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. 2017-01202

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,545,468

CLAIMS 4, 7, 10-13, 15, 17, 19

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I. INTRODUCTION

Petitioners Abiomed, Inc. and Abiomed R&D, Inc. (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 4, 7, 10-13, 15, 17, and 19 (the "Challenged Claims") of U.S. Patent No. 9,545,468 (the "'468 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) petitions for IPR of claims 1-3, 5, 6, 8, 14, 16, 18, 20-24, and 26 of the '468 patent; (2) petitions for IPR of U.S. Patent Nos. 9,561,314 and 9,597,437; and (3) petitions for IPR of U.S. Patent Nos. 7,022,100 (IPR2017-01025), 8,888,728[1] (IPR2017-01026 and IPR2017-01027), and 9,327,068 (IPR2017-01028 and IPR2017-01029) (the "related patents") which are related to the '468 patent.

C. Counsel

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

[1] Referred to herein as the '728 patent.

Backup Counsel: Charles D. Larsen (Reg. No. 48,533); Christopher Carroll (Reg. No. 55,776)

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 '468 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[2]:

[2] The pre-AIA statutory framework applies to the '468 patent.

1. WO99/02204 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).

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).[3]

4. U.S. Patent No. 5,061,273 to Yock (EX1006, "Yock"), filed June 1, 1989 and issued October 29, 1991, is prior art under 35 U.S.C. § 102(b).

5. 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).[4]

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

[4] 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).

5. 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 these claims under the following statutory grounds:

- Ground 1: Claims 4, 7, 11-13, 15, and 19 are rendered obvious by Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler under 35 U.S.C. § 103(a).
- Ground 2: Claims 4, 7, 11-13, 15, and 19 are rendered obvious by Aboul-Hosn in view of Yock, and further in view of Siess and Wampler under 35 U.S.C. § 103(a).
- Ground 3: Claims 10 and 17 are rendered obvious by Aboul-Hosn in view of Jegaden, and further in view of Siess, Wampler, and Wampler_712 under 35 U.S.C. § 103(a).
- Ground 4: Claims 10 and 17 are rendered obvious by Aboul-Hosn in view of Yock, and further in view of Siess, Wampler, and Wampler_712 under 35 U.S.C. § 103(a).

V. CONVENTIONAL TECHNOLOGY

A. Conventional Intravascular Blood Pumps[5]

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; 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[Seiss '913] 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. (Collins ¶¶60, 70-72, 79.)

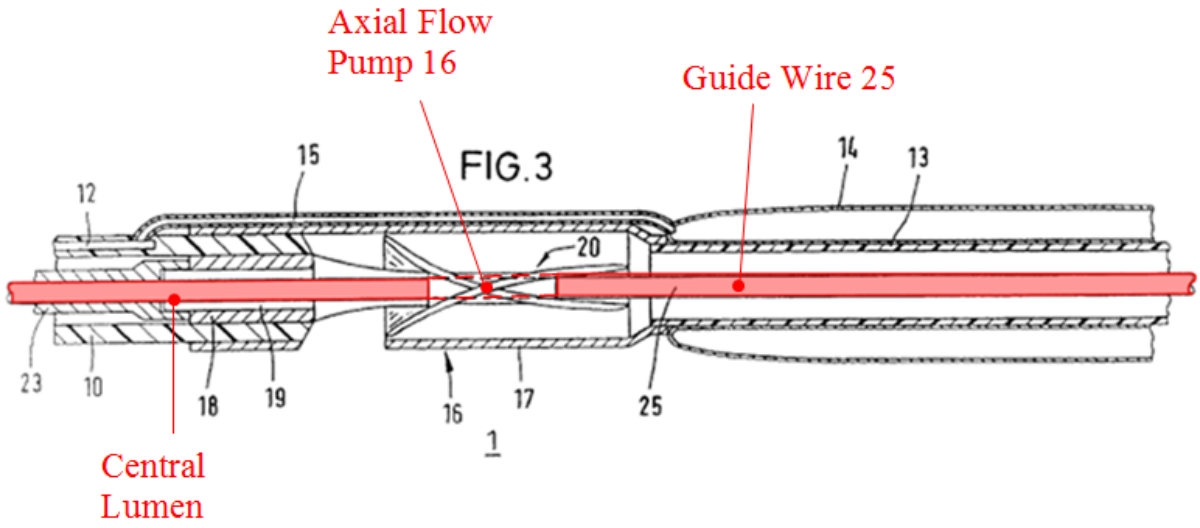
B. Placing Intravascular Blood Pumps

[5] For background, Dr. Collins discusses the circulatory anatomy and function, and development of intravascular blood pumps. (Collins ¶¶36-51.)

Along with "over-the-wire" and "guide catheters," the rapid-exchange technique of the Challenged Claims was used routinely to position blood pumps intravascularly. (Collins ¶¶80-81.)

1. Over-the-Wire

POSITAs used "over-the-wire" guide mechanisms to place intravascular blood pumps. (Collins ¶85-87.) As shown below in FIG. 3, U.S. Patent No. 6,248,091 to Voelker (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 ¶87; EX1011[Voelker] 3:56-60 *see also* EX1004[Aboul-Hosn] 22:10-16, FIG. 3.)



(Collins ¶87; EX1011[Voelker] FIG. 3, annotated.)

2. Rapid-Exchange

"Rapid-exchange" was a well-known catheterization technique. (Collins ¶89.) Yock disclosed placing a conventional "rapid-exchange" catheter by sliding it along a guide wire extending through a sleeve secured to the exterior of the cannula or embedded within the cannula wall itself. (*Id.* ¶90; EX1006[Yock] FIG. 10, 7:64-8:2.)

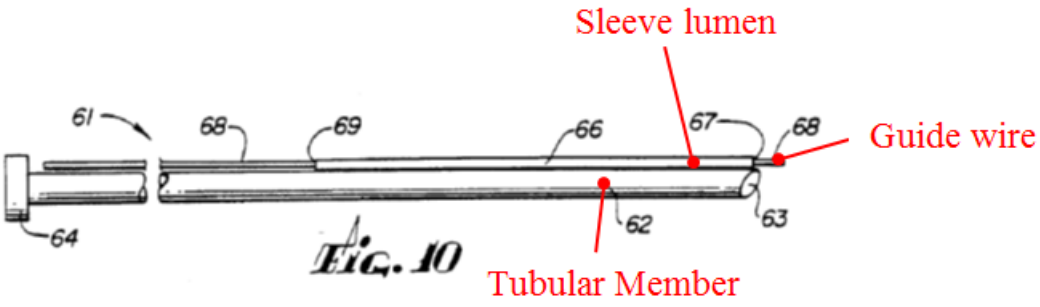
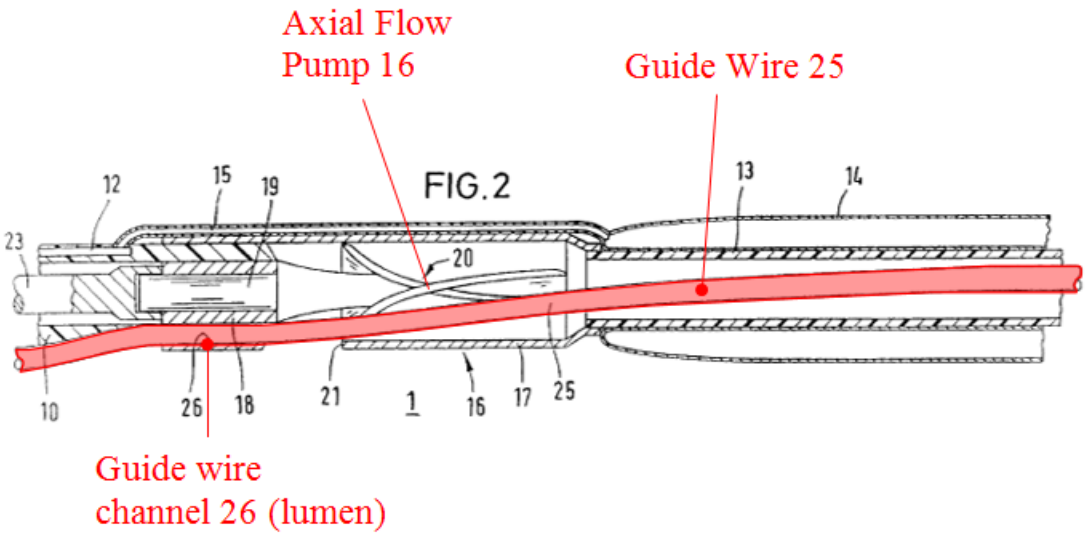


FIG. 10

(Collins ¶90; 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 26 of a pump for positing the pump, as illustrated below. (Collins ¶92; EX1011[Voelker] 3:34-43.)



(Collins ¶92; EX1011[Voelker] FIG. 2, annotated.)

As explained in further detail in Sections VII.A and X below, a POSITA could also readily deploy Aboul-Hosn's blood pump using the conventional "rapid-exchange" technique. (*Id.* ¶¶127-132.)

3. Guide Catheter

Yock also discloses using a guide catheter to position a guide wire. (Collins ¶82; 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 ¶83; EX1001['468 Patent] 2:35-55.)

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. (Collins ¶95; EX1023[Faxon] 58-59; EX1006[Yock] 8:16-25;

EX1011[Voelker] FIGS. 2 and 3; EX1042[Coleman] 34:14-39.) Over-the-wire and rapid-exchange were part of a limited set of delivery techniques. (Collins ¶96.)

The interchangeability of over-the-wire and rapid-exchange was also well understood for intravascular blood pump applications. (Collins ¶97.) 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 ¶98; EX1011[Voelker] 3:34-55.)

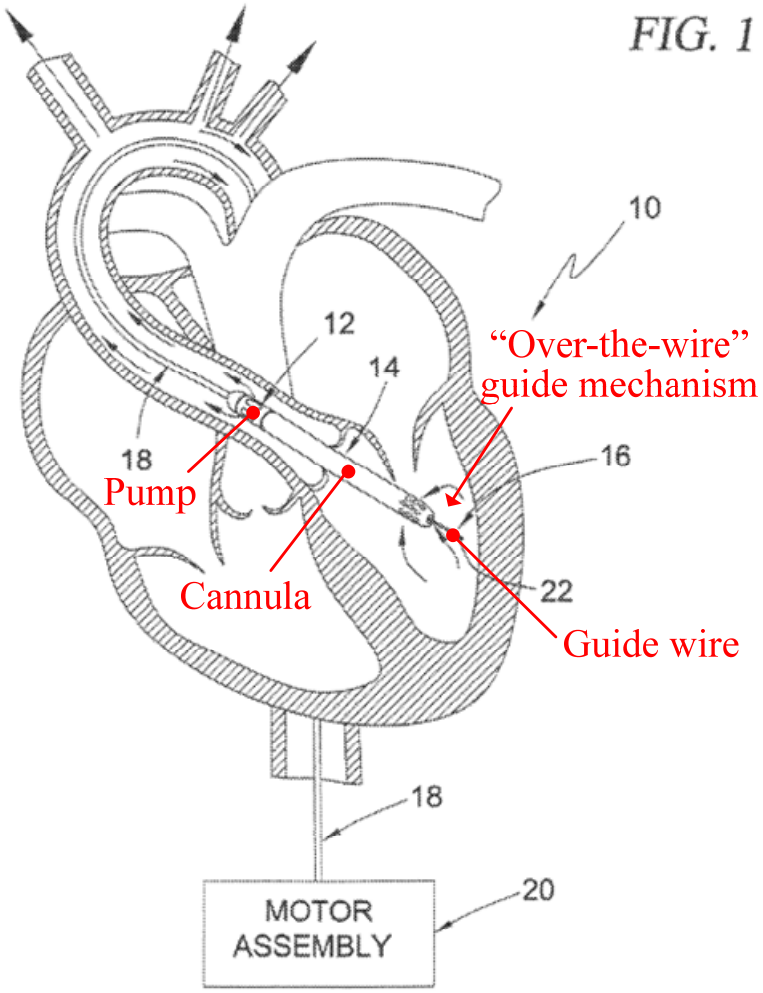
Further, there are a number of known advantages to using rapid-exchange compared to over-the wire. (Collins ¶¶99-100.)

VI. OVERVIEW OF THE '468 PATENT

A. Summary of the '468 Patent

The '468 patent describes placement of a conventional intravascular blood pump system using the same three conventional guide wire delivery techniques discussed above. (EX1001['468 patent] 9:13-32, 13:62-14:10, 15:5-21; Collins ¶101-103.) The '468 patent openly admits that it is not the first to use "guide mechanism[s]" to place an intravascular pump. (EX1001['468 patent] 2:35-45.)

FIG. 1 of the '468 patent illustrates a conventional over-the-wire placement technique. (*Id.* 5:25-30.)

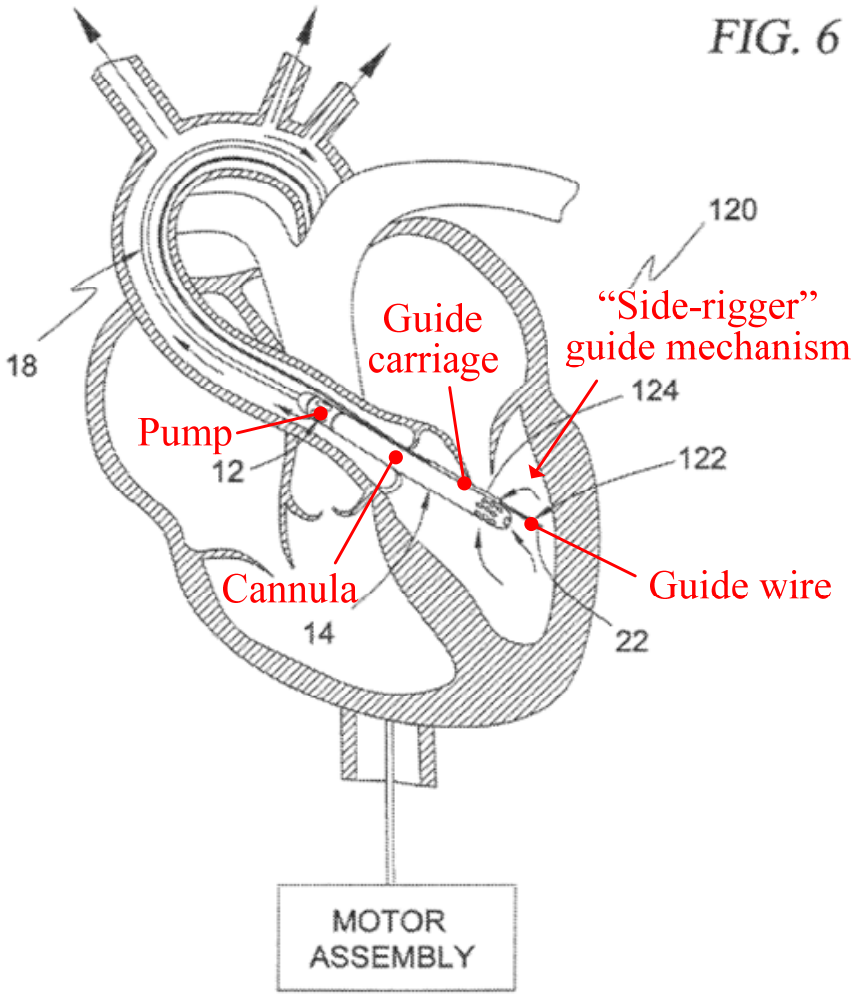


(Collins ¶104; EX1001['468 patent] FIG. 1, annotated.)

The conventional intravascular blood pump system 10 includes an intravascular blood pump 12 rotor hub, cannula 14, and over-the-wire guide mechanism 16 with a guide wire lumen that passes through the center of the rotor hub and the cannula 14. (*Id.* 9:13-24; Collins ¶104.) The blood pump 12 provides

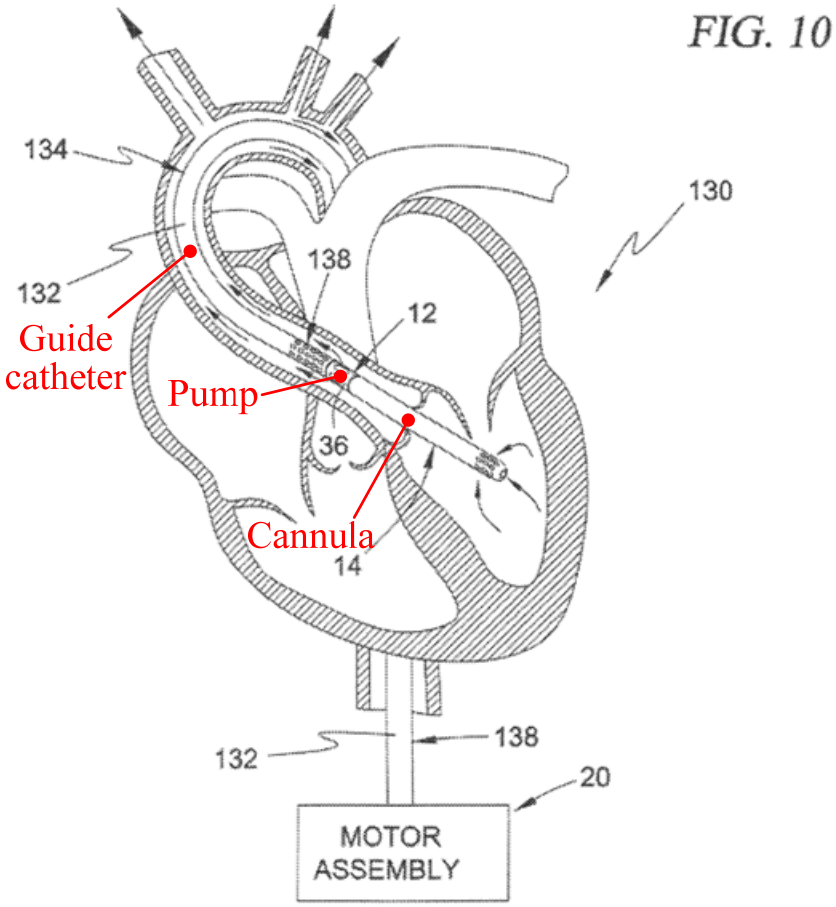
heart support in the same manner as conventional axial-flow intravascular blood pumps. (*C.f.* EX1001['468 patent] 20:43-48 *with id.* 2:16-19; Collins ¶103.)

FIG. 6 shows the conventional "rapid-exchange" guide mechanism of the prior art. (*Id.* 5:47-52.) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a … guide wire 22 … dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (*Id.* 14:17-21; Collins ¶¶106-107.)



(Collins ¶106; EX1001['468 patent] FIG. 6, annotated.)

Finally, the ’468 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[’468 patent] 5:65-6:3; Collins ¶109.)



(Collins ¶109; EX1001[’468 patent] FIG. 10, annotated.)

B. Prosecution History

During prosecution of the ’468 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['468 PH] 743.) There is no patentable synergy between the recited guide wire configuration and the purge system feature that the Examiner found missing. (Collins ¶110.) 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.*)

C. The Earliest Possible Priority Date is September 1, 2000

The September 1, 2000 priority date of the '468 patent is the earliest possible priority date (the "EPD") for the Challenged Claims.[6] Several elements of the Challenged Claims are not supported by its claimed earlier-filed provisional application, Provisional U.S. Application No. 60/152,249 (EX1012, the "'249 provisional application").

Claim 1, from which the Challenge Claims depend, requires "an elongate lumen associated with the cannula" where the elongate lumen "is sized smaller cross sectionally than the cannula lumen, both the elongate lumen and cannula lumen not extending through the rotor hub," "a pressure sensing element," and "a

[6] The '468 Patent claims priority to PCT Application No. PCT/US00/24515, filed on September 1, 2000.

purge lumen extending through the catheter and operatively arranged to deliver purge fluid." (EX1001['468 patent] 33:66-34-42, 36:7-59.) None of these limitations are supported in the '249 provisional application.[7] (Collins ¶¶121-123; *Dynamic Drinkware, LLC. v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("the specification of the *provisional* must 'contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.") (quoting *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002) (emphasis in original).)

[7] During prosecution of the '728 patent, which is related to the '468 patent, the Examiner found that the claims directed to "the 'side-rigger' or 'rapid-exchange' guide mechanism," "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 which the Patent Owner never challenged in any subsequent response. (*See* EX1043['728 PH] 259-280.)

Accordingly, the EPD for the Challenged Claims is September 1, 2000.[8] (Collins ¶¶124-125.)

VII. OVERVIEW OF THE PRIOR ART[9]

A. Overview of Aboul-Hosn

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 '468 patent. (Collins ¶126; EX1004[Aboul-Hosn] 11:9-14; 30:1-2.)

Annotated FIGS. 21 and 23, below, show a percutaneous approach to delivering the intravascular blood pump using a guide wire. (Collins ¶146; EX1004[Aboul-Hosn] 30:1-2, 20-27.) FIG. 21 shows how the blood pump (green)

[8] 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 35 U.S.C. § 102(b).

[9] Aboul-Hosn, Siess, and Wampler_712 were cited in an Information Disclosure Statement dated August 19, 2016 but there is no record that the Examiner relied upon them. (EX1003['468 PH] 414-450.) There is no record of Jegaden, Yock, or Wampler being disclosed during prosecution of the '468 patent.

passes along the guide wire up the femoral artery, so the cannula 411[10] (blue) goes through the aorta and into the left ventricle. In FIG. 23, the cannula then also continues into the left atrium, where it is positioned to pump blood from the left atrium to the aorta. (Collins ¶¶146-147; EX1004[Aboul-Hosn] 29:17-28, 30:1-2, 30:20-27.) The cannula's inflow tip of may be placed in "the left ventricle, … or any of the left heart vessels" to provide left heart support. (*Id.* 26:10-13.)

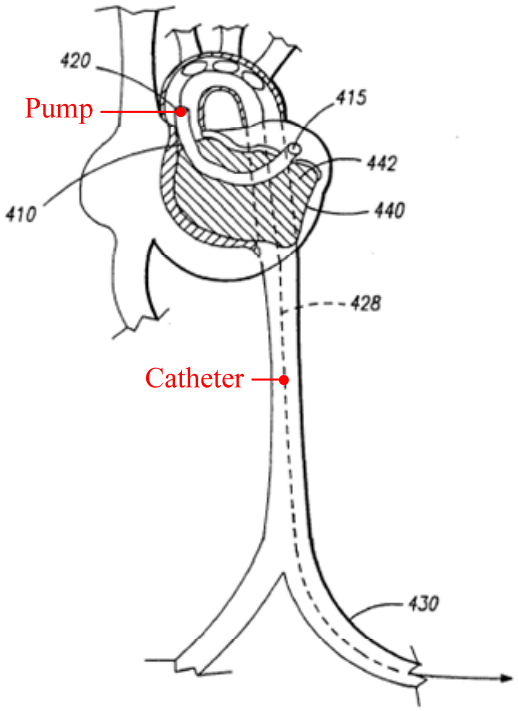


FIG.–21

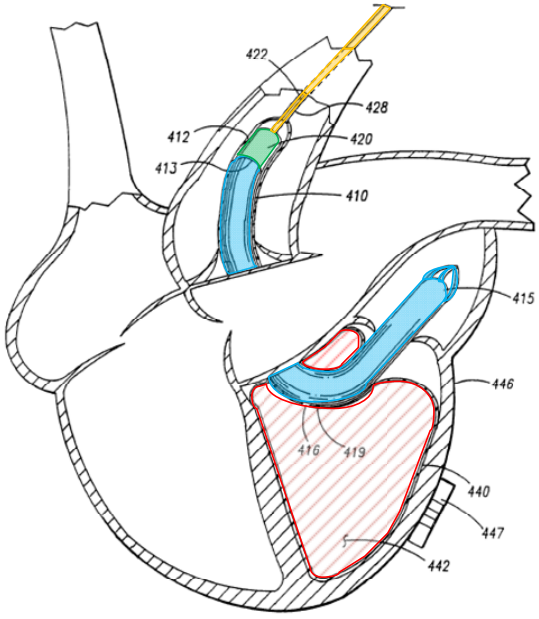
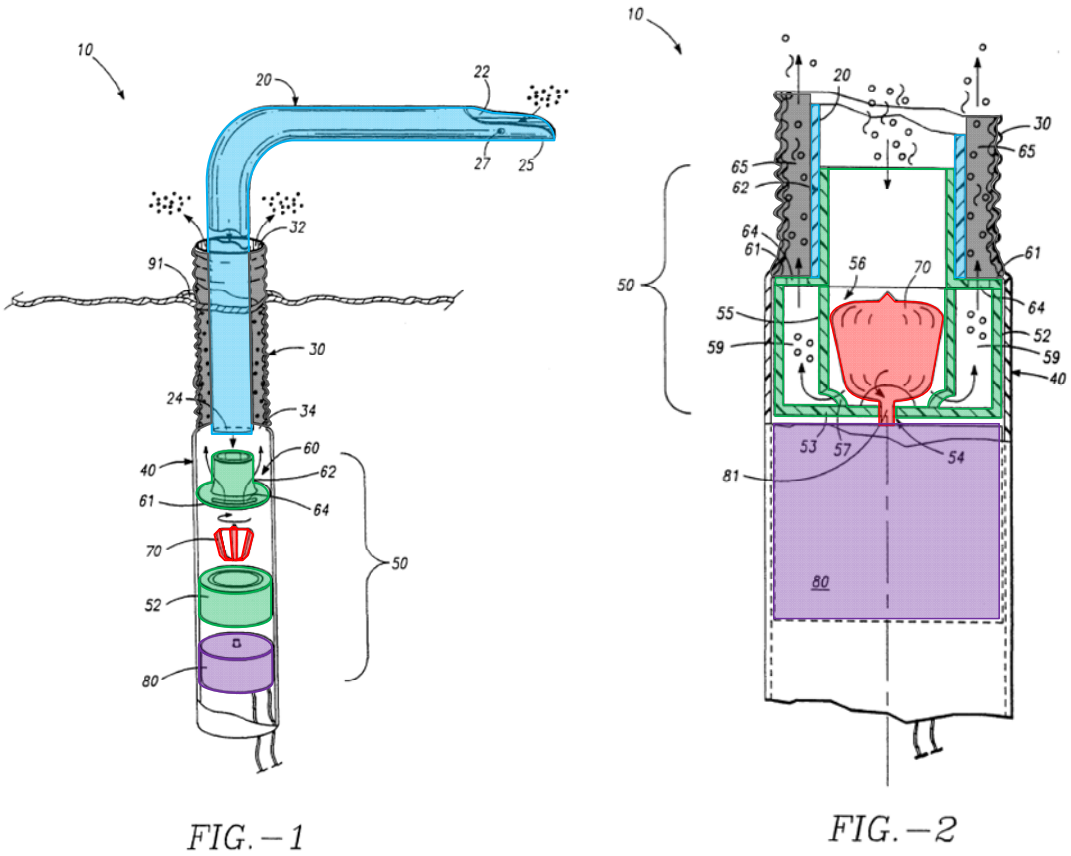


FIG.–23

(Collins ¶146; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

[10] 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.)

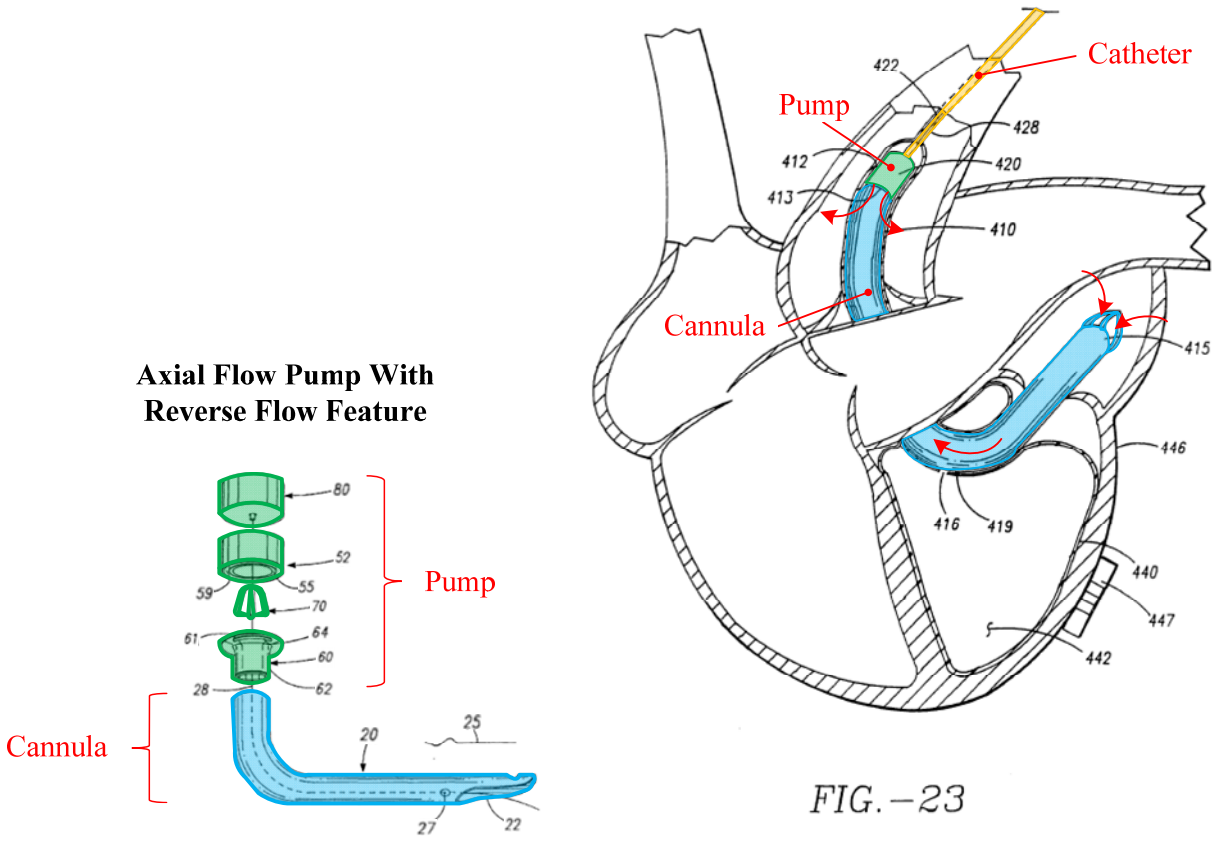
FIGS. 1-13 show a surgical approach with details about the interior of the pump and cannula. (Collins ¶¶133-135.)As shown below in FIGS. 1 and 2, and similar to the '468 patent, the pump system has a conventional drive motor 80 (purple) connected to a rotor and associated blades 70 (red), within a housing body 52 (green), and a cannula 20 (blue) coupled to a housing cap 62 (green).[11] (EX1004[Aboul-Hosn] 12:12-13:13.)



(Collins ¶133; EX1004[Aboul-Hosn] FIGS. 1, 2, annotated.)

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

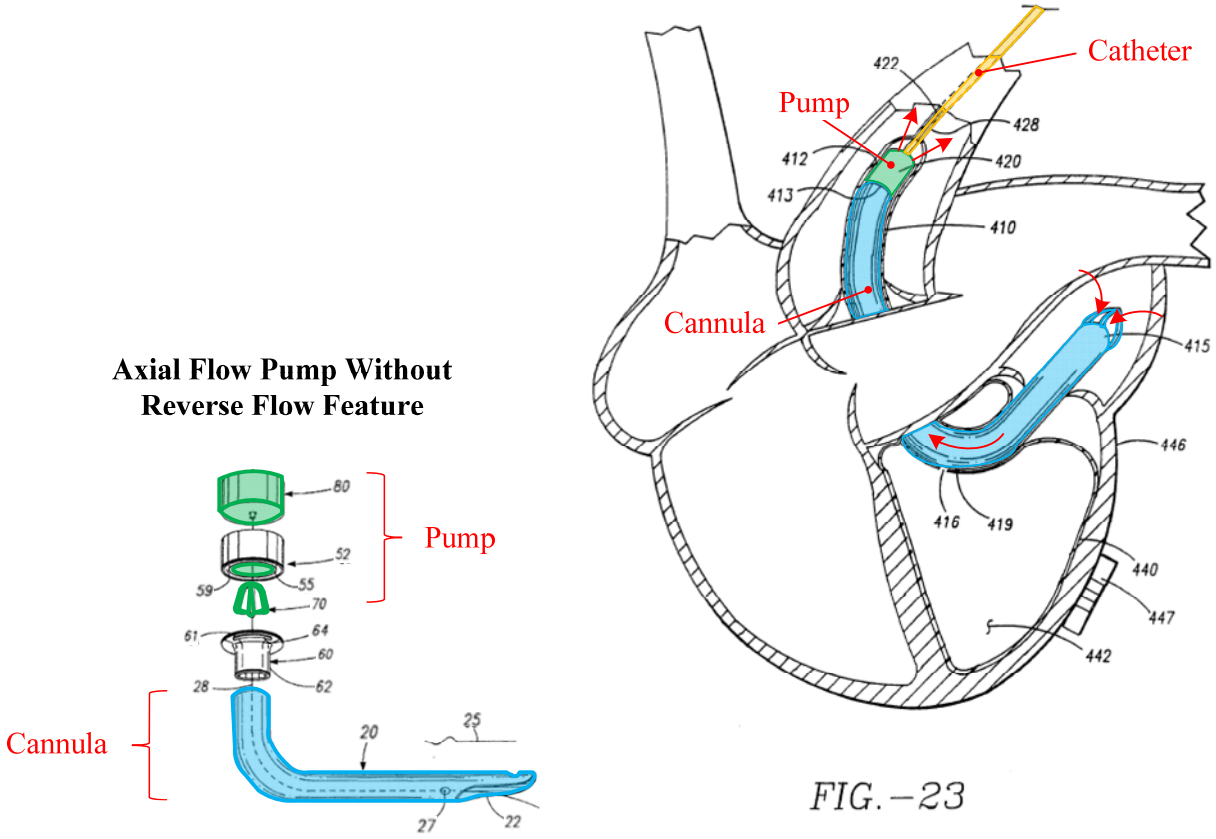
As shown below, to apply the percutaneous approach in the reverse flow configuration, the pump (green) in the system of FIGS. 1-13 (i.e. an intravascular pump "provided for by the present invention") would be readily connected to the multilumen catheter 428 (yellow). (Collins ¶¶142-143.) In this configuration, 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 ¶143; EX1004[Aboul-Hosn] 29:18-25.)



(Collins ¶136; 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 ¶¶137-139; *see also* EX1004[Aboul-

Hosn] 31:6-9.) In this configuration, the pump 420 would not include the components that cause the blood flow to reverse course (i.e. housing body 52, housing cap 60, and outer cannula 30). (Collins ¶137.) Instead, the blood (represented by the red arrows) discharges axially over the drive unit and out the pump 420 (green). (*Id.*)



(Collins ¶137; EX1004[Aboul-Hosn] FIGS. 1, 23, annotated.)

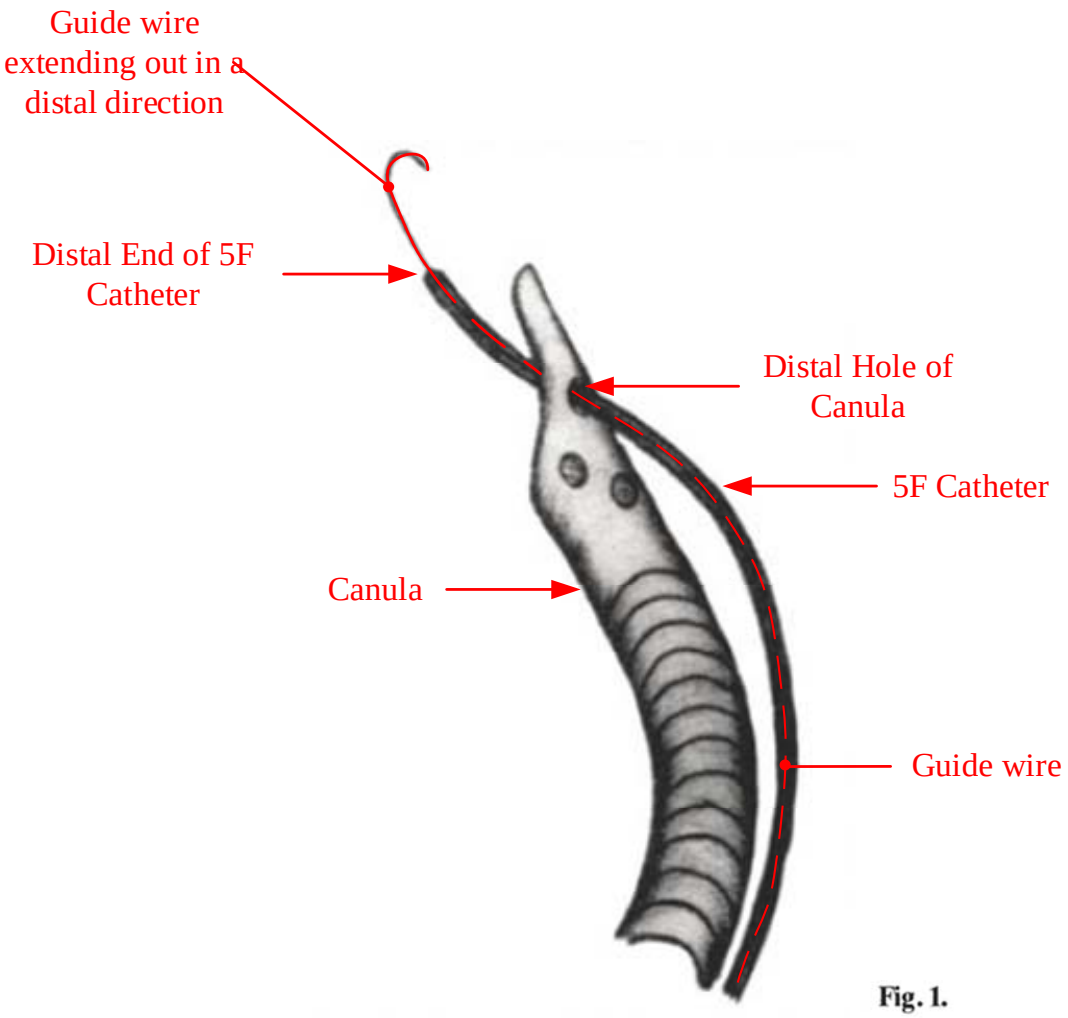
As explained in greater detail in Section X.A.1(i) below, Aboul-Hosn uses a guide wire to deploy the pumps intravascularly using the over-the-wire technique. (Collins ¶127; EX1004[Aboul-Hosn] 11:26-28, 14:13-16, 14:20-24, 21:22-24,

22:10-16.) FIG. 3 shows the conventional over-the-wire technique. (Collins ¶127; EX1004[Aboul-Hosn] 14:17-15:18, 17:19-22, FIG. 12.)

Aboul-Hosn also suggests inserting a guide wire through cannula opening 27 as seen in FIGS. 1 and 2 to place the pump, consistent with the rapid-exchange technique. (*Id.* ¶128; EX1004[Aboul-Hosn] 11:24-26.")

B. 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 ¶¶150-154; 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 the pump is advanced along the 5F catheter to the desired location. (Collins ¶151; EX1033[Jegaden] 61-62.) The 5F catheter and distal hole function as a rapid-exchange guide mechanism for the pump. (Collins ¶¶152-154.)

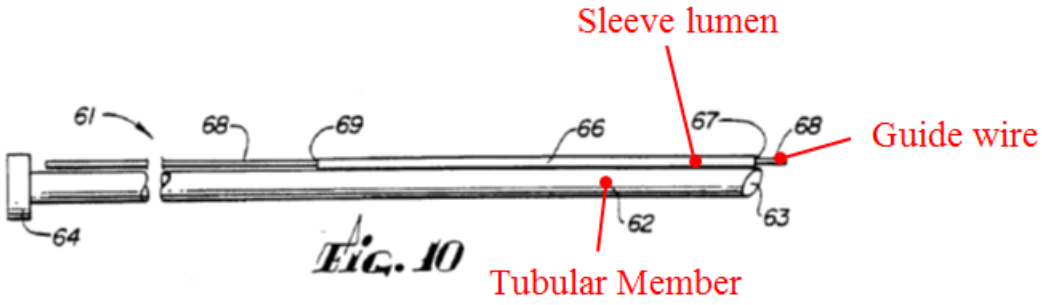


(Collins ¶153; EX1033[Jegaden] FIG. 1, annotated.)

C. Overview of Yock

Yock discloses a conventional rapid-exchange catheter, shown in FIG. 10 below, which includes an elongate tubular member, such as a cannula, and a sleeve (with an interior lumen for a guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (*Id.* ¶¶156-159; EX1006[Yock] FIG. 10, 7:64-8:2.) A guide wire is placed in a desired location in the body and inserted through the sleeve, and the catheter is advanced along the

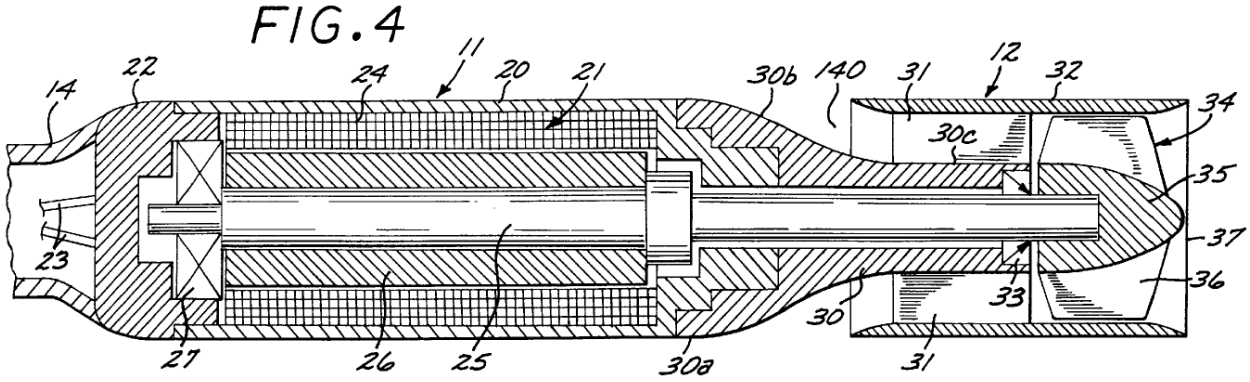
guide wire to the desired location. (Collins ¶159; EX1006[Yock] 7:64-8:25.) The orientation of the sleeve along the side of the cannula allows for the rapid exchange of catheters. (Collins ¶159; EX1006[Yock] 2:31-37.)



(Collins ¶159; EX1006[Yock] FIG. 10, annotated.)

D. 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 ¶¶167-173; 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.)



(EX1005[Siess] FIG. 4.)

E. 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 ¶¶161-165; 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 ¶¶163-165; EX1007[Wampler] 233-34.)

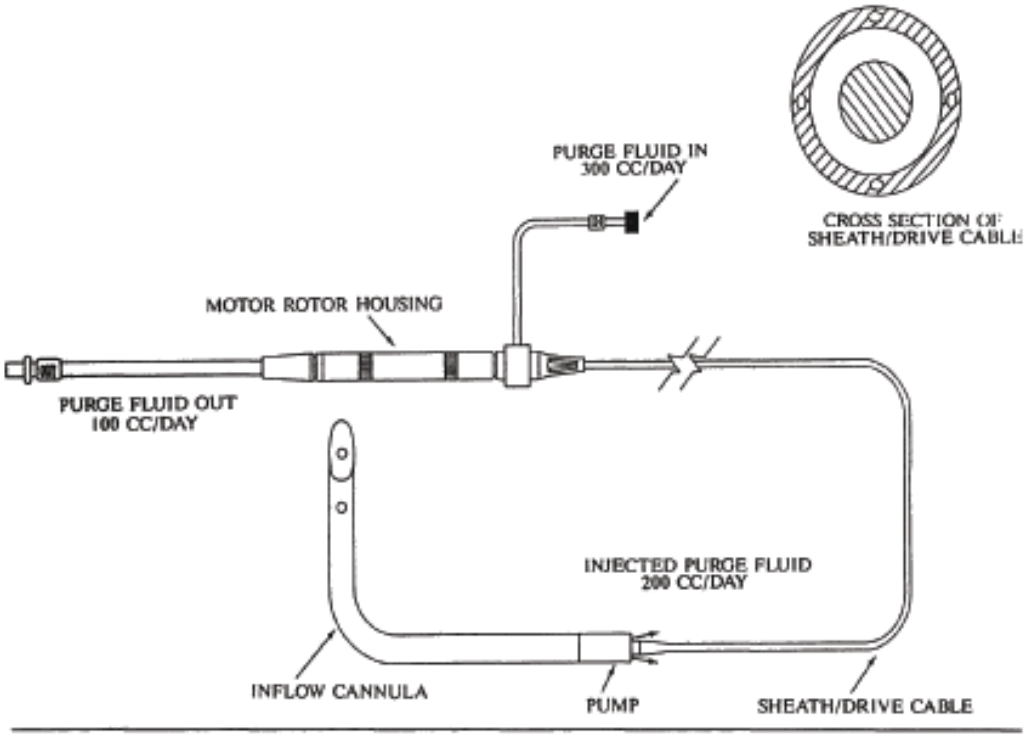
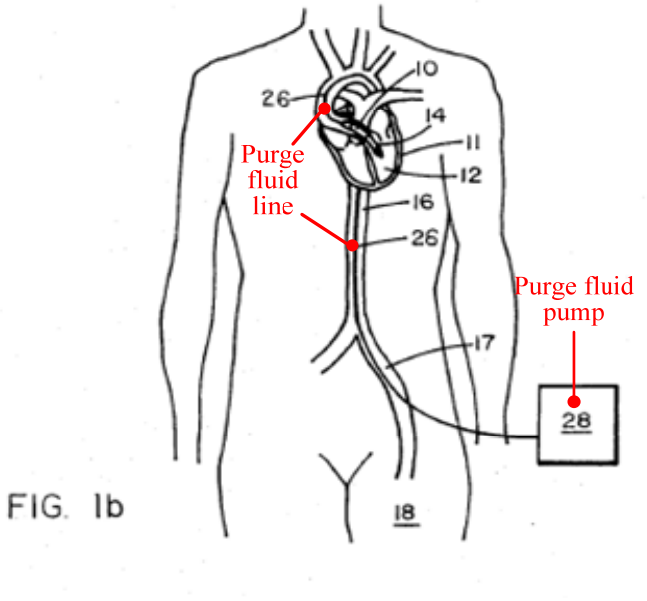


Figure 14-2. Schematic of the Hemopump.

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

F. Overview of Wampler_712

Wampler_712 discloses a conventional purge fluid system for an intravascular blood pump, such as the Hemopump. (Collins ¶¶172-173.) As shown in FIG. 1b below, purge fluid pump 28 connects to a catheter 26 to deliver a "continuous flow of purge fluid 50 … into the pump 10 under pressure through the catheter 26." (EX1008[Wampler_712] 3:40-44.)



(Collins ¶173; EX1008[Wampler_712] FIG. 1b, annotated.)

VIII. CLAIM CONSTRUCTION

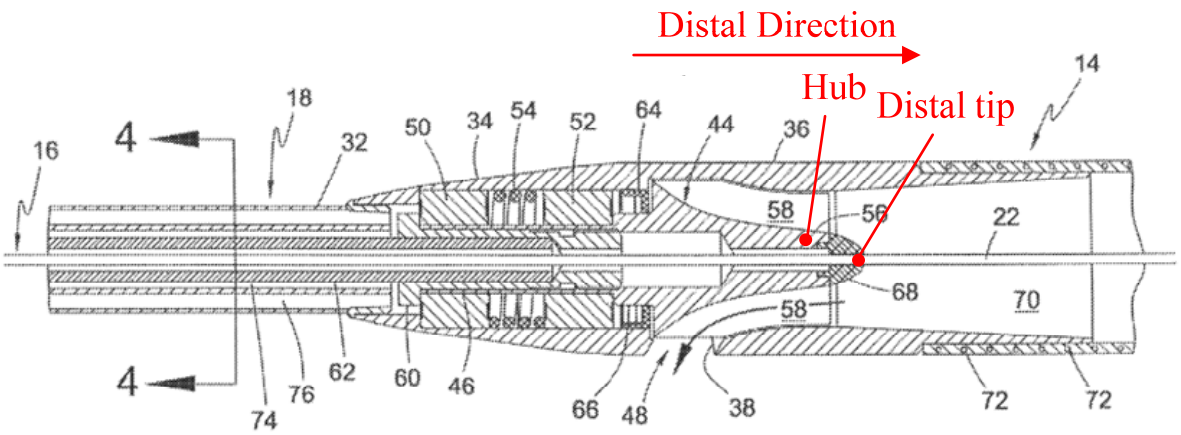
A claim in IPR is given the "broadest reasonable construction in light of the specification." (37 C.F.R. § 42.100(b).) Any claim term that lacks a definition in the specification is therefore also given a broad interpretation. (*In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).) Consistent with 37 C.F.R.

§ 42.100(b), Petitioner submits the following claim term constructions.[12] Any claim terms not included in the following discussion are to be given their broadest reasonable construction in light of the specification as commonly understood by those of ordinary skill in the art.

A. "distal"

The Challenged Claims recite the term "distal," which refers to being directed toward the far end of the cannula relative to the position of the pump. (*Id.* ¶113-116.) Referring to FIG. 3, as reproduced below, the '468 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['468 patent] 12:34-37.)

FIG. 3



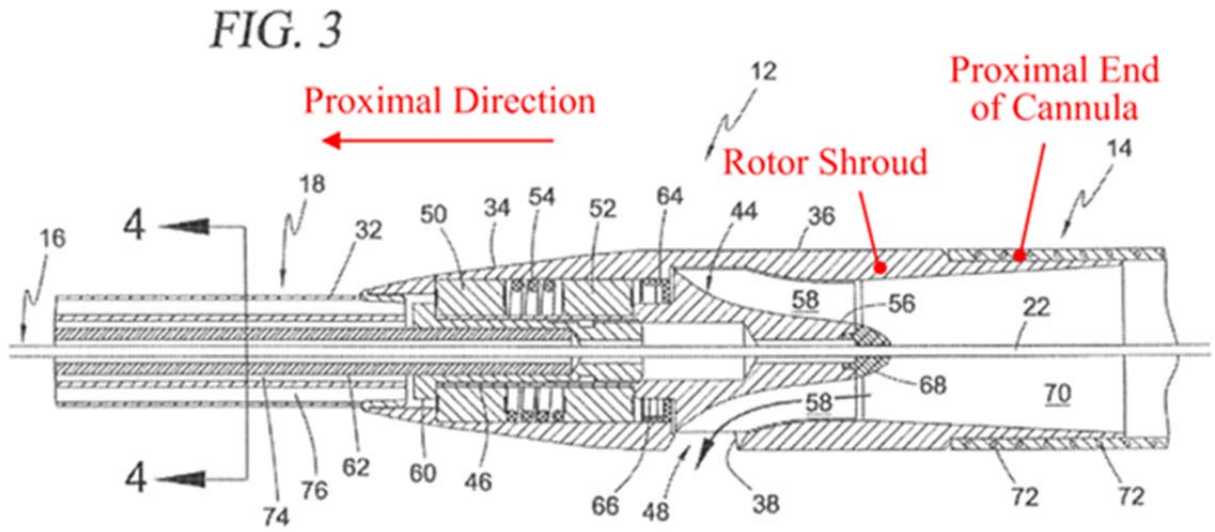
[12] Petitioner reserves the right to pursue different constructions in a district court, where a different standard applies.

(Collins ¶113; EX1001[’468 patent] FIG. 3, annotated.)

As shown in FIG. 3, the “distal flow” travels through the blood pump in a direction towards the cannula indicating that the distal direction runs from left-to-right moving away from the pump body towards the opening of the cannula into the patient’s heart. (Collins ¶¶114-116.)

B. “proximal”

The Challenged Claims also recite the term “proximal.” This term refers to the opposite of “distal,” i.e., it refers to being directed away from the far end of the cannula relative to the position of the pump. (Collins ¶¶117-119.) For example, the ’468 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.* ¶117; EX1001[’468 patent] 10:27-30, 11:60-61.)



(Collins ¶117; EX1001[’468 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 4, 7, 11-13, 15, and 19 are obvious over Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler

1. Claim 1[13]

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

Aboul-Hosn discloses an intravascular blood pump system. (Collins ¶¶219-226; EX1004[Aboul-Hosn] 6:6-7: "a reverse flow pump system that transports

[13] Claims 4, 7, 11-13, 15, and 19 depend from claim 1, which is also obvious in view of the cited prior art.

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.)

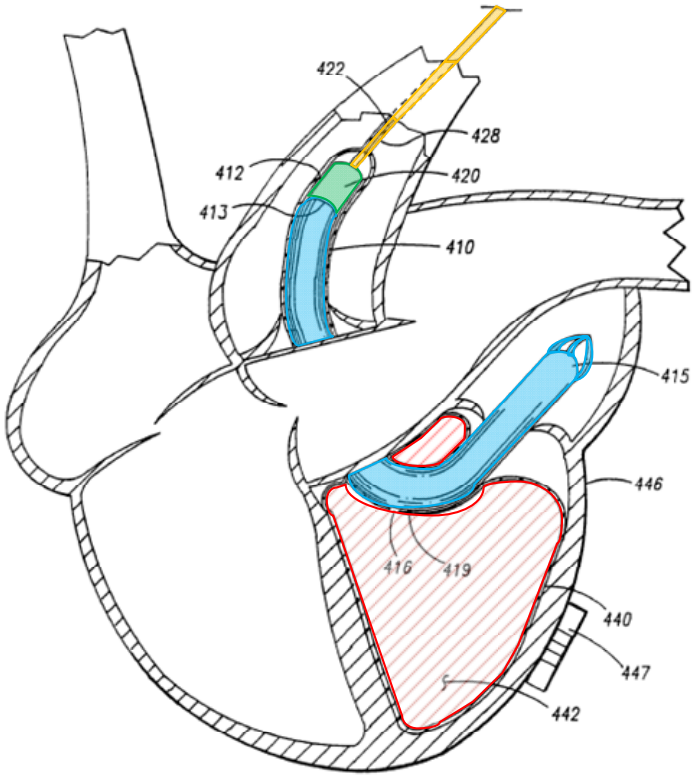


FIG.–23

(Collins ¶222; 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 ¶223; 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 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 ¶¶227-231; EX1004[Aboul-Hosn] 8:20-9:13, 29:18-30:28, 14-:13-16.) Aboul-Hosn discloses extending a guide wire through a lumen to place the blood pump in a desired location within the patient. (Collins ¶227; 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 ¶228; 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 ¶228; 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 '468 patent. (Collins ¶230; EX1004[Aboul-Hosn] 29:31-30:2: "[a]fter proper positioning, a pump may be activated to take over the left ventricle function"; EX1001['468 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 ¶230.)

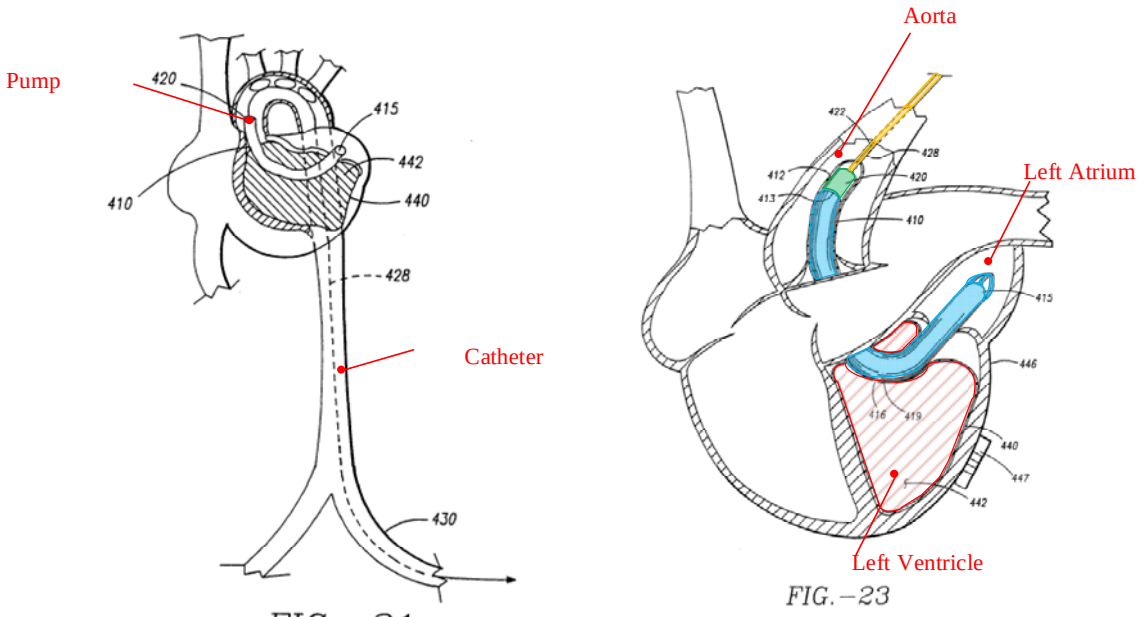


FIG.–21

FIG.–23

(Collins ¶231; 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 ¶¶233-234; EX1004[Aboul-Hosn] FIGS. 15-17, 19.)

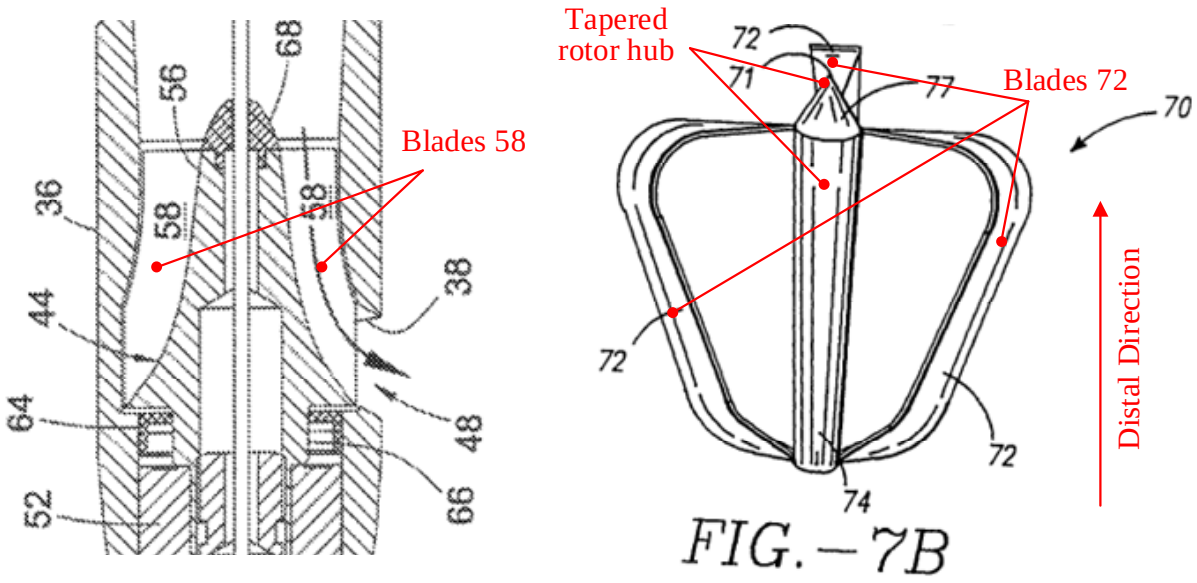
Thus, Aboul-Hosn discloses this limitation. (Collins ¶235.)

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 ¶¶236-238; EX1004[Aboul-Hosn] 12:30-13:1: "[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 ¶236.) 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 of Aboul-Hosn, below illustrates the rotor 70 having three blades 72 each extending radially outward from the central hub 74. (Collins ¶236; EX1004[Aboul-Hosn] 17:1-2.)



(Collins ¶236; EX1001['468 patent] FIG. 3, annotated (left); EX1004[Aboul-Hosn] FIG. 7B, annotated (right).)

Aboul-Hosn thus discloses this limitation. (Collins ¶¶238-239.)

d) *"a catheter coupled to a proximal end of the intravascular blood pump,"*

Aboul-Hosn discloses this limitation in the same manner as the '468 patent. (Collins ¶¶240-244) As shown in annotated 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. (*Id.* ¶¶241-242.)

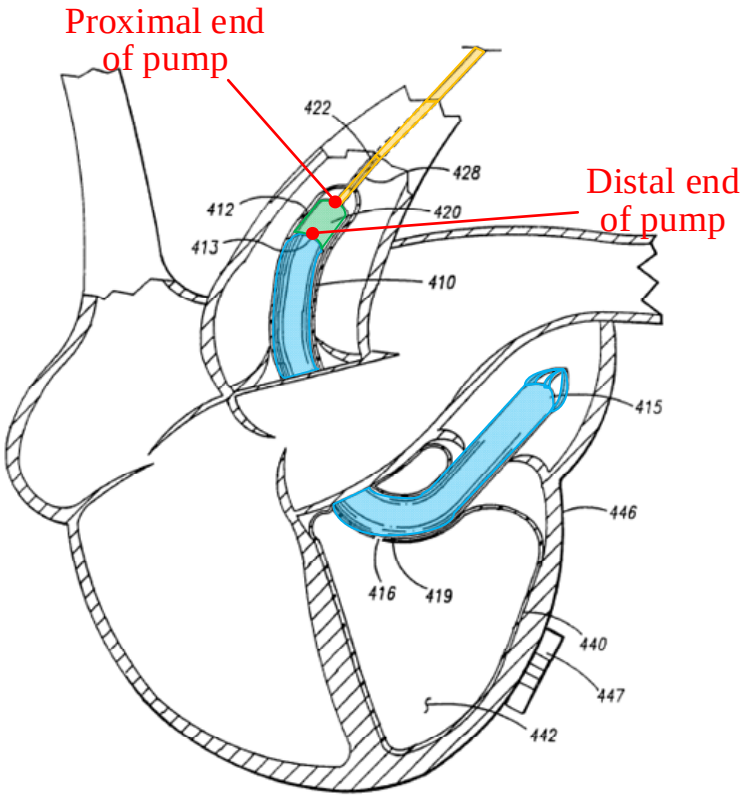


FIG.–23

(Collins ¶242; 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*. ¶243.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶244.)

e) *"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 ¶¶245-258.) 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.)

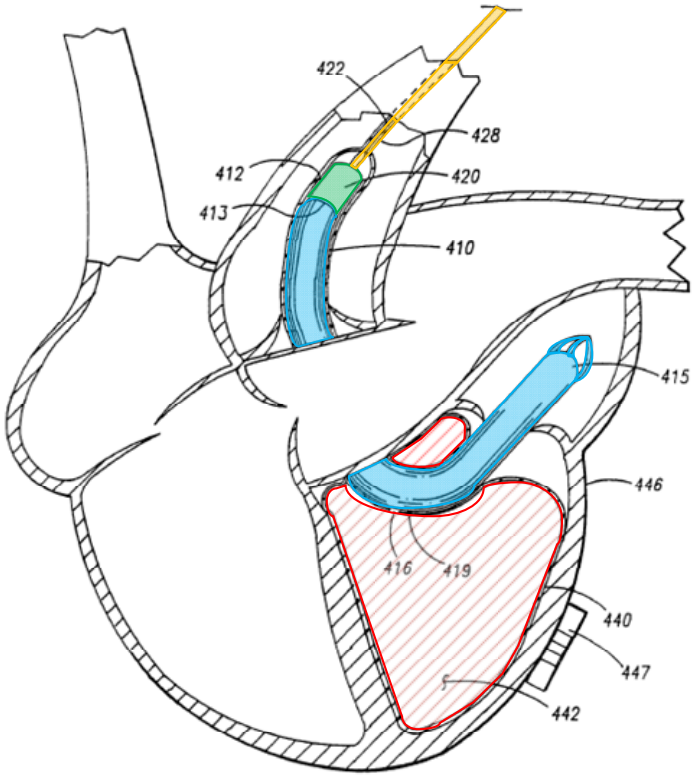


FIG.–23

(Collins ¶246; 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 ¶¶247-

249; 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 ¶250; EX1004[Aboul-Hosn] 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.)

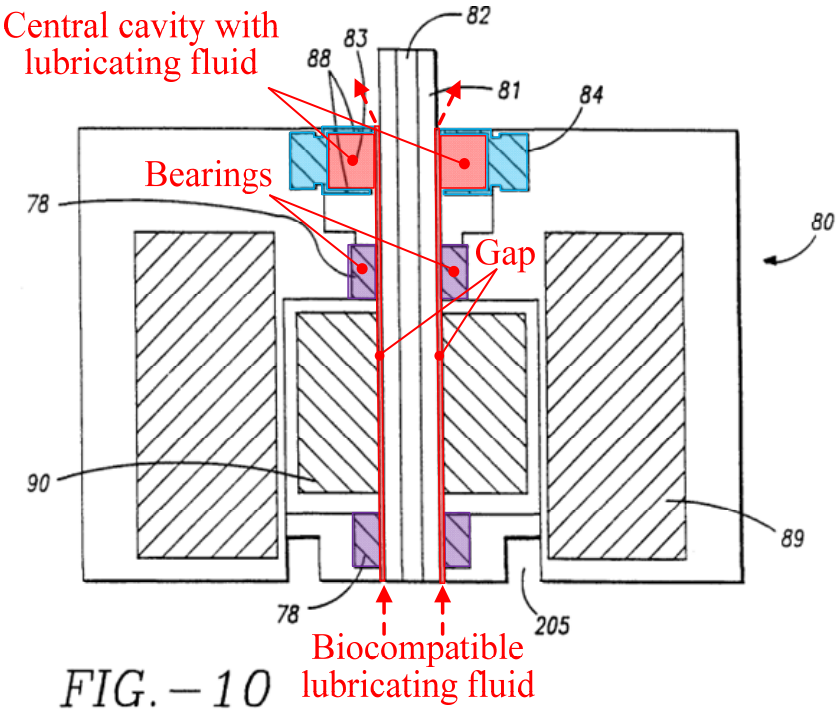


FIG. – 10

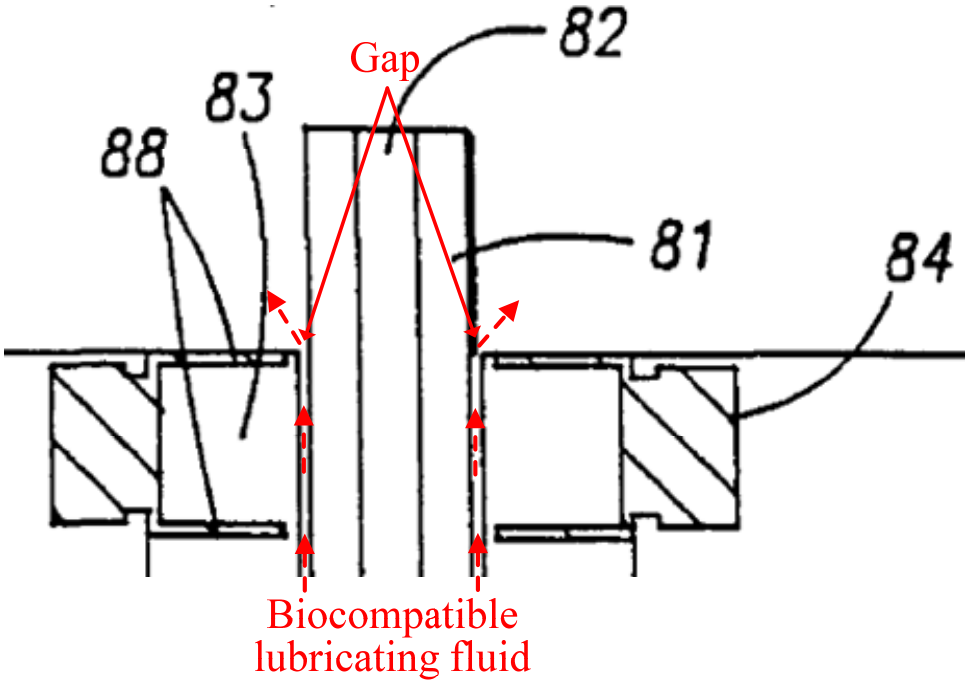
(Collins ¶249; EX1004[Aboul-Hosn] FIG. 10, annotated.)

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 ¶248.)

The '468 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['468 patent] 12:30-46.) The biocompatible lubricating fluid of Aboul-Hosn serves the same purpose. (Collins ¶186.) 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*. ¶¶249-253.)

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 - there is a gap between the thin lips 88 of the central cavity 83 and the outside diameter of the shaft 81. (*Id.* ¶¶247-251.)



(Collins ¶251; 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.* ¶252; 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 ¶252.)

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.* ¶¶253-254; EX1004[Aboul-Hosn] 29:19-25.)

Such a configuration was well known in the art and expressly disclosed by Siess. (Collins ¶254.) Siess discloses a "proximal end" of a blood pump coupled to a catheter 14 such 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] 5:47-50, 8:31-36.)

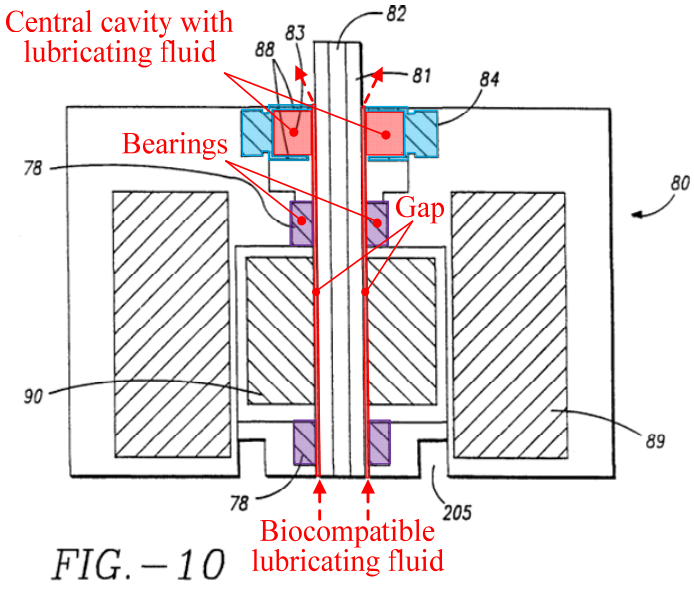


FIG. – 10

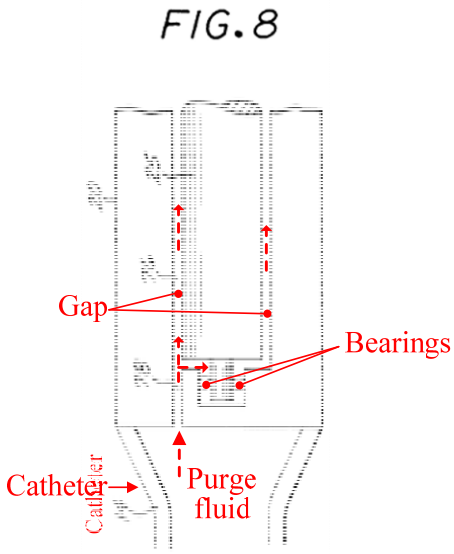


FIG. 8

(Collins ¶254; 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 ¶254;

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 ¶255.)

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 ¶256.)

Doing so would have been nothing more than 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.* ¶257.) 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.*; EX1008[Wampler_712] 3:40-51.)

Thus, Aboul-Hosn in view of Siess discloses this limitation. (Collins ¶258.)

f) ***"****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,****"***

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 ¶¶259-262; EX1004[Aboul-Hosn] 30:27-28.)

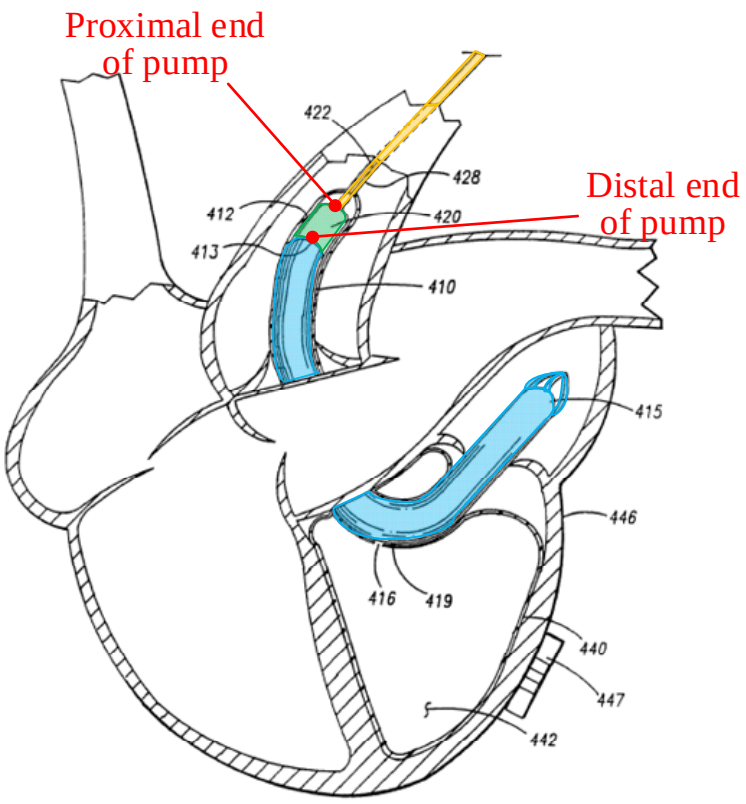
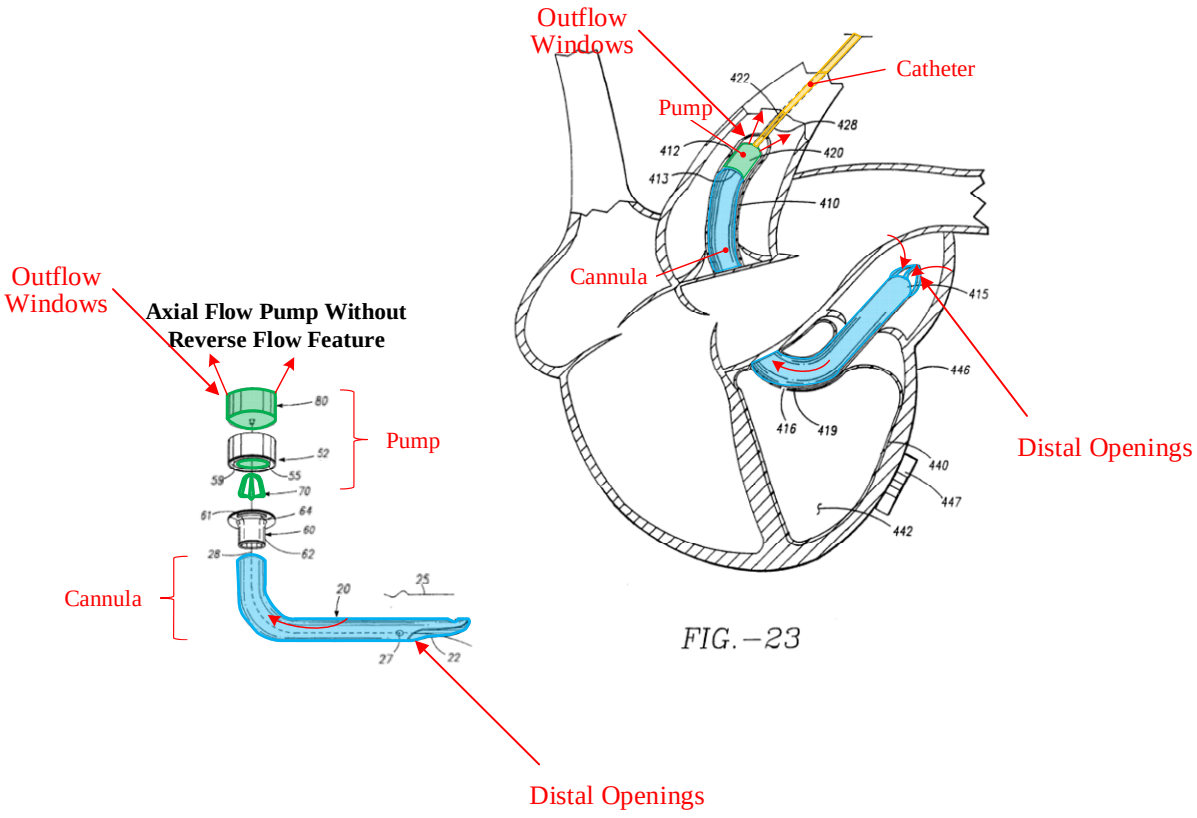


FIG.–23

(Collins ¶261; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As previously discussed in Sections VII.A and X.A.1(a), 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 ¶¶263-264.) 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 ¶¶265-273; 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".)



(Collins ¶273; EX1004[Aboul-Hosn] FIGS. 3, 23, annotated.)

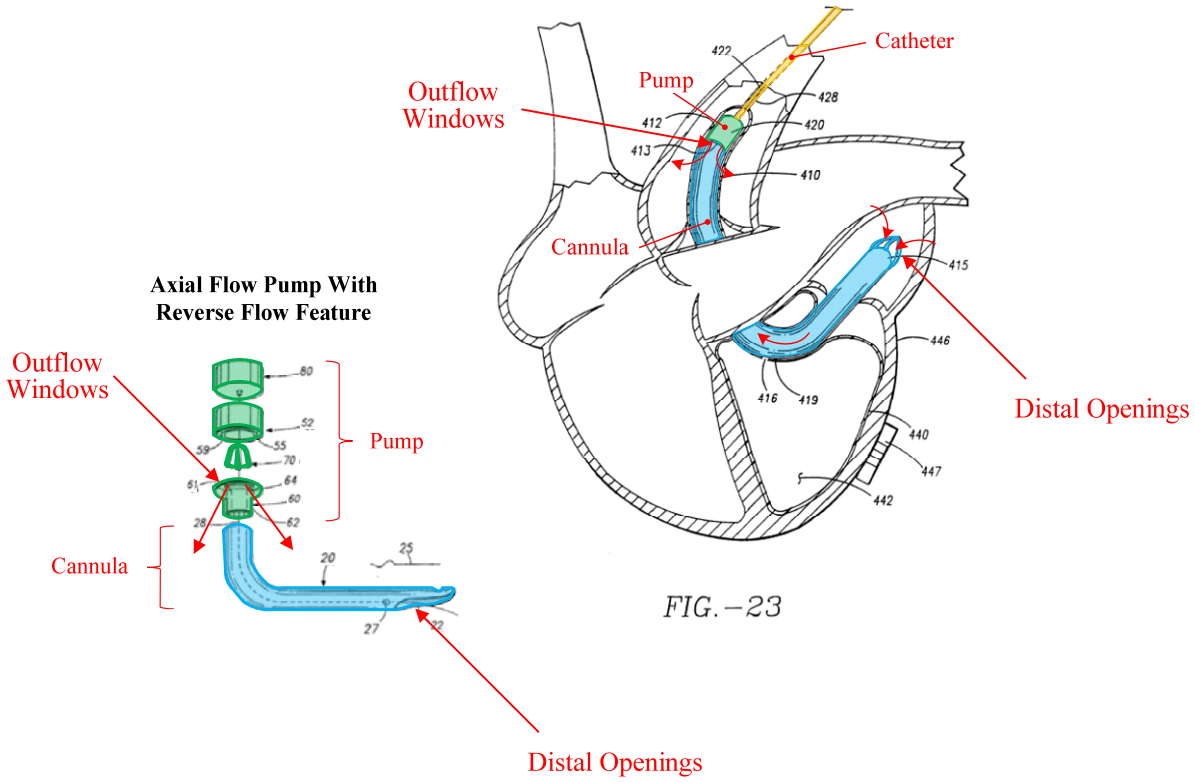


FIG.–23

(Collins ¶273; EX1004[Aboul-Hosn] FIGS. 3, 23, annotated.)

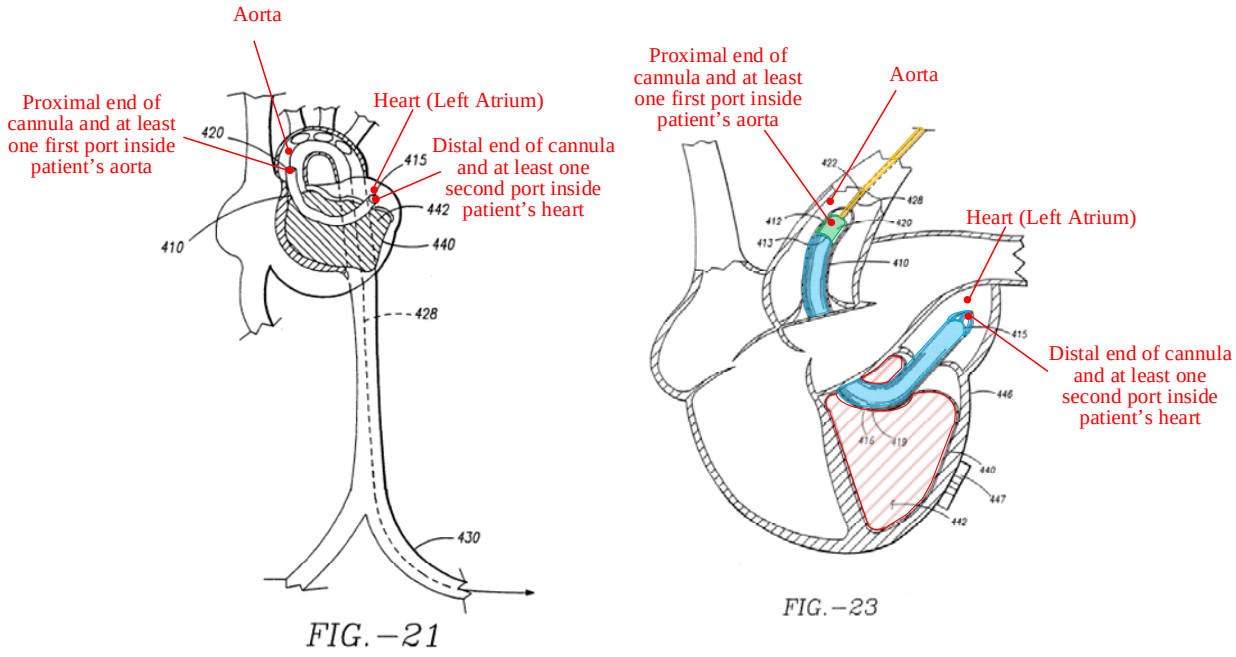
When the pump 420 is activated, blood flows through the distal opening 22, openings 27, and outflow windows in the pump housing thereby establishing fluid communication between a lumen of the inner cannula 20 and an exterior region of the inner cannula 20. (Collins ¶270-271.) Moreover FIGS. 3 and 23 of Aboul-Hosn show, for both the axial flow pump with or without the reverse flow feature, the distal opening 22 and openings 27 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.* ¶¶268-272.)

Thus, while the pump is activated, the distal opening 22 along with openings

27 are "one or more second ports," and the outflow windows would be "one or more first ports," 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 being spaced apart from and located distal to the at least one first port. (Collins ¶¶270-275.)

g) **"***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 when used for such support. (Collins ¶¶276-280; 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. (Collins ¶278.)



(Collins ¶278; 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 ¶¶279-280.) The outflow windows are formed in the pump 420 housing (i.e. the "at least one first port") and 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.*)

h) ***"****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." (EX1004[Aboul-Hosn]

11:8-11, 11:24-28, 22:10-12.) As discussed immediately above, in the configuration shown in FIG. 23, Aboul-Hosn discloses that 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 ¶281.) "After proper positioning, a pump may be activated to take over the left ventricle function." (EX1004[Aboul-Hosn] 29:31-30:2.)

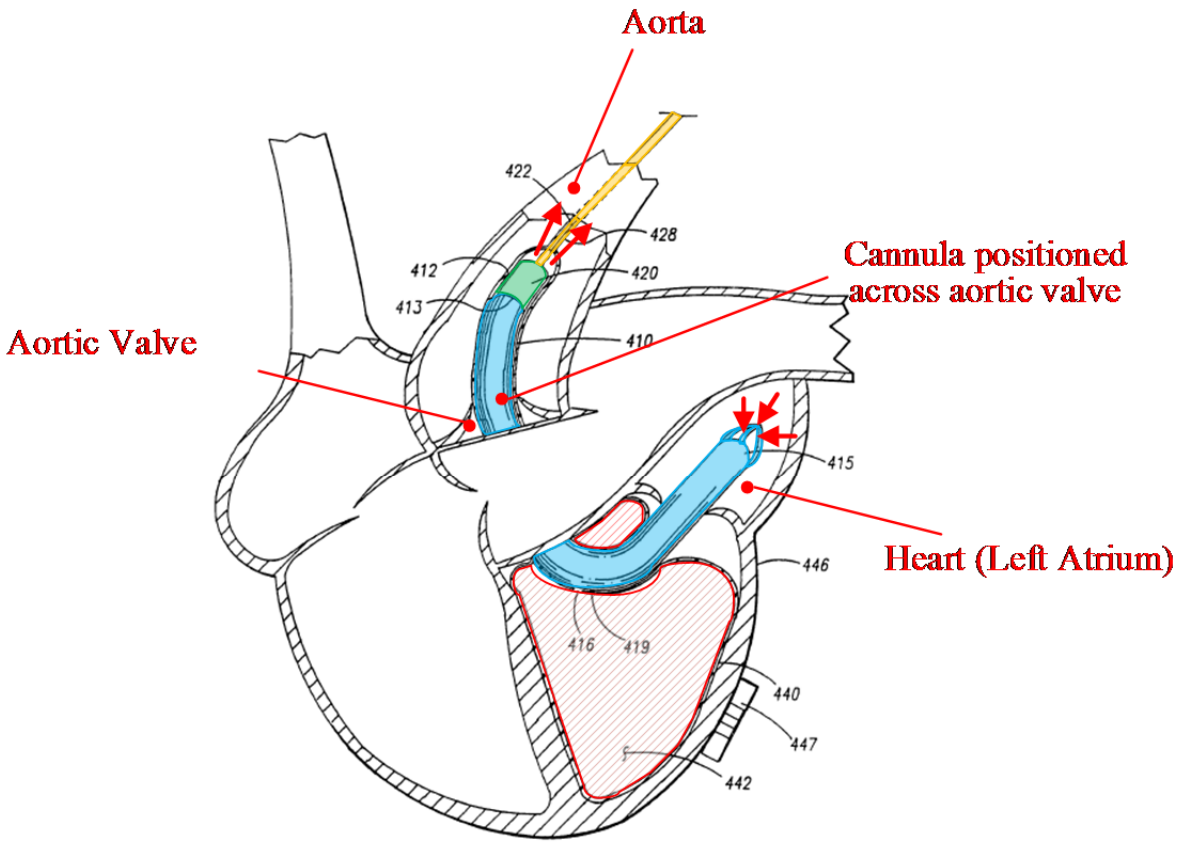


FIG.–23

(Collins ¶281; 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. (Collins ¶¶281-282.) Thus, Aboul-Hosn discloses this limitation. (*Id.*)

i) **"***an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen,***"**

The '468 patent does not specify what it means to be an *elongate* lumen, much less an elongate lumen *associated with* the cannula. (Collins ¶283.) Notwithstanding, Aboul-Hosn in view of Jegaden, discloses the "elongate lumen associated with the cannula" in the same manner as the '468 patent. (*Id.*)

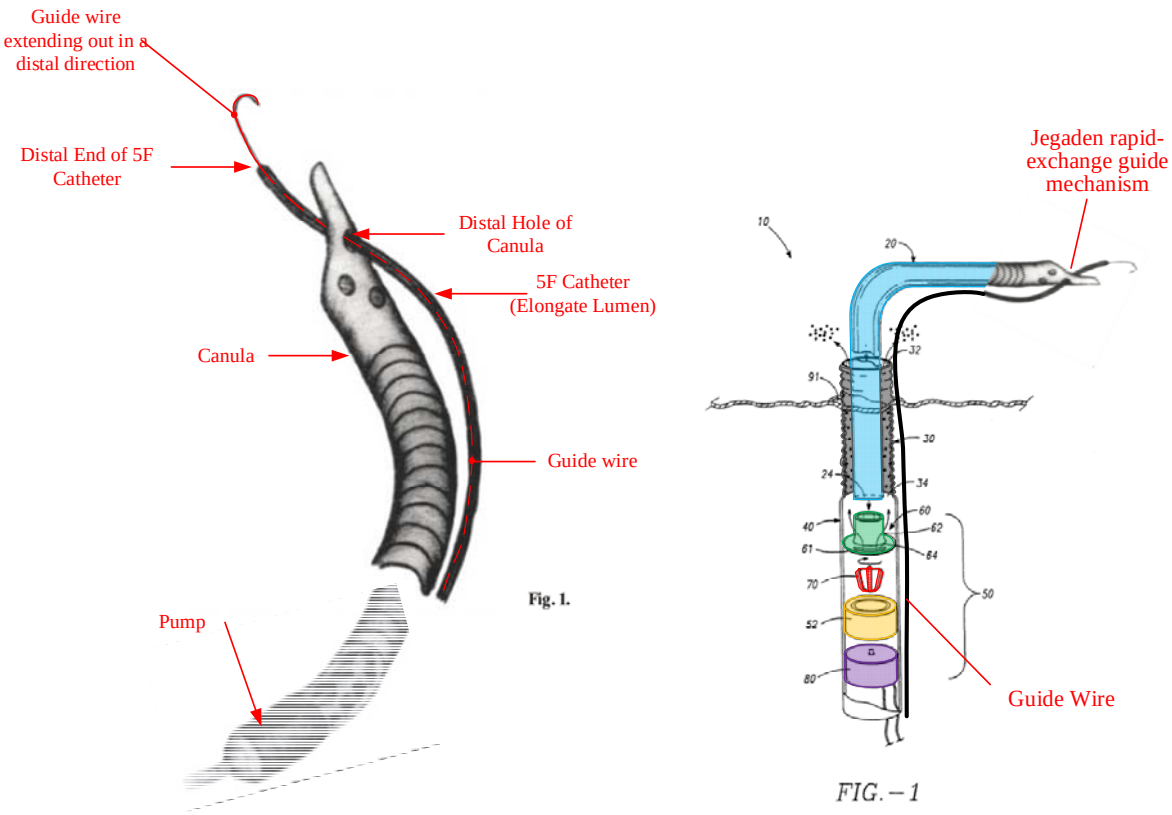
Aboul-Hosn discloses how a blood pump system may be placed in a desired location within a patient, such as within the left side of the heart, by using a guide wire. (Collins ¶¶285-289; EX1004[Aboul-Hosn] 11:24-27, 17:19-20, 24:7-14.) Aboul-Hosn teaches delivering the intravascular blood pump using the over-the-wire technique, and further suggests delivering the intravascular blood pump using the rapid-exchange techniques. (Collins ¶¶285-289; EX1004[Aboul-Hosn] 17:8-20, 20:23-26, 24:7-14, 11:24-26.) In the context of Fig. 1, Aboul-Hosn discloses that "[a] catheter guide wire may also be extended through the cannula openings 27 to dispose the inner cannula 20 at desired locations throughout the body including the heart region." (EX1004[Aboul-Hosn] 11:24-26.) Moreover, in Fig. 1 the rotor

hub 70 does not have a guide wire extending through it, as compared to Fig. 3 which illustrates an over-the-wire configuration. (*C.f. id.* FIG. 1 *with* FIG. 3.) As such, a POSITA would understand that the catheter guide wire "extended through the cannula opening 27" but not through the rotor hub 70 is consistent with a rapid-exchange configuration. (Collins ¶¶288-289.)

This is the same rapid-exchange mechanism disclosed by Jegaden and would also include an elongate lumen according to this claim element. (*Id.* ¶¶290-296.) Jegaden discloses a 5F catheter having a guide wire that extends coaxially through its lumen (i.e. an elongate lumen) and exits its distal end, where that catheter 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 guide catheter). (Collins ¶¶291-293; EX1033[Jegaden] 61-62.) A POSITA would understand that the guide wire of Jegaden would be placed within the elongate lumen of the 5F catheter by sliding. (Collins ¶293.)

As Dr. Collins shows in FIGS. 1 and 2 of Jegaden and FIG. 1 of Aboul-Hosn below, the distal hole of Jegaden's cannula is the same as the opening 27 at the distal region of Aboul-Hosn's cannula, and as such, Aboul-Hosn's "catheter guide wire" can be used in a similar manner as shown in Jegaden (as illustrated by the superposition of the distal end of Jegaden's cannula onto Aboul-Hosn's cannula) to

place the intravascular blood pump "at desired locations throughout the body including the heart region." (Collins ¶294; EX1004[Aboul-Hosn] 11:24-26.)



(Collins ¶¶291-294.)

Jegaden's 5F catheter contains an elongate lumen through which the guide wire extends and the elongate lumen is associated with the cannula, satisfying this claim element. (Collins ¶¶293-294.)

A POSITA would have been motivated to apply Jegaden's teachings extending a guide wire and catheter through the opening 27 at the distal end of Aboul-Hosn's cannula to guide Aboul-Hosn's pump using the rapid-exchange technique at least because: (1) both Jegaden and Aboul-Hosn are directed to the

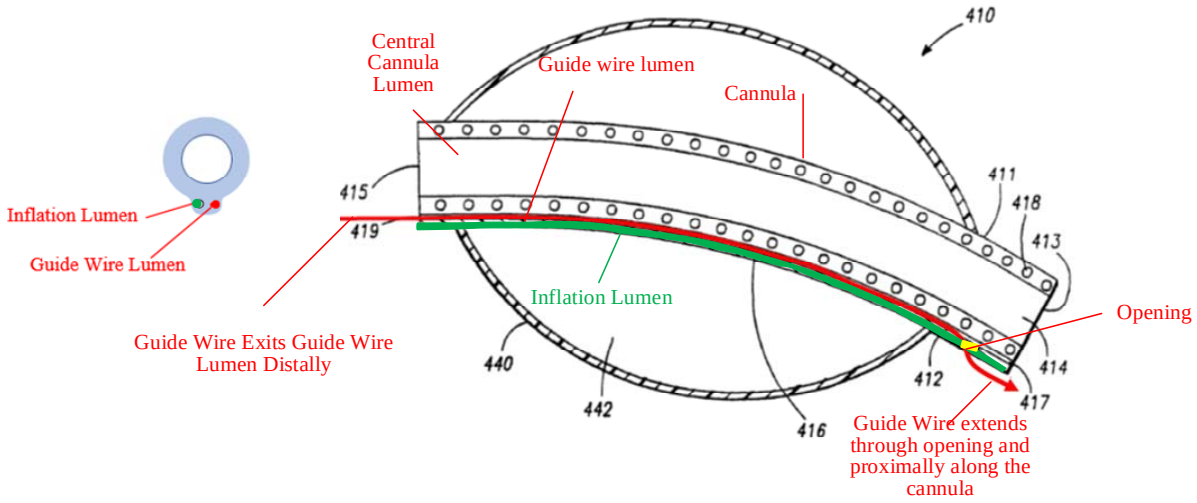
placement of intravascular blood pumps; (2) both expressly disclose extending a guide wire through the distal opening (e.g. Aboul-Hosn's opening 27), consistent with rapid exchange; and (3) Jegaden further discloses that its guide catheter insertion technique is "easy, safe, and fast to use in all cases, especially when fluoroscopic guidance can be avoided," which are well-known advantages of a rapid-exchange mechanism. (*Id.* ¶¶297-206; EX1004[Aboul-Hosn] 11:24-26; EX1033[Jegaden] 63.)

Additionally, Aboul-Hosn discloses a number of side lumens in the cannula that "may be formed adjoining to or concentric with the cannula 20," and would, therefore, also be elongate lumens according to the claim. (EX1004[Aboul-Hosn] 28:10-12.) For example, FIG. 19 of Aboul-Hosn shows cannula 20 with passageway 198 that provides a therapeutic agent to the patient. (Collins at ¶¶295-296; EX1004[Aboul-Hosn] 27:23-28:12.)

A POSITA would readily appreciate that existing therapeutic agent lumens within the wall of the cannula can be easily used for a guide wire in a rapid-exchange configuration in light of Aboul-Hosn's general teaching that the various lumens of the intravascular blood pump are flexible, and can be used for a variety of purposes including delivering fluid and guide wires. (Collins ¶¶209-216, 295-298; EX1004[Aboul-Hosn] 28:1-17, 29:19-25.) Indeed, using lumens

interchangeably for fluid or guide wires was well-known at the time. (Collins ¶131; U.S. Patent No. 6,544,216 to Sammler (EX1018, "Sammler") at 5:9-15.)

A POSITA would thus readily understand that the existing lumens of Aboul-Hosn's cannula could be used for delivering the guidewire, just as well as the lumen of Jegaden. (Collins ¶¶214, 296.) The guide wire would extend proximally along the cannula and enter a side lumen in the wall of the cannula through an opening (such as a port 187 formed in the sidewall of the cannula), slide coaxially through the lumen, and exit the side lumen through its distal end. (*Id.*)



(Collins ¶213; EX1004[Aboul-Hosn] FIG. 20, annotated.)

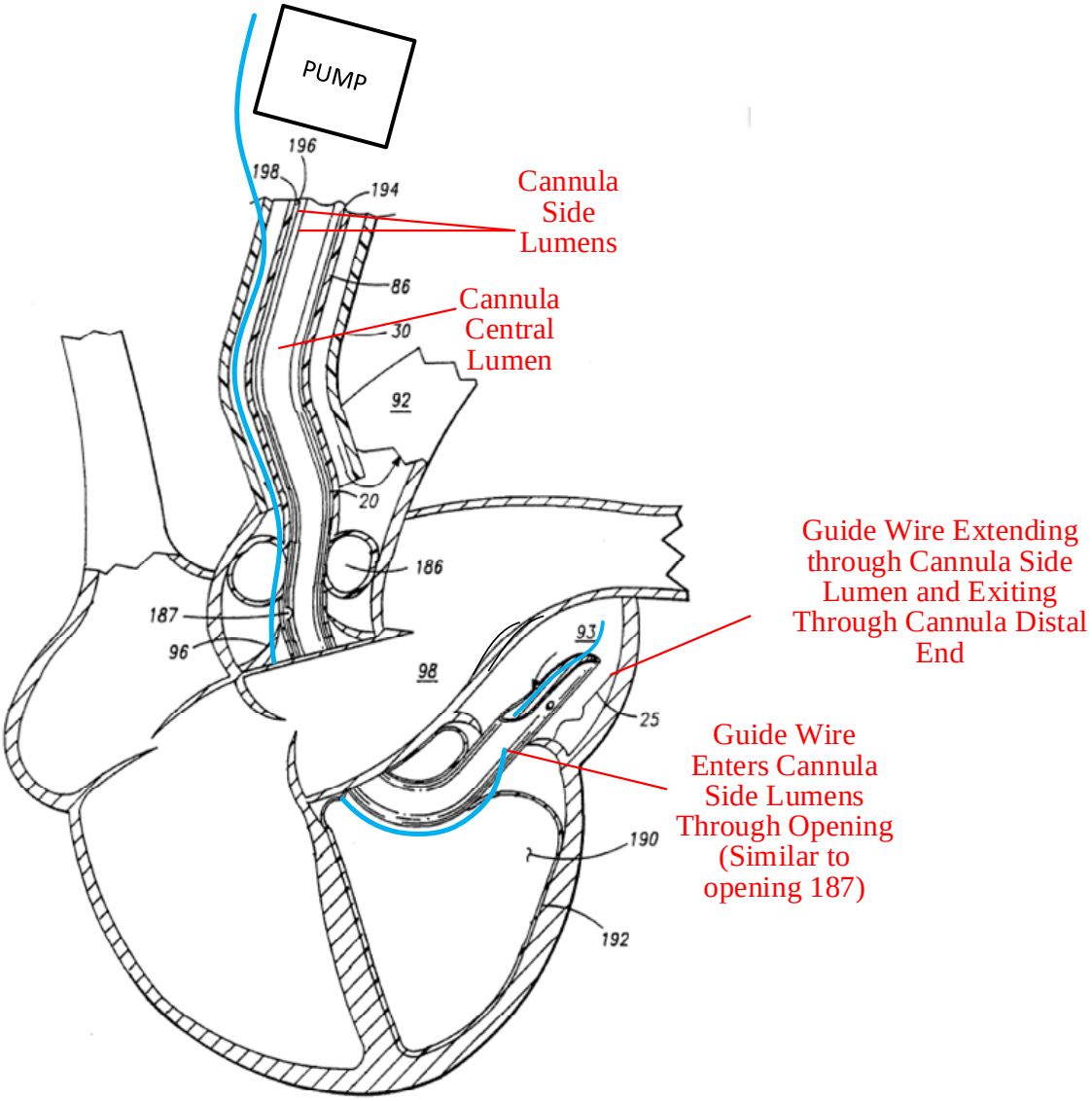


FIG.–19

(Collins ¶297; EX1004[Aboul-Hosn] FIG. 19, annotated.)

As in the case of Jegaden's 5F catheter, the guide wire would guide the distal end of the cannula into a desired position within the patient's body. (Collins ¶297; EX1004[Aboul-Hosn] 11:24-26; EX1033[Jegaden] 62.)

Similarly, a POSITA would understand that the same configuration can be applied to the percutaneous approach shown in FIG. 23, reproduced below, where a guide wire would similarly extend proximally along the side of the cannula and enter a side lumen in the wall of the cannula (e.g. the side lumen shown in FIG. 20, above) through an opening, slide through the length of the lumen, and exit the side lumen through its distal end in order to facilitate the placement of the intravascular blood using the rapid-exchange technique. (Collins ¶298.)

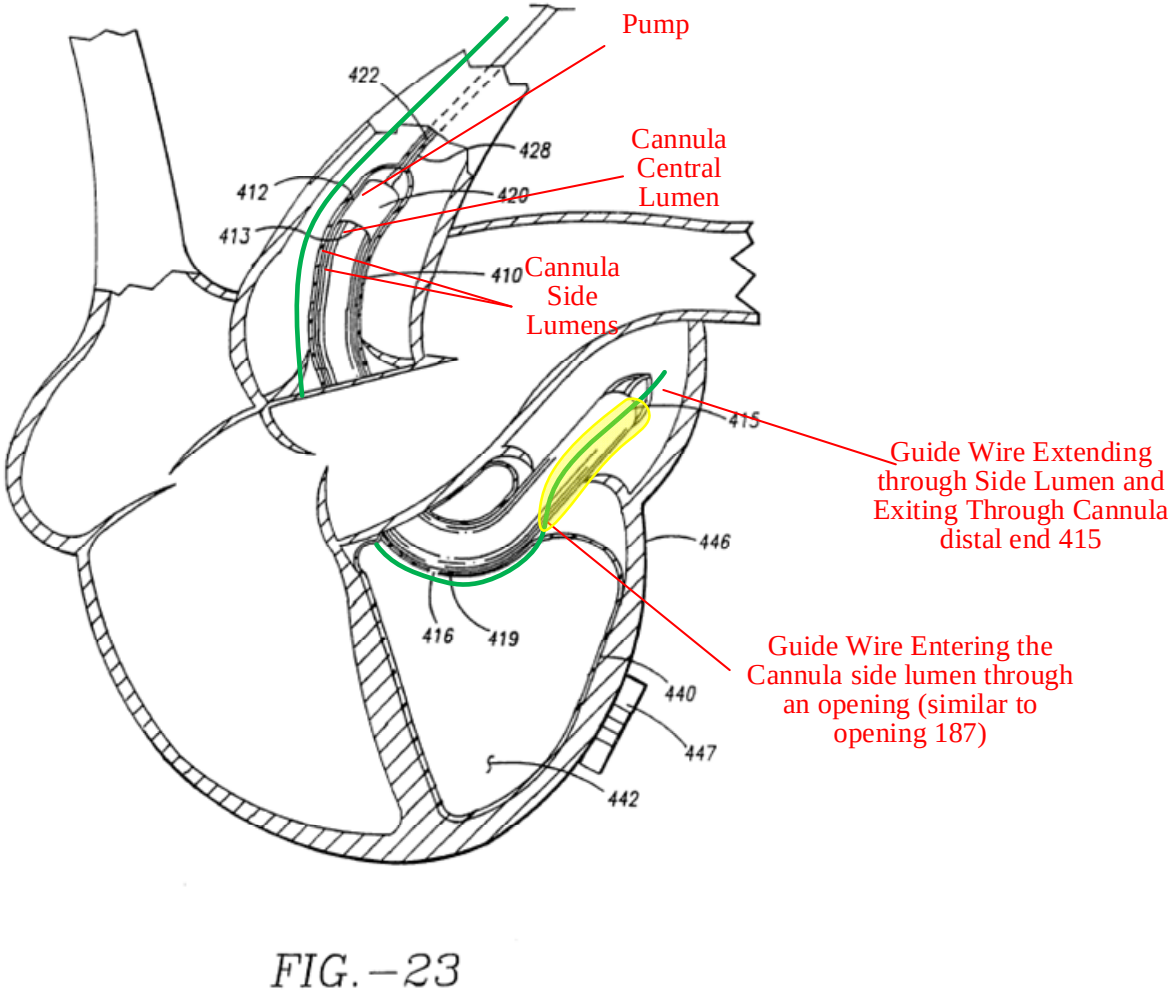


FIG.–23

(Collins ¶298; EX1004[Aboul-Hosn] FIG. 23, annotated.)

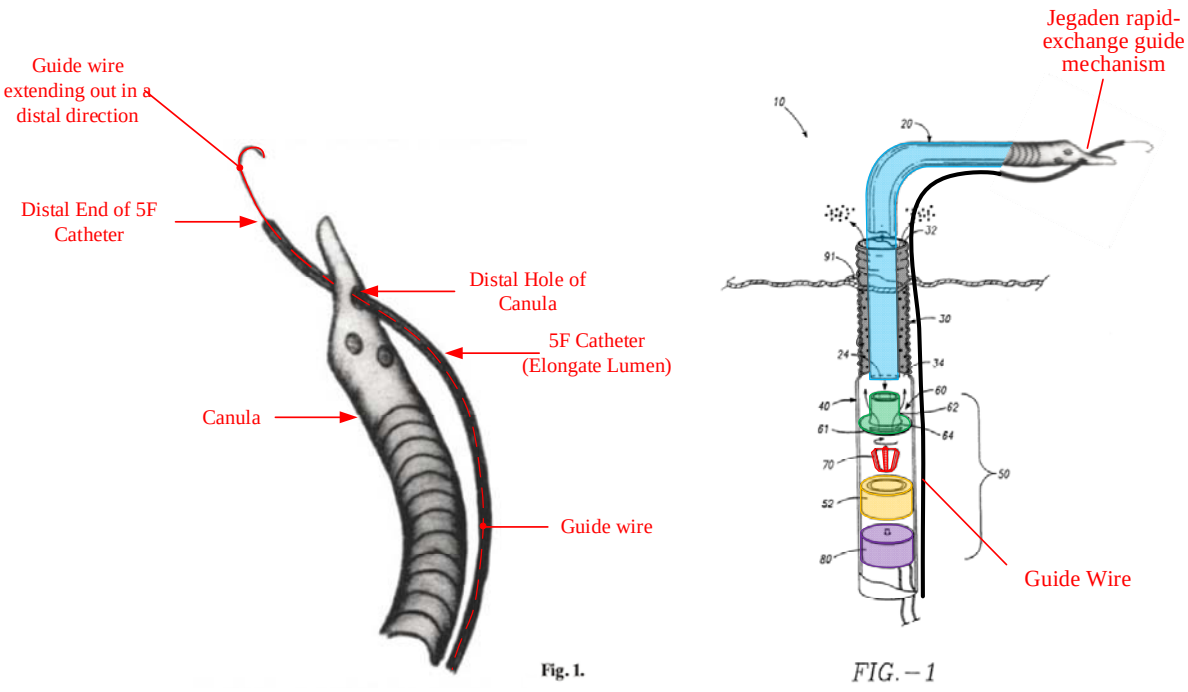
As discussed above, while over-the-wire and rapid-exchange are interchangeable guidance techniques, there were known advantages of using rapid-exchange compared to over-the wire. (Collins ¶¶99-100.) Rapid-exchange allows the procedure to be carried out by a single person instead of two as rapid-exchange does not require pre-loading the guide wire through the intravascular blood pump (which is typically equal in length to the length of the guide wire entering the patient's body). (*Id.* ¶99.) Thus, rapid-exchange reduces the required length of the guide wire, and also reduces the required sterilization area for performing the procedure. (*Id.*; EX1006[Yock] 1:15-25.) Accordingly, the procedure is simplified. (Collins ¶99; EX1023[Faxon] 59.) Moreover, compared to over-the-wire, rapid exchange does not require a central lumen to pass through the pump and the rotor and provides additional design flexibility (e.g. using a smaller diameter rotor hub, eliminating the need to provide a seal in the rotor, etc.) (Collins ¶100.)

Thus, a POSITA would have been motivated to place Aboul-Hosn's intravascular blood pump using the rapid-exchange technique, either by using a catheter guide wire (e.g. a 5F guide catheter) through opening 27 at the distal region of the cannula or by passing a guide wire through an existing side lumen within the cannula and exiting the distal end of the cannula, as disclosed by Aboul-Hosn and Jegaden. (Collins ¶¶201-216.)

In either rapid-exchange configuration, the elongate lumen (i.e. lumen of the 5F guide catheter or a side lumen of the cannula) is associated with the cannula (i.e. the catheter lumen is associated with the cannula where the catheter guide wire passes through the opening 27 in the cannula, or the side lumens are formed within the sidewall of the cannula). (Collins ¶¶294, 297; EX1004[Aboul-Hosn] 11:24-26, 28:7-12.) Moreover, the 5F guide catheter lumen and side lumen of the cannula are dimensioned such that the guide wire passes slideably and coaxially through. (Collins ¶¶293-297.) Thus, Aboul-Hosn in view of Jegaden discloses this limitation. (*Id.* ¶299.)

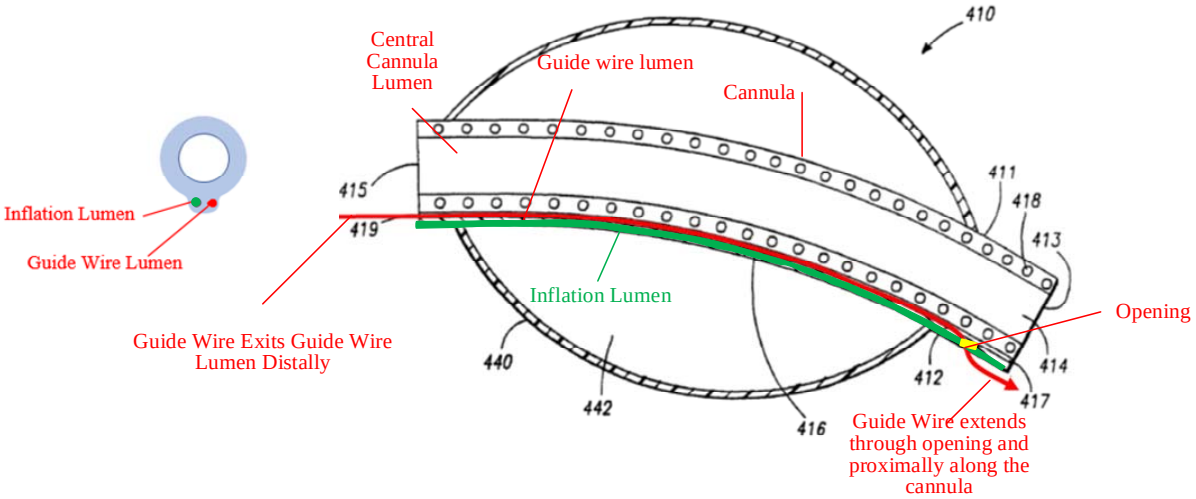
j) ***"****the elongate lumen is sized smaller cross sectionally than the cannula lumen,****"***

As previously discussed immediately above, when using the preferred rapid-exchange technique, the elongate lumen may either be (1) the catheter lumen of the catheter guide wire passing through the opening 27 in the cannula, or (2) a side lumen within the wall of the cannula. (Collins ¶301.) Both lumens have smaller cross-sections than the cannula lumen. (*Id*.) With respect to the catheter lumen, as Dr. Collins shows below in FIG. 1 of Jegaden and Aboul-Hosn, the catheter lumen that passes through the distal opening 27 of Aboul-Hosn's cannula has a cross-section that is smaller than a cross-section of the cannula. (*Id.* ¶302.)



(Collins ¶¶301-302.)

With respect to the side lumens within the cannula, these lumens must have a smaller cross-section than the cannula lumen as they are formed within the sidewall of the cannula itself, as shown below in FIG. 20. (Collins ¶301.)



(Collins ¶301; EX1004[Aboul-Hosn] FIG. 20, annotated.)

Indeed, a POSITA would expect the cross section of the 5F guide catheter lumen or side lumen to be sized smaller than the lumen of the cannula given the limited space within the patient's vasculature, the majority of the space would be used for the components that provide the blood pumping function (i.e. the cannula, the rotor blades, etc.). (Collins ¶302.) This is confirmed by FIG. 1 of Jegaden and FIGS. 1 and 20 of Aboul-Hosn, above.

Accordingly, Aboul-Hosn in view of Jegaden discloses this limitation. (Collins ¶303.)

> k) ***"****both the elongate lumen and the cannula lumen not extending through the rotor hub, the intravascular blood pump system configured for the guide wire to extend proximally away from the intravascular blood pump, the guide wire not passing through the rotor hub or the catheter, and the guide wire extending out of the intravascular blood pump system in a distal direction through the elongate lumen;****"***

This limitation is a characteristic feature of a rapid-exchange guide mechanism applied to an intravascular blood pump, and is disclosed by Aboul-Hosn in view of Jegaden. (Collins ¶304.) As Dr. Collins shows below in FIG. 2 of Jegaden and FIG. 1 of Aboul-Hosn, where the catheter guide wire extending through cannula 27 is used, the elongate lumen (i.e. 5F guide catheter lumen) does not extend through the rotor hub because the elongate lumen runs alongside the intravascular blood pump. (*Id.* ¶¶305-306.) The cannula lumen also does not extend through the rotor hub because the cannula is coupled to the rotor housing,

and as such, the cannula lumen does not extend through the rotor hub within the rotor housing. (*Id.*)

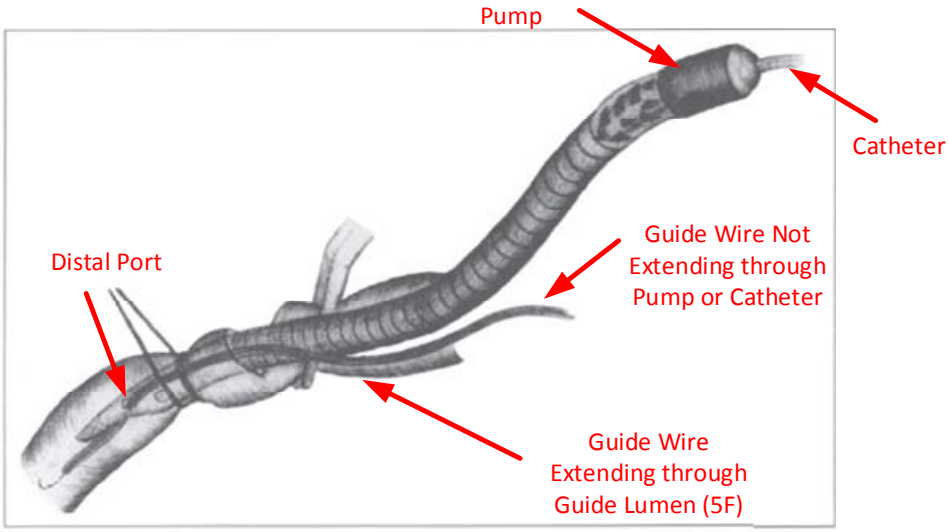


Fig. 2.

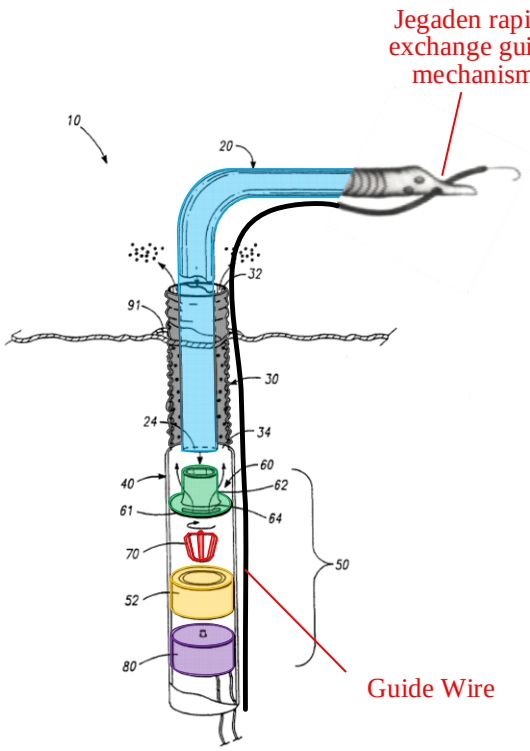


FIG.—1

(Collins ¶306-307.)

Further, as shown in FIG. 2 of Jegaden and FIG. 1 of Aboul-Hosn above, the guide wire along with the 5F guide catheter extends proximally away from the intravascular blood pump without passing through the rotor hub or the catheter coupled to the proximal end of the pump. (*Id.* ¶¶306-307.) This is also the case where the side lumens of the cannula are used to pass the guide wire as shown in FIG. 23 of Aboul-Hosn, reproduced below. (*Id.* ¶307.)

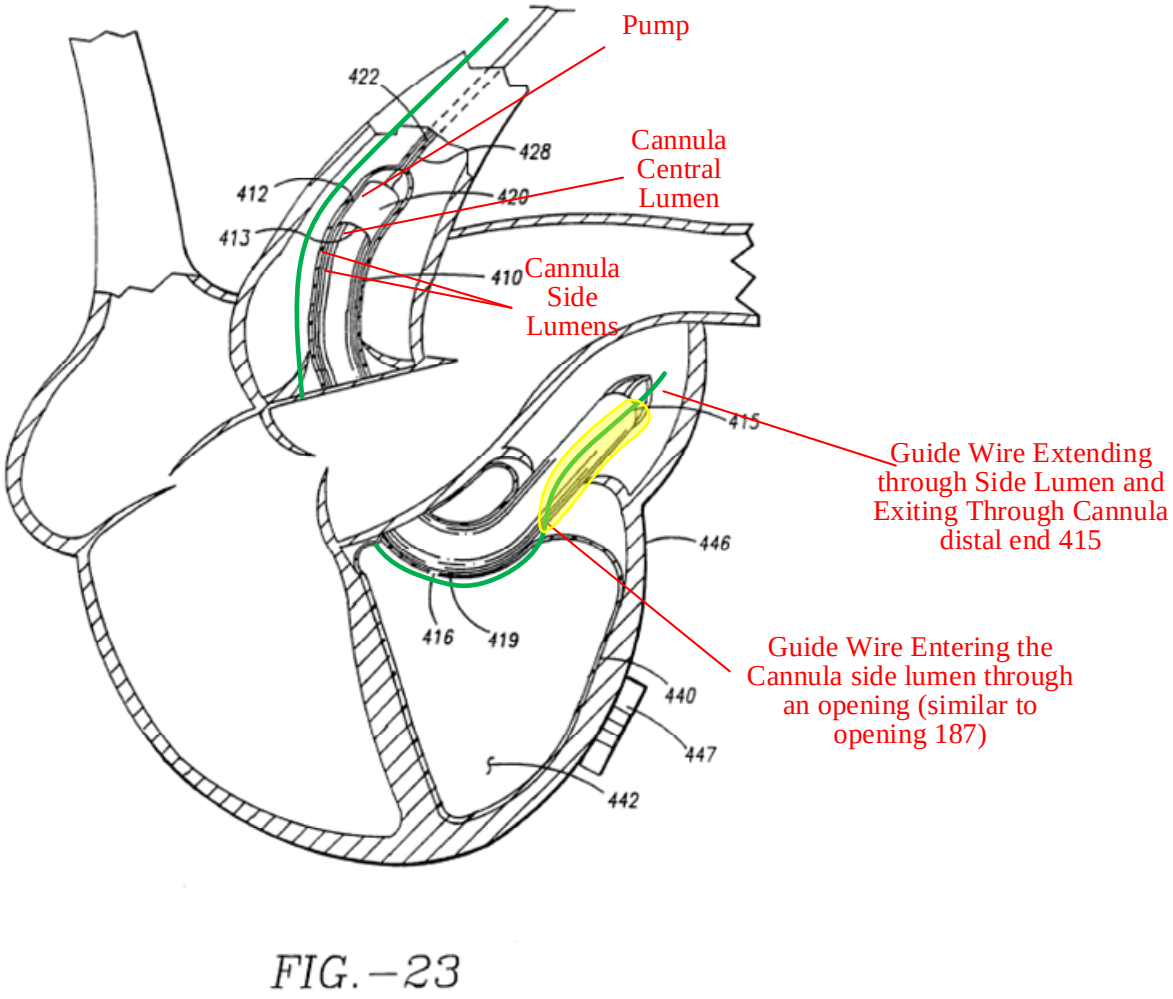


FIG.—23

(Collins ¶307; EX1004[Aboul-Hosn] FIG. 23, annotated.)

In either rapid-exchange configuration, the guide wire extends out of the intravascular blood pump system in a distal direction through the distal end of the catheter lumen (as shown in FIG. 1 of Aboul-Hosn and FIG. 1 of Jegaden, above) or the distal end of the side lumen (as shown in FIG. 23 of Aboul-Hosn, above.) (*Id.* ¶308.)

Thus, Aboul-Hosn in view of Jegaden discloses this limitation. (*Id.* ¶309.)

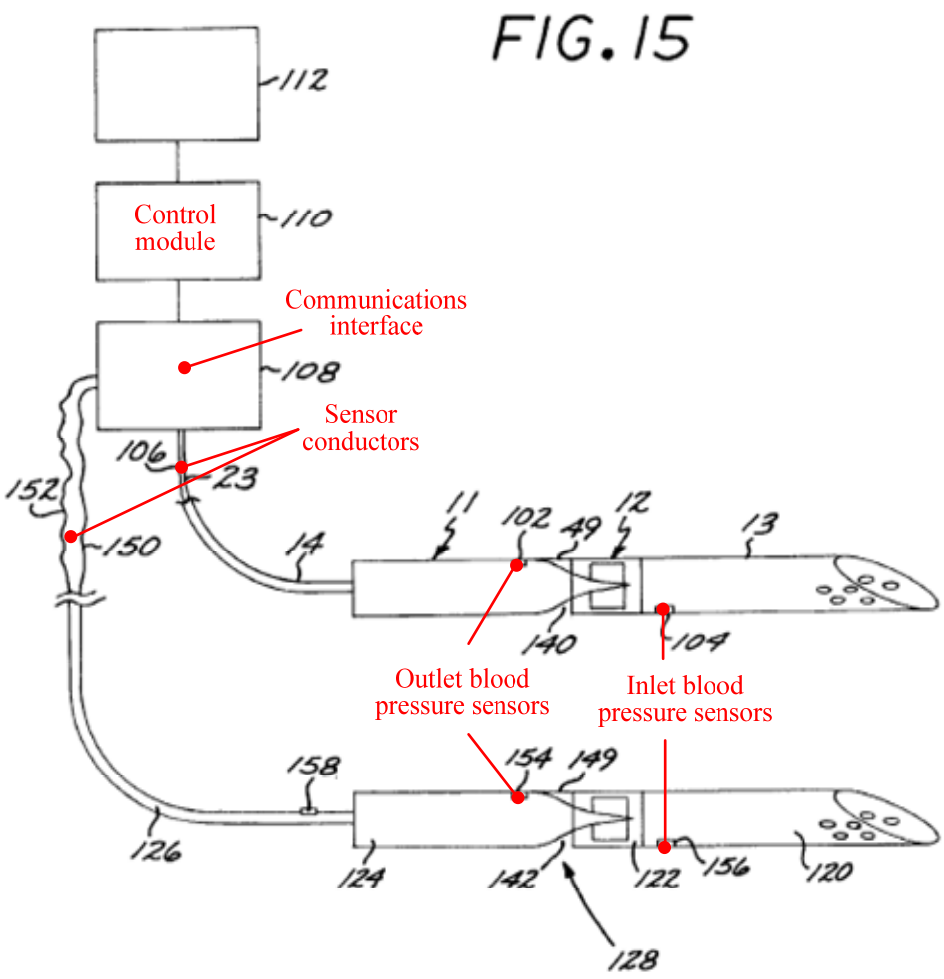
l) ***"****a pressure sensing element configured to sense pressure proximate the intravascular blood pump;"*

The '468 patent is silent as to what it means to "sense pressure proximate the intravascular blood pump." (Collins ¶311.) Under the BRI standard, we assume this limitation requires sensing the blood pressure near the blood pump (*id.*), which Aboul-Hosn in view of Siess discloses.

Monitoring the blood pressure to aid in controlling the operation of a blood pump was well-known. (*Id.* ¶312.) Aboul-Hosn's 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 that is adjacent 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.) 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 ¶¶312-315.)

Siess confirms this well-understood preference for measuring blood pressure near the pump. (*Id.* ¶¶316-318.) As previously discussed in Section VII.D and shown in annotated FIG. 15 of Siess below, 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 ¶317; 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 ¶¶316-317) Moreover, one of ordinary skill in the art 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.* ¶318.)

Thus, Aboul-Hosn in view of Siess discloses this limitation. (*Id*. ¶319.)

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

As previously discussed in Section X.A.1(e), 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 ¶321; 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 ¶¶322-323.) As shown in FIG. 1b of Wampler_712, below, a purge fluid pump 28 connects to a catheter 26 to deliver a "continuous flow of purge fluid 50 … into the pump 10 under pressure through the catheter 26." (EX1008[Wampler_712] 3:40-44.)

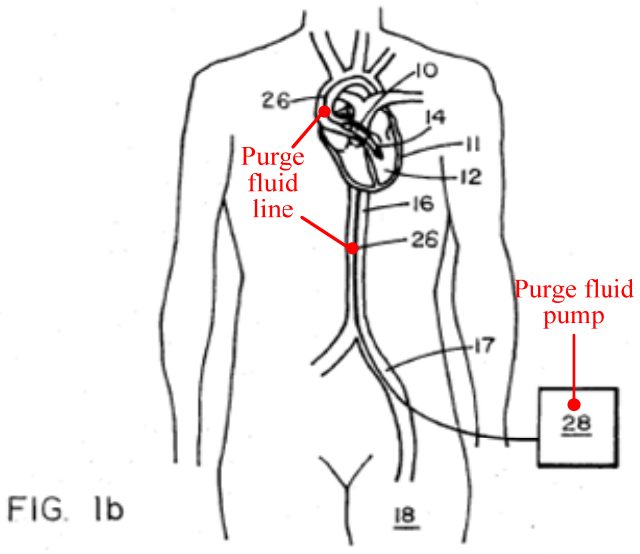
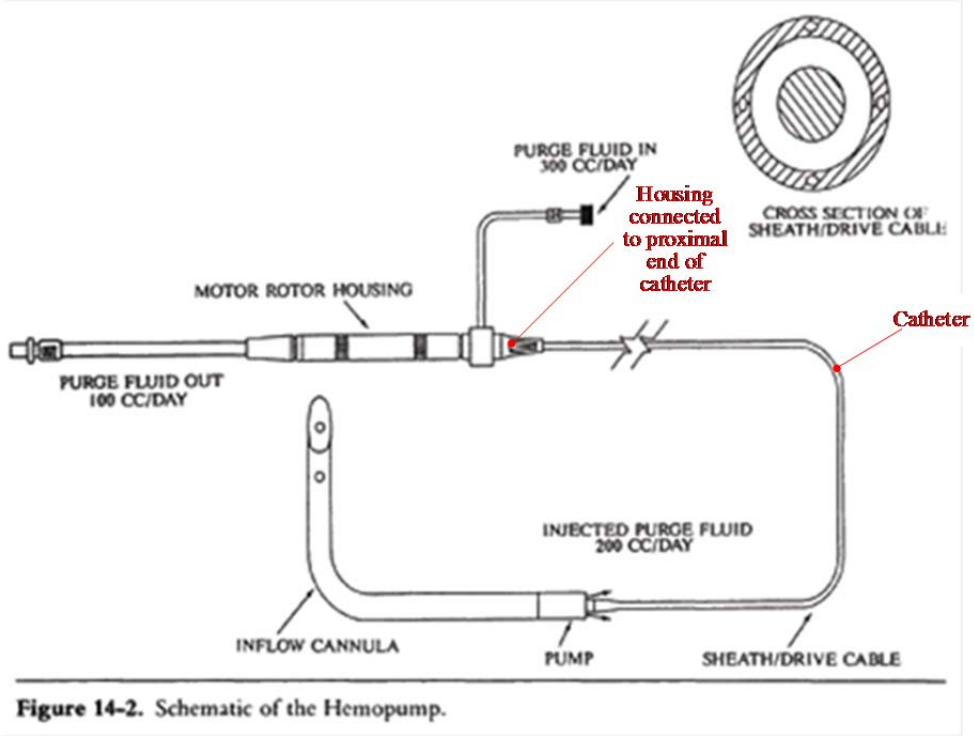


FIG. 1b

(Collins ¶67; EX1008[Wampler_712] FIG. 1b, annotated.)

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



(Collins ¶325; EX1007[Wampler] Figure 14-2, annotated.)

As shown in Figure 14-2 of Wampler, 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 sheath/drive cable) through which the purge fluid flows. (Collins ¶325; 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 ¶¶192-195, 326.) 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*. ¶195; 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 ¶196.)

Thus, Aboul-Hosn in view of Wampler discloses this limitation. (*Id.* ¶327.)

n) **"***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.***"**

As previously discussed immediately above, 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.* ¶¶328-337.) 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 ¶336; EX1007[Wampler] 233-34.)

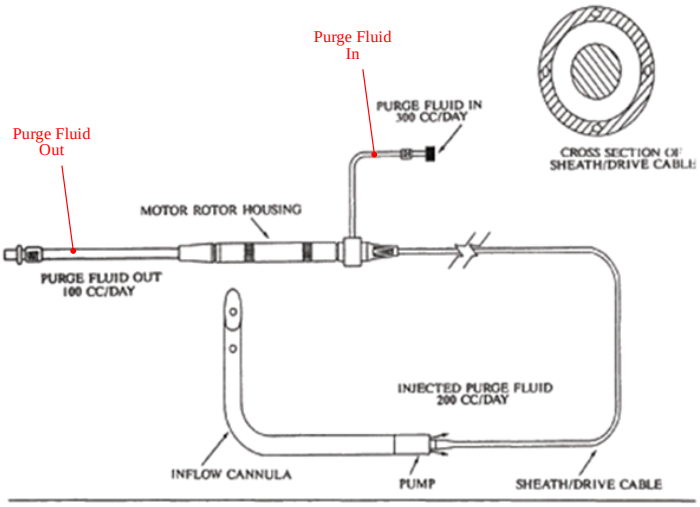


Figure 14-2. Schematic of the Hemopump.

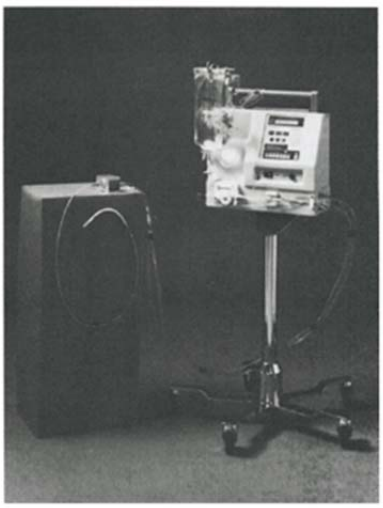


Figure 14-3. Hemopump system.

(Collins ¶323; EX1007[Wampler] Figures 14-2, annotated, 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 ¶336; 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 ¶337.)

2. 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.

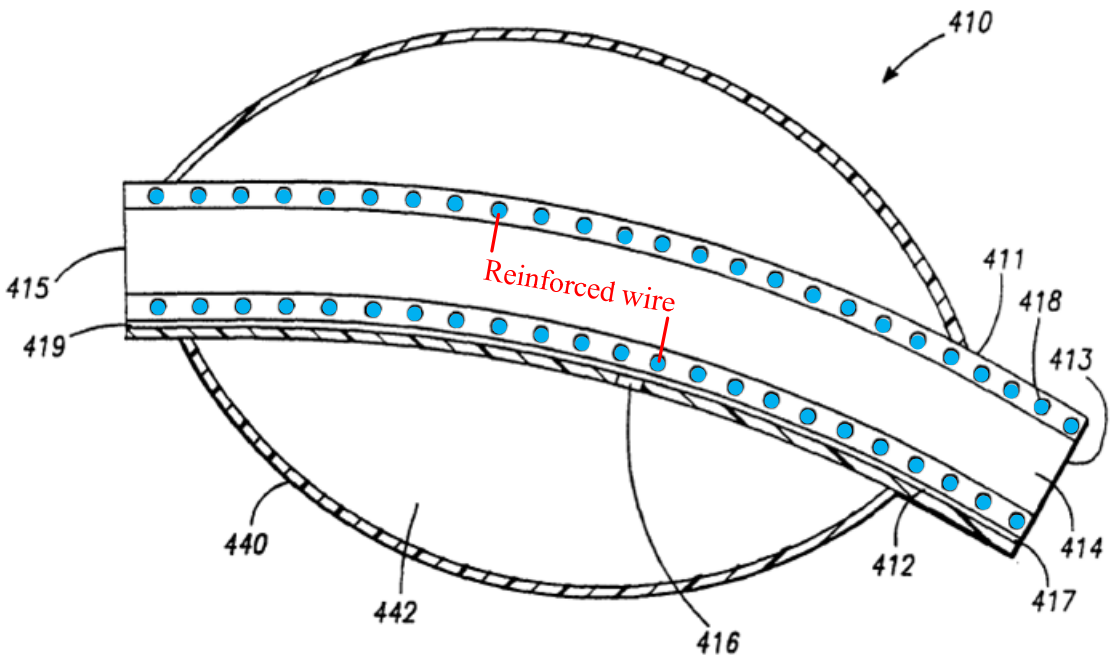


FIG.—20

(Collins ¶341; EX1004[Aboul-Hosn] FIG. 20, annotated.)

A POSITA would have understood that the reinforced wire 418 is a spiral wire. (Collins ¶¶342-344.) 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.* ¶342.) 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.* ¶343) 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.* ¶344; 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 ¶344; EX1004[Aboul-Hosn] 28:23-25, 29:4-7.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶345.)

3. Claim 7

Claim 3 depends from claim 1 and recites "*wherein the pressure sensing element is used to determine a differential pressure.*"

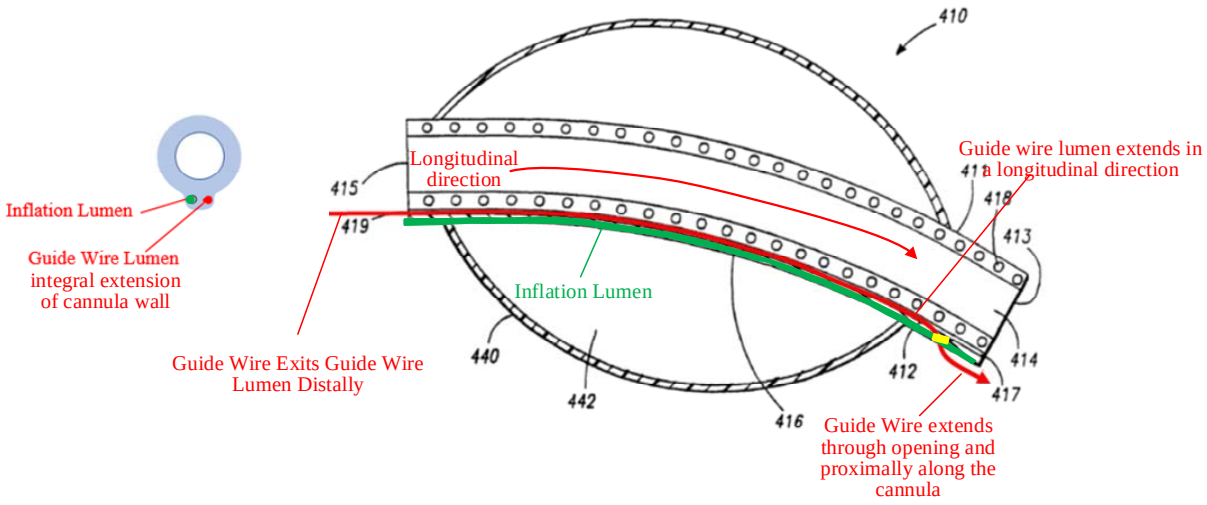
As previously discussed in Section X.A.1(l), it would have been obvious for a POSITA to measure the blood pressure adjacent Aboul-Hosn blood pump 420 with either the multilumen catheter 428 or the sensors in the cannula in the manner shown in FIG. 15 of Siess. (Collins ¶346.) It would have also been obvious to a POSITA to use both 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. (Collins ¶¶349-351)

4. Claim 11

Claim 11 depends from claim 1 and recites "*wherein the elongate lumen runs longitudinally through and is an integral extension of a wall of the cannula.*"

As previously discussed in Section X.A.1(i), in one preferred rapid-exchange configuration side lumens within Aboul-Hosn's cannula are used for a guide wire to place the intravascular blood pump using the rapid-exchange technique. (Collins ¶¶352-353.) The guide wire extends proximally along the cannula and enters a side lumen in the wall of the cannula through an opening (such as a port 187 formed in the sidewall of the cannula), and exits the side lumen through its distal end. (*Id.* ¶¶354-359.) As shown in FIG. 20, reproduced below, the side lumen (i.e. elongate lumen) through which the guide wire passes extends longitudinally and is an integral extension of the wall of the cannula. (*Id.* ¶359.)



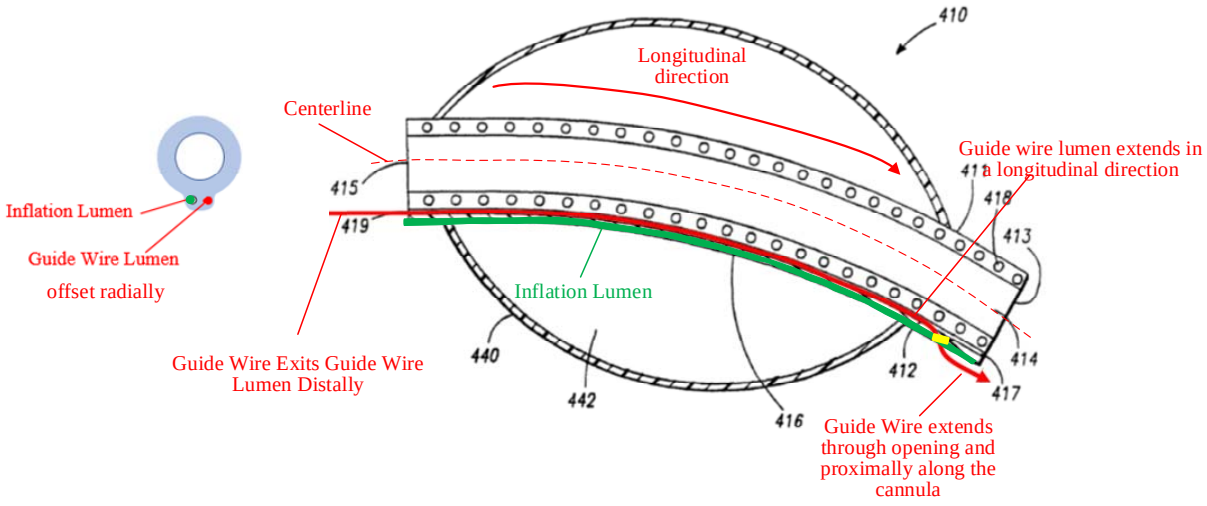
(Collins ¶359; EX1004[Aboul-Hosn] FIG. 20, annotated.)

Thus, Aboul-Hosn in view of Jegaden discloses this limitation. (Collins ¶360.)

5. Claim 12

Claim 12 depends from claim 1 and recites "*wherein the elongate lumen is a side lumen extending longitudinally but offset radially from a central axis of the cannula along at least a portion of the cannula.*"

As previously discussed in Section X.A.1(i), in one preferred rapid-exchange configuration side lumens within Aboul-Hosn's cannula are used for a guide wire to place the intravascular blood pump using the rapid-exchange technique. (Collins ¶361.) As shown in FIG. 20, reproduced below, the side lumen (i.e. elongate lumen) within the sidewall of the cannula through which the guide wire passes extends longitudinally and is, by definition, offset radially from a central axis of the cannula. (*Id.*)



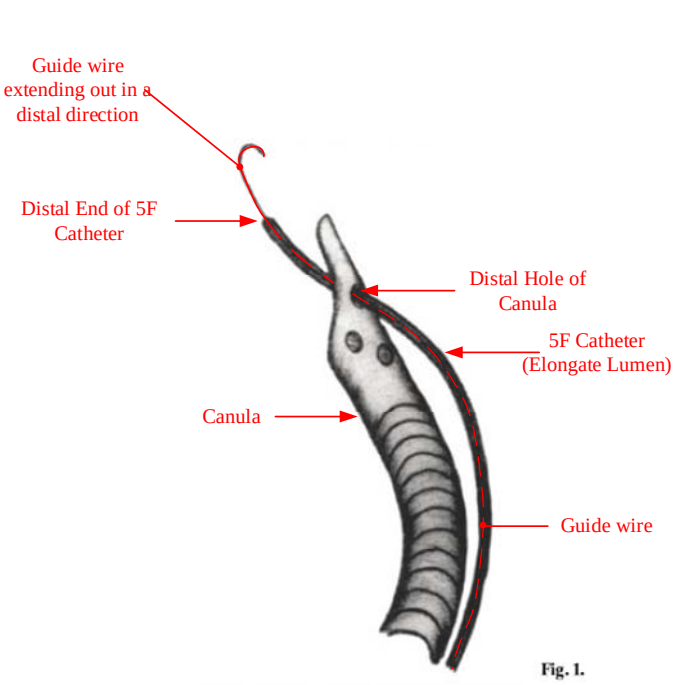
(Collins ¶361; EX1004[Aboul-Hosn] FIG. 20, annotated.)

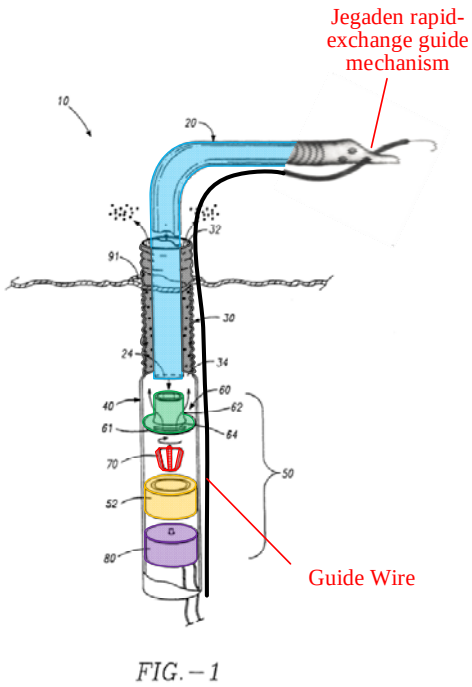
Thus, Aboul-Hosn in view of Jegaden discloses this limitation. (*Id.* ¶362.)

6. Claim 13

Claim 13 depends from claim 1 and recites "*wherein the elongate lumen is adapted to guide the guide wire through a distal end of the intravascular blood pump system.*"

As previously discussed in Section X.A.1(i), it would have been obvious to place Aboul-Hosn's intravascular blood pump using the rapid-exchange technique, either by using a catheter guide wire (e.g. a 5F guide catheter) through opening 27 at the distal region of the cannula or by passing a guide wire through an existing side lumen within the cannula and exiting the distal end of the cannula, as disclosed by Aboul-Hosn and Jegaden. (Collins ¶¶364-365.) In either rapid-exchange configuration, the elongate lumen is adapted to guide the guide wire through the distal end of the intravascular blood pump as shown by Dr. Collins, below. (*Id.*)





(Collins ¶¶205, 365.)

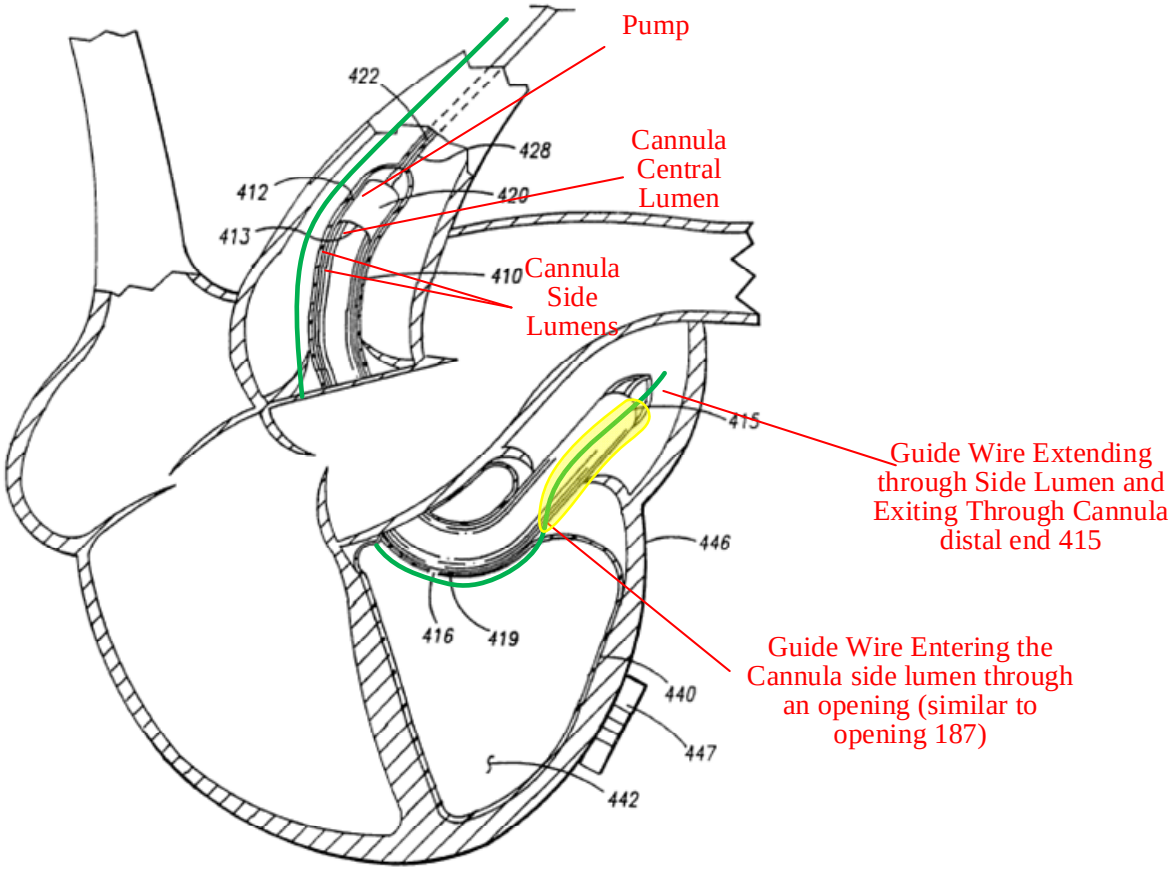


FIG.—23

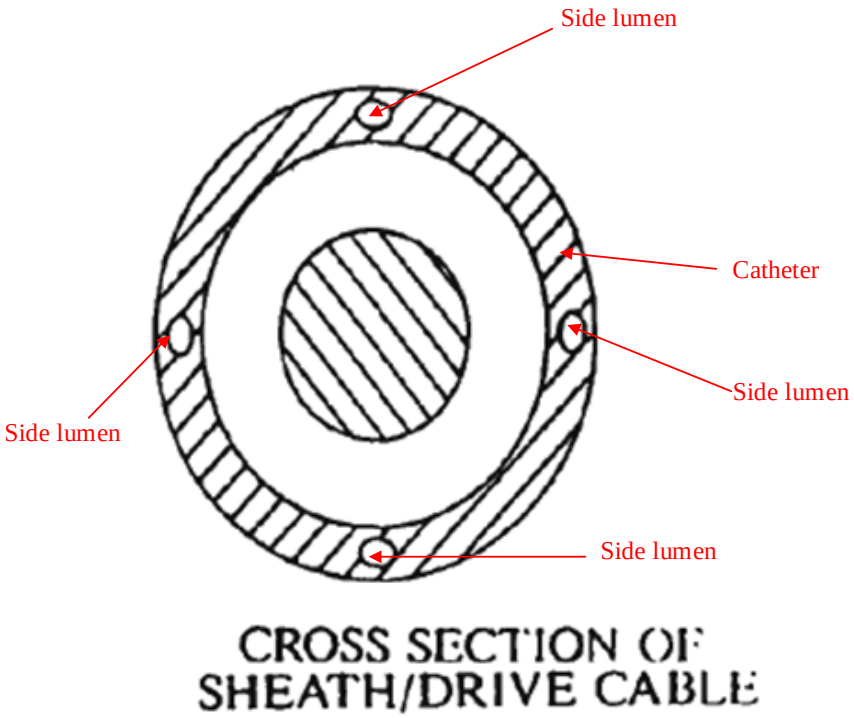
(Collins ¶366; EX1004[Aboul-Hosn] FIG. 23, annotated.)

Indeed, as Dr. Collins explains, a POSITA would understand that it would be preferable to introduce the guide wire at the distal end of the intravascular blood pump to improve steerability when placing the pump. (Collins ¶366.) Thus, Aboul-Hosn in view of Jegaden discloses this limitation. (*Id.* ¶367.)

7. Claim 15

Claim 15 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.*"

As previously discussed in Section X.A.1(e), 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 ¶¶369-371; 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 ¶¶369-371.) 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 ¶372; EX1007[Wampler] FIG. 14-2.)

These "four outer lumens" (i.e. side lumens) are offset radially from a central axis of the catheter. (Collins ¶372.) Thus, Aboul-Hosn in view of Wampler discloses this limitation. (*Id.* ¶373.)

8. Claim 19

Claim 19 depends from claim 1 and further recites "*a rotor shroud disposed about the rotor and wherein a proximal portion of the cannula is disposed about a distal portion of the rotor shroud, the distal portion of the rotor shroud having an outer diameter smaller than a diameter of a more proximal portion of the rotor shroud.*"

As previously discussed in Section VII.A, the percutaneously delivered pump 420 shown in FIG. 23 can either be configured with or without the reverse flow feature of the pump system of FIGS. 1-13. (Collins ¶¶136-139.) As shown in FIG. 2 below, in the reverse flow configuration, the rotor 70 (red) is housed within a housing body 52 (yellow) 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.* ¶377; EX1004[Aboul-Hosn] 12:12-13:25, 18:15-19.)

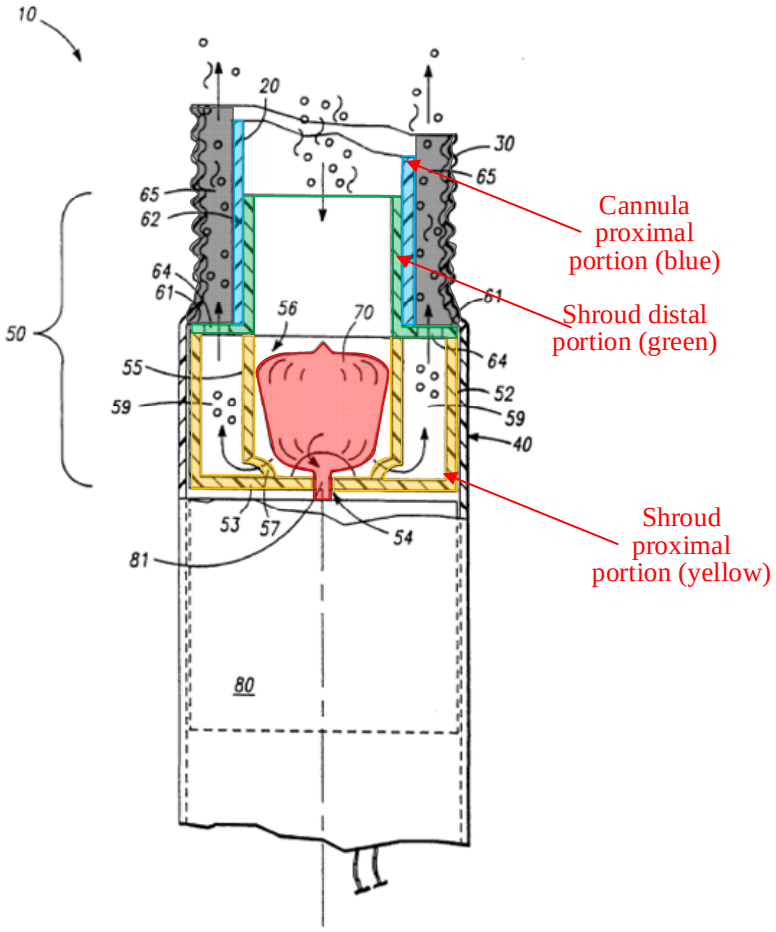


FIG.—2

(Collins ¶377; 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 ¶377; EX1004[Aboul-Hosn] 12:22-23, 13:3-4.) As shown above in FIG. 2 of Aboul-Hosn, 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 ¶377.) 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.* ¶378.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶379.)

B. Ground II: Claims 4, 7, 11-13, 15, and 19 are obvious over Aboul-Hosn in view of Yock, and further in view of Siess and Wampler

1. Claim 1[14]

a) *See* element 1(a) – 1(h), Sections X.A.1(a)-(h), above.

Elements 1(a) – 1(h) are the same as in Ground I.

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

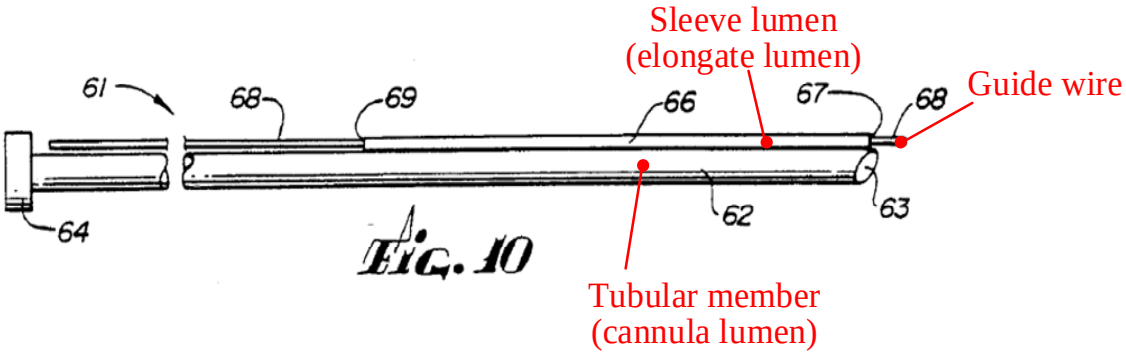
The ’468 patent does not specify what it means to be an *elongate* lumen, much less an elongate lumen *associated with* the cannula. (Collins ¶387.) Notwithstanding, Aboul-Hosn in view of Yock discloses the “elongate lumen associated with the cannula” as recited by this limitation in the same manner as the ’468 patent. (*Id.*)

Aboul-Hosn suggests delivering the intravascular blood pump using the preferred rapid-exchange mechanism. (Collins ¶¶392-407; EX1004[Aboul-Hosn] 11:24-26; EX1006[Yock] 1:15-25; EX1023[Faxon] 59.)

Yock discloses a conventional rapid-exchange mechanism in connection with a minimally invasive device for angioplasty. (Collins ¶394; EX1006[Yock]

[14] Claims 4, 7, 11-13, 15, and 19 depend from claim 1, which is also obvious in view of the cited prior art.

7:64-8:25.) As shown below in FIG. 10, the orientation of the sleeve along the side of the tubular member allows for the rapid exchange of the catheter. (Collins ¶398; EX1006[Yock] 2:31-37.)



(Collins ¶398; EX1006[Yock] FIG. 10, annotated.)

Yock's tubular member is similar to Aboul-Hosn's cannula as both are polymer tubes that are delivered by cathertization techniques into the patient's vasculature. (Collins ¶399.) As explained in greater detail below, it would have been obvious to a POSITA to apply Yock's conventional sleeve and guide wire rapid-exchange configuration to Aboul-Hosn's cannula (as Dr. Collins shows below in FIG. 1) to guide the intravascular blood pump using the preferred rapid-exchange technique. *(Id.* ¶¶400-405.)

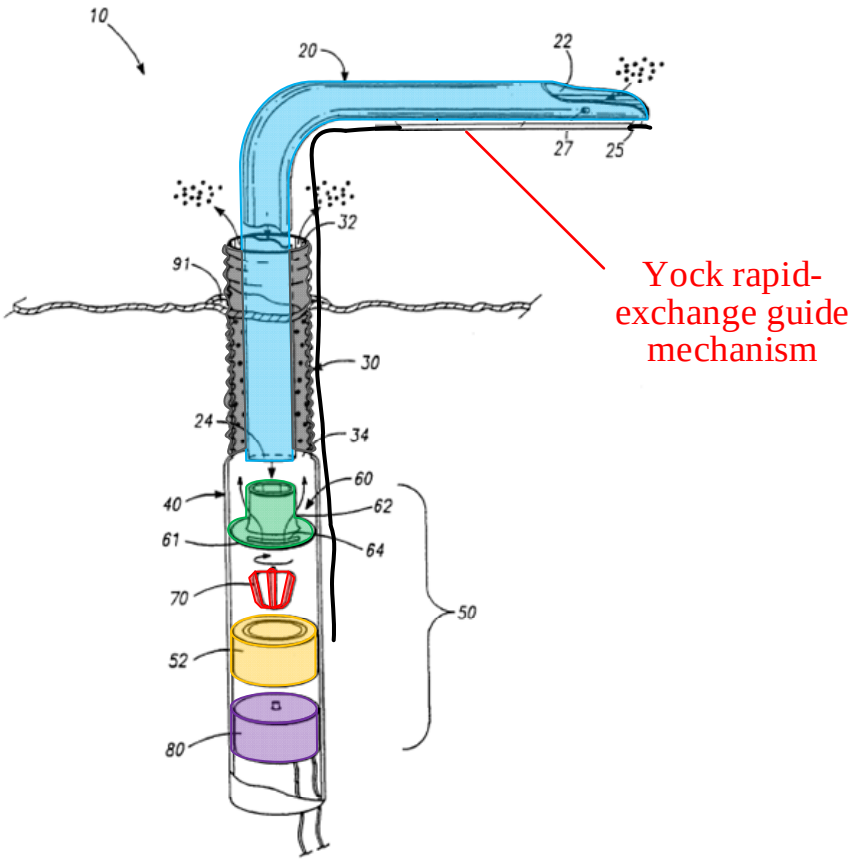
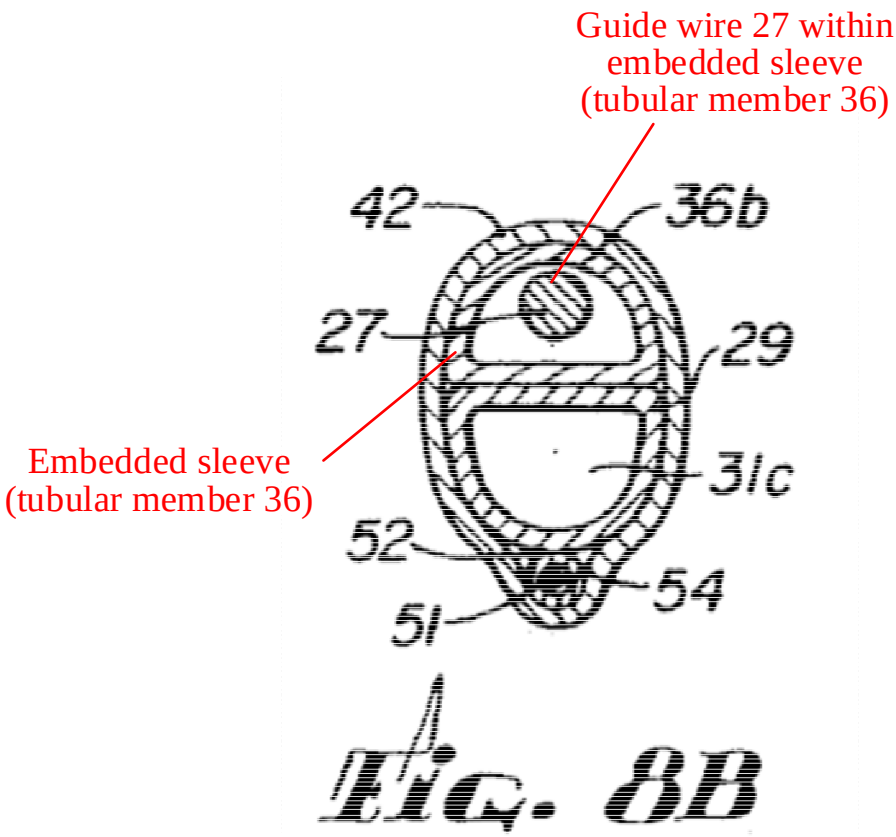


FIG.—1

(Collins ¶401.)

Additionally, a POSITA would readily understand that lumens embedded within Aboul-Hosn's cannula would also be used for delivering the guidewire using the rapid-exchange technique. (Collins ¶402.) In fact, Yock expressly discloses that the sleeve 66 of FIG. 10 "can be formed integral with the flexible tubular member 62." (EX1006[Yock] 7:68-8:2.) Yock shows an example of such an embedded sleeve in FIG. 8, reproduced below. (Collins ¶¶403-404; EX1006[Yock] 6:59-63.)

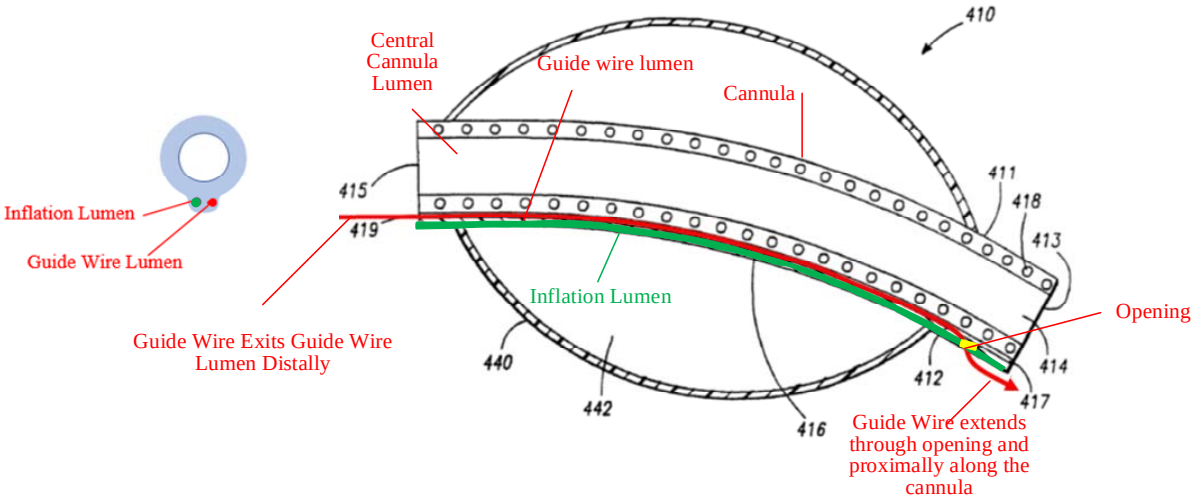


(Collins ¶403; EX1006[Yock] FIG. 8B, annotated.)

As shown above, the embedded sleeve of Yock is structurally similar to the side lumens within Aboul-Hosn's cannula (i.e. a passageway within the cannula wall running parallel to the central cannula lumen). (Collins ¶404.) As a result, a POSITA would readily appreciate that Aboul-Hosn's cannula can be similarly configured to include an embedded sleeve for a guide wire, as in Yock. (*Id.*) Further, a POSITA would also readily understand that the existing side lumens of Aboul-Hosn's cannula can be used for delivering the guidewire just as well as an

embedded sleeve given their similar structures, and thus, would provide a natural and obvious choice for an embedded rapid-exchange system. (*Id.* ¶405.)

In the embedded rapid-exchange configuration, the guide wire extends proximally along the cannula and enters a side lumen (either an embedded sleeve or a preexisting passageway) in the wall of the cannula through an opening (such as a port 187 formed in the sidewall of the cannula), and exits the side lumen through its distal end. (*Id.* ¶¶405-406.)



(Collins ¶409; EX1004[Aboul-Hosn] FIG. 20, annotated.)

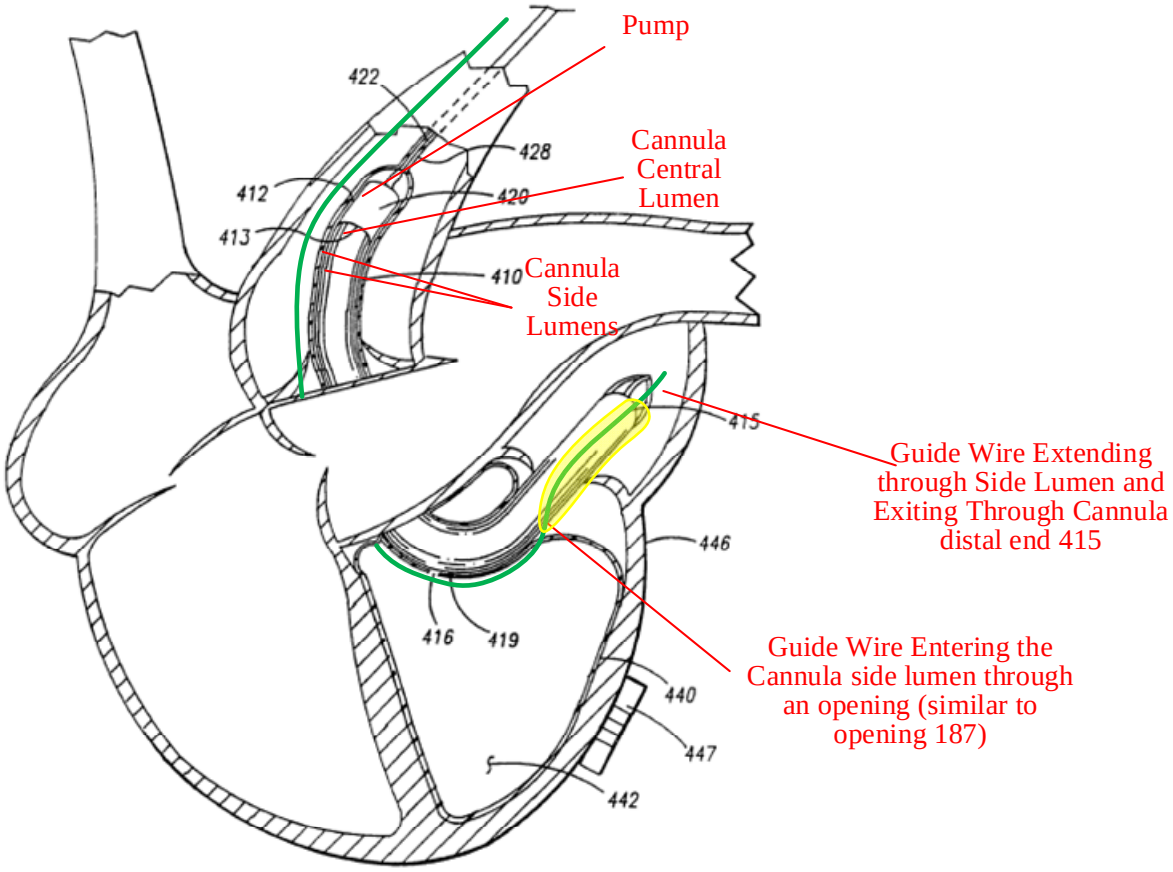


FIG.–23

(Collins ¶406; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As of the EPD, it was well-known to POSITAs that conventional cathertization techniques used for angioplasty devices (such as in Yock) were applicable to intravascular blood pumps (such as Aboul-Hosn's) because of the substantial overlap between the angioplasty and intravascular blood pump applications. (Collins ¶¶396-397; EX1042[Coleman] 34:25-32; EX1023[Faxon] Ch. 7, "Selection of Balloon Catheters and Guidewires" and 18, "Percutaneous Support Techniques.") Moreover, both types of devices were delivered with the

same objective of placing the device by catheter in the vasculature to apply treatment to the appropriate location. (Collins ¶397.) Indeed, as explained by Dr. Collins, the same approach (i.e. the Seldinger technique) would have been used by cardiologists to introduce percutaneous devices, including catheters and intravascular blood pumps. (*Id.*; U.S. Patent No. 4,692,148 to Kantrowitz et al. (EX1044, "Kantrowitz") at 5:1-15; U.S. Patent No. 4,468,224 to Enzmann et al. (EX1045, "Enzmann") at 2:5-20.)

Moreover, a POSITA would have been motivated to adapt Aboul-Hosn's intravascular blood pump to be delivered using a rapid-exchange technique, such as using the sleeve and guide wire of Yock, because of known advantages to using rapid-exchange, including a simplified exchange procedure, reduced guide wire length, increased insertion speed, reduced handling during insertion, and additional design flexibility. (Collins ¶¶99-100.)

Thus, a POSITA would have found it natural, and would have been motivated to configure the cannula of Aboul-Hosn's intravascular blood pump with Yock's conventional sleeve and guide wire rapid-exchange elements (either by forming a sleeve along the outside of the cannula, embedding the sleeve within the sidewall of the cannula, or using a preexisting side lumen within the cannula wall), as doing so would have been merely an application of a known technique, in a conventional manner, to achieve a predictable result. (*Id.* ¶397.)

In any of the rapid-exchange configurations, the elongate lumen (i.e. a sleeve along the outside of the cannula, an embedded sleeve within the sidewall of the cannula, or a preexisting side lumen within the cannula wall) is associated with the cannula (i.e. the sleeve is associated with the cannula where it is formed along the side of the cannula, and the embedded sleeve and preexisting side lumens are associated with the cannula as they are formed in the sidewall of the cannula). (Collins ¶¶399, 404; EX1006[Yock] FIG. 10, 7:68-8:2; EX1004[Aboul-Hosn] 11:24-26, 28:7-12.) Moreover, the sleeve lumen and side lumen of the cannula are dimensioned such that the guide wire passes slideably and coaxially through. (Collins ¶¶398-399, 404-405.) Thus, Aboul-Hosn in view of Yock discloses this limitation. (*Id.* ¶407.)

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

Aboul-Hosn in view of Yock discloses this limitation. (*Id.* ¶¶408-410) When using the preferred rapid-exchange technique, the elongate lumen may either be a sleeve along the outside of the cannula, an embedded sleeve within the sidewall of the cannula, or a preexisting side lumen within the cannula wall, all of which have smaller cross-sections than the cannula lumen. (*Id.* ¶¶408-409.) With respect to the sleeve lumen, as Dr. Collins shows below by attaching the sleeve in FIG. 10 of Yock to the cannula in FIG. 1 of Aboul-Hosn, the sleeve lumen has a cross section that is smaller than a cross section of the cannula. (*Id.* ¶408.)

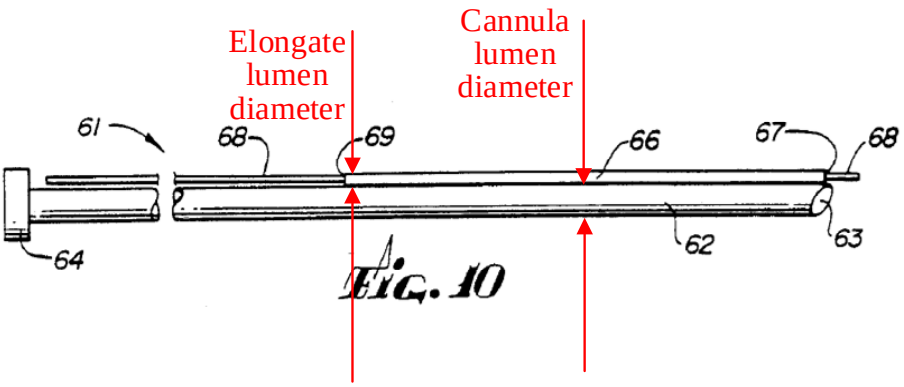


FIG. 10

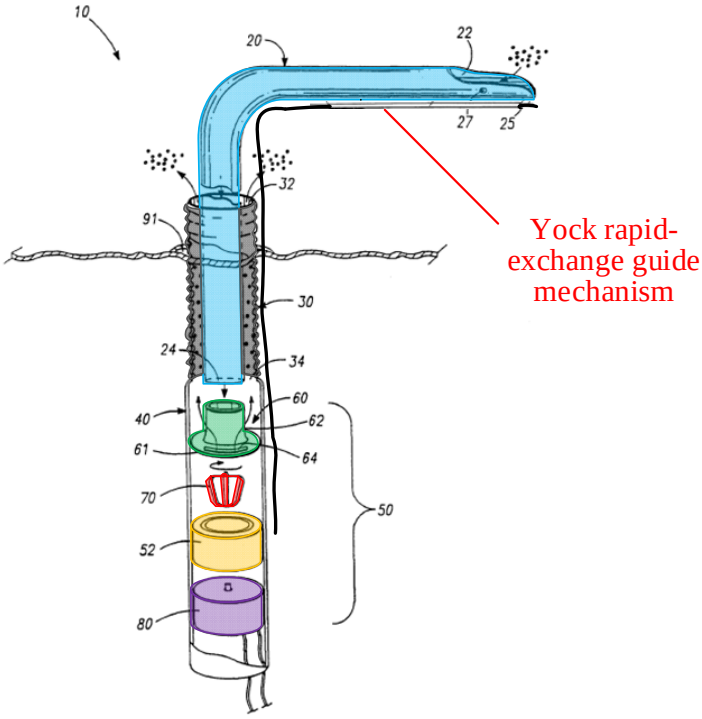


FIG.—1

(Collins ¶408.)

Moreover, with respect to the side lumens within the cannula, these lumens must have a smaller cross section than the cannula lumen as they are formed within the sidewall of the cannula itself, as shown below in FIG. 8B of Yock and FIG. 20 of Aboul-Hosn. (Collins ¶409.)

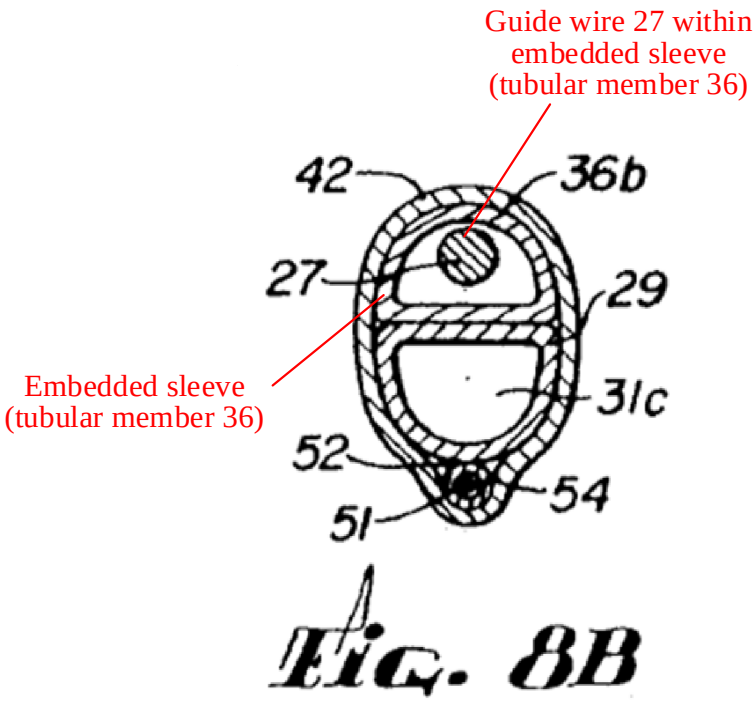
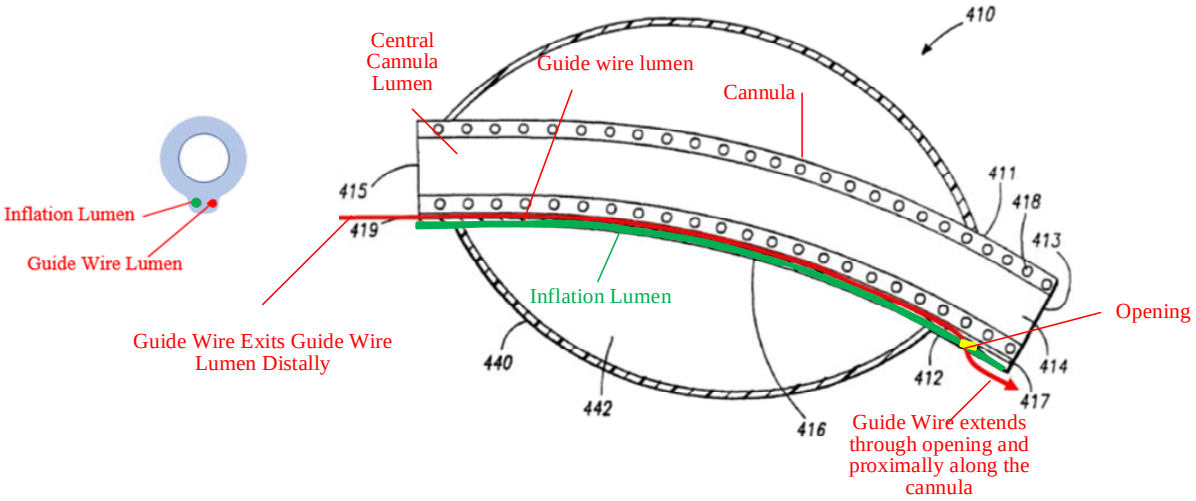


FIG. 8B



(Collins ¶¶403, 409; EX1006[Yock] FIG. 8B, annotated (above); EX1004[Aboul-Hosn] FIG. 20, annotated (below).)

Accordingly, Aboul-Hosn in view of Yock discloses this limitation. (Collins ¶410.)

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

As previously discussed in Section X.A.1(k), this limitation is a characteristic feature of a rapid-exchange guide mechanism applied to an intravascular blood pump. (Collins ¶¶411-422.) As previously discussed in Section X.B.1(b), Aboul-Hosn in view of Yock discloses the intravascular blood pump can be placed using the rapid-exchange technique, and as such, discloses this limitation. (*Id*.) As Dr. Collins shows below in FIG. 1 of Aboul-Hosn, where the sleeve lumen of Yock (shown in FIG. 10) is attached to the cannula 27 and is used to pass the guide wire, the elongate lumen (i.e. sleeve lumen) does not extend through the rotor hub because the elongate lumen is attached to the distal end of the cannula of the intravascular blood pump. (*Id.* ¶413.) The cannula lumen also does not extend through the rotor hub because the cannula is coupled to the rotor housing, and as such, the cannula lumen does not extend through the rotor hub within the rotor housing. (*Id.* ¶416.)

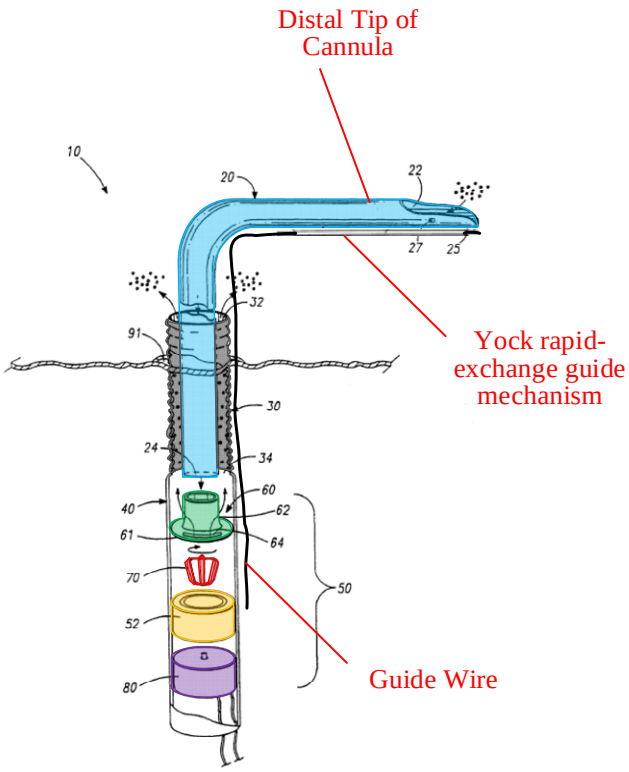


FIG.—1

(Collins ¶413.)

As shown above, the guide wire along extends proximally away from the intravascular blood pump without passing through the rotor hub or the catheter coupled to the proximal end of the pump. (*Id.*) This is also the case where the side lumens of the cannula are used to pass the guide wire as shown in FIG. 23 of Aboul-Hosn, reproduced below. (*Id.* ¶419.)

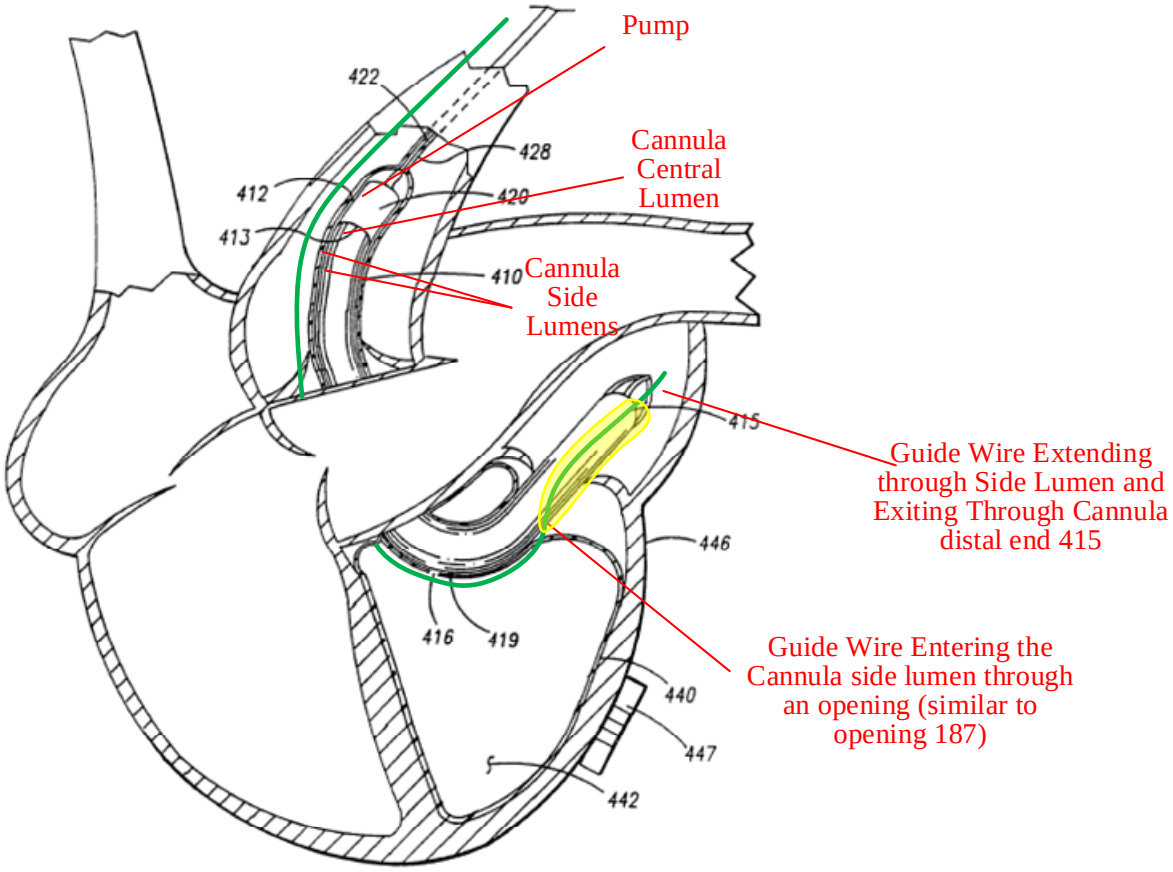


FIG.–23

(Collins ¶419; EX1004[Aboul-Hosn] FIG. 23, annotated.)

In either rapid-exchange configuration, the guide wire extends out of the intravascular blood pump system in a distal direction through the distal end of the sleeve lumen (as shown in FIG. 1 of Aboul-Hosn, above) or the distal end of the side lumen (as shown in FIG. 23 of Aboul-Hosn, above.) (*Id.* ¶¶417-421.)

e) *See* elements 1(l) – 1(n), Sections X.A.1(l)-(n), above.

The remaining elements 1(l) – 1(n) are the same as in Ground I.

1. Claims 4, 7, 15, and 19

Grounds for these claims are identical to Ground I and neither rely on Jegaden or Yock. *See* Sections X.A.2-3 and X.A.7-8.

2. Claim 11

As previously discussed in Section X.B.1(b), in one rapid-exchange configuration, a sleeve (such as disclosed by Yock) would be attached to the side of Aboul-Hosn's cannula. (Collins ¶429.) Yock further discloses that the sleeve "can be formed integral with the flexible tubular member" (i.e. the cannula) "if desired" such that the sleeve is an integral extension of the wall of the cannula. (*Id.*; EX1006[Yock] 7:68-8:2.) As Dr. Collins shows below, the elongate lumen that extends through the integrally formed sleeve runs longitudinally.

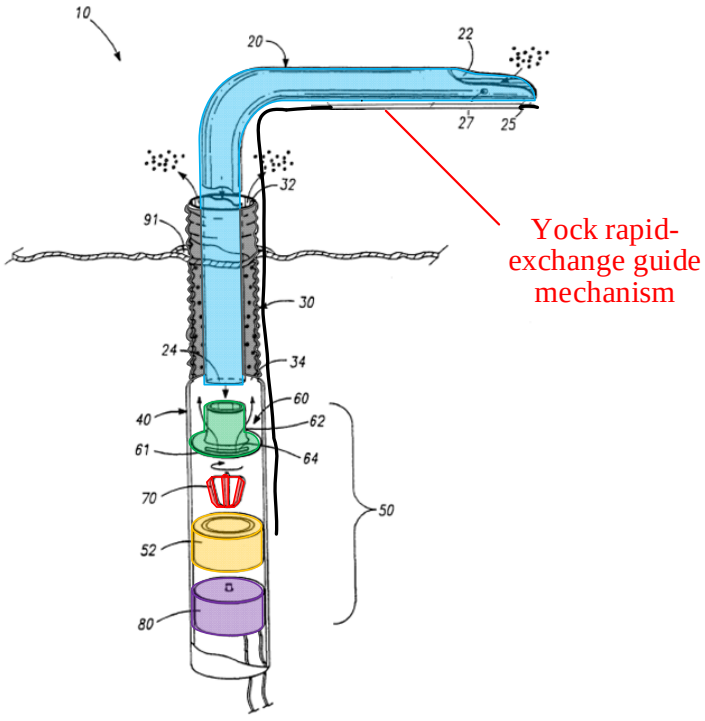
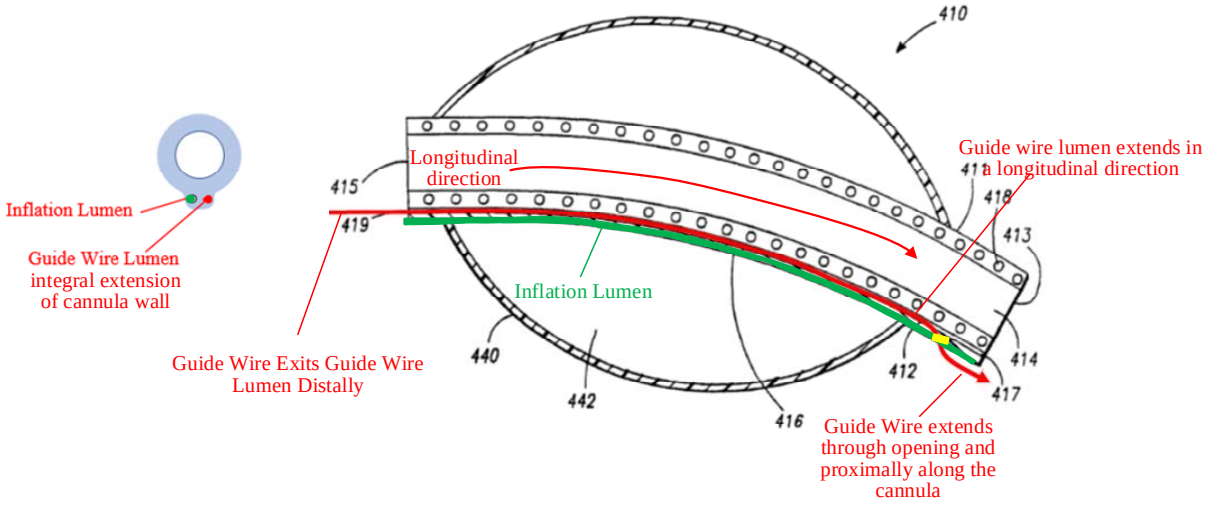


FIG.—1

(Collins ¶429.)

In another rapid-exchange configuration, side lumens (i.e. an embedded sleeve lumen or a preexisting passageway) within Aboul-Hosn's cannula are used for a guide wire to place the intravascular blood pump using the rapid-exchange technique. (Collins ¶¶428-435.) As shown below, the side lumen (i.e. elongate lumen) through which the guide wire passes also extends longitudinally and is an integral extension of the wall of the cannula. (*Id.* ¶435.)



(Collins ¶435; EX1004[Aboul-Hosn] FIG. 20, annotated.)

Thus, Aboul-Hosn in view of Yock discloses this limitation. (*Id.* ¶436.)

3. Claim 12

As previously discussed in Section X.B.1(b), either a sleeve attached to Aboul-Hosn's cannula or side lumens (i.e. an embedded sleeve or preexisting passageway) within Aboul-Hosn's cannula are used for a guide wire to place the intravascular blood pump using the rapid-exchange technique. (Collins ¶¶361,

437.) As previously discussed in Section X.B.2, the sleeve lumen or side lumen (i.e. elongate lumen) through which the guide wire passes extends longitudinally. Moreover, these lumens that are formed along the side of, or within a side wall of, the cannula are by definition offset radially from a central axis of the cannula. (*Id.* ¶437)

Thus, Aboul-Hosn in view of Yock discloses this limitation. (*Id*. ¶438.)

4. Claim 13

As previously discussed in Section X.B.1(b), it would have been obvious to place Aboul-Hosn's intravascular blood pump using the rapid-exchange technique, either by using a guide wire passing through a sleeve (i.e. an elongate lumen) attached at the distal region of the cannula or by passing a guide wire through an opening in the cannula and extending through a side lumen (i.e. an elongate lumen) within the cannula and exiting the distal end of the cannula, as disclosed by Aboul-Hosn and Yock, to improve steerability when placing the pump. (Collins ¶¶364-366, 439-441.) In either rapid-exchange configuration, the elongate lumen is adapted to guide the guide wire through the distal end of the intravascular blood pump as Dr. Collins shows in FIGS. 1 and 23 of Aboul-Hosn, below.

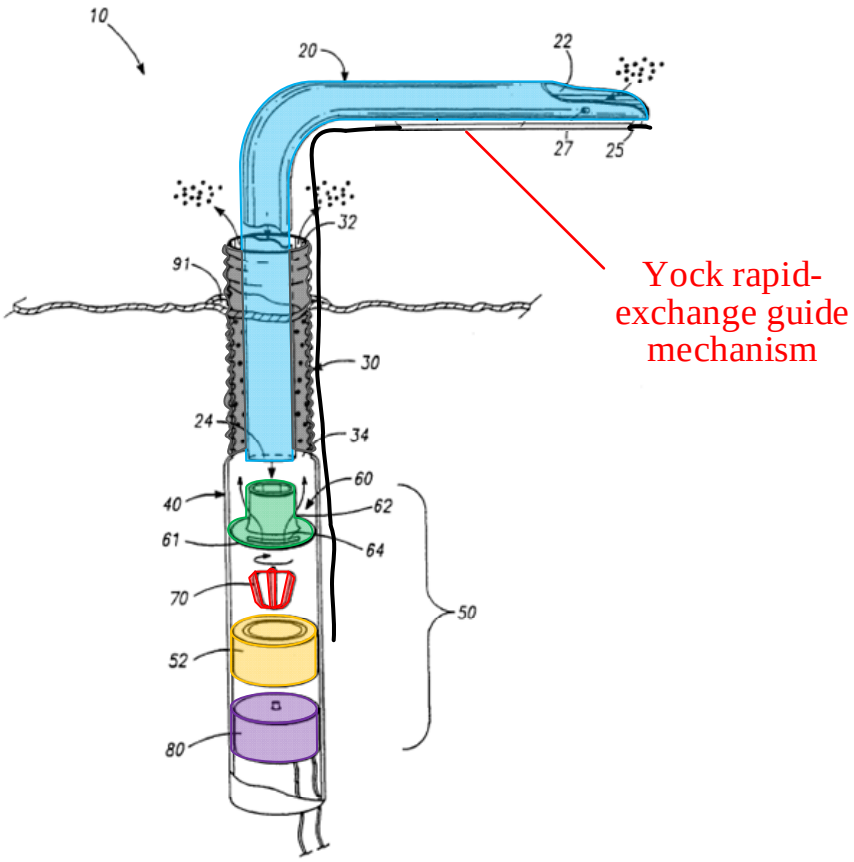


FIG.—1

(Collins ¶401.)

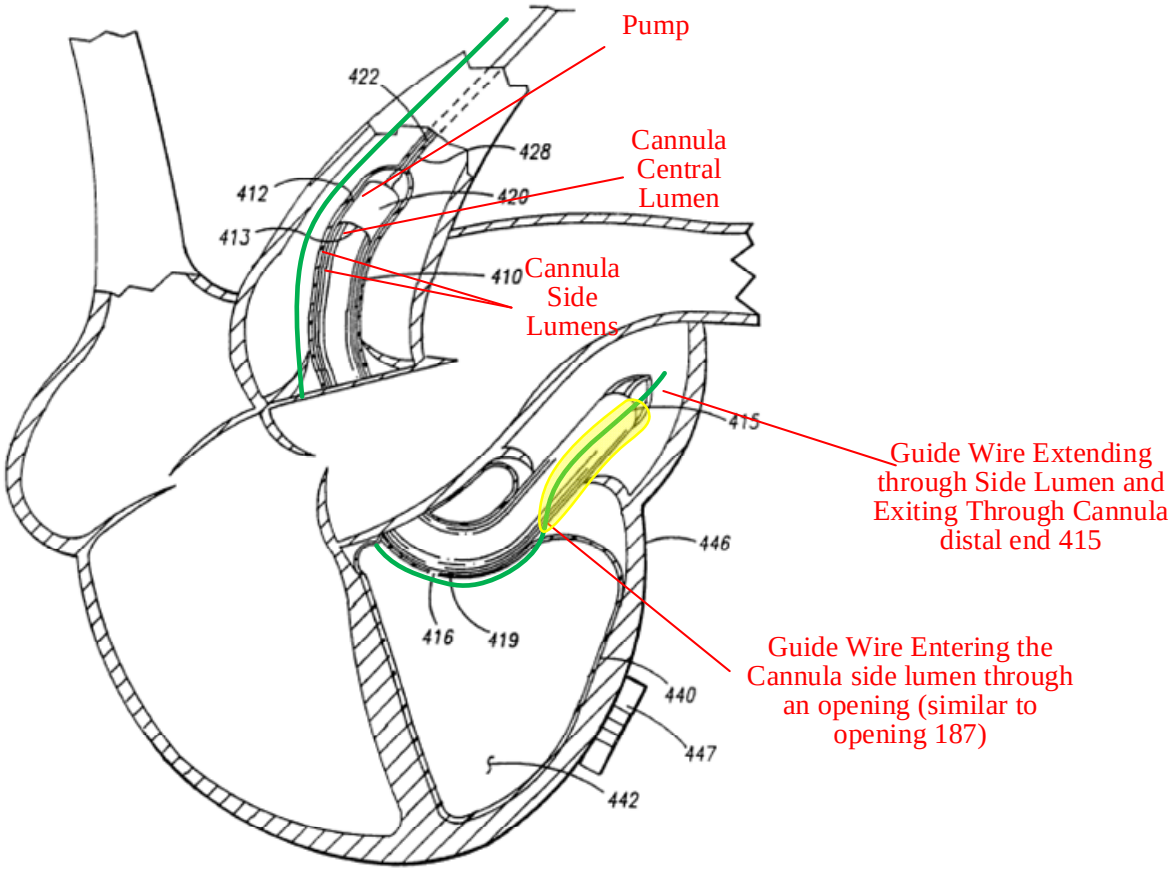


FIG.–23

(Collins ¶441; EX1004[Aboul-Hosn] FIG. 23, annotated.)

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

C. Ground III: Claims 10 and 17[15] are obvious in view of Aboul-Hosn in view of Jegaden, and further in view of Siess, Wampler, and Wampler_712

[15] Claims 10 and 17 depend from claim 1. Claim 1 is obvious over Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler as discussed in Sections X.A.1(a)-(n).

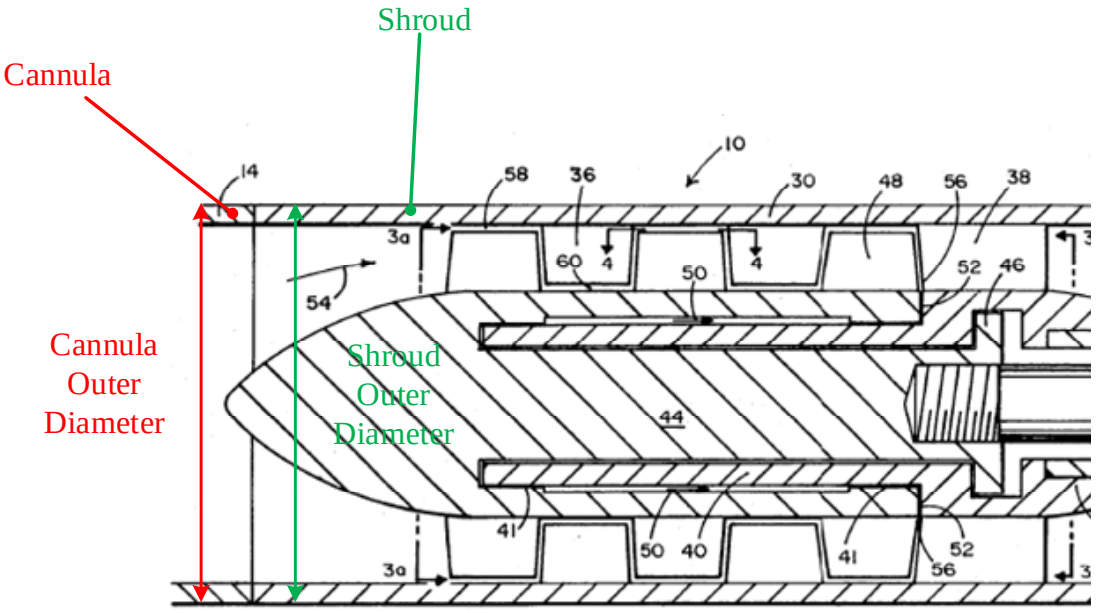
1. Claim 10

Claim 10 depends from claim 1, and further recites "*a rotor shroud, at least a portion of the rotor shroud having the same outer diameter as the cannula*."

As previously discussed in Section VII.A, Aboul-Hosn's axial-flow blood pump can be configured with or without the reverse flow feature. (Collins ¶446.) Aboul-Hosn discloses "[a] rotor 70 may be disposed longitudinally inside the inlet tube 55 as shown in FIG. 2," and that "[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." (EX1004[Aboul-Hosn] 13:7-15, 15:26-16:1.) As such, where the axial-flow blood pump is configured without the reverse-flow feature, the housing body 52 and the housing cap 60 may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "rotor shroud." (Collins ¶446; EX1004[Aboul-Hosn] 13:3-4.)

While Aboul-Hosn illustrates the cannula 20 disposed about the inlet neck 62 of the housing cap, a POSITA would understand that this is only one possible connection between the rotor shroud and the cannula; that the cannula 20 and the inlet neck 62 (as well as the inlet tube 55) could be configured to have the same outer diameter such that Aboul-Hosn's to maximize the amount of space for the pump rotor within the shroud thereby improving pump capacity and efficiency; and that doing so would have been a matter of design choice. (Collins ¶447.)

For example, Wampler_712 discloses an axial flow intravascular blood pump similar to Aboul-Hosn's that has a cannula with the same outer diameter as the rotor shroud as shown in FIG. 2, below. (*Id.* ¶448.)



(Collins ¶448; EX1008[Wampler_712] FIG. 2, annotated.)

As shown above in FIG. 2 of Wampler_712, by matching the outer diameter of the rotor shroud with the outer diameter of the cannula, the amount of space within the rotor shroud is maximized for the rotor hub and blades, which improves the amount of blood that can be pumped and the pumping efficiency of the system in light of the limited space available for the pump within the patient's vasculature. (Collins ¶451.) A POSITA would, therefore, have been motivated to connect Aboul-Hosn's cannula and rotor shroud in the manner shown above in

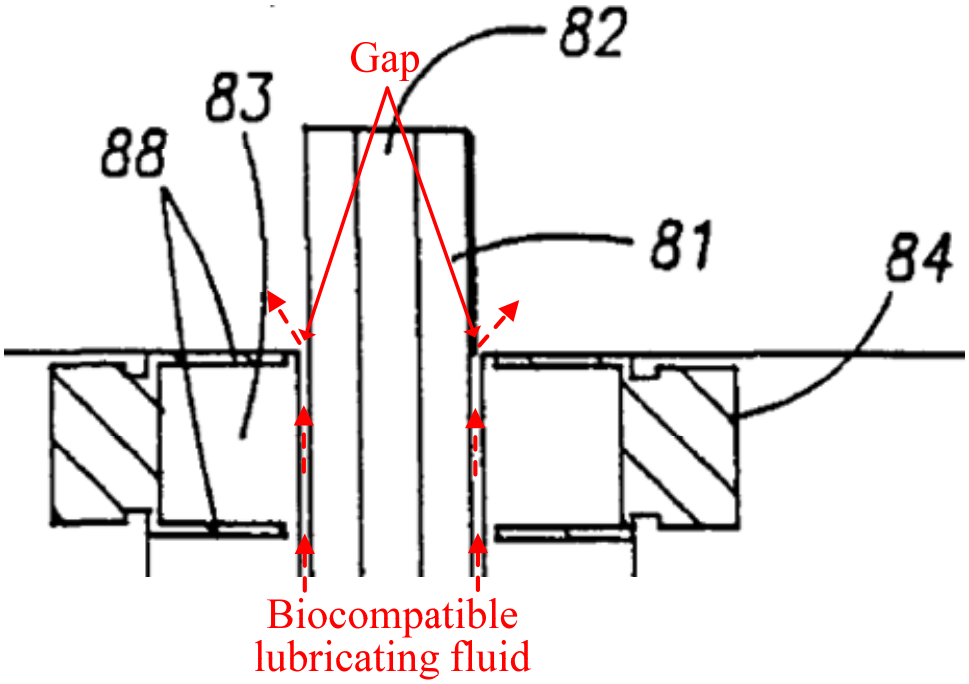
Wampler_712 such that the cannula and rotor shroud have the same outer diameter, and as such, Aboul-Hosn and Wampler_712 discloses this limitation. (*Id*. ¶¶451-452.)

2. Claim 17

Claim 17 depends from claim 16, 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*." Claim 16 depends from claim 1, and further recites "*a fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump*."

As previously disclosed in Sections X.A.1(m)-(n), Aboul-Hosn in view of Wampler discloses a roller pump (i.e. a purge fluid delivery 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 ¶454; EX1004[Aboul-Hosn] 20:16-19, 21:1-3, 29:19-25; EX1007[Wampler] 234.)

Moreover, as previously discussed in Section X.A.1(e), 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.* ¶251.)



(Collins ¶251; 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 ¶¶252, 455; 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 ¶¶252, 455-456.) 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 ¶¶455-456; EX1009[Wampler_152] 4:8-15; EX1047[Reich] claim 9.)

Thus, Aboul-Hosn in view of Wampler_712 discloses this limitation. (Collins ¶458.)

D. Ground IV: Claims 10 and 17[16] are obvious in view of Aboul-Hosn in view of Yock, and further in view of Siess, Wampler, and Wampler_712

1. Claims 10 and 17

Grounds for these claims are identical to Ground III and neither rely on Jegaden or Yock. *See* Sections X.C.1-2.

[16] Claims 10 and 17 depend from claim 1. Claim 1 is obvious over Aboul-Hosn in view of Yock, and further in view of Siess and Wampler as discussed in Sections X.A.1(a)-(n).

XI. CONCLUSION

Based on the foregoing, claims 4, 7, 10-13, 15, 17, and 19 of the ’468 patent recite subject matter that is unpatentable. The Petitioner requests institution of an IPR to cancel these claims.

Respectfully Submitted,

/David M. Tennant/

David M. Tennant
Registration No. 48,362

Table of Exhibits for U.S. Patent 9,545,468 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 9,545,468 ("'468 patent")
1002	Collins Declaration ("Collins")
1003	File History of U.S. Patent No. 9,545,468 ("'468 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_152")
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 ("Siess_359")
1014	E.P. Publication No. 0157859 ("Moise")
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	Zentraliboliothek der Medizin Koln (The Central Library of Medicine, Cologne, Germany), Catalog Record of *Temporary Cardiac Assist with an Axial Pump*, ed. W. Flaming (1991)
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	Declaration of Susanne Leupold
1047	U.S Patent No. 4,135,243 ("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 13,825 words excluding the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, and the listing of exhibits.

Respectfully Submitted,

__/David M. Tennant/___

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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 14, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 9,545,468 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. 9,545,468 (EX1001-1047)
- Exhibits 1001-1047
- 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

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

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

/s/ Daniel Shults
Daniel Shults