Docket No. 1846265-0012
Petitioners: Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Maquet Cardiovascular, LLC
Patent Owner

Case No. IPR2017-01025

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,022,100 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.9-, 42.100-.123

CLAIMS 16-18

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I. INTRODUCTION

Petitioners Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") petition for *inter partes* review of claims 16-18 (the "Challenged Claims") of U.S. Patent No. 7,022,100 (the "'100 patent") and cancellation of those claims as unpatentable under 35 U.S.C. § 103.

The Challenged Claims recite nothing more than an obvious standard intravascular blood pump with the same conventional guide wire mechanism disclosed by a named inventor of the '100 Patent, well before the earliest possible priority date of the '100 patent (the "EPD") (*see* Section VI.B). The Challenged Claims attempt to add minor conventional intravascular blood pump features with respect to blood pressure measurement, but those features add nothing patentable—the claimed features were well known to persons of ordinary skill in the art ("POSITA") before the EPD. The Challenged Claims add nothing new to the art and should be canceled.

II. MANDATORY NOTICES

A. Real Party-in-Interest

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

B. Related Matters

Abiomed Inc. has filed a declaratory judgment action against Maquet Cardiovascular LLC ("Maquet" or "Patent Owner") for non-infringement of the

'100 patent in the District of Massachusetts. Case No. 1:16-cv-10914. Petitioner has filed, or will file, concurrently with the present Petition, petitions for *inter partes* review of U.S. Patent Nos. 8,888,728 and 9,327,068 (the "related patents") which are related to the '100 patent.

C. Counsel

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

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

D. Service Information

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

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III. GROUNDS FOR STANDING

Petitioner certifies pursuant to Rule 42.104(a) that the '100 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting IPR of the Challenged Claims. Patent Owner served Abiomed, Inc. and

Abiomed R&D, Inc. with a counterclaim asserting infringement of the '100 patent on September 22, 2016 and November 1, 2016, respectively. Patent Owner named Abiomed Europe GmbH on the counterclaim as well and served Abiomed Europe GmbH[1] through the Hague convention.

IV. RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner requests *inter partes* review of the Challenged Claims and a ruling that the Challenged Claims are unpatentable.

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

1. WO 99/02204 to Aboul-Hosn (EX1024, "Aboul-Hosn"), published January 21, 1999, is prior art to the '100 patent under 35 U.S.C. § 102(b).

2. U.S. Patent No. 5,921,913 to Siess (EX1005, "Siess '913"), filed June 24, 1997 and issued July 13, 1999, is prior art to the '100 patent under 35 U.S.C. § 102(b).

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

[2] Based on the '100 patent filing date, Petitioner uses the pre-AIA statutory framework to refer to the prior art herein this petition.

3. U.S. Patent No. 6,176,822 to Nix (EX1019, "Nix"), filed November 24, 1998 and issued January 23, 2001, is prior art to the '100 patent under 35 U.S.C. § 102(b).

B. Grounds for Challenge

This Petition, supported by the declaration of Dr. John Collins ("Collins" (EX1002)), demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one Challenged Claim and that each Challenged Claim is not patentable. *See* 35 U.S.C. § 314(a). Petitioner requests cancellation of Challenged Claims 16-18 under the following statutory grounds:

- Ground 1: Claims 16-17 are rendered obvious by Aboul-Hosn in view of Siess '913 under 35 U.S.C. § 103(a).
- Ground 2: Claim 18 is rendered obvious by Aboul-Hosn in view of Siess '913 and further in view of Nix under 35 U.S.C. § 103(a).

V. CONVENTIONAL TECHNOLOGY PRIOR TO SEPTEMBER 2000

The '100 patent alleges its invention to be a guide mechanism that "eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art." (EX1001 ['100 Patent] at 2:51-55.) But the problem of reducing the size of the catheter had long been appreciated by the art, as had the solutions taught by the '100 patent. (Collins ¶90; EX1011 [Voelker] at 3:34-65.)

Indeed, the Challenged Claims recite nothing more than a conventional combination of well-known features to achieve a predictable result – a conventional intravascular blood pump delivered to the vasculature by a conventional guide-mechanism, as disclosed by Aboul-Hosn, with only minor added details from the other prior art references. (Collins ¶¶36-39.)

A. Conventional Intravascular Blood Pumps[3]

The conventional blood pump features of the Challenged Claims were disclosed by Aboul-Hosn and well-known before the EPD, including (1) a cannula formed as a tube, connected at its proximal end to an axial flow pump and with a distal end to be disposed in a heart chamber, such as the left ventricle (Collins ¶¶57-61; *see also* EX1004 [Aboul-Hosn] at 30:20-28; U.S. Patent No. 4,625,712 to Wampler (EX1008, "Wampler '712") at 3:40-51; EX1005 [Siess '913] at 5:28-61); (2) a pump having a tapered rotor with a distally extending tip and multiple blades disposed within a shroud, to pump blood axially along the pump and through the cannula (Collins ¶62-66; *see also* EX1004 [Aboul-Hosn] at 12:28-13:31, 16:30-17:26; EX1008 [Wampler '712] at 3:26-39; U.S. Patent No. 4,846,152 to Wampler et al. (EX1009, "Wampler '152") at 2:63-3:23; EX1005 [Siess '913] at 6:26-7:21); and (3) techniques for monitoring blood pressure near the pump (Collins ¶67-73;

[3] For background, Dr. Collins discusses the circulatory anatomy and function, and development of intravascular blood pumps. (Collins ¶¶40-41.)

see also EX1004 [Aboul-Hosn] at 29:16-25; EX1005 [Siess '913] at 11:25-56). The few other minor details of the Challenged Claims were also well-known before the EPD – i.e., pressure sensor selection and location (in Siess '913). (Collins ¶53.)

B. Conventional Guide Wire Techniques for Placing Intravascular Blood Pumps

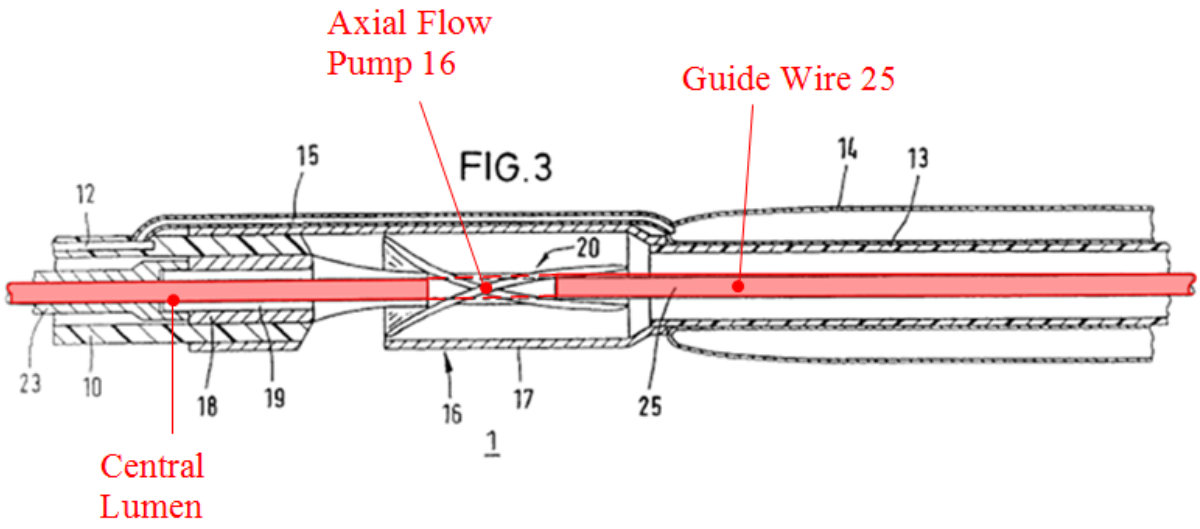
Well-known catheterization techniques including "guide" catheters, "over-the-wire" catheters, and "rapid-exchange" catheters, have been used routinely to position blood pump intravascularly (i.e. within a patient's circulatory system). (Collins ¶¶74-75.)

1. Over-the-Wire Catheter

The conventional "over-the-wire" technique was used to place a catheter such as disclosed by U.S. Patent No. 4,479,497 to Fogarty et al. (EX1010, "Fogarty"). (Collins ¶¶78-80; EX1010 [Fogarty] at 3:4-10.) First, the guide wire was placed at a desired location within the patient (i.e., at "the area of stenosis"). (*Id.* at 3:4-6.) Then, the catheter was "advanced over the guide wire without difficulty or damage" to the desired location. (*Id.* at 3:4-10.)

Subsequently but long before the EPD, POSITAs adapted that "over-the-wire" guide mechanism to place intravascular blood pumps. (Collins ¶¶78-81.)

As shown below in FIG. 3, U.S. Patent No. 6,248,091 to Voelker[4] (EX1011, "Voelker") applied the "over-the-wire" guide mechanism to an axial flow intravascular blood pump. (Collins ¶80.) Voelker discloses that "the guide wire 25 extends coaxially through the flexible shaft 23, the shaft 19 and the impeller wheel 20" where "[t]hese parts have corresponding axial channels to be slipped over the guide wire (over-the-wire technique)." (EX1011 [Voelker] at 3:56-60.)



(Collins ¶80; EX1011 [Voelker] at FIG. 3, annotated.)

As explained in further detail in Sections VII and X below, Aboul-Hosn disclosed that same well-known "over-the-wire" catheterization technique and used it in delivering intravascular blood pumps into the heart. (Collins ¶80.)

2. Rapid-Exchange Catheter

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

As Dr. Collins explains further, the "rapid-exchange" technique was also well-known to be used to place intravascular blood pumps. (Collins ¶¶82-88.) As Yock discloses, a conventional "rapid-exchange" catheter generally includes an elongate tubular member, such as a cannula, and a sleeve (with an interior lumen for a guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (*Id.* ¶82; EX1006 [Yock] at FIG. 10, 7:64-68.) As shown below in FIG. 10, a guide wire is placed in a desired location in the body and inserted through the sleeve. (Collins ¶82; EX1006 [Yock] at 7:64-8:19.) Then, the catheter is advanced along the guide wire to the desired location. (Collins ¶82; EX1006 [Yock] at 8:20-25.) The orientation of the sleeve along the side of the cannula allows for the rapid exchange of catheters. (Collins ¶82; EX1006 [Yock] at 2:31-37.)

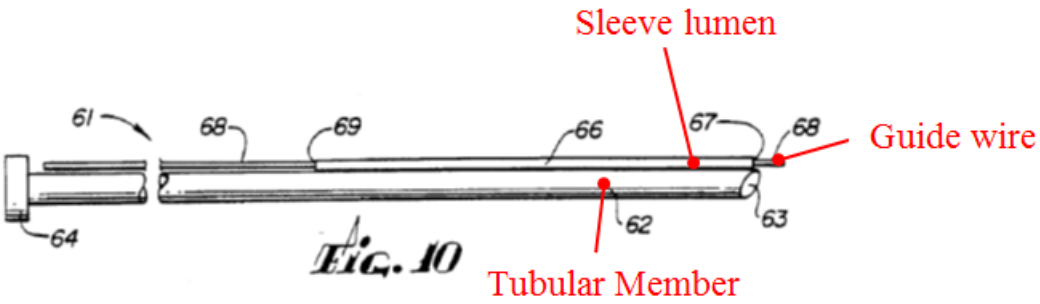
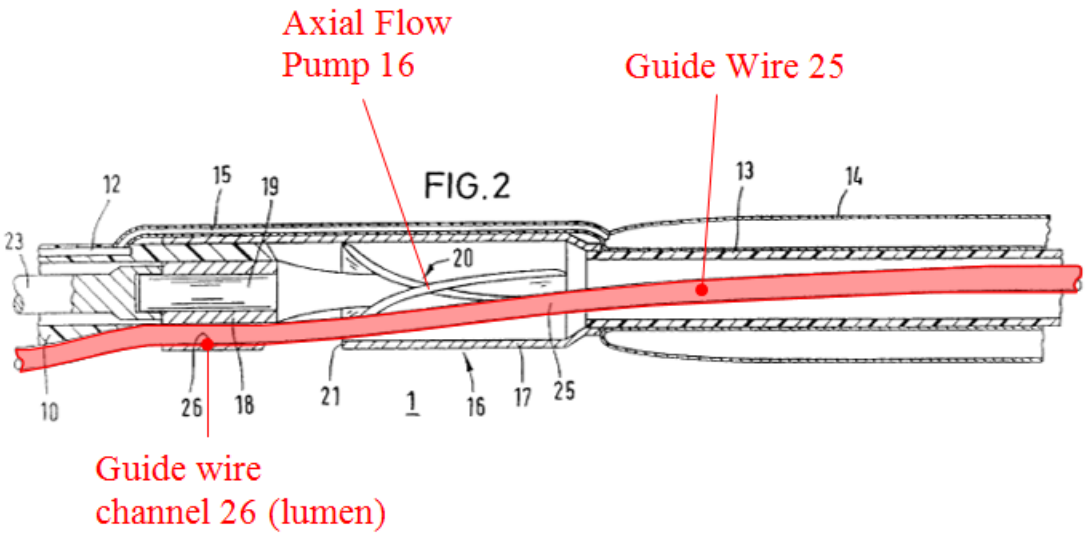


FIG. 10

(Collins ¶82; EX1006 [Yock] at FIG. 10, annotated.)

Voelker, at Fig. 2 (below) also discloses this rapid exchange approach -- a guide wire 25 "that is placed first in the blood vessel and over which the catheter is then slipped "where "a longitudinally extending channel 26 is provided that forms

a guide portion (monorail) through which the guide wire 25 is guided into the pump housing 17." (Collins ¶84; EX1011 [Voelker] at 3:34-43.)



(Collins ¶84; EX1011 [Voelker] at FIG. 2, annotated.)

3. Guide Catheter

As explained by Dr. Collins, Yock discloses using a guide catheter to position a guide wire so that a dilation balloon can be advanced over the guide wire to a desired location within the patient's body. (Collins ¶76; EX1006 [Yock] at 3:56-4:50.) First, "[t]he guiding catheter 17 is inserted into the coronary artery in a conventional manner." (EX1006 [Yock] at 3:56-57.) Then, the guide wire is advanced through the guide catheter 17 into the desired arterial vessel and the balloon is advanced into place. (*Id.* at 4:25-30.)

The same technique as disclosed by Yock has been adapted to place axial flow intravascular blood pumps. (Collins ¶77.) In fact, the '100 Patent

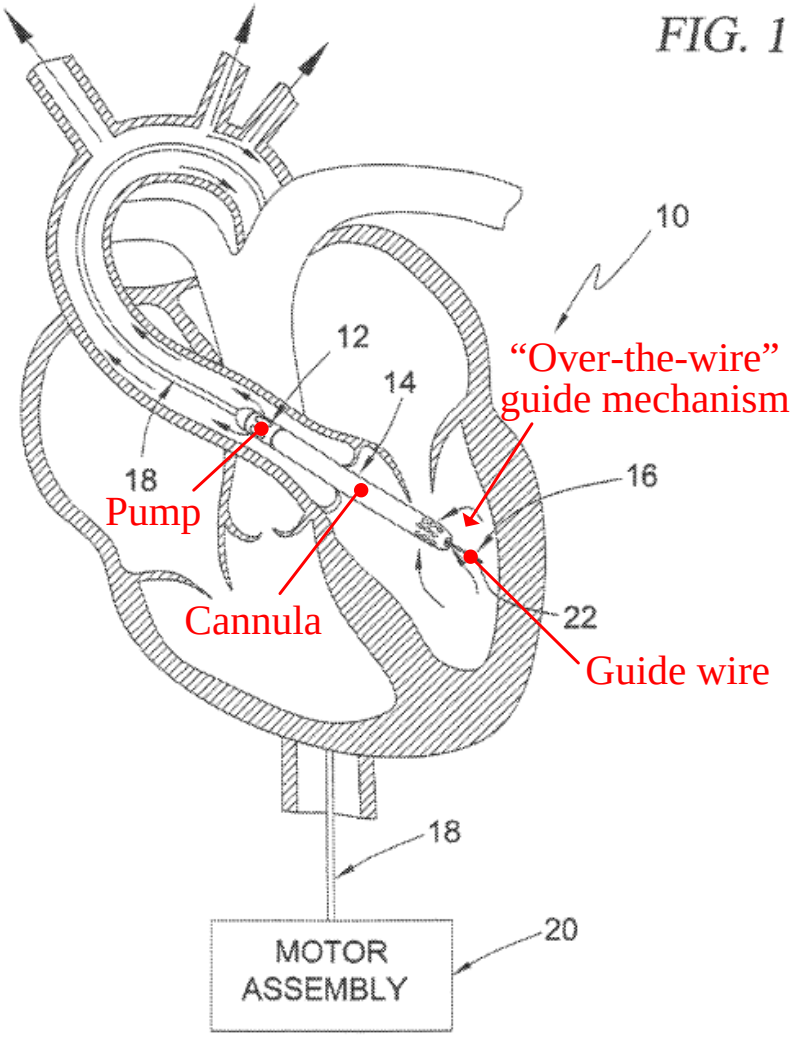
acknowledges that a guide catheter was a well-known and conventional guide mechanism for intravascular blood pumps. (*Id*.; EX1001 ['100 Patent] at 2:19-29)

VI. OVERVIEW OF THE '100 PATENT

A. Summary of Alleged Invention of the '100 Patent

The '100 patent's disclosure concerns placement of a conventional intravascular blood pump system using the same three conventional delivery techniques of the prior art discussed above -- (1) a "over-the-wire" type guide mechanism; (2) a "rapid-exchange" or "side-rigger" type guide mechanism; and (3) a "guide catheter" type guide mechanism. (EX1001 ['100 patent] at 2:56-3:41; Collins ¶91.) The background of the '100 patent openly admits that it is not the first to use such "guide mechanism[s]" to place an intravascular pump. (EX1001 ['100 patent] at 2:19-21).

The conventional over-the-wire technique is illustrated in FIG. 1, which purports to be "a partial sectional view of a human heart illustrating an intravascular blood pump system having an over-the-wire type guide mechanism … positioned, by way of example, in a trans-valvular configuration to provide left-heart assist." (EX1001 ['100 patent] at 5:8-12).

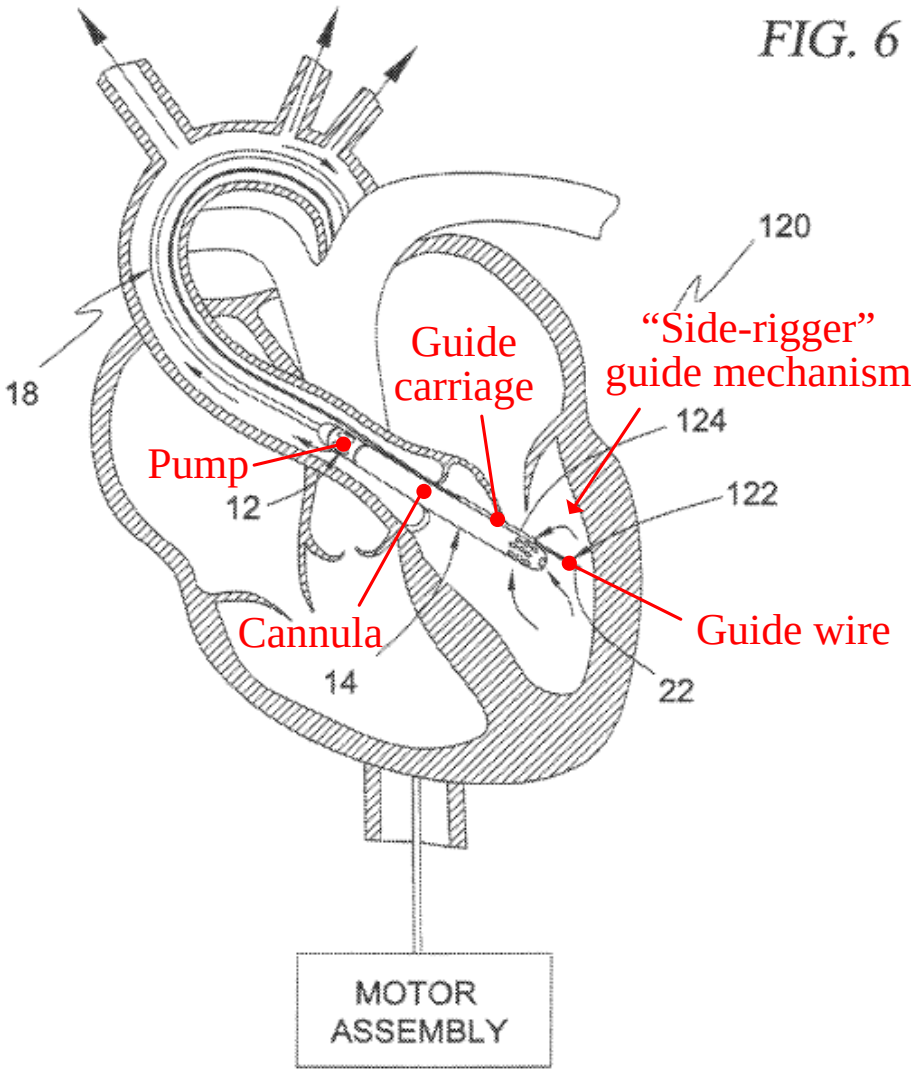


(Collins ¶92; EX1001 ['100 patent] at FIG. 1, annotated.)

The intravascular blood pump system 10 is conventional and 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.* at 7:10-54; Collins at ¶92.) "[T]he guide wire 22 is first introduced into the vascular system of a patient through any suitable access point" where the "guide wire 22 can then be advanced within the patient to a

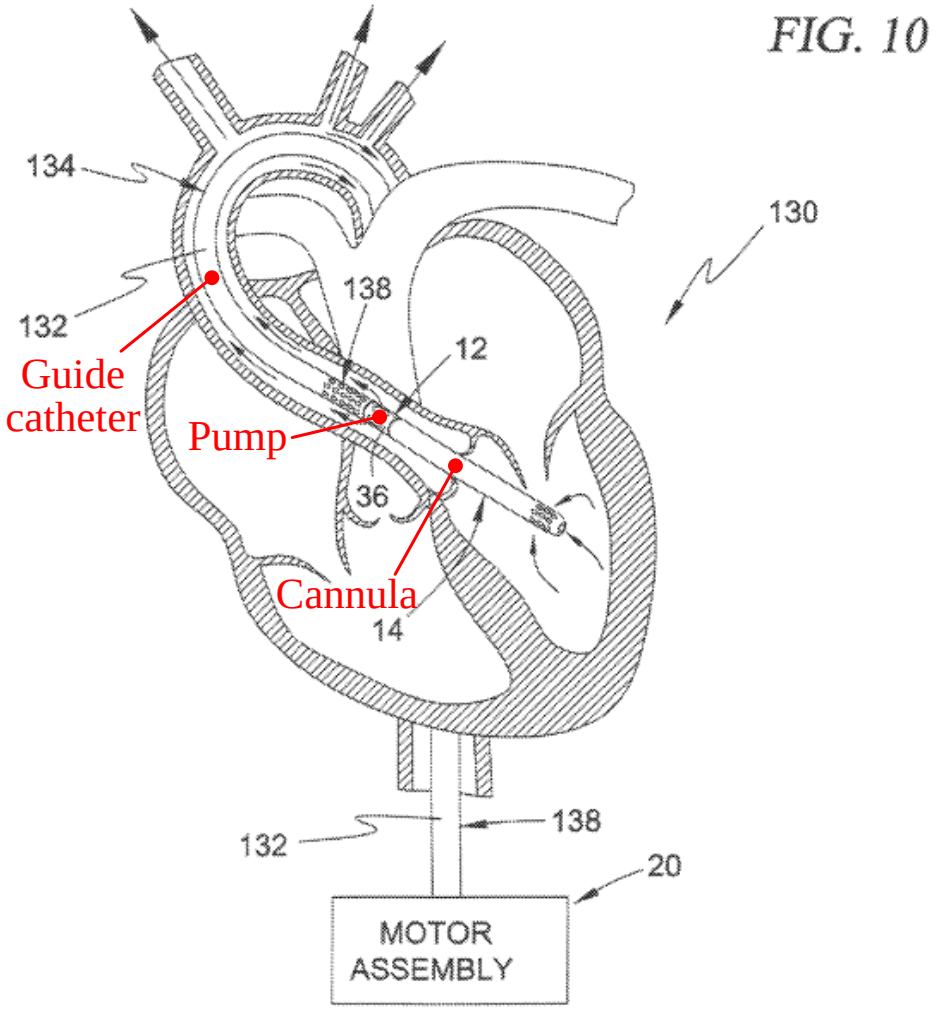
desired location within the circulatory system of the patient." (EX1001 ['100 patent] at 7:30-35.) "Once the guide wire 22 is positioned at the desired location (such as in the left ventricle as shown), the blood pump 12 and cannula 14 may thereafter be advanced centrally along the guide wire 22 and positioned in the trans-valvular configuration shown." (*Id.* at 7:42-46.) After passing through the center of the rotor, the guide wire exits out the distal end of the cannula 14. (*Id.* at FIG. 1.) As explained in detail below, this is the same over-the-wire guide mechanism disclosed in Aboul-Hosn. (Collins ¶92).

FIG. 6 shows the conventional "rapid-exchange" or "side-rigger" guide mechanism of the prior art. (EX1001 ['100 Patent] at 5:30-35.) 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.* at 12:13-19); Collins ¶93-94.)



(Collins ¶93; EX1001 ['100 patent] at FIG. 6, annotated.)

Finally, the '100 patent at FIG. 10 shows a "guide catheter" mechanism 132 as in the prior art. (EX1001 ['100 patent] at 5:49-54; Collins at ¶96.)



(Collins ¶96; EX1001 ['100 patent] at FIG. 10, annotated.)

B. The Earliest Possible Priority Date for the '100 Patent is September 1, 2000

The September 1, 2000 priority date of the '100 patent is the earliest possible priority date (as defined above, the "EPD") for the Challenged Claims.[5] The subject matter of the Challenged Claims is not supported by an earlier-filed

[5] The '100 Patent was filed July 19, 2002, and claims priority to PCT Application No. PCT/US00/24515, which was filed on September 1, 2000.

provisional application. Indeed, during prosecution of the ’728 patent, to which the ’100 patent claims priority, the Examiner came to the same conclusion and found that claim 29 of the ’728 patent was not entitled to the priority date of Provisional U.S. Application No. 60/152,249 (EX1012, the “’249 provisional application”), filed on September 3, 1999 because the ’249 provisional application did not disclose “a blood pressure detection mechanism comprising a fluid column.” (*See* EX1044 [’728 PH] at 261.) The Patent Owner did not challenge the lack of priority to the ’249 provisional in any subsequent response. (*See* EX1044 [’728 PH] at 259-280.)

Independent claim 16 in the ’100 Patent requires “a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.” (EX1001 [’100 Patent] at 20:20-28.) However, as noted by the examiner, the ’249 provisional application does not define or use the terms “blood pressure detecting mechanism,” or “proximate.” There is no support for “a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula” as claimed. *Id.*

The ’249 provisional application fails to provide written description support for, and is non-enabling with respect to, the aforementioned claimed feature. (Ex.1012 [’249 provisional application] at 12; Collins ¶112; *Dynamic Drinkware,*

LLC. v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("the specification of the *provisional* must 'contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.") (quoting *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002) (emphasis in original).)

Accordingly, the EPD for Challenged Claims 16-18 of the '100 patent is September 1, 2000.[6] (Collins ¶11.)

VII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Overview of Aboul-Hosn

Aboul-Hosn discloses the conventional blood pump features and over-the-wire guide mechanism noted above in Section V and disclosed in the '100 patent, along with variations and further examples of how to implement those features for

[6] If the Board finds that one or more Challenged Claims is entitled to the September 3, 1999 filing date of the '249 provisional application, Aboul-Hosn (EX1004) would still qualify as prior art under 35 U.S.C. § 102(a), and Siess '913 (EX1005) and Nix (EX1024) would remain prior art under 35 U.S.C. §§ 102(b) and (e), respectively.

left ventricular function support. (Collins ¶¶104-120; EX1004 [Aboul-Hosn] at 11:9-14, 30:1-2.).

Aboul-Hosn discloses both percutaneous and surgical approaches for delivering an intravascular blood pump. (Collins ¶106; EX1004 [Aboul-Hosn] at FIG. 21, 21:19-22:30, 11:8-12.)

FIGS. 21 and 23, below, show the percutaneous approach using a guide wire to place a stabilization cannula 411[7] (blue) and the blood pump 420 (green) in the left side of a patient's heart. (Collins ¶106; EX1004 [Aboul-Hosn] at 30:1-2, 20-27.) FIG. 21 shows how the blood pump passes along the guide wire up the femoral artery, so the cannula 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, bypassing the left ventricle to replace the left ventricular function. (Collins ¶106; EX1004 [Aboul-Hosn] at 29:17-28, 30:1-2, 30:20-27.)

[7] 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] at 28:23-27.)

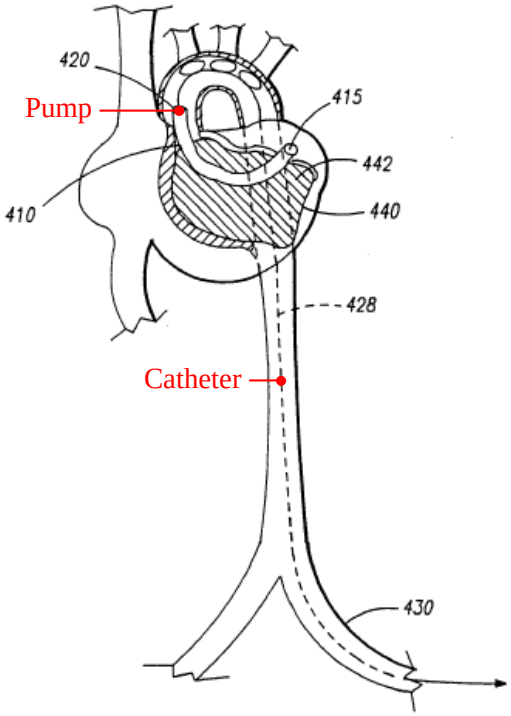


FIG.–21

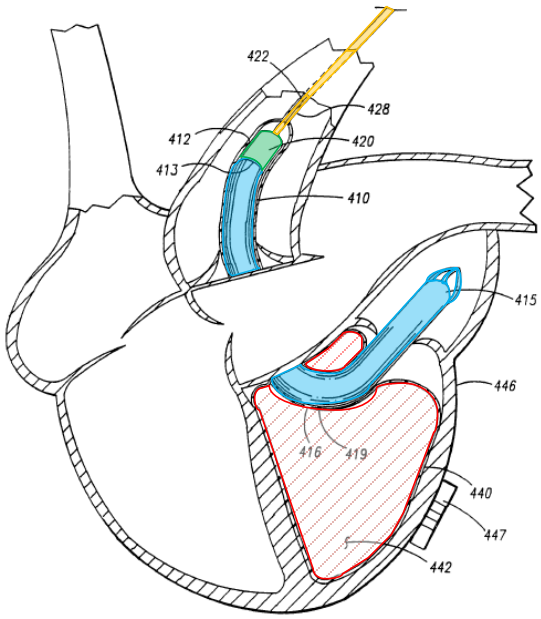


FIG.–23

(Collins ¶106; EX1004 [Aboul-Hosn] at FIGS. 21 and 23, annotated.)

As in the '100 patent, the guide wire passes through the multilumen catheter 428 (yellow) and its "separate lumens to … enable the passage of small diameter guides or leads." (*Id.* at 29:19-23; Collins ¶106.)

The pump 420 could be selected from a variety of available pumps. (EX1004 [Aboul-Hosn] at 30:20-28, 31:6-9: "[t]he stabilization systems shown in FIGS. 23 and 24 illustrate only some of the various types of commercially

available intravascular and extracorporeal pumps that are compatible or provided for by the present invention.")[8]

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, along with a "reverse flow" feature that reverses the direction of blood flow as it exits the cannula. (Collins ¶¶110-12.)

As shown below in FIGS. 1 and 2, and similar to the '100 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)[9]. (EX1004 [Aboul-Hosn] at 12:12-13:13.) An inner cannula 20 (blue) is coupled to the housing cap 62 (green), and extends beyond the distal opening 32 of the outer conduit 30 (dark grey). (*Id.* at 12:12-13:13)

[8] Regarding the "present invention," Aboul-Hosn lists various claims that refer to "reverse flow pump" (e.g., claims 6, 11) with features of the pumps of FIGS. 1-13. (EX1004 [Aboul-Hosn] at 34:26-35:2, 35:17-30.)

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

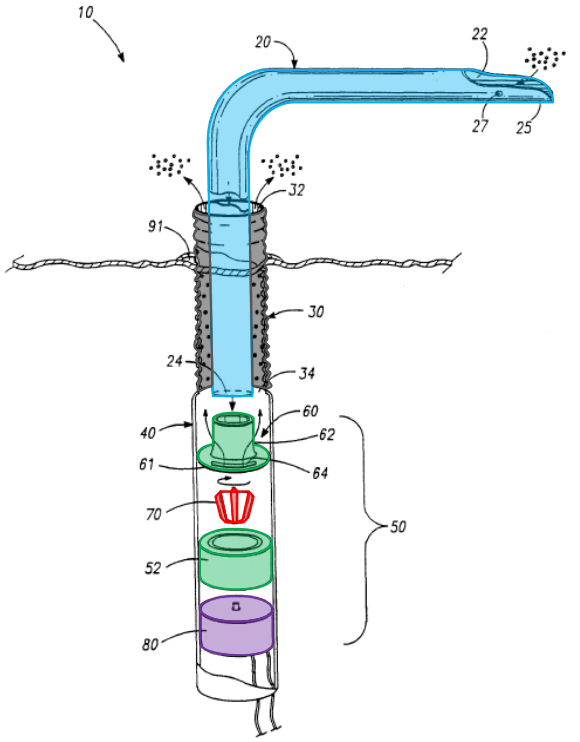


FIG.—1

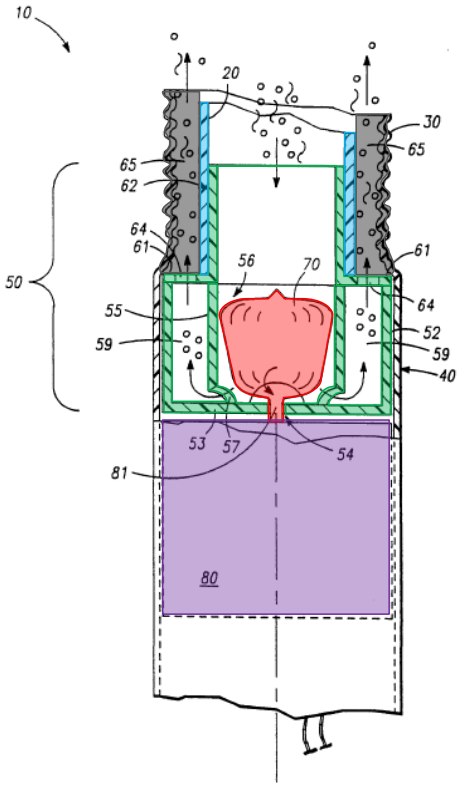


FIG.—2

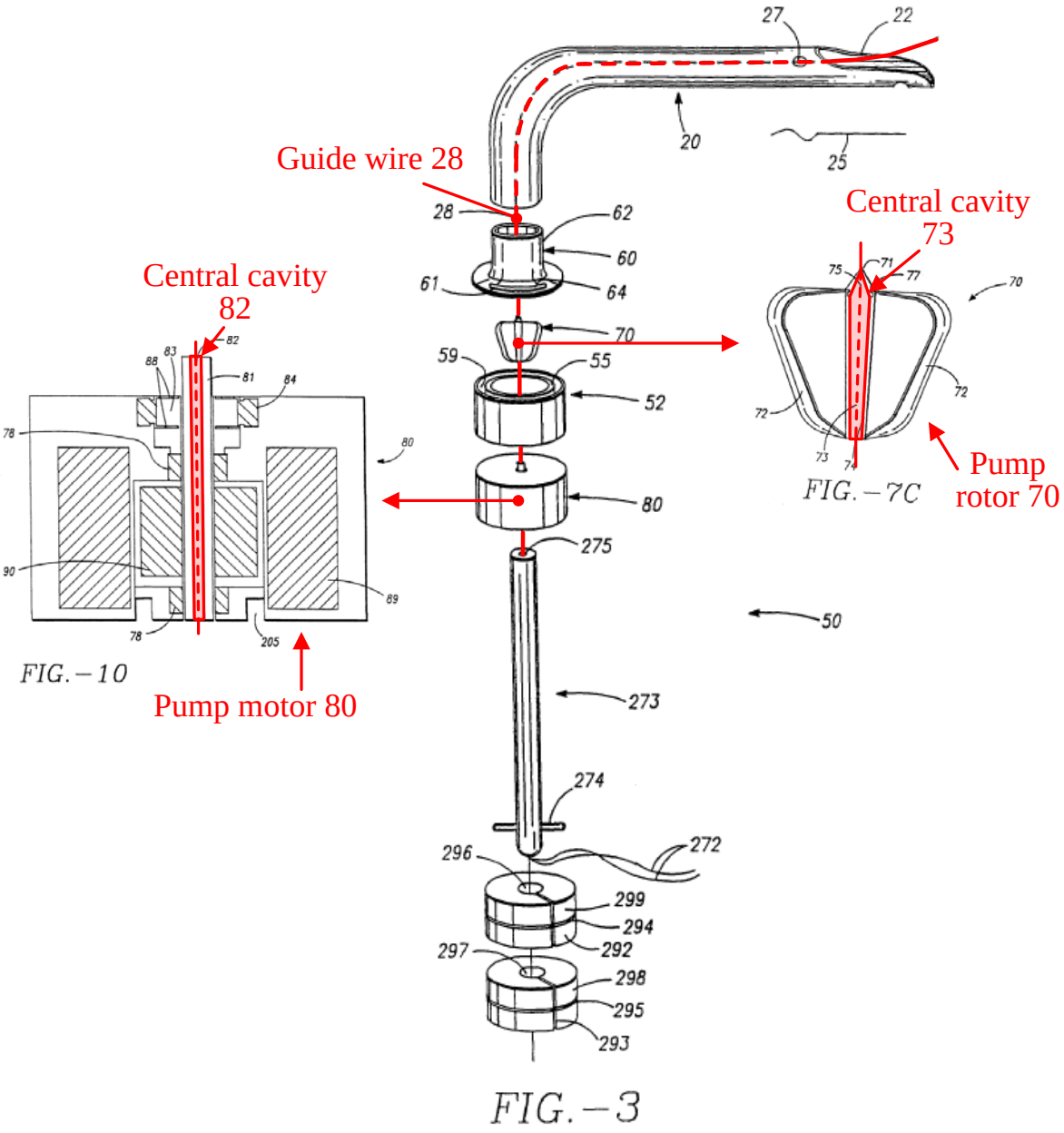
(Collins ¶110; EX1004 [Aboul-Hosn] at FIGS. 1 and 2, annotated.)

In operation, the blood pump draws blood through the distal opening 22 of the inner cannula 20 (blue) by the rotation of the rotor and associated blades 70 (red) driven by the motor 80 (purple), consistent with any conventional axial flow pump. (Collins ¶111; EX1004 [Aboul-Hosn] at 13:14-18.) The rotor 70 and associated blades (red) generate an axial flow of blood (that also has a radial component), which is then "reversed" when the blood exits the inlet tube 55, as shown in FIG. 2 by the directional arrows. (Collins ¶111; EX1004 [Aboul-Hosn] at 13:15-18, 18:15-19.)

Like the pump system in FIG. 23, the design of the pump system of FIGS. 1-13 allows it to be delivered to the heart using a guide wire. (Collins ¶112; EX1004 [Aboul-Hosn] at 11:26-28, 14:13-16, 14:20-24, 21:22-24, 22:10-16.) FIG. 3 shows the conventional over-the-wire technique of FIG. 1 in detail, where the guide wire 28 (red) passes through a central lumen through the center of the motor 80, the rotor 70, and the inner cannula 20, in order to be positioned at a desired location within the patient's vasculature.[10] (Collins ¶117; EX1004 [Aboul-Hosn] at 14:17-15:18, 17:19-22, FIG. 12.) Next, the blood pump is advanced along the guide wire 28 to the desired location using a positioning rod 273[11]. (Collins at ¶117; EX1004 [Aboul-Hosn] at 22:10-21.)

[10] A POSITA could also readily adapt the pump system of FIGS. 1-13 to be delivered using the conventional "rapid-exchange" technique. (Collins ¶117, n. 8.)

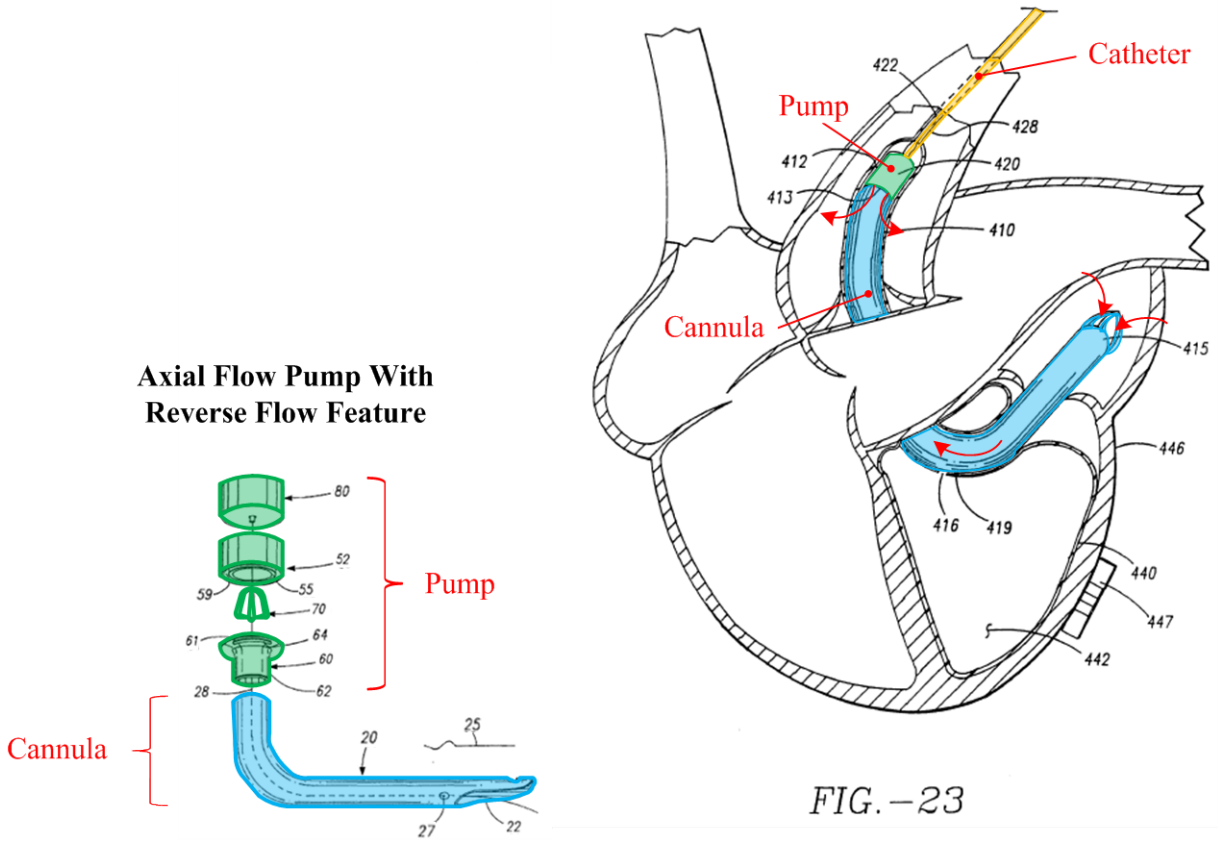
[11] The guide wire also passes through the center of the positioning rod 273. (EX1004 [Aboul-Hosn] at 14:20-24.)



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

The pump system of FIGS. 1-13 can also be introduced percutaneously shown in FIGS. 21 and 23 by varying the length and shape of the inner cannula 20 and outer conduit 30. (Collins Decl. ¶109; EX1004[Aboul-Hosn] at 11:26-28, 14:13-16: "[t]he lengths of the inner cannula 20 and outer conduit 30 may further

be varied in accordance with particular applications such as open heart surgery, or during closed heart or other laproscopic procedures which involve forming other openings to provide percutaneous access to the inner body regions.")

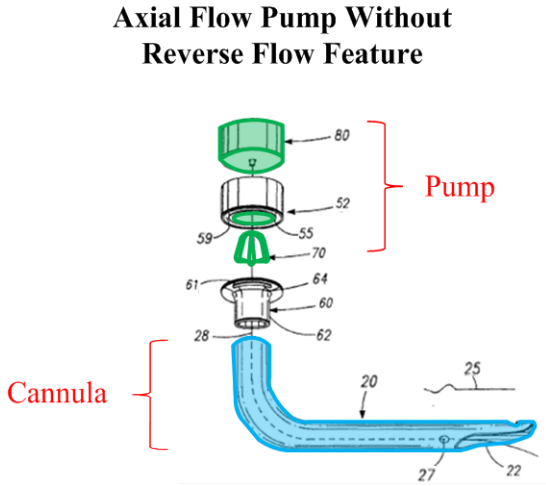


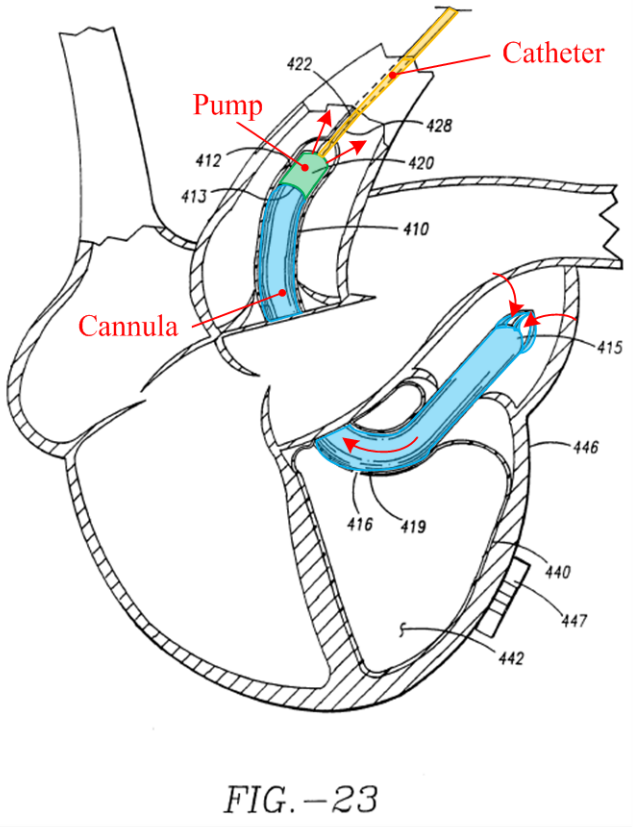
(Collins ¶118; EX1004 [Aboul-Hosn] at FIGS. 1 and 23, annotated.)

As shown above, to apply the percutaneous approach in the reverse flow configuration, the pump (green) in the system of FIGS. 1-13 (i.e. an intravascular pump "provided for by the present invention") would be readily connected to the multilumen catheter 428 (yellow). (Collins ¶118.) In this configuration, the central guide wire lumen of the pump system of FIGS. 1-13 would align with the

catheter 428 guide wire lumen, and the catheter 428 would be used to advance the pump 420 and stabilization cannula 411 in the conventional over-the-wire approach to the desired location within the patient's heart through the femoral artery. (Collins ¶120; EX1004 [Aboul-Hosn] at 29:17-25.)

A POSITA would also have readily understood that the pump 420 could also be configured without the reverse flow feature of the pump system of FIGS. 1-13 and delivered by a similar over-the-wire guide mechanism. (Collins ¶113; *see also* EX1004 [Aboul-Hosn] at 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) but retaining the central guide wire lumen. (Collins ¶114.) Instead, the blood (represented by the red arrows) discharges axially over the drive unit and out the pump 420 (green). (*Id*.)



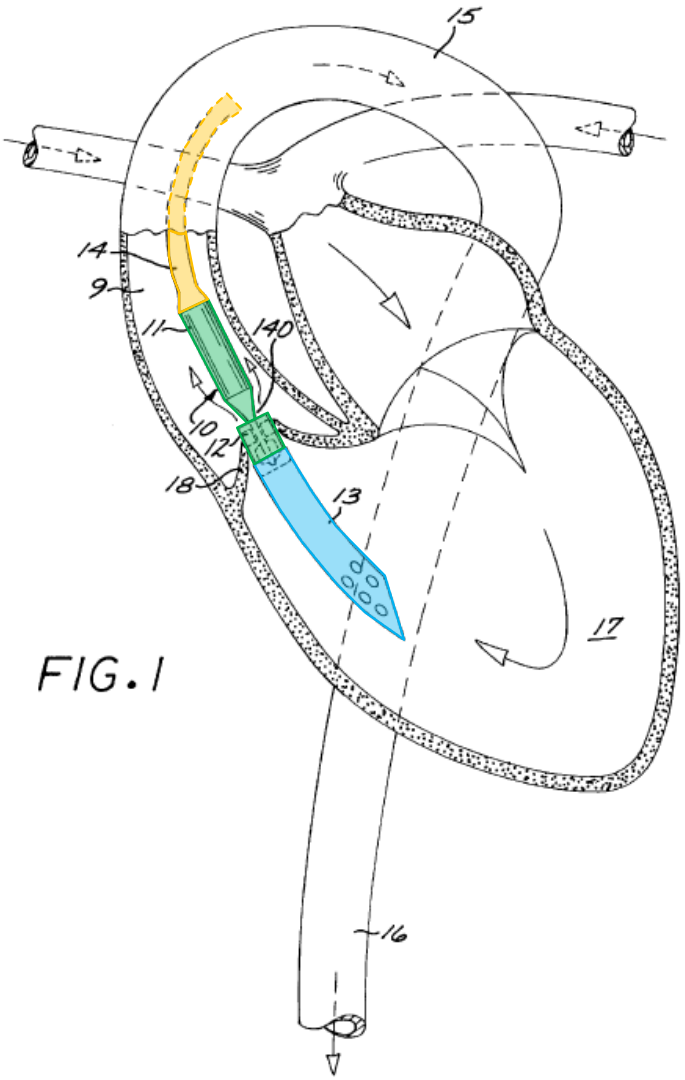


(Collins ¶114; EX1004 [Aboul-Hosn] at FIGS. 1 and 23, annotated.)

B. Overview of Siess '913

Siess '913 also discloses using a guide wire to place an intravascular axial blood pump and cannula at a desired location with the patient's vasculature. (Collins at ¶121; EX1005 [Siess '913] at 5:55-58.) As shown in annotated FIG. 1, below, the microaxial pump 10 (green) "includes a drive unit 11 and a pumping segment 12" connected to an inlet cannula 13 (blue). The inlet cannula 13 is "[d]istally extending from the pumping segment." (*Id.* at 5:41-47.) "The proximal end" of the microaxial pump 10 (green) couples to a catheter 14 (yellow) "which

has been inserted via the femoral artery through the aortic arch 15 and into the ventricle 17." (*Id.* at 5:47-50.)



(Collins ¶121; EX1005 [Siess '913] at FIG. 1, annotated.)

C. Overview of Nix

Nix discloses an intracardiac blood pump, and different pressure measuring means (e.g., a single differential pressure sensor, or a combination of motor current

and speed) to determine the position of the pump in the heart. (Collins ¶124; EX1019 [Nix] at 1:3 and 1:48-49.)

VIII. CLAIM CONSTRUCTION

A claim in *inter partes* review 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).)

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

Pursuant to Rule 42.104(b)(4)-(5), 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: Claims 16-17 are obvious over Aboul-Hosn in view of Siess '913

1. Claim 16

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

Aboul-Hosn discloses an intravascular blood pump system having an intravascular blood pump. (Collins ¶126; EX1004 [Aboul-Hosn] at 6:6-8: "a reverse flow pump system that transports fluid between different regions within the body," 6:26-29: "[a] reverse flow blood pump system may be passed through a conduit and positioned in a heart chamber or a vessel.") FIG. 23 of Aboul-Hosn, annotated below, shows "a partial sectional view of the heart and a stabilization system used in cooperation with an intravascular pump" that was delivered percutaneously into the heart through the femoral artery. (*Id.* at 10:10-11, 29:17-19.)

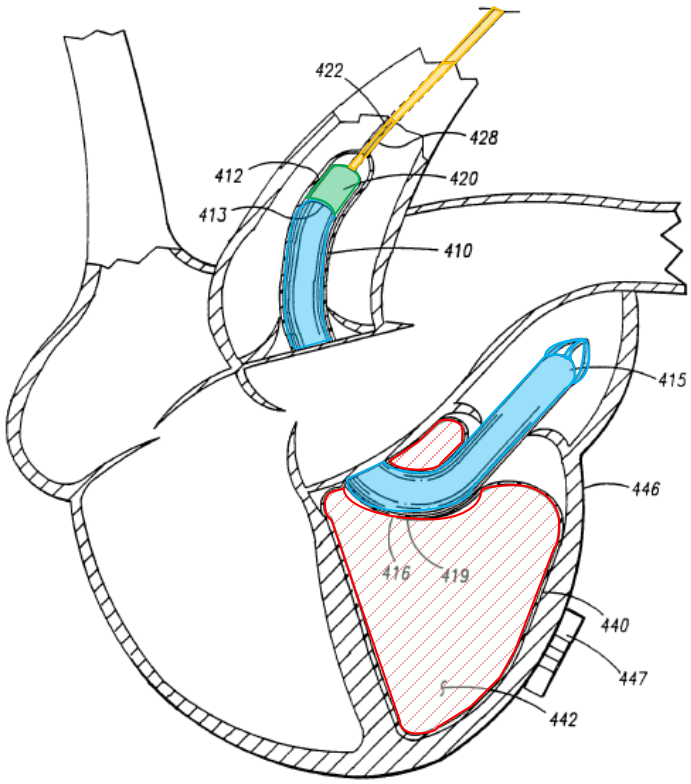
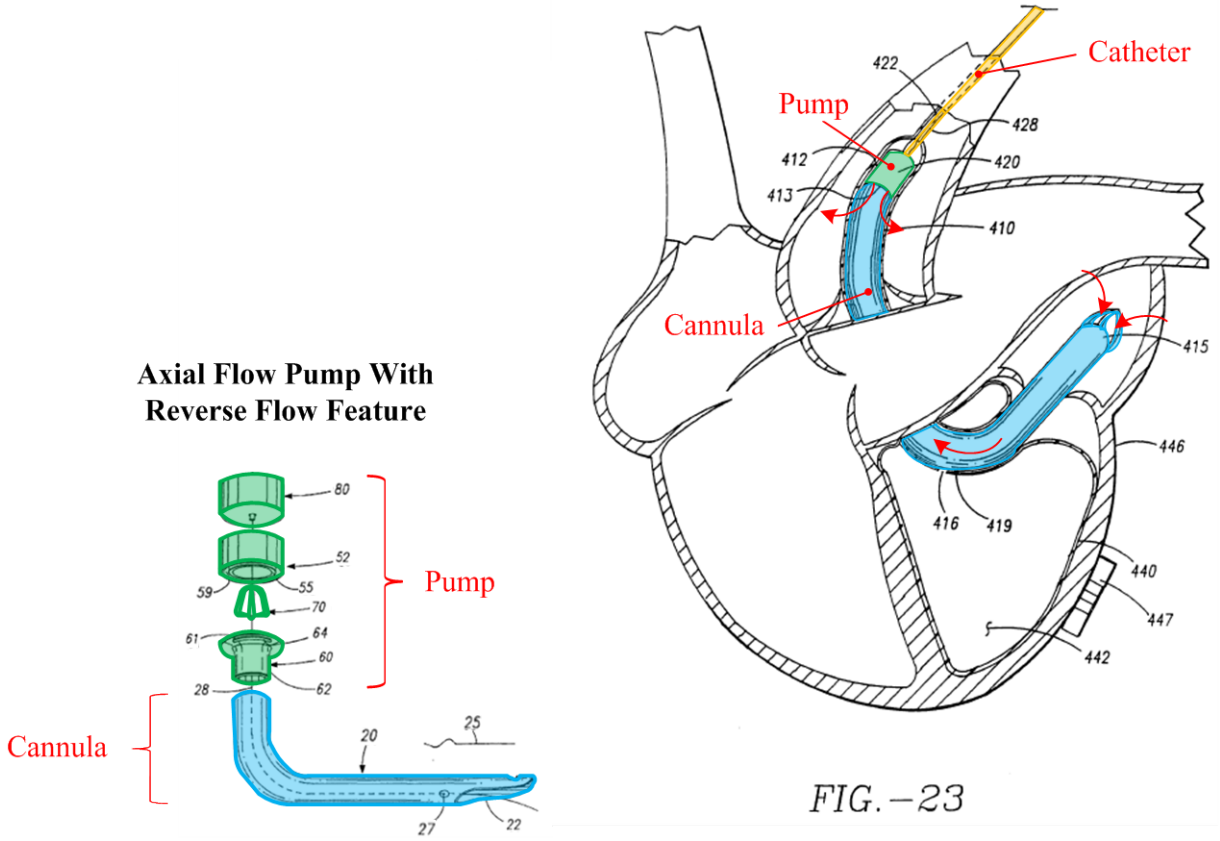


FIG.–23

(Collins ¶128; EX1004 [Aboul-Hosn] at FIG. 23, annotated.)

As discussed in Section VII.A, Aboul-Hosn discloses that the axial flow pump system of FIGS. 1-13 with reverse flow feature can be delivered to the heart percutaneously as shown in FIG. 23, below, by connecting the pump components illustrated in FIGS. 1-13 with the multilumen catheter 428 and adapting the inner cannula 20 and the outer conduit 30 as the stabilization cannula 411 in FIG. 23. (Collins ¶¶128-29, 136; EX1004 [Aboul-Hosn] at 8:20-9:15, 29:18-30:28, 14:13-16: "[t]he lengths of the inner cannula 20 and outer conduit 30 may further be varied in accordance with particular applications such as…during closed heart or

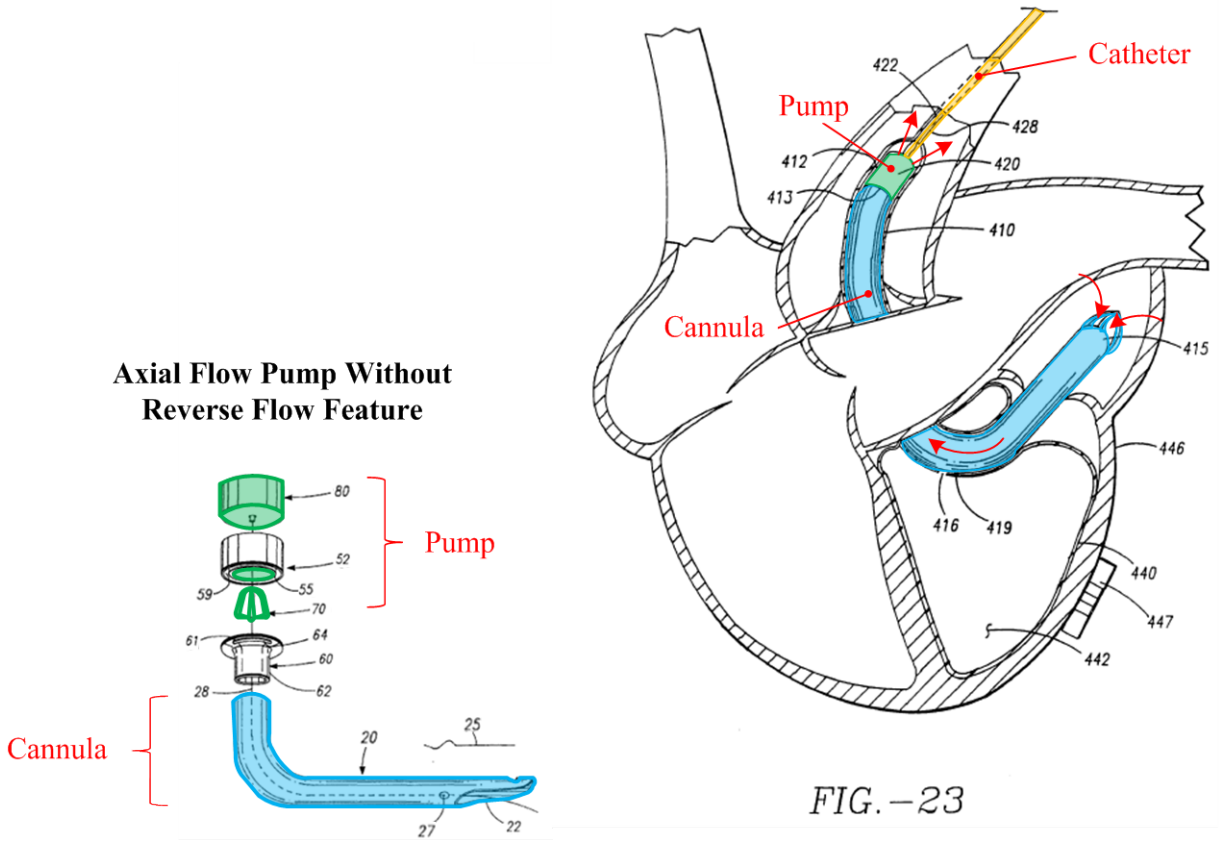
other laproscopic procedures which involve forming other openings to provide percutaneous access to inner body regions.") In this configuration, the cannula 20 mates with housing cap 62. (Collins ¶138).



(Collins ¶132; EX1004 [Aboul-Hosn] at FIGS. 1 and 23, annotated.)

In addition to the reverse flow configuration, the pump 420 may also be configured without the reverse flow feature of the axial flow pump system of FIGS. 1-13 as shown in the annotated figures below. (Collins ¶133; EX1004 [Aboul-Hosn] at 31:6-9: "[t]he stabilization systems shown in FIGS. 23 and 24 illustrate only some of the various types of commercially available intravascular and extracorporeal pumps that are compatible or provided for by the present

invention.") In this configuration, the cannula 20 mates with inlet tube 55. (Collins ¶139).



(Collins ¶133; EX1004 [Aboul-Hosn] at FIGS. 1 and 23, annotated.)

Thus, Aboul-Hosn discloses an intravascular blood pump system. (*Id*. at ¶135.)

b) "*an intravascular blood pump having a cannula coupled thereto*"

Aboul-Hosn discloses a direct connection between the pump and the cannula at the pump's distal end. (Collins at ¶136; EX1004[Aboul-Hosn] at FIG. 23,

annotated). Annotated FIG. 23 below illustrates the cannula 411 coupled to the blood pump 420 at the pump's distal end.

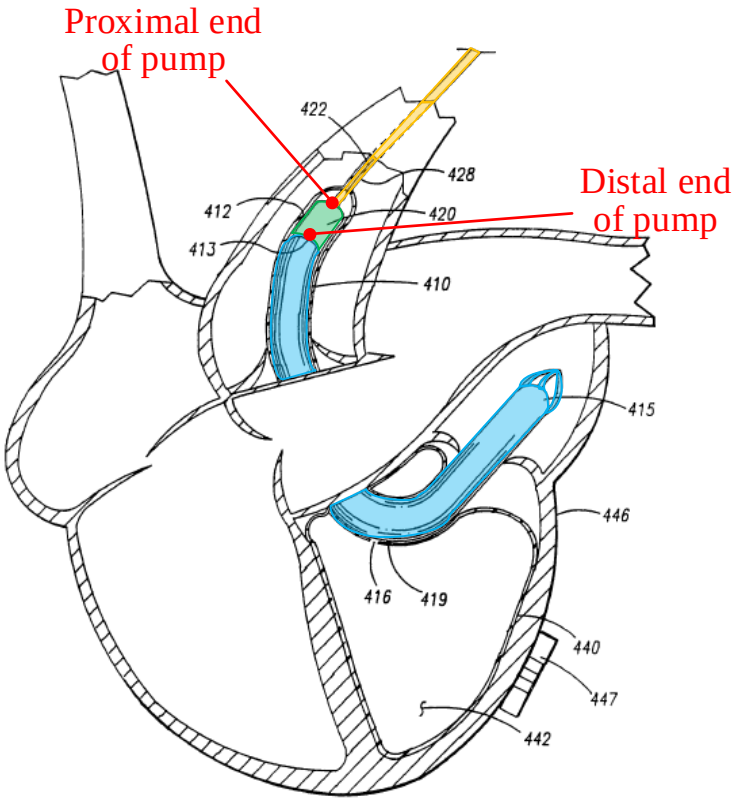
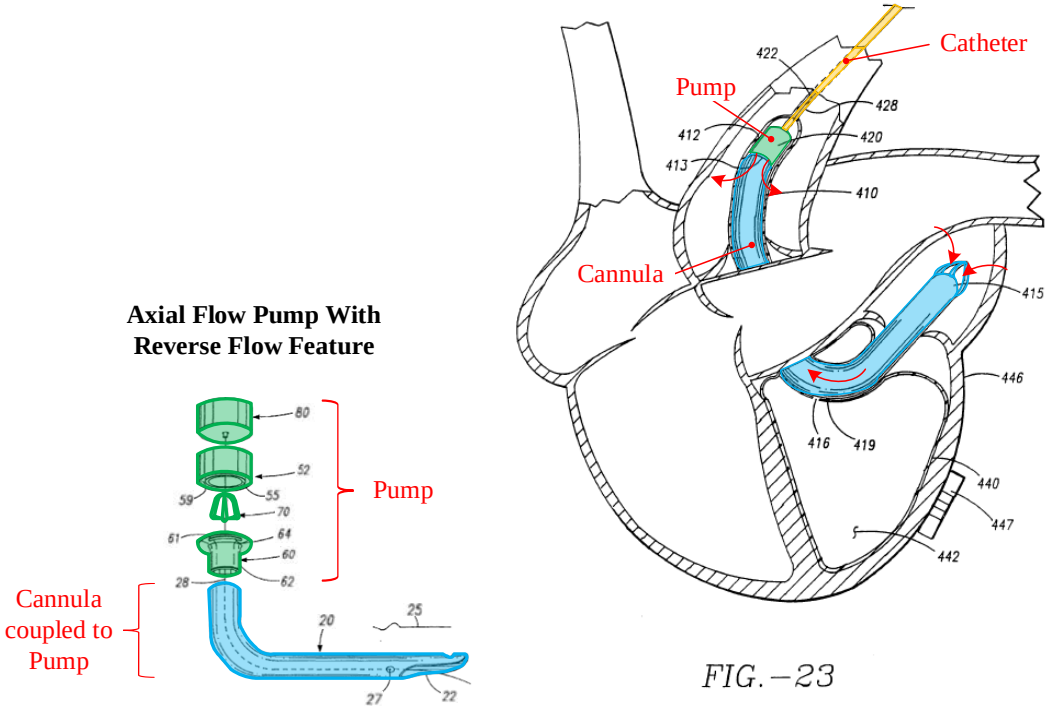


FIG.–23

(Collins ¶136; EX1004 [Aboul-Hosn] at FIG. 23, annotated.)

Aboul-Hosn discloses that the axial blood pump components of FIGS. 1-13 can be used for the blood pump 420, and thus would connect to the cannula 411 in the same configuration as in FIGS. 1-13 (i.e. at the inlet tube 55 and inlet neck 62). The inner cannula 20 and outer conduit 30 as illustrated in FIGS. 1-13 can be adapted for percutaneous access, such as in the manner as shown in FIG. 23 with the stabilization cannula 411. (Collins ¶137; EX1004 [Aboul-Hosn] at 14:13-16.

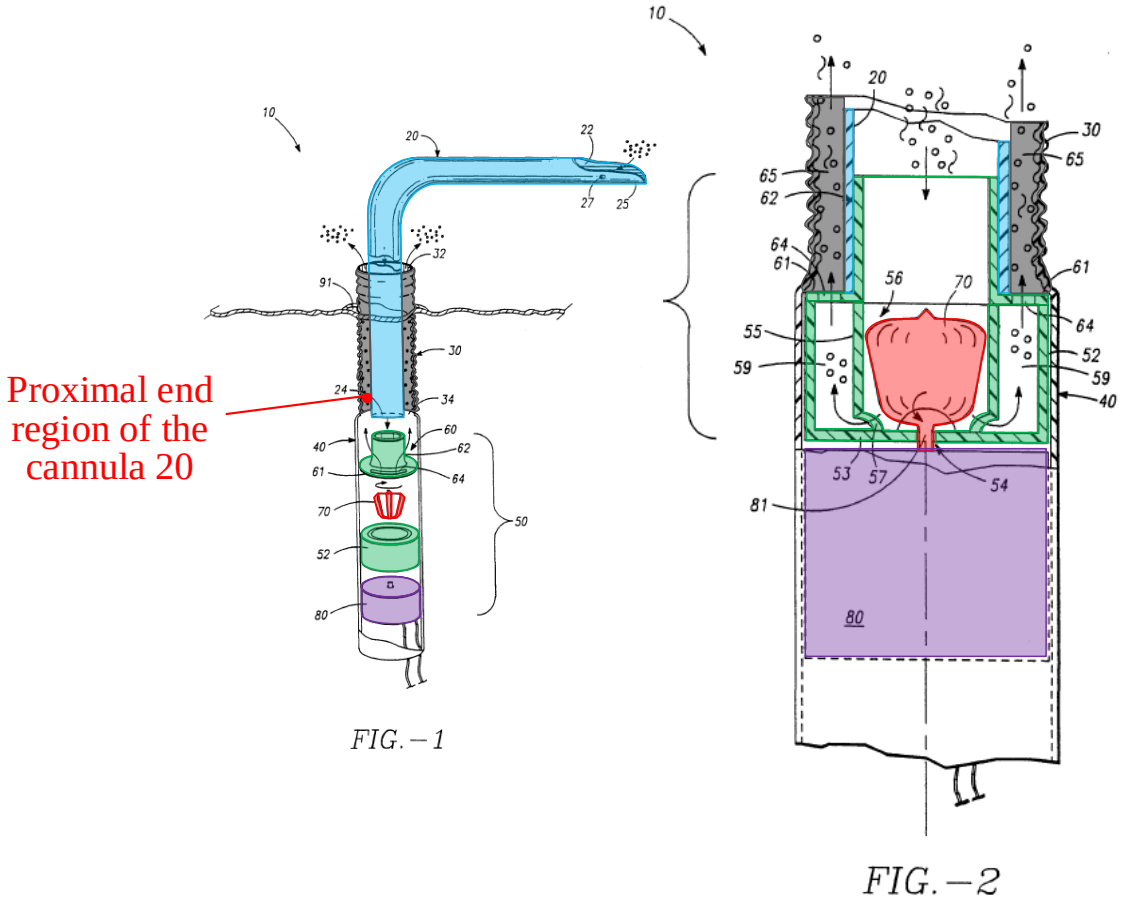
Annotated FIGS. 3 and 23 below show how the pumping components in FIGS. 1-13, such as disclosed in FIG. 3, would apply in the percutaneous configuration in FIG. 23.



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

As detailed further in annotated FIGS. 1 and 2, below, inner cannula 20 (blue) extends from the shroud's inlet neck 62 within the housing cap 60 (green) and the inlet tube 55 (green) within the housing body 52; this would occur in the proximal end region of the cannula 20, where that region would fit concentrically about the inlet neck 62 – in the distal end region of the pump. Analogously, in the percutaneous application, cannula 411 (i.e. the inner cannula 20 and the outer

conduit 30 adapted for percutaneous access) would extend from the inlet neck 62 and inlet tube 55.



(Collins ¶138; EX1004 [Aboul-Hosn] at FIGS. 1 and 2, annotated.)

Aboul-Hosn also discloses this element in the axial flow pump configuration without the reverse flow features—i.e., the cannula 20 would extend directly from the inlet tube 55 (shroud). As shown below in annotated FIGS. 3 and 23, the proximal end of cannula 20 (green below) would fit concentrically around the inlet

tube 55 (green), analogously to how it would fit around the inlet neck 62 of the housing cap 60 in the reverse flow mode.

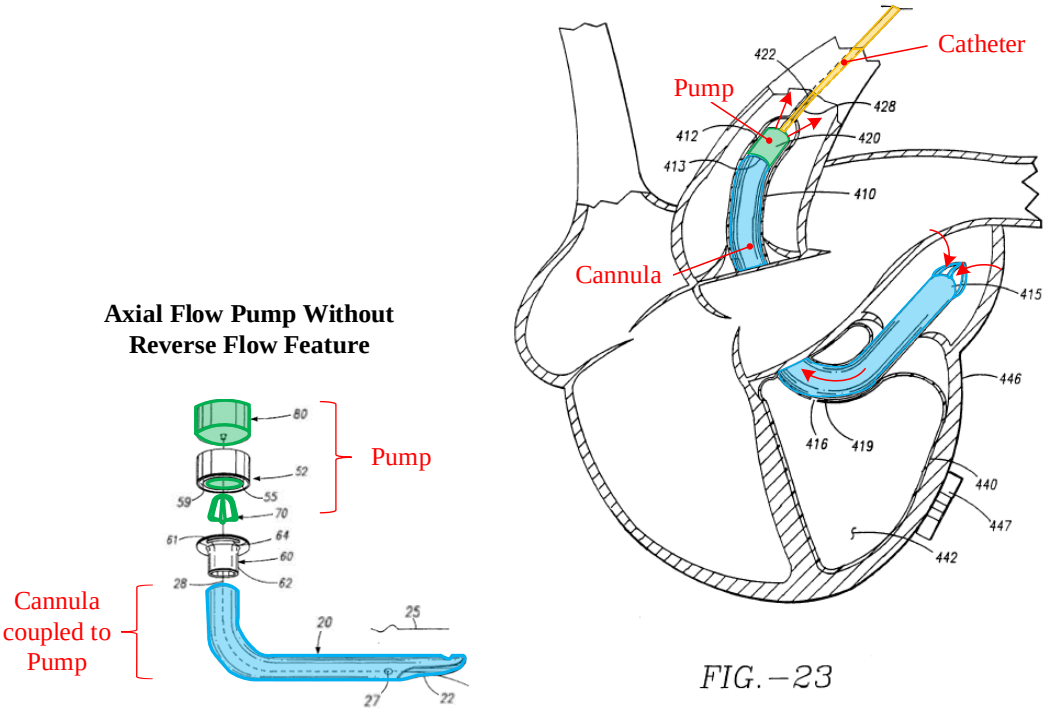


FIG.–23

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

Thus, Aboul-Hosn discloses an intravascular blood pump having a cannula coupled thereto. (Collins ¶140)

> c) *"a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient"*

As previously discussed in Section VII.A, Aboul-Hosn discloses how a blood pump system may be placed in a desired location within a patient, such as within the left side of the heart, by using a guide wire 28. (Collins ¶141; EX1004 [Aboul-Hosn] at 17:19-22, 24:7-14.) As shown in FIG. 3 annotated below, the

guide wire 28 passes through a central passage (i.e. a lumen) that runs through the motor 80, the rotor 70, the housing cap 60, and the inner cannula 20, and then exits out of the distal opening 22 of the cannula. (Collins ¶142.) FIG. 3 is an exploded perspective view of the blood pump assembly in FIGS. 1 and 2.

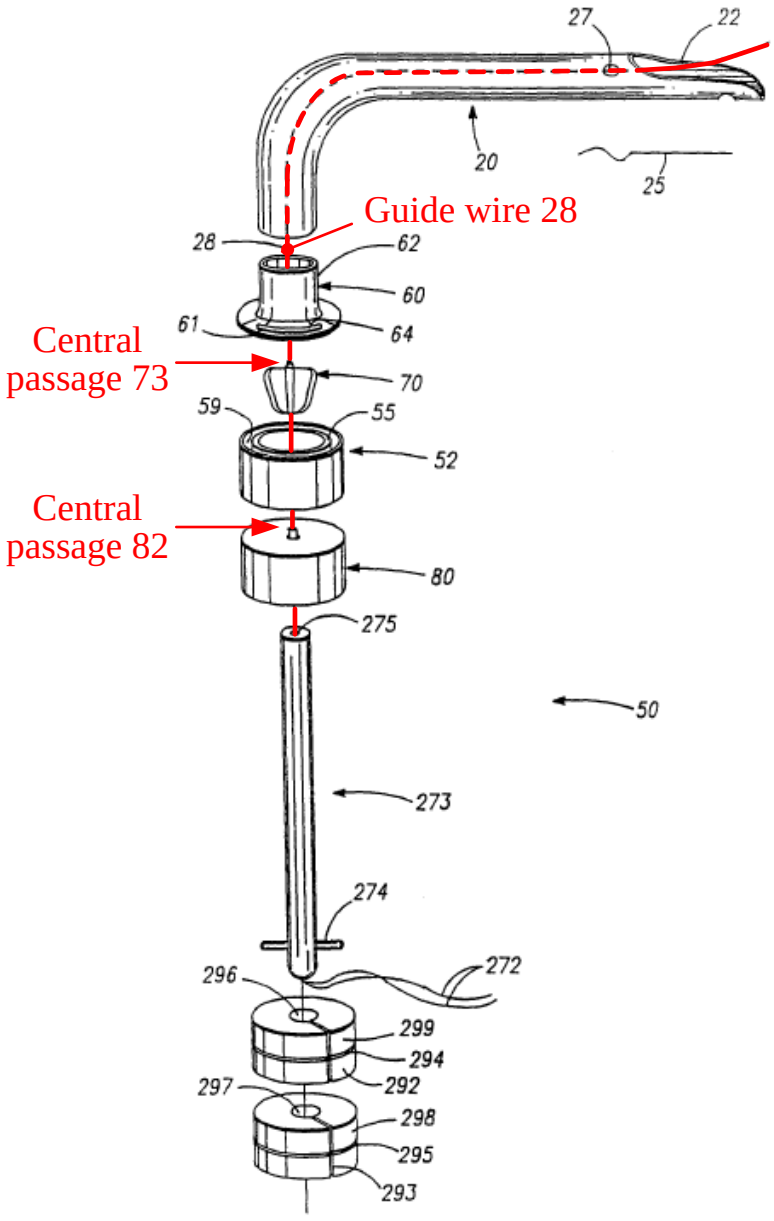


FIG.—3

(Collins ¶142; EX1004 [Aboul-Hosn] at FIG. 3, annotated)

Aboul-Hosn discloses that "a central rotor passage 73 may extend the entire length of the rotor 70 and preferably forms a continuation of central passage 82 of drive unit 80." (EX1004 [Aboul-Hosn] at 17:8-10.)

As discussed above in Section VII.A, for percutaneous access through the femoral artery, the intravascular blood pump system shown in FIGS. 1-13 (with or without the reverse flow feature) may be adapted in a straight forward manner as the pump 420 in FIG. 23 by aligning the central passages of the pump system of FIG. 3 with the guide wire lumen of catheter 428 of Fig. 23. (Collins ¶¶146-47; EX1004 [Aboul-Hosn] at 29:19-25.) The guide wire lumen of the catheter 428 forms a continuation of the central passages of the pump system. (Collins ¶146.)

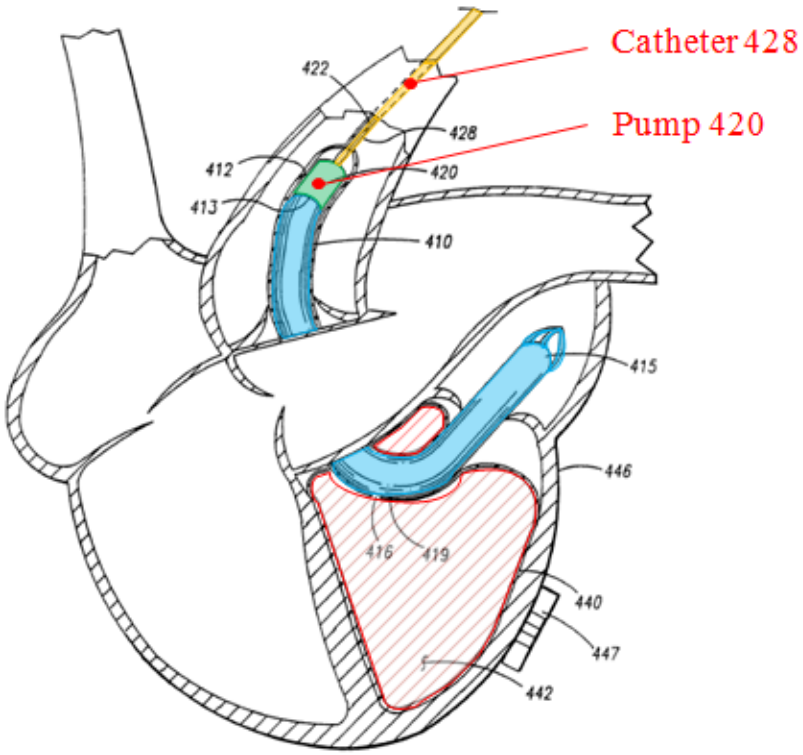
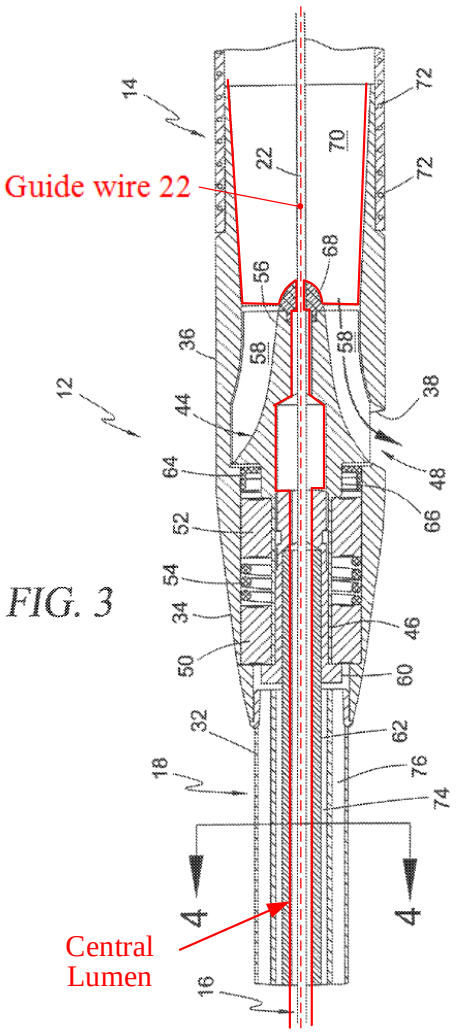


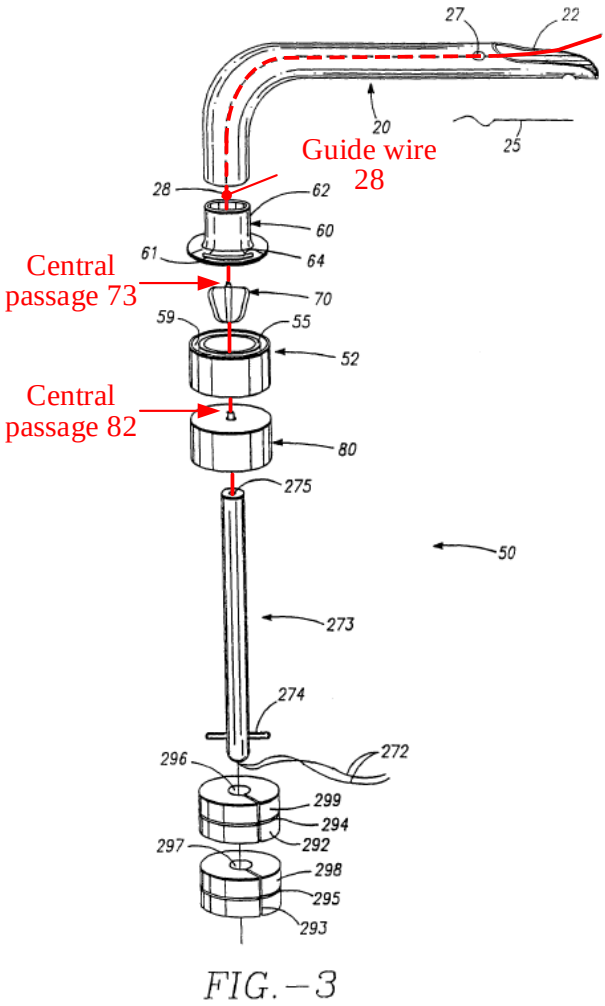
FIG.–23

(Collins ¶153; EX1004 [Aboul-Hosn] at FIG. 23, annotated)

As shown in the side-by-side comparison below, this central passage disclosed in Aboul-Hosn (right) has the same configuration as the guide mechanism in the over-the-wire embodiment of the ’100 patent (left). (*Id.* ¶147.)



‘100 Patent



Aboul-Hosn

(Collins ¶147; EX1001 [’100patent] at FIG. 3, annotated (left); EX1004 [Aboul-Hosn] at FIG. 3, annotated)

As the ’100 Patent explains, “[t]his central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14.” (EX1001 [’100 Patent] at 10:49-53.) Correspondingly, Aboul-Hosn discloses that

the catheter 428, motor 80, rotor 70, and inner cannula 20 have respective lumens or central passages that are co-aligned to create a single continuous lumen through those components—consistent with the "over the wire" guide mechanism of the '100 Patent. (Collins ¶148.)

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

With the guide wire 28 positioned in the desired location within the patient's vasculature, such as within the left side of the heart as shown in FIG. 23, the distal end of the cannula 20 (or cannula 411) of the blood pump can be advanced by passing over the guide wire 28 via the central passages of the cannula, the blood pump components (e.g., central passages 73 and 82) and through a lumen of the

multilumen catheter 428.[12] (Collins ¶117, 141-145; EX1004 [Aboul-Hosn] at 22:12-16: "[t]he guide wire 28 may be inserted and positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20. As a result, the distal end of the inner cannula 20 may be guided to a location before removing the guide wire 28.") Aboul-Hosn discloses that its technique can be used generally to position a cannula "at desired locations throughout the body including the heart region." (EX1004 [Aboul-Hosn] at 11:24-28.) By this technique, the distal tip of the cannula can be placed in ventricle heart chamber for directing blood into another vessel or region of the heart, such as shown in FIG. 23. (*Id*. at 11:9-14; 30:20-28.)

Thus, Aboul-Hosn discloses a guide mechanism adapted to guide a distal portion of the intravascular blood pump system to a predetermined location within the circulatory system of a patient, including the left ventricle of the patient's heart. (Collins ¶150.)

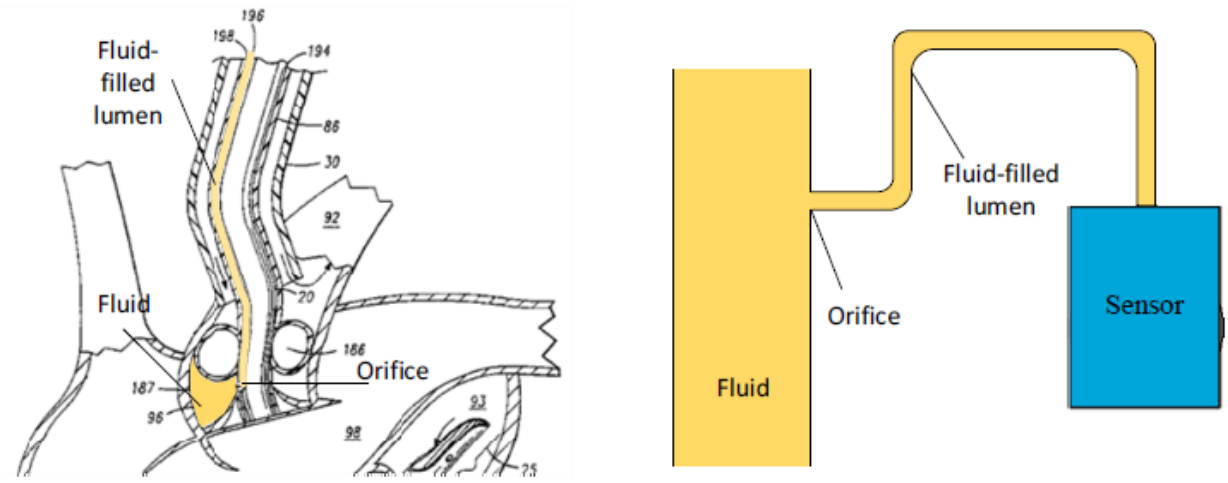
[12] As previously discussed in Section VII.A, cannula 411 shown in FIG. 23 is simply the inner cannula 20 and outer conduit 30 (in the reverse flow configuration) adapted for percutaneous access. (Collins ¶ 148; EX1004 [Aboul-Hosn] at 14:13-16.)

d) "*a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.*"

The '100 patent is silent as to what it means to "detect the pressure of the blood proximate the intravascular blood pump and cannula." (Collins ¶151.) Notwithstanding, Aboul-Hosn in view of Siess '913 disclose these elements -- in more detail than does the '100 patent.

Aboul-Hosn discloses measuring pressure proximate the cannula. Aboul-Hosn forms an orifice in the surface of the cannula 20 to "measure pressure in areas proximal to the orifice" where the orifice 187 "may also be positioned anywhere along cannula 20 surfaces." (EX1004 [Aboul-Hosn] at 28:12-18.)

A fluid column in the cannula of Aboul-Hosn would be used to detect blood pressure. For the cannula, Aboul-Hosn discloses that the orifice 187 connects to a fluid source located outside the patient to allow for delivery of fluids such as medication or drugs during surgery. (Collins ¶¶154-55; EX1004 [Aboul-Hosn] at FIG. 19, 27:5-8, 27:14-20, 27:31-28:3, 28:7-10.) Thus, it is necessarily the case that orifice 187, when used to measure pressure, would be a point of entry of fluid that similarly communicate through a fluid column with a pressure detector located outside the body as illustrated below. (Collins ¶155.)



(Collins ¶154; EX1004 [Aboul-Hosn] at FIG. 19, annotated.)

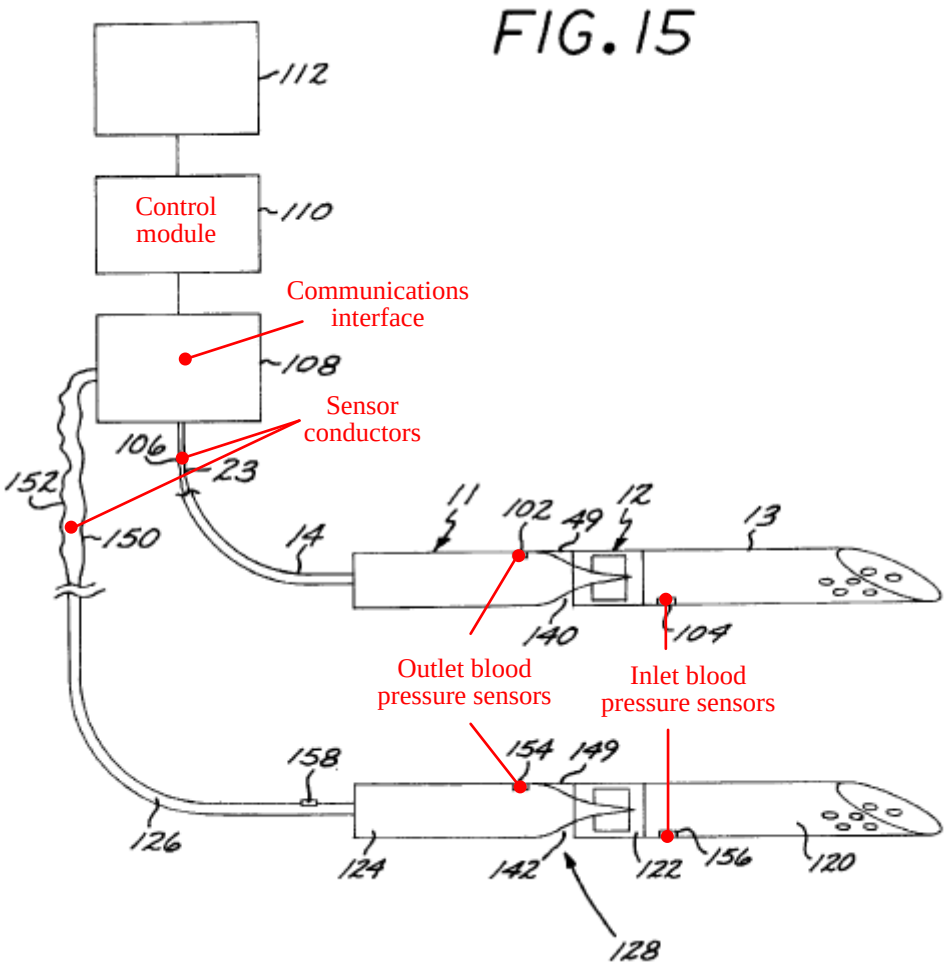
Aboul-Hosn also discloses detecting the pressure of the blood proximate the intravascular blood pump. The Aboul-Hosn catheter 428 has multiple lumens to perform various functions related to the operation of the intravascular blood pump 420, including "to measure pressure in the vicinity of the catheter along its entire length," i.e. a blood pressure lumen. (*Id.* ¶152; EX1004 [Aboul-Hosn] at 29:19-23.) This necessarily includes measuring pressure proximate to the blood pump 420. (Collins ¶152; EX1004 [Aboul-Hosn] at 29:19-23.) In fact, detecting blood pressure to aid in controlling the operation of the pump was well-known. Since the distal end of the multilumen catheter 428 couples to the pump, a POSITA would detect the pressure at the distal end of the multilumen catheter 428, where it connects to the pump 420, to obtain the most accurate reading of pump 420's output. (Collins ¶152.)

A POSITA would understand from Aboul-Hosn's disclosure that to measure the pressure near an orifice in the cannula or catheter with a fluid column, a pressure detector located outside the body could be used. (Collins ¶155.)

As an alternative, Aboul-Hosn discloses sensors to detect the blood pressure from the fluid column, either proximate the blood pump or proximate the cannula. "The pump 50 may be also be equipped with sensing devices (not shown) for measuring various body conditions such as blood pressure…that would suggest the need for altering the flow rate of the fluid transport apparatus 10." (Collins ¶157; EX1004 [Aboul-Hosn] at 23:4-8). In addition, the blood pump "may include pressure sensors along the inner cannula 20" where the orifice 187 "may be positioned anywhere along cannula 20 surfaces." (Collins ¶157; EX1004 [Aboul-Hosn] at 23:8-10; 28:12-18). In either placement, i.e. in the pump 50 itself, or anywhere along the inner cannula 20, Aboul-Hosn's blood pressure sensors would detect the pressure of the blood proximate the blood pump. (Collins ¶157).

Siess '913 confirms the placement of the Aboul-Hosn sensors to detect the pressure of the blood proximate the blood pump or the cannula. Specifically, Siess '913 discloses the use of pressure sensors positioned at the desired pressure measurement location. (Collins ¶158; EX1005 [Siess '913] 4:28-38; 11:23-40). A POSITA would understand pressure can be measured in any number of ways and that some of the mechanisms for measuring pressure may be combined with the

pressure sensors of Aboul-Hosn, such as using the sensors disclosed in Siess '913 to measure the pressure in the fluid columns of Aboul-Hosn, to form a blood pressure detection mechanism comprising a fluid column and configured to detect the pressure of the blood. (Collins ¶158). Siess '913 confirms this well-understood preference for measuring blood pressure near the pump. (*Id*. ¶159.) As previously discussed in Section VII.B and shown in annotated FIG. 15 of Siess '913 below, Siess '913 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 to the pump housing." (EX1005 [Siess '913] at 11:25-28.) Siess '913 further teaches that "[w]ith the information provided by such sensors, it is possible to discern the position of the pump relative to the external sealing member such as the heart valve" and "[b]y comparing the pressure differential to the current drawn by the motor, it is possible to identify blockage conditions as well as cavitation." (*Id.* at 11:42-55.) While the sensors in Siess '913 communicate with the control module through sensor conductors 106 and 162 instead of a fluid column, Siess '913 demonstrates that it was preferred to measure the blood pressure near the pump to control the operations of the pump.



(Collins ¶158; EX1005 [Siess '913] at FIG. 15, annotated.)

It would have been obvious, indeed routine, for a POSITA to measure the blood pressure adjacent Aboul-Hosn blood pump 420 with the multilumen catheter 428 or cannula 20 in the position shown in FIG. 15 of Siess '913 to measure the pumped blood pressure, as that would provide the most accurate reading of the blood pressure near the output of pump 420. (Collins ¶160.) Moreover, one of ordinary skill in the art would have been motivated to do so "to discern the position of the pump" and to "identify blockage conditions and cavitation" by comparing

the pressure differential to the current drawn by the motor as taught by Siess '913. (Collins ¶160; Siess 11:42-44 and 11:53-55)

Thus, Aboul-Hosn, alone or alternatively in view of Siess '913, discloses a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula. (*Id*. ¶161.)

2. Claim 17

Claim 17 depends from claim 16 and recites "*The intravascular blood pump system of claim 16 and further, wherein said blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of said cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula.*"

A POSITA would understand that pressure can be measured by any number of well-known ways. (Collins ¶169.) Aboul-Hosn discloses using a fluid column disposed within at least a portion of the cannula to measure blood pressure in the cannula 20. (Collins ¶164.) The measurement is done by using the orifice 187 which is located in the cannula 20, and is in fluid communication with lumens 196, 198. (*Id.* ¶164.) As previously mentioned in relation to claim 16, this is a conventional hydrostatic pressure measurement, which would be done with the lumens 196, 198, and "pressure sensors along the inner cannula 20" and where the

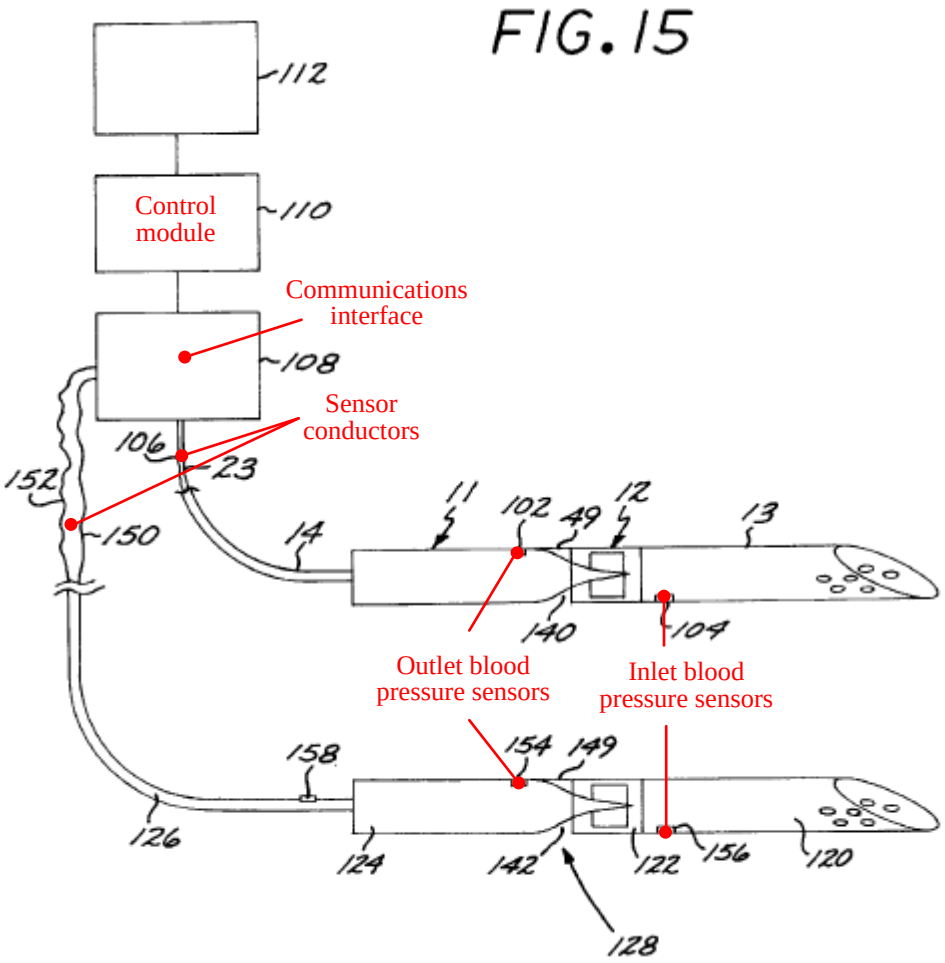
orifice 187 "may be positioned anywhere along cannula 20 surfaces." EX1004 [Aboul-Hosn] at 23:8-10; 28:12-18. Aboul-Hosn's blood pressure sensors, which can be located anywhere along the inner cannula 20, i.e. which could be located within the pump 50 itself, detect the pressure of the blood proximate the blood pump. (Collins ¶164.) As indicated by Dr. Collins, a POSITA would understand that if the orifice 187 may be positioned anywhere along cannula 20, it is because the fluid filled column is disposed within at least a portion of the cannula. (Collins ¶165). Thus, Aboul-Hosn discloses that the blood pressure detecting mechanism comprises at least a fluid filled column disposed within at least a portion of the cannula. (*Id.* ¶166.)

Aboul-Hosn also discloses other pressure detection mechanism for detecting blood pressure near the blood pump. (Collins ¶168.) As indicated by Dr. Collins, a POSITA would understand that pressure can be measured by any number of well-known ways. (Collins ¶169.) Aboul-Hosn also discloses that pressure can be measured in the intravascular blood pump by using pressure sensors to detect the blood pressure from the fluid column: "The pump 50 may be also be equipped with sensing devices (not shown) for measuring various body conditions such as blood pressure…that would suggest the need for altering the flow rate of the fluid transport apparatus 10." (Collins ¶169.) Aboul-Hosn at 23:4-8. Aboul-Hosn's blood pressure sensors, which can be located anywhere along the inner cannula 20,

i.e. which could be located within the pump 50 itself, detect the pressure of the blood proximate the blood pump and cannula. (Collins ¶169.)

Siess '913 also discloses the use of pressure sensors positioned at the desired pressure measurement location. *See* Siess '913 4:28-38; 11:23-40. As indicated by Dr. Collins, a POSITA would understand that the mechanisms for measuring pressure in Aboul-Hosn, such as the fluid columns disclosed in Aboul-Hosn, may be combined with the pressure sensors of Aboul-Hosn or Siess. (Collins ¶169.) For example, a POSITA would appreciate that one or more of the sensors disclosed in Siess '913 may be used to measure the pressure in the fluid columns of Aboul-Hosn. (Collins ¶169.) For example, one of the sensors 154 and 156 of Siess '913 may be positioned at the proximal end of Aboul-Hosn's fluid lumen. (Collins ¶169.)

Moreover, a POSITA would understand that the pressure sensors of Siess '913, sensors 102, 104 and 154, 156 could be replaced by a piezoelectric element which captures pressure differentials by detecting pressure acting on two opposing faces of the piezoelectric element. (Collins ¶171.)



Thus, Aboul-Hosn, alone or alternatively in view of Siess '913, discloses a blood pressure detection mechanism comprising at least one of fluid filled column disposed within at least a portion of said cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula. (Collins ¶172.)

B. Ground II: Claim 18 is obvious over Aboul-Hosn in view of Siess '913 and further in view of Nix

1. Claim 18

Claim 18 depends from claim 16 and recites "*wherein said blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive said rotor*."

As indicated by Dr. Collins, a POSITA would understand that the system of Aboul-Hosn, with the motor located in the pump head, results in a load positioning with a signal to noise ratio which is more favorable for calculating pressure than the signal to noise ratio for a system with an external motor. (Collins ¶174.) Aboul-Hosn itself discloses the use of an external controller, with electrical leads, and discloses the use of the external controller to monitor performance of the pump system. (EX1004 [Aboul-Hosn] at 23:13-17; Collins ¶¶175-6.)

As indicated by Dr. Collins, a POSITA would know to infer pressure from motor current, and would recognize the benefits from not having to add a dedicated pressure sensor, e.g., a smaller device with fewer parts and increased reliability. (*Id.* ¶177.) For example, Maslen indicates that while pressure can be measured directly with a transducer "it is highly undesirable to include a pressure transducer in the implantable pump due to reliability problems." (EX1035, "Maslen" at 8.) As an alternative to a pressure transducer, Maslen suggests obtaining "an estimate of the pressure across the pump and/or flow by measuring motor current and pump speed" or "infer[ing] [blood inlet pressure] from some combination of the suspension currents in the pump, the motor currents, and the motor speed."

(EX1035 [Maslen] at 9.) Maslen also notes that "this method of pressure estimation has been used as a basis for control in previous systems." (*Id.*; Collins ¶177.) A POSITA would therefore naturally be motivated to find an alternative to a pressure transducer, at least to avoid having the added manufacturing expense and bulk of a dedicated pressure sensor. (*Id.*)

It was well-known to determine the differential pressure across the pump by measuring changes in the pump's motor current and speed. (*Id.* ¶178.) The relationship between the differential pressure across the pump and changes in the pump's motor current and speed is established because the electrical power that drives the pump (determined by the current and voltage) is converted to the pump's mechanical power (determined by its rotational speed and torque) and finally to the fluid power (determined by the flow rate and pressure) adjusted for known conversion efficiencies. (*Id.* ¶178; *see also* EX1019 [Nix] at 2:7-11: "the pressure may also be determined indirectly via a current measuring means that measures the motor current and calculates the differential pressure between the delivery side and the intake side of the pump from the motor current and the rotational speed.")

As explained by Dr. Collins, in view of at least the disclosure of the controller in Aboul-Hosn, the positioning of the motor in Aboul-Hosn, and the state of the art as of the EPD (e.g., in Maslen), a POSITA would recognize the benefits of no longer needing a dedicated pressure sensor, such as a smaller device

with less constraints and increased reliability. (Collins ¶179.) As indicated by Maslen, "it is highly undesirable to include a pressure transducer in the implantable pump due to reliability problems." (EX1035 [Maslen] at 8.)

Accordingly, a POSITA would be motivated to look to references for alternative blood pressure mechanisms, not requiring pressure sensors. For example, as explained by Dr. Collins, a POSITA would be motivated to look to Nix for such an alternative blood pressure detecting mechanism. (Collins ¶179.) A POSITA would realize that eliminating the pressure sensor, as in Nix, would advantageously allow for a smaller more reliable device, with less bulk and lower manufacturing constraints and costs. (*Id.*) Nix discloses a blood pressure detection mechanism that involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive said rotor. (*Id.*) Nix specifically describes how the motor current and speed can be used to calculate pressure: "The pressure measuring means need not have one or more pressure sensors. Rather, the pressure may also be determined indirectly via a current measuring means that measures the motor current and calculates the differential pressure between the delivery side and the intake side of the pump from the motor current and the rotational speed." (EX1019 [Nix] at 2:6-11; Collins ¶126.)

Thus, Aboul-Hosn discloses that the blood pressure detecting mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive said rotor. (*Id.* ¶173.)

XI. CONCLUSION

Based on the foregoing, claims 16-18 of the ’100 patent recite subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel these claims.

Respectfully Submitted,

___/David M. Tennant/_____

David M. Tennant
Registration No. 48,362

Table of Exhibits for U.S. Patent 7,022,100 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 7,022,100 ("'100 patent")
1002	Collins Declaration ("Collins")
1003	File History of U.S. Patent No. 7,022,100 ("'100 PH")
1004	WO 99/02204 ("Aboul-Hosn")
1005	U.S. Patent No. 5,921,913 ("Siess '913")
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	EP 0157859 ("Moise")
1015	U.S. Patent No. 3,879,516 ("Wolvek")
1016	U.S. Patent No. 4,764,324 ("Burnham")
1017	U.S. Patent No. 4,944,745 ("Sogard")
1018	U.S. Patent No. 6,544,216 ("Sammler")
1019	U.S. Patent No. 6,176,822 ("Nix")
1020	U.S. Patent No. 6,849,068 ("Bagaoisan")
1021	*Diastolic Balloon Pumping (With Carbon Dioxide) in the Aorta – a Mechanical Assistance to the Failing Circulation* by S.D. Moulopoulos (1962) ("Moulopoulos")
1022	Pierce, W. S. et al., *Portable artificial heart systems*, ASAIO Journal 29.1: 757-59 (Apr. 1983) ("Pierce")
1023	*Practical Angioplasty* (David P. Faxon, M.D. ed., Raven Press 1993) ("Faxon")
1024	Abou-Awdi N.L., et al., *Hemopump Left Ventricular Support in the Peripartum Cardiomyopathy Patient*, 8 J. Cardiovascular Nursing, Issue 2 (Jan. 1994) ("Abou-Awdi")

1025	Lynn R. Williams, *Reference Values for Total Blood Volume and Cardiac Output in Humans*, Oak Ridge Nat'l Lab. (Sept. 1994) ("Williams")
1026	E.E. Kunst, J.A. van Alste, T. Arts, and H. B. K. Boom, *Integrated Unit for Programmable Control of the 21F Hemopump and Registration of Physiological Signals*, Med. & Biol. Eng. & Comput. 694-95 (Nov. 1994) ("Kunst")
1027	Konishi, H. et al., *Controller for an Axial Flow Blood Pump*, Artificial Organs 20(6): 618–20 (Jun. 1996) ("Konishi")
1028	*Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996) ("Guyton")
1029	Lawrence K. Altman, *A Tiny Heart Pump Saves Its First Life, Researchers Report*, N.Y. Times, May 5, 1988.
1030	Andre F. Cournand et al, Nobel Prize in Physiology or Medicine 1956, Nobel Prize, http://www.nobelprize.org/nobel_prizes/medicine/laureates/ (last visited Jan. 25, 2017)
1031	Andre F. Cournand, *Control of the pulmonary circulation in man with some remarks on methodology*, Nobel Lecture, December 11, 1956, page 531 and page 533.
1032	Frank M. White. *Fluid Mechanics*, 2nd edition, 1986. ("White")
1033	O. Jegaden, "Clinical results of Hemopump support in surgical cases," 1991. ("Jegaden")
1034	Wu, Z. et al, *Fluid Dynamic Characterization of Operating Conditions for Continuous Flow Blood Pumps*. ASAIO Journal (1999) ("Wu")
1035	Maslen, E.H. et al. *Feedback Control Applications in Artificial Hearts*, IEEE Control Systems Magazine, vol. 18, no. 6, 1998. pp. 26-34.
1036	Declaration of Pamela Stransbury
1037	Declaration of Kiersten Batzli
1038	Library of Congress, Catalog Record of *Supported Complex and High Risk Coronary Angioplasty*, ch. 14, 231-49 (Springer 1st ed. 1991)
1039	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

1040	Library of Congress, Catalog Record of Konishi et al., "Controller for an axial flow blood pump," in Artificial Organs Journal, vol. 20, no. 6 (Jun. 1996) 618-620
1041	Library of Congress, Catalog Record of *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996)
1042	Library of Congress, Catalog Record of *Fluid Mechanics*, 2nd edition, ed. Frank M. White, (1986)
1043	Library of Congress, Catalog Record of Maslen et al., "Feedback Control Applications in Artificial Hearts," in IEEE Control Systems Magazine, vol. 18, no. 6 (1998)
1044	File History of U.S. Patent No. 8,888,728 ("'728 PH")

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 8,317 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 March 11, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 7,022,100 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. 7,022,100 (EX1001-1045)
- Exhibits 1001-1045
- 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