UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Maquet Cardiovascular, LLC
Patent Owner

Case No. IPR2017-01253

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,597,437

CLAIMS 28, 29

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I. INTRODUCTION

Petitioner Abiomed, Inc. and Abiomed R&D, Inc. (collectively, "Petitioner") petitions for *inter partes* review ("IPR") of claims 28, 29 (the "Challenged Claims") of U.S. Patent No. 9,975,437 (the "'437 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 1-5, 7-16, 18-27 of the '437 patent; (2) petitions for *IPR* of U.S. Patent Nos. 9,561,314 and 9,545,468; and (3) petitions for *IPR* of U.S. Patent Nos. 7,022,100 (IPR2017-01025), 8,888,728 (IPR2017-01026 and IPR2017-01027), and 9,327,068 (IPR2017-01028 and IPR2017-01029) (the "related patents") which are related to the '437 patent.

C. Counsel

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

IV. RELIEF REQUESTED

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

A. The Challenged Claims Are Invalid in View of the Following Prior Art[1]:

1. WO99/02204 to Aboul-Hosn (EX1004, "Aboul-Hosn"), published January 21, 1999, is prior art under 35 U.S.C. § 102(b).

[1] The pre-AIA statutory framework applies to the '437 patent.

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).[2]

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).[3]

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

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

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

B. Grounds for Challenge

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

1. Claim 28 is rendered obvious by Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler under 35 U.S.C. § 103(a).
2. Claim 29 is rendered obvious by Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler, and further in view of Wampler_712 under 35 U.S.C. § 103(a).
3. Claim 28 is rendered obvious by Aboul-Hosn in view of Yock, and further in view of Siess and Wampler under 35 U.S.C. § 103(a).
4. Claim 29 is rendered obvious by Aboul-Hosn in view of Yock, and further in view of Siess and Wampler, and further in view of Wampler_712 under 35 U.S.C. § 103(a).

V. THE CHALLENGED CLAIMS RECITED NOTHING MORE THAN CONVENTIONAL TECHNOLOGY

A. Conventional Intravascular Blood Pumps[4] and Use and Installation of Intravascular Blood Pumps

The features of the Challenged Claims were well known and included methods of "providing left-heart support using an intravascular blood pump

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

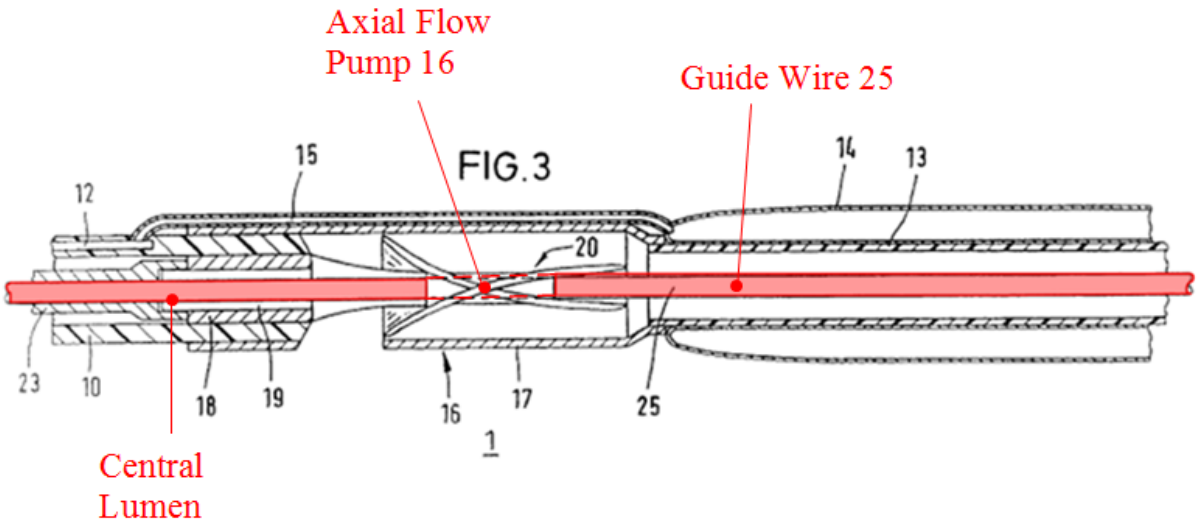
system" using a cannula connected to an axial flow pump (Collins ¶¶52, 56-59), pumping blood axially along the pump and through the cannula (Collins ¶¶61-65), passing purge fluid to the intravascular blood pump to through a catheter connected to the pump (Collins ¶¶66-72), and measuring blood pressure near the pump (Collins ¶¶73-79). The few other remaining details of the Challenged Claims were also well-known in the prior art. (Collins ¶¶60, 67, 74.)

B. Conventional Techniques for Placing Intravascular Pumps

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

1. Over-the-Wire

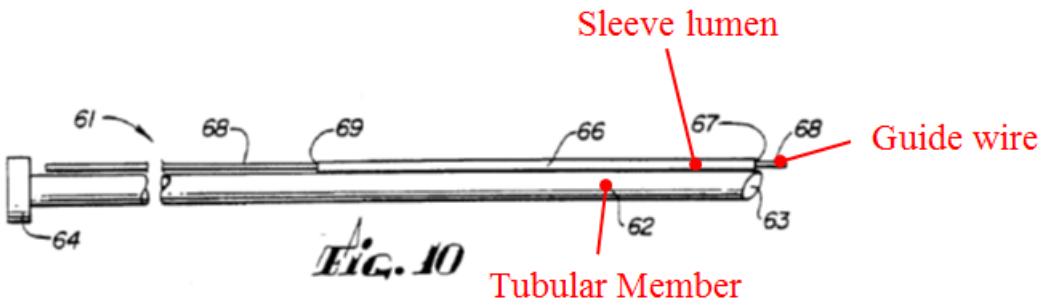
Persons of ordinary skill in the art ("POSITAs") have used "over-the-wire" guide mechanisms to place intravascular blood pumps. (Collins ¶85.) For example, as shown below in FIG. 3, U.S. Patent No. 6,248,091 to Voelker (EX1011, "Voelker") applied the "over-the-wire" guide mechanism to an axial flow intravascular 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, FIG. 3; *see also* EX1004[Aboul-Hosn] 11:24-26, FIG. 3.]



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

2. Rapid-Exchange

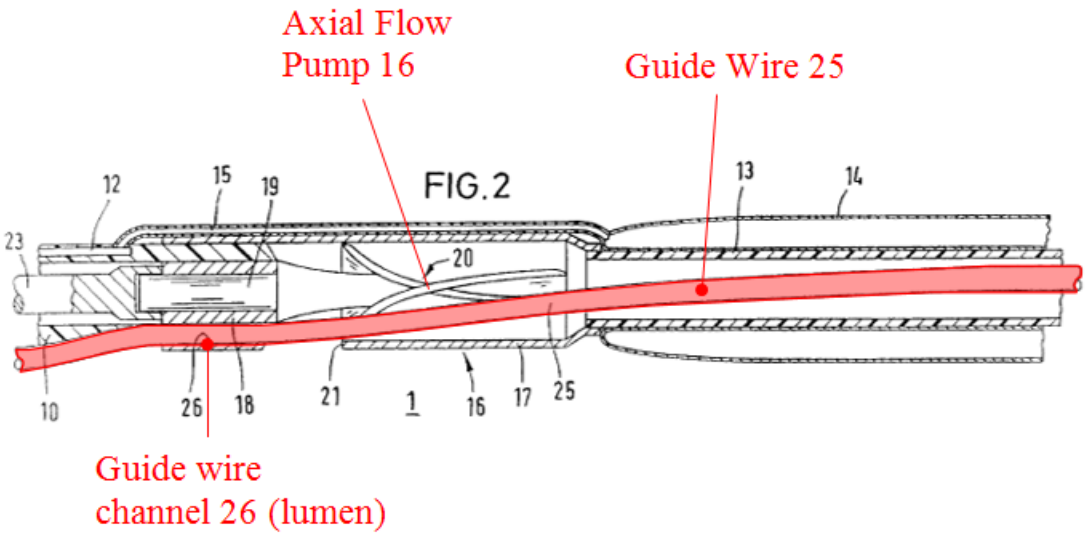
"Rapid-exchange" was well-known catheterization technique. (Collins ¶89.) Yock placed a conventional "rapid-exchange" catheter by sliding it along a guide wire extending through a sleeve secured to the exterior of the cannula or embedded within the cannula wall itself. (*Id.* ¶90; EX1006[Yock] FIG. 10,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



(Collins ¶90; EX1006[Yock] FIG. 10, annotated.)

Voelker FIG. 2 (below) applied this rapid exchange approach as applied to an intravascular blood pump -- a guide wire 25 extended through a side channel 26

of a pump for positioning 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 and X below, a POSITA could also readily deploy Aboul-Hosn's blood pump using the conventional "rapid-exchange" technique. (*Id.* ¶¶93-94.)

3. Guide Catheter

Yock also disclosed using a guide catheter to position a guide wire. (Collins ¶82; EX1006[Yock] 3:56-4:50.) The same technique has also been adapted to place axial flow intravascular blood pumps (Collins ¶83), as acknowledged by the '437 Patent. (EX1001['437 Patent] 2:36-56.)

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

Over-the-wire and rapid-exchange techniques have long been used interchangeably, with minimal differences in design, to deliver cardiac assist devices, including blood pumps. (Collins ¶95; EX1023[Faxon] 58-59; EX1006[Yock] 8:16-25; EX1011[Voelker] FIGS. 2 and 3.) Over-the-wire and rapid-exchange were part of a limited set of delivery techniques. (Collins ¶96.) For example, U.S. Patent No. 5,928,181 to Coleman et al. discloses that catheters coupled to a cardiopulmonary bypass pump may be suitably guided into position using either technique. (EX1042[Coleman] 34:14-39.)

The interchangeability of over-the-wire and rapid-exchange was also well understood for intravascular blood pump applications. (Collins ¶97.) For example, Voelker's blood pump could be configured to use either technique. (*Id.*; EX1011[Voelker] FIG. 2 (over-the-wire), 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; EX1001[Voelker] 3:34-55.)

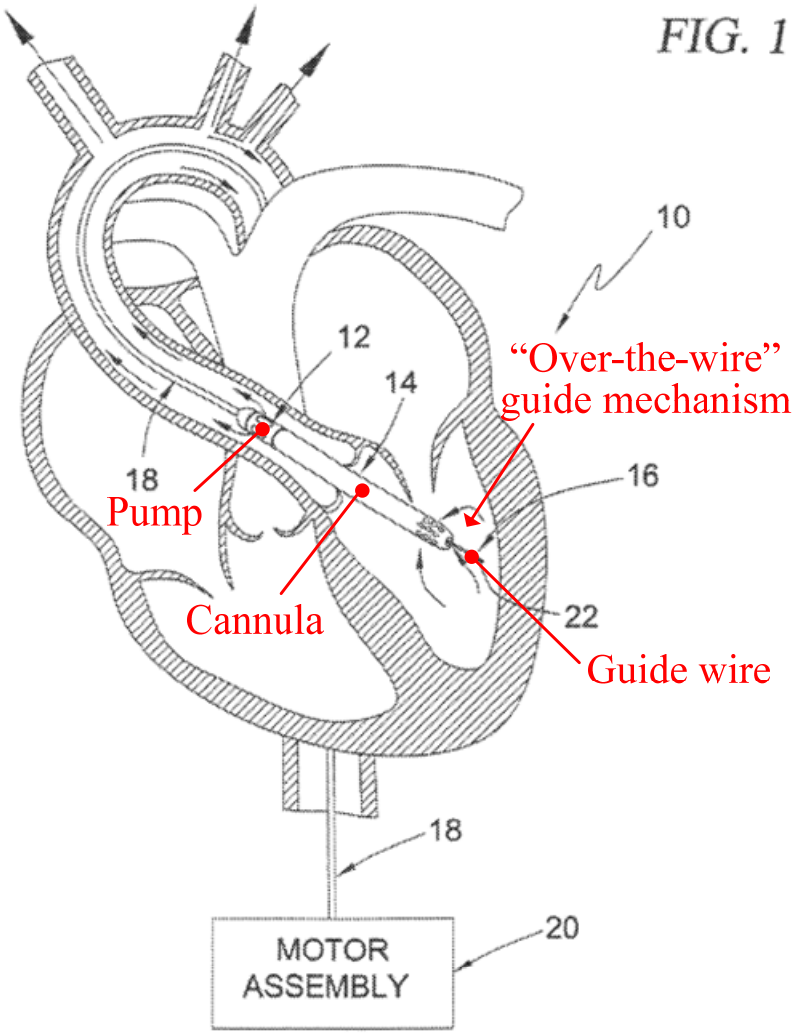
There were a number of known advantages to using rapid-exchange compared to over-the wire, including a simplified exchange procedure, increased insertion speed, additional design flexibility. (Collins ¶¶99-100.)

VI. OVERVIEW OF THE ’437 PATENT

A. Summary of Alleged ’437 Patent Invention

The ’437 patent describes conventional placement of a conventional intravascular blood pump system using the same three conventional guide wire delivery techniques discussed above. (EX1001[’437 patent] 9:13-32, 13:62-14:10, 15:5-21; Collins ¶113.) The background of the ’437 patent openly admits that it is not the first to use “guide mechanism[s]” to place an intravascular pump. (EX1001[’437 patent] 2:36-46.)

FIG. 1 of the ’437 patent illustrates a conventional over-the-wire placement technique. (*Id.* 5:25-30.)

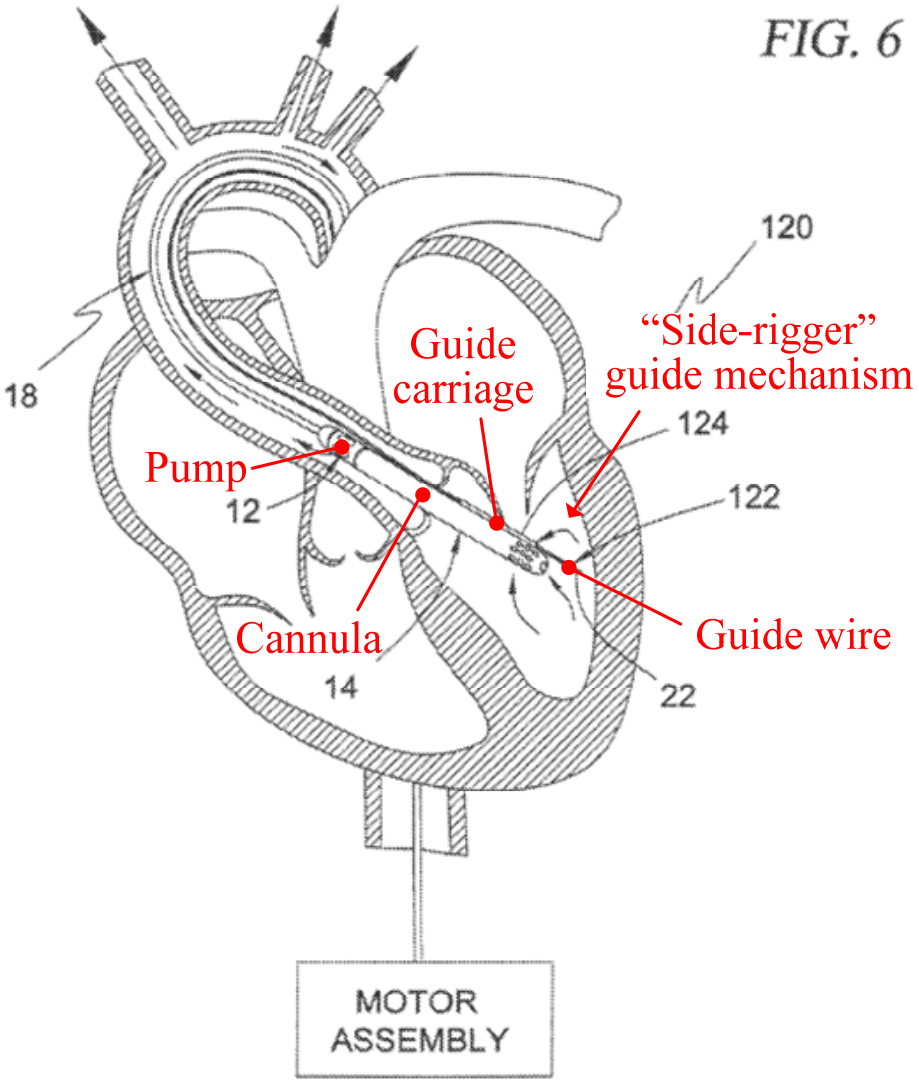


(Collins ¶114; EX1001['437 patent] FIG. 1, annotated.)

The conventional intravascular blood pump system includes an intravascular blood pump 12 rotor hub, cannula 14, and over-the-wire guide mechanism 16 with a guide wire lumen that passes through the center of the rotor hub and the cannula 14. (*Id.* 9:13-24; Collins ¶114.) The blood pump 12 provides heart support in the same manner as conventional axial-flow intravascular blood pumps – by "deliberately re-rout[ing] through and past the right and/or left ventricle in an

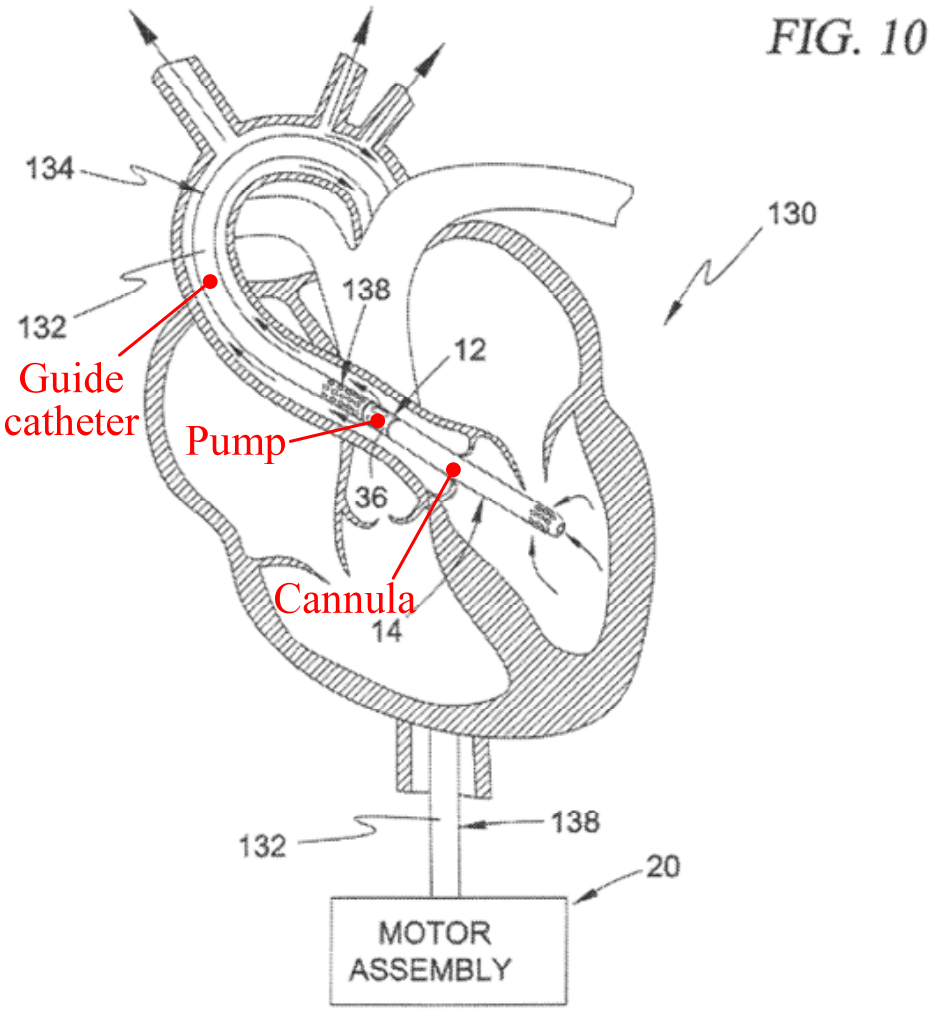
effort to reduce the volume of blood to be pumped by the particular ventricle." (*C.f.* EX1001['437 patent] 20:43-48 *with id.* 2:16-19; Collins ¶114.)

FIG. 6 shows the conventional "rapid-exchange" or "side-rigger" guide mechanism of the prior art. (EX1001['437 patent] 5:47-52.) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (*Id.* 14:15-21; Collins ¶¶116-17.) As with the prior art (Collins ¶117), the guide carriage 124 may be formed as "an integral extension of the wall of the cannula 14." (EX1001['437 patent] 14:37-39.)



(Collins ¶116; EX1001['437 patent] FIG. 6, annotated.)

Finally, the '437 patent at FIG. 10 shows a "guide catheter" mechanism 132 as in the prior art, with the rotor and shroud delivered – two separate steps. (EX1001['437 patent] 5:65-6:3; Collins ¶119.)



(Collins ¶119; EX1001[’437 patent] FIG. 10, annotated.)

A. No Patentable Synergy

As Dr. Collins explains, claim 1 recites various features which are disparate and unrelated, including a catheter, a purge lumen, an elongate lumen associated with the cannula and sized to slidably receive the guide wire, the elongate lumen and the cannula lumen not extending through the rotor hub. (Collins ¶122.) There is no patentable synergy between the guide configuration and purge system feature presented in the Challenged Claims. (*Id.*) Both recited features were conventional

elements and that were well-known as of the earliest priority date, starting with the Hemopump years before, and disclosed by prior art references not relied on by the Examiner. (*Id*.)

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

The September 1, 2000 priority date of the '437 patent is the earliest possible priority date (the "EPD") for the Challenged Claims.[5] The subject matter of the Challenged Claims is not supported by its claimed earlier-filed provisional application.

Independent claim 1 recites "a purge lumen extending through the catheter," "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 elongate lumen is sized smaller cross-sectionally than the cannula lumen," "both the elongate lumen and the cannula lumen not extending through the rotor hub" and "measuring pressure adjacent the intravascular blood pump." (EX1001['437 patent] 33:55-56, 33:64-67, 33:67-34:1, 34:1-3, 34:25-26.) Yet, nowhere in the '249 provisional application is there

[5] The '437 Patent claims priority to PCT Application No. PCT/US00/24515, filed on September 1, 2000.

support for these limitations.[6] (Collins ¶131-134; *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 *provisional* application.") (quoting *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002) (emphasis in original).)

Accordingly, the EPD for Challenged Claims is September 1, 2000.[7] (Collins ¶134.)

VII. OVERVIEW OF THE PRIOR ART[8]

A. Overview of Aboul-Hosn

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[7] 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).

[8] Aboul-Hosn and Siess '913 were cited in an Information Disclosure Statement dated August 19, 2016 but there is no record that the Examiner relied upon them. (EX1003['437 PH] 254-274. There is no record of Jegaden, Yock, or Wampler being disclosed during prosecution of the '437 patent.

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 ¶135; EX1004[Aboul-Hosn] 11:9-14; 30:1-2.) Aboul-Hosn further discloses both percutaneous and surgical approaches for delivering the blood pump. (Collins ¶154-158; EX1004[Aboul-Hosn] FIG. 21, 21:19-22:30, 11:8-12.)

Annotated FIGS. 21 and 23, below, show the percutaneous approach using a guide wire. (Collins ¶155; EX1004[Aboul-Hosn] 30:1-2, 20-27.) FIG. 21 shows how the blood pump (green) passes along the guide wire up the femoral artery, so the cannula 411[9] (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 ¶¶155-156; EX1004[Aboul-Hosn] 29:17-28, 30:1-2, 30:20-27.) In addition, the cannula's inflow tip may be placed in "the left ventricle,…or any of the left heart vessels" to provide left heart support. (*Id.* 26:10-13.)

[9] 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.)

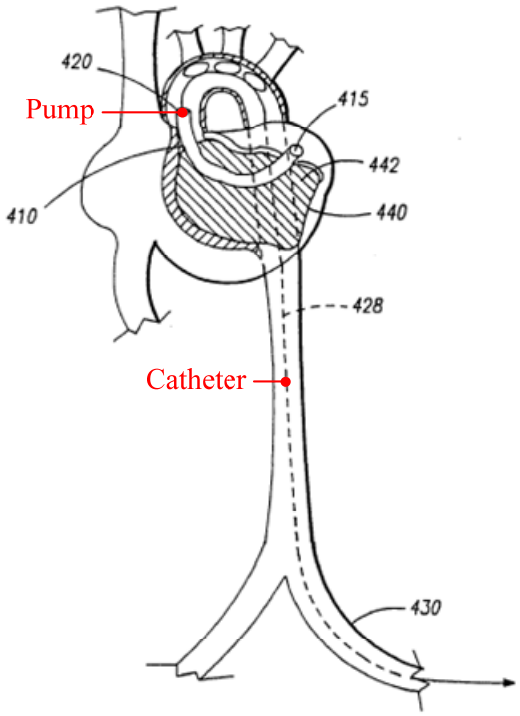


FIG.–21

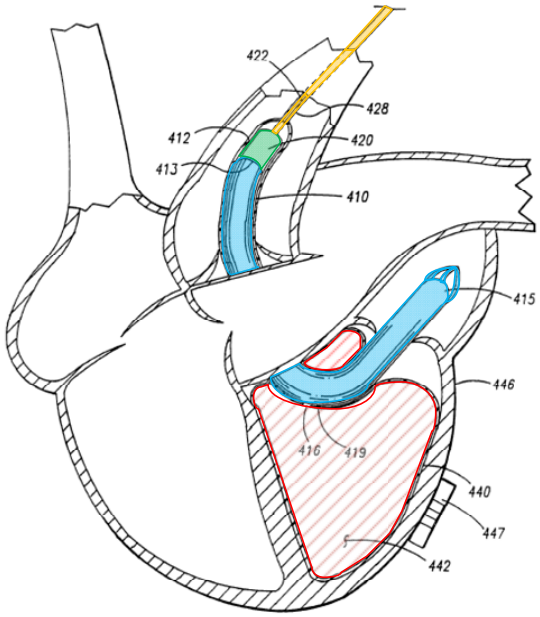


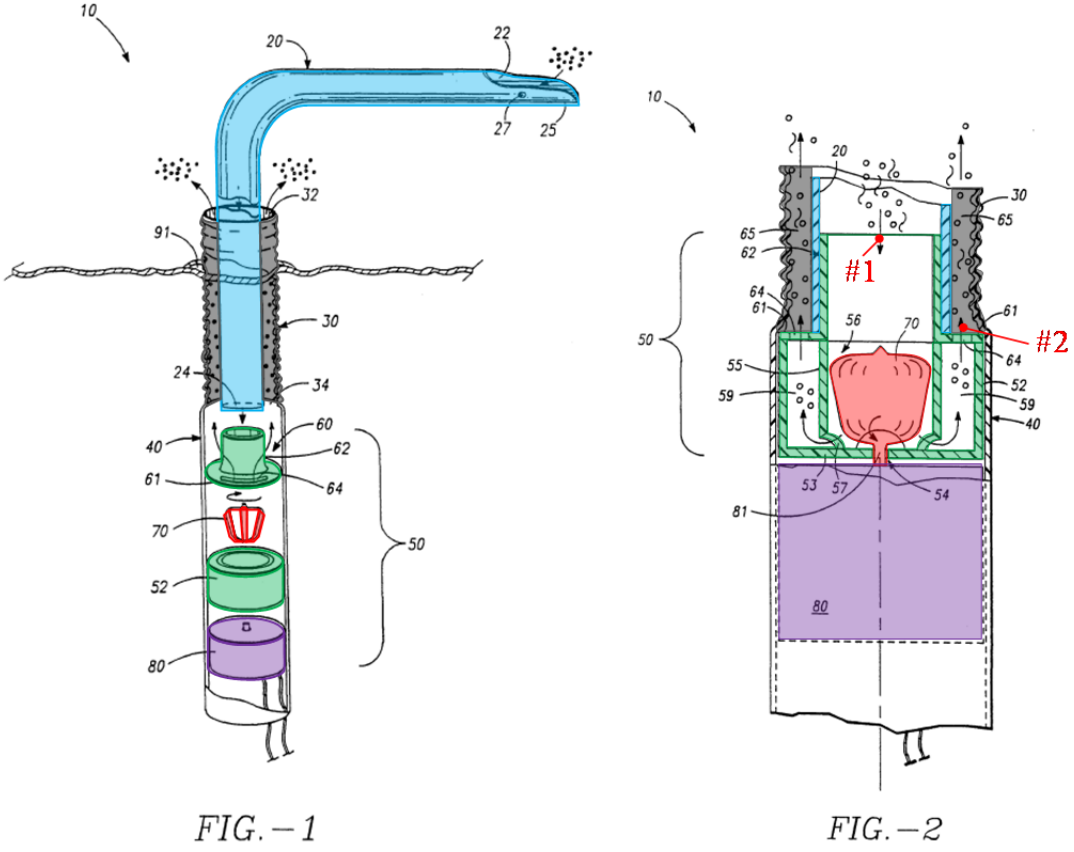
FIG.–23

(Collins ¶155; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

FIGS. 1-13 show the surgical approach with details about the interior of the pump and cannula. Numerous conventional features of intravascular blood pumps are disclosed, including a "commercially available" cannula (EX1004[Aboul-Hosn] 11:14), together with a "reverse flow" feature that reverses the direction of blood flow as it exits the pump. (Collins ¶¶151, 157.)

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 housing cap 62

(green).[10] (EX1004[Aboul-Hosn] 12:12-13:13.) The inner cannula 20 (blue) is coupled to the housing cap 62 (green), and extends beyond the distal opening 32 of the outer conduit 30 (dark grey). (*Id*.)

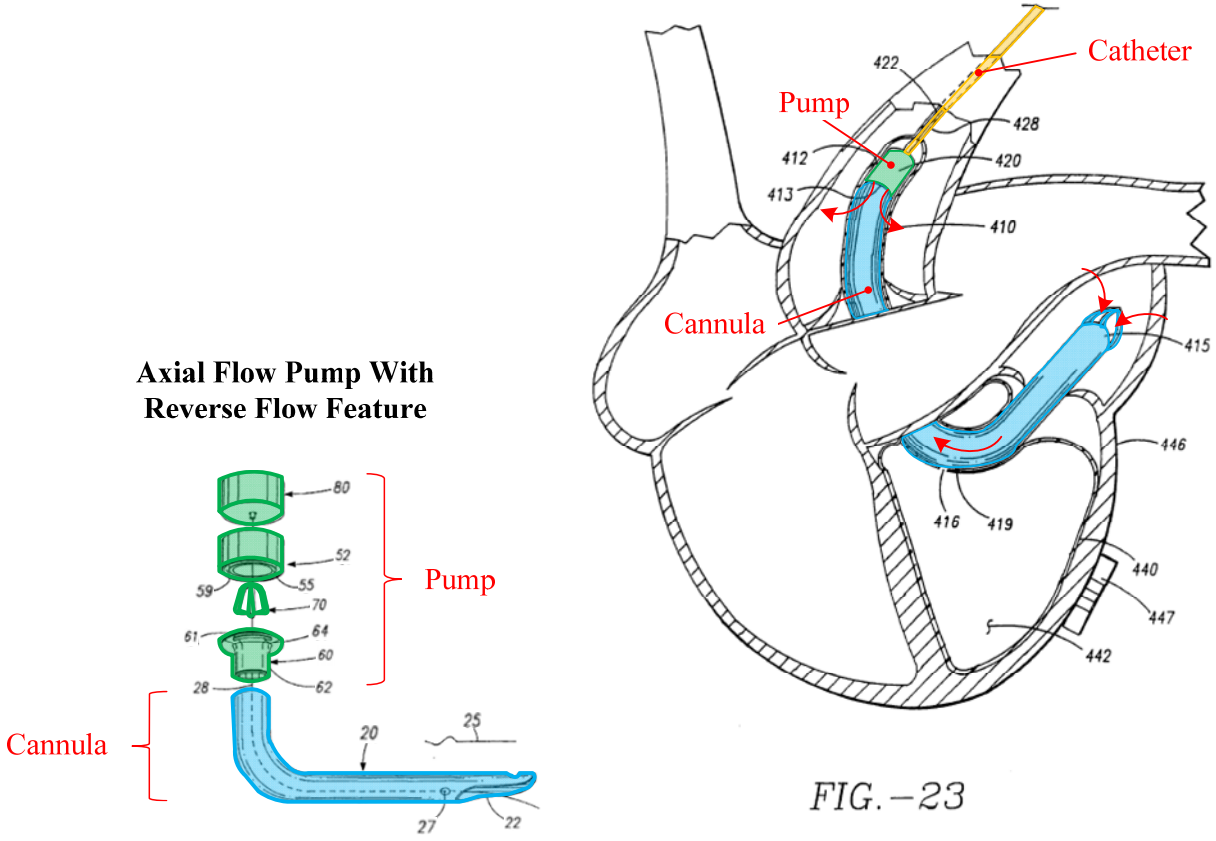


(Collins ¶142; EX1004[Aboul-Hosn] FIGS. 1, 2, annotated.)

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

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

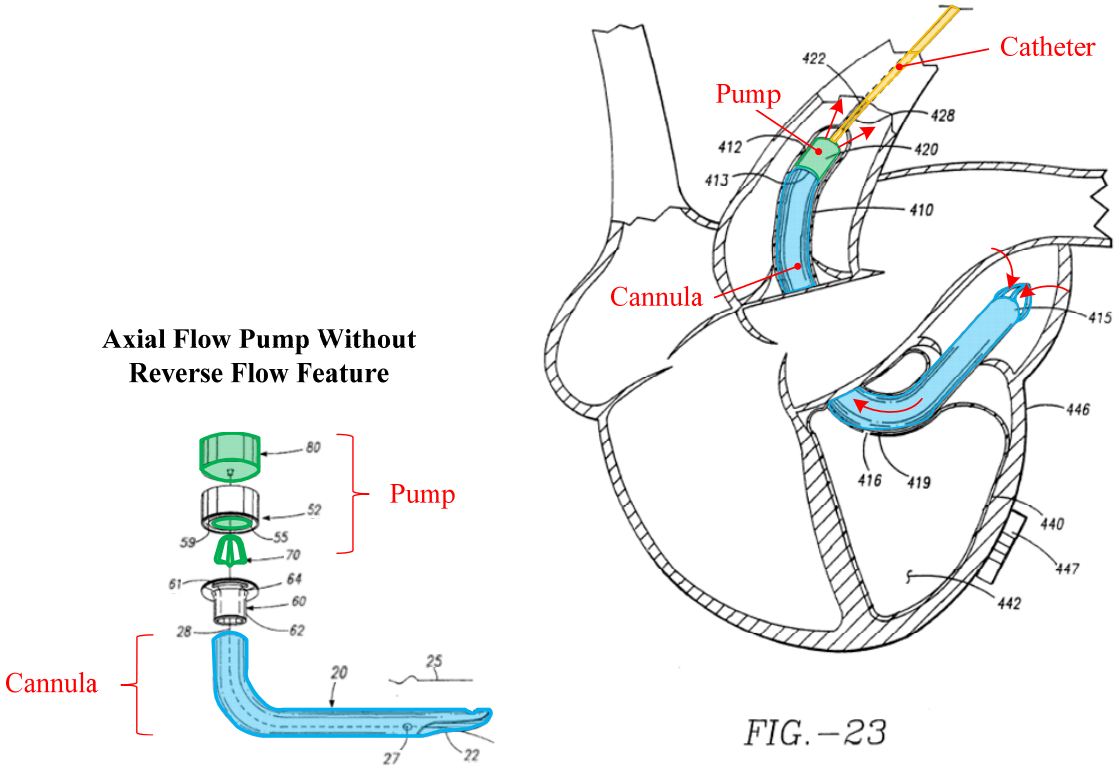
pump "provided for by the present invention") would be readily connected to the multilumen catheter 428 (yellow). (Collins ¶¶145-146.) In this configuration, the catheter 428 would be used to advance the pump 420 and stabilization cannula 411 over a guide wire to the desired location within the patient's heart through the femoral artery. (Collins ¶155; EX1004[Aboul-Hosn] 29:18-25.)



(Collins ¶145; 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 ¶146; *see also* EX1004[Aboul-Hosn] 31:6-9.) In this configuration, the pump 420 would include the components of the pump system of FIGS. 1-13 that generate the axial flow of blood through the pump

(i.e. rotor 70 and inlet tube 55, connected to drive unit 80), without the components that cause the blood flow to reverse course (i.e. housing body 52, housing cap 60, and outer cannula 30). (Collins ¶146.) Instead, the blood (represented by the red arrows) discharges axially over the drive unit and out the pump 420 (green). (*Id.*)



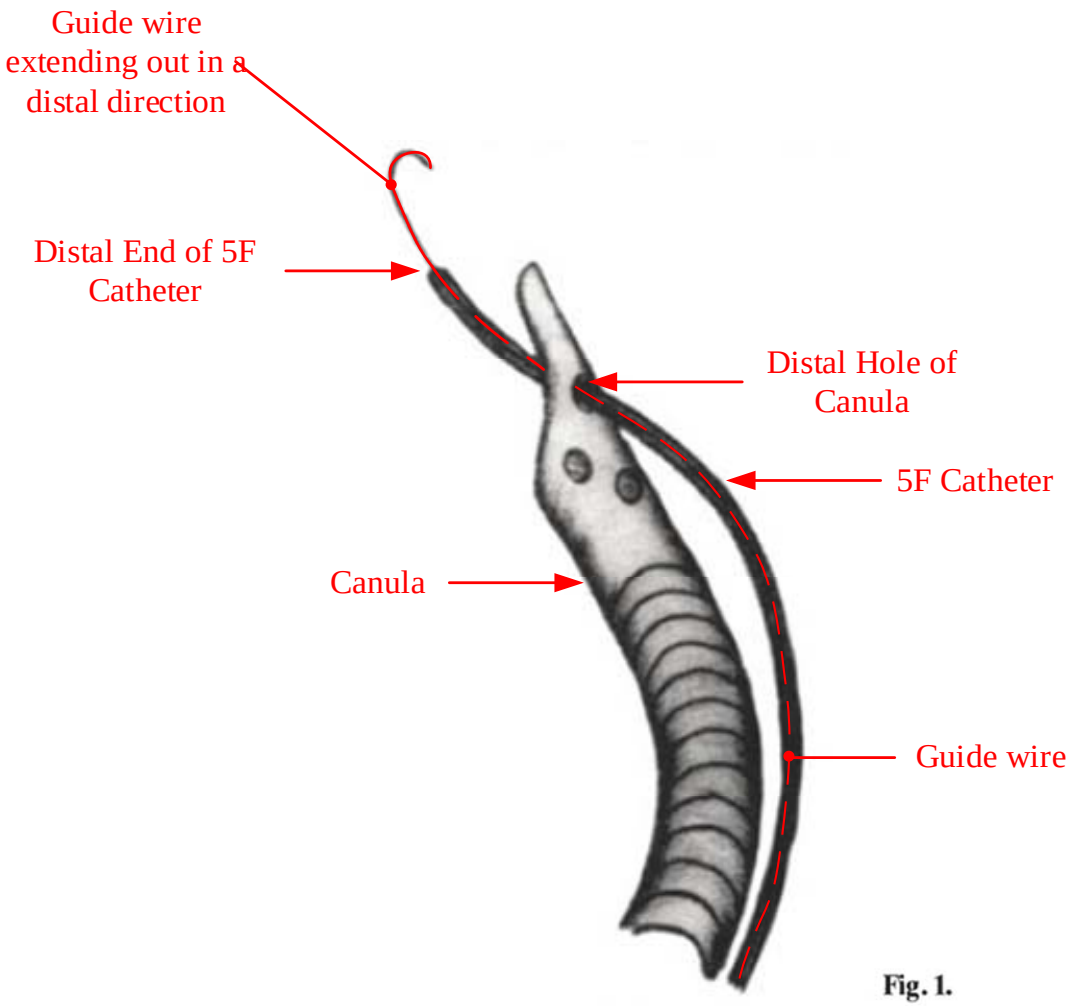
(Collins ¶146; EX1004[Aboul-Hosn] FIGS. 1, 23, annotated.)

As explained in greater detail in Section X.A.1(l) below, Aboul-Hosn uses a guide wire to deploy the pumps intravascularly using the over-the-wire technique. (Collins ¶¶154-155; 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 ¶151; 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. (Collins ¶¶137-138; EX1004[Aboul-Hosn] 11:24-26: "[a] catheter guide wire may also be extended through the cannula openings 27 to dispose the inner cannula 20 at desired locations.")

B. Overview of Jegaden

Jegaden discloses placing a conventional axial flow intravascular pump system in a desired location using the conventional rapid-exchange technique. (Collins ¶159; EX1033[Jegaden] 61-62.) As shown in FIG. 2, a guide catheter (i.e. 5F catheter) having a guide wire extending coaxially through its lumen and exiting its distal end is "passed through the distal hole of the cannula and introduced into the femoral artery up to the aorta," and "[t]hen the cannula is introduced into the femoral artery and is pushed into the aorta, guided by the vasculature catheter" (i.e. the 5F guide catheter). (Collins ¶160; EX1033[Jegaden] 61-62.) The 5F guide catheter and distal hole function as a rapid-exchange guide mechanism for the pump. (Collins ¶161.) FIG. 2 shows a J-shaped distal tip at the end of the guide wire. (Collins ¶164; EX1033[Jegaden] FIG. 2.)

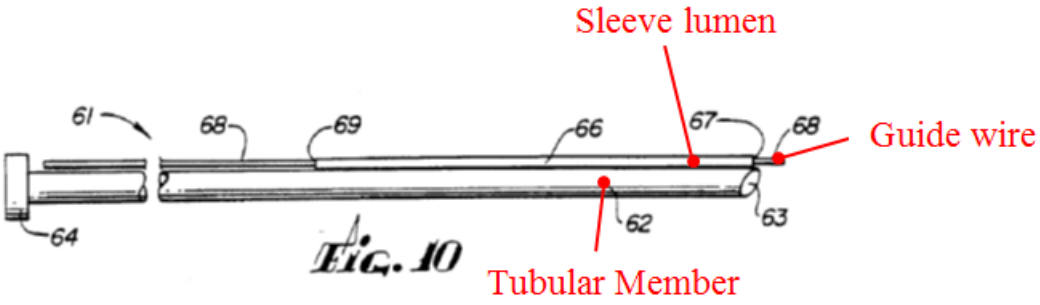


(Collins ¶161; EX1033[Jegaden] FIG. 1, annotated.)

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. (Collins ¶168; 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 ¶168; 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 ¶168; EX1006[Yock] 2:31-37.)



(Collins ¶168; 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 ¶176; EX1005[Siess] 5:55-58.) The pump includes a lumen to deliver a "biocompatible purge fluid[,] … that is pressurized so as to maintain a slow purge rate over the seals of about 1-5ml/hr[,]" to the microaxial pump 10. (*Id.* 8:31-44.) Additionally, it can have "electrical conduits extending therethrough to allow the operation of the drive unit to be monitored and controlled." (*Id.* 3:16-18, 8:31-38, 11:23-40.)

E. Overview of Wampler

Wampler discloses the Hemopump, introduced in Jegaden, which was the original catheter-based blood pump. (Collins ¶170; EX1007[Wampler] 232-36.)

Wampler provides a schematic of the Hemopump in FIG. 14-2, below, showing purge fluid inlet and outlet conduits connected to a purge fluid pump that delivers a continuous infusion of purge fluid to the Hemopump via lumens within the drive cable sheath. (Collins ¶172; EX1007[Wampler] 233-34.)

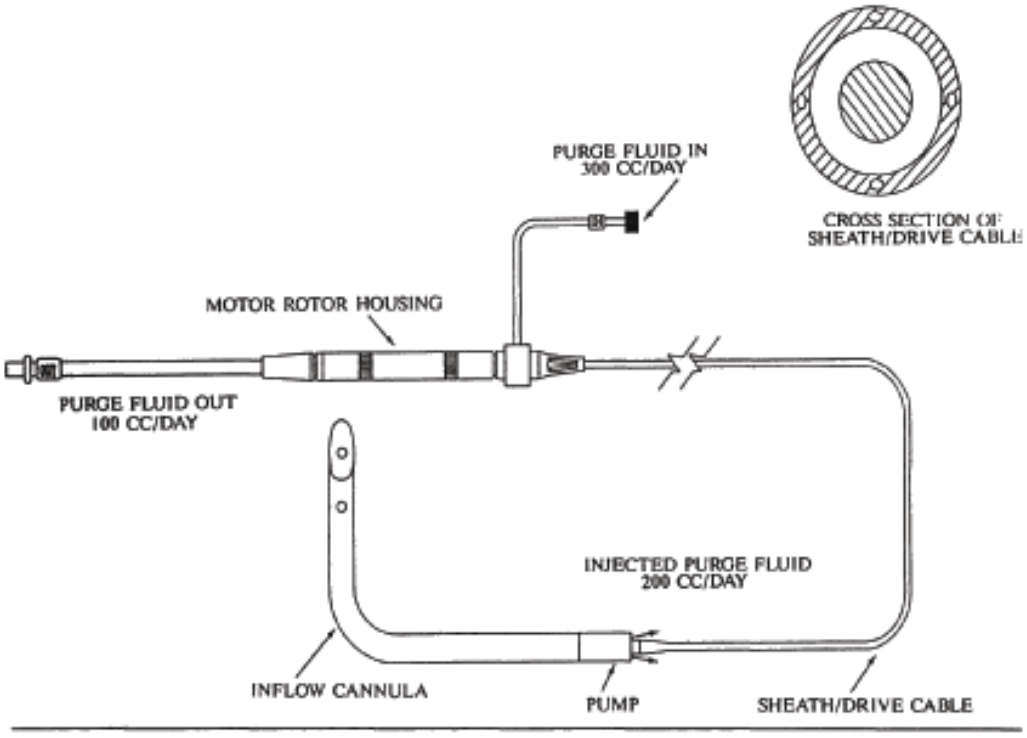


Figure 14-2. Schematic of the Hemopump.

(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 ¶181.) 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.) Wampler discloses that the

"catheter also provides a conduit to supply the pump bearings with a blood-compatible purge fluid at a rate and pressure sufficient to prevent thrombus formation and introduction of blood elements between rotating and stationary elements of the pump." (*Id.* Abstract.)

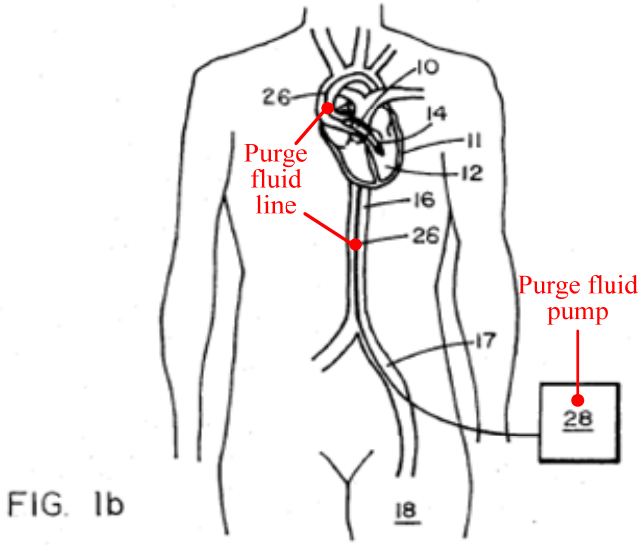


FIG. 1b

(Collins ¶182; 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.

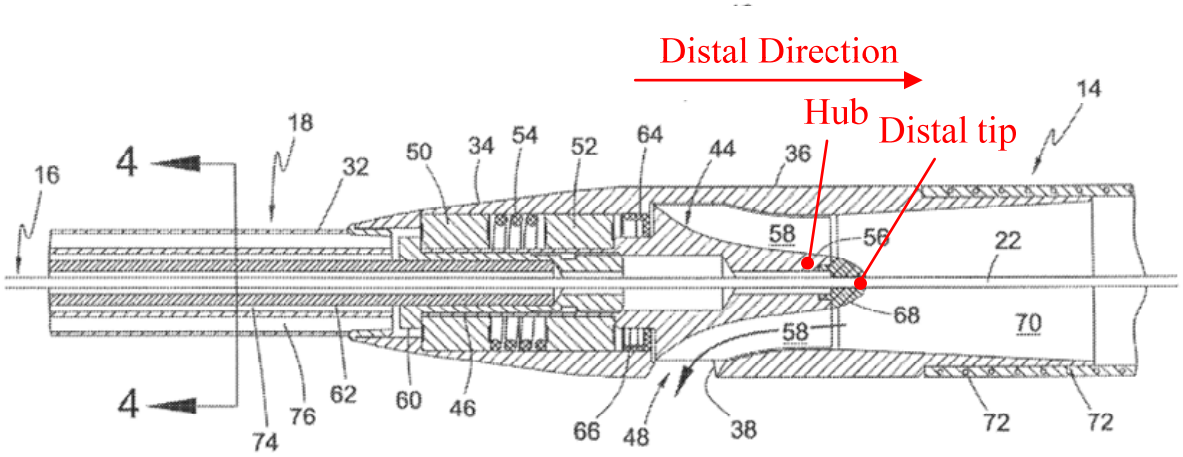
§ 42.100(b), Petitioner submits the following claim term constructions.[11] Any claim terms not included in the following discussion are to be given their broadest reasonable construction in light of the specification as commonly understood by those of ordinary skill in the art.

A. "Distal"

The Challenged Claims recite the term "distal." This term refers to the relative position of the components of the intravascular blood pump system, or certain aspects thereof. (Collins ¶124.) More specifically, the term "distal" refers to being directed toward the far end of the cannula relative to the position of the pump. (*Id.* ¶¶125-26.) Referring to FIG. 3, as reproduced below, the '437 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['437 patent] 12:34-37.)

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

FIG. 3



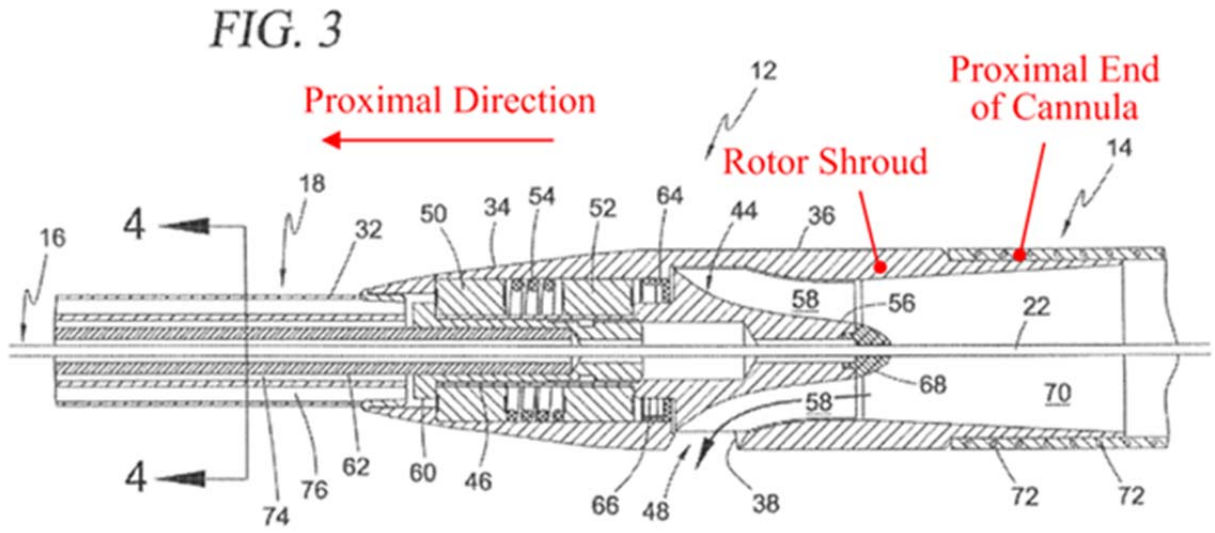
(Collins ¶124; EX1001[’437 patent] FIG. 3, annotated.)

As shown in FIG. 3, the “distal flow” referred to by the ’437 patent 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 ¶124.) Moreover, the ’437 patent makes numerous references to a “distal end” or “distal tip” with respect to certain components, including, a seal member 68 at the “distal tip” of the rotor hub 56 as shown in FIG. 3 (above), fenestrations 40 about the “distal region” of the cannula 14 as shown in FIG. 2, and so forth. (*Id.* ¶¶125-26; EX1001[’437 patent] 10:27-31, 11:37-39.)

Thus, distal refers to “towards the far end of the cannula relative to the position of the pump.” (Collins ¶127.)

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 ¶¶128-29.) For example, the '437 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.* ¶129; EX1001['437 patent] 10:27-31, 11:60-61.)



(Collins ¶128; EX1001['437 patent] FIG. 3, annotated.)

Thus, proximal refers to "away from the far end of the cannula relative to the position of the pump." (Collins ¶130.)

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. As shown below, the Challenged Claims refer to nothing more than conventional intravascular blood pump systems, applied in a conventional guide-wire technique, to achieve the predictable outcome of placing the blood pump in the heart. The declaration by Dr. Collins (EX1002) confirms these analyses and conclusions.

A. Ground I: Claim 28 is obvious in over Aboul-Hosn in view of Jegaden, and further in view of Siess and Wampler

1. Claim 28

a) *"A method for providing left-heart support using an intravascular blood pump system, wherein the intravascular blood pump system comprises:"*

Aboul-Hosn discloses a method for providing left-heart support using an intravascular blood pump system. (Collins ¶¶230-32; EX1004[Aboul-Hosn] 6:6-8; 6:26-29.)

The Aboul-Hosn intravascular blood pump system (EX1004[Aboul-Hosn] 6:6-8) can be inserted percutaneously (*Id.* FIG. 23) or surgically (*Id.* FIG. 24). (Collins ¶231-232.) Figure 23 demonstrates an intravascular blood pump 420 (green) coupled at its proximal end to cannula 411 (blue) and positioned in the left side of the heart through the femoral artery using a multi-lumen catheter 428 (yellow). (*See* EX1004[Aboul-Hosn] 10:10-11 ("FIG. 23 is a partial sectional view of the heart and a stabilization system used in cooperation with an intravascular pump."); 29:17-19 ("The stabilization apparatus 410 and a pump 420 may be introduced into the body as shown in FIG. 21 through the femoral artery 430 with a catheter 428 linking the device to the exterior of the body.").)

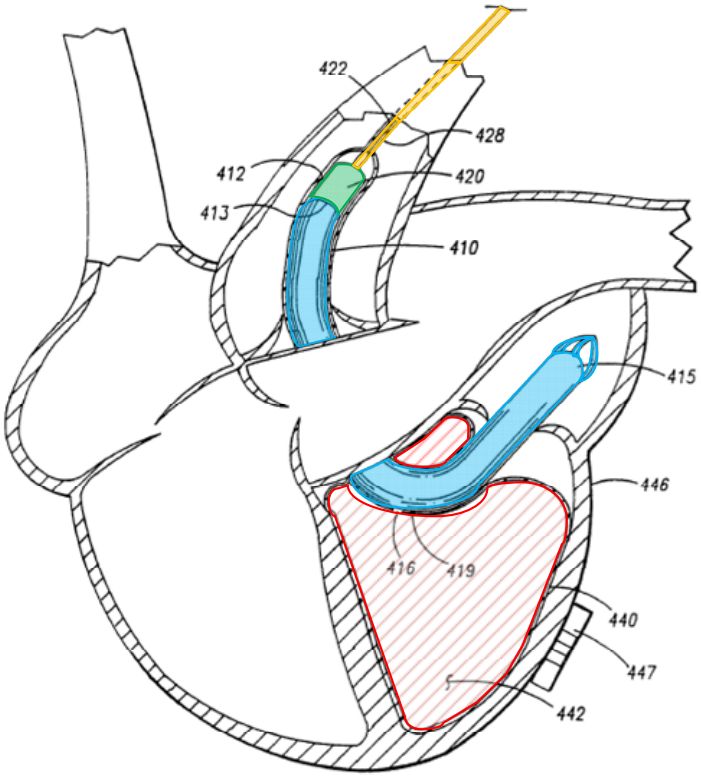


FIG.–23

(Collins ¶232; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As discussed below, the various blood pump elements claimed in the '437 patent are disclosed by Aboul-Hosn alone or in view of a small number of other references. Thus, Aboul-Hosn discloses this limitation. (Collins ¶239.)

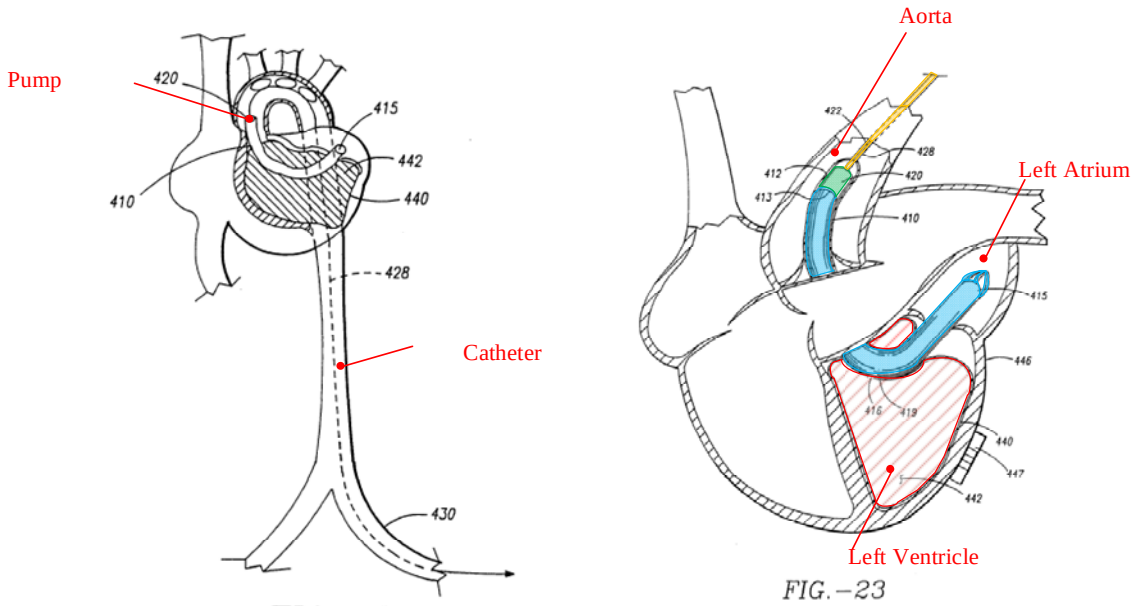
b) *"an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support,"*

Aboul-Hosn discloses that the axial flow blood pump system of FIGS. 1-13, either with or without the reverse flow feature (*See* Section VII.A), can be delivered to the heart percutaneously as shown in FIG. 23. (Collins ¶241; 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 ¶242; EX1004[Aboul-Hosn] 11:24-26, 17:19-23, 22:10-16, 24:7-14, 29:23-25.)

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 ¶242; EX1004[Aboul-Hosn] 22:12-16.) 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." (EX1004[Aboul-Hosn] 11:8-11, 11:24-28, 22:10-12; Collins ¶244.) This includes the left ventricle or atrium to provide left-heart support in the same conventional manner as disclosed by the '437 patent. (Collins ¶244; EX1004[Aboul-Hosn] 26:10-13, 29:31-30:2: "[a]fter proper positioning, a pump may be activated to take over the left ventricle function.")

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 ¶245.)



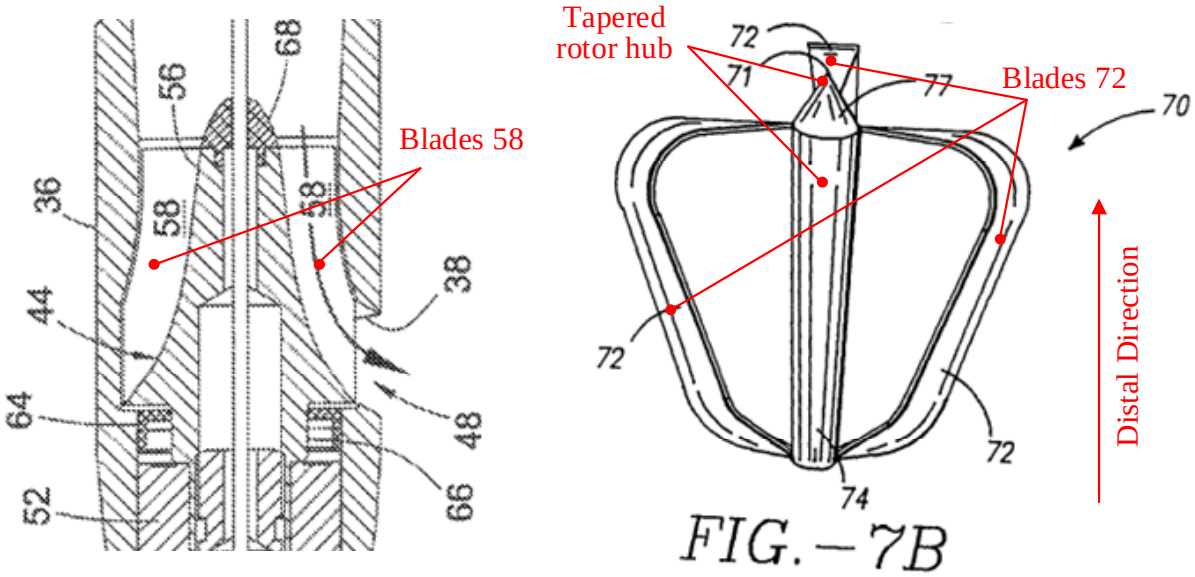
(Collins ¶245; EX1004[Aboul-Hosn] FIGS. 21 and 23, annotated.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶249.)

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

Aboul-Hosn's intravascular blood pump has a rotor having a rotor hub. (Collins ¶250; 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.) FIG. 7B (annotated below) shows a rotor 70 having a central hub 74 tapering in the distal direction. (Collins ¶250.)

FIG. 7B illustrates the rotor 70 having three blades 72 each extending radially outward from the central hub 74. (Collins ¶250; EX1004[Aboul-Hosn] 17:1-2.)



(Collins ¶250; EX1001[’728 patent] FIG. 4, annotated (left); EX1004[Aboul-Hosn] FIG. 7B, annotated (right).)

In addition, FIG. 7B demonstrate that the “rotor hub ha[s] a distal end extending distally beyond a most distal portion of the at least one blade.” Specifically, in FIG. 7B, the distal end of the rotor hub (71), extends more distally than any of the blades (72).

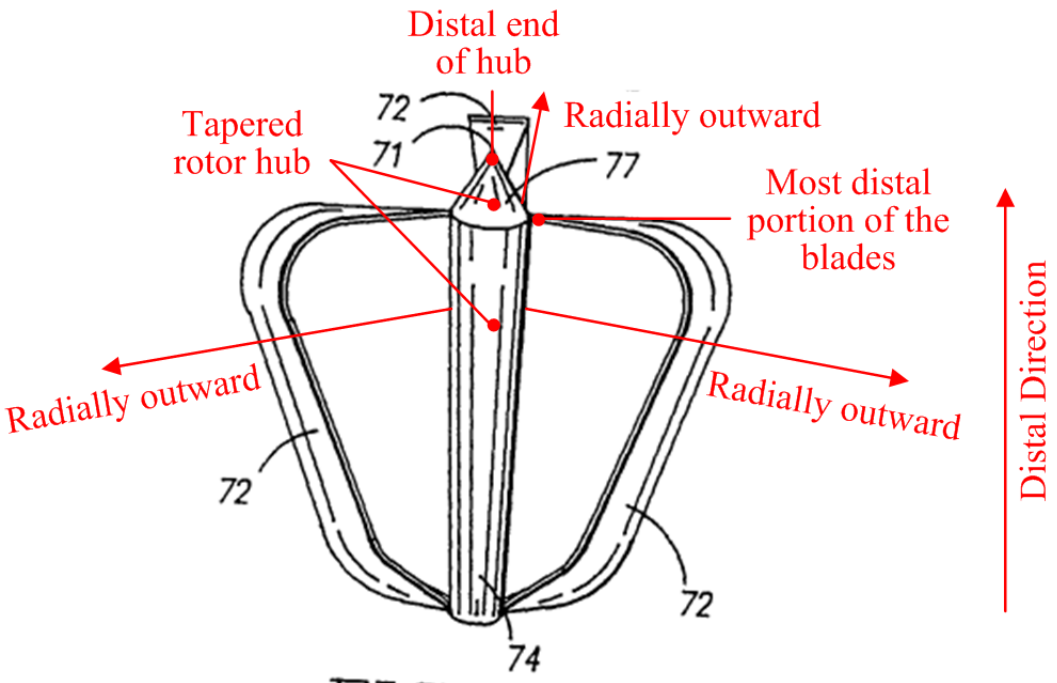


FIG. – 7B

(Collins ¶251; EX1004[Aboul-Hosn] FIG. 7B, annotated.)

Indeed, as Dr. Collins explains, the claimed rotor configuration (i.e. having a tapered hub, blades extending from the surface of the hub) was conventional. (*Id.* ¶252.) Aboul-Hosn also recognizes that the specific configuration of the rotor is not limited, and that a variety of suitable configurations may be used. (*Id.*; EX1004[Aboul-Hosn] 19:28-31.)

Moreover, pump 50 of Aboul-Hosn includes a housing body 52 that houses the rotor 70. (Collins ¶255; EX1004[Aboul-Hosn] 12:12-14, 12:31-31:1, 13:7-15.) Aboul-Hosn further discloses that "[t]he housing body 52 illustrated in this embodiment of the present invention is generally cylindrical-shaped and includes a longitudinally and concentrically aligned inlet tube 55" where "[a] rotor 70 may be

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

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

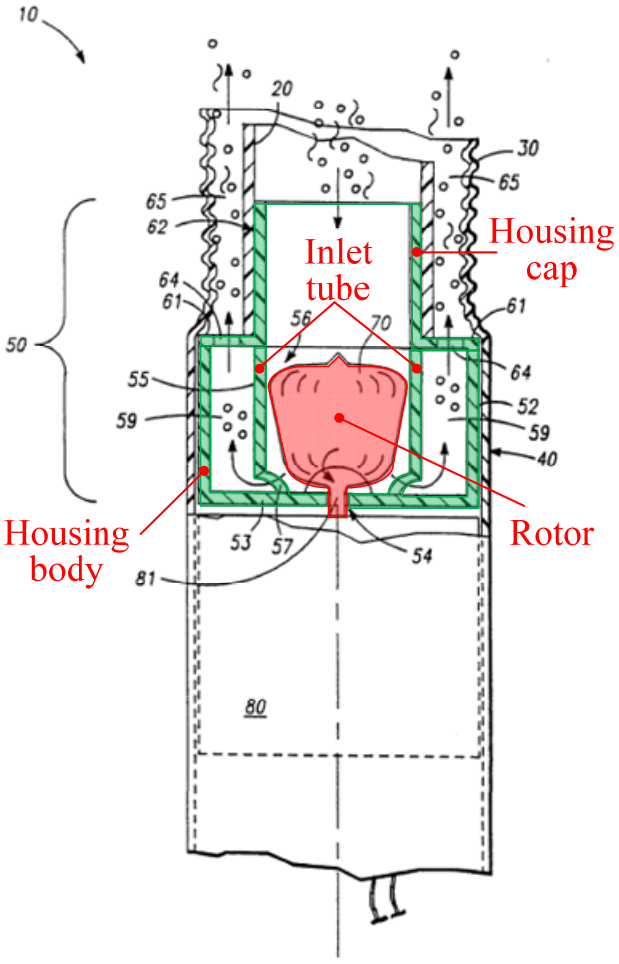


FIG.—2

(Collins ¶256; EX1004[Aboul-Hosn] FIG. 2, annotated.)

Thus, the inlet tube 55 forms the "rotor shroud." (Collins ¶257.) Moreover, the housing body 52 and the housing cap 60 further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "rotor shroud." (I*d.*;

EX1004[Aboul-Hosn] 13:3-4.). This "rotor shroud" is "partially disposed" around the rotor.

Aboul-Hosn discloses this limitation. (Collins ¶258.)

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

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 ¶¶260-62.)

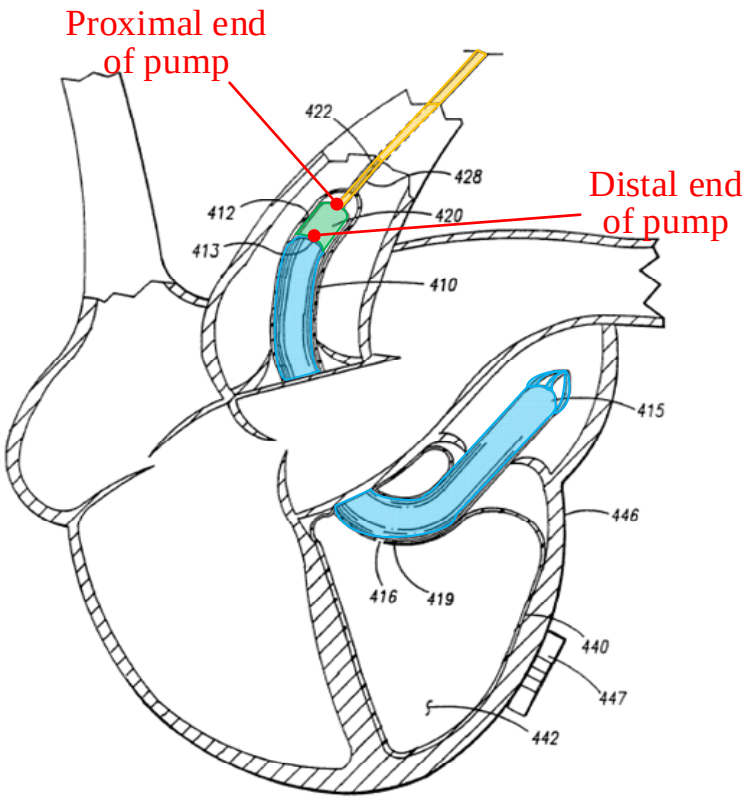


FIG.–23

(Collins ¶261; 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.* ¶¶ 260-62.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶263.)

e) *"a purge lumen extending through the catheter;"*

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." (*Id.* ¶¶264-265; EX1004[Aboul-Hosn] 29:17-19.)

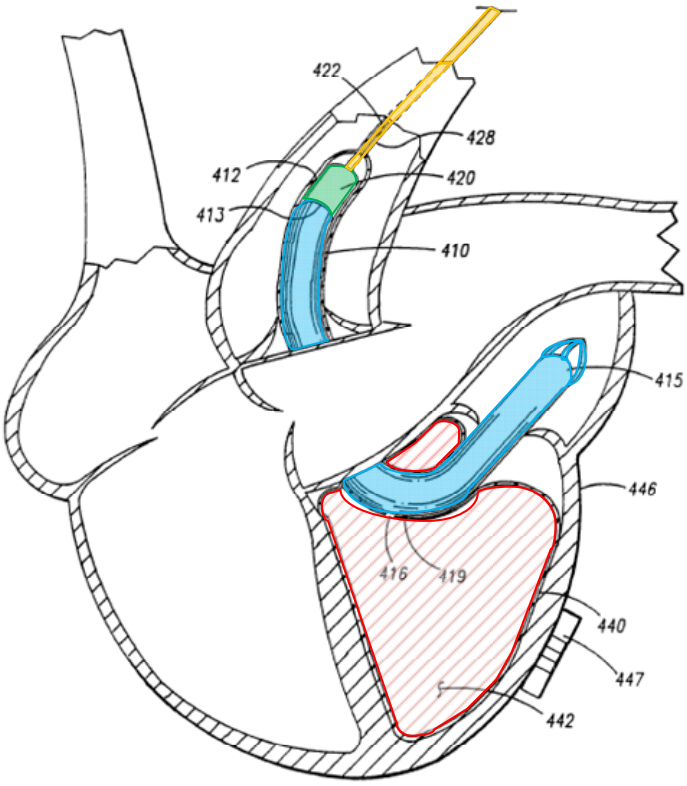


FIG.–23

(Collins ¶265; 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." (Collins ¶266; EX1004[Aboul-Hosn] 29:19-25, emphasis added.) Specifically, Aboul-Hosn discloses using such fluid to lubricate the "drive unit 80 that may be used in accordance with the present fluid control and delivery system." (EX1004[Aboul-Hosn] 20:16-29.) Aboul-Hosn discloses that the fluid is a

"biocompatible lubricating fluid," for example a 40% dextrose solution. (EX1004[Aboul-Hosn] 21:1-3.) Dextrose is a commonly used biocompatible fluid to lubricate mechanical parts of the pump. (Collins ¶269.) Further, a POSITA would understand that the "biocompatible lubricating fluid" of Aboul-Hosn is the "purge fluid" as disclosed by the '437 patent because it serves the same purposes. (*Id*. ¶¶268-270.)

The '437 patent discusses that the "purge fluid" serves the dual purpose of "thwart[ing] the ingress of blood past the radial seal 64, 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['437 patent] 12:30-46.) The biocompatible lubricating fluid of Aboul-Hosn serves the same purpose. (Collins ¶¶269-70.) 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*. ¶¶267-270.)

Thus, Aboul-Hosn discloses this limitation. (Collins ¶271.)

f) *"a cannula coupled to a distal end of the intravascular blood pump,"*

As shown in FIG. 23 reproduced 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 ¶274-276; EX1004[Aboul-Hosn] 30:27-28.)

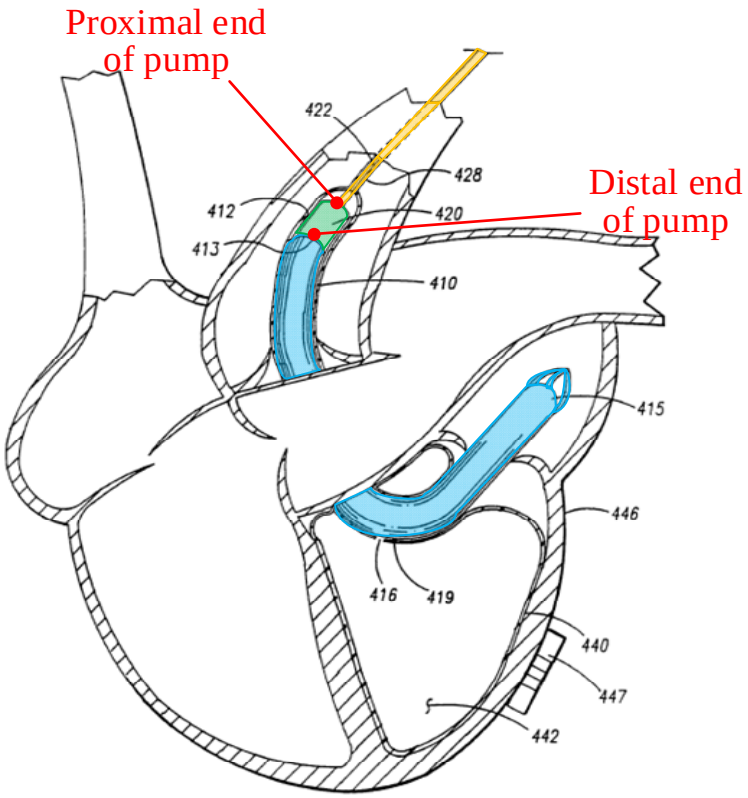


FIG.–23

(Collins ¶274; EX1004[Aboul-Hosn] FIG. 23, annotated.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶277.)

g) *"a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula, the proximal portion of the cannula disposed about a distal end of the rotor shroud,"*

"[A] portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula" is disclosed by Aboul-Hosn. (Collins ¶281.) Pump 50 of Aboul-Hosn includes a housing body 52 that houses

the rotor 70. (Collins ¶257; EX1004 [Aboul-Hosn] 12:12-14, 12:31-31:1, 13:7-15.)

Aboul-Hosn requires "[a] clearance between the inlet tube 55 profile and the rotor 70 should exist to permit the rotor 70 to rotate without contacting the walls of the inlet tube 55." (*Id.* 15:26-16:1.) Thus, the inlet tube 55 forms the "rotor shroud." (Collins ¶257.) Moreover, the housing body 52 and the housing cap 60 further may form a unitary body such that the inlet neck 62 and inlet tube 55 together forms the "rotor shroud." (*Id.*; EX1004[Aboul-Hosn] 13:3-4.) As shown above in FIG. 2 of Aboul-Hosn, the proximal end of the cannula 20 is coupled to the inlet neck 62. (EX1004 [Aboul-Hosn] 13:24-25.) As such, where the inlet neck 62 and inlet tube 55 together form the "rotor shroud," an outer diameter of the "rotor shroud" matches the inner diameter of the cannula 20 at its proximal end where it couples to the inlet neck 62. (Collins ¶¶279-281.)

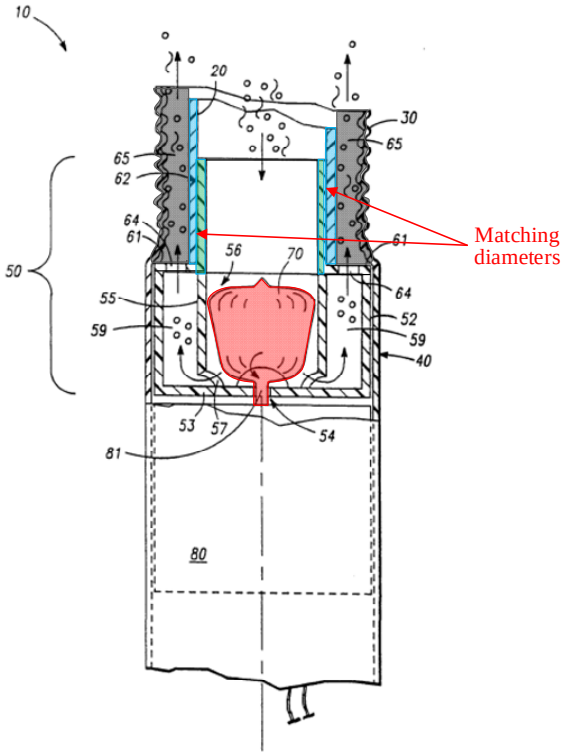


FIG.—2

(Collins ¶279; EX1004[Aboul-Hosn] FIG. 2, annotated.)

"The proximal portion of the cannula disposed about a distal end of the rotor shroud" is also disclosed by Aboul-Hosn. (Collins ¶281.) 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. (*Id.* ¶280.)

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

h) *"one or more first ports and one or more second ports establishing fluid communication between a cannula lumen 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 discussed above Section VII.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 ¶283.) 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 ¶¶284-291; 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".)

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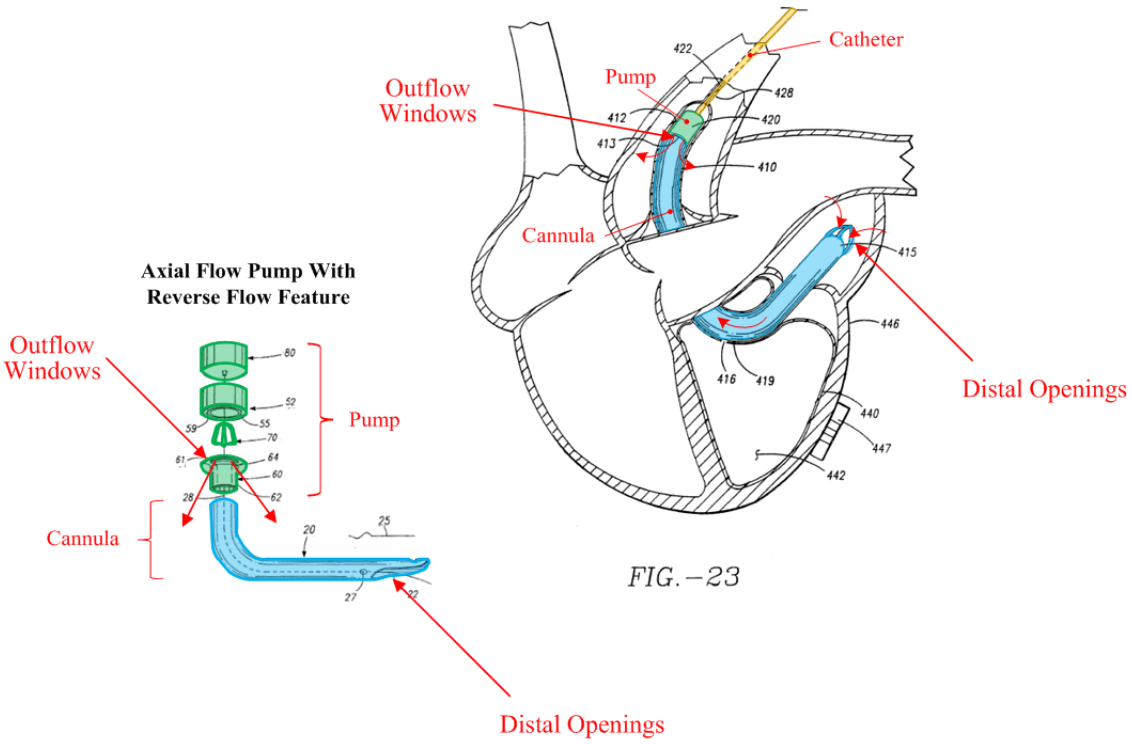

Axial Flow Pump With Reverse Flow Feature
Outflow Windows
Pump
Cannula
Distal Openings
Catheter
Outflow Windows
Pump
Cannula
Distal Openings

FIG.–23

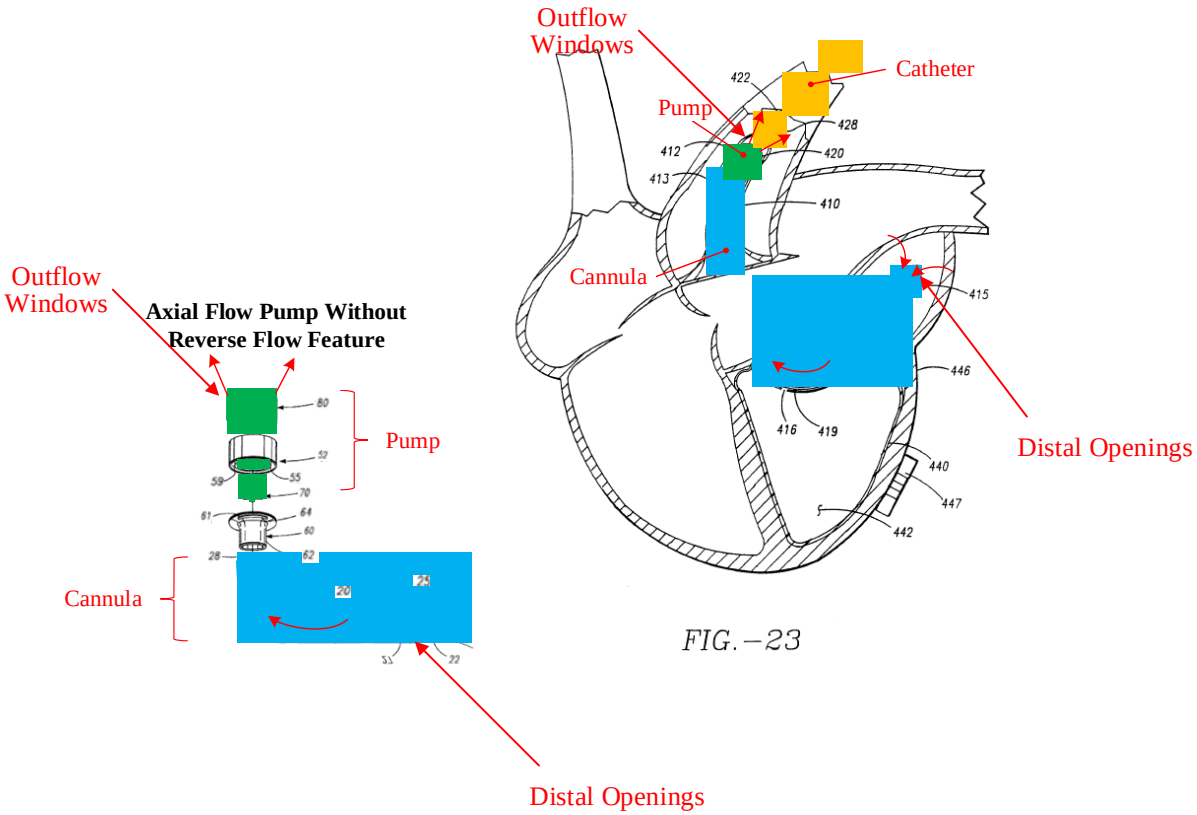

Outflow Windows
Axial Flow Pump Without Reverse Flow Feature
Pump
Cannula
Distal Openings
Outflow Windows
Catheter
Pump
Cannula
Distal Openings

FIG.–23

(Collins ¶290; EX1004[Aboul-Hosn] FIGS. 3, 23, annotated.)

When the pump 420 is actuated, 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 during operation of the blood pump 420. (Collins ¶285.) Moreover, as shown in FIGS. 3 and 23, Aboul-Hosn discloses that for both the axial flow pump with or without the reverse flow feature, the distal opening 22 and openings 27 are located at the distal region of the cannula, whereas the outflow windows are located at the opposite end of the blood pump 420 adjacent the rotor 70 within the housing body 62. (*Id.* ¶¶284-291.)

Thus, when 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," where the one or more first ports and the one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, and at least one first port is in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port. (*Id.* ¶¶284-291.)

Thus, Aboul-Hosn discloses this limitation. (*Id.* ¶292.)

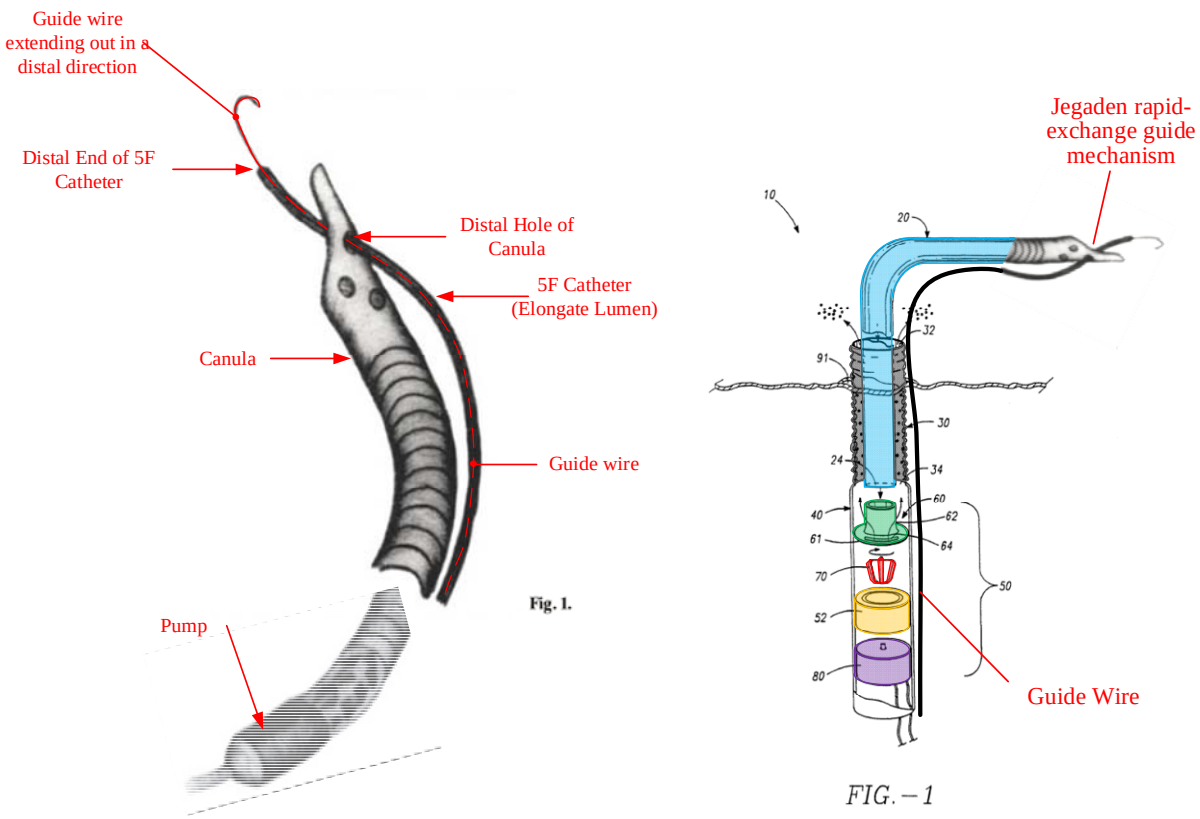
i) *"an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen,"*

The ’437 patent does not specify what it means to be an *elongate* lumen, much less an elongate lumen *associated with* the cannula. (Collins ¶293.) Notwithstanding, Aboul-Hosn in view of Jegaden, discloses the “elongate lumen associated with the cannula” as recited by this limitation in the same manner as the ’437 patent. (*Id.*)

Aboul-Hosn discloses how a blood pump system may be placed in a desired location within a patient by using a guide wire that passes through an elongate lumen. (Collins ¶295; EX1004[Aboul-Hosn] 11:24-28, 17:19-21, 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 technique. (Collins ¶¶295-98; EX1004[Aboul-Hosn] 11:24-26, 17:8-22, 20:23-26, 24:7-14.) 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, FIG. 1 does not illustrate the rotor hub 70 having 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 ¶298.)

This is the same rapid-exchange mechanism disclosed by Jegaden and would also include an elongate lumen according to this claim element. (Collins ¶¶300-01.) 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 ¶¶302-03; 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. (*Id*. ¶304)

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. (Collins ¶305; EX1004[Aboul-Hosn] 11:24-26.)



(Collins ¶¶302-305)

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 ¶303.)

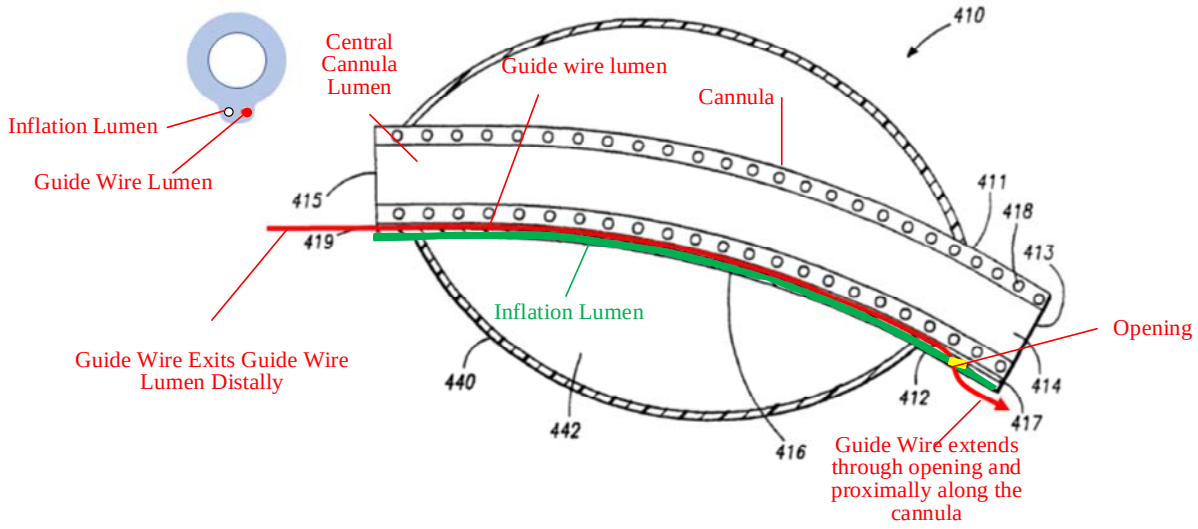
A POSITA would have been motivated to apply Jegaden's teachings of extending a guide wire and catheter through the opening 27 at the distal end of Aboul-Hosn's cannula to guide Aboul-Hosn's pump using the rapid-exchange technique at least because: (1) both Jegaden and Aboul-Hosn are directed to the placement of intravascular blood pumps; (2) both expressly discloses extending a guide wire through a 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.* ¶¶206-216, 300-305; 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 ¶308; 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 functions of the various lumens of the intravascular blood pump can be used for a variety of purposes, including delivering fluid and guide wires. (Collins ¶¶306-310; EX1004[Aboul-Hosn] 27:31-28:18, 29:19-25.) Indeed, using lumens interchangeably for fluid or guide wires was well-known at the time. (Collins ¶140; U.S. Patent No. 6,544,216 to Sammler (EX1018, "Sammler") 5:9-17.)

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 ¶307.) 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.* ¶308.)



(Collins ¶223; EX1004[Aboul-Hosn] FIG. 20, annotated.)

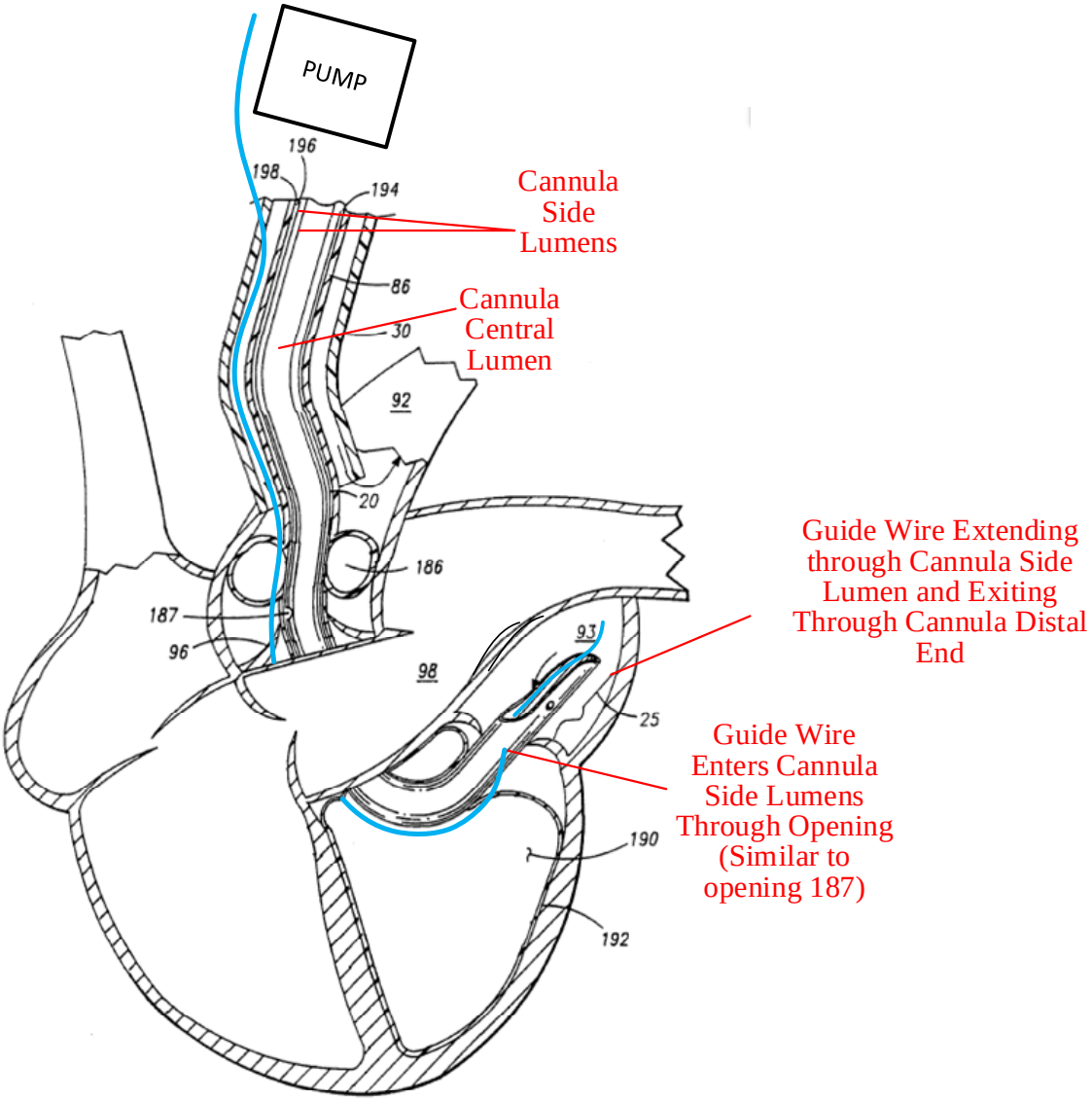


FIG.–19

(Collins ¶308; 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 ¶308; 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, 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 ¶309.)

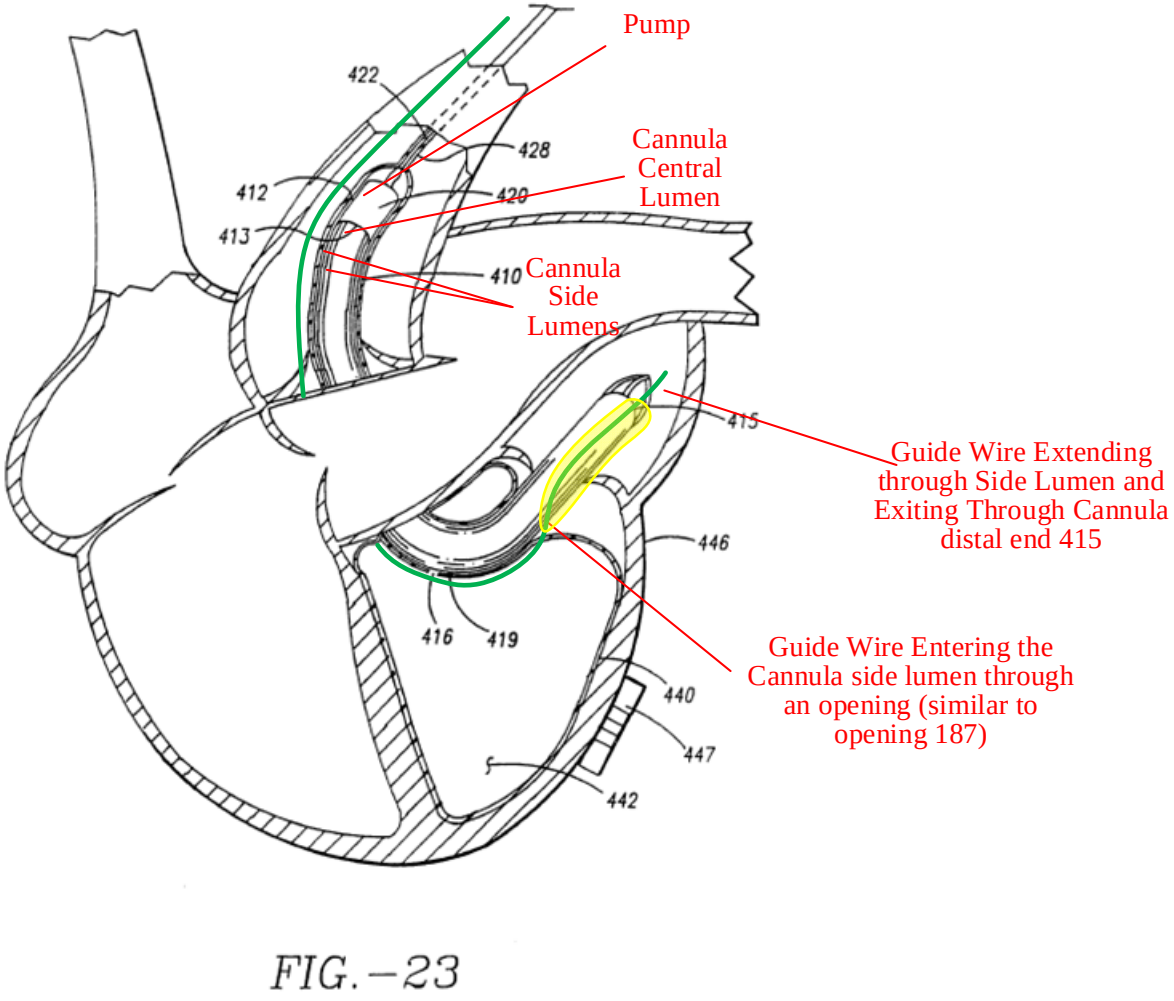


FIG.–23

(Collins ¶309; EX1004[Aboul-Hosn] FIG. 23, annotated.)

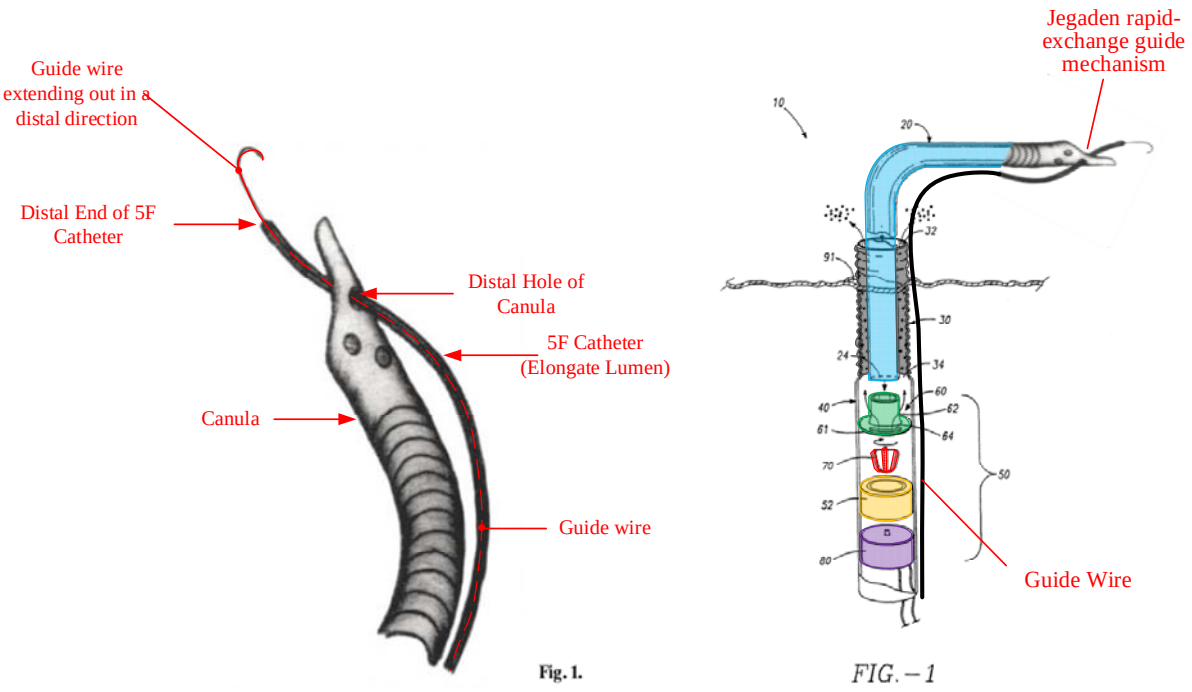
As discussed above, while over-the-wire and rapid-exchange are interchangeable guidance techniques, there were known advantages of using rapid-exchange, compared to over-the-wire.. (Collins ¶¶99-100, 310.) Rapid-exchange allows the procedure to be carried out by a single person instead of two as rapid-exchange 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 as such, 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 ¶¶310.)

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 ¶¶303, 306; 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 ¶¶303-311.) Thus, Aboul-Hosn in view of Jegaden, discloses this limitation. (*Id*.)

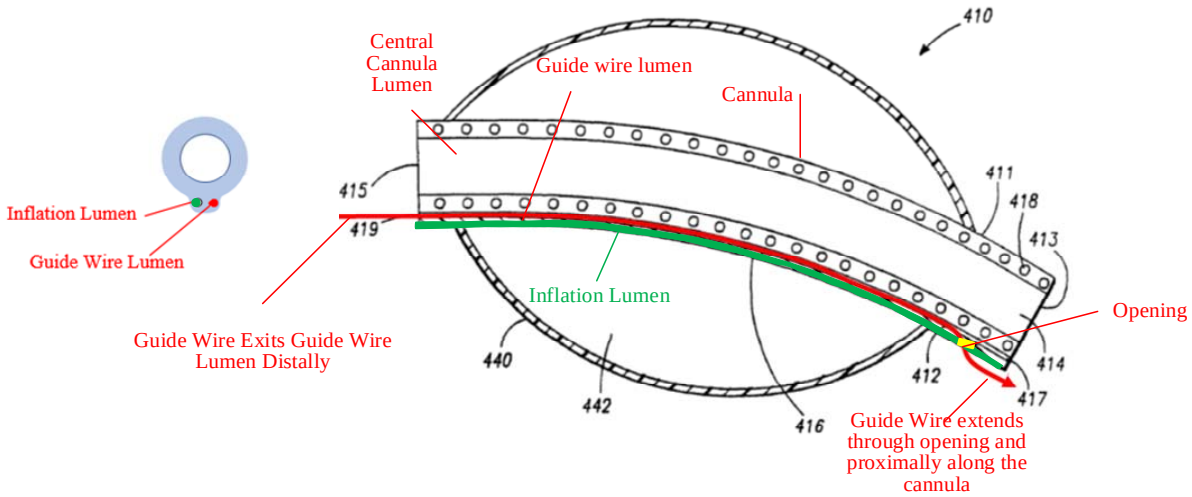
j) *"the elongate lumen is sized smaller cross sectionally than the cannula lumen,"*

Aboul-Hosn in view of Jegaden discloses this limitation. (Collins ¶¶312-16.) 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. (*Id.* ¶313.) 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*.¶314)



(Collins ¶¶313-14.)

With respect to the side lumens within the cannula, these lumens must have a smaller cross section than the cross section of the cannula lumen because they are formed within the sidewall of the cannula itself, as shown below in FIG. 20. (Collins ¶313.)



(Collins ¶313; 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 ¶315.) 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 ¶316.)

k) *"both the elongate lumen and the cannula lumen not extending through the rotor huh (sic);"*

This limitation is a characteristic feature of a rapid-exchange guide mechanism applied intravascular blood pumps, and is disclosed by Aboul-Hosn in view of Jegaden. (Collins ¶317.)

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.* ¶¶318-20.) 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.*)

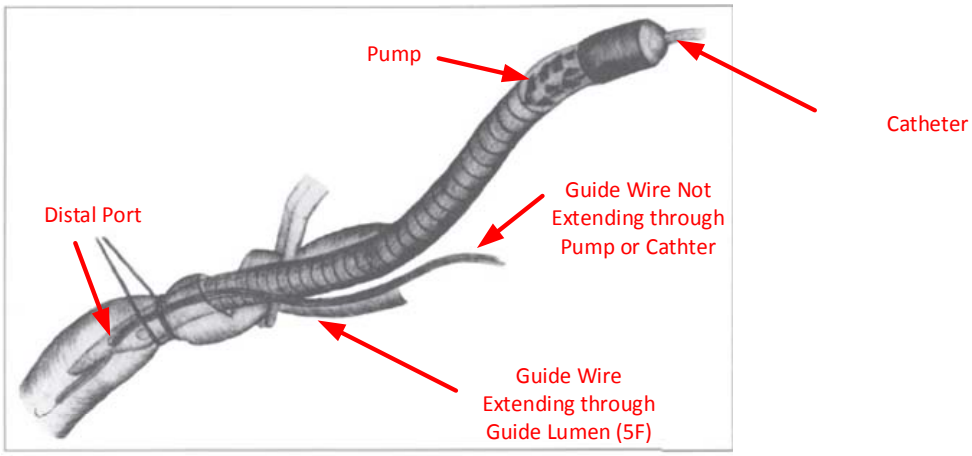


Fig. 2.

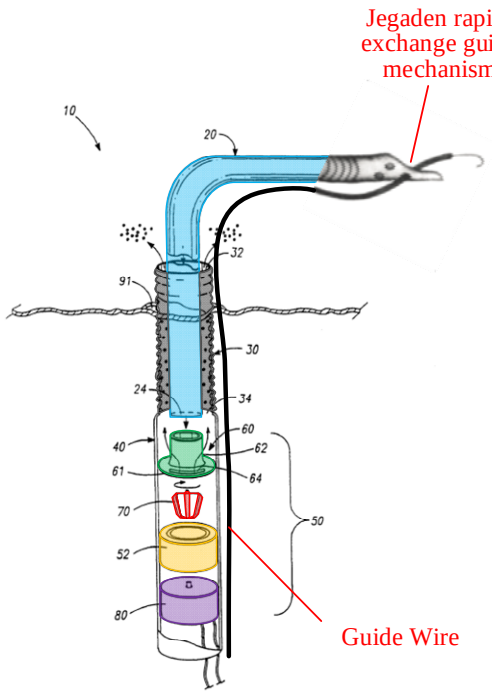


FIG.—1

(*Id.*)

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.*; *see also* EX1033[Jegaden] 61-62)

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.* ¶320.)

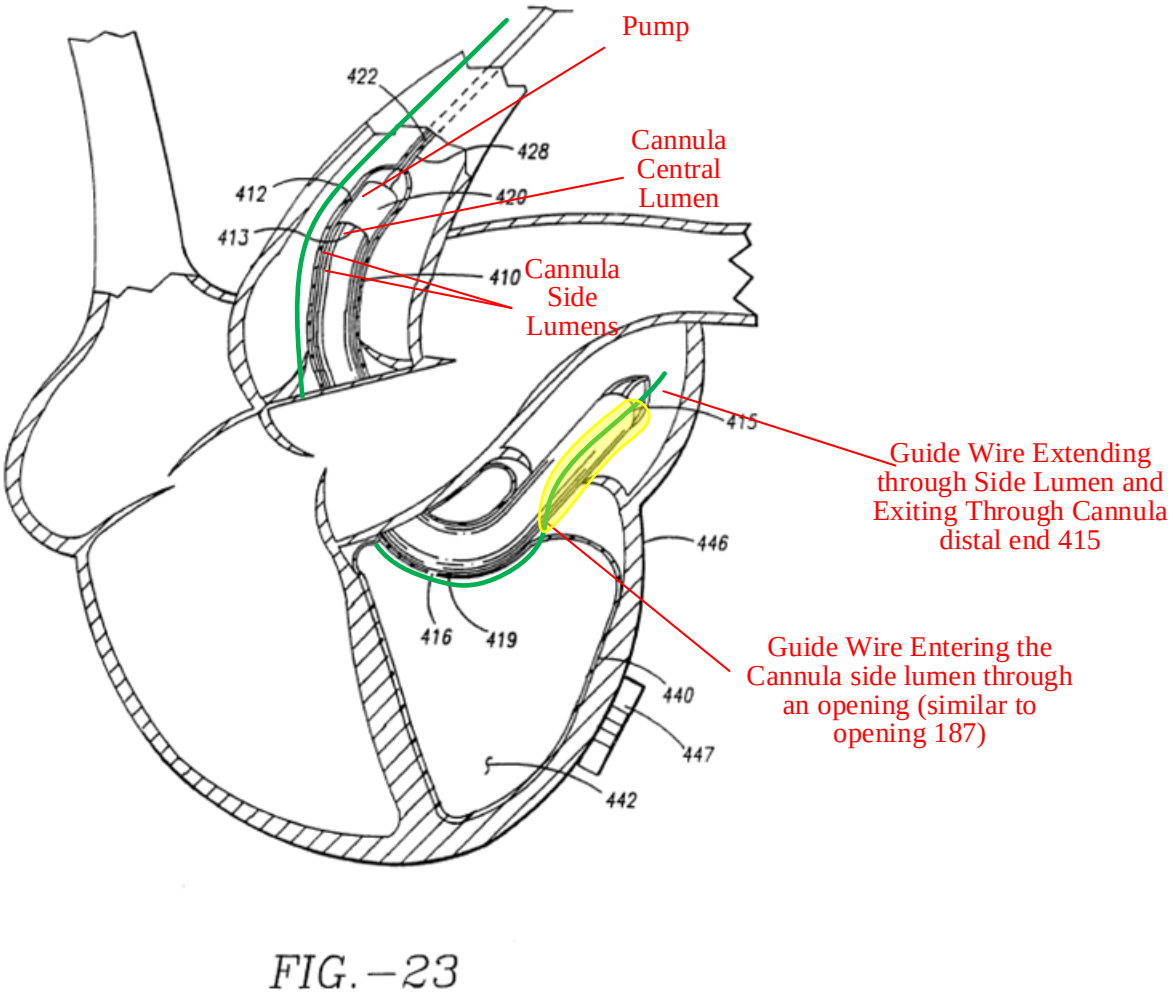


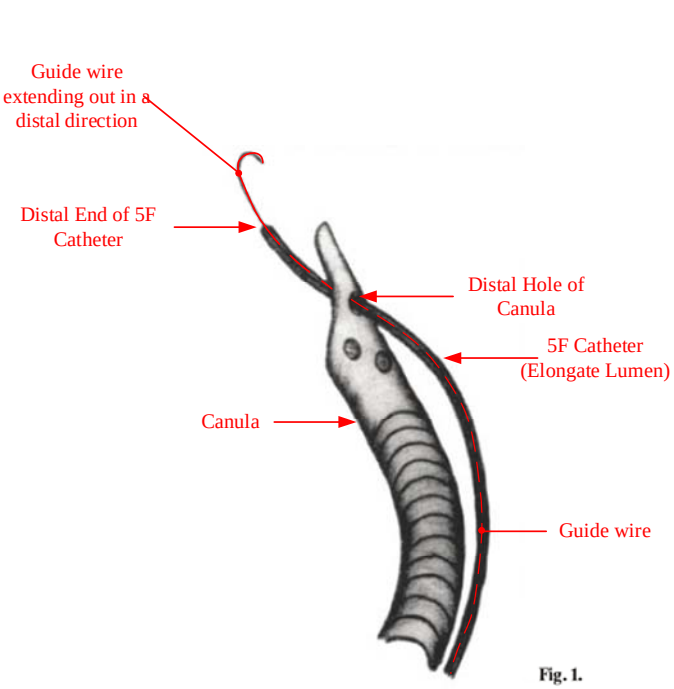
FIG.–23

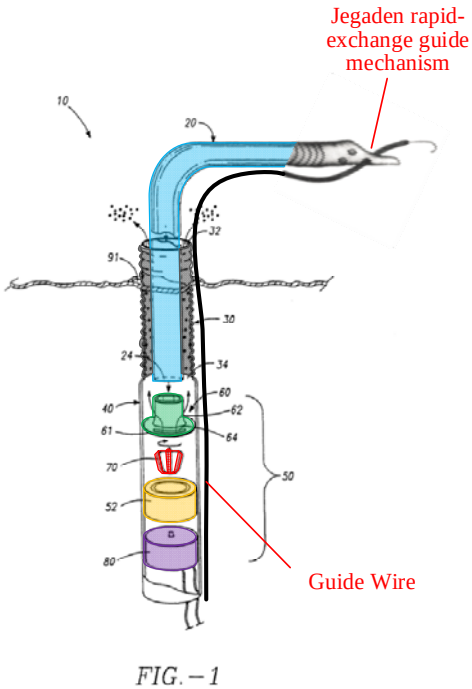
(Collins ¶320; EX1004[Aboul-Hosn] FIG. 23, annotated.)

Thus, Aboul-Hosn in view of Jegaden, discloses this limitation. (*Id.* ¶323.)

l) *"the elongate lumen adapted to guide the guide wire through a distal end of the intravascular blood pump system, the elongate lumen is at least partially disposed within an outer surface of the cannula;"*

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 through opening 27 at the distal region of the cannula or by passing a guide wire through an opening in the cannula and extending through an existing side lumen within the cannula and exiting the distal end of the cannula, as disclosed by Aboul-Hosn and Jegaden. (Collins ¶¶326-27.) 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 FIG. 1 of Jegaden and FIGS. 1 and 23 of Aboul-Hosn, below. (*Id.*)





(Collins ¶¶320, 326, 335.)

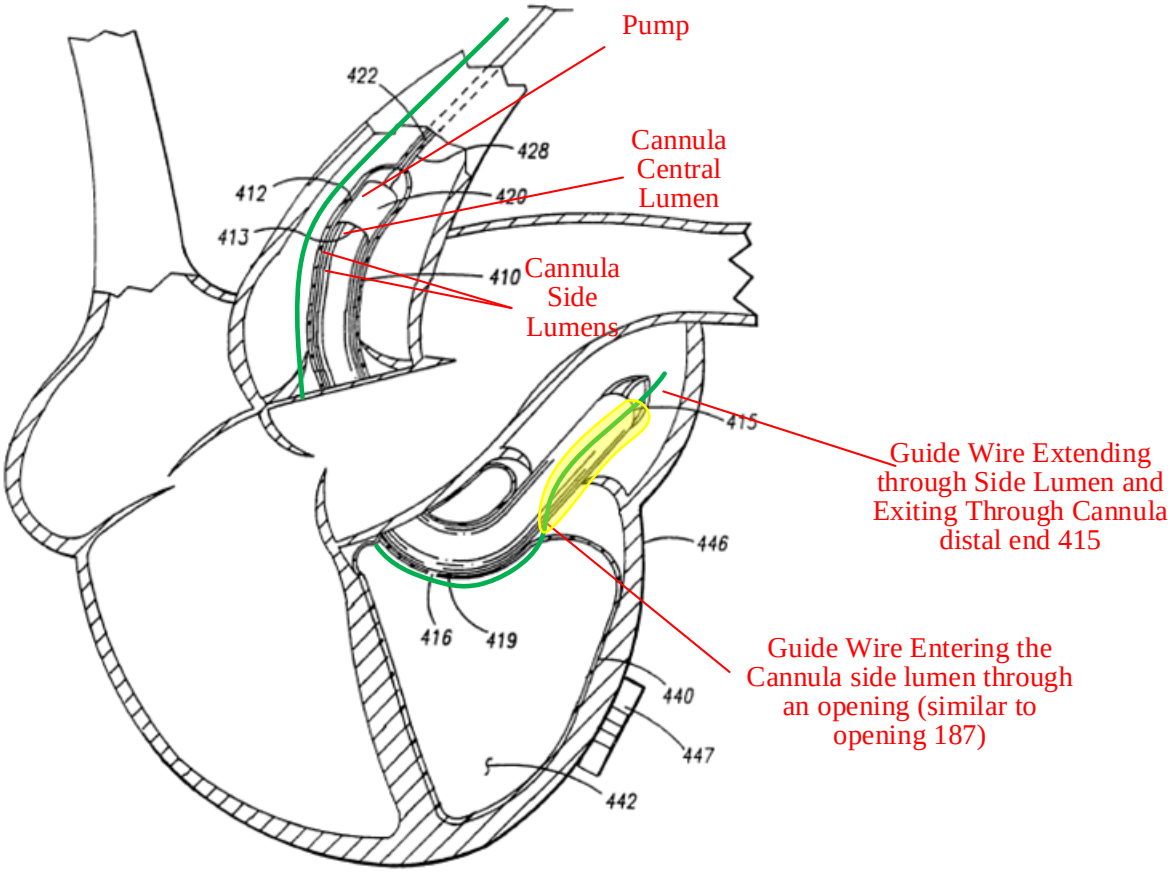


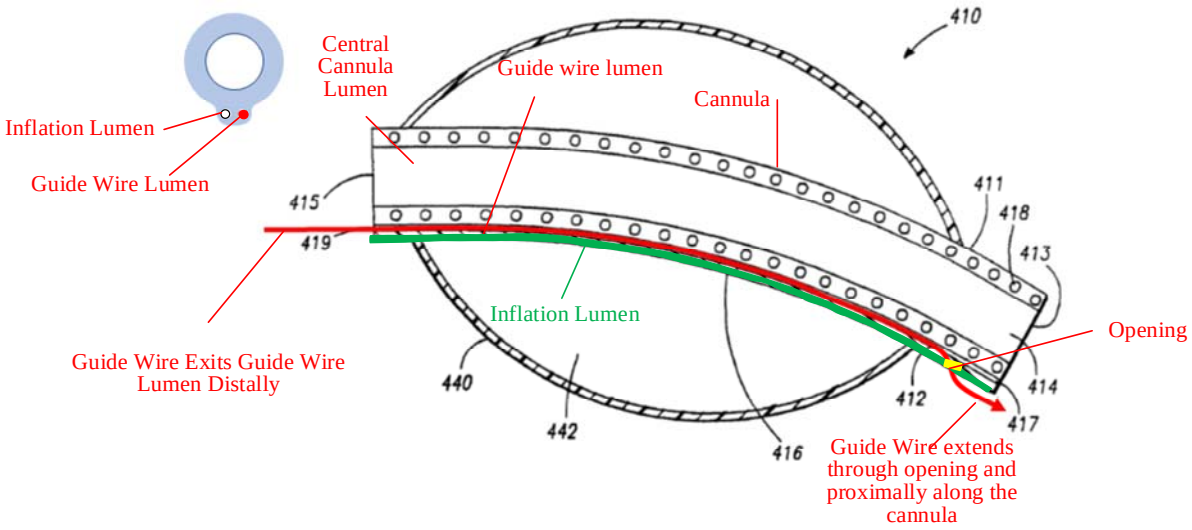
FIG.–23

(Collins ¶327; 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 ¶327.)

Moreover, as previously discussed in Section X.A.1(i) and shown in FIG. 23 above, 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. (*Id.* ¶329.) As shown in FIG. 20, below, Aboul-Hosn discloses that these lumens are at least partially disposed within an outer surface of the cannula. (*Id.* ¶¶330-31; EX1004 [Aboul-Hosn] 28:10-12: "[t]he ports and passageways … may be formed adjoining to or concentric with cannula 20.")



(Collins ¶331; EX1004 [Aboul-Hosn] FIG. 20, annotated.)

Thus, Aboul-Hosn in view of Jegaden, discloses this limitation. (Collins ¶332.)

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

Aboul-Hosn discloses a multilumen catheter coupled to the proximal end of the pump to continuously deliver purge fluid to the i pump. (Collins ¶334; EX1004[Aboul-Hosn] 20:16-19, 29:19-25.) 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 ¶¶66-72.) Figure 14-2 of Wampler,

reproduced below, shows a schematic of the Hemopump with its purge fluid system.

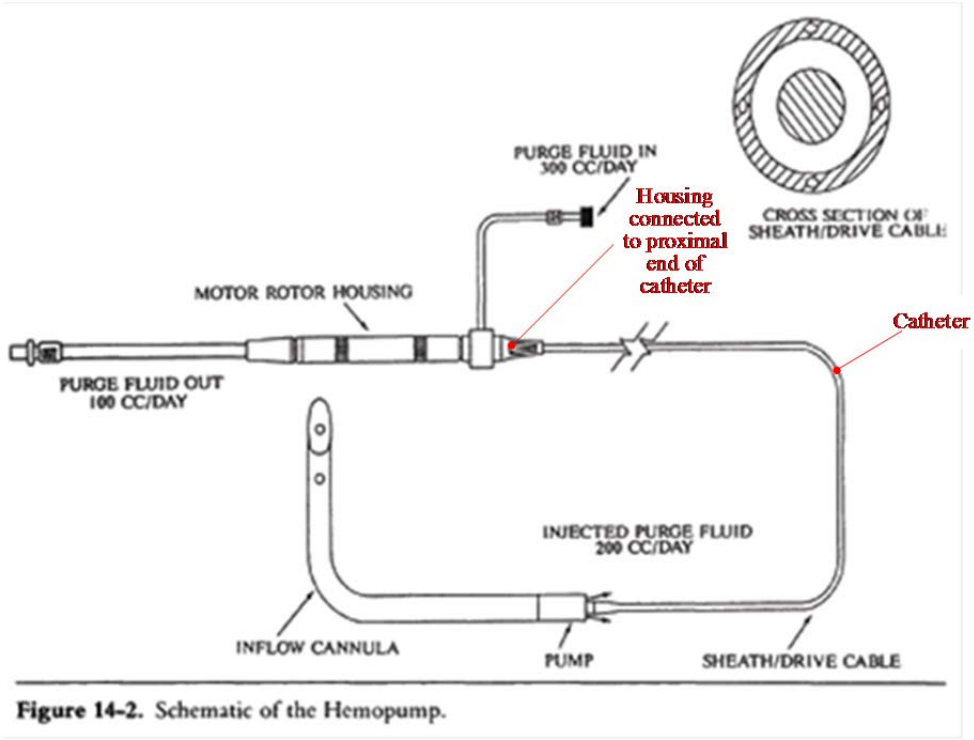


Figure 14-2. Schematic of the Hemopump.

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

As disclosed by Wampler in describing Figure 14-2, a "roller pump that controls the delivery and collection rates of the purge fluid lubricant" has a "motor rotor housing" connected to a proximal end of the catheter (i.e. the sheath/drive cable) through which the purge fluid flows. (Collins ¶336; EX1007[Wampler] 233-34.) Wampler figure 14-2 further 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. (*Id.* ¶173) 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. (*Id.* ¶¶266, 337; EX1004[Aboul-Hosn] 21:1-3, 29:19-23.)

To provide the "continuous infusion of dextrose" to the blood pump as taught by Aboul-Hosn, it would have been POSITA that Aboul-Hosn used a purge fluid pump having a pump housing and 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 ¶¶337, 345.) 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.* ¶346; 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 ¶¶338, 347.)

As a result, Aboul-Hosn in view of Wampler discloses this limitation. (Collins ¶338.)

n) "*and 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, the housing remains outside the patient while providing left-heart support;*"

As discussed above in Section X.A.1(m), Aboul-Hosn in view of Wampler discloses this limitation. (Collins ¶¶339-48.)

o) "*wherein the method for providing left-heart support comprises the steps of passing the guide wire through the patient's femoral artery such that a distal end of the guide wire is positioned in the left ventricle of the patient's heart;*"

This limitation is simply the recitation of the conventional step of delivering a guide wire through the circulatory system to the left ventricle of the heart. Aboul-Hosn describes that the guide wire is inserted to the desired location before the cannula is positioned (using the guide wire). (Collins ¶349; EX1004[Aboul-Hosn] 22:12-14 ("The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20.").) Aboul-Hosn further describes that the guide wire may be advanced to a specific location within the patient, including any heart chamber or blood vessel or artery. (Collins ¶350; EX1004[Aboul-Hosn] 11:8-11, 11:24-28, 22:10-14.)

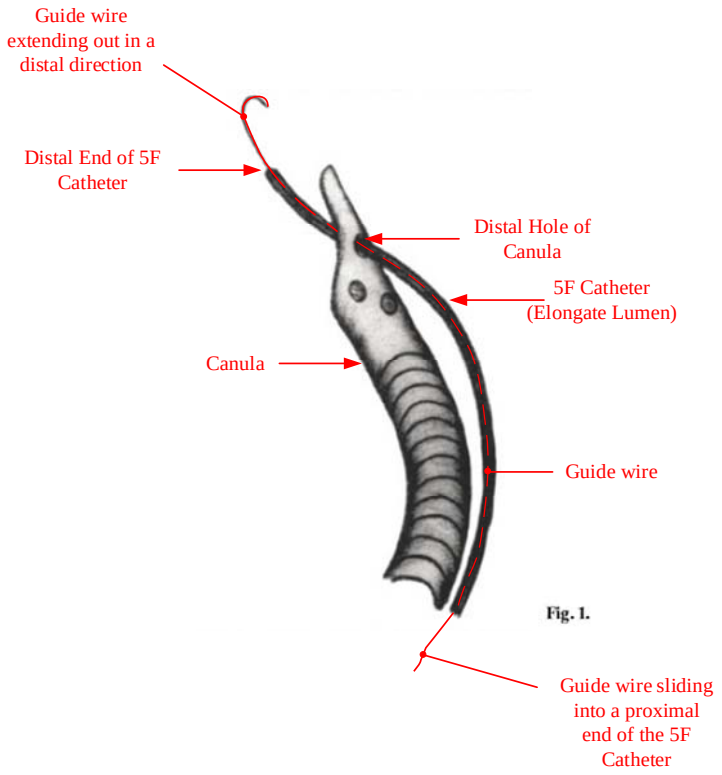
One of the locations in which Aboul-Hosn positions the distal tip of the cannula is the left ventricle. (Collins ¶354; EX1004[Aboul-Hosn] 26:10-13,

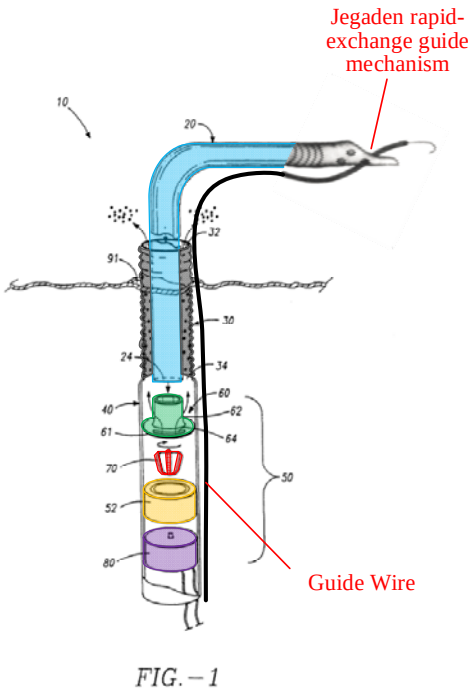
29:31-30:2. ("Meanwhile, the stabilization cannula 411 may be positioned within a ventricle or atrium. After proper positioning, a pump may be activated and take over the left ventricle function.") When the cannula is delivered to the left ventricle, the guide wire would conventionally be delivered to that ventricle such that the distal end of the guide wire is in the left ventricle. (Collins ¶354.) The cannula would then follow. (*Id*.)

Moreover, as discussed above (Section VII.A), passing the cannula and blood pump through the femoral artery was a well-known technique, the same technique used by the hemopump and other intravascular blood pumps. (Collins ¶351.) Jegaden also describes inserting a Hemopump and guidewire through a femoral insertion. (*Id.*; EX1033[Jegaden] 61-62.) The guide wire and the 5F catheter are passed through the distal hole of the cannula and introduced into the femoral artery up to the aorta. (Collins ¶351.) Guided by the vascular catheter, the cannula is then introduced into the femoral artery and is pushed into the aorta. (*Id.*)

p) "*placing the guide wire through both the cannula and the elongate lumen, wherein the guide wire enters the intravascular blood pump system through one end of the elongate lumen and exits the intravascular blood pump system through an opposite end of the elongate lumen, the guide wire not passing through the rotor hub or the catheter;*"

This limitation is a characteristic feature of a rapid-exchange guide mechanism as applied to intravascular blood pumps, and is disclosed by Aboul-Hosn in view of Jegaden. (Collins ¶357.) As previously discussed in Section X.A.1(i) and as Dr. Collins shows below, Aboul-Hosn's intravascular blood pump can be placed using the rapid-exchange technique by using a catheter guide wire (such as Jegaden's 5F catheter) extending through Aboul-Hosn's cannula opening 27 (superimposed with Jegaden's distal end to show the 5F catheter passing through the distal opening of Aboul-Hosn's cannula), or by passing the guide wire through side lumens of the cannula. (*Id.* ¶¶358-59.)


Guide wire extending out in a distal direction
Distal End of 5F Catheter
Distal Hole of Canula
5F Catheter (Elongate Lumen)
Canula
Guide wire
Guide wire sliding into a proximal end of the 5F Catheter
Fig. 1.


Jegaden rapid-exchange guide mechanism
Guide Wire
FIG. – 1

(*Id.* ¶358.)

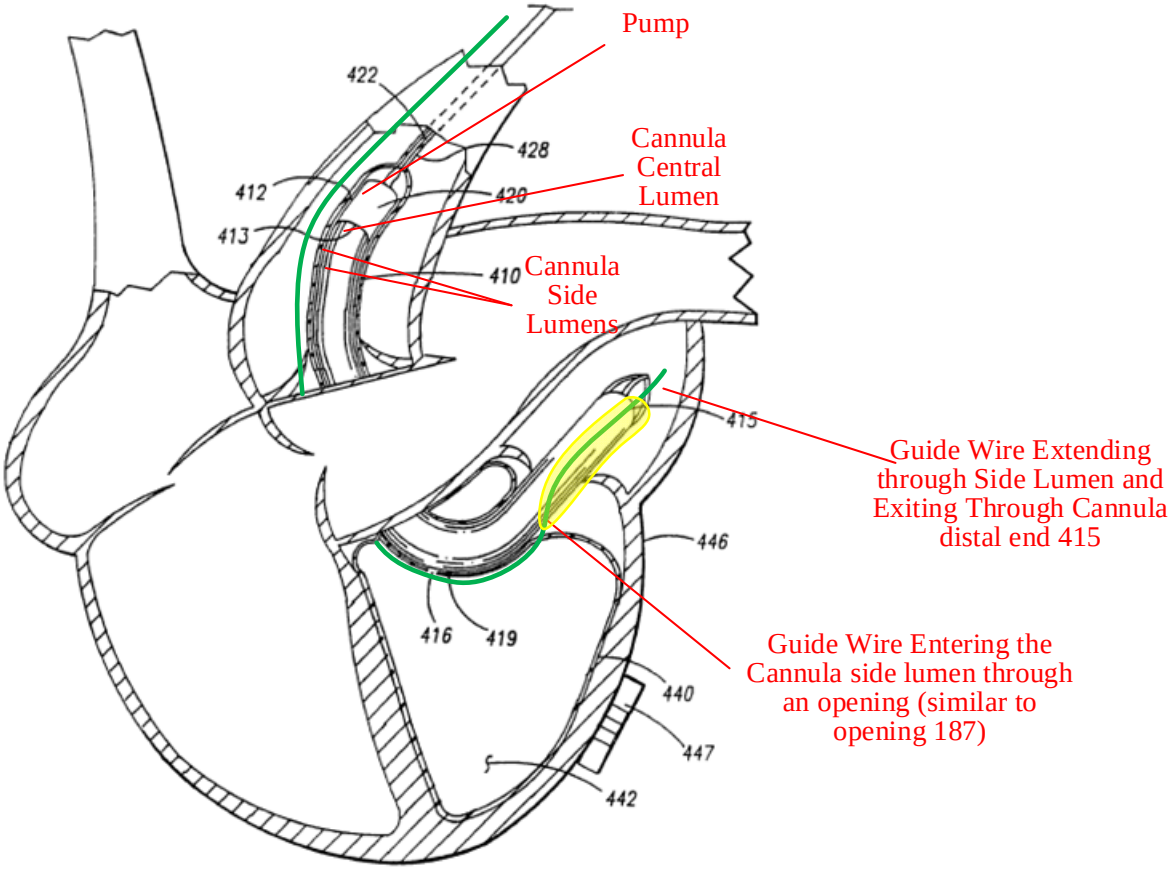


FIG.–23

(Collins ¶359; EX1004[Aboul-Hosn] FIG. 23, annotated.)

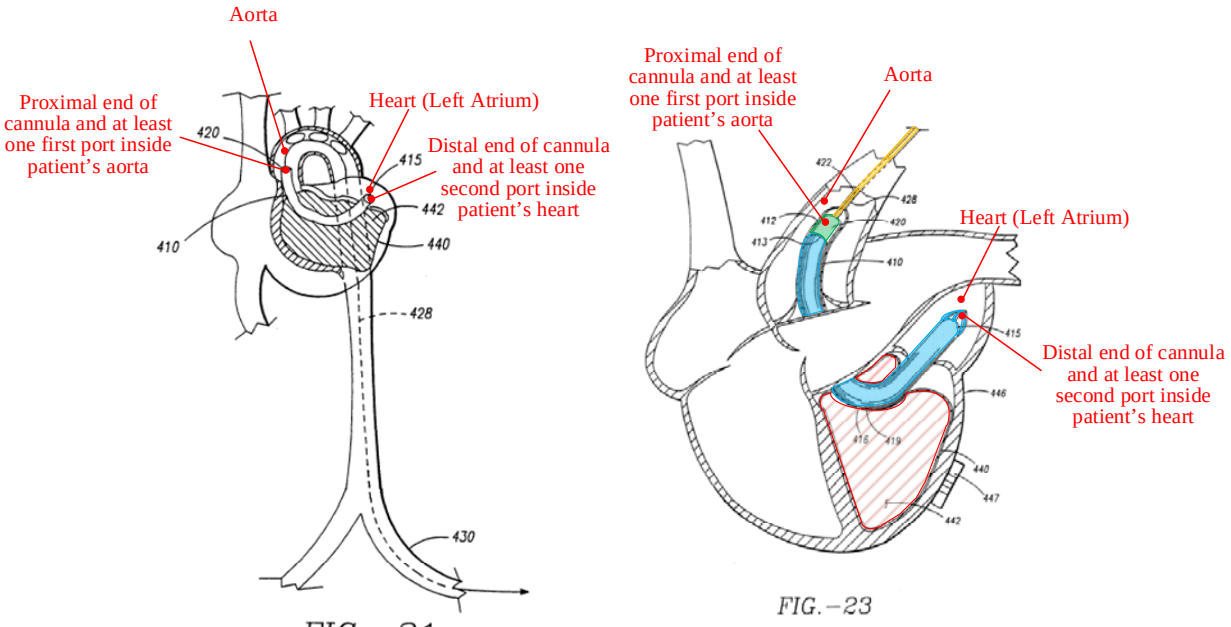
In either rapid-exchange configuration, the guide wire enters the intravascular blood pump system through one end of the elongate lumen, and exits through an opposite end as shown in FIG. 1 of Aboul-Hosn and FIG. 1 of Jegaden, above (using the catheter guide wire for rapid-exchange), and FIG. 23 of Aboul-Hosn, above (using the side lumens of the cannula for rapid-exchange). (Collins ¶¶358-59.) Moreover, as discussed in Section X.A.1.(k), in either rapid-exchange configuration, the cannula and elongate lumen to do not extend through central

rotor hub. (*Id.* ¶¶360-61.) Accordingly, the guide wire along with the 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.* ¶362.)

q) *"advancing the cannula into the patient using the guide wire and positioning the cannula across an aortic valve of the patient such that a distal end of the cannula and the at least one second port are positioned in the left ventricle and a proximal end of the cannula and the at least one first port are positioned in the aorta;"*

Again, this limitation simply recites the conventional step of delivering the blood pump system through the circulatory system to the left ventricle of the heart using the positioned guide wire. (Collins ¶363.) Aboul-Hosn discloses that once the guide wire is positioned, the cannula can be guided into position using the guide wire. (*Id.*; EX1004[Aboul-Hosn] 22:12-16 ("The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28.").)

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 ¶364.)



(Collins ¶364; EX1004[Aboul-Hosn] FIGS. 21 and 23, annotated.)

In this configuration, where the distal end 415 of the cannula extends into the left atrium, 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, and the outflow windows formed in the pump 420 housing (i.e. "the at least one first port") along with the proximal end of the cannula which is connected to the pump 420 are positioned in the aorta. (Collins ¶365.) But, as previously discussed in Section X.A.1(b), Aboul-Hosn discloses the distal end of the cannula, along with the distal opening 22 and openings 27 (i.e. the "at least one second port") may be positioned in the left ventricle to provide left-heart support in the same conventional manner as

disclosed by the ’437 patent. (Collins ¶¶365-366; EX1004[Aboul-Hosn] 26:10-13, 29:31-30:2; EX1001[’437 patent] 20:43-48.)

Thus, Aboul-Hosn discloses this limitation. (*Id* ¶367.)

r) *“passing purge fluid through one of the first and second conduits, through the housing and purge lumen to the intravascular blood pump;”*

This feature recites the conventional use of a purge lumen in blood pumps – passing purge fluid through a tube. (Collins ¶368.) As discussed above in Section X.A.1(e), Aboul-Hosn discloses a purge lumen extending through the catheter, whose purpose is to deliver purge fluid to the blood pump. (*See, e.g.* Collins ¶¶265-66, 371; EX1004[Aboul-Hosn] 20:16-29.)

Moreover, the “through one of the first and second conduits, through the housing” is disclosed by Aboul-Hosn in view of Wampler. (Collins ¶¶344-47.) Again, this limitation merely recites the conventional step of using purge fluid lumen to pass purge fluid to the pump. (*Id.*)

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 ¶369; EX1007[Wampler] 233-34.)

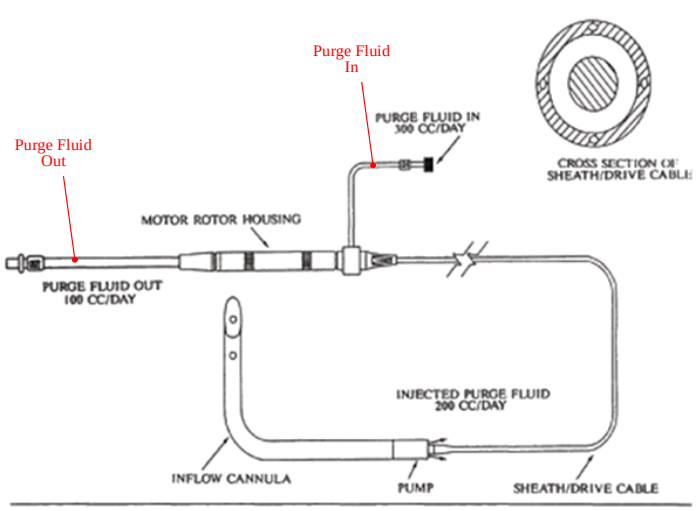


Figure 14-2. Schematic of the Hemopump.

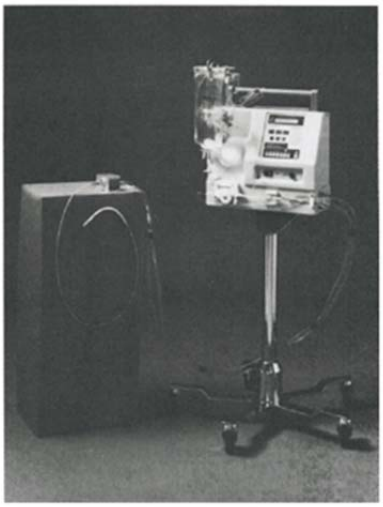


Figure 14-3. Hemopump system.

(Collins ¶368; EX1007[Wampler] FIGS. 14-2, annotated, 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 ¶369; 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 purge fluid is passed through the "Purge Fluid In" conduit through the purge fluid pump within the "Motor Rotor Housing" and towards the pump through one of the purge lumens within the catheter. (Collins ¶369.)

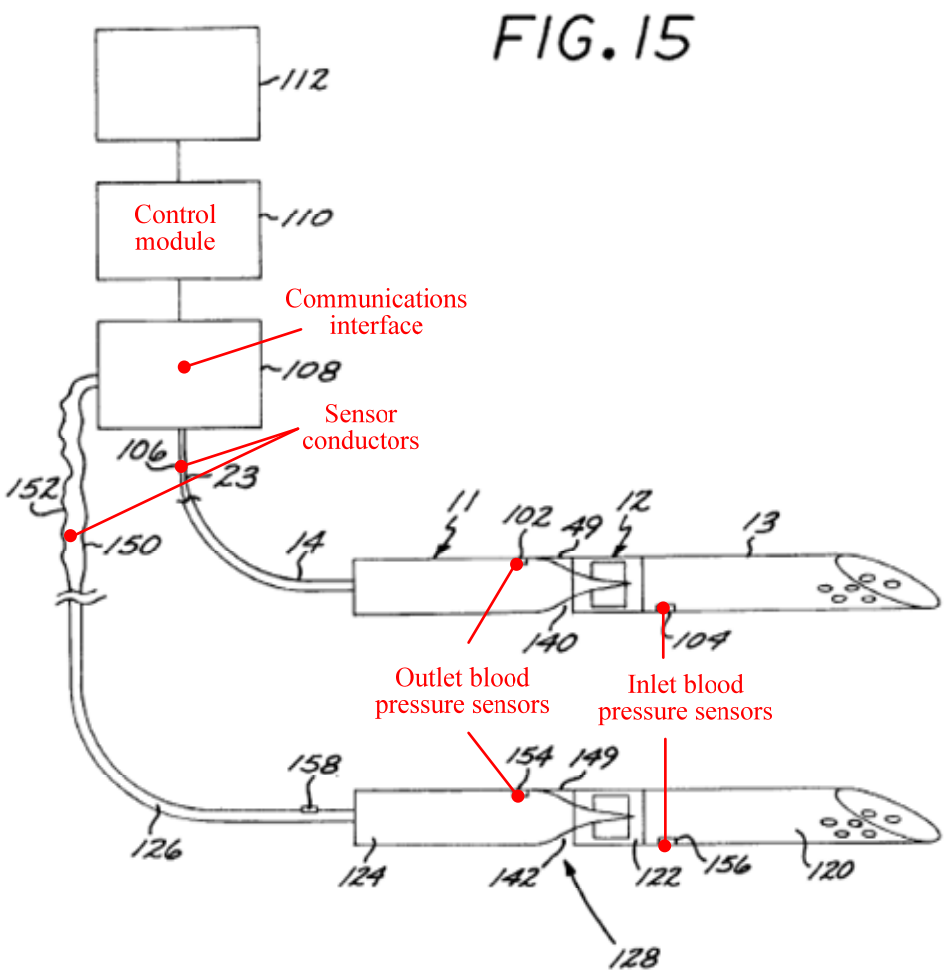
Thus, Aboul-Hosn in view of Wampler discloses this limitation. (*Id.* ¶373.)

s) *"measuring pressure adjacent the intravascular blood pump; and"*

Measuring blood pressure to aid in controlling the operation of the pump was well-known and Aboul-Hosn discloses several examples of measuring it adjacent the blood pump. (*Id.* ¶¶375-77.) The Aboul-Hosn catheter 428 has multiple lumens to perform various functions related to the operation of the intravascular blood pump 420, including "to measure pressure in the vicinity of the catheter along its entire length," which would include the area adjacent the blood pump 420. (*Id.* ¶375; 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." (Collins ¶375; EX1004[Aboul-Hosn] 28:14-17.) The Aboul-Hosn 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." (Collins ¶378; EX1004[Aboul-Hosn] 23:4-10.) Since the proximal end of the cannula couples to the pump, positioning sensors along the inner cannula would necessarily include the position 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 ¶378.)

Siess confirms this well-understood preference for measuring blood pressure near the pump. (*Id.* ¶378.) 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." (*Id.* ¶380; 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." (Collins ¶381; EX1005[Siess] 11:41-56.) 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 ¶380.)



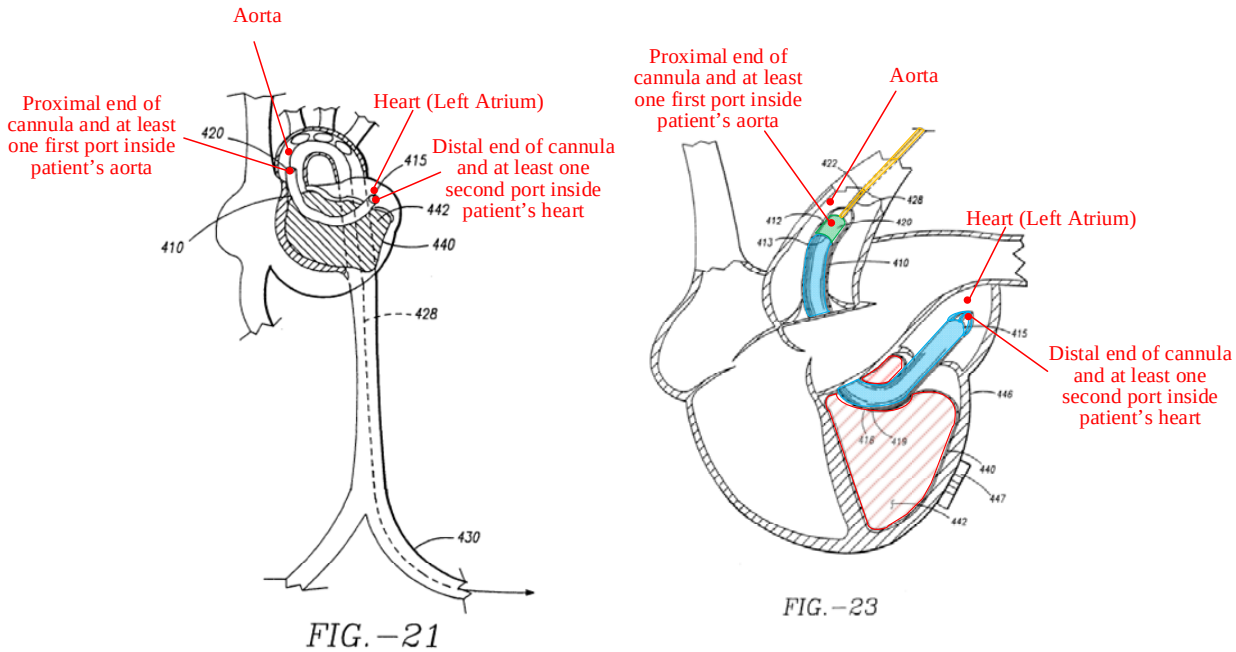
(Collins ¶380; EX1005[Siess] FIG. 15, annotated.)

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 ¶381.) Moreover, a POSITA would have been motivated to do so "to discern the position of the pump" and to "identify blockage conditions as well as cavitation" by comparing the pressure differential to the current drawn by the motor as taught by Siess. (*Id.*)

Thus, Aboul-Hosn in view of Siess, discloses this limitation. (*Id*. ¶382.)

t) *"spinning the rotor so as to pump 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."*

This limitation recites nothing more than the conventional actuation of a rotor once the blood pump has been positioned as previously set forth in Sections X.A.1.(p), (q) and (m). (*See also* Collins ¶384.) Aboul-Hosn not only discloses the positioning of the cannula and left-heart support (*see* Section X.A.1(o)-X.A.1(q)), **Error! Reference source not found.**but also spinning a rotor to pump blood. (Collins ¶¶385-87.)



(Collins ¶387; EX1004[Aboul-Hosn] FIGS. 21, 23, annotated.)

In the configuration shown above, the distal end of the cannula and the at least one second port at the distal end of the cannula are positioned in the left side

of the patient's heart (i.e. the left ventricle), and the at least one first port (i.e. the outflow windows) and the pump are positioned in the aorta. (Collins ¶388; EX1004[Aboul-Hosn] 29:31-30:2.) In operation, as shown below in FIGS. 3 and 23 for either an axial flow pump with or without the reverse flow feature, Aboul-Hosn's blood pump draws blood through the distal opening (i.e. at least one second port) of the cannula by the rotation of the rotor and associated blades of the pump driven by the pump motor which generates an axial flow of blood that exits the pump out of the outflow windows of the pump. (Collins ¶388; EX1004[Aboul-Hosn] 13:14-18, 18:15-19.)

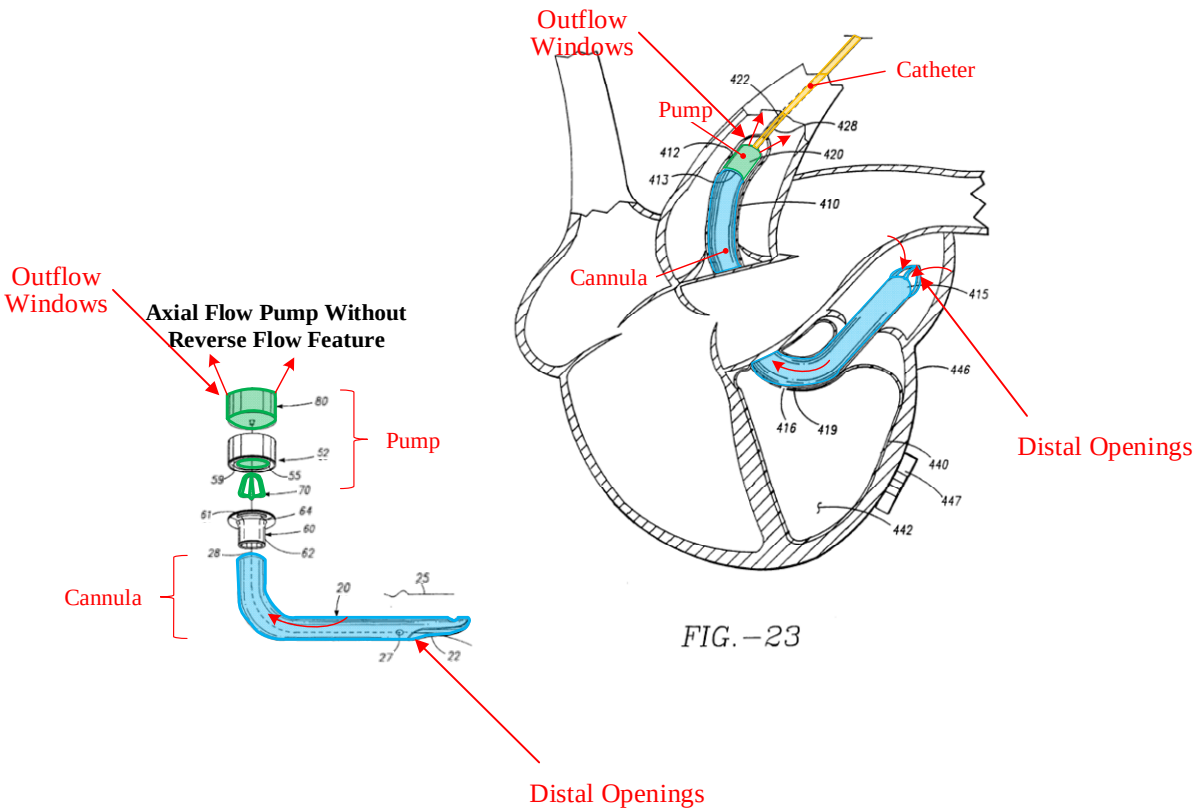


FIG.–23

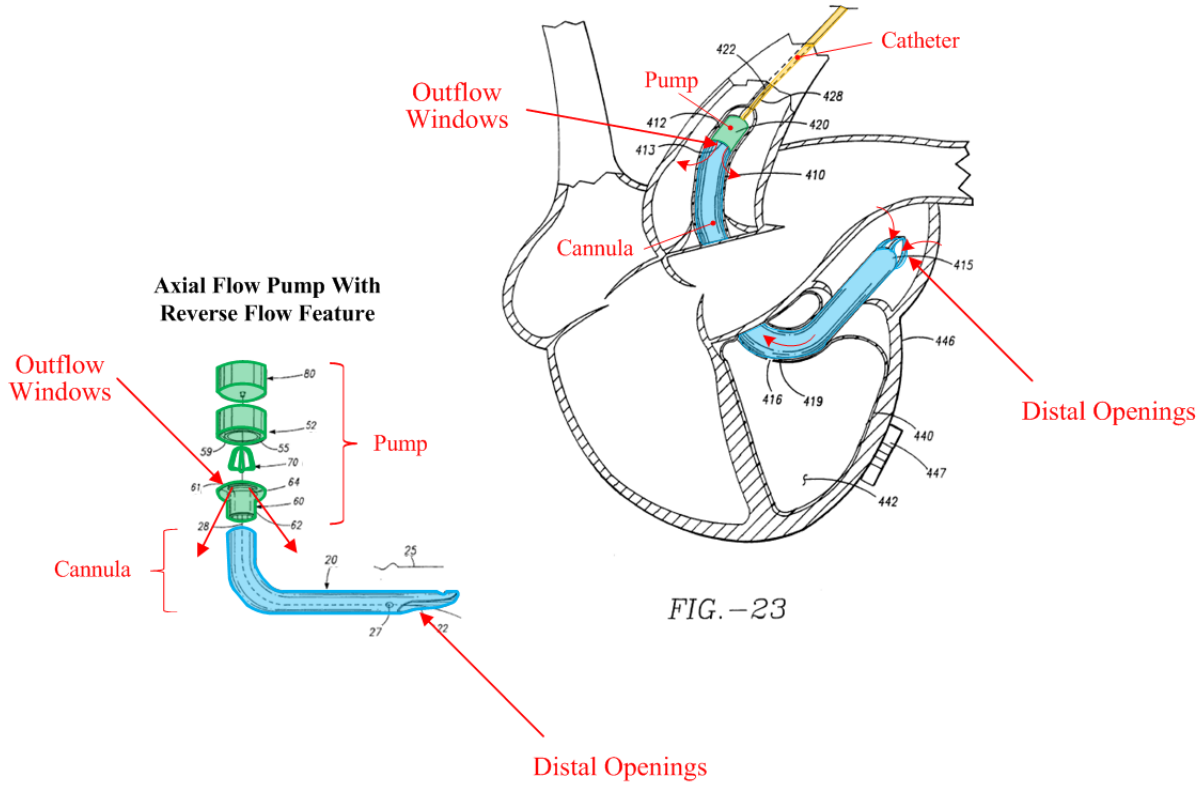


FIG.–23

(Collins ¶388; EX1004[Aboul-Hosn] FIGS. 3 and 23, annotated.)

Thus, Aboul-Hosn discloses this limitation. (*Id*. ¶389.)

B. Ground II[12]: Claim 29 is obvious under Ground I, and further in view of Wampler_712

1. Claim 29

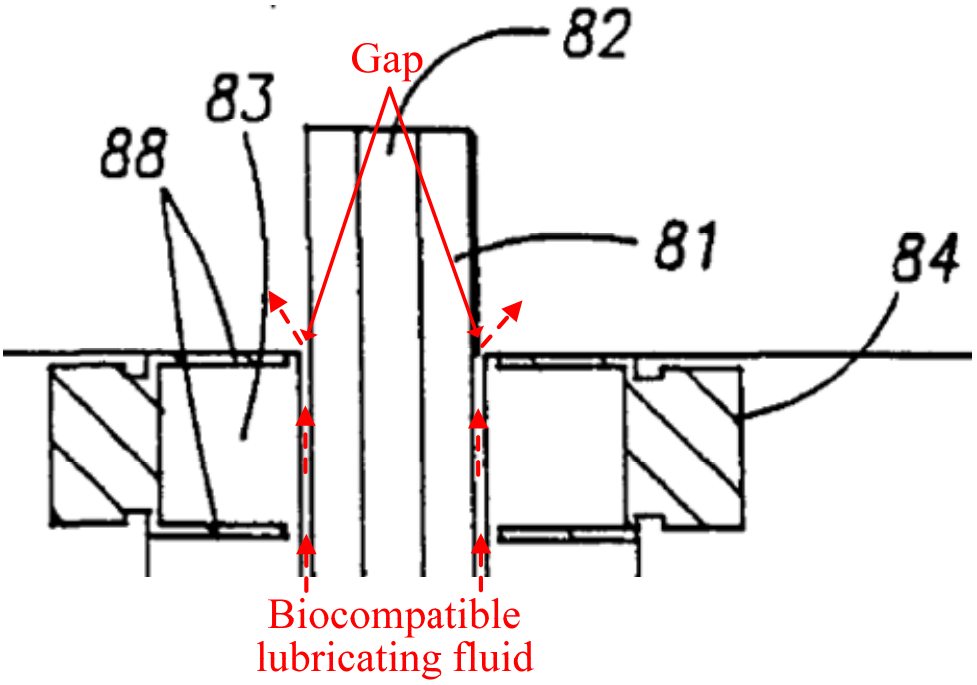
Claim 29 depends from claim 28 and recites "*wherein the intravascular blood pump system further comprising a fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump at a*

[12] Dr. Collins addresses this ground for claim 29 in Ground III of his declaration. (EX1002).

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."

As previously disclosed in Section X.A.1(m), 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 ¶458; EX1004[Aboul-Hosn] 20:16-19, 21:1-3, 29:19-25; EX1007[Wampler] 234.)

Moreover, 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. (Collins ¶460; EX1004[Aboul-Hosn] 20:23-31.)



(Collins ¶460; 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 ¶461; 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 ¶¶462-63.) 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." (Collins ¶458; 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 ¶463; EX1009[Wampler '152] 4:8-15; EX1047[Reich] claim 9.)

It would have been obvious to adapt Aboul-Hosn's pump with features of the Hemopump disclosed in Wampler_712. (Collins ¶¶189-194.) For example, a POSITA would have found it obvious to do so in order to prevent clotting. (Collins ¶190; EX1008[Wampler_712] Abstract ("The catheter also provides … the pump bearings with … purge fluid at a rate a pressure sufficient to prevent thrombus formation…"); EX1004[Aboul-Hosn] 20:26-31 ("A blood seal … "form[s] a closed chamber to retain the lubricating fluid inside the central cavity 83 during the pump operation.").) A POSITA also would have been motivated to pressurize the purge fluid to a higher level than the blood pressure, as taught in Wampler_712, to accomplish the "continuous infusion of dextrose" disclosed in Aboul-Hosn. (Collins ¶¶189-192; EX1004[Aboul-Hosn] 21:1-3; EX1008[Wampler_712] Abstract.)

Thus, Aboul-Hosn in view of Wampler_712, discloses this limitation. (Collins ¶461.)

C. Ground III[13]: Claim 28 is obvious over Aboul-Hosn in view of Yock, and further in view of Siess and Wampler

1. Claim 28

a) *See* element 28(a) – 28(h), Sections X.A.1.a-g, above.

[13] Dr. Collins addresses this ground for claim 28 in Ground II of his declaration. (EX1002).

Elements 28(a) – 28(h) are the same as in Ground I and rely on Aboul-Hosn.

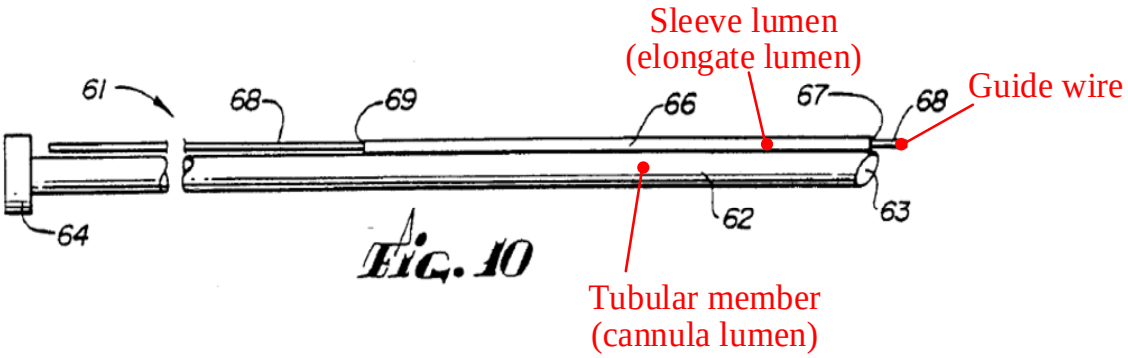
b) *"an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen,"*

This element corresponds to Element 28 (i) addressed above for Ground I (*see* Section X.A.1.i), but for the subject Ground, Petitioner relies on Yock as explained below.

Again, the '437 patent does not specify what it means to be an *elongate* lumen, much less an elongate lumen *associated with* the cannula. (Collins ¶398.) 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 '437 patent. (*Id.*)

Aboul-Hosn suggests delivering the intravascular blood pump using the preferred rapid-exchange mechanism. (Collins ¶¶403-04; 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 ¶405; EX1006[Yock] 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 ¶409; EX1006[Yock] 2:31-37.)



(Collins ¶409; 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 catheterization techniques into the patient's vasculature. (Collins ¶¶405, 407-08.) 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 (shown below in FIG. 1) to guide the intravascular blood pump using the preferred rapid-exchange technique. (*Id.* ¶411.)

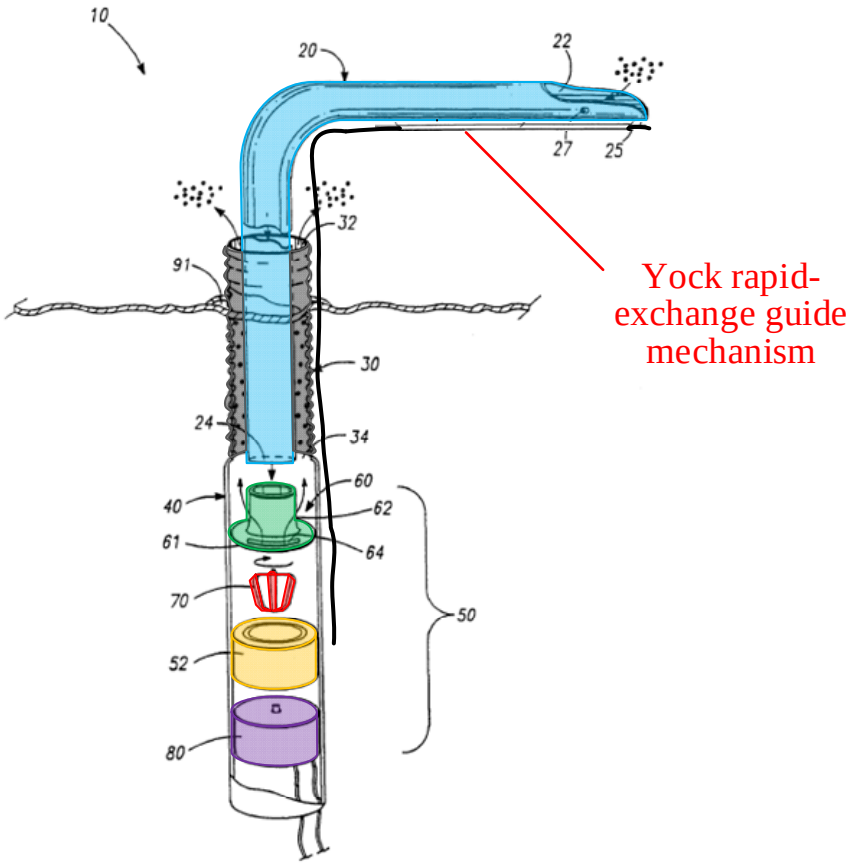
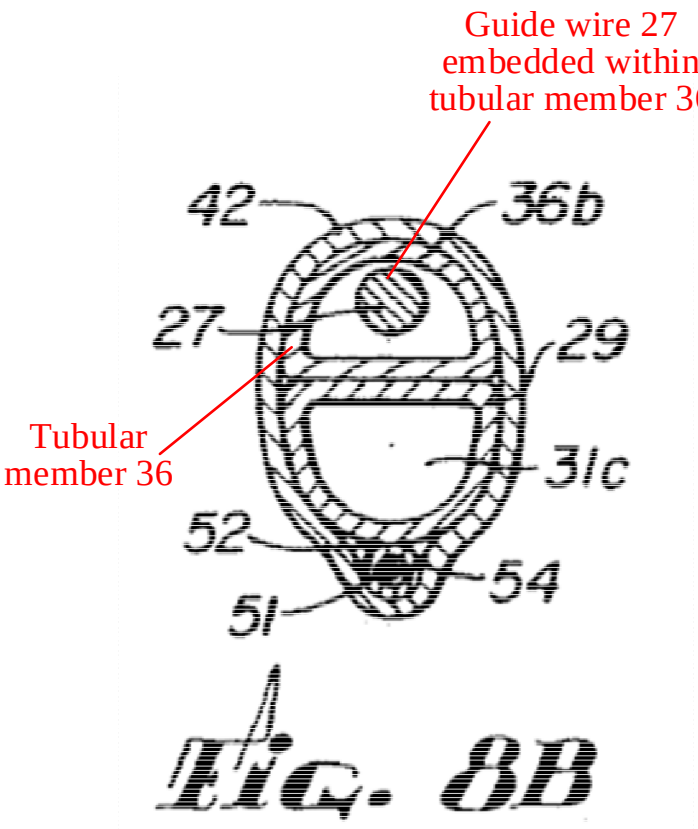


FIG. – 1

(Collins ¶412.)

Additionally, a POSTIA would readily understand that lumens within Aboul-Hosn's cannula would also be used for delivering the guidewire using the rapid-exchange technique. (Collins ¶¶413-17.) In fact, Yock expressly discloses that the sleeve 66 of FIG. 10 "can be formed integral with the flexible tubular member 62." (EX1006[Yock] 7:68-7:2.) Yock shows an example of such an embedded sleeve in FIG. 8, reproduced below. (Collins ¶414; EX1006[Yock] 6:59-63.)



(Collins¶414; 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 ¶415.) 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 POSTIA would also readily understand that the existing side lumens of Aboul-Hosn's cannula can also be used for delivering the guidewire just as well as an embedded sleeve given their similar structures, and as such, would provide a natural and obvious choice for an embedded rapid-exchange system. (*Id.*)

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.* ¶417.)

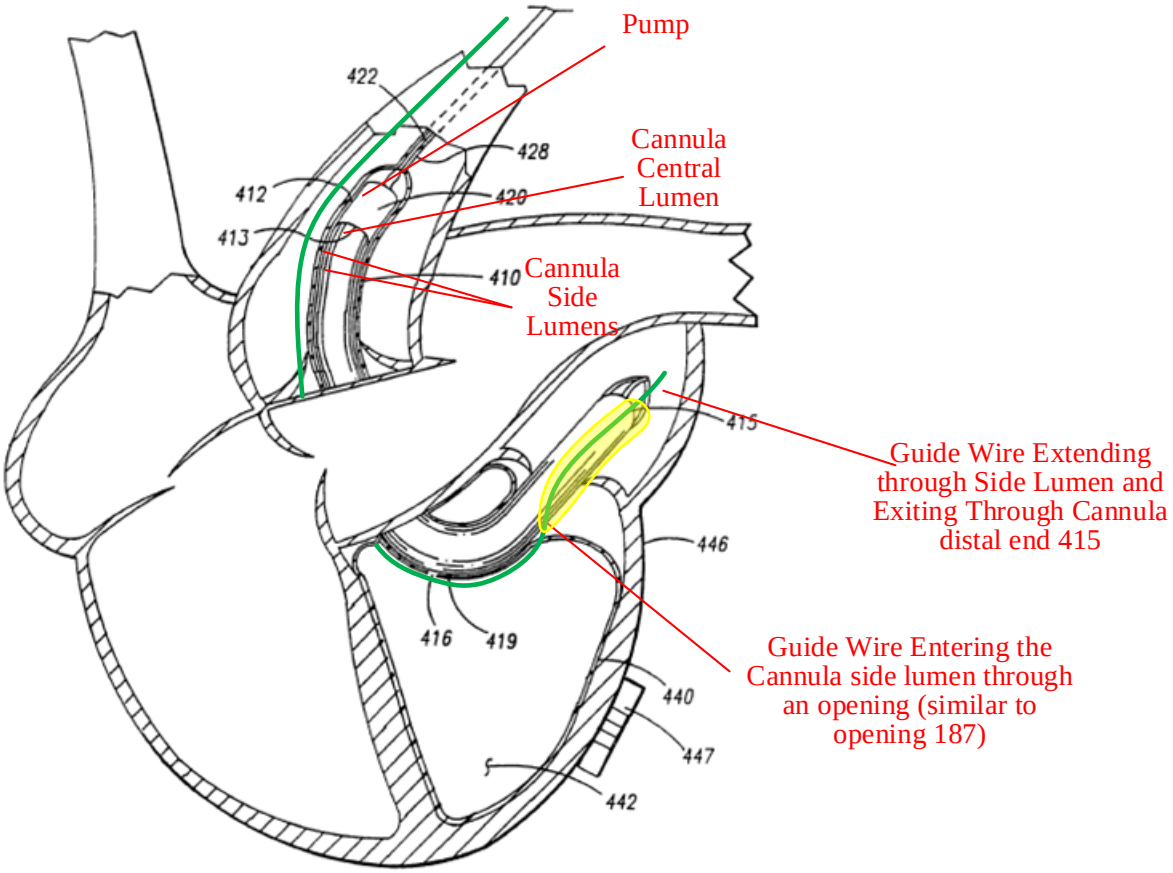


FIG.–23

(Collins ¶417; EX1004[Aboul-Hosn] FIG. 23, annotated.)

As of the EPD, it was well-known to POSITAs that conventional catheterization 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 fields of angioplasty and intravascular blood pumps. (Collins ¶406; 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 in the vasculature to apply treatment to the appropriate location. (Collins ¶407.) Indeed, as explained by Dr. Collins, the same approach (i.e. the Seldinger technique) would have been used conventionally by cardiologists to introduce percutaneous devices, including catheters and intravascular blood pumps, within the patient's vasculature. (*Id.*; U.S. Patent No. 4,692,148 to Kantrowitz et al. (EX1044, "Kantrowitz") 5:1-15; U.S. Patent No. 4,468,224 to Enzmann et al. (EX1045, "Enzmann") 2:5-20).

A POSITA would have been motivated to adapt Aboul-Hosn's intravascular blood pump to be delivered using a rapid-exchange technique, such as by applying the sleeve and guide wire technique 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, 411.)

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.* ¶¶218-220, 224, 411-42.)

Any 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 ¶¶ 405-17; 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 ¶¶410, 416.) Thus, Aboul-Hosn in view of Yock discloses this limitation. (*Id*. ¶418.)

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

Aboul-Hosn in view of Yock discloses this limitation. (*Id.* 419.)

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.* ¶¶420-21.) 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.* ¶420.)

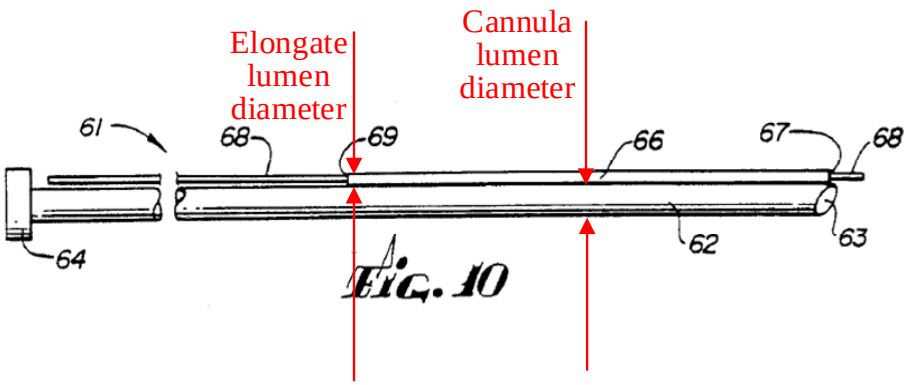


FIG. 10

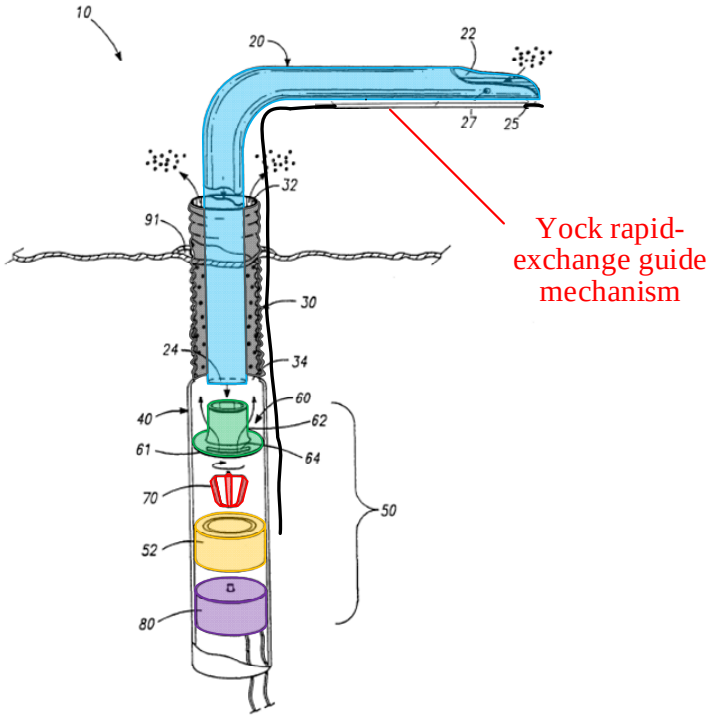


FIG.—1

(Collins ¶420.)

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 ¶421.)

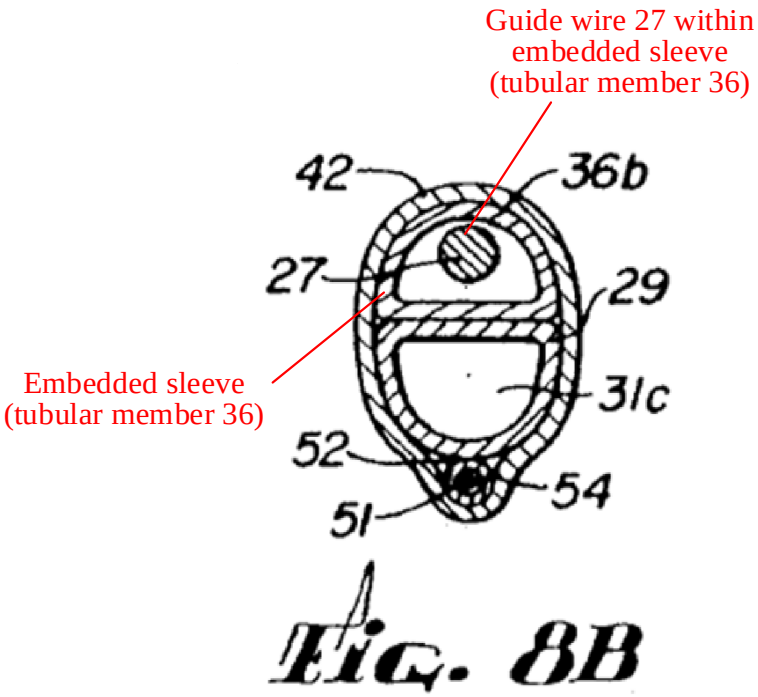
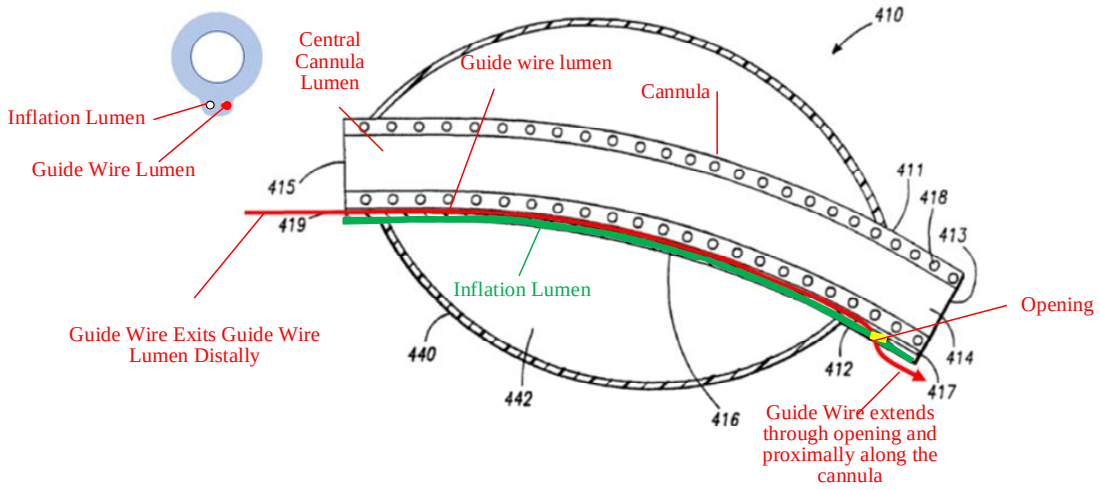


FIG. 8B



(Collins ¶¶414, 421; EX1006[Yock] FIG. 8B, annotated (top); EX1004[Aboul-Hosn] FIG. 20, annotated (bottom).)

Indeed, a POSITA would expect the cross section of the catheter lumen or side lumen to be sized smaller than the lumen of the cannula given the limited space within the patient's vasculature, as the majority of the space would be used for the components that provide the blood pumping function, for example the cannula lumen and rotor blades. (Collins ¶422.) Accordingly, Aboul-Hosn in view of Yock discloses this limitation. (*Id.* ¶423.)

d) *"both the elongate lumen and the cannula lumen not extending through the rotor huh (sic)"*

This limitation is a characteristic feature of a rapid-exchange guide mechanism, applied intravascular blood pumps. As previously discussed in Section X.C.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.* ¶425) 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.* ¶¶425-28.) 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.* ¶429.)

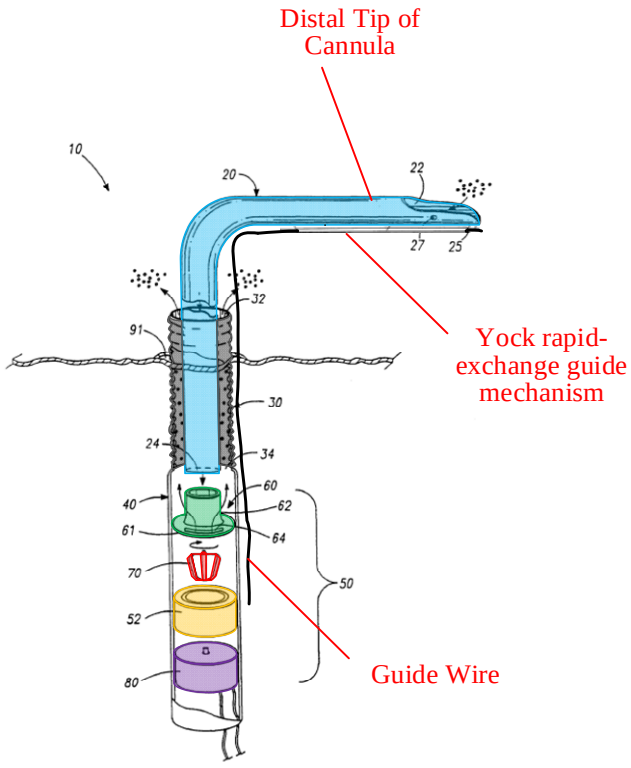


FIG.—1

(Collins ¶426.)

As shown in FIG. 1 of Aboul-Hosn 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.*¶426) 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.* ¶425.)

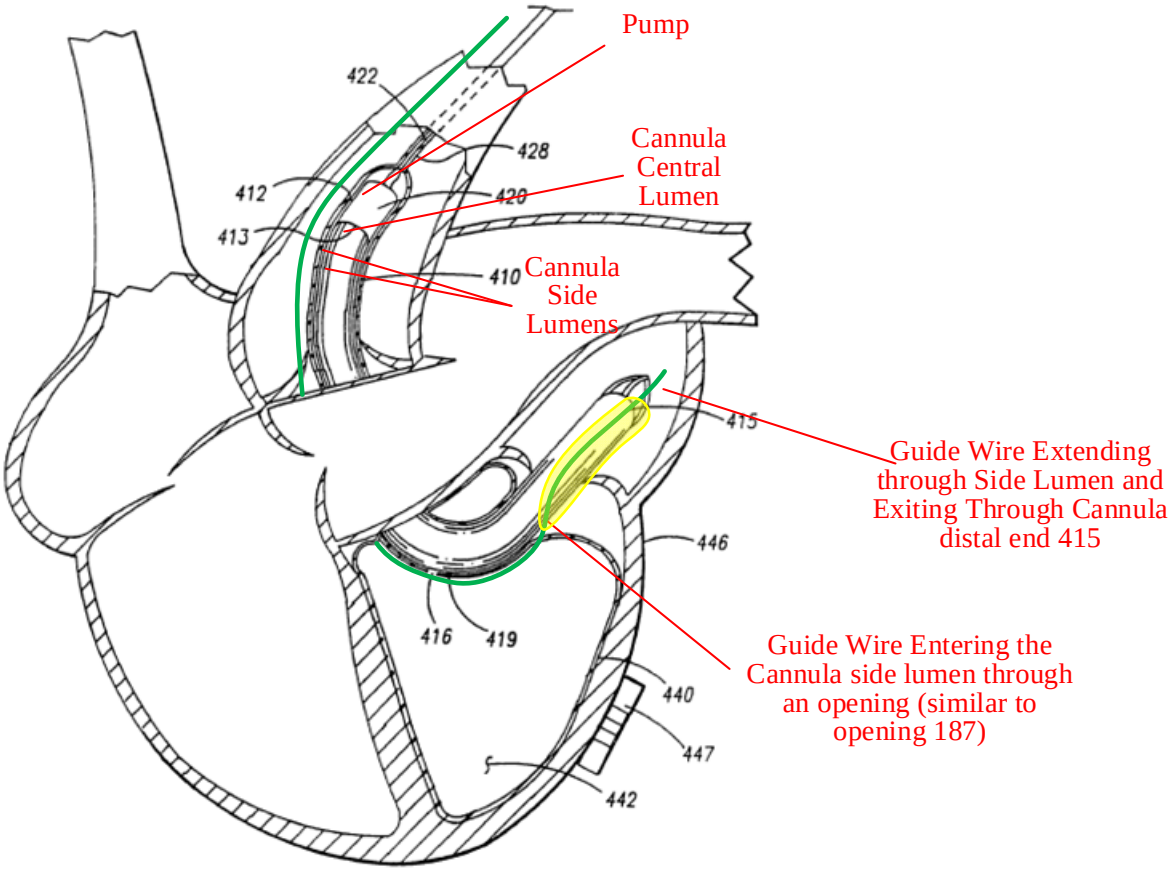


FIG.–23

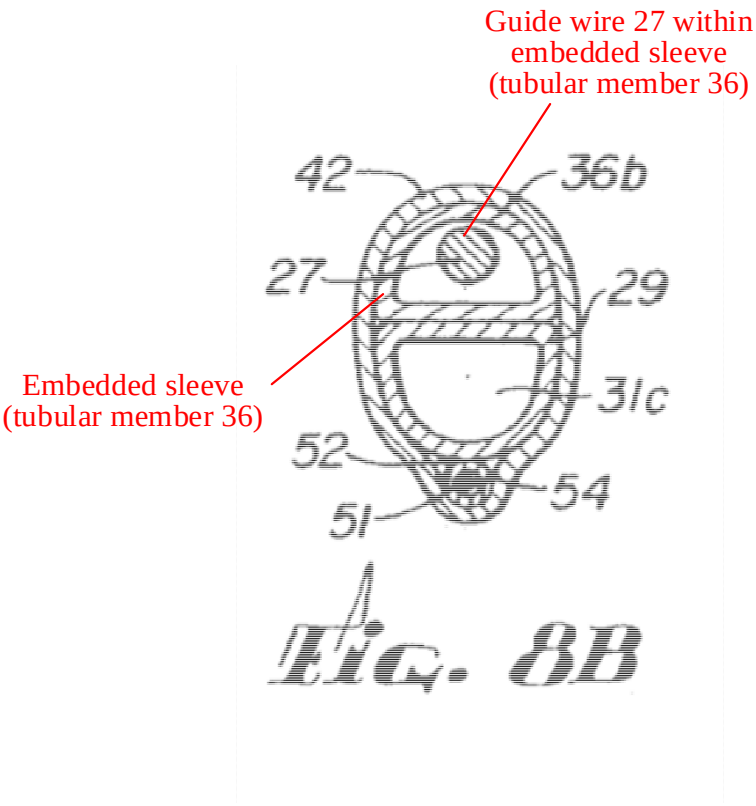
(Collins ¶429; EX1004[Aboul-Hosn] FIG. 23, annotated.)

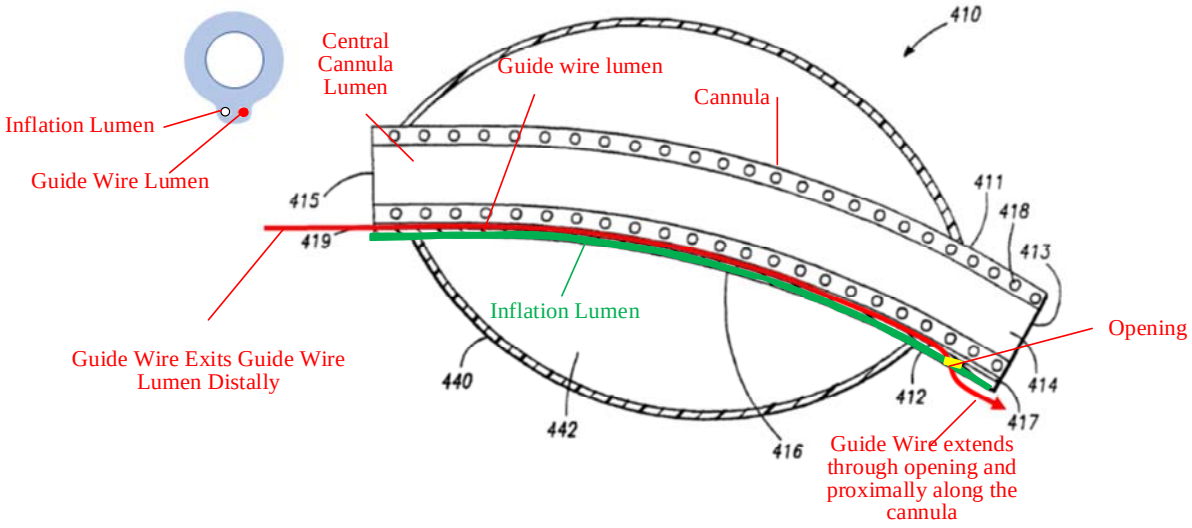
e) *"the elongate lumen adapted to guide the guide wire through a distal end of the intravascular blood pump system, the elongate lumen is at least partially disposed within an outer surface of the cannula;"*

As previously discussed in Sections X.C.1(b) and (d), in either rapid-exchange configuration demonstrated by Aboul-Hosn and Yock, 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.* ¶¶434-35.)

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 ¶434.)

Where Yock's sleeve is attached to the side of Aboul-Hosn's cannula, Yock further discloses that the sleeve "can be formed integral with the flexible tubular member" (i.e. the cannula) "if desired." (EX1006[Yock] 7:68-8:2.) Where the sleeve is integrally formed with the cannula, the outer surface of the sleeve is the outer surface of the cannula, and the sleeve lumen (i.e. the elongate lumen) would be partially disposed within an outer surface of the cannula. (Collins ¶435.) Moreover, as shown in FIG. 8B of Yock and FIG. 20 of Aboul-Hosn, below, the side lumens (i.e. an embedded sleeve or preexisting passageway within the sidewall of Aboul-Hosn's cannula) are at least partially disposed within an outer surface of the cannula. (*Id.*; EX1004[Aboul-Hosn] 28:10-12: "[t]he ports and passageways … may be formed adjoining to or concentric with cannula 20.")





(Collins ¶439; EX1006[Yock] FIG. 8B, annotated (top); EX1004[Aboul-Hosn] FIG. 20, annotated (bottom).)

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

f) *See element 28(m) – 28(n), Sections X.A.1.m-n, above.*

Elements 28(m) – 28(n) are the same as in Ground I rely on Aboul-Hosn in view of Wampler.

g) *"wherein the method for providing left-heart support comprises the steps of passing the guide wire through the patient's femoral artery such that a distal end of the guide wire is positioned in the left ventricle of the patient's heart;"*

This limitation is simply the recitation of the conventional step of delivering a guide wire through the circulatory system to the left ventricle of the heart. (Collins ¶439.) Aboul-Hosn describes that the guide wire is inserted to the desired location before the cannula is positioned (using the guide wire). (*Id.*; EX1004[Aboul-Hosn] 22:12-14 ("The guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20.").) Aboul-Hosn further describes that the guide wire may be advanced to a specific location within the patient, including any heart chamber or blood vessel or artery. (Collins ¶440; EX1004[Aboul-Hosn] 11:8-11, 11:24-28, 22:10-14.)

One of the locations in which Aboul-Hosn positions the distal tip of the cannula is the left ventricle. (Collins ¶445; EX1004[Aboul-Hosn] 29:31-30:2.) ("Meanwhile, the stabilization cannula 411 may be positioned within a ventricle or atrium. After proper positioning, a pump may be activated and take over the left

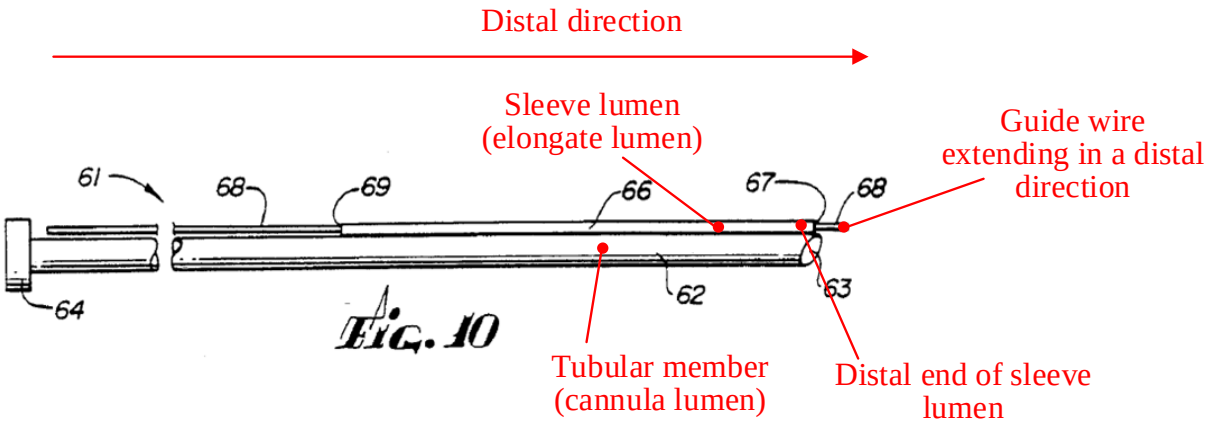
ventricle function.") When the cannula is delivered to the left ventricle, the guide wire would conventionally be delivered to that ventricle such that the distal end of the guide wire is in the left ventricle. (*Id*.) The cannula would then follow. (*Id*.)

Moreover, as discussed above (Section VII.A), passing the cannula and blood pump through the femoral artery was a well-known technique, the same technique used by the hemopump and other intravascular blood pumps. (*See, e.g.*, Collins ¶¶442-43.) Yock also describes inserting a guide wire and using the guide wire for rapid-exchange of devices using a femoral insertion with the guidance of a guide catheter. (*See* Collins ¶442; EX1006[Yock] 10:47-54). The guiding catheter is inserted into the patient by a femoral artery, and then the guide wire inserted through the guiding catheter. (*See* Collins ¶442; EX1006[Yock] 10:47-11:16.)

h) *"placing the guide wire through both the cannula and the elongate lumen, wherein the guide wire enters the intravascular blood pump system through one end of the elongate lumen and exits the intravascular blood pump system through an opposite end of the elongate lumen, the guide wire not passing through the rotor hub or the catheter;"*

Yock in combination with Aboul-Hosn discloses this limitation. (Collins ¶447.) As previously discussed in Section X.C.1(b), Aboul-Hosn's intravascular blood pump can be delivered with the rapid-exchange technique by using a sleeve lumen (such as Yock's) attached along the side of the cannula or using an embedded sleeve lumen or preexisting passageway (i.e. side lumens) within the

sidewall of the cannula, any of which can be the "elongate lumen" and receive a guide wire passing through it. (*Id.* ¶¶448-450.) Where the sleeve lumen attached to the side of the cannula is used, as shown in annotated FIG. 10 of Yock below, the guide wire enters the intravascular blood pump system through one of the elongate lumen, and exits through an opposite end. (*Id.* 448; EX1006[Yock] 8:10-16.)



(Collins ¶448; EX1006[Yock] FIG. 10, annotated).

This is also the case where the side lumens within Aboul-Hosn's cannula are used, as shown in FIG. 23 of Aboul-Hosn below. (Collins ¶¶450-52.)

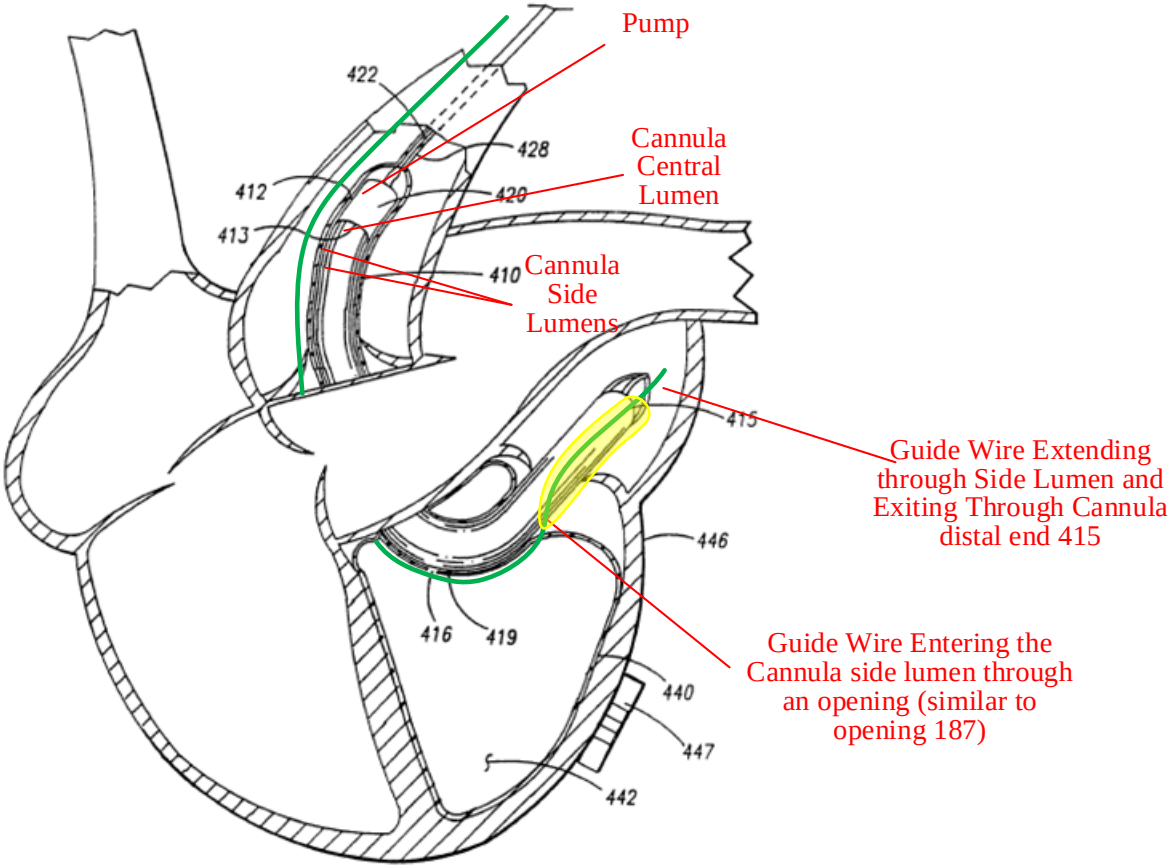


FIG.–23

(Collins ¶450; EX1004[Aboul-Hosn] FIG. 23, annotated.)

In either configuration, as shown above in FIG. 10 of Yock and FIG. 23 of Aboul-Hosn, the elongate lumen does not pass through the rotor hub or the catheter coupled to the proximal end of the pump. (Collins ¶¶449-50; EX1006[Yock] FIG. 10; EX1004[Aboul-Hosn] FIG. 20.)

Thus, Aboul-Hosn in view of Yock, discloses this limitation. (*Id.* ¶452.)

i) *See element 28(q) – 28(t), Sections X.A.1.q-t, above.*

Elements 28(q) – 28(t) are the same as in Ground I and rely on Aboul-Hosn (and Wampler or Siess for certain limitations).

D. Grounds IV: Claim 29 is obvious under Ground II, and further in view of Wampler_712

1. Claim 29

Ground for this claim is identical to Ground II and relies on Aboul-Hosn in view of Wampler_712. *See* Sections X.B.1.

XI. CONCLUSION

Based on the foregoing, claims 28, 29 of the ’437 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 9,597,437 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 9,597,437 ("'437 patent")
1002	Collins Declaration ("Collins")
1003	File History of U.S. Patent No. 9,597,437 ("'437 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 (June 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 (June 1996) 618-620
1039	Library of Congress, Catalog Record of *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th edition (1996)
1040	Library of Congress, Catalog Record of *Fluid Mechanics*, 2nd edition, ed. Frank M. White (1986)
1041	ZB Med, 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	Leupold Declaration - Jegaden
1047	U.S. Patent No. 4,135,253 ("Reich")
1048	R.W. Smalling, *The use of mechanical assist devices in the management of cardiogenic shock*, Texas Heart Institute Journal, vol. 18, No. 4, 1991, 275-81.
1049	U.S. Patent No. 5,421,338 ("Crowley")

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 13,504 excluding the table of contents, table of authorities, mandatory notices under § 42.8, certificate of service, certificate of word count, and the listing of exhibits.

Respectfully Submitted,

__/David M. Tennant/__

David M. Tennant
Lead Counsel
Registration No. 48,362

CERTIFICATE OF SERVICE

I, Daniel Shults, hereby certify that I am a resident of the State of Maryland and over the age of eighteen years, and not a party to the within action; my business address is 701 13th Street NW, #600, Washington, DC, 20005. On April 18, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 9,975,437 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. 9,975,437 (EX1001-1049)
- Exhibits 1001-1049
- 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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Charlotte, NC 28280-4000

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

__/s/Daniel Shults__
Daniel Shults