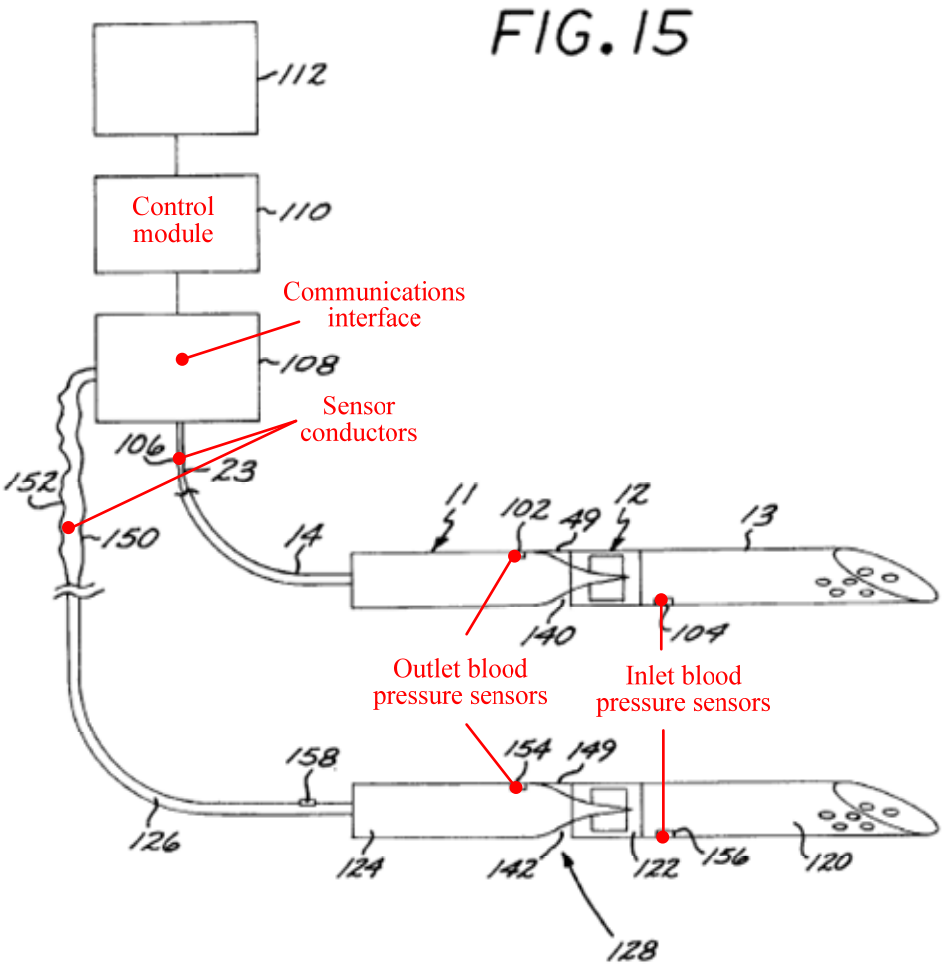
The '314 patent is silent as to what it means to "sense pressure proximate the intravascular blood pump." (Collins ¶286.) Under the BRI standard, this limitation requires sensing the blood pressure near the blood pump (*Id.*¶287), which Aboul-Hosn view of Siess, discloses.

Monitoring the blood pressure to aid in controlling the operation of the pump was well-known. (*Id.*) The Aboul-Hosn catheter 428 has multiple lumens to

perform various functions related to the operation of the intravascular blood pump 420, including "to measure pressure in the vicinity of the catheter along its entire length," including in the area adjacent to the blood pump 420. (EX1004[Aboul-Hosn] 29:19-24.) Moreover, an "orifice 187 may be positioned anywhere along the cannula 20 surfaces," also adjacent the pump 420, and may be "used as … a port for measuring pressure in areas proximal to the surface." (EX1004[Aboul-Hosn] 28:14-17.) The Aboul-Hosn's pump "may also be equipped with sensing devices (not shown) for measuring various body conditions such as the blood pressure" such as "pressure sensors along the inner cannula 20." (*Id.* 23:4-10) Since the distal end of the multilumen catheter 428 and the proximal end of the cannula couples to the pump, a POSITA would be naturally motivated to measure the pressure at the distal end of the multilumen catheter 428 or at the proximal end of the cannula, where they connect to the pump 420, to obtain the most accurate reading of pump 420's output. (Collins ¶¶287, 291-293)

Siess confirms this well-understood preference for measuring blood pressure near the pump. (*Id.* ¶¶294-296) Siess discloses positioning "a first pressure sensor" at "the surface of the drive unit 11 near the pumping segment discharge 140" and "a second sensor 104… near the inlet of the pump housing." (EX1005[Siess] 11:25-28.) Siess further teaches that "[w]ith the information provided by such sensors, it is possible to discern the position of the pump relative

to the external sealing member such as the heart valve" and "[b]y comparing the pressure differential to the current drawn by the motor, it is possible to identify blockage conditions as well as cavitation." (*Id.* 11:42-56.) While the sensors in Siess communicate with the control module through sensor conductors 106 and 162 instead of a fluid column, Siess demonstrates that it was preferred to measure the blood pressure near the pump to control the operations of the pump.



(Collins ¶296; EX1005[Siess] FIG. 15, annotated)

It would have been obvious for a POSITA to measure the blood pressure adjacent Aboul-Hosn blood pump 420 with either the multilumen catheter 428 or the sensors in the cannula in the manner shown in FIG. 15 of Siess. (Collins ¶¶294-296.) Moreover, a POSITA would have been motivated to do so "to discern the position of the pump" and to "identify blockage conditions as well as cavitation" by comparing the pressure differential to the current drawn by the motor as taught by Siess. (*Id.* ¶297.)

Thus, Aboul-Hosn in view of Siess, discloses this limitation. (*Id*. ¶298.)

k) ***"****a housing connected to a proximal end of the catheter; and****"***

Aboul-Hosn in view of Siess discloses a multilumen catheter coupled to the proximal end to continuously deliver purge fluid to the intravascular blood pump. (Collins ¶300; EX1004[Aboul-Hosn] 20:16-19, 29:19-25; EX1005[Siess] 8:31-41.) It was well-known that a purge fluid pump connects to the catheter outside of the patient's body to deliver the continuous flow of purge fluid. (Collins ¶302.) Figure 14-2 of Wampler, reproduced below, shows a schematic of the Hemopump.

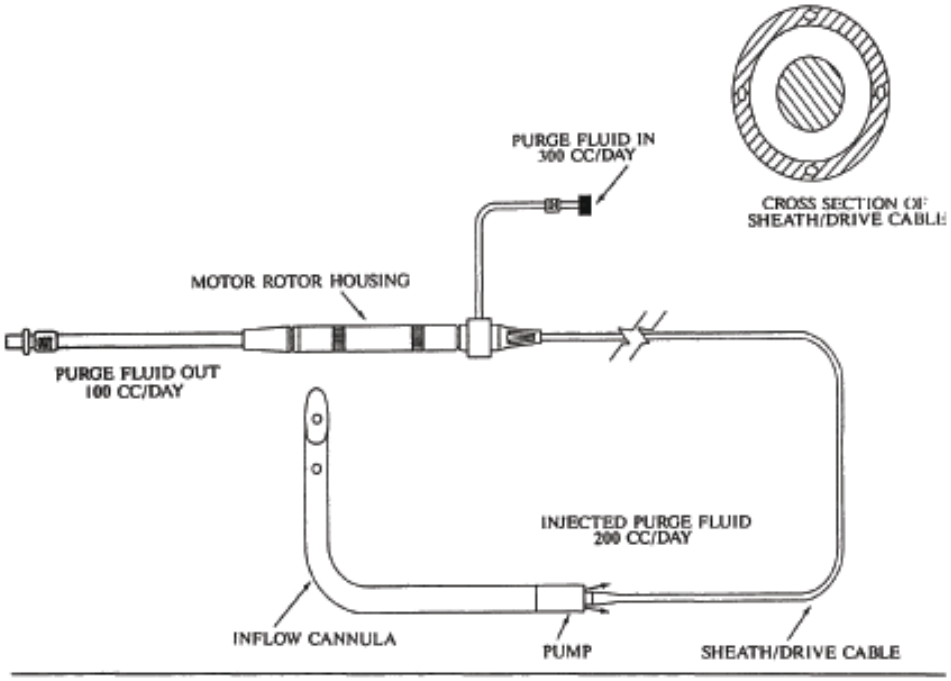


Figure 14–2. Schematic of the Hemopump.

(Collins ¶302; EX1007[Wampler] Figure 14-2, annotated.)

As shown in Figure 14-2, a "roller pump that controls the delivery and collection rates of the purge fluid lubricant" has a "motor rotor housing" connected to a proximal end of the catheter (i.e. the sheat/drive cable) through which the purge fluid flows. (Collins ¶304; EX1007[Wampler] 233-34.) Similar to Wampler, Aboul-Hosn discloses the multilumen catheter 428 connected to the blood pump has "separate lumens … to deliver or remove fluid" and 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 that Aboul-Hosn used a purge fluid pump having a pump housing connected to the proximal end of the catheter as disclosed by Wampler to provide purge fluid through the multilumen catheter 428 of Aboul-Hosn. (Collins ¶¶ 194-198, 305.) 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*. ¶198; EX1004[Aboul-Hosn] 20:16-19, 21:1-3, 29:19-25; EX1007[Wampler] 234.) Moreover, doing so would have been nothing more than an application of a well-known and conventional element that was originally used in the Hemopump to achieve the "continuous infusion of dextrose into the seal area" taught by Aboul-Hosn. (Collins ¶305.)

Thus, Aboul-Hosn in view of Wampler discloses this limitation. (*Id.* ¶306.)

> l) "*first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen.*"

It would have been obvious to connect Aboul-Hosn's multilumen catheter 428 to a purge fluid pump like Wampler's to provide a continuous infusion of dextrose to Aboul-Hosn's intravascular blood pump. (*Id.* ¶¶307-316.) As shown in Figure 14-2, Wampler discloses that the purge fluid is provided to the pump via

"Purge Fluid In" and "Purge Fluid Out" conduits that are fitted to the "motor rotor housing" on one end, and the control console shown in Figure 14-3 on the other end. (Collins ¶312; EX1007[Wampler] 233-34.)

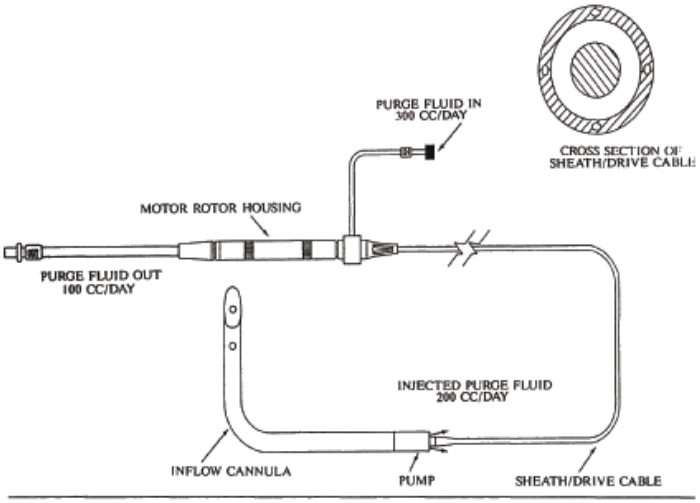


Figure 14-2. Schematic of the Hemopump.

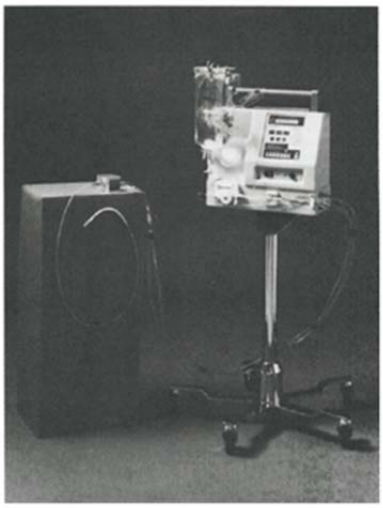


Figure 14-3. Hemopump system.

(EX1007[Wampler] Figures 14-2 and 14-3.)

In operation, the roller pump draws purge fluid in through the "Purge Fluid In" conduit and pumps the purge fluid through a purge lumen of the catheter to deliver the pure fluid to the intravascular blood pump, and excess purge fluid flows back from the intravascular blood pump through another purge lumen in the catheter, through the roller pump, and out of the "Purge Fluid Out" conduit. (Collins ¶315; EX1007[Wampler] 233-34.) Thus, the both the "Purge Fluid In" and "Purge Fluid Out" conduits are in fluid communication with the purge lumens in the catheter, and Aboul-Hosn in view of Wampler discloses this limitation. (Collins ¶316.)

2. Claim 2

Claim 2 depends from claim 1 and recites "*wherein the rotor further comprises a second blade extending radially from the rotor hub and wherein the hub has a distal end extending distally beyond a most distal portion of the blades.*"

Aboul-Hosn discloses that "the rotor 70 may comprise a single or multiple blades 72 extending from a longitudinally aligned central hub 74," and FIG. 7B shows an embodiment of the rotor 70 having three blades 72 extending radially outward from the rotor hub 74. (Collins ¶215; EX1004[Aboul-Hosn] 16:30-17:2.) Moreover, as shown below in FIG. 7B, the rotor hub has a distal end extending distally beyond a most distal portion of the blades. (Collins ¶317.)

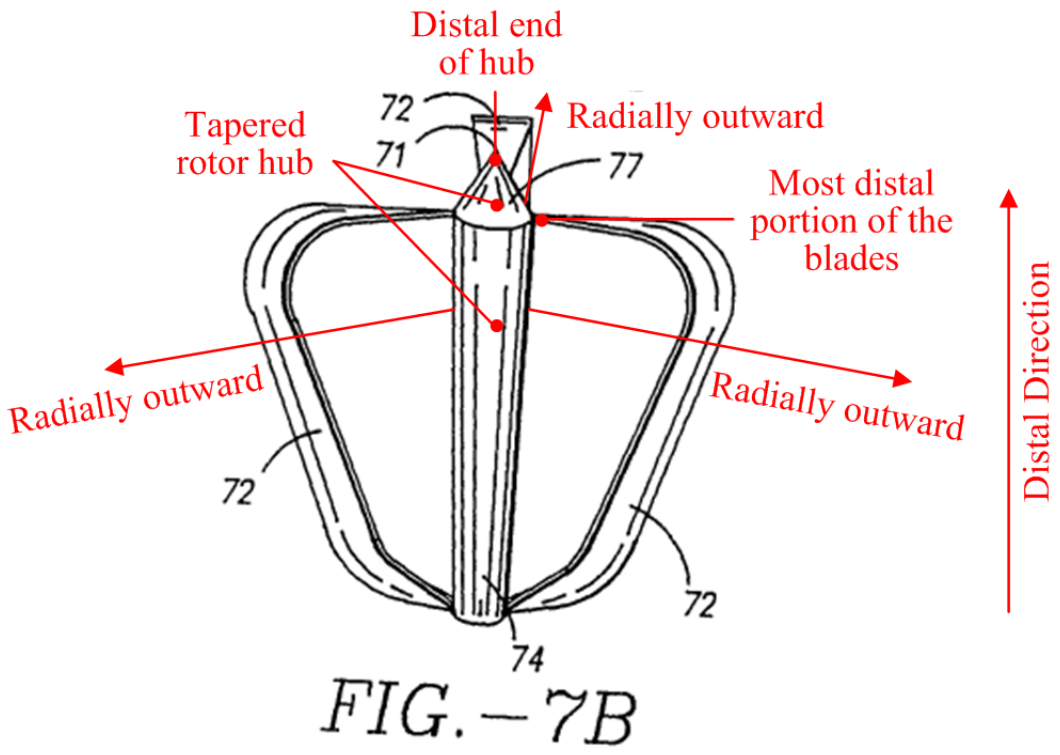


FIG. – 7B

(Collins ¶317; EX1004[Aboul-Hosn] FIG. 7B, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶319.)

3. Claim 3

Claim 3 depends from claim 1 and recites "*wherein the housing is configured to have the purge fluid pass through it.*"

It would have been obvious to connect Aboul-Hosn's multilumen catheter 428 to Wampler's purge fluid pump to provide a continuous infusion of dextrose to Aboul-Hosn's intravascular blood pump. (*Id.* ¶321.) As shown in Figure 14-2, in operation, the roller pump within the "Motor Rotor Housing" draws purge fluid in through the "Purge Fluid In" conduit and pumps the purge fluid through a purge lumen of the catheter to deliver the pure fluid to the intravascular blood pump, and excess purge fluid flows back from the intravascular blood pump through another purge lumen in the catheter, through the roller pump within the "Motor Rotor Housing," and out of the "Purge Fluid Out" conduit. (Collins ¶¶323-324; EX1007[Wampler] 233-34; EX1007[Wampler] 233-34.) Thus, the "Motor Rotor Housing" that houses Wampler's roller pump is configured to have purge fluid pass through it, and Aboul-Hosn in view of Wampler discloses this limitation. (Collins ¶325.)

4. Claim 4

Claim 4 depends from claim 1 and recites "*wherein the cannula is reinforced with a spiral wire.*"

Aboul-Hosn discloses that the cannula 411 "is formed of a reinforced wire 418" to "provide some degree of kink resistance." (EX1004[Aboul-Hosn] 28:23-27, 29:4-7.) A cross-section of the cannula 411 is shown in FIG. 20, below.

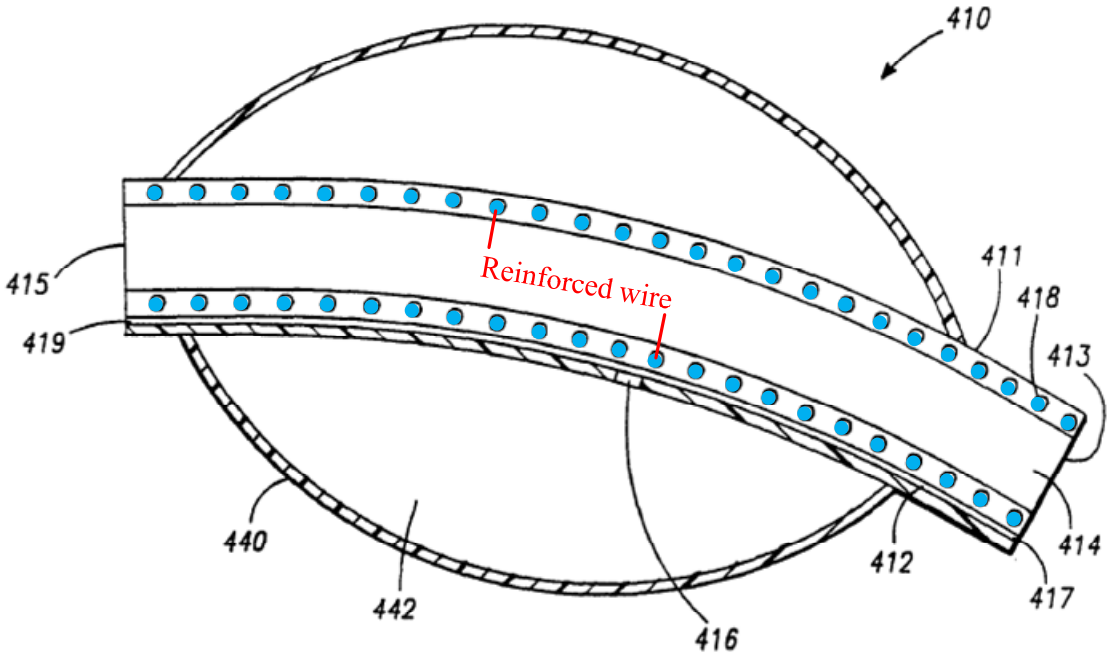


FIG.—20

(Collins ¶329; EX1004[Aboul-Hosn] FIG. 20, annotated.)

A POSITA would have understood that the reinforced wire 418 is a spiral wire. (Collins ¶¶330-332.) First, Aboul-Hosn refers to the reinforced wire 418 in the singular, and in order for a singular reinforced wire 418 to produce the cross section shown in FIG. 20, the reinforced wire 418 is wrapped in a spiral within the stabilization cannula 411. (*Id.* ¶330.) Second, as shown in FIG. 20, the upper row of circles representing the reinforced wire 418 is offset from the lower row, also

indicating that the reinforced wire is wrapped spirally as it extends through the stabilization cannula 411. (*Id.* ¶331.) Third, 25 wire cross-sections of the reinforced wire 418 are shown in the upper row, whereas 23 wire cross-sections of the reinforced wire 418 are shown in the lower row, which is consistent with a coiled wire (as opposed to a series of rings which would have an equivalent number of wire cross-sections in the upper and lower rows). (*Id*.)

Indeed, it was well-known in the art that a cannula reinforced with a spiral wire when embedded within the wall of the cannula "imparts significant resistance to radial deformation." (*Id.* at ¶332; EX1013[Siess '359] 6:37-43.) Thus, to "provide some degree of kink resistance" with Aboul-Hosn's reinforced wire 418, the reinforced wire 418 would have been configured as a spiral wire within Aboul-Hosn's stabilization cannula 411 in view of well-known teachings of the prior art. (Collins ¶332; EX1004[Aboul-Hosn] 28:23-25, 29:4-7.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶333.)

5. Claim 5

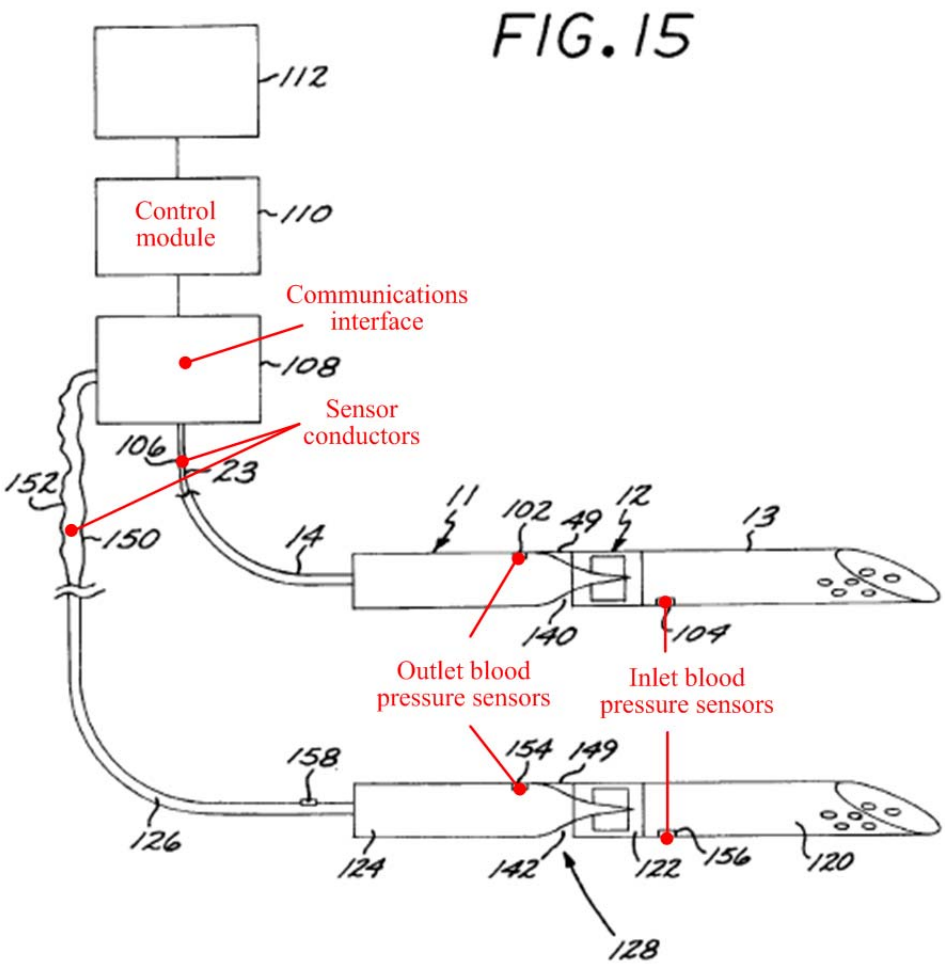
Claim 5 depends from claim 1 and recites "*wherein the pressure sensing element comprising at least one of a piezo-electric pressure sensing element and a strain gauge.*"

Aboul-Hosn discloses that pressure can be measured in the intravascular blood pump by using pressure sensors to detect the blood pressure from the fluid

column. (Collins ¶336; EX1004[Aboul-Hosn] 23:4-8: "[t]he pump 50 may be also be equipped with sensing devices (not shown) for measuring various body conditions such as blood pressure…that would suggest the need for altering the flow rate of the fluid transport apparatus 10.") Aboul-Hosn's blood pressure sensors, which can be located anywhere along the inner cannula 20 or which could be located within the pump 50 itself, detects the pressure of the blood proximate the blood pump and cannula. (Collins ¶336; EX1004[Aboul-Hosn] 23:8-10.) Siess also discloses the use of pressure sensors positioned at the desired pressure measurement location. (Collins ¶336; EX1005[Siess] 4:28-38; 11:23-40.)

A POSITA would understand that the pressure sensors of Aboul-Hosn and Siess could be piezo-electric pressure sensing elements. (Collins ¶338.) Such devices were well-known in the art for measuring pressure in intravascular blood pumps. (*Id*.) Indeed, the '314 Patent concedes that pressure transducers comprising "a piezo-electric crystal housed in an integrated circuit (IC) chip" are "of the type known in the art," and that "[d]ifferential pressure transducers are also well known in the art and comprise for example a piezo-electric crystal electro-mechanically configured to be responsive to a pressure difference between two opposing sides thereof." (EX1001['314 Patent] 30:28-34, 31:66-32:3.) As such, it would have been obvious to a POSITA to use a piezoelectric pressure sensing element as the pressure sensors along the inner cannula 20 of Aboul-Hosn, and

doing so would have simply been a straightforward application of a well-known type of pressure sensor to Aboul-Hosn's intravascular blood pump to yield predictable results. (Collins ¶338)



(Collins ¶338; EX1005[Siess] FIG. 15, annotated.)

Thus, Aboul-Hosn in view of Siess, discloses this limitation. (Collins ¶339.)

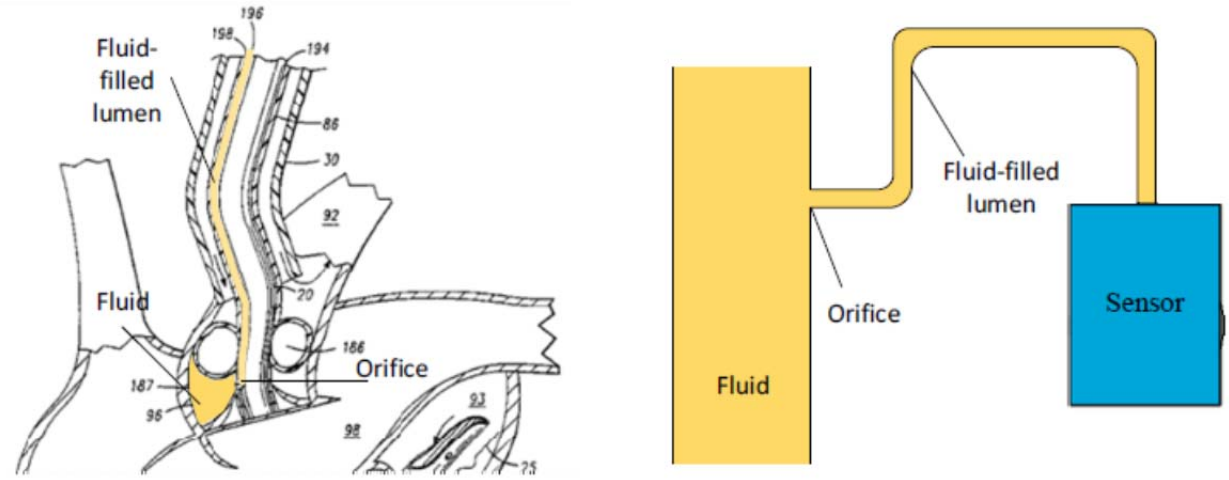
6. Claim 6

Claim 6 depends from claim 5 and further recites *"wherein the pressure sensing element further comprising a fluid column extending through the catheter."*

The '314 patent is silent about what constitutes the "fluid column" and how the "fluid column extend[s] through the catheter." (Collins ¶340.) Under the BRI standard, this limitation requires the elongate catheter to have a fluid column for transmitting blood pressure near the blood pump (*id.*¶341.), which Aboul-Hosn discloses. Aboul-Hosn's multilumen catheter 428 has multiple lumens to perform various functions related to the operation of the intravascular blood pump 420, including "to measure pressure in the vicinity of the catheter along its entire length," i.e. a blood pressure lumen. (*Id.*; EX1004[Aboul-Hosn] 29:19-24.) A POSITA would understand that the lumen inside the multilumen catheter 428 used "to measure pressure in the vicinity of the catheter" is filled with fluid so that the pressure can be measured hydrostatically. (Collins ¶¶342-344.)

Indeed, Aboul-Hosn teaches one technique for measuring pressure using the intravascular blood pump by forming an orifice in the surface of the cannula 20 to "measure pressure in areas proximal to the orifice" where the orifice 187 "may be positioned anywhere along cannula 20 surfaces." (EX1004[Aboul-Hosn] 28:12-18.) Aboul-Hosn discloses that the orifice 187 that connects to a fluid source

located outside the patient to allow for delivery of fluids such as medication or drugs during surgery. (Collins ¶344; EX1004[Aboul-Hosn] FIG. 19, 27:8, 27:14-20, 28:1-2, 28:9-10.) Thus, it is necessarily the case that orifice 187, when used to measure pressure, would be a point of entry of fluid that similarly communicate through a fluid column with a pressure detector located outside the body as illustrated below. (Collins ¶343.)



(Collins ¶344; EX1004[Aboul-Hosn] FIG. 19, annotated.)

The same teaching is equally applicable to the multilumen catheter 428. (Collins ¶344.) That is, a POSITA would understand from Aboul-Hosn's disclosure that a similar orifice can be formed on the surface of the multilumen catheter 428 that intersects the blood pressure lumen, allowing a pressure detector located outside the body to measure the pressure near the orifice using the blood pressure lumen. (*Id.*)

Moreover, a POSITA would understand that the mechanisms for measuring pressure in Aboul-Hosn, such as the fluid columns, may be combined with the pressure sensors of Aboul-Hosn or Siess.[11] (Collins ¶347.) For example, a POSITA would appreciate that one or more of the piezo-electric sensing elements may be used to measure the pressure in the fluid columns of Aboul-Hosn in a similar manner as they would measure pressure within Aboul-Hosn's cannula 20. (*Id.*.)

It would have also been obvious to a POSITA to use both piezo-electric pressure sensors along the inner cannula 20 and the fluid columns within the multilumen catheter proximate Aboul-Hosn's intravascular blood pump to measure the pressure differential between the inlet and outlets of the pump. (*Id.*) As disclosed by Siess, "[i]nformation relating to the inlet and outlet pressure" of the intravascular blood pump "provides a wealth of information relevant to the function of the pump device," including the ability "to discern the position of the pump relative to the external sealing member such as the heart valve" to ensure that the pump is properly placed, and the ability to "identify blockage conditions as well as cavitation." (EX1005[Siess] 11:42-56, 12:8-20.)

Thus, Aboul-Hosn in view of Siess, discloses this limitation. (*Id.* ¶348.)

[11] As discussed in Section X.A.5., these pressure sensors may be piezo-electric pressure sensing elements. (Collins ¶338.)

7. Claim 7

Claim 7 depends from claim 1 and recites "*wherein the pressure sensing element is used to determine a differential pressure.*"

It would have been obvious for a POSITA to measure the blood pressure adjacent Aboul-Hosn blood pump 420 with either the multilumen catheter 428 or the sensors in the cannula in the manner shown in FIG. 15 of Siess. (Collins ¶¶351-352.) It would have also been obvious to a POSITA to measure the pressure differential between the inlet and outlets of the pump by using both sensors along the inner cannula 20 and the fluid columns within the multilumen catheter proximate Aboul-Hosn's intravascular blood pump. (*Id.*) As disclosed by Siess, "[i]nformation relating to the inlet and outlet pressure" of the intravascular blood pump "provides a wealth of information relevant to the function of the pump device," including the ability "to discern the position of the pump relative to the external sealing member such as the heart valve" to ensure that the pump is properly placed, and the ability to "identify blockage conditions as well as cavitation." (EX1005[Siess] 11:42-56, 12:8-20.)

Thus, Aboul-Hosn in view of Siess, discloses this limitation. (Collins ¶¶353-356.)

8. Claim 8

Claim 8 depends from claim 1 and recites "*a rotor shroud, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula.*"

Aboul-Hosn's pump 50 of includes a housing body 52 that houses the rotor 70. (Collins ¶¶359-361; 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." (EX1004[Aboul-Hosn] 13:7-15.)

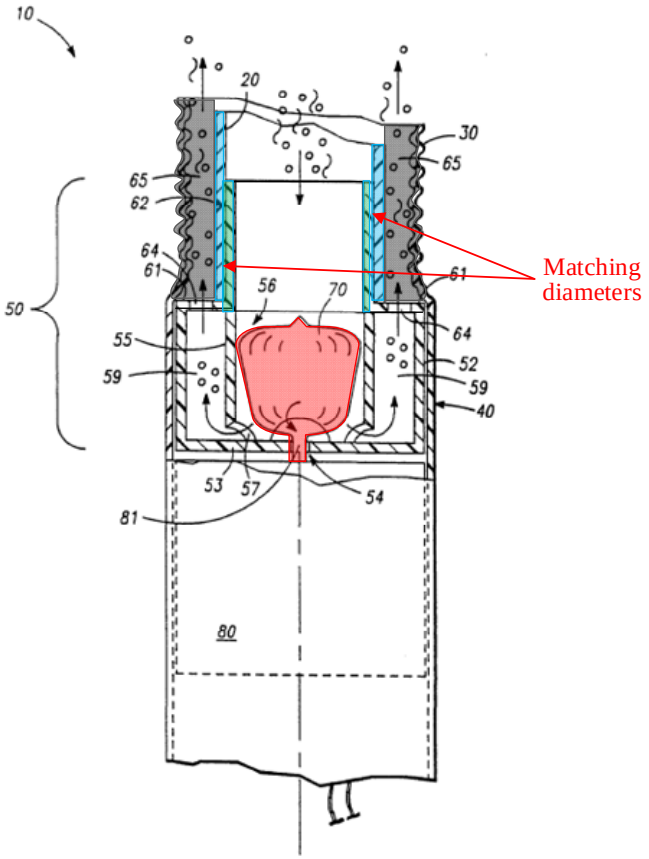


FIG.—2

(Collins ¶361; 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 "rotor shroud." (Collins ¶360.) Moreover, the housing body 52 and the housing cap 60 further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "rotor shroud." (*Id.*; EX1004[Aboul-Hosn] 13:3-4.) As shown above in FIG. 2 of Aboul-Hosn, the proximal end of the cannula 20 is coupled to the inlet neck 62. (EX1004[Aboul-Hosn] 13:24-25.) As such, where the inlet

neck 62 and inlet tube 55 together forms the "rotor shroud," an outer diameter of the "rotor shroud" matches the inner diameter of the cannula 20 at its proximal end where it couples to the inlet neck 62. (Collins ¶¶361-362.)

9. Claim 14

Claim 14 depends from claim 1 and recites "*further comprising a fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump.*"

Aboul-Hosn in view of Wampler discloses a roller pump within the "Motor Rotor Housing" shown in Figure 14-2 of Wampler that is configured to provide a continuous infusion of dextrose to Aboul-Hosn's intravascular blood pump through purge lumens within the multilumen catheter 428. (Collins ¶¶363-371; EX1004[Aboul-Hosn] 20:16-19; EX1007[Wampler] 233-234.)

10. Claim 16

Claim 16 depends from claim 1 and recites "*The intravascular blood pump system of claim 1 further comprising a rotor shroud disposed about the rotor and wherein a proximal end of the cannula is disposed about a distal end of the rotor shroud.*"

Aboul-Hosn discloses this limitation. Aboul-Hosn's percutaneously delivered pump 420 shown in FIG. 23 can be configured with or without the reverse flow feature of the pump system of FIGS. 1-13. (Collins ¶¶372-376.) As

shown in FIG. 2 below, in the reverse flow configuration, the rotor 70 (red) is housed within a housing body 52 and a housing cap 62 (green), and the cutouts 57 of the inlet tube 55 and outflow ports 64 of the housing cap 62 act to reverse the flow of blood that is pumped axially through the inner cannula 20 (blue) as it exits the inlet tube 55 (as shown by the directional arrows in FIG. 2.) (*Id.* ¶375; EX1004[Aboul-Hosn] 12:12-13:25, 18:15-19.)

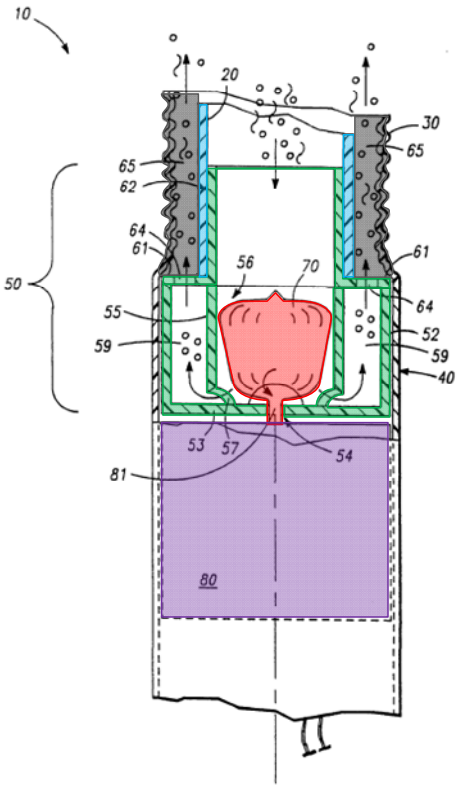


FIG.—2

(Collins ¶375; EX1004[Aboul-Hosn] FIG. 2, annotated.)

Aboul-Hosn further discloses that the housing body 52 and the housing cap 60 may form "a unitary body" such that the housing body 52 and the housing cap

60 together forms the "rotor shroud." (Collins ¶375; EX1004[Aboul-Hosn] 12:22-23, 13:3-4.) The proximal end of the cannula 20 (blue) is disposed about the inlet neck 62 (green) of the housing cap 60 (green) at the distal end of the rotor shroud. (Collins ¶375.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶376.)

11. Claim 17

Claim 17 depends from claim 1 and recites "*further comprising a rotor shroud having a distal portion with a first outer diameter and a more proximal portion with a second outer diameter larger than the first outer diameter.*"

See Claim 16, above.

Moreover, the inlet neck 62 (i.e. the distal portion of the rotor shroud) has a smaller outer diameter than the housing body 52 (i.e. the proximal portion of the rotor shroud.) (*Id.* ¶¶377-380.)

12. Claim 18

Claim 18 depends from claim 1 and recites "*further comprising an elongate tubular element defining the elongate lumen.*"

Aboul-Hosn discloses this element. (Collins ¶381.) Aboul-Hosn discloses that "[a] central passage 82 with a diameter of approximately 0.040 inches may also extend through the entire length of the shaft 81," meaning the elongate lumen must include a tubular element to have a diameter of approximately 0.040 inches.

(*Id.*; EX1004[Aboul-Hosn] 20:23-25.) FIG. 3 (below) confirms that the central 82, e.g., elongate lumen, extending through the catheter 428, the blood pump drive unit 80 and rotor 70 and the cannula 20, is an elongate tubular lumen. (Collins ¶381.)

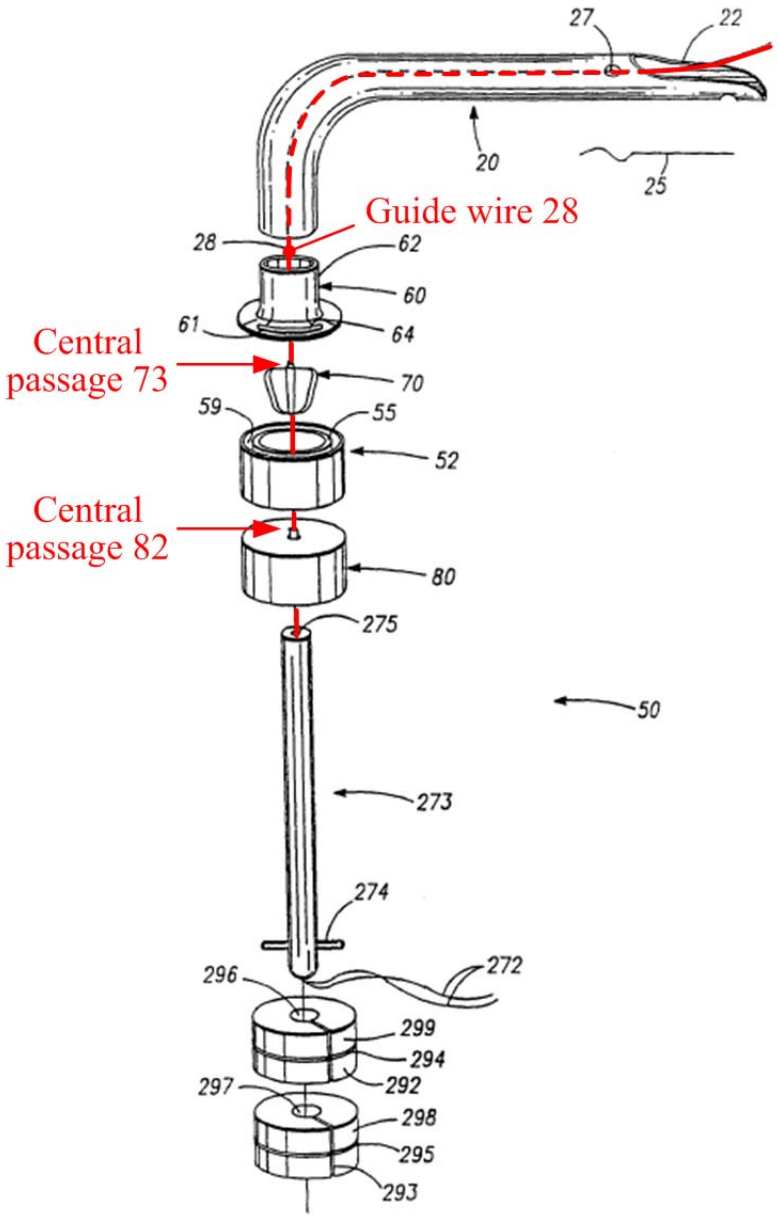


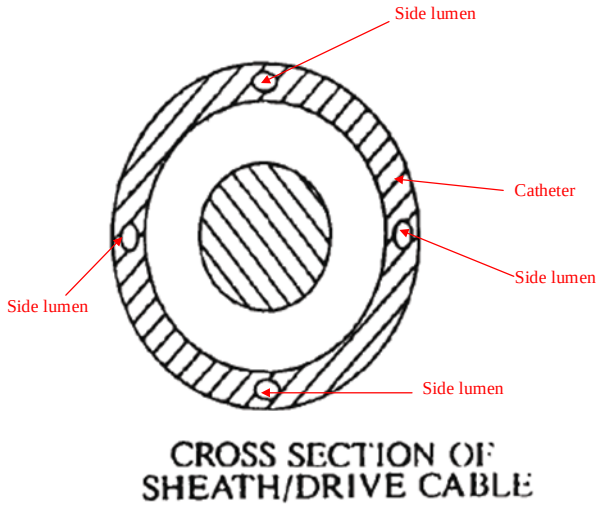
FIG.–3

(Collins ¶381; EX1004[Aboul-Hosn] FIG. 3 (annotated))

13. Claim 19

Claim 19 depends from claim 1 and recites "*wherein the purge lumen is a side lumen extending longitudinally through the catheter but offset radially from a central axis of the catheter*."

Aboul-Hosn discloses the multilumen catheter 428 coupled to the distal end of the pump has purge fluid lumens, in addition to other lumens for driving the pump, measuring pressure, delivering a guide wire, etc., that are in fluid communication with the pump and operatively arranged to deliver purge fluid to the pump. (Collins ¶¶383-385; EX1004[Aboul-Hosn] 29:19-25.) A POSITA would understand that the lumens within the multilumen catheter 428 would have been radially offset from the central axis of the catheter to conserve space, and that doing so would have been a matter of design choice. (Collins ¶¶383-385.) For example, FIG. 14-2 of Wampler, below, shows a cross section of a catheter coupled to the distal end of the Hemopump having "four outer lumens in the sheath" (i.e. catheter) configured to deliver a continuous infusion of purge fluid ("[a]pproximately 300 cc/day of D40W") to the pump. (EX1007[Wampler] 234.)



(Collins ¶386; EX1007[Wampler] FIG. 14-2.)

These "four outer lumens" (i.e. side lumens) are offset radially from a central axis of the catheter. (Collins ¶386.) Thus, Aboul-Hosn in view of Wampler, discloses this limitation. (*Id.* at ¶387.)

14. Claim 20

a) *"An intravascular blood pump system comprising:"*

See X.A.1.a).

b) *"an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support,"*

See X.A.1.b).

c) *"the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and a rotor shroud at least partially disposed about the rotor hub, at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade;"*

See X.A.1.c) and X.A.2.

Additionally, Aboul-Hosn's pump 50 includes a housing body 52 that houses the rotor 70. (Collins ¶¶391-392; 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." (EX1004[Aboul-Hosn] 13:7-15.)

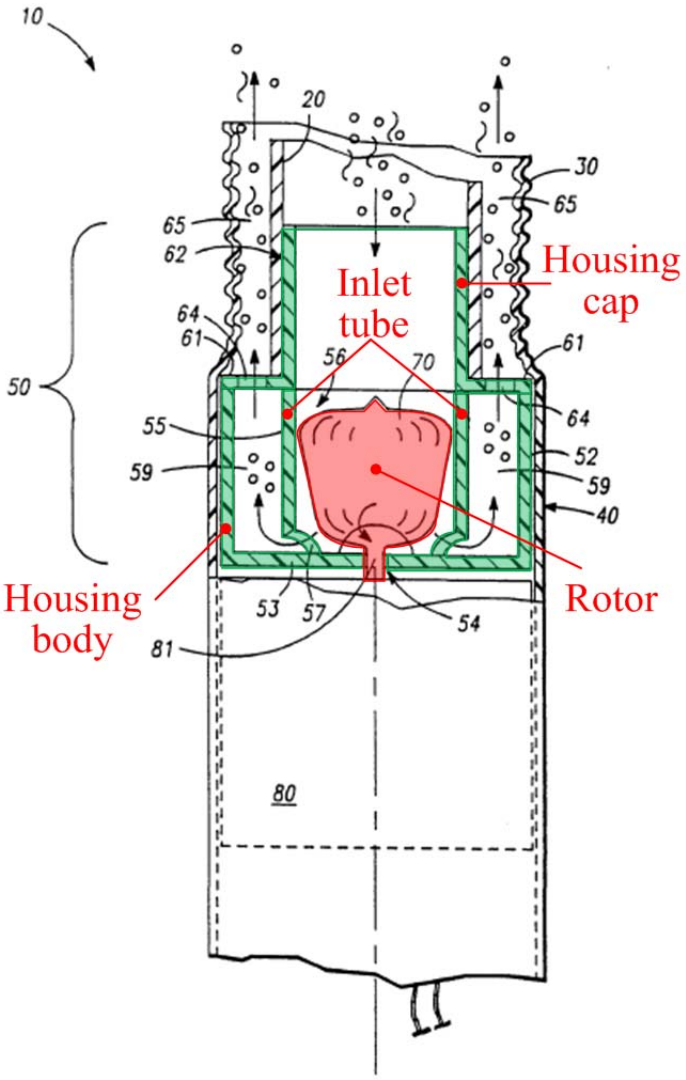


FIG.—2

(Collins ¶392; 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 "rotor shroud." (Collins ¶393.) Moreover, the housing body 52 and the housing cap 60

further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "rotor shroud." (*Id.* ¶394; EX1004[Aboul-Hosn] 13:3-4.)

Aboul-Hosn thus discloses this limitation. (Collins ¶395.)

> d) "*a cannula coupled to a distal end of the intravascular blood pump, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula, the proximal portion of the cannula disposed about a distal end of the rotor shroud, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port, and*"

See X.A.1.d) and X.A.8.

> e) "*wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient,*"

See X.A.1.e).

> f) "*the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta;*"

See X.A.1.e).

> g) "*a catheter connected to a proximal end of the intravascular blood pump,*"

See X.A.1.g).

> h) *"a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump;"*

See X.A.1.h).

> i) *"an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula, and an end of the elongate lumen is adjacent an end of the cannula, the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen;"*

See X.A.1.i).

> j) *"a pressure sensing element configured to sense pressure proximate the intravascular blood pump and comprising a fluid column extending through the catheter;"*

See X.A.1.j) and X.A.6.

> k) *"a housing connected to a proximal end of the catheter, the housing configured to have the purge fluid passing through it;"*

See X.A.1.k) and X.A.3.

> l) *"first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen; and"*

See X.A.1.l).

> m) *"a fluid delivery pump configured to deliver purge fluid through at least one of the first and second conduits, and through the housing and the purge lumen towards the intravascular blood pump. "*

Aboul-Hosn in view of Wampler discloses "a fluid delivery pump configured to deliver purge fluid through the purge lumen towards the

intravascular blood pump." (Collins ¶¶404-413.) Aboul-Hosn in view of Siess and Wampler discloses a first lumen within the catheter in fluid communication with the intravascular blood pump to deliver purge fluid to the blood pump. (Collins ¶405.)

The specific mechanical fittings to connect a basic purge fluid bag would have been obvious to a POSITA and were basic components in the Hemopump disclosed by Wampler. (Collins ¶406) Wampler discloses a "roller pump" that supplies "300 cc/day" of purge fluid towards the pump through the "Purge Fluid In" conduit. (Collins ¶408; EX1007[Wampler] 233-34; FIG. 14-2.)

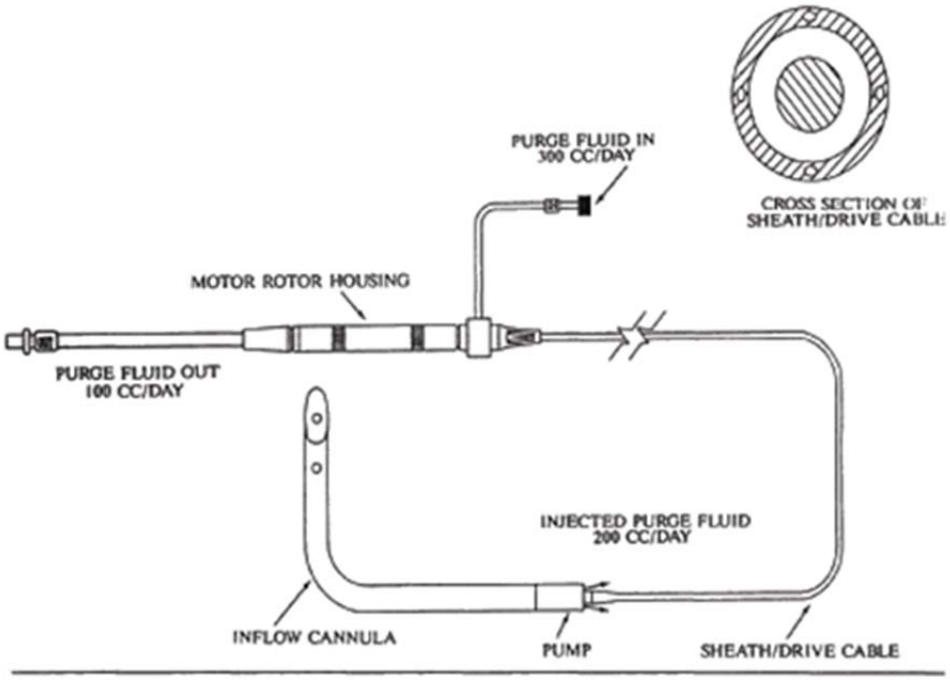


Figure 14-2. Schematic of the Hemopump.

(Collins ¶407; EX1007[Wampler] FIG. 14-2.)

The purge fluid "is pushed by a roller pump through purge tubing toward the pump via four outer lumens in the sheath," where "[a]bout 200 cc/day of the purge fluid flows across the seal into the patient" to lubricate the pump components and prevent blood from migrating through the seal into the pump components" and the "remaining 100 cc/day of purge fluid is drawn away from the pump around the drive cable and motor magnet to a return bag" through the "Purge Fluid Out" conduit, illustrated above in FIG. 14-2. (Collins ¶408; EX1007[Wampler] 234.) The "Purge Fluid In" and "Purge Fluid Out" conduits each have a conventional fitting at their respective ends to be connected to the roller pump and the return bag and are connected to an integrated controller, outside of the patient's body, which also includes the roller pump and return bag. (Collins ¶409; EX1007[Wampler] 234.)

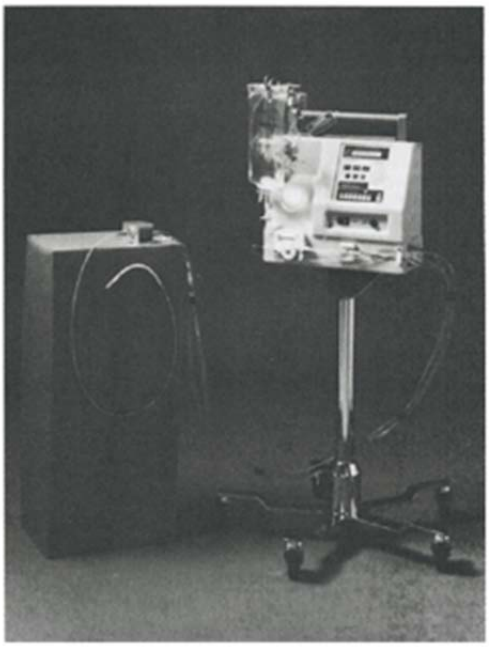


Figure 14-3. Hemopump system.

(Collins ¶409; EX1007[Wampler] Fig. 14-3.)

It would have been obvious for a POSITA to use the roller pump of the Hemopump in Wampler, which is a well-known method of providing purge fluid through a catheter linking the blood pump to the exterior of the body, with the Aboul-Hosn system to provide "a continuous infusion of dextrose into the seal area." (Collins ¶410; EX1006[Aboul-Hosn] 21:1-3.) A POSITA would have been motivated to use conventional mechanical fittings located outside the patient to contain the fluid within the system before it reaches the seal area and infusion site. (Collins ¶410.)

The blood pump in Aboul-Hosn uses the same 40% dextrose solution as the purge fluid as the Hemopump, and delivers the purge fluid by a catheter that extends to the outside of the patient's body, similar to the lumens within the sheath used by the Hemopump purge fluid system. (Collins ¶411; EX1006[Aboul-Hosn] 20:16-19; 21:1-3; 29:19-25; EX1007[Wampler] 234.) Moreover, Aboul-Hosn and Wampler also used the 40% dextrose solution for the same purpose—to lubricate the pump components while preventing blood from entering through the seal into the drive unit. (Collins ¶411; EX1006[Aboul-Hosn] 21:1-3; EX1007[Wampler] 234.)

In view of the similarities between Aboul-Hosn's and Wampler's disclosure of the composition of the purge fluid, the continuous delivery of purge fluid, and

the method of delivering the purge fluid to the intravascular blood pump, in conjunction with the well-known purge fluid system used by the Hemopump, as well as the routine nature of the use of mechanical fittings to contain fluid in a medical device, it is obvious that Aboul-Hosn used a roller pump, or a similar pump to the Hemopump's purge fluid system along with the "Purge Fluid In" and "Purge Fluid Out" conduits with their associated fittings, to deliver the purge fluid to Aboul-Hosn's intravascular blood pump through its multi-lumen catheter. (Collins ¶412.)

15. Claim 25

Claim 25 depends from claim 20 and recites "*wherein the pressure sensing element further comprising at least one of a piezo-electric pressure sensing element and a strain gauge.*"

See X.A.5 (Claim 5).

16. Claim 26

Claim 26 depends from claim 1 and recites "*wherein the purge lumen is a side lumen extending longitudinally through the catheter but offset radially from a central axis of the catheter.*"

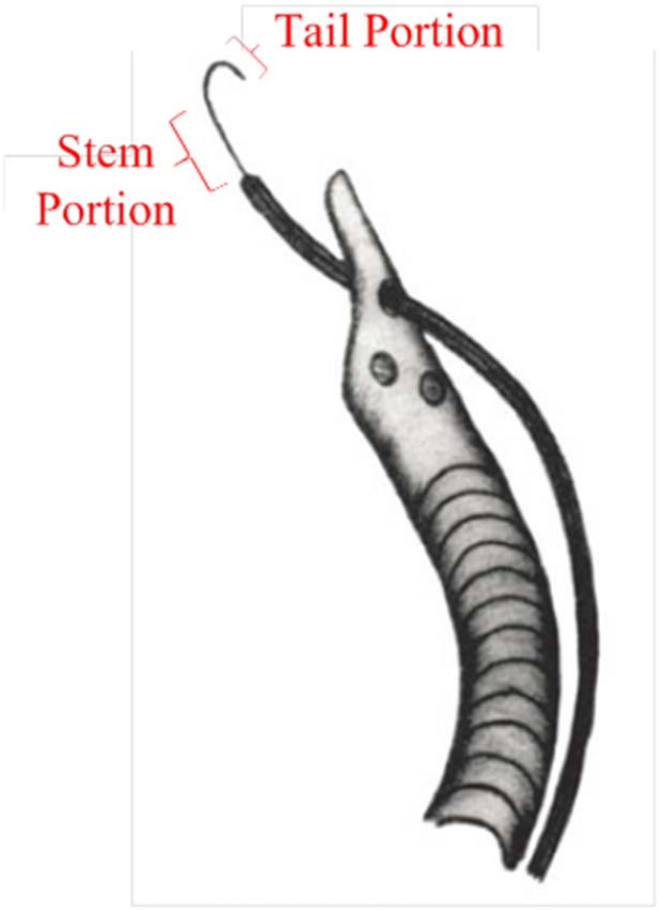
See X.A.13 (Claim 19).

B. Ground II: Claims 10-11, 13, 21, and 23 are obvious over Aboul-Hosn in view of Siess and Wampler, and further in view of Jegaden.

1. Claim 10

Claim 10 depends from claim 1 and recites "*further comprising a distal tip member at one end, the distal tip member comprising a stem portion, extending distally away from a distal end of the cannula lumen, and a curved tail portion located distal to the stem portion.*"

It was well-known to use a distal tip member to improve placement of intravascular blood pumps and catheters within the heart. (Collins ¶80.) For example, FIG. 1 of Jegaden shows the distal end of the guide wire including a J-shaped distal tip. (Collins ¶¶416-417; EX1033[Jegaden] FIG. 1) The stem portion that extends from the cannula lumen, and distal to that stem, the j-shaped tip contains the tail (curled).



(Collins ¶417; EX1033[Jegaden] FIG. 1 (annotated))

Thus, Aboul-Hosn in view of Jegaden discloses this limitation.

2. Claim 11

Claim 11 depends from claim 10 and recites "*wherein the elongate lumen is located proximal to the distal tip member.*"

A POSITA would understand that the distal tip member is at the end of the guide wire. The elongate lumen must be proximal to a guide wire distal tip member to enable the guide wire distal tip member to traverse a heart valve to realize the technical advantage of using a J-shaped distal tip. (Collins ¶420.) For

example, Jegaden FIG. 2 shows the distal end of the guide wire including a J-shaped distal tip where the elongate lumen is proximal to the distal tip member.

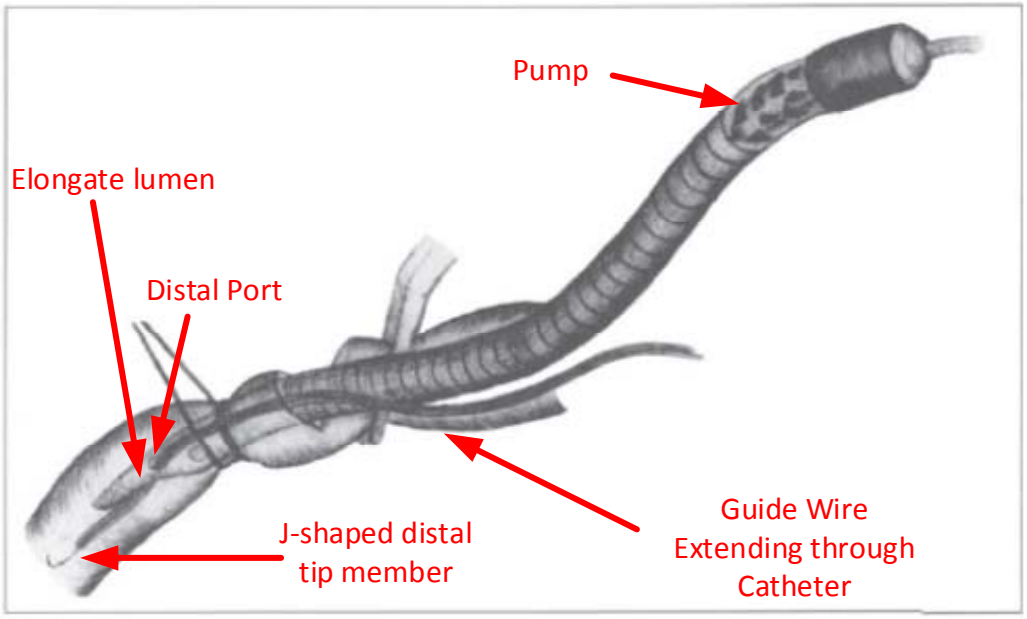


Fig. 2.

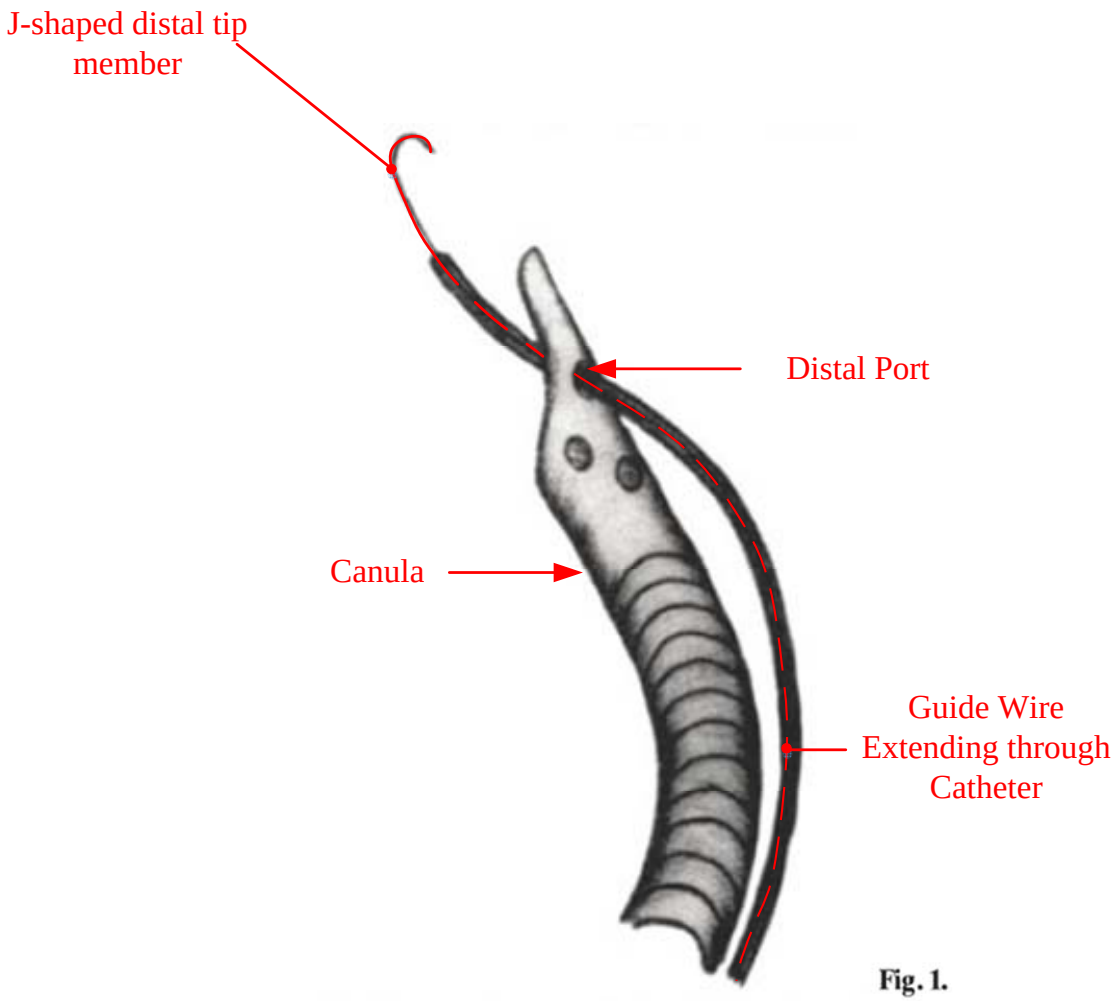
(Collins ¶420; EX1033[Jegaden] FIG. 2, annotated.)

Hence, Aboul-Hosn in view of Jegaden discloses this limitation. (Collins ¶¶421-422.)

3. Claim 13

Claim 13 depends from claim 1 and recites "*further comprising a J-shaped distal tip member at one end.*"

It was well-known to use a distal tip member to improve placement of devices within the heart. (Collins ¶80.) For example, FIG. 1 of Jegaden shows the distal end of the guide wire including a J-shaped distal tip. (Collins ¶394.)



(Collins ¶424; EX1033[Jegaden] FIG. 1, annotated.)

A POSITA would understand that the J-shaped distal tip member enables the guidewire and catheter to efficiently traverse a valve such as of the heart. (Collins ¶80.) A POSITA would therefore naturally adapt the guide wire of Aboul-Hosn such that it would include a distal tip member like Jegaden's to enable more efficient placement of the intravascular blood pump system at the desired location with the heart. (Collins ¶425.)

Aboul-Hosn in view of Jegaden discloses this limitation.

4. Claim 21

Claim 21 depends from claim 20 and recites "*further comprising a distal tip member at one end of the cannula, the distal tip member comprising a stem portion, extending distally away from a distal end of the cannula lumen, and a curved tail portion located distal to the stem portion.*"

See X.B.1 (Claim 10).

5. Claim 23

Claim 23 depends from claim 1 and recites "*wherein the distal tip member is J-shaped.*"

See X.B.3. (Claim 13).

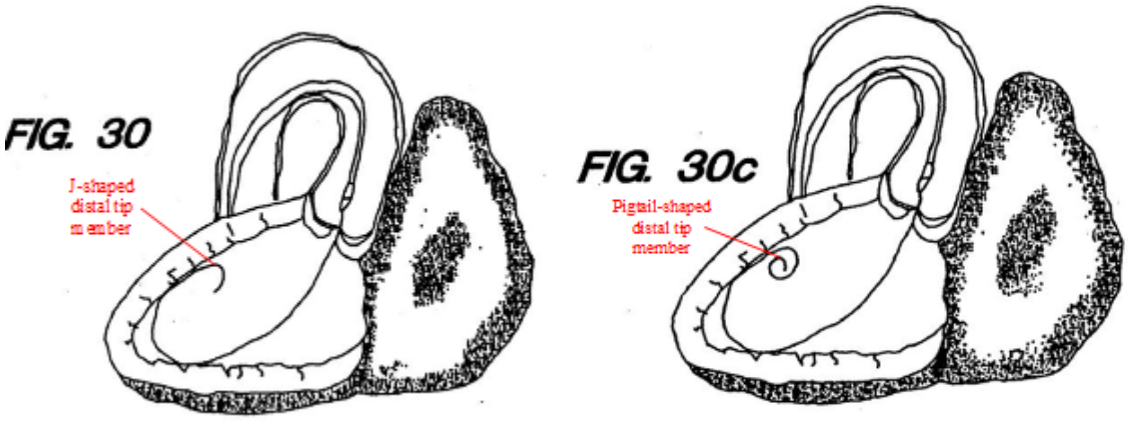
C. Ground III: Claim 12 and 22 are obvious over Aboul-Hosn in view Siess and Wampler, and further in view of Crowley.

1. Claim 12

Claim 12 depends from claim 1 and recites "*further comprising a pigtail shaped distal tip member at one end.*"

It was also well-known to use a distal tip on a guide wire to improve placement devices within the heart. (Collins ¶431.) It was also well-known before the EPD that a pigtail shape tip could also be used. Crowley disclosed an ultrasound catheter having a guide wire with a pigtail-shaped distal tip. (*Id*. ¶¶432-33; EX1047 [Crowley] FIG. 30c.) This distal tip was "used in guiding and

penetrating through the moving opening of a human heart valve." (Collins ¶433; EX1047[Crowley] 27:11-14.). FIG. 30c illustrates a device deployed in the left ventricle and having a pigtail-shaped distal tip member.



(Collins ¶432; EX1047[Crowley] FIGS. 30-30c annotated.)

A POSITA would have been motivated to include a pigtail distal tip on Aboul-Hosn's guide wire to be "used in guiding and penetrating through the moving opening of a human heart valve" as expressly taught by Crowley. (Collins ¶433; EX1049[Crowley] 27:11-14). Thus, Aboul-Hosn in view of Crowley discloses this limitation. (Collins ¶434.)

2. Claim 22

Claim 22 depends from claim 21 and recites "*wherein the distal tip member is pigtail shaped.*"

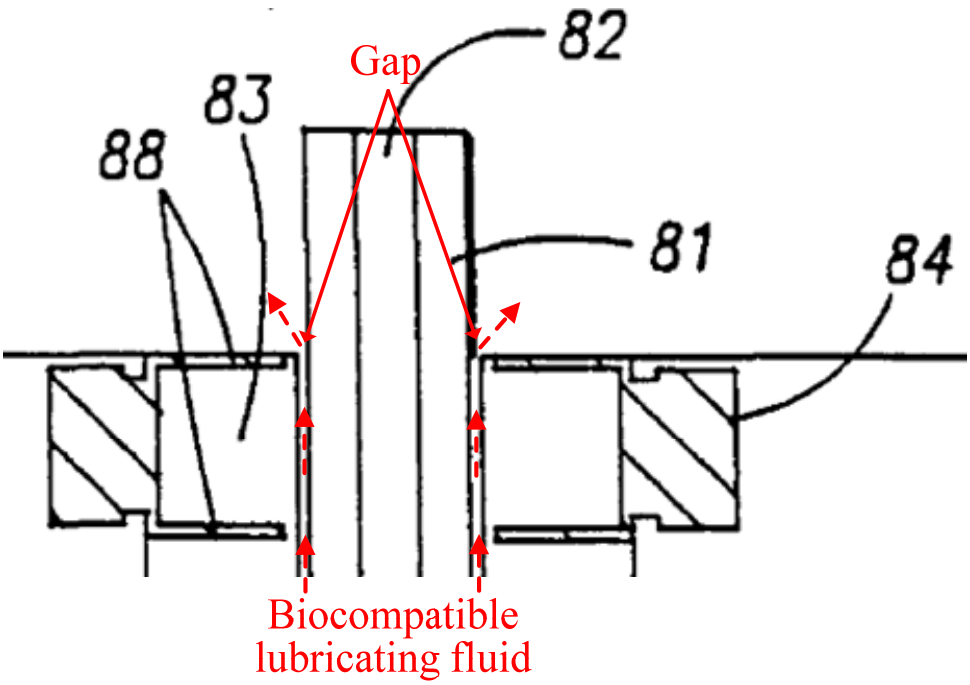
See X.C.1 (Claim 12).

D. Ground IV: Claim 15 is obvious over Aboul-Hosn in view of Siess and Wampler, and further in view of Wampler_712.

1. Claim 15

Claim 15 depends from claim 14 and recites "*wherein the fluid delivery pump is configured to deliver the purge fluid at a pressure that is both sufficient to avoid clotting of the patient's blood and that is higher than a blood pressure of the patient adjacent the intravascular blood pump.*"

Aboul-Hosn's pump is configured with a gap between the drive shaft and the central cavity 83 to permit purge fluid to flow out of the pump as shown in FIG. 10 below. (*Id.* ¶265.)



(Collins ¶265; EX1004[Aboul-Hosn] FIG. 10, annotated.)

This gap allows for the biocompatible lubricating fluid to slowly seep outwards from the central cavity 83, which 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 ¶¶266, 439; EX1004[Aboul-Hosn] 21:1-3.)

In order for the biocompatible lubricating fluid to seep out of and to prevent blood from entering the blood pump, a POSITA would have understood that the pressure of the biocompatible lubricating fluid provided by the purge fluid pump to the blood pump through the multilumen catheter must be higher than a blood pressure of the patient adjacent the blood pump – otherwise blood would enter the blood pump through the gap and clot. (Collins ¶¶266, 439-440.) Indeed, this is confirmed by Wampler_712 which discloses "[t]he catheter also provides a conduit to supply the pump bearings with a blood-compatible purge fluid at a rate and pressure sufficient to prevent thrombus formation and introduction of blood elements between rotating and stationary elements of the pump." (EX1008[Wampler_712] Abstract.) Moreover, pressurizing purge fluid to a greater pressure than the blood pressure of the patient adjacent the blood pump was well-known in the art. (Collins ¶¶439-440; EX1009[Wampler_152] 4:8-15; EX1048[Reich] claim 9.)

Thus, Aboul-Hosn in view of Wampler_712 discloses this limitation. (Collins ¶442.).

XI. CONCLUSION

Based on the foregoing, claims 1-8, 10-23, and 25-27 of the '314 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 9,561,314 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 9,561,314 ("'314 patent")
1002	Collins Declaration ("Collins")
1003	File History of U.S. Patent No. 9,561,314 ("'314 PH")
1004	WO 99/02204 ("Aboul-Hosn")
1005	U.S. Patent No. 5,921,913 ("Siess")
1006	U.S. Patent No. 5,061,273 ("Yock")
1007	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")
1008	U.S. Patent No. 4,625,712 ("Wampler_712")
1009	U.S. Patent No. 4,846,152 ("Wampler")
1010	U.S. Patent No. 4,479,497 ("Fogarty")
1011	U.S. Patent No. 6,248,091 ("Voelker")
1012	U.S. Provisional Patent Appln. 60/152,249 ("'249 provisional application")
1013	E.P. Publication No. 0916359 ("Siess359")
1014	Reserved
1015	U.S. Patent No. 3,879,516 ("Wolvek")
1016	U.S. Patent No. 4,764,324 ("Burnham")
1017	U.S. Patent No. 4,944,745 ("Sogard")
1018	U.S. Patent No. 6,544,216 ("Sammler")
1019	U.S. Patent No. 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. & Biol. Eng. & Comput. 694-95 (Nov. 1994) ("Kunst")
1027	Konishi, H. et al., *Controller for an Axial Flow Blood Pump*, Artificial Organs 20(6): 618–20 (Jun. 1996) ("Konishi")
1028	*Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996) ("Guyton")
1029	Lawrence K. Altman, *A Tiny Heart Pump Saves Its First Life, Researchers Report*, N.Y. Times, May 5, 1988.
1030	Andre F. Cournand et al, Nobel Prize in Physiology or Medicine 1956, Nobel Prize, http://www.nobelprize.org/nobel_prizes/medicine/laureates/ (last visited Jan. 25, 2017)
1031	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.
1032	Frank K. White. *Fluid Mechanics*, 2nd edition (1986) ("White")
1033	O. Jegaden, "Clinical results of Hemopump support in surgical cases," 1991. ("Jegaden")
1034	Declaration of Pamela Stransbury
1035	Declaration of Kiersten Batzli
1036	Library of Congress, Catalog Record of *Supported Complex and High Risk Coronary Angioplasty*, ch. 14, 231-49 (Springer 1st ed. 1991)
1037	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
1038	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
1039	Library of Congress, Catalog Record of *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996)

1040	Library of Congress, Catalog Record of *Fluid Mechanics*, 2nd edition, ed. Frank M. White, (1986)
1041	ZB Med Card Catalog (Jegaden)
1042	U.S. Patent No. 5,928,181 ("Coleman")
1043	File History of U.S. Patent No. 8,888,728 ("'728 PH")
1044	U.S. Patent No. 4,692,148 (Kantrowitz)
1045	U.S. Patent No. 4,468,224 (Enzmann)
1046	Leupold Declaration (Jegaden)
1047	U.S. Patent No. 5,421,338 ("Crowley")
1048	U.S. Patent No. 4,135,253 ("Reich")

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 13,464 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 April 15, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 9,561,314 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. 9,561,314 (EX1001-1048)
- Exhibits 1001-1048
- 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:

Alston & Bird LLP

Bank of America Plaza

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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