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. IPR2017-02135

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,022,100

CLAIMS 16-17

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I. INTRODUCTION

Petitioners Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 16-17 (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 known in the prior art. The Challenged Claims attempt to add conventional intravascular blood pump features with respect to a drive cable and purge fluid, but those features add nothing patentable—the claimed features were well known to persons of ordinary skill in the art ("POSITA") before the alleged invention. 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. filed a declaratory judgment action ("Litigation") 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 will file concurrently with the present Petition petitions

challenging certain additional claims of the '100 patent, certain claims of U.S. Patent No. 9,327,068 (the "'068 patent"), and certain claims of U.S. Patent No. 8,888,728 (the "'728 patent"). Petitioner has previously filed: (1) petitions for IPR of the '728 patent (IPR2017-01026 and IPR2017-01027); (2) petitions for IPR of the '068 patent (IPR2017-01028 and IPR2017-01029); (3) petition for IPR of the '100 patent (IPR2017-01025); (4) petitions for IPR of U.S. Patent No. 9,545,468 (the "'468 patent") (IPR2017-01201, IPR2017-01202, and IPR2017-01203); (5) petitions for IPR of U.S. Patent No. 9,561,314 (the "'314 patent") (IPR2017-01204 and IPR2017-01205); and (6) petitions for IPR of U.S. Patent No. 9,597,437 (the "'437 patent") (IPR2017-01207, IPR2017-01208, IPR2017-01209, and IPR2017-01253). The '068, '728, '469, '314, and '437 patents 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.

David M. Tennant (Reg. No. 48,362)

E-mail: WCAbiomedIPR@whitecase.com

Post and hand delivery: White & Case LLP

701 Thirteenth Street, NW

Washington, DC 20005

Telephone: (202) 626-3684 Fax: (202) 639-9355

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 *inter partes* review 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 IPR of the Challenged Claims and a ruling that the Challenged Claims are unpatentable.

[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.

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

1. DE 19821307 to Sammler (EX1045, "Sammler")[3], published October 21, 1999, is prior art under 35 U.S.C. § 102(a).

2. WO 99/02204 to Aboul-Hosn (EX1004, "Aboul-Hosn"), published January 21, 1999, is prior art 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 under the following statutory ground:

- Claims 16-17 are rendered obvious by Sammler in view of Aboul-Hosn under 35 U.S.C. § 103(a).

[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] Throughout the present petition "Sammler" refers to EX1045, which is a certified English translation of DE 19821307 (EX1065).

V. CONVENTIONAL TECHNOLOGY

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 ¶92; 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. (Collins ¶39-42.)

A. Conventional Intravascular Blood Pumps[4]

The Hemopump implemented the conventional blood pump features of the Challenged Claims, 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; *see also* EX1007 [Wampler] at 232; U.S. Patent No. 4,625,712 to Wampler (EX1008, "Wampler '712") at 3:40-51; (2) a pump having a rotor with multiple blades disposed within a shroud, to

[4] For background, Dr. Collins discusses the circulatory anatomy and function, and development of intravascular blood pumps. (Collins ¶¶39-90.)

pump blood axially along the pump and through the cannula (Collins ¶57; *see also* 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; (3) a purge fluid delivery system to deliver purge fluid to the rotor (Collins ¶57; *see also* EX1007 [Wampler] at 233; EX1008 [Wampler '712] at 3:40-45; EX1024 [Abou-Awdi] at FIGS 1, 37); and (4) a blood pressure monitoring system to control pump operation (Collins ¶57; *see also* EX1045 [Sammler] at 2:29-31; EX1004 [Aboul-Hosn] at 23:8-13). The few other minor details of the Challenged Claims were also well-known – i.e., forming a side lumen in the cannula (in Yock). (Collins ¶57.)

B. Conventional Guide Wire Techniques for Placing Intravascular Blood Pumps

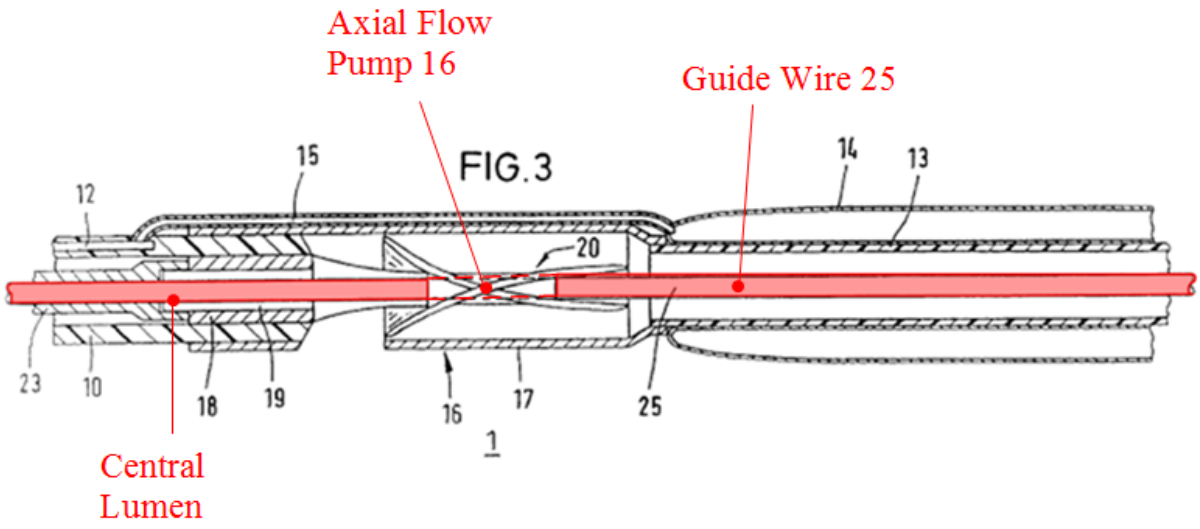
Well-known catheterization techniques including "guide" catheters, "over-the-wire" catheters, and "side-rigger" catheters, have been used routinely to position blood pump intravascularly (i.e. within a patient's circulatory system). (Collins ¶¶66-90.)

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 ¶¶80-83; EX1010 [Fogarty] at 3:4-10.) First, a surgeon positioned the guide wire at a desired location within the patient (i.e., at "the area

of stenosis"). (*Id.* at 3:4-6.) Then, the surgeon advanced the catheter "over the guide wire without difficulty or damage" to the desired location. (*Id.* at 3:4-10.)

Before the alleged invention of the '100 patent, POSITAs further adapted that "over-the-wire" guide mechanism to place intravascular blood pumps. (Collins ¶¶80-83.) As shown below in FIG. 3, U.S. Patent No. 6,248,091 to Voelker[5] (EX1011, "Voelker") applied the "over-the-wire" guide mechanism to an axial flow intravascular blood pump. (Collins ¶¶80-83.) 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.)

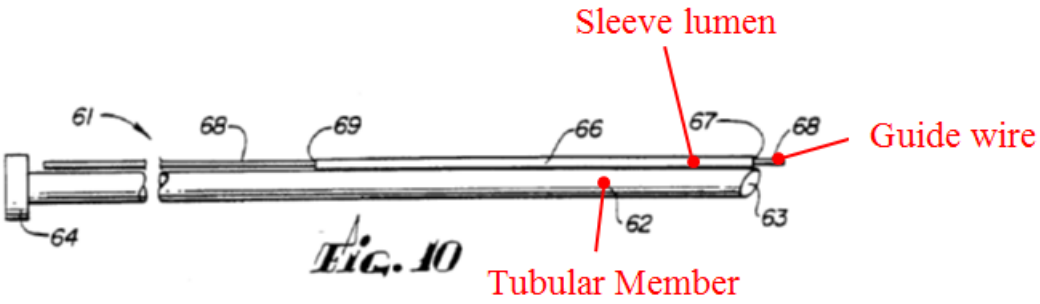


(Collins ¶82; EX1011 [Voelker] at FIG. 3, annotated.)

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

2. Side-Rigger Catheter

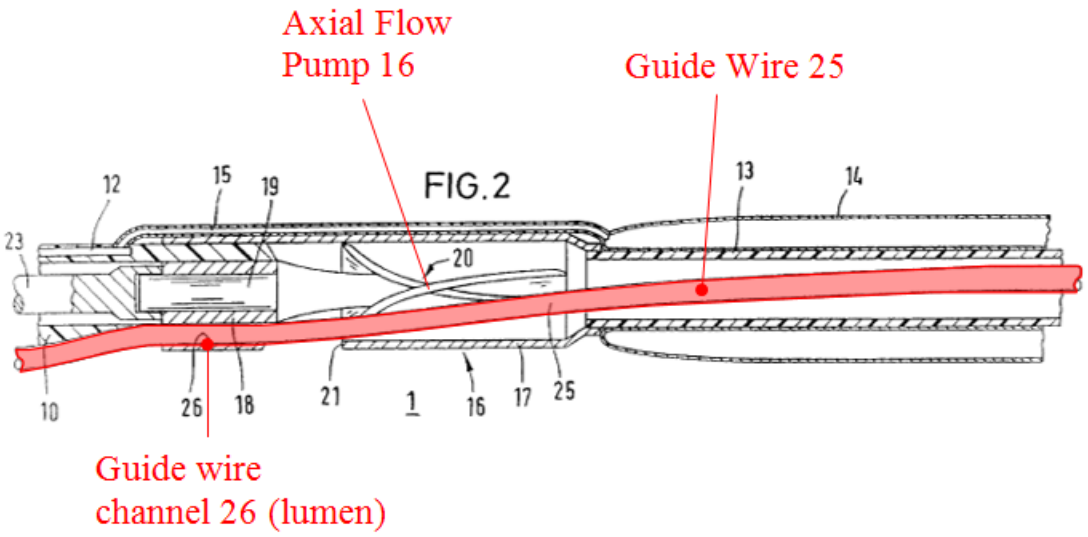
As Dr. Collins explains further, the "side-rigger" or "monorail" technique was also well-known to be used to place intravascular blood pumps. (Collins ¶¶84-90.) As Yock discloses, a conventional "side-rigger" catheter generally includes an elongate tubular member, such as a cannula, and a sleeve (with an interior lumen for a guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (Collins ¶84; EX1006 [Yock] at FIG. 10, 7:64-68.) As shown below in FIG. 10, a surgeon places a guide wire in a desired location in the body and inserted through the sleeve. (Collins ¶84; EX1006 [Yock] at 7:64-8:19.) Then, the surgeon advances the catheter along the guide wire to the desired location. (Collins ¶84; EX1006 [Yock] at 8:20-25.) The orientation of the sleeve along the side of the cannula allows for the exchange of catheters. (Collins ¶84; EX1006 [Yock] at 2:31-37.)



(Collins ¶84; EX1006 [Yock] at FIG. 10, annotated.)

Voelker, at FIG. 2 (below) also discloses this side-rigger 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 ¶¶86-87; EX1011 [Voelker] at 3:34-43.)



(Collins ¶86; 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 ¶¶78-79; 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 ¶¶78-79.) 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; (Collins ¶79).

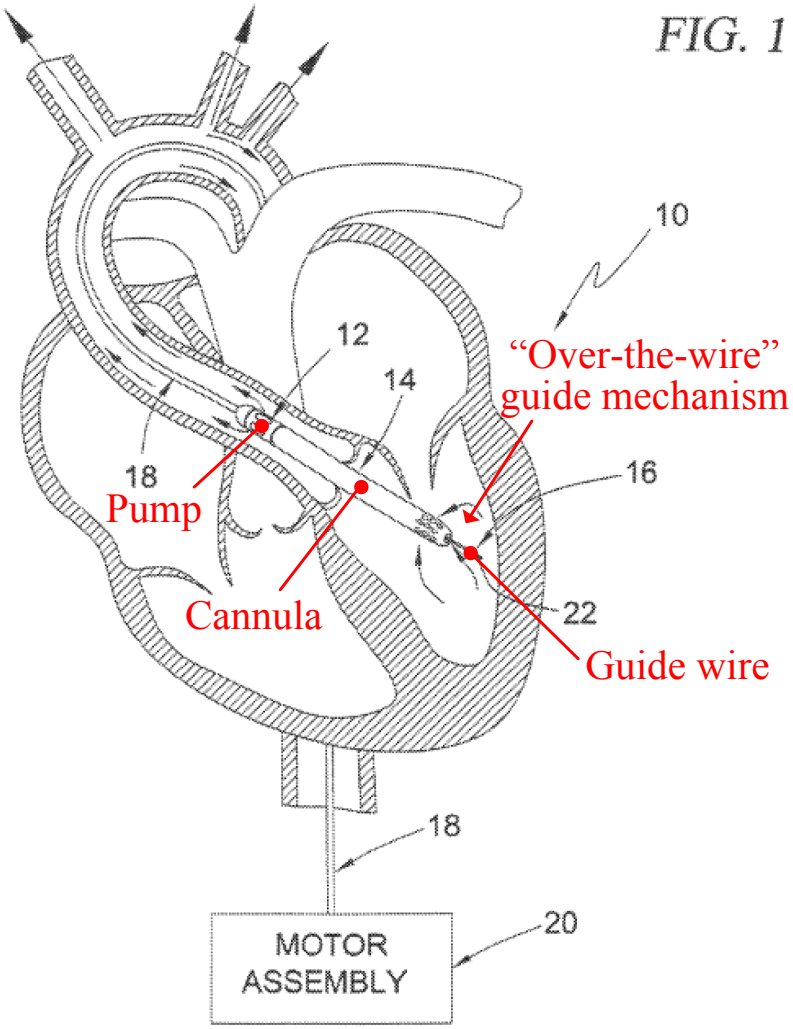
VI. OVERVIEW OF THE '100 PATENT

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 "side-rigger" type guide mechanism; and (3) a "guide catheter" type guide mechanism. (EX1001 ['100 patent] at 2:56-3:41; Collins ¶91-93.) 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).

a) *Over-the-Wire Guide Mechanism*

The conventional over-the-wire technique illustrated in FIG. 1 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 ¶¶94-95).



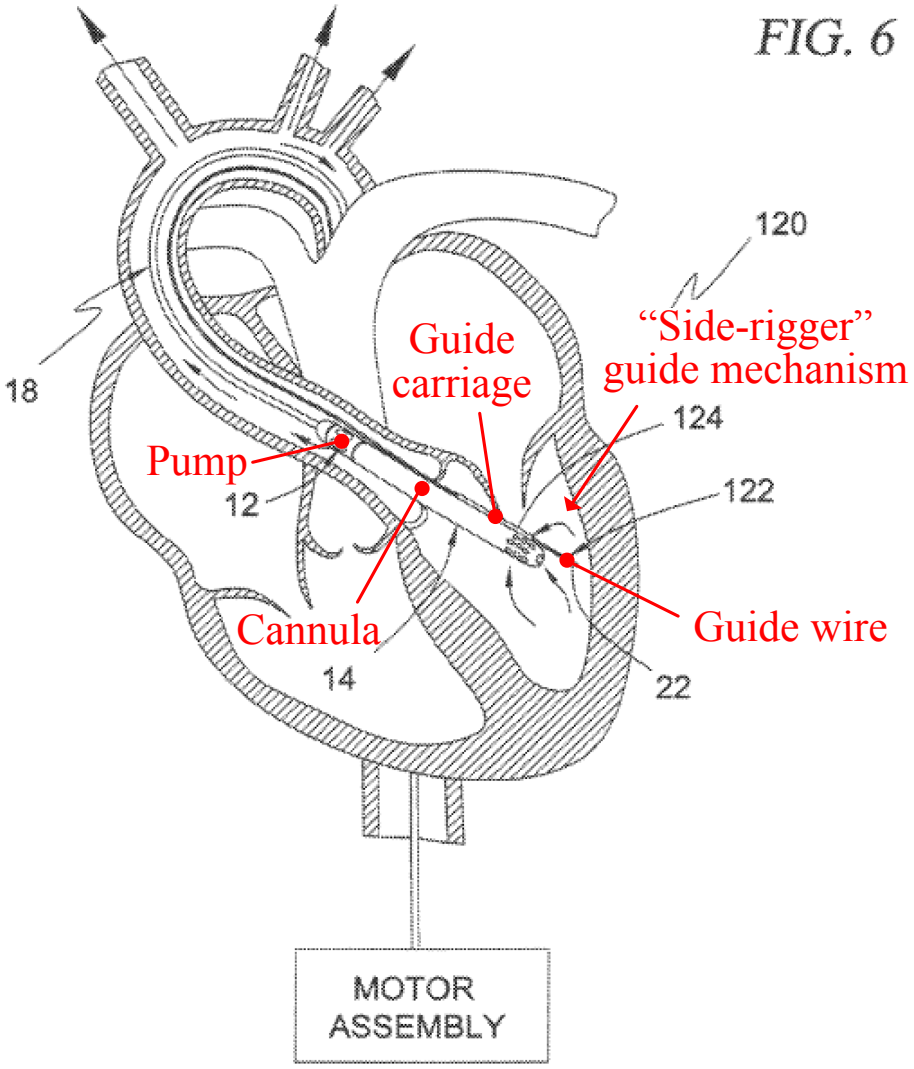
(Collins ¶94; EX1001 ['100 patent] at FIG. 1, annotated.)

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. (EX1001 ['100 patent] at 7:10-54; Collins ¶94.) "[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; Collins ¶94). "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." (EX1001 ['100 patent] at 7:42-46; Collins ¶¶94-95). After passing through the center of the rotor, the guide wire exits out the distal end of the cannula 14. (*Id.)*

b) ***Side-Rigger Guide Mechanism***

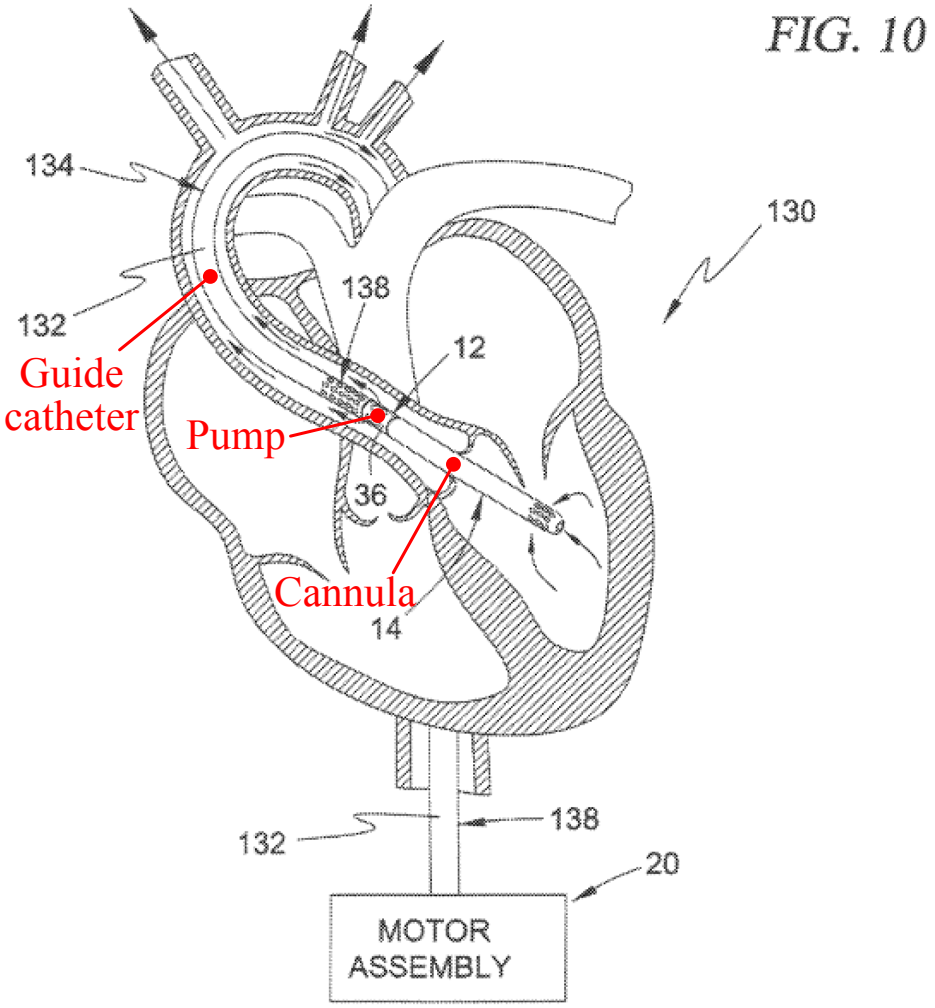
FIG. 6 shows the conventional "side-rigger" guide mechanism of the prior art. (EX1001 ['100 Patent] at 5:30-35; Collins ¶¶96-98) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (EX1001 ['100 Patent] at 12:13-19; Collins ¶¶96-98)



(Collins ¶96; EX1001 ['100 patent] at FIG. 6, annotated.)

c) ***Guide Catheter Guide Mechanism***

Finally, the '100 patent at FIG. 10 shows a "conduit assembly" mechanism as in the prior art. (EX1001 ['100 patent] at 5:49-54; Collins ¶99.)



(Collins ¶99; EX1001 ['100 patent] at FIG. 10, annotated.)

d) ***Techniques to Introduce the Intravascular Blood Pump***

The intravascular blood pump system of the '100 patent is introduced into the patient's vasculature using the various conventional techniques described above. (Collins ¶100.) The '100 patent contemplates that "the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the

brachiocephalic vein, carotid artery, axillary artery femoral vein, femoral artery, and subclavian artery." (EX1001 ['100 Patent] at 17:27-33; Collins ¶100.) As the '100 patent explains: the "intravascular blood pump systems of the present invention" can be introduced into the patient's vasculature using either the conventional surgical approach "via direct introduction" into the heart, or alternatively, "[a]s is well known in the art, such intravascular access may be achieved percutaneously." (EX1001 ['100 Patent] at 17:59-65; Collins ¶100.)

e) ***Pressure Measurement***

The '100 patent briefly mentions a blood pressure detecting mechanism. (EX1001 ['100 Patent] at 4:18-32 and 18:19-35; Collins ¶101.)

B. The Earliest Possible Priority Date for Claims 16-17 of the '100 Patent is September 1, 2000

The September 1, 2000 priority date of the '100 patent is the earliest possible priority date (the "EPD") for the Challenged Claims.[6] The subject matter of the Challenged Claims is not supported by an earlier-filed provisional application. (Collins ¶¶105-107.) 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

[6] 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 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." (EX1044 ['728 File History] at 261.) 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 ¶¶105-107; *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 is September 1, 2000. (Collins ¶107.)

VII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Overview of Sammler

Sammler discloses an intravascular blood pump system positioned "as a right heart pump such that it delivers [blood] from the right atrium 21 into the pulmonary artery 26," as shown in FIG. 1, below. (Collins ¶¶120-121 EX1045 [Sammler] 4:15-40.)

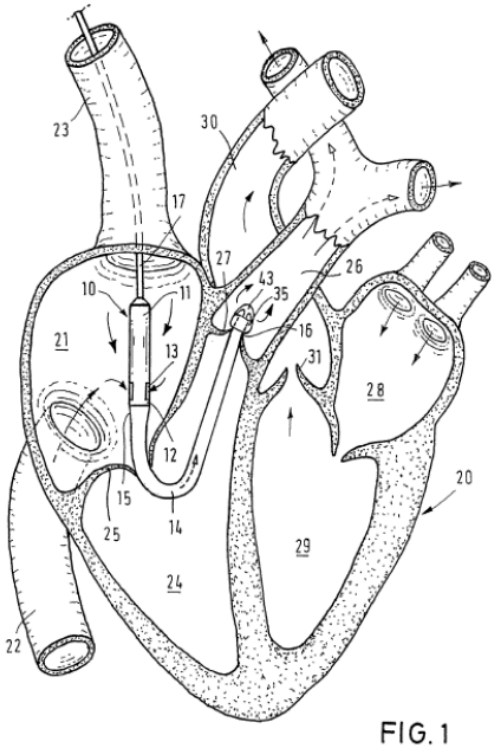


FIG. 1

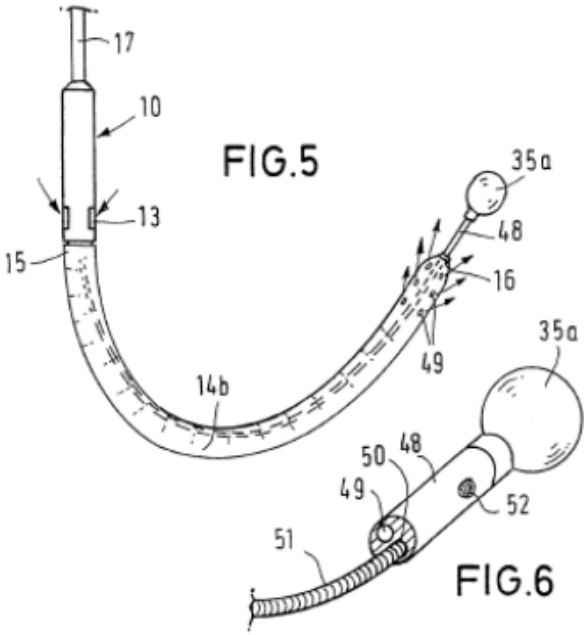
(EX1045 [Sammler] FIG. 1; Collins ¶121)

Sammler discloses that the blood pump 10 comprises two distinct parts: (1) a drive section 11 and (2) a pump section 12 that "comprises an impeller … which drives the blood in an axial direction." (Collins ¶¶121-122; EX1045 [Sammler] 4:17-18, 4:21-22.) Sammler discloses the "pump corresponds, e.g., to that of WO 97/37696," referring to Rau.[7] (Collins ¶122; EX1045 [Sammler] 4:18-19.)

Sammler further discloses configuring the intravascular blood pump system with an integrated guide mechanism comprising a guide wire and lumen to position the intravascular blood pump system within the right side of the patient's heart.

[7] EX1057 is a certified English translation of WO97/37696, which is published in German (EX1066).

(Collins ¶123; EX1045 [Sammler] 6:3-12.) As shown in FIGS. 5 and 6 below, a guide wire 51 extends through a lumen 50 within the catheter 48 and pump hose 14b, the pump 10, and the catheter 17. (Collins ¶¶123-124 EX1045 [Sammler] 3:24-27, 6:3-7.) The lumen 50 will be used to detect blood pressure in the pulmonary artery after the guide wire 51 is removed. (Collins ¶¶123-124; EX1045 [Sammler] 6:8-12.)



(EX1045 [Sammler] FIGS. 5 and 6; Collins ¶123)

B. Overview of Aboul-Hosn

Aboul-Hosn discloses an intravascular blood pump system incorporating an over-the-wire guide mechanism to position the pump system "in a heart chamber or a vessel to completely or partially stop the heart in order to operate on the organ." (Collins ¶¶109-110; EX1004 [Aboul-Hosn] 6:24-29, 11:9-14, 30:1-2, 31:6-9.) Like the '100 patent, Aboul-Hosn discloses the intravascular blood pump

system positioned using both percutaneous and surgical approaches. (Collins ¶109; EX1004 [Aboul-Hosn] FIGS. 21, 23-24, 6:16-29, 11:8-11, 21:19-22:30, 29:17-19, 32:9-13; EX001 ['100 patent] 1:53-55, 17:27-39.)

As shown below in FIGS. 1 and 2,[8] and similar to the '100 patent, the blood pump has a drive unit 80 (purple) connected to a conventional blood pump having rotor and associated blades 70 (red) within a housing body 52 (green) and a housing cap 62 (green).[9] (EX1004 [Aboul-Hosn] 12:12-13:13; Collins ¶¶109-110.) The blood pump draws blood through an inner cannula 20 (blue) is coupled to the housing cap 62 (green) by the rotation of the rotor 70 driven by the drive unit 80. (*Id*.; EX1004 [Aboul-Hosn] 13:14-18.)

[8] As noted by Dr. Collins, FIGS. 1 and 2 show an extracorporeal blood pump system, however, Aboul-Hosn discloses that the intravascular blood pump system can comprise the same components which are properly sized in order to fit into an introducer for positioning within the vascular system of the patient. (Collins n. 7; EX1004 [Aboul-Hosn] FIGS. 3, 4, and 12.)

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

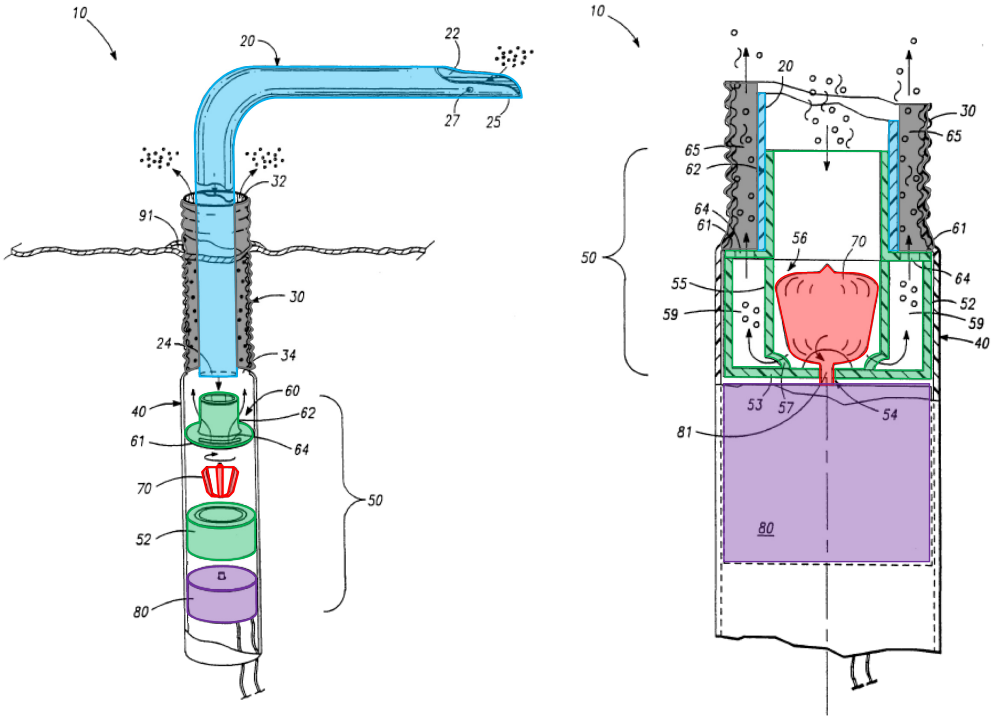


FIG.—1 FIG.—2

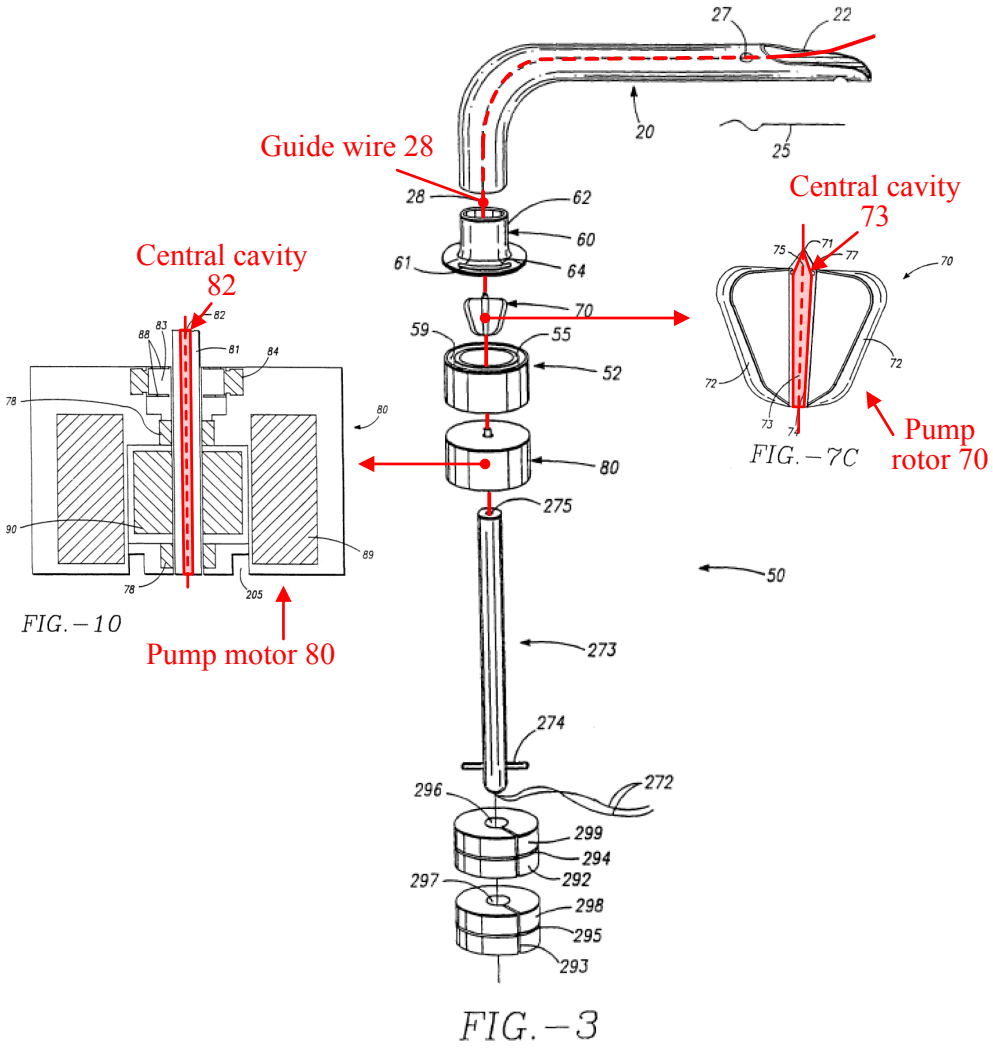
(Collins ¶110; EX1004 [Aboul-Hosn] FIGS. 1 and 2, annotated.)

The rotor 70 and associated blades (red) generate an axial flow of blood (that also has a radial component), which is then "reversed" when the blood exits the inlet tube 55, as shown in FIG. 2 by the directional arrows. (Collins ¶¶110-111; EX1004 [Aboul-Hosn] 13:25-18, 18:15-19.)

Like the '100 patent, the design of Aboul-Hosn's intravascular pump system allows it to be positioned in "in a heart chamber or a vessel" using a guide wire. (Collins ¶¶111-112; EX1004 [Aboul-Hosn] 11:26-28, 14:13-16, 14:20-24, 21:22-24, 22:10-16.) FIGS. 3, 7C, and 10 show the integration of the conventional over-the-wire technique in Aboul-Hosn's intravascular blood pump system in detail, where the guide wire 28 (red) passes through a central lumen extending through

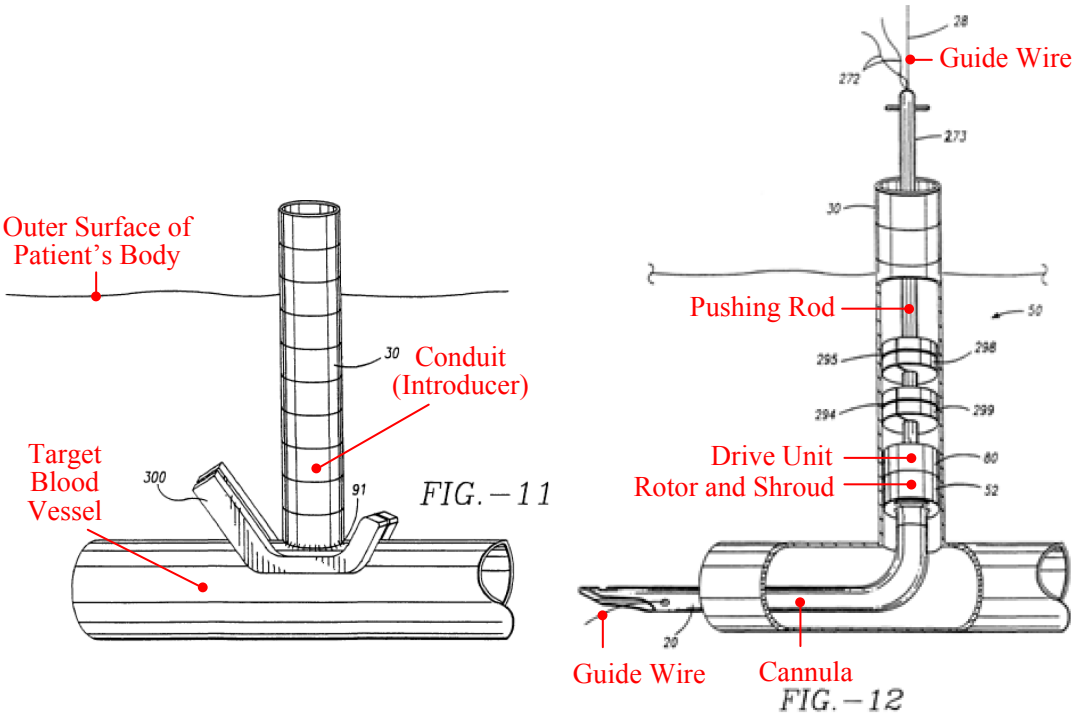
the center of the positioning rod 273, drive unit 80, the rotor 70, and the inner cannula 20.[10] (Collins ¶112; EX1004 [Aboul-Hosn] 14:17-15:18, 17:19-22, FIG. 12.) As shown in FIG. 3 the intravascular blood pump system comprises the same pump components as the extracorporeal pump system shown in FIGS. 1 and 2, along with the addition of a pushing rod 273 to push the intravascular blood pump system into the patient's body. (*Id.* ¶112.)

[10] A POSITA could also readily adapt the Aboul-Hosn's pump system to be positioned using the conventional "side-rigger" technique. (Collins ¶112, n. 9.)



(Collins ¶112; EX1004 [Aboul-Hosn] FIGS. 3, 7C, and 10, annotated.)

As shown in FIGS. 11 and 12, below, to position the pump system inside the patient, an outer conduit 30 is first inserted through a small incision in the patient's body and attached to "a targeted blood vessel or [heart] chamber using thorascopic suturing or microstapling." (Collins ¶114; EX1004 [Aboul-Hosn] 6:24-7:5, 12:7-9, 21:11-18.)



(Collins ¶113; EX1004 [Aboul-Hosn] FIGS. 11 and 12, annotated.)

After securing the outer conduit 30 to the target blood vessel or heart chamber, "a commercially available high stiffness guide wire" is inserted through the outer conduit 30 and "positioned to a desired location before being passed through an opening or orifice formed on the distal end of the inner cannula 20." (Collins ¶115; EX1004 [Aboul-Hosn] 22:10-16.) Using the positioning rod 273, a surgeon pushes the pump system over the guide wire 28 through the outer conduit 30 and to the desired position within the patient's vasculature. (Collins ¶116; EX1004 [Aboul-Hosn] 21:27-29, 22:10-25.) Aboul-Hosn describes the intravascular blood pump system introduced through the conduit and positioned within the patient's vasculature in the manner shown in FIGS. 11 and 12 as "an

endovascular method and system."[11] (Collins ¶117; EX1004 [Aboul-Hosn] 6:24-29.") Using Aboul-Hosn's "endovascular method and system," the intravascular blood pump system will be placed in a variety of configurations to provide both left-heart and right-heart support, such as in the configurations shown in FIGS. 14-19, 21, and 23. (Collins ¶¶117-119; EX1004 [Aboul-Hosn] 9:16-31.)

C. Analogous Art

Sammler and Aboul-Hosn are analogous art to the '100 patent. As Dr. Collins explains throughout his Declaration, a POSITA would naturally look to analogous art. (Collins ¶¶125-131).

First, a POSITA would naturally look to Sammler and Aboul-Hosn, as they are both directed to axial flow intravascular blood pump systems, and as such are in the same field of endeavor as the '100 patent. *See In re Bigio,* 381 F.3d 1320, 1325 (Fed. Cir. 2004) (a reference is analogous art to the claimed invention if it is in "the same field of endeavor, regardless of the problem addressed").) (Collins ¶125). Sammler expressly discloses an intravascular blood pump system (i.e. the blood pump, cannula, and catheter) being introduced into the vascular system of the patient. (EX1045 [Sammler] at 1:4-7; 3:54-62; see infra Section X.A.1. and

[11] According to Dr. Collins, in the medical devices field, endovascular has the same meaning as intravascular. (Collins n. 10; EX1058 [Stedman's Medical Dictionary] 590 ("endo"), 916 ("intra").)

(a)). Aboul-Hosn also expressly discloses an intravascular blood pump system (i.e. the blood pump, cannula, and catheter) being introduced into the vascular system of the patient through the conduit attached to the femoral artery such that the blood pump and the catheter are positioned in the circulatory system of the patient. (EX1004 [Aboul-Hosn] 29:17-19, 30:21-24;Collins ¶126)

Second, both Sammler and Aboul-Hosn are directed to the same problem addressed by the '100 Patent, i.e. positioning intravascular blood pump systems within the vascular system to provide left or right heart support. *See In re Bigio,* 381 F.3d at 1325 (a reference is also analogous art to the claimed invention if it "is reasonably pertinent to the particular problem with which the inventor is involved.") (Collins ¶¶126-127).

Sammler is reasonably pertinent to the problems addressed by the '100 patent. *See* infra Section X.A.1.(c). Specifically, Sammler discloses that guide wire 51 "passes through the catheter 17 and the pump 10" in order to place its intravascular blood pump system in the desired location within the patient's vasculature. *See id*. (Collins ¶¶126-127).

Additionally, Aboul-Hosn is reasonably pertinent to the problems addressed by the '100 patent (positioning intravascular blood pump systems within the vascular system to provide left or right heart support) and discloses three approaches: an extracorporeal blood pump system (EX1004 [Aboul-Hosn] 21:11-

22:30; FIG. 13), an intravascular catheter (FIGS. 21, 23) (referenced below), or an intravascular graft (FIG. 12)). (Collins ¶¶126-127).

Moreover, Aboul-Hosn expressly indicates that his pump with the guide mechanism can be used in most of Aboul-Hosn's embodiments, or compatible therewith. (Collins ¶¶126-127).

Aboul-Hosn discloses that the "stabilization system" shown in FIGS. 21 and 23 are "provided in accordance with the present invention" and "provided for by the present invention," respectively. (*Id.* ¶128; EX1004 [Aboul-Hosn] 10:6-7, 31:6-9.) This would have motivated a POSITA to look at the blood pump systems expressly disclosed by Aboul-Hosn in the preceding pages of his published PCT application to discern what the "present invention" is that provides for the "stabilization system" shown in FIGS. 21 and 23. (Collins ¶128.) It would have been imminently clear to and understood by a POSITA that the "stabilization system" shown in FIGS. 21 and 23 as "provided by the present invention" uses the intravascular blood pump of FIGS. 3, 4, and 12. because the blood pump of Aboul-Hosn's intravascular blood pump system is miniaturized so that it can be introduced through a graft that is attached to a target blood vessel (such as the femoral artery in FIG. 21), and inserted into the patient's circulatory system. (Collins ¶128; EX1004 [Aboul-Hosn] 21:11-22:18, 24:26-25:1.)

This is further reinforced by Aboul-Hosn's disclosure of the rotor in FIGS. 7A-7C, which is used in Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12. (Collins ¶129.) Aboul-Hosn expressly states that "Figs. 7A-C and 8 illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus," which indicates to a POSITA that the rotor 70 of Aboul-Hosn's intravascular blood pump system shown in FIGS. 3, 4, and 12 can be used in "**any other type of fluid transport apparatus**." (*Id*. ¶129; EX1004 [Aboul-Hosn] 16:30-31 (emphasis added).) The "stabilization system" shown in FIGS. 21 and 23 qualifies as "any other type of fluid transport apparatus." (Collins ¶129.)

Aboul-Hosn's express teaching would directly motivate a POSITA to use rotor of FIGS. 7A-7C in the stabilization system of FIGS. 21 and 23. (*Id.*) As the rotor 70 would not function without the corresponding shroud (i.e. housing 52, cap 60, etc) as it provides the axial flow of blood for the blood pump as explained above in Section VII.B, a POSITA would logically find it straightforward to use the corresponding shroud (i.e. housing 52, cap 60, etc.) along with the rotor 70 in the stabilization system of FIGS. 21 and 23. (Collins ¶129; EX1004 [Aboul-Hosn] 16:30-31.) As the shroud and the rotor make up the blood pump portion of Aboul-Hosn's intravascular blood pump system (and in fact, in relation to the "intravascular blood pump" of the claim, the claim only requires the "intravascular

blood pump comprising a rotor"), a POSITA would readily be motivated to use Aboul-Hosn's intravascular blood pump shown in FIGS. 3, 4, and 12 in the "stabilization system" shown in FIGS. 21 and 23. (Collins ¶129; EX1004 [Aboul-Hosn] 10:6-7, 31:6-9.) Indeed, Aboul-Hosn provides no specific details of the pump 420 used in FIGS. 21 and 23, which signals to a POSITA to look elsewhere in the specification to discern the details of the pump 420, which would lead them to Aboul-Hosn's express teachings to use the rotor 70 (that can be used in "any type of fluid transport apparatus") and the corresponding shroud of the intravascular blood pump of FIGS. 3, 4, and 12, which are miniaturized so as to be capable of being inserted into the vasculature as discussed in Section X.A.1(b), and use them for the "stabilization system" shown in FIGS. 21 and 23 for the reasons detailed above. (Collins ¶129.)

Moreover, as Dr. Collins further explains, Aboul-Hosn does not expressly limit or constrain the location in which the graft to introduce the intravascular blood pump system in the patient can be sutured or attached, broadly stating that the graft can be attached to a portal that "is created in the desired blood vessel or body cavity." (*Id.* ¶130; EX1004 [Aboul-Hosn] 21:19-23.) Aboul-Hosn expressly discloses that intravascular blood pumps can be introduced percutaneously through the femoral artery, as shown in FIG. 21. (*Id.* ¶130; EX1004 [Aboul-Hosn] 29:17-19.) As such, where Aboul-Hosn's intravascular blood pump system is introduced

into the patient's femoral artery through the graft, a POSITA would have been motivated to advance the intravascular blood pump system (i.e. cannula, blood pump, and positioning rod 273 or multilumen catheter 428 depending on the distance the pump system needs to travel within the vasculature) through the graft and into the patient's circulatory system to obtain the advantages of a shorter cannula length to reduce hydrodynamic losses and to maintain sufficient pumping capacity with the miniaturized pump components of the intravascular pump. (Collins ¶130.)

To percutaneously insert and position intravascular blood pumps within the patient's vasculature such that the pump system is inserted closer to the patient's heart was well-known in the art – as evidenced by, *inter alia*, Sammler which also discloses positioning an intravascular blood pump system through the upper vena cava and into the right side of the heart over a guide wire. (See infra Section X(A)(1)(c); Collins ¶131; EX1045 [Sammler] 4:38-40, 6:5-7, FIGS. 1, 5, and 6; EX1005 [Siess] FIG. 1, 5:55-58; EX1008 [Wampler '712] FIG. 1a.) Positioning Aboul-Hosn's intravascular blood pump, catheter, and cannula in the manner shown in FIGS. 21 and 23 (i.e. through the femoral artery and into the heart) in the manner as shown in FIG. 12 (i.e. via a conduit 30 attached to the femoral artery and pushing the blood pump over the guide wire into the patient's femoral artery) is, therefore, not only consistent with Aboul-Hosn's teachings and disclosures, it is

also generally consistent with the teachings and techniques that were already well-known in the art. (Collins ¶131.)

Accordingly, Sammler and Aboul-Hosn are analogous art to the '100 patent.

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).) Petitioner addresses relevant claim constructions under 35 U.S.C. § 112(f) below in the Ground.

IX. PERSON HAVING ORDINARY SKILL IN THE ART

A POSITA before the alleged invention of the '100 patent 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 ¶¶33-35.)

In IPR2017-01025 challenging other claims of the '100 patent, Patent Owner takes a position that a POSITA must have either an undergraduate degree in

mechanical engineering or bioengineering or similar subject matter and at least 10 years of experience designing intravascular heart assist devices; or have an advanced degree in mechanical engineering or bioengineering (either a masters, Ph.D., or equivalent course work) and at least five years of experience designing intravascular heart assist devices. (EX1056 [IPR2017-01025 POPR] at 66).

Patent Owner overstates the requirement to qualify as a POSITA. (Collins ¶¶33-37.) Patent Owner provided absolutely no justification for requiring such a stringent "ordinary" level of skill with intravascular heart assist devices. As the Board previously acknowledged, both experience and education should be factored in the level of skill of the POSITA.[12] Moreover, the Board has found that "a person of ordinary skill in the art *designs* devices, and, thus, actively monitors the relevant technical literature, rather than is merely familiar with devices (e.g., an operator or a manufacturer)." *See Dynamic Air Inc. v. M-I Drilling Fluids UK Ltd.,* IPR2016-00259, Paper 54 at 17 (P.T.A.B. May 23, 2017); *see also Stryker Corp. v. Zimmer, Inc.*, 2012 U.S. Dist. LEXIS 12329, *39 (W.D. Mich. Feb. 1,

[12] *See Symantec Corp. vs. Finjan Inc.*, IPR2015-01552, Paper 9 (P.T.A.B. January 14, 2016) (holding that "additional graduate education might substitute for experience, while significant experience in the field … might substitute for formal education."); *see also Samsung Electronics Co. Ltd. v. Queen's University at Kingston*, IPR2015-00583, Paper 54 (P.T.A.B. July 27, 2016) (same).

2012) (defining a POSITA for patents directed to "pulsed lavage irrigation systems … commonly used in orthopedic surgeries" to possess "a bachelor's degree in mechanical engineering and 2-3 years of industry experience relating to the design of medical devices."); *Cook Grp. Inc. v. Boston Scientific Scimed, Inc.*, IPR2017-00133, Paper 7 at 7 (P.T.A.B. May 3, 2017) (adopting Petitioner's definition of a POSITA to be "an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices" for patents directed to compression clips used to cause hemostasis of blood vessels along the gastrointestinal tract).

Dr. Collins was not "merely familiar with devices," but was involved in the design of a variety of medical devices, including intravascular heart assist devices, as detailed in his Declaration and accompanying CV. (Collins ¶¶33-37.) As Dr. Collins explains, his skill level meets or exceeds that of a POSITA due to his necessary familiarity with the relevant design challenges and Federal safety regulations associated with his work designing such intravascular heart assist devices. (Collins ¶¶33-37.)

Even under Patent Owner's unduly restrictive definition, Dr. Collins is a POSITA for the purposes of the '728 patent. (Collins ¶37.) Dr. Collins received his Ph.D from MIT in 1988 with a focus on biomedical applications, and from

1998 to 2002,[13] he worked as a design engineer helping to form Arthur D. Little Inc's ("ADL") medical devices business including working on the design of numerous medical products related to vascular and intravascular medical devices. (Collins ¶37.) That experience is more than ample.

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 Sammler in view of Aboul-Hosn.

1. Claim 16

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

Sammler discloses an intravascular blood pump system, shown in FIG. 1 below, that is inserted through the blood vessel system, into the heart. (Collins ¶133-135; EX1045 [Sammler] at 2:6-9 ("The invention relates to an intracardiac

[13] The EPD of the '728 patent is September 1, 2000, 12 years after Dr. Collins began working at ADL.

blood pump according to the preamble of Claim 1 and is especially suitable for a blood pump that can be inserted completely into the heart through adjacent blood vessels to support the natural pumping function of the heart or replace it by continuous pumping operation"), 4:15-16 ("According to Fig. 1 the blood pump 10 is an intravascular blood pump, i.e., a blood pump that can be inserted through a patient's blood vessel system to enter the heart.").)

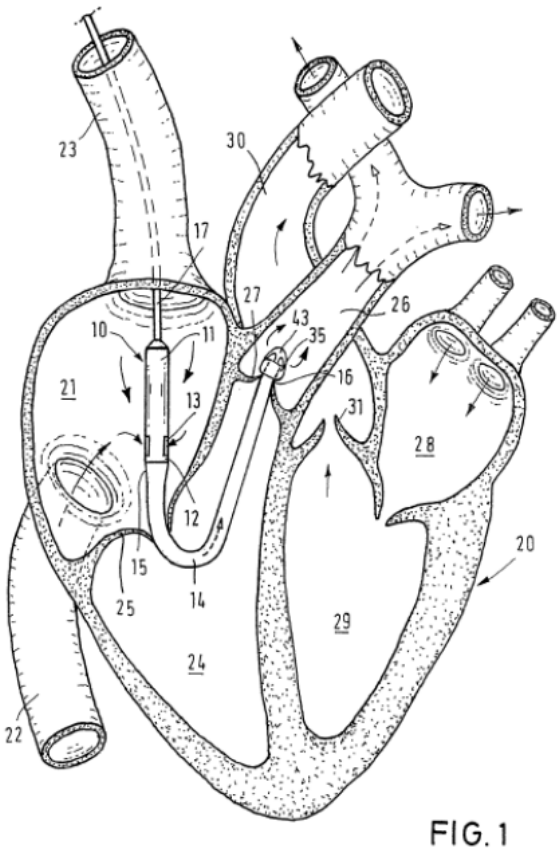


FIG. 1

(Collins ¶133; EX1045 [Sammler] at FIG. 1.)

The intravascular blood pump system of Sammler will be inserted through either the vena cava into the right atrium of the heart. (Collins ¶133; EX1045

[Sammler] at 4:38-40 ("The pump 10 is positioned as a right heart pump such that it delivers from the right atrium 21 into the pulmonary artery 26. For this purpose in the embodiment shown it is passed through the upper vena cava 23. It would also be possible to perform the laying through the lower vena cava 22."), FIG. 1 (showing insertion through the upper vena cava 23).) Petitioner presents further details of Sammler's intravascular blood pump system below.

Thus, Sammler discloses an intravascular blood pump system. (Collins ¶135).

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

The intravascular blood pump system of Sammler, including intravascular blood pump 10, will be inserted through the patient's vascular system into the heart. (Collins ¶¶136-138; EX1045 [Sammler] at 4:15-16 ("According to Fig. 1 the blood pump 10 is an intravascular blood pump, *i.e.*, a blood pump that can be inserted through a patient's blood vessel system to enter the heart.").) As shown in annotated FIG. 1 below, the blood pump 10 (highlighted in green), which includes a drive section 11 connected to a pump section 12, will be inserted into the heart through the patient's vascular system. (Collins ¶¶136-138; EX1045 [Sammler] at 4:17-18.)

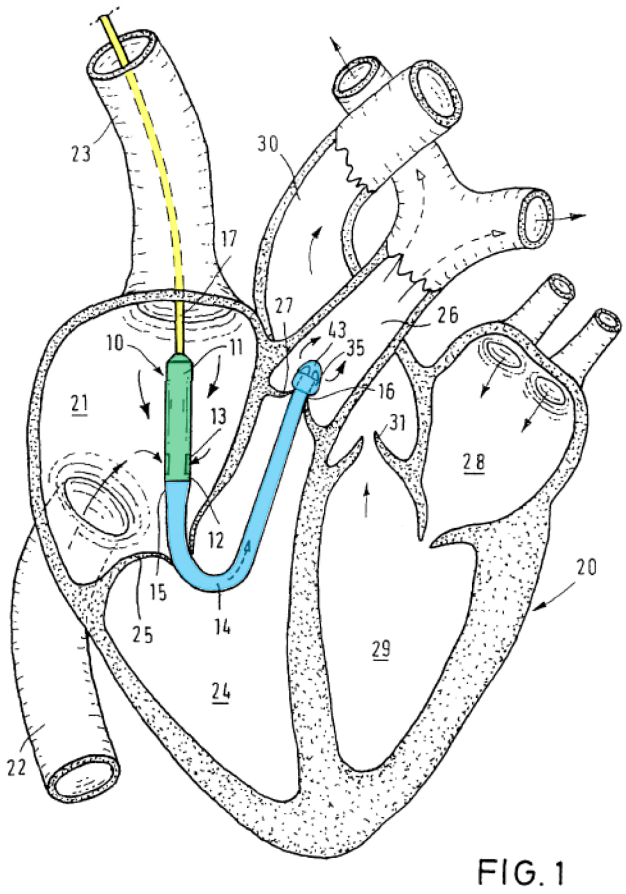


FIG. 1

(Collins ¶136; EX1045 [Sammler] at FIG. 1, annotated.)

As shown in FIG. 1 above, Sammler's intravascular blood pump system also includes a cannula (pump hose 14, highlighted in blue) coupled to the outlet of the intravascular blood pump (pump section 12, highlighted in green). (Collins ¶¶137-138; EX1045 [Sammler] at 4:22-23 ("To the outlet of the pump section 12 a pump hose 14 is connected. This has a proximal end 15 connected with the pump outlet and a distal end 16 forming the hose outlet.").)

Thus, Sammler discloses an intravascular blood pump having a cannula coupled thereto. (Collins ¶138)

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

This claim element should be construed under 35 U.S.C. § 112(f). The claim requires a "guide mechanism" adapted to guide the intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient. The underlined language is the claimed function of the guide mechanism.[14] (Collins ¶140).

As discussed above in Part VI, the '100 patent discloses three alternative embodiments for carrying out the function: (1) a guide wire passing slideably through a co-aligned central lumen passing centrally though the intravascular blood pump system –a drive cable assembly, blood pump, and cannula (EX1001 ['100 patent] at 2:47:3-2, 7:10-7:29, 8:44-61, 10:45-57; Collins ¶141); (2) a guide wire passing slideably through a lumen extending through a guide carriage

[14] The claim recites no structure to carry out the recited function. The claim term should be construed under 35 U.S.C. 112(f), and as noted herein the prior art relied on expressly teaches a structure disclosed in the '100 patent specification for performing the recited function. Regardless, prior art expressly disclose the element under the plain and ordinary meaning.

integrally formed along at least a portion of the cannula sidewall (EX1001 ['100 patent] at 3:3-16, 12:9-23; Collins ¶141); and (3) a conduit assembly, including a guide catheter, a rotor shroud, and a cannula, which is capable of docking to a separate pump assembly. (EX1001 ['100 patent] at 3:23-41, 14:35-49; Collins ¶141) The Prior Art relied on in this petition, Sammler in view of Aboul-Hosn, discloses the same over-the-wire type guide mechanism disclosed in the '100 patent: a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient. (Collins ¶140-141).

As discussed in Part VII.A above, and as shown in annotated FIGS. 5 and 6 of Sammler, a removable guide wire 51 extends through the catheter 17 (highlighted in yellow) and pump 10 (highlighted in green), and into the catheter 48 (highlighted in red) that extends through the cannula 14 (highlighted in blue). (Collins ¶¶142-143; EX1045 [Sammler] at 3:24-27; 6:3-7 ("To facilitate placement, the catheter 48 according to Fig. 6, outside of the pressure lumen 49 leading to the balloon 35a, may contain an additional lumen 50 to accommodate a guide wire 51 and, after removal of the guide wire, for external pressure measurement. **This guide wire 51, which also passes through the catheter 17 and the pump 10**, makes it possible for the operating surgeon to controllably

influence the laying of the pump hose. The guide wire 51 is subsequently removed.") (emphasis added).)

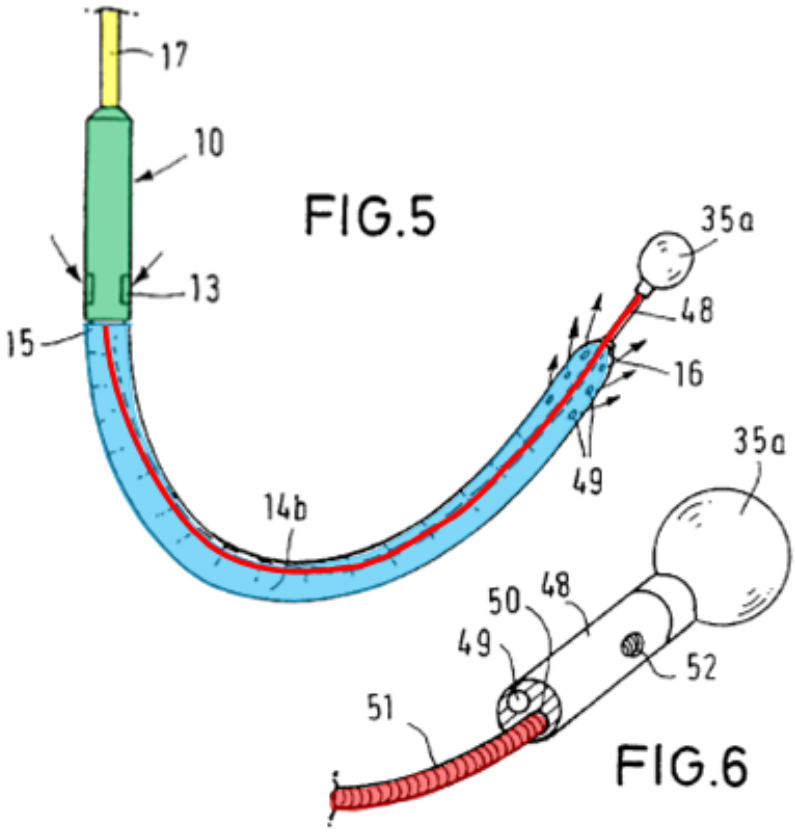


FIG.5

FIG.6

(Collins ¶143; EX1045 [Sammler] at FIGS. 5-6, annotated.)

To place Sammler's intravascular blood pump system in the desired location within the patient's vasculature (the right-side of the heart), a POSITA places the distal end of the guide wire 51 (highlighted in red in annotated FIG. 6 above) into the desired location. (Collins ¶143). Using any conventional placement techniques described in Section V.B, the POSITA then advances the intravascular

blood pump system through the lumen 50 over the guide wire 51. (Collins ¶143; EX1004 [Aboul-Hosn] at 22:12-16.)

Sammler discloses that guide wire 51 "passes through the catheter 17 and the pump 10", but not how this is accomplished. (Collins ¶144; EX1045 [Sammler] at 6:3-7.) Sammler points to Rau's intravascular blood pump, for the details of the pump 10, but Rau also does not indicate how the guide wire 51 would pass through the pump 10 as well as the catheter 17 on the proximal end of the pump 20 and cannula 14 on the distal end of the pump 20. (Collins ¶¶144-145; EX1045 [Sammler] at 4:18-19 ("The pump corresponds, *e.g.*, to that of WO 97/37696, and therefore its internal structure will not be explained in greater detail here."); 4:38-39.)

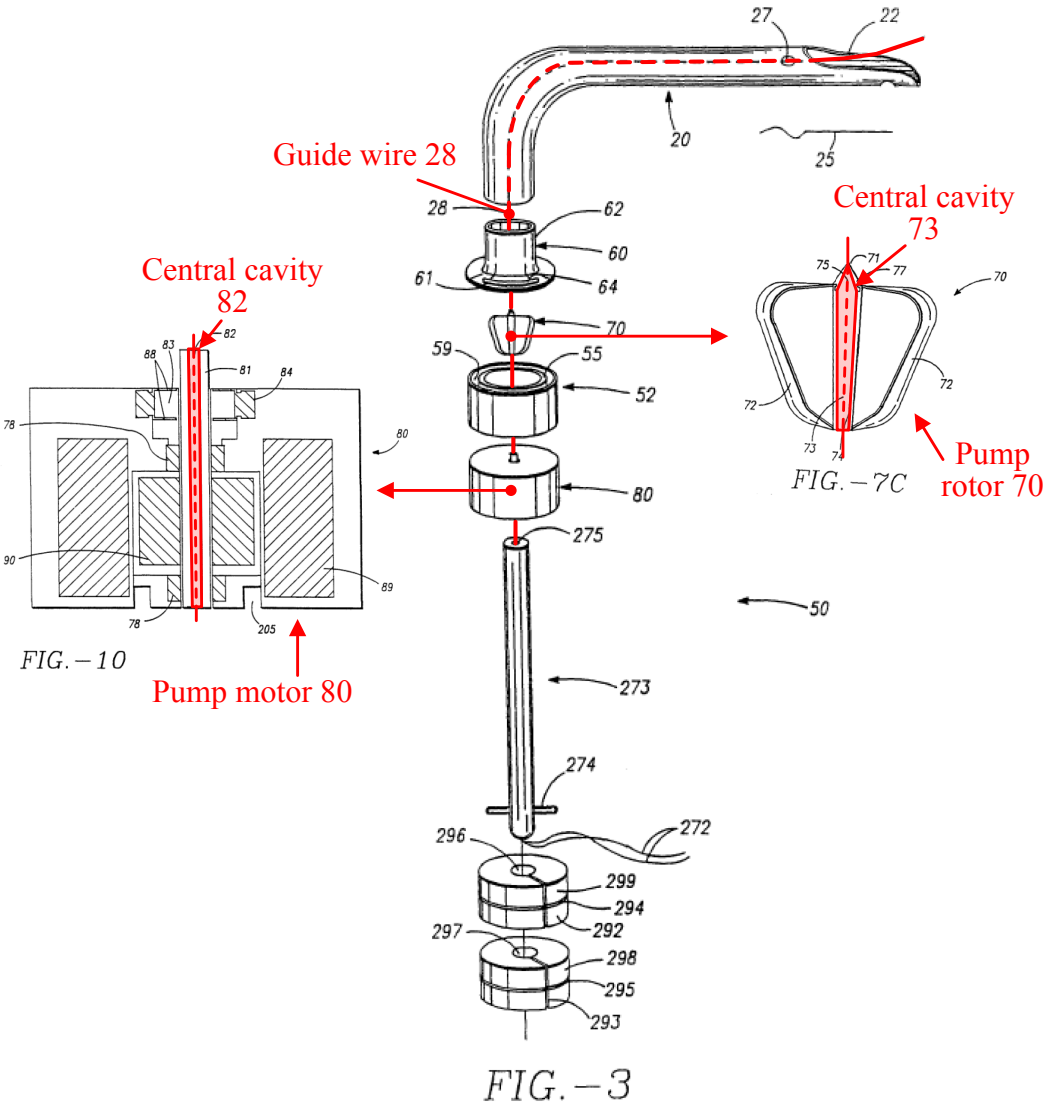
As explained by Dr. Collins, to determine how to configure Sammler's system so that the guide wire 51 passes through Sammler's catheter 17, pump 10, and cannula 14, a POSITA would readily consider analogous intravascular blood pump system art. (Collins ¶146). As discussed above in Section VII.C., Sammler and Aboul-Hosn are analogous art to the '100 patent, and accordingly a POSITA would have been motivated to consider analogous art such as Aboul-Hosn. (Collins ¶¶146-147).

Aboul-Hosn, as discussed above in Part VII.B discloses an intravascular blood pump consistent with Sammler, and providing both left and right-heart

support. (EX1004 [Aboul-Hosn] at 16:30-31; Collins ¶¶147-151). As Dr. Collins explains, a POSITA would have been naturally motivated to look to Aboul-Hosn to determine how to pass through the catheter 17 and the pump 10, as expressly contemplated by Sammler. (Collins ¶147-151; EX1045 [Sammler] at 6:3-7.)

As discussed in further detail below, although Aboul-Hosn does not have the same "drive cable assembly 18 and a motor assembly 20 … provided to drive the intravascular blood pump 12" present in the '100 patent, Aboul-Hosn has a drive mechanism which, like the drive mechanism in the '100 patent, includes a central lumen extending through the elements proximal of the pump (e.g. the drive unit 80 and positioning rod), through the center of the pump rotor, and through the elements distal of the pump, (e.g. the cannula). (EX1001 ['100 patent] at 7:10:7-29). A POSITA would readily recognize that this central lumen of Aboul-Hosn, similar to the central lumen of the '100 patent, would straightforwardly be implemented in Sammler by having a central lumen extend through the catheter 17, pump 10 and cannula 14 of Sammler.

Aboul-Hosn discloses extending a guide wire through a central lumen extending through the blood pump 50, drive unit 80 and cannula 20 to place a blood pump system in a desired location in the heart, as shown in annotated FIGS. 3, 7C, and 10 below. (Collins ¶149)



(Collins ¶149; EX1004 [Aboul-Hosn] at FIGS. 3, 7C, 10, annotated.)

Specifically, Aboul-Hosn's guide wire 28 passes through co-aligned central passages through the drive unit 80, pump 50 (including rotor hub 74 and housing cap 60) and through the cannula 20, exiting at the distal end of the cannula 20. (Collins ¶150; EX1004 [Aboul-Hosn] at 14:20-26; 22:12-14. As Dr. Collins explains, a POSITA would readily understand that in the same manner Aboul-Hosn's guide wire 28, Sammler's guide wire 51 "passes through the catheter 17

and the pump 10" through co-aligned central passages of the pump rotor, drive unit of the pump 10, and catheter 17. (Collins ¶¶150-151; EX1045 [Sammler] at 6:3-7.) Sammler's guidewire lumen 50 necessarily extends through the cannula 14 and catheter 17, connecting with the central cavities of the pump and drive unit, as in Aboul-Hosn, in order to function as intended, as a blood pressure detection lumen. (Collins ¶¶150-151)

A POSITA would further recognize the straightforward implementation of similar co-aligned central passages within Sammler's catheter 17, pump 10 and cannula 14. (Collins ¶151-152) Indeed, doing so would have been a straight-forward application of the well-known over-the-wire guidance technique to Sammler's intravascular blood pump system. (Collins ¶¶151-152) As such, as Dr. Collins explains, a POSITA would have been motivated to extend the guide wire 51 through co-aligned central passageways as shown in Aboul-Hosn, to provide a straightforward path for the guide wire 51 to extend through catheter 48 and continuing through catheter 17. (Collins ¶¶151-152). The guide wire 51 and its lumen would extend through this central passageway within the components of pump 10 between a proximal end of catheter 17 to beyond the distal end of cannula 14, guiding Sammler's intravascular blood pump system into the patient's vasculature to provide right-heart support. (Collins ¶151-152; EX1045 [Sammler] at 6:3-7.)

A POSITA would be further motivated to form co-aligned central passages within Sammler's catheter 17, pump 10 and cannula 14, as expressly taught by Aboul-Hosn, in order to form an "over-the-wire" guide mechanism, consistent with the disclosure of the '100 patent identified above. (Collins ¶150). Aboul-Hosn's guide wire 28 passes through co-aligned central passages through the drive unit 80, rotor hub 74, and housing cap 60 and through the cannula 20, exiting at the distal end of the cannula 20, to place the intravascular blood pump "in a heart chamber or a vessel in preparation to completely or partially stop the heart in order to operate on the organ". (Collins ¶150; EX1004 [Aboul-Hosn] at 6:26-29; 14:20-26; 22:12-14. As Dr. Collins explains, a POSITA would readily understand that in the same manner as Aboul-Hosn's guide wire 28, Sammler's guide wire 51 "passes through the catheter 17 and the pump 10" through co-aligned central passages of the pump rotor, drive unit of the pump 10, and catheter 17 to advance the intravascular blood pump through the vascular system and into a ventricle. (Collins ¶¶150-151; EX1045 [Sammler] at 6:3-7; 2:6-9; 2:12-16; 3:24-27). This also enables the intravascular blood pump in Sammler, as in Aboul-Hosn to "transport[[s]] fluid between different regions within the body in order to support a wide variety of surgical procedures" (EX1004 [Aboul-Hosn] at 6:6-8; EX045 [Sammler] at 4:38-42).

As explained above, the foregoing, i.e., having co-aligned central passages within Aboul-Hosn's intavascular blood pump system, is consistent with the "over-the-wire" "guide mechanism" disclosed in the '100 patent. (EX1001 ['100 patent] at 3:3-16; 12:9-23; Collins ¶152).

Accordingly, Sammler in view of Aboul-Hosn discloses a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient. (Collins ¶152-153)

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

This claim element should be construed under 35 U.S.C. § 112(f). The claim requires a "blood pressure detection mechanism" to detect the pressure of blood proximate at least one of the intravascular blood pump and cannula. The underlined language is the claimed function of the blood pressure detection mechanism[15]. (Collins ¶154).

[15] The claim recites no structure to carry out the recited function. The claim term should be construed under 35 U.S.C. 112(f), and as noted herein the prior art relied on expressly teaches a structure disclosed in the '100 patent specification for performing the recited function. Regardless, prior art expressly disclose the element under the plain and ordinary meaning.

The ’100 patent briefly mentions that its “blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the 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 ¶154; EX1001 [’100 Patent] at 4:18-32. The ’100 patent also refers to a “further embodiment” where the blood pressure detection mechanism involves “calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor.” (Collins ¶154; EX1001 [’100 Patent] at 4:18-32.) The ’100 patent also refers to “incorporat[ing] various pressure sensing and/or guidability features into at least one of the cannula 14 and pump 12,” including a reference to two other patent applications: application Ser. No. 09/280,988 (filed Mar. 30, 1999) entitled “Steerable Cannula,” and U.S. patent application Ser. No. 09/280,970 (filed Mar. 30, 1999) entitled “Pressure Sensing Cannula,” that the ’100 patent purports to incorporate by reference.” (Collins ¶154; EX1001 [’100 Patent] at 18:19-35.) Finally, the ’100 patent makes general reference to: “These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump).” (Collins ¶154; EX1001 [’100 Patent] at 18:19-35.)

The Prior Art relied on in this petition discloses the same "blood pressure detection mechanism" disclosed in the '100 patent. (Collins ¶158).

Pressure detection mechanisms were conventionally used with intravascular blood pump systems, as described in Section VI.A.e, and specifically Sammler discloses this element in more detail than the '100 patent. (Collins ¶155; EX1004 [Aboul-Hosn] at 28:14-17; 29:19-25.)

Sammler discloses removing the guide wire 51, leaving a fluid column formed by the lumen 50 in the catheter 48 running through cannula 14 and extending through the entirety of the pump system - a blood pressure detection mechanism. (Collins ¶¶156-157; EX1045 [Sammler] at 6:8-13 ("According to Fig. 6, an opening 52 can be provided on the catheter 48, which is connected to the lumen 50 and which is blocked by the guide wire 51. After the guide wire 51 is withdrawn from the lumen 50, blood enters the lumen 50 through the opening 52. The lumen 50 can be connected to a blood pressure measuring instrument, so that the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process")); 6:3-7 ("To facilitate placement, the catheter 48 according to Fig. 6, outside of the pressure lumen 49 leading to the balloon 35a, may contain an additional lumen 50 to accommodate a guide wire 51 and, after removal of the guide wire, for external pressure measurement. **This guide wire 51, which also passes through the catheter 17 and the pump 10,**

makes it possible for the operating surgeon to controllably influence the laying of the pump hose. The guide wire 51 is subsequently removed.")

Sammler further positions an opening 52 proximate the distal end of the cannula 14 to detect the pressure of the blood being pumped out of the intravascular blood pump system. (Collins ¶157; EX1045 [Sammler] at 6:8-15). Specifically, annotated FIG. 5 below shows opening 52, from FIG. 6, alongside arrows indicating blood outflow of the cannula 14 where Sammler detects the blood pressure. (Collins ¶157; EX1045 [Sammler] at 6:10-12 ("The lumen 50 can be connected to a blood pressure measuring instrument, so that the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process.")

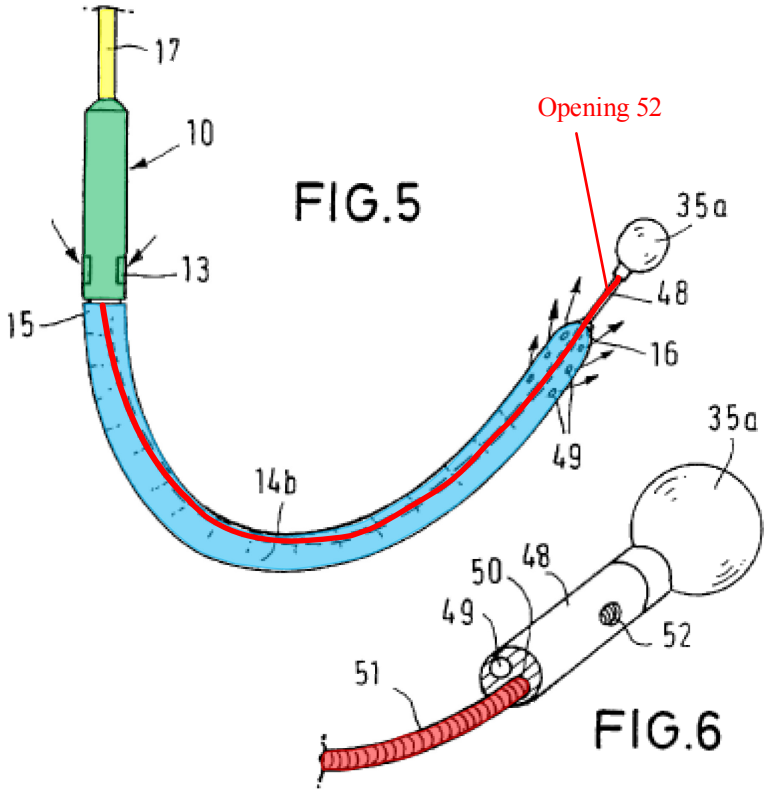


FIG.5

FIG.6

(Collins ¶157; EX1045 [Sammler] at FIGS.5-6, annotated.)

As Dr. Collins indicates, Sammler expressly discloses, and a POSITA would readily understand, that lumen 50 extends through the device to the outside, at least because lumen 50 is also used as a guidewire lumen (see annotated FIG. 6 above), which prevents blood from leaking into the catheter when the guidewire is removed for operation of the device. (Collins ¶158; EX1045 [Sammler] at 6:5-7). Lumen 50 extends through the cannula (highlighted in blue) and catheter 17 (highlighted in yellow) extending proximally with respect to the intravascular blood pump, and reaches outside the patient to connect to "a blood pressure

measuring instrument" for "external pressure measurement." (Collins ¶158; EX1045 [Sammler] at 5:39-41, 6:3-12.) As noted above, the '100 patent briefly mentions that its "blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the cannula." (EX1011 ['100 Patent] at 4:18-32.) Sammler discloses the same - pressure measurement lumen 50 necessarily runs through the cannula 14. (Collins ¶158).

As explained above, this is consistent with the "blood pressure detection mechanism" disclosed in the '100 patent. (EX1001 ['100 patent] at 4:18-32; 18:19-35; Collins ¶¶158-159).

Thus, Sammler in view of Aboul-Hosn, discloses a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump. (Collins ¶159).

2. Claim 17

Claim 17 depends from claim 16 and recites "*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.*"

Dependent claim 17 only requires the blood pressure detecting mechanism to comprise one of a "fluid 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 ¶160)

As discussed above in Part X.A.1.d, Sammler discloses "a fluid column disposed within at least a portion of the cannula". (Collins ¶161) The FIGS 5-6 embodiment of Sammler shows a removable guide wire 51 that extends through the catheter 17 (highlighted in yellow) and pump 10 (highlighted in green), and into the catheter 48 (highlighted in red) through the cannula 14 (highlighted in blue). (Collins ¶161; EX1045 [Sammler] at 3:24-27; 6:3-7 ("To facilitate placement, the catheter 48 according to Fig. 6, outside of the pressure lumen 49 leading to the balloon 35a, may contain an additional lumen 50 to accommodate a guide wire 51 and, after removal of the guide wire, for external pressure measurement. This guide wire 51, which also passes through the catheter 17 and the pump 10, makes it possible for the operating surgeon to controllably influence the laying of the pump hose. The guide wire 51 is subsequently removed."))

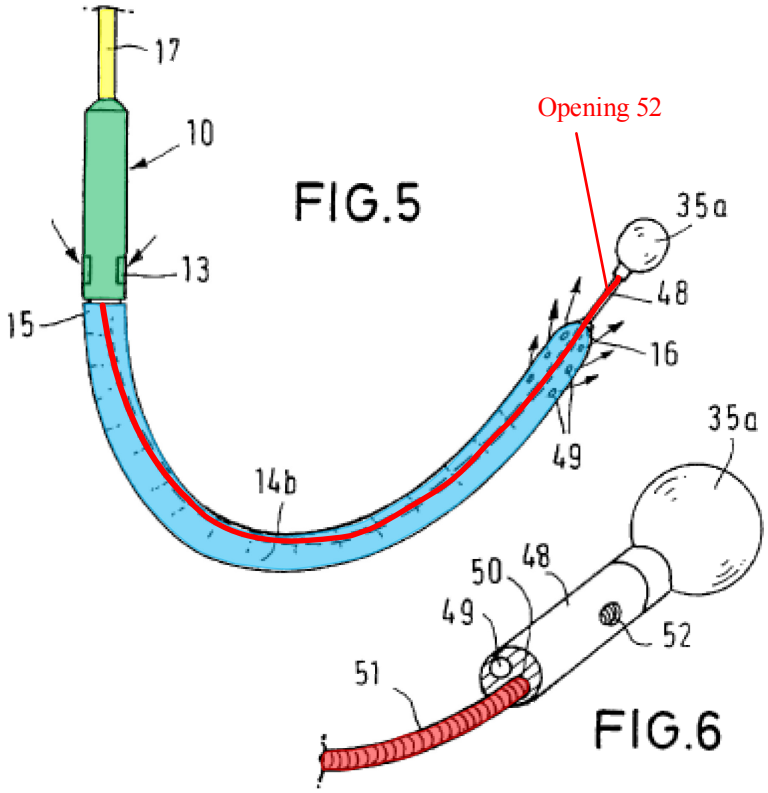


FIG.5

FIG.6

(Collins ¶161; EX1045 [Sammler] at FIGS. 5-6, annotated.)

Removable guide wire 51 and its insertion lumen 50 extend through the catheter 17 and the pump 10. Accordingly, as Dr. Collins explains, a POSITA would readily recognize that the lumen 50 also necessarily extends through both the cannula 14 (highlighted in blue) and the catheter 17 (highlighted in yellow). (Collins ¶156) Accordingly, fluid filled pressure measurement lumen 50 is disposed within at least a portion of the cannula 14. (Collins ¶162)

Thus, Sammler in view of Aboul-Hosn discloses this claim element. (Collins ¶163)

XI. INSTITUTION IS PROPER UNDER 35 U.S.C. § 325

Institution of this Petition is proper under 35 U.S.C. § 325(d). This is true notwithstanding the IPR2017-01025 (the "'1025 Proceeding") in consideration of the factors recently reiterated by the Board in *General Plastic Industrial Co., Ltd., v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper No. 19 at 15-16 (PTAB September 6, 2017). The instant petition presents specific and targeted additional arguments focusing on a subset of the claims asserted in the Litigation. The fairness factors weigh heavily against the exercise of discretion to deny institution under § 325(d). *See, e.g.*, *Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2013-00250, Paper 25 at 11-12 (P.T.A.B. Sept. 3, 2013) (declining to exercise discretion not to institute IPR of later-filed petition involving "the same parties, the same patent, and much of the same prior art" when later filed petition corrected "oversight" from the first petition). Institution of trial for a limited number of challenged claims is fair and not prejudicial to Patent Owner.

First, trial should be instituted to include the new grounds, relying on new prior art (Sammler), that was neither pursued nor the "same or substantially the same prior art or arguments" pursued in the '1025 Proceeding. The Board's discretion, whether or not to institute under Section 325(d), is not applicable to timely filed *new grounds*. *See* 35 U.S.C. § 325(d) (the Board only has discretion as to whether to (i) "stay, transfer, consolidate[e], or terminat[e]" trial or (ii) institute

proceedings based on "the same or substantially the same prior art or arguments" as previously presented). Indeed, Petitioner is merely exercising its statutory right pursuant to 35 U.S.C. § 311 to petition for IPR not "more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent" 35 U.S.C. § 315(b). As such one-year bar has yet to expire, this Petition is proper and timely.

Second, Petitioner filed the instant petition without undue delay. Petitioner received service of Patent Owner's infringement contentions on May 25, 2017 and needed sufficient time to review, digest and formulate its views with respect to those positions that bear directly on the application of the language of the claims. Petitioner is also required to operate under a litigation schedule set by the court, which set a deadline of September 8, 2017 for invalidity contentions. Meanwhile, Patent Owner continues to file and prosecute patent applications with specifications common to this patent, which influence the potential construction and application of the '100 patent. Moreover, Petitioner has filed the instant petition only after denial of a request for a reply to address the Patent Owner's misrepresentations, discussed below.

The instant petition seeks to conserve the limited resources of the Board by challenging two of the three claims challenged in the '1025 Proceeding. Thus, this case is distinct from *General Plastic Industrial Co., Ltd., v. Canon Kabushiki*

Kaisha, IPR2016-01357 PTAB Sep. 6, 2017), *NVIDIA Corp. v. Samsung Electronics Co.*, IPR2016-00134 (PTAB May 4, 2016) and *Alarm.com Inc. v. Vivint, Inc*., IPR2016-01110, (PTAB Nov. 28, 2016) where the petitioners filed serial petitions to expand the scope of the review. To further conserve the Board's resources, Petitioner has sought to join this Petition with the '1025 Proceeding.

Institution, especially in this limited manner, is not fundamentally unfair to Patent Owner. Indeed, any alleged prejudice to the Patent Owner is mitigated in light of its own tactics and long history of delay. *See SK Hynix v. Netlist, Inc*, IPR2017-00561 (PTAB July 7, 2017), Paper 7 at 4 (finding period of three years between first and second petitions did not weigh against institution when "mitigating factors" existed). Patent Owner made significant misrepresentations[16] in its preliminary responses in the '1025 Proceeding that Petitioners could not have addressed following the Board's denial of Petitioner's requested reply, and those misrepresentations seem to have influenced the Board's decision to deny institution.

[16] For example, the Patent Owner incorrectly represented that the disclosure in Aboul-Hosn is limited to extracorporeal applications. *See* EX1056[IPR2017-01025, POPR] 22-28. Patent Owner also incorrectly represented that Claim 1 requires that the blood pump be placed within the vasculature system. *See id.* at 44-45.

As another mitigating factor, Patent Owner asserted 98 claims from the '100 patent and 5 other patents from its patent family, many of them repetitive, against Petitioner in the parallel Litigation. *See* EX1061[Infringement Contentions]. Patent Owner continues to seek further continuations, again with much repetition, by extracting old abandoned prior art and incorporating it into its specification, submitting all of Petitioners' prior art and petitions to the USPTO and conducting non-public examiner interviews, all in an effort to obtain additional claims to assert against the same products, but without having to take a position on the record regarding their bases of patentability. *See* EX1062[Notice Letters]. The intent is clearly to proliferate the litigation and drive up costs. EX1063['669 Notice of Allowance]; EX1064[Status Conference Transcript.] That practice, although not subject to the Board's authority, is far more abusive than Petitioner's submission of one more petition focused solely on claims asserted in the Litigation. Exercising the Board's discretion to not institute trial would fundamentally prejudice Petitioner, as it would deny Petitioner's use of a statutory right provided specifically to aid Petitioner in patent litigation. *See, e.g.* 157 Cong. Rec. H. 4495 (daily ed. June 23, 2011) (statement of Rep. Smith).

For the reasons above, institution of trial on all grounds is fundamentally and justifiably fair.

XII. CONCLUSION

Based on the foregoing, claims 16-17 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")
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	[RESERVED]
1017	[RESERVED]
1018	[RESERVED]
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	[RESERVED]
1035	[RESERVED]
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	[RESERVED]
1044	File History of U.S. Patent No. 8,888,728 ("'728 PH")
1045	Certified translation of DE19821307 ("Sammler")
1046	Colombo, Selection of Coronary Stents, Journal of the American College of Cardiology, 2002. ("Colombo")
1047	[RESERVED]
1048	[RESERVED]
1049	[RESERVED]
1050	[RESERVED]
1051	[RESERVED]
1052	[RESERVED]
1053	[RESERVED]
1054	[RESERVED]
1055	[RESERVED]
1056	IPR2017-01025 POPR
1057	PCT Pub. No. WO97/37696 ("Rau")
1058	Stedman's Medical Dictionary, 27th edition, 1999 ("Stedman")
1059	U.S. Patent No. 4,944,722 ("Carriker")
1060	Leupold Declaration – Jegaden
1061	Infringement Contentions
1062	Notice Letters from Maquet Cardiovascular to Abiomed ("Notice Letters")
1063	Notice of Allowance, Application No. 14/966,669 ("'669 Notice of Allowance")
1064	Status Conference Transcript, Abiomed Inc. v. Maquet Cardiovascular LLC, No. 1:16-CV-10914 (D. Mass. Jun. 1, 2017) ("Status Conference Transcript")
1065	DE 19821307 German Language
1066	PCT Pub. WO 97/037696 German Language

CERTIFICATE OF WORD COUNT UNDER 37 CFR § 42.24(d)

Pursuant to 37 C.F.R. §§ 42.24(d) and 42.24(a)(1), I hereby certify that the number of words in this Petition is 9,905 excluding the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, and the listing of exhibits.

Respectfully Submitted,

___/David M. Tennant /___

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

CERTIFICATE OF SERVICE

I, Daniel Shults, hereby certify that I am a resident of the State of Maryland and over the age of eighteen years, and not a party to the within action; my business address is 701 13th Street NW, #600, Washington, DC, 20005. On September 22, 2017, I caused the within documents:

- Petition for Inter Partes Review of U.S. Patent No. 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 (EX1001-1066)
- Exhibits 1001-1066
- Power of Attorney

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

Getinge US Legal Shared Services

1300 MacArthur Boulevard

Mahwah NJ 07430

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

Michael S. Connor

Alston & Bird LLP

Bank of America Plaza

101 South Tryon Street, Suite 4000

Charlotte, NC 28280-4000

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

__/s/ Daniel Shults
Daniel Shults