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. IPR2017-02134

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

CLAIMS 9-12 AND 14

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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 9-12 and 14 (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. Petitioner has not challenged the Challenged Claims previously in any petition for *inter partes* review.

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 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.

Petitioner has not challenged the Challenged Claims previously in any petition for *inter partes* review.

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 *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 *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. R. Wampler et al., *Clinical Experience with the Hemopump Left Ventricular Assist Device*, Springer (1991) (EX1007, "Wampler") published in 1991, is prior art to the '100 patent under 35 U.S.C. § 102(b). (EX1037, "Declaration of Kiersten Batzli")

[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. All applied prior art is prior art under 35 U.S.C. § 102(b) regardless of the date to which Patent Owner may allege the '100 patent is entitled to priority.

2. U.S. Patent No. 4,625,712 to Wampler (EX1008, "Wampler '712"), filed September 28, 1983 and issued December 2, 1986, is prior art to the '100 patent under 35 U.S.C. § 102(b).

3. O. Jegaden, *Clinical Results of Hemopump Support in Surgical Cases*, Springer (1991) (EX1033, "Jegaden"), published in 1991, is prior art to the '100 patent under 35 U.S.C. § 102(b). (EX1060, "Leupold Declaration")

4. U.S. Patent No. 5,061,273 to Yock (EX1006, "Yock"), filed July 5, 1990 and issued October 29, 1991, 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 9-12 and 14 under the following statutory grounds:

- Claims 9-12 and 14 are rendered obvious by the Hemopump art: Wampler in view of Wampler '712 and further in view of Jegaden, and further in view of Yock, under 35 U.S.C. § 103(a).

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 ¶88; EX1011 [Voelker] at 3:34-65; EX1020 [Bagaosian] at FIG. 6, 5:12-16; EX1023 [Faxon] at 43, 57-58.)

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 the Hemopump art, with only minor added details from Yock. (Collins ¶¶40-42.)

A. Conventional Intravascular Blood Pumps[3]

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 ¶¶55-56; *see also* EX1007 [Wampler]

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

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 pump blood axially along the pump and through the cannula (Collins ¶¶55-56; *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 drive cable driving the pump (Collins ¶¶55-56; *see also* EX1008 [Wampler] at 233-234, FIG 14-2; EX1059 [Carriker] at 2:55-59, 2:1-10, FIG. 1B; EX1033 [Jegaden] FIG. 2; and (4) a purge fluid delivery system to deliver purge fluid to the rotor (Collins ¶¶55-56; *see also* EX1007 [Wampler] at 233; EX1008 [Wampler '712] at 3:40-45; EX1024 [Abou-Awdi] at FIGS 1, 37). 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 ¶¶40-42.)

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 ¶¶73-74.)

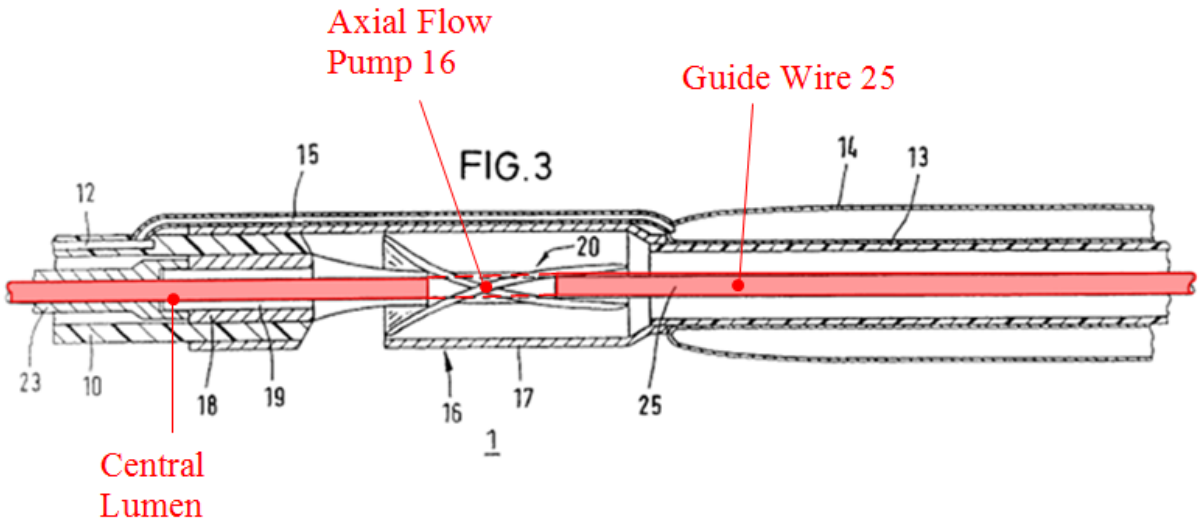
1. Over-the-Wire Catheter

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 ¶¶76-79; 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 ¶¶76-79.) 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 ¶78.) 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.)

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

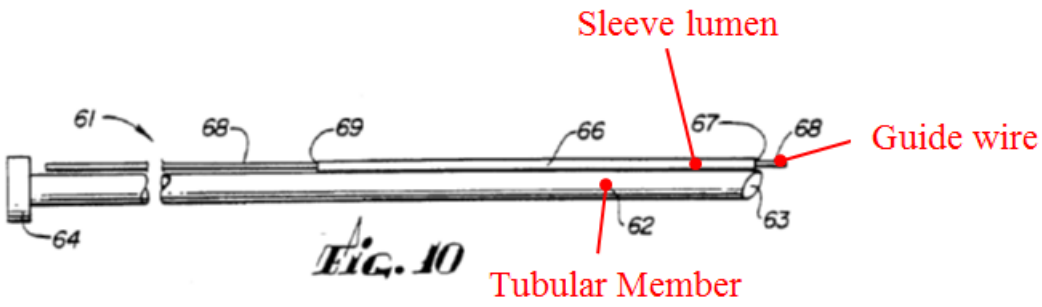


(Collins ¶78; EX1011 [Voelker] at FIG. 3, annotated.)

2. Side-Rigger Catheter

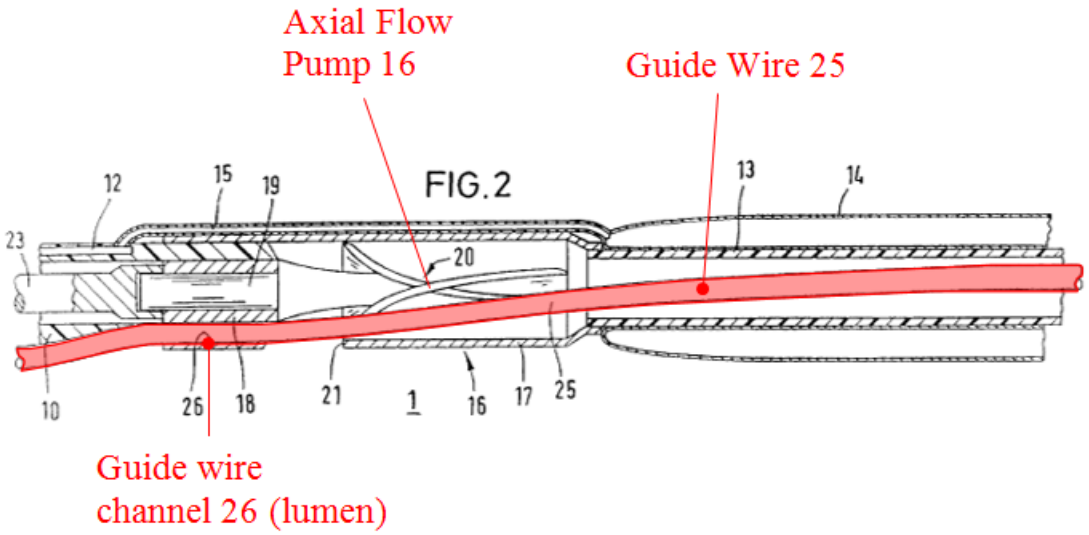
As Dr. Collins explains, the "side-rigger" or "monorail" technique was also well-known to be used to place intravascular blood pumps. (Collins ¶¶80-86.) As Yock discloses, a conventional "side-rigger" catheter generally includes an elongate tubular member, such as a cannula, and a sleeve (with an interior lumen for a guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (*Id.* ¶80; 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 ¶80; EX1006 [Yock] at 7:64-8:19.) Then, the surgeon advances the catheter along the guide wire to the desired location. (Collins ¶80; EX1006 [Yock] at 8:20-25.) The orientation of the sleeve

along the side of the cannula allows for the exchange of catheters. (Collins ¶80; EX1006 [Yock] at 2:31-37.)



(Collins ¶80; 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 ¶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 ¶75; 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 ¶75.) 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

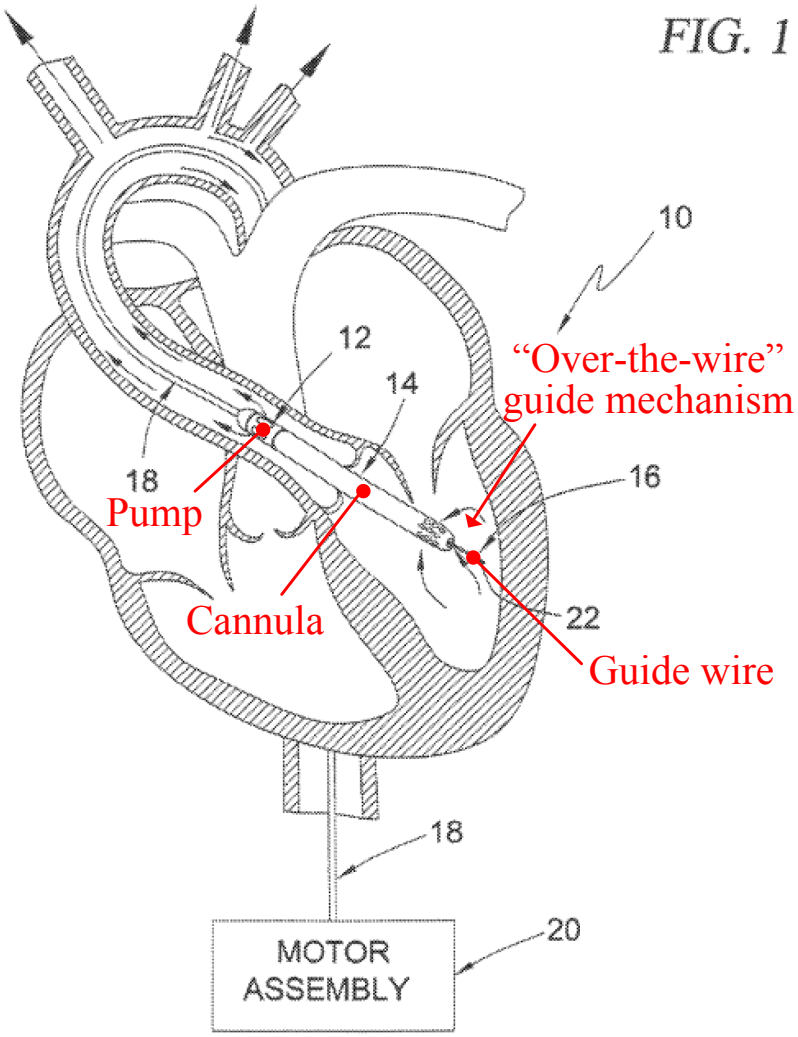
A. Summary of Alleged Invention of the '100 Patent

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 "side-rigger" type guide mechanism; and (3) a "guide catheter" type guide mechanism. (EX1001 ['100 patent] at 2:56-3:41; Collins ¶¶87-89.)

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; Collins ¶¶87-89).

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 ¶¶90-91).



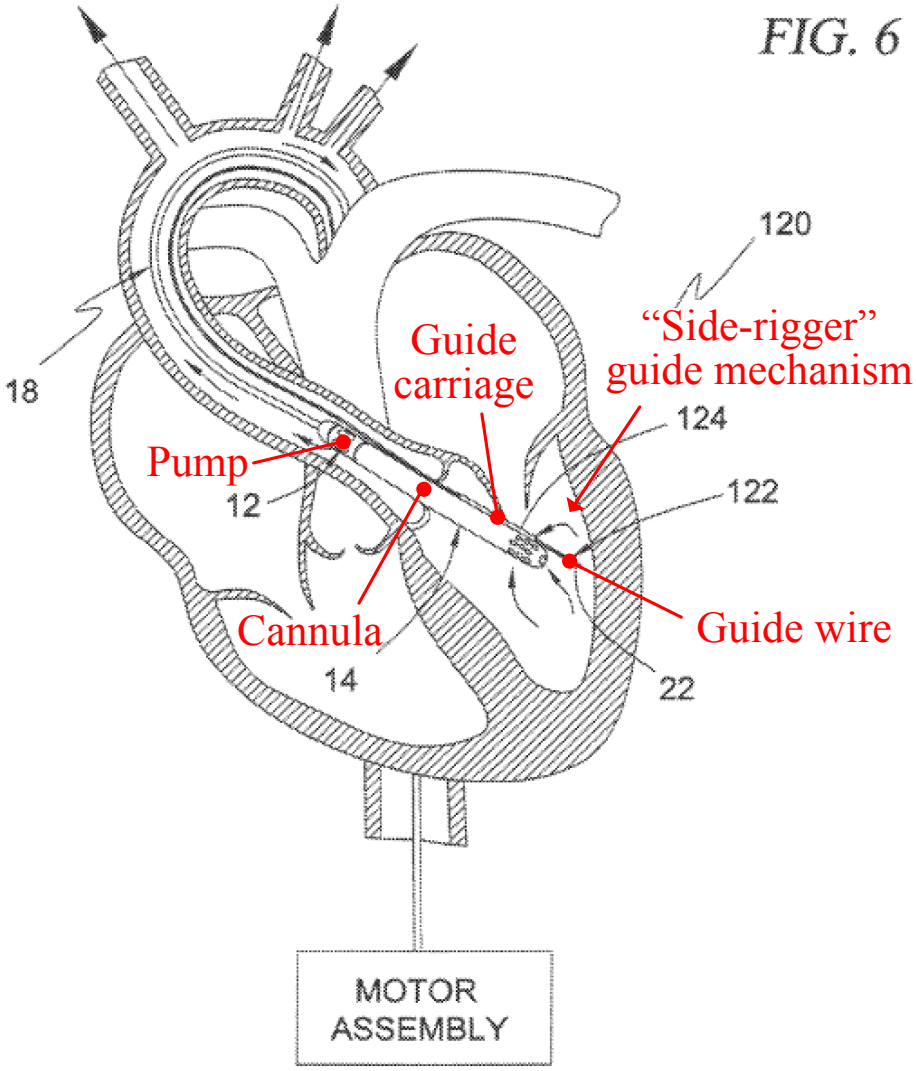
(Collins ¶90; EX1001 ['100 patent] at FIG. 1, annotated.)

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 ¶90.) "[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.)

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

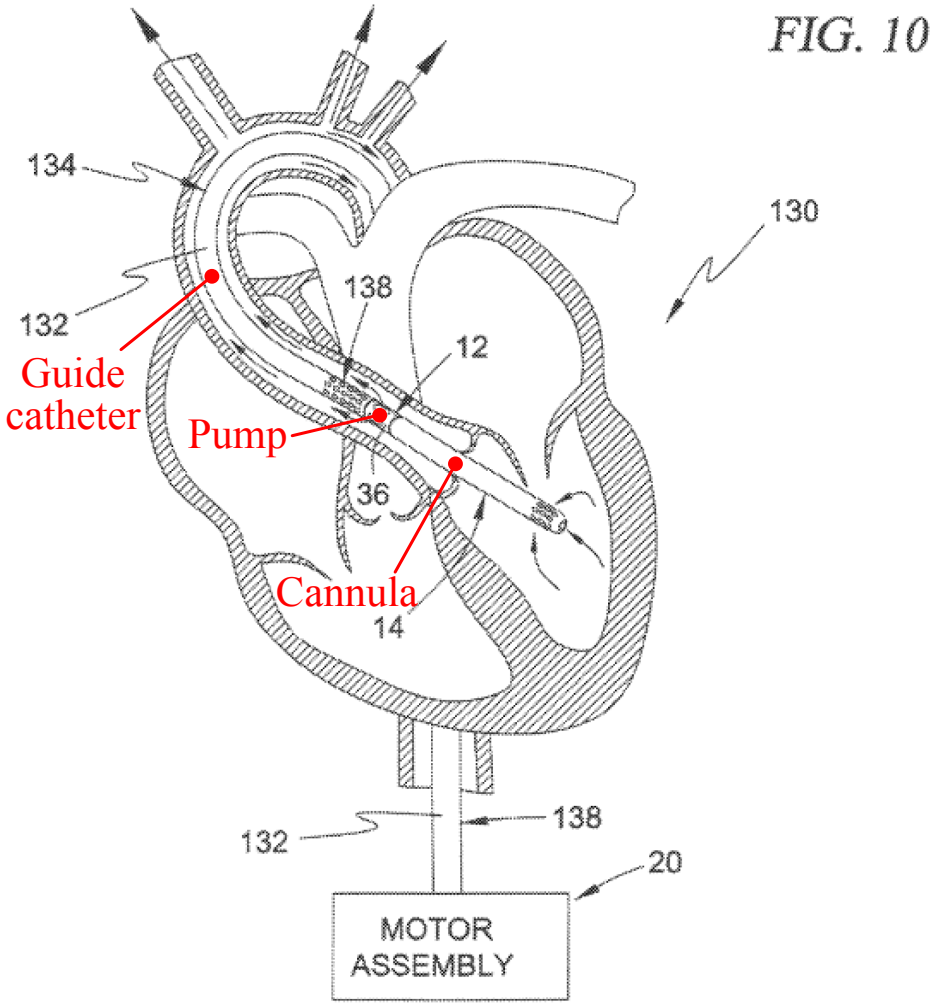
FIG. 6 shows the conventional "side-rigger" guide mechanism of the prior art. (EX1001 ['100 Patent] at 5:30-35; Collins ¶92) The guide mechanism 122 "includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slideably through a lumen (not shown) extending through the guide carriage 124." (*Id.* at 12:13-19); Collins ¶¶93-94.) As explained in detail below, this is the same guide-wire guide-catheter guide mechanism disclosed in the Hemopump art. (Collins ¶¶92-94).



(Collins ¶92; 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 at ¶¶95-96.)



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

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

Before reaching the desired location using the various conventional techniques described above, the intravascular blood pump system of the '100 patent must be first introduced into the patient's vasculature. (Collins at ¶97) 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 at ¶97.) The '100 Patent explains that 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 10:38-44; Collins at ¶97.)

e) ***Drive Cable and Purge Fluid***

The '100 Patent teaches to operate its pumps by an external drive cable, well-known from the Hemopump. (Collins at ¶¶98-99.) The '100 patent specifically discusses a drive cable assembly, including a drive cable and a drive cable sheath with lumens for purge fluid flow. (EX1001 ['100 Patent] at 10:12-27; Collins at ¶¶98-99.) The rotating drive cable is driven by an external power source, and conveying rotational movement to the rotor. (EX1001 ['100 Patent] at 1:59-67; Collins at ¶¶98-99.) The '100 Patent further describes that there is a mechanical connection between the external power source, and the drive cable. (EX1001 ['100 Patent] at 7:66-8:2; Collins at ¶¶98-99.) The '100 Patent also describes that the drive cable sheath can include a side lumen for delivering purge

fluid towards the rotor, and a central lumen through which a fraction of the purge fluid is routed back from the rotor. (EX1001 ['100 Patent] at 4:1-7; 10:29-44; Collins at ¶¶98-99.)

VII. OVERVIEW OF THE PRIOR ART REFERENCES

A. Overview of the Hemopump Art

As discussed above in Section V, the Hemopump is a well-known intravascular axial flow blood pump, described in a number of references. (Collins at ¶106).

Wampler discloses the Hemopump's operation and ongoing clinical trials of the Hemopump in the treatment of cardiogenic shock as of July 1991. (EX1007 [Wampler] Abstract; Collins at ¶107.) Wampler includes a system description of the Hemopump system, with its inflow cannula, pump, drive cable, monitoring console and purge fluid system, along with a description of an insertion procedure for the Hemopump. (EX1007 [Wampler] Abstract; Collins at ¶107.) Specifically, FIG. 14-2, below, illustrates a schematic of the Hemopump in assembled form with the motor connected via sheath/drive cable to the pump and inflow cannula, and to a purge fluid system. The purge fluid pump delivers a continuous infusion of purge fluid at the rate of 300 cc/day through an inlet (i.e. "purge fluid in"). Using lumens within a drive cable sheath, 200 cc/day passes through the pump and into the blood stream (i.e. "injected purge fluid") and the remaining 100 cc/day returns

from the Hemopump after lubricating the pump, drive cable, and sheath (i.e. "purge fluid out"). (EX1007 [Wampler] at 233-234; Collins at ¶107.)

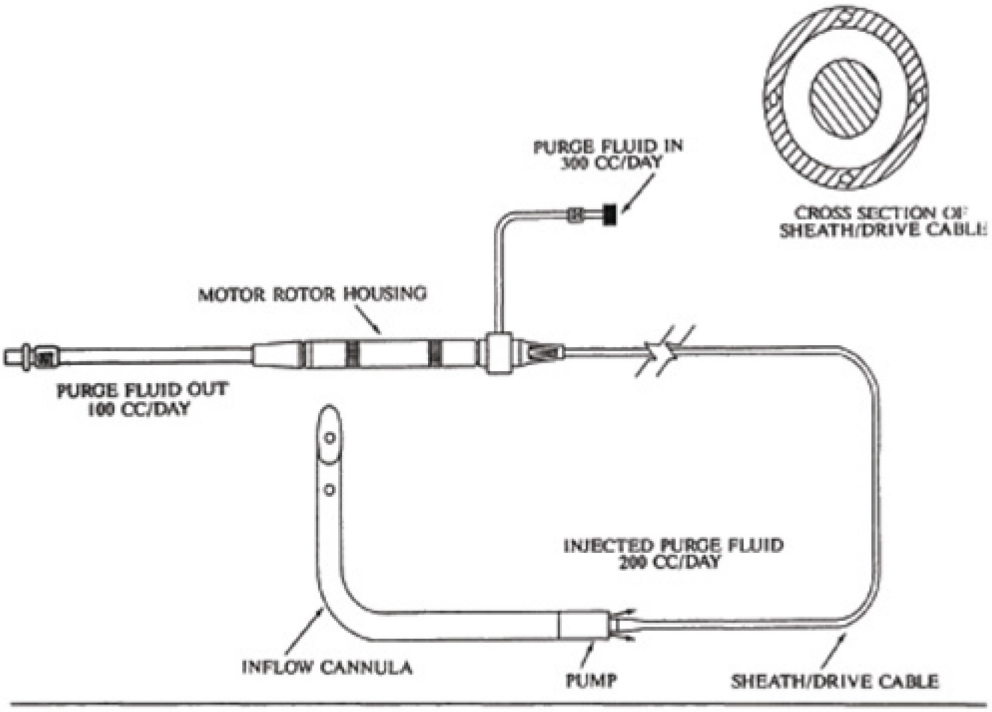


Figure 14-2. Schematic of the Hemopump.

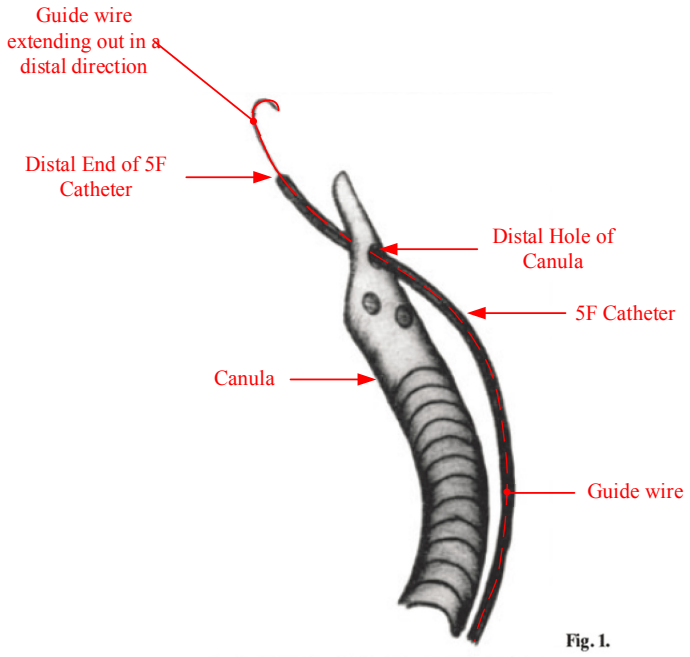
(Collins ¶107; EX1007 [Wampler] at FIG. 14-2, annotated.)

As shown in FIG. 14-2, the "Purge Fluid In" and "Purge Fluid Out" conduits each have a conventional fitting at their respective ends to be connected to the roller pump and the return bag, respectively. (Collins at ¶108). The "Purge Fluid In" conduit and the "Purge Fluid Out" conduit connect to an integrated controller, outside of the patient's body, which also includes the roller pump and return bag. (EX1007 [Wampler] at 233-234 and FIG. 14-3; Collins at ¶108-109.)

Wampler '712 also describes the Hemopump, as confirmed in the Hemopump Manual. (EX1054 [Hemopump Manual] at 1-1; Collins at ¶110.) Wampler '712 discloses both the drive cable providing rotational movement from the motor to the rotor, and a purge fluid system. The support unit 28 in FIG. 1b of Wampler '712 is a purge fluid pump system, which provides purge fluid through a catheter 26 to the blood pump 10. (EX1008 [Wampler '712] at 3:40-42; Collins at ¶110.)

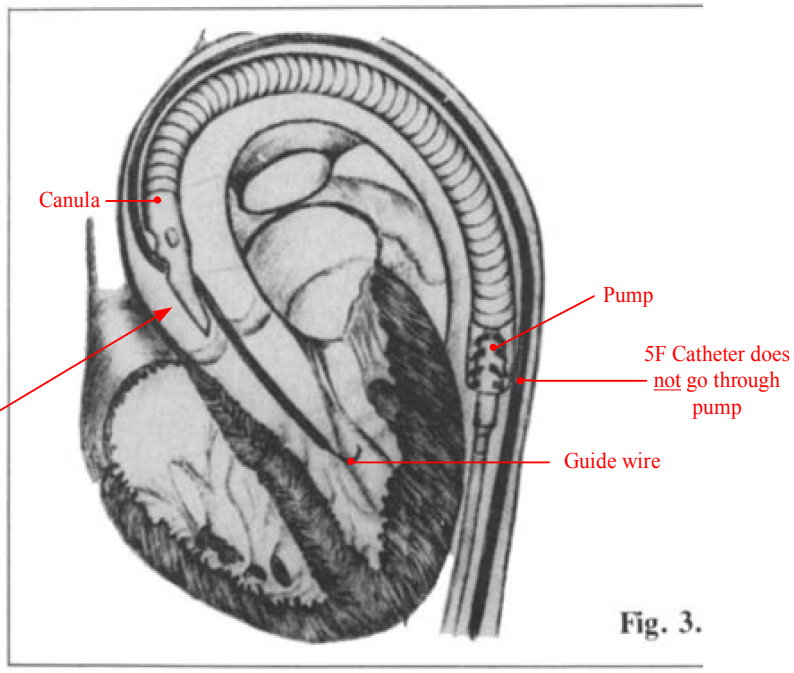
Jegaden discloses clinical results obtained with the Hemopump in surgical cases. As Jegaden discloses, a common method of Hemopump implantation was by the left femoral artery approach. (EX1033 [Jegaden] at 62; Collins at ¶¶111-115.) Specifically, Jegaden discloses using a guide mechanism for inserting the Hemopump, including the guide wire and guiding catheter (i.e. 5 French or 5F catheter) extending along the side of the cannula, with the guide catheter and guide wire being "passed through the distal hole of the cannula and introduced into the femoral artery up to the aorta." (EX1033 [Jegaden] at 62; Collins at ¶112.)

As shown in annotated FIG. 1 below, in Jegaden the guide wire passes through the 5F guide catheter and distal hole in the cannula wall, such that the 5F guide catheter and cannula side-hole both receive the guide wire and lead the guide wire along the side of the cannula, functioning as a side-rigger mechanism. (EX1033 [Jegaden] at FIG. 2; Collins at ¶113.)



(Collins ¶113; EX1033 [Jegaden] at FIG. 1, annotated.)

As shown in Jegaden FIG. 3 below, the guide wire passes along the outside of the cannula. The 5F catheter passes along the outside of the cannula as well but does not materially increase the width of the cannula, because its diameter, by definition 1.67mm, is substantially smaller than that of the cannula, which is about 7-9mm. (EX1033 [Jegaden] at 61-62 and FIG. 3; Collins at ¶¶114-115)



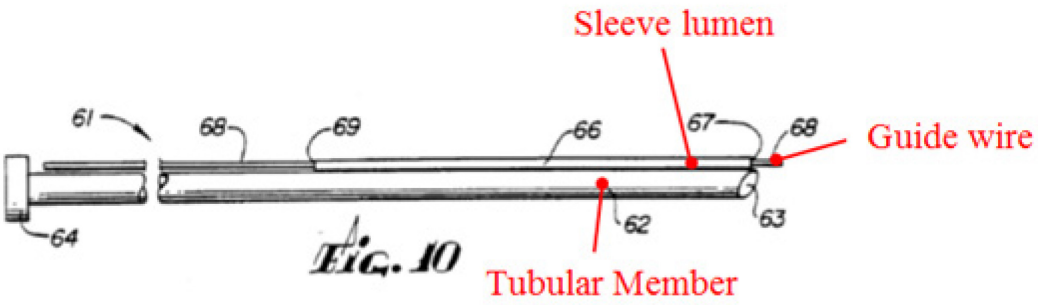
(Collins ¶114; EX1033 [Jegaden] at FIG. 3, annotated.)

B. Overview of Yock

Yock discloses how to use a conventional guiding catheter to position the guide wire, and to subsequently advance a balloon catheter into a desired location in the body through the guide wire into the guiding catheter. (EX1006 [Yock] at 3:56-4:50; Collins at ¶¶116-120)

While Yock discloses the use of a "side-rigger" mechanism in connection with a minimally invasive catheter for angioplasty, the similarities between the structure of a catheter used for angioplasty and a cannula of an intravascular blood pump are such that the teachings of Yock would readily be applied to an intravascular blood pump, such as the Hemopump. (Collins at ¶¶116-117). For example, Yock discloses the use of a "conventional guiding catheter," a long,

flexible tube with a central lumen through which a guide wire and a balloon dilation catheter can be inserted and slide over the guide wire until the balloon is positioned at a desired location within the patient's body, along with a rapid-exchange catheter. (EX1006 [Yock] at 3:56-4:50 and 7:64-8:2; Collins at ¶¶118-119). The side-rigger catheter of Yock includes a cannula, and a sleeve (with an interior lumen for the guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (EX1006 [Yock] at 7:64-8:2, 8:16-19 and FIG. 8B, FIG. 10; Collins at ¶¶118-119)



(Collins ¶119; EX1006 [Yock] at FIG. 10, annotated.)

Yock recognizes the downsides of over-the-wire guide mechanisms to side-rigger catheters, and the techniques of Yock for angioplasty have been adapted for use to place an axial flow intravascular blood pump such as the Hemopump, for example as discussed in Jegaden. (EX1006 [Yock] at 1:15-25; EX1011 [Voelker] at 1:15-25; Collins at ¶¶119-120)

C. Analogous Art

Wampler, Wampler '712, Jegaden and Yock are analogous art to the '100 patent. As Dr. Collins explains throughout his Declaration, a POSITA would naturally look to this analogous art. (Collins at ¶121)

First, a POSITA would naturally look to the Hemopump art: Wampler, Wampler '712, and Jegaden as all of these references are 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 at ¶121)

Second, the Hemopump art (Wampler, Wampler '712, and Jegaden) and Yock are directed to the same problem addressed by the '100 patent, i.e. positioning systems within the vascular system. *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 at ¶121) Specifically, each Hemopump art is directed to positioning intravascular blood pump systems within the vascular system of a patient, such as for left or right heart support. (EX1007 [Wampler] at 232; EX1008 [Wampler_712] at 1:5-9; EX1033 [Jegaden] at 62; Collins at ¶¶116-120).

Similarly, Yock discloses how to use a conventional guiding catheter to position the guide wire, and to subsequently advance a balloon catheter into a desired location in the vascular system of the body. (EX1006 [Yock] at 3:56-4:50; Collins at ¶¶116-120)

That Yock and the Hemopump art are reasonably pertinent to the problem is also indicated by references such as Faxon – Faxon's practical angioplasty guides disclosed angioplasty devices similar to Yock's, along with general catheterization techniques and blood pumps including the Hemopump (Chapter 18). (EX1023 [Faxon] at Chapter 18, Chapter 7; Collins at ¶121)

Accordingly, Wampler, Wampler '712, Jegaden and Yock are all analogous art to the '100 patent, and a POSITA would have looked interchangeably to any of these references.

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 ¶¶33-38.)

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; Collins ¶¶33-38.)

Patent Owner overstates the requirement to qualify as a POSITA. (Collins ¶¶33-38.) Patent Owner provided absolutely no justification for requiring such a stringent "ordinary" level of skill with intravascular heart assist devices. (*Id.* ¶¶33-38.) As the Board previously acknowledged, both experience and education

should be factored in the level of skill of the POSITA.[5] 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, 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

[5] *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).

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 ¶¶33-38.) 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. (*Id.* ¶¶33-38.)

Even under Patent Owner's unduly restrictive definition, Dr. Collins is a POSITA for the purposes of the '100 patent. (*Id.* ¶¶33-38.) Dr. Collins received his Ph.D from MIT in 1988 with a focus on biomedical applications, and from 1998 to 2002, 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. (*Id.* ¶¶33-38.) 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. (Collins ¶122.)

A. Ground I: Claims 9-12 and 14 are obvious over the Hemopump Art (Wampler in view of Wampler '712 and further in view of Jegaden) and in view of Yock.

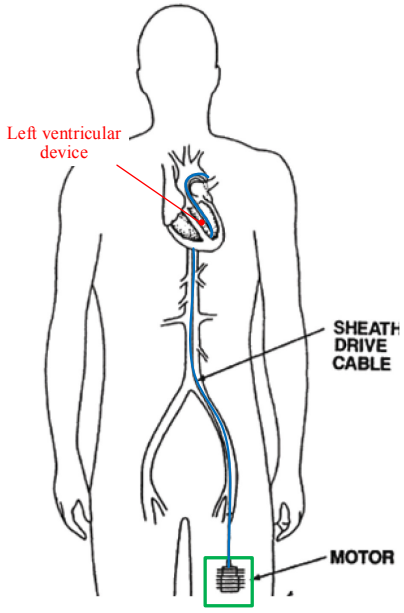
1. Claim 9

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

Wampler discloses an intravascular blood pump system, the Hemopump. (Collins ¶¶123-126) Wampler provides a comprehensive description of the Hemopump, then a new circulatory assist device capable of supporting the left ventricle without the need for a major surgical procedure. (Collins ¶¶123-126; EX1007 [Wampler] at 232)

Wampler Figure 14-1 shows "The Hemopump … a temporary left ventricular assist device utilizing axial flow technology to draw blood out of the left ventricle and expel it into the aorta." Wampler further indicates that the Hemopump of Figure 14-1 "can be placed via a peripheral **vascular access** and support up to 80% of the left ventricular work load." As shown in annotated Figure 14-1 below a left ventricular device is inserted intravascularly into the heart

and connected by a sheath drive cable (blue) to the external motor (boxed in green). (Collins ¶124).



(Collins ¶124; EX1007 [Wampler] at FIG. 14-1, annotated.)

Annotated FIG. 14-2 below shows the Hemopump system which is to be inserted via vascular access, including its pump (shaded in red), its inflow cannula and its sheath/drive cable. (Collins ¶125; EX1007 [Wampler] at 232).

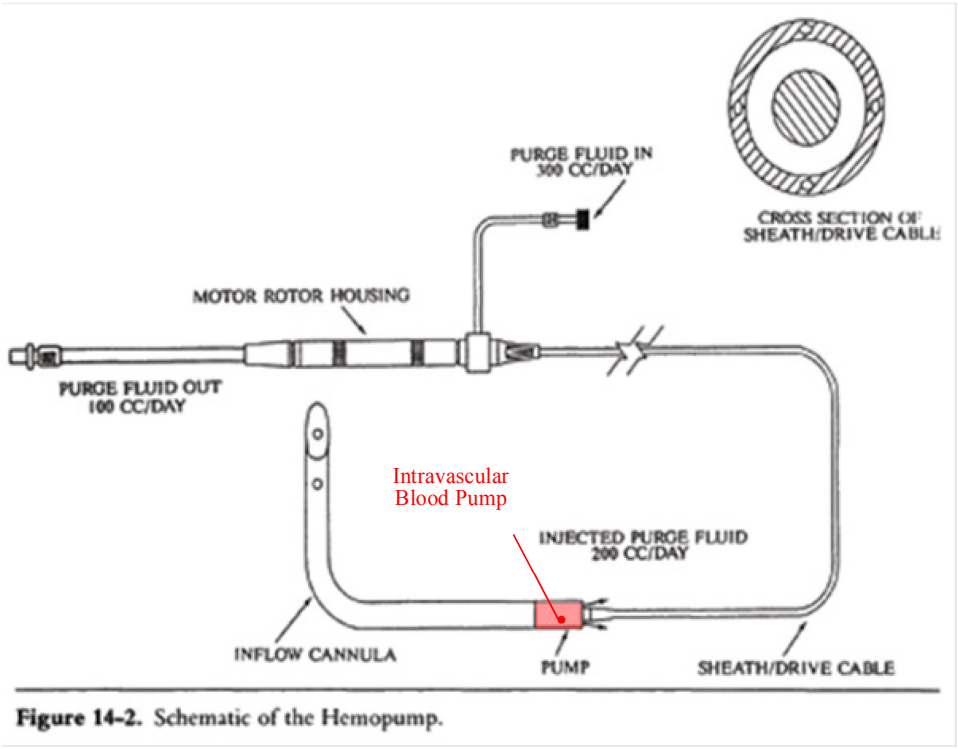


Figure 14-2. Schematic of the Hemopump.

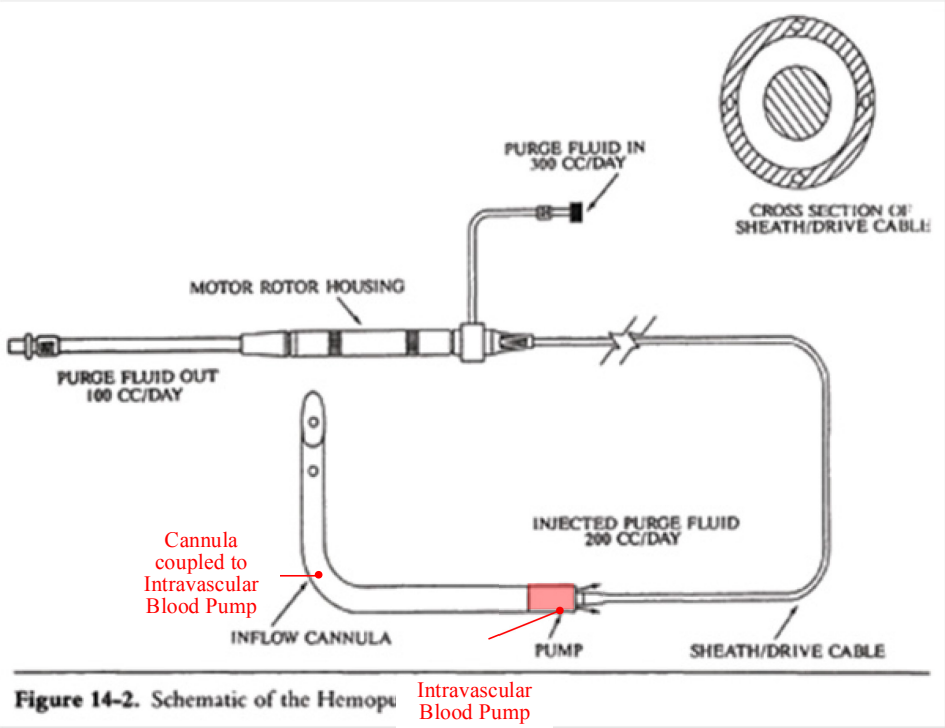
(Collins ¶125; EX1007 [Wampler] at FIG. 14-2, annotated.)

Thus, Wampler discloses an intravascular blood pump system. (Collins ¶126.) Petitioner describes below the elements of Wampler's intravascular blood pump system in greater detail.

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

As discussed above, Figure 14-1 shows the left ventricular device (including the inflow cannula, pump, and sheath/drive cable) of Figure 14-2 inserted intravascularly into the heart. Accordingly, the Hemopump was an intravascular blood pump system. (Collins ¶126; EX1007 [Wampler] at 233) Wampler further discloses that "attached distally to the pump housing is a … curved inflow

cannula." (Collins ¶127; EX1007 [Wampler] at 233). Annotated FIG. 14-2 below shows the intravascular blood pump (in red), and the inflow cannula coupled to the intravascular blood pump. (Collins ¶128).



(Collins ¶128; EX1007 [Wampler] at FIG. 14-2, annotated.)

Thus, Wampler discloses an intravascular blood pump having a cannula coupled thereto. (Collins ¶129.)

c) *"said intravascular blood pump including a rotor, a shroud for receiving said rotor"*

Wampler in view of Wampler '712 discloses the rotor and a shroud for receiving said rotor, as used in the Hemopump. (Collins ¶¶130-136.)

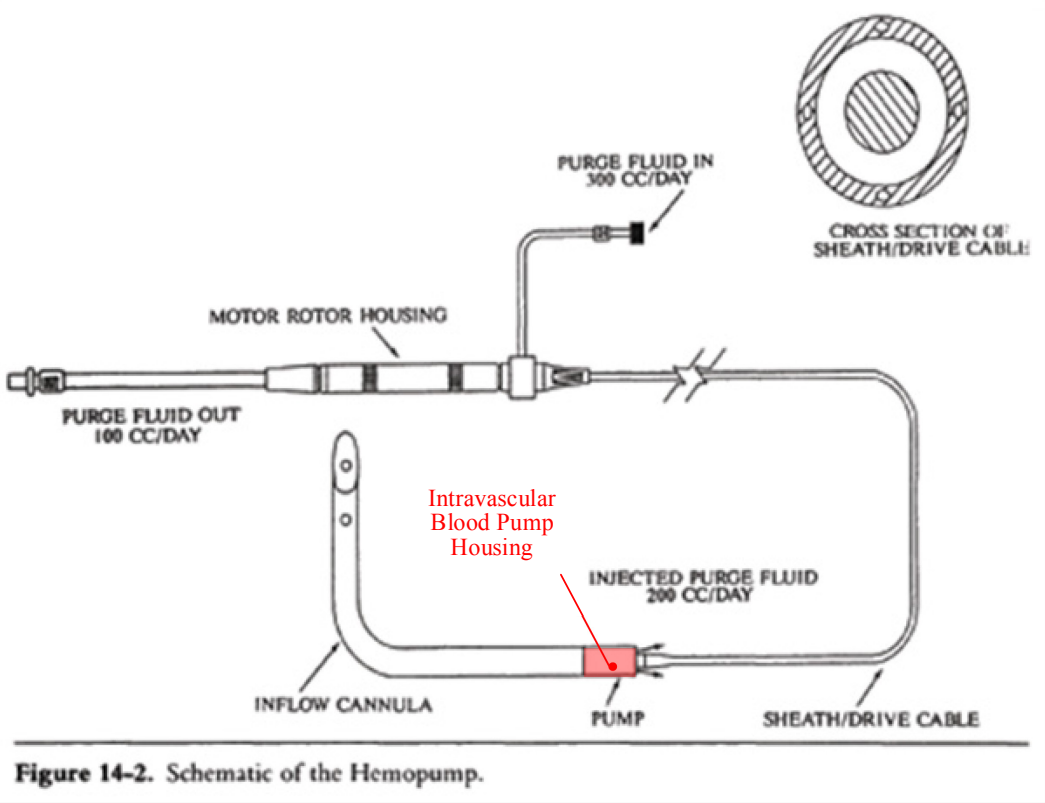


Figure 14-2. Schematic of the Hemopump.

(Collins ¶130; EX1007 [Wampler] at FIG. 14-2, annotated.)

In Wampler, as shown in annotated FIG. 14-2 above, the intravascular blood pump housing hides the rotor. However, as indicated by Dr. Collins, the Hemopump necessarily includes a rotor and a shroud receiving that rotor. (Collins ¶131). Even if a prior art reference does not explicitly disclose all features of the claimed invention, the reference may inherently do so.[6]

[6] *See Schering Corp. v. Geneva Pharms., Inc.,* 339 F.3d 1373, 1377 (Fed. Cir. 2003). "[A]nticipation by inherent disclosure is appropriate only when the [single prior art] reference discloses prior art that must necessarily include the unstated limitation." Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364,

Notwithstanding, Wampler ’712 expressly discloses such configuration.

As discussed above in Part VII.C, one test for analogous art is whether the art is from the same field of endeavor, regardless of the problem addressed. This field of endeavor can be correctly determined "by consulting the structure and function of the claimed invention as perceived by one of ordinary skill in the art" with "reference to explanations of the invention's subject matter in the patent application." *Bigio, 381 F.3d at 1325-26.* The Hemopump Manual identifies the Wampler ’712 patent as describing the Hemopump. (Collins ¶131; EX1054 [Hemopump Manual] at 1-1. Indeed, as indicated by Dr. Collins, a POSITA starting from Wampler would have been motivated to turn to art directed to the same field of endeavor, such as Wampler ’712, a patent by the lead author of

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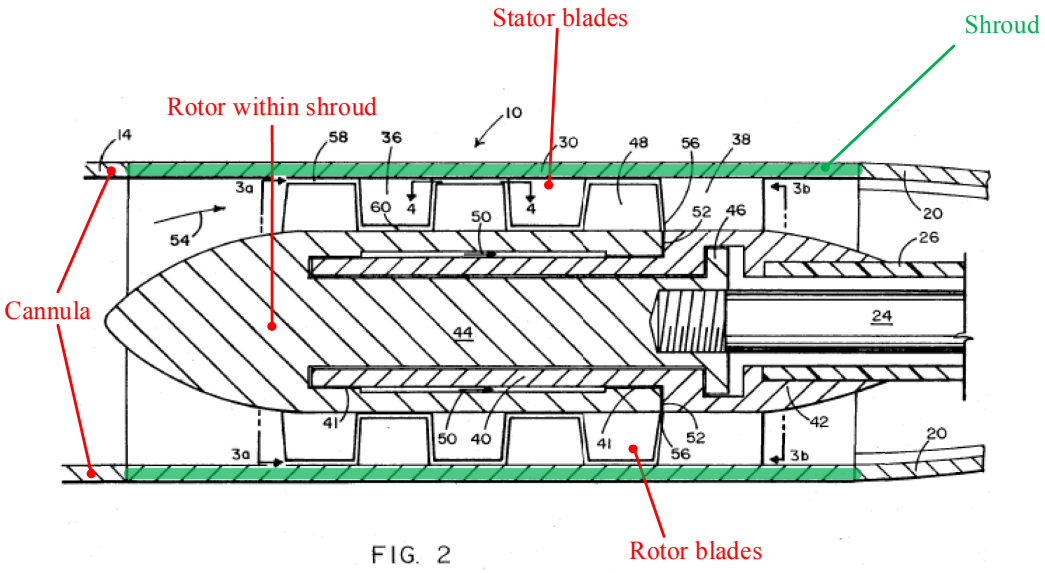
1373 (Fed. Cir. 2002) (citation omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Cont'l Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991) (internal quotation marks and citations omitted). Rather, "[t]he inherent result must inevitably result from the disclosed steps . . . ." In re Montgomery, 677 F.3d 1375, 1380 (Fed. Cir. 2012).

Wampler, which describes the Hemopump in greater detail, to identify the components of the Hemopump pump that Wampler does not expressly disclose. (Collins at ¶¶131).

Wampler '712 specifically teaches a rotor and a shroud for receiving said rotor. As shown in annotated Wampler '712 FIG. 2 below, in the Hemopump the rotor is positioned within the housing, which acts as a shroud (highlighted in green below).



(Collins ¶131; EX1008 [Wampler_712] at FIG. 2, annotated.)

Accordingly, Wampler in view of Wampler '712 (another Hemopump reference) discloses an intravascular blood pump including a rotor, and a shroud for receiving said rotor. (Collins ¶131.)

> d) *"and a drive cable coupled to said rotor for driving said rotor within said shroud"*

Wampler discloses a drive cable coupled to the rotor within the shroud. (Collins ¶¶132-134; EX1007 [Wampler] at 233) As shown in annotated FIG. 14-2 below, the blood pump housing (red) connects to the hollow cable sheath (blue), allowing the drive cable within the cable sheath to mechanically transfer rotational motion to the rotor within the blood pump housing. (Collins ¶¶132-134; EX1007 [Wampler] at 233-234, FIG. 14-2, annotated)

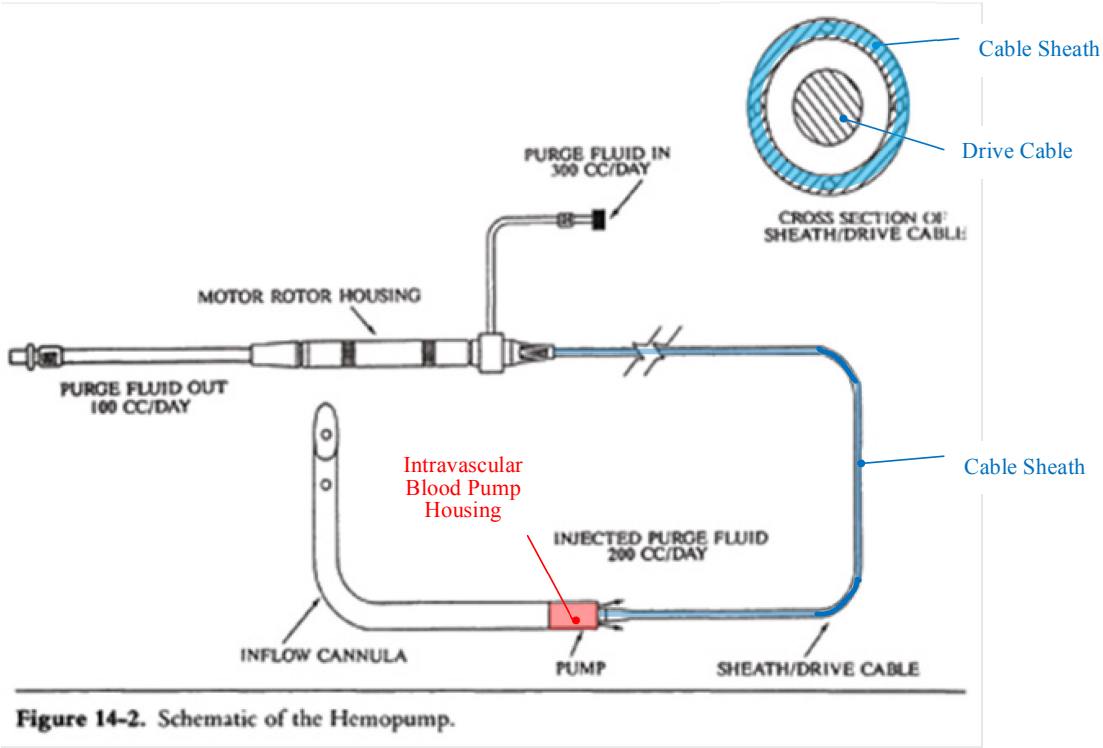


Figure 14-2. Schematic of the Hemopump.

(Collins ¶133; EX1007 [Wampler] at FIG. 14-2, annotated.)

As noted above with respect to claim element 9(c), even if a prior art reference does not explicitly disclose all features of the claimed invention, the reference may inherently do so. In Wampler, a coupling between the drive cable and the rotor must necessarily be present in the Hemopump in order for the rotor to

be mechanically driven by the drive cable. (Collins ¶134; EX1007 [Wampler] at 233-234, FIG. 14-2, annotated)

Accordingly, Wampler inherently discloses a drive cable "coupled to said rotor for driving said rotor within said shroud." (Collins ¶134).

To the extent that Patent Owner alleges that this feature is not inherently disclosed, it would have been obvious in view of Wampler '712. (Collins ¶135).

As discussed above, a POSITA would have been motivated to turn to additional references describing the Hemopump for an explicit description of the features of the pump taught by Wampler, including the coupling between the drive cable and the rotor. (Collins ¶135). As shown in annotated FIG. 2 below, in the Hemopump of Wampler '712, rotor 44 is positioned within the housing 30, and connected to drive cable 24 by a screw. (Collins ¶135; EX1008 [Wampler_712] at FIG. 2)

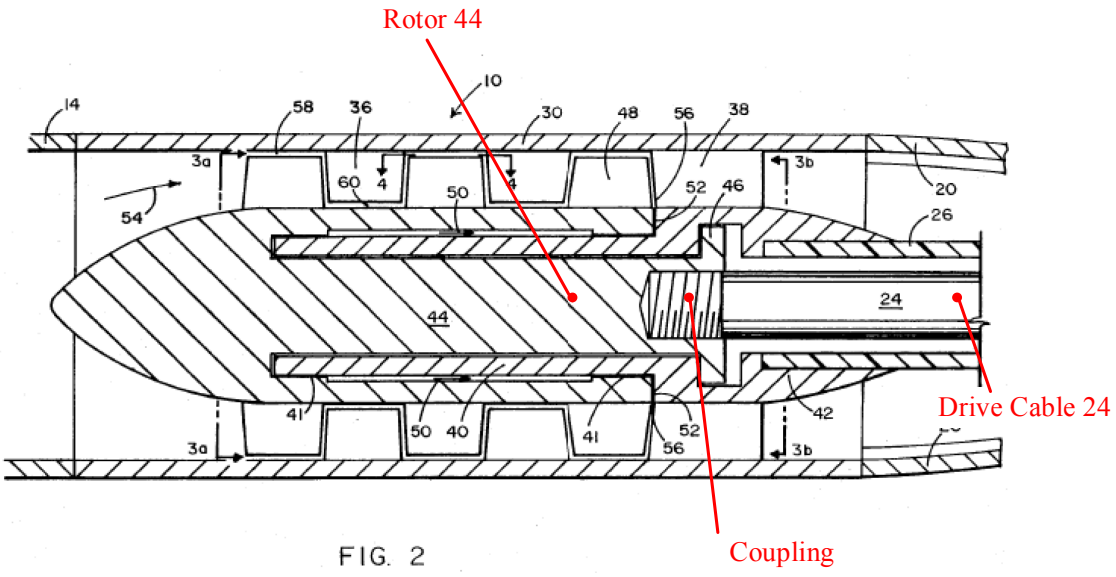


FIG. 2

(Collins ¶135; EX1008 [Wampler_712] at FIG. 2, annotated.)

Accordingly, Wampler alone and alternatively in view of Wampler '712 (another Hemopump reference) discloses a drive cable coupled to said rotor for driving said rotor within said shroud. (Collins ¶136.)

> e) *"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[7].

As discussed above in Section VI.A, the '100 patent discloses three alternative embodiments for carrying out the function: (1) a guide wire passing slideably through a central lumen extending through 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); (2) a guide wire passing slideably through a lumen extending through a guide

[7] 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, the prior art expressly disclose the element under the plain and ordinary meaning.

carriage integrally formed along at least a portion of the cannula sidewall (EX1001 ['100 patent] at 3:3-16, 12:9-23); 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) The Prior Art relied on in this petition discloses the same "guide mechanism" as the "side-rigger" type guide mechanism disclosed in the '100 Patent.

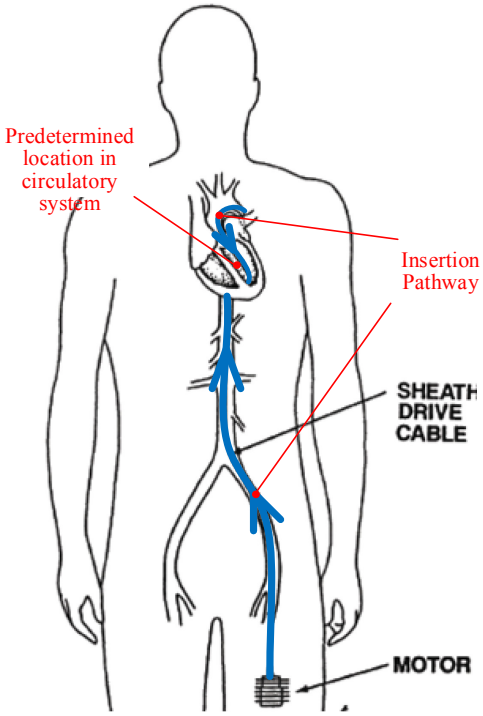
The Hemopump art (Wampler in view of Wampler '712 (pump design) and Jegaden) in view of Yock discloses a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient. (Collins ¶137.)

Wampler explains that the intravascular blood pump, i.e., the Hemopump, can be advanced within the circulatory system of a patient, and that catheter guidance can be used when needed. (Collins ¶138; EX1007 [Wampler] at 236.)

As explained by Dr. Collins, catheter guidance was well known, and insertion of the Hemopump using a guide-wire guide-catheter mechanism was also well-known. (Collins ¶¶139-140; EX1033 [Jegaden] at 61-62; EX1052 [Scholz] at FIGS 5A-B ("monofilament wire is placed through the eyelet of the Hemopump inflow cannula and the pump is passed over the wire into the exchange conduit using a 16 Fr. Shuttle sleeve").) A POSITA dealing with the Hemopump would have been motivated to use established catheter guidance practice and, if needed,

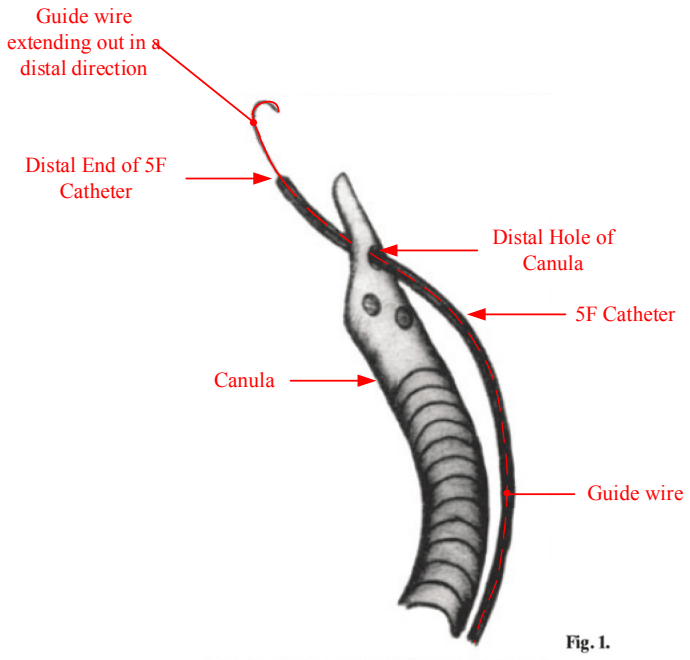
look to other references for catheter guidance of Hemopumps, such as in Jegaden. (Collins ¶140.) Wampler explicitly mentions "three surgical approaches that can be used to insert the Hemopump", and that "the preferred approach is through the femoral artery," which would explicitly motivate a POSITA to use this preferred approach. (Collins ¶140)

Wampler explicitly references and shows (in FIG. 14-1) a left femoral artery approach, and Jegaden recognizes that "the most common method of Hemopump implantation is by the left femoral artery approach." (Collins ¶140; EX1033 [Jegaden] at 61-62) Patent Owner asserts that "nothing in Jegaden teaches or suggests modifying an existing pump design to include a lumen within the cannula" and that "Jegaden teaches that instead of modifying the cannula to accommodate a side lumen, a separate catheter should be used." (Collins ¶168; EX1061 [IPR2017-01201 POPR] at 47-48). However, as discussed above, a POSITA would have found it obvious to apply Jegaden's guide-wire guide mechanism to insert Wampler's Hemopump, at least because Wampler explicitly references insertion through the femoral artery as a preferred approach, and Jegaden discloses how to insert the Hemopump through the femoral artery. (Collins ¶¶141-145; EX1033 [Jegaden] at 61-62)



(Collins ¶140; EX1007 [Wampler] at FIG. 14-1, annotated.)

As shown in annotated FIG. 2 below, in Jegaden the Hemopump is slipped over a guide wire for insertion of the Hemopump and its cannula into the body and to a predetermined location within the circulatory system of a patient. (Collins ¶141-144; EX1033 [Jegaden] at 61-62, FIGS 2-3)



(Collins ¶142; EX1033 [Jegaden] at FIG. 1, annotated.)

Furthermore, while Jegaden discloses a type of side-rigger mechanism to insert the Hemopump, as discussed in Section V.B.2, side-rigger mechanisms were very well-known in the field in general, and thus a POSITA would have found it obvious to apply a side-rigger to the Hemopump. (Collins ¶145; EX1023 [Faxon] at Chapter 18, Chapter 7.) In addition, Yock discloses how to advance an intravascular cardiac assist device to a desired location in the body using a guide catheter and a side rigger. (Collins ¶145; EX1006 [Yock] at 3:56-4:50.) Although Yock relates to a cardiac angioplasty device, a POSITA would have also known that there was much overlap between the fields of angioplasty and intravascular blood pumps, and that catheterization guide wire techniques used in angioplasty were applicable to blood pumps because both types of devices were delivered with

the same goal of placing devices in the vasculature to improve circulatory function by applying treatment to the appropriate location. (Collins ¶146; EX1023 [Faxon] at Chapter 7, Chapter 18.) Indeed, Yock is analogous art to the '100 patent. See supra, Section VII.C.

As discussed above in Section V.B.2, and as shown in Yock, the conventional side-rigger catheter, included an elongate tubular member, i.e. a cannula, and a sleeve (with an interior lumen for the guide wire) secured to the exterior of the tubular member or embedded within the cannula wall itself. (Collins ¶147; EX1006 [Yock] at 7:64-8:2.) FIG. 8B of Yock reproduced and annotated below is an example of an integral sleeve, an embedded sleeve 36 through which guide wire 27 passes. (Collins ¶147). FIG. 10 of Yock, reproduced and annotated below shows another example of a sleeve 66 through which guide wire 68 passes. (Collins ¶147). Yock's sleeves were permanent lumens along the catheter and were thus advantageous to further constrain the guide wire along the length of the cannula in Wampler and would prevent the guide wire from interfering with other elements of Wampler's system during insertion. (Collins ¶¶147-148; EX1006 [Yock] at FIG. 8B).

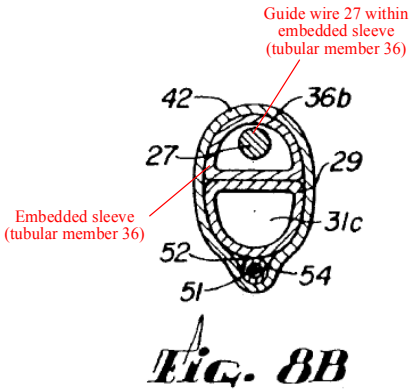


Fig. 8B

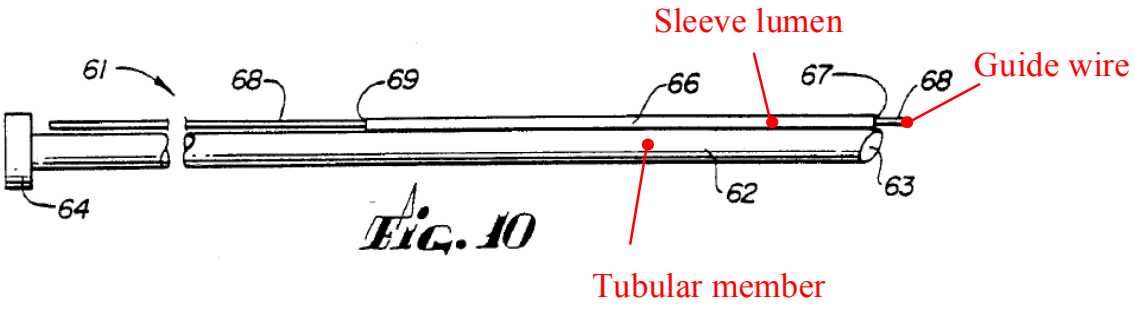


Fig. 10

(Collins ¶147; EX1006 [Yock] at FIG. 8B, annotated and FIG. 10, annotated.)

As explained by Dr. Collins, a POSITA would recognize that Yock's conventional side rigger lumen would have been obvious to apply to the Hemopump, as suggested by Jegaden, to help position the Hemopump in a desired location by guide wire. (Collins ¶147-148).

A POSITA would have thus found it natural, and indeed would have been motivated, to use the well-known elements of Yock, in a known way, to achieve a predictable result - configuring an intravascular device according to these known techniques because they were familiar to cardiologists, to achieve the same result: delivering an intravascular device (e.g., a catheter or other tubular therapeutic

device) to the appropriate place in the vasculature. (Collins ¶146) As explained by Dr. Collins, it would have been obvious, indeed a POSITA would be motivated based on Jegaden's use of the 5F catheter, to use Yock's side rigger guide wire lumen (Yock FIG. 8B or FIG. 10) for guide wire delivery of the Hemopump, as the Yock sleeve would further constrain the guide wire along the length of the cannula in Wampler and would prevent the guide wire from interfering with other elements of Wampler's system during insertion. (Collins ¶¶147-148.)

As explained above, the foregoing is consistent with the same "guide mechanism" as the "side-rigger" type guide mechanism disclosed in the '100 Patent. (EX1001 ['100 patent] at 3:3-16, 12:9-23); Collins ¶149.)

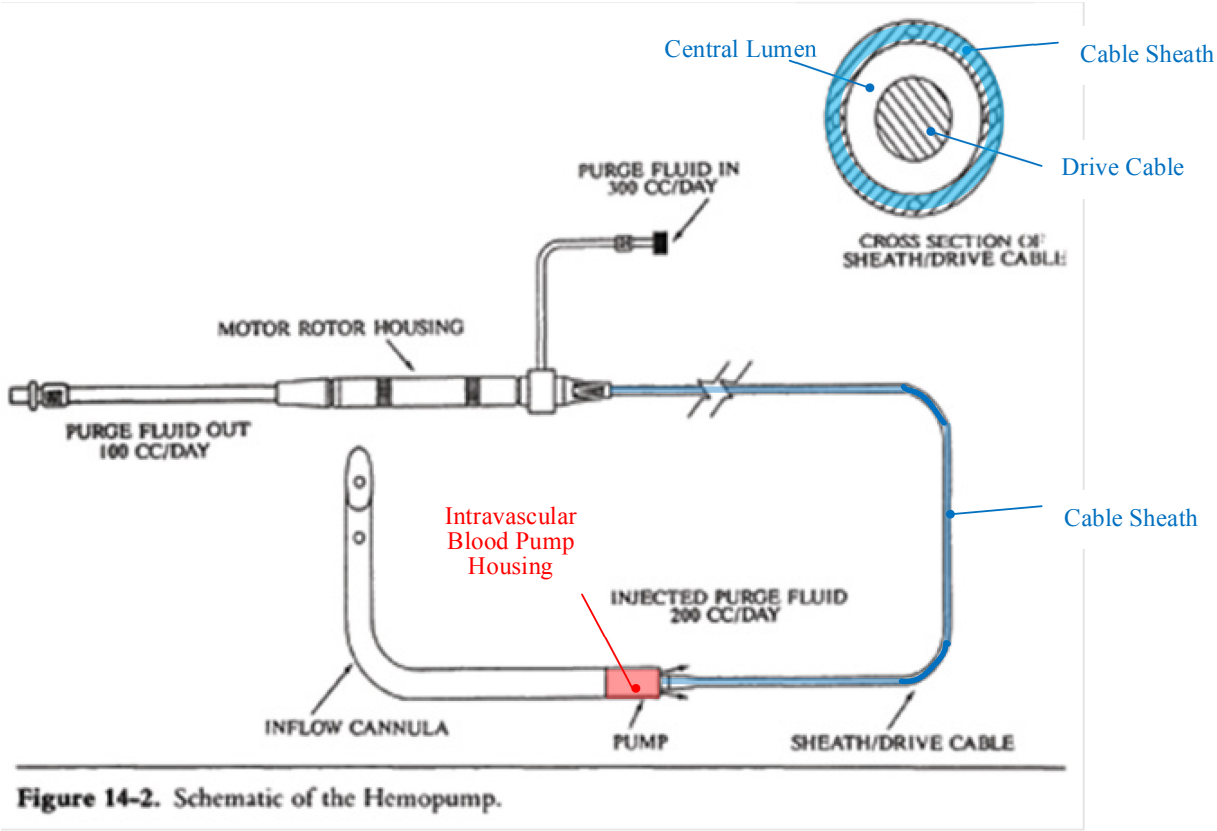
Accordingly, the Hemopump art in view of Yock discloses a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient. (Collins ¶149.)

f) *"wherein a drive cable sheath is provided having a central lumen for receiving said drive cable"*

Wampler discloses a drive cable sheath having a central lumen for receiving said drive cable. (Collins ¶150.)

As discussed above, with respect to claim element 9(b), Wampler discloses a drive cable rotatably driven within a drive cable sheath. (Collins ¶151; EX1007 [Wampler] at FIG. 14-2) Annotated FIG. 14-2 of Wampler shows the drive cable

sheath (blue), and as shown in the cross-section portion of FIG. 14-2, the drive cable is located within the central lumen of the cable sheath (blue). *Id.*



(Collins ¶151; EX1007 [Wampler] at FIG. 14-2, annotated.)

Accordingly, Wampler discloses a drive cable sheath having a central lumen for receiving said drive cable. (Collins ¶152.)

g) *"and wherein a purge fluid delivery system is coupled to said drive cable sheath to deliver purge fluid to said rotor."*

This claim element should be construed under 35 U.S.C. § 112(f). The claim requires "a purge fluid delivery system" coupled to the drive cable sheath,

for delivering purge fluid to said rotor. The underlined language is the claimed function of the purge fluid delivery system[8].

As discussed above in Section VI.A, the '100 patent discloses a purge fluid delivery system that has a fluid inlet conduit for introducing pressurized purge fluid from a fluid source for delivery into the blood pump, where the line splits and a fluid outlet conduit withdraws a return flow of purge fluid through the drive cable sheath to lubricate the drive cable. (EX1001 ['100 patent] at 3:64-4:12, 7:55-66, 10:28-44, 11:23-59). The Prior Art relied on in this petition discloses the same "purge fluid delivery system" disclosed in the '100 patent. (Collins ¶158).

The Hemopump art, including Wampler in view of Wampler '712, discloses a purge fluid delivery system coupled to the drive cable sheath to deliver purge fluid to the rotor. (Collins ¶153.)

As shown in annotated FIG. 14-2 below, the purge fluid delivery system of Wampler takes purge fluid in, injects purge fluid into the blood stream at the

[8] 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, the prior art expressly disclose the element under the plain and ordinary meaning.

pump, and routes purge fluid out. The sheath/drive cable of Wampler is connected at one end to the motor rotor housing and at the other end to a connector (purple) and the purge fluid delivery system. (Collins ¶¶154-155; EX1007 [Wampler] at FIG. 14-2)

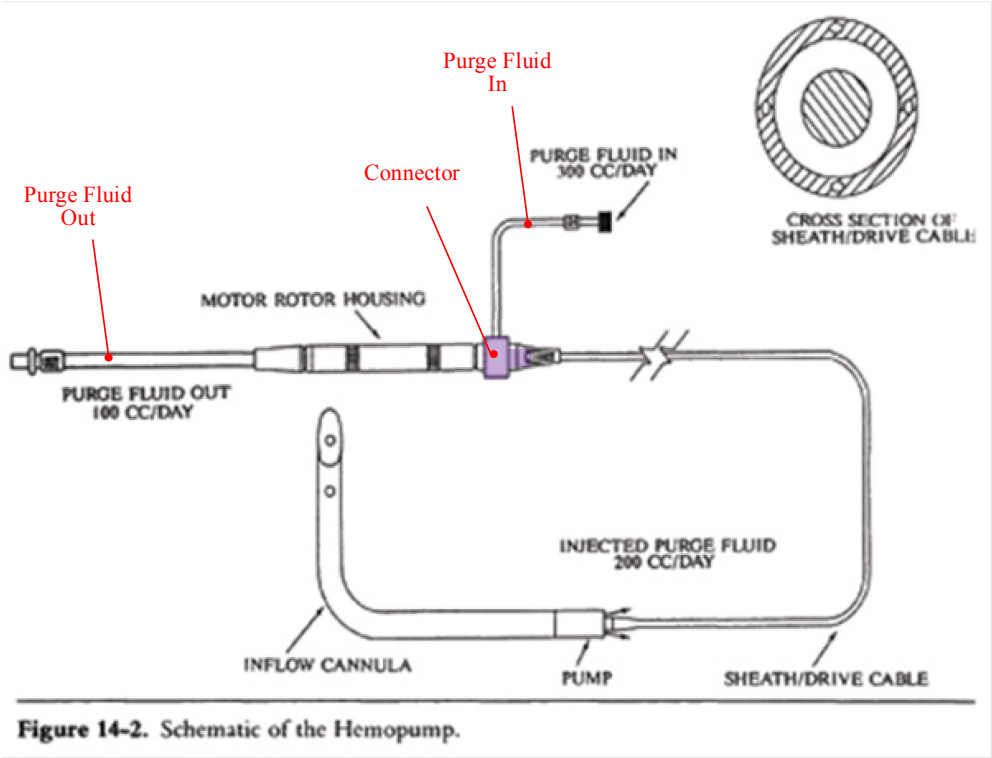


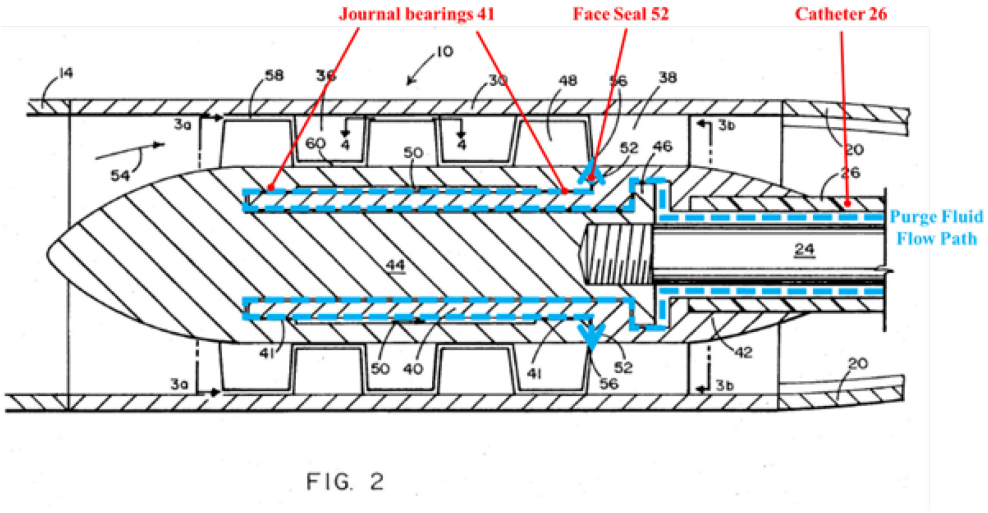
Figure 14-2. Schematic of the Hemopump.

(Collins ¶155; EX1007 [Wampler] at FIG. 14-2, annotated.)

Wampler discloses that purge fluid flows from the purge fluid delivery system to the pump: "about 200 cc/day of the purge fluid flows across the seal into the patient and *prevents blood elements from migrating into the pump*" and that "the remaining 100cc/day of the purge fluid is *drawn away from the pump around the drive cable* and motor magnet to a return bag, flushing cable-generate debris

away from the pump." (Emphasis added). (Collins ¶¶155-156; EX1007 [Wampler] at 234). Accordingly, Wampler inherently discloses delivery of purge fluid to the pump rotor, preventing blood elements from migrating into the pump. (Collins ¶¶155-156).

Alternately, it would have been obvious in view of Wampler '712 to deliver purge fluid to the pump rotor. As indicated by Dr. Collins, a POSITA would readily recognize that because Wampler and Wampler '712 both describe the Hemopump, their described features would be readily combined. (Collins ¶157) For example, a POSITA would be motivated to look to Wampler '712 for additional features of a purge fluid delivery system used with the drive cable sheath to deliver purge fluid to the rotor. (Collins ¶157) As shown in annotated FIG.2 below, Wampler '712 explicitly teaches that the purge fluid is delivered to the rotor: the continuous flow of purge fluid (highlighted in blue) prevents blood elements from contacting the rotor and stator. (Collins ¶¶157-158; EX1008 [Wampler_712] at 3:40-51)



(Collins ¶157; EX1008 [Wampler_712] at FIG. 2, annotated.)

Accordingly, Wampler '712 discloses that the purge fluid delivery system is coupled to the drive cable sheath, and that the purge fluid is delivered to the rotor. (Collins ¶158).

As explained above, this is consistent with the "purge fluid delivery system" disclosed in the '100 patent. (EX1001 ['100 patent] at 3:64-4:12, 7:55-66, 10:28-44, 11:23-59; Collins ¶158).

Thus, Wampler alone or in view of Wampler '712 discloses a purge fluid delivery system coupled to said drive cable sheath to deliver purge fluid to said rotor, as claimed. (Collins ¶159.)

2. Claim 10

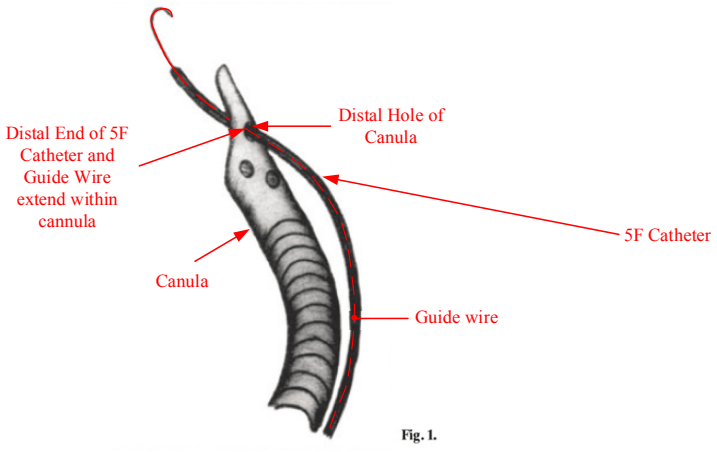
Claim 10 depends from claim 9 and recites "*wherein said guide mechanism comprises a guide element disposed at least partially within said cannula.*"

The Hemopump art (Wampler in view of Wampler '712 (pump design) in view of Jegaden (Hemopump insertion)) in view of Yock teaches a guide mechanism for guiding the Hemopump into a desired location, the guide mechanism comprising a guide element disposed at least partially within the cannula. (Collins ¶160.)

Jegaden teaches using a guide catheter with a guide wire for guiding the Hemopump into a desired location, the guide wire being disposed at least partially within the cannula. (Collins ¶¶161-162.)

As explained above, Wampler suggests using a catheter guide mechanism to help deliver the Hemopump into the vasculature. (Collins ¶161; EX1007 [Wampler] at 233) As explained by Dr. Collins, and as described above for claim 9, a POSITA would be motivated to look for references also related to the Hemopump that provide further details, such as Jegaden, which specifically discloses a Hemopump insertion technique by guidewire. (Collins ¶¶161-162; EX1033 [Jegaden] at FIG. 1). As shown in annotated FIG. 1 below, in Jegaden the 5F guide catheter and guide wire extends at least partially within the cannula: through a distal hole of the cannula and past the distal end of the cannula. *Id.*

Accordingly, Jegaden discloses a guide element disposed at least partially within said cannula as the claim requires.[9]



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

In the alternative, adapting the 5F catheter of Jegaden as an embedded sleeve, such as the sleeve 36 of Yock shown in annotated FIG. 8B above, would

[9] As already established above for claim element 9(e), a POSITA would have found it obvious to apply Jegaden's guide-wire guide mechanism to insert Wampler's Hemopump, at least because Wampler explicitly references insertion through the femoral artery as a preferred approach, and Jegaden discloses how to insert the Hemopump through the femoral artery. (Collins ¶¶141-145; EX1033 [Jegaden] at 61-62).

result in the guide element being disposed at least partially within the cannula of Wampler.[10] (Collins ¶¶163-165).

Thus, the Hemopump art[11] (Wampler in view of Wampler '712 (pump design) and further in view of Jegaden (Hemopump insertion)) in view of Yock discloses that the guide mechanism comprises a guide element disposed at least partially within said cannula. (*Id.* ¶¶163-165.)

3. Claim 11

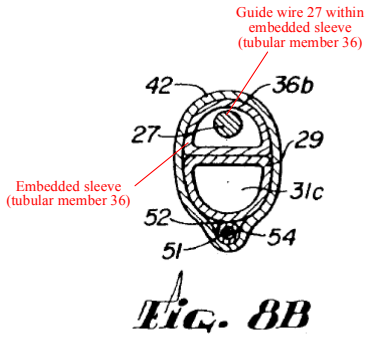
Claim 11 depends from claim 10 and recites "*wherein said guide element comprises a guide wire for passage through a side lumen formed in said cannula.*"

The Hemopump art, Wampler in view of Wampler '712 (pump design) in view of Jegaden (Hemopump insertion), and further in view of Yock discloses this claim element. (Collins ¶166.)

[10] As already established above with respect to claim 9(e) based on Jegaden's use of the 5F catheter, a POSITA would have been motivated to use Yock's side rigger guide wire lumen (Yock FIG. 8B or FIG. 10) for guide wire delivery of the Hemopump (Collins ¶¶162-163, 172, 174; EX1006 [Yock] at Abstract and 7:64-8:2; see supra, Section X(A)(1)(e)).

[11] Petitioner addressed the combination of the Hemopump art including Wampler '712 (pump design) for claim 9 to which claim 10 depends.

FIG. 8B of Yock reproduced and annotated below is an example of an integral sleeve, an embedded sleeve 36 through which guide wire 27 passes. As explained by Dr. Collins, a POSITA looking to Jegaden would eliminate the 5F catheter, instead using the side lumen of Yock along the side of the Hemopump cannula of Wampler, such that the wire extends directly through the lumen without the guide catheter. (Collins ¶¶167-171; EX1006 [Yock] at 7:67-8:2). Tubular member 36 of Yock, as shown in Yock FIG. 8B would replace the 5F catheter of Jegaden for use along the side of the Hemopump cannula of Wampler. (Collins ¶¶171-172).



(Collins ¶171; EX1006 [Yock] at FIG. 8B, annotated.)

Thus, the Hemopump art[12], Wampler in view of Wampler '712 (pump design) in view of Jegaden (Hemopump insertion), and further in view of Yock

[12] Petitioner addressed the combination of the Hemopump art including Wampler '712 (pump design) for claim 9 to which claim 10 depends.

discloses that the guide element comprises a guide wire for passage through a side lumen formed in the cannula. (Id. ¶173.)

4. Claim 12

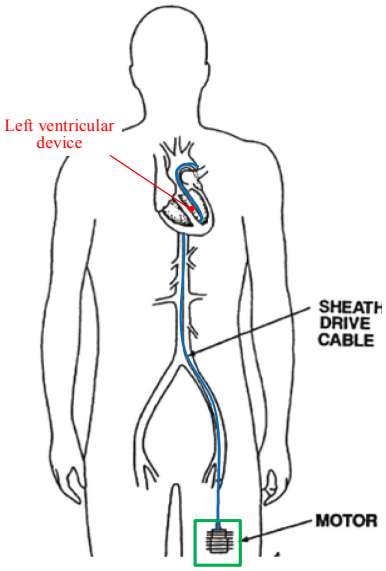
Claim 12 depends from claim 11 and recites "*wherein said intravascular blood pump and cannula may be selectively advanced to said predetermined location with the vasculature of the patient by first passing said guide wire to said predetermined location and thereafter sliding said intravascular blood pump and cannula along said guide wire to said predetermined location.*"

The Hemopump art, Wampler in view of Wampler '712 (pump design) in view of Jegaden (Hemopump insertion), and further in view of Yock discloses this claim element. (Collins ¶174-176.)

As discussed above with respect to claims 9 and 10, a POSITA would be motivated to look to Jegaden for implementation information regarding Hemopump insertion techniques. (Collins ¶174).

As indicated by Dr. Collins, a POSITA would have found it obvious to apply Jegaden's guide catheter and guide wire approach, alone or modified to include a side lumen instead of the guide catheter, to insert Wampler's pump into the vasculature, at least because Jegaden is explicitly concerned with the insertion of the Hemopump itself ("the most common method of Hemopump implantation is by the left femoral artery approach."), using the same left femoral insertion

technique as shown in Wampler FIG. 14-1 below, and with the routine adaptation of the Yock side rigger. (Collins ¶¶175-176; EX1007 [Wampler] FIG. 14-1; EX1033 [Jegaden] at 61-62)



(Collins ¶175; EX1007 [Wampler] at FIG. 14-1, annotated.)

Thus, Jegaden discloses the guide mechanism comprising the intravascular blood pump and cannula being selectively advanced to a predetermined location with the vasculature of the patient by first passing said guide wire to said predetermined location, then introducing the cannula into the femoral artery. (Collins ¶176.)

Accordingly, the Hemopump art discloses this claim element. (Collins ¶¶174-176.)

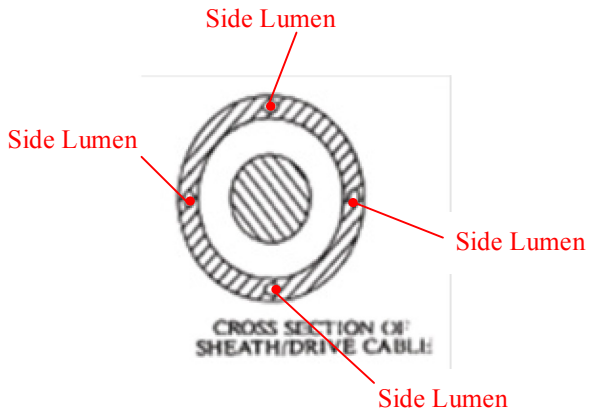
5. Claim 14

Claim 14 depends from claim 9 and recites "*wherein said drive cable sheath includes at least one side lumen for delivering said purge fluid towards said rotor.*"

Wampler discloses this claim element. (Collins ¶¶177-182.)

As discussed above with respect to claim limitation 9(g), Wampler discloses a purge fluid delivery system coupled to the drive cable sheath to deliver purge fluid to the rotor. (Collins ¶¶177-178)

The drive cable sheath of Wampler includes four side lumens for purge fluid, shown in truncated and annotated FIG. 14-2 below. (Collins ¶179). These "four outer lumens in the sheath" convey "approximately 300cc/day of D40W … through purge tubing toward the pump." (Collins ¶179-180 EX1007 [Wampler] at 234.)



(Collins ¶179; EX1007 [Wampler] at FIG. 14-2, annotated.)

Thus, Wampler discloses the drive cable sheath including at least one side lumen for delivering said purge fluid towards said rotor. (Collins ¶181.)

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

Institution of this Petition is proper under Section 325(d) notwithstanding the pending IPR2017-01025 (the "'01025 Proceeding") - Claims 9-12 and 14 were not previously challenged in the '01025 Proceeding.

XII. CONCLUSION

Based on the foregoing, claims 9-12 and 14 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	[RESERVED]
1016	[RESERVED]
1017	[RESERVED]
1018	[RESERVED]
1019	[RESERVED]
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	[RESERVED]
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	[RESERVED]
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	[RESERVED]
1031	[RESERVED]
1032	[RESERVED]
1033	O. Jegaden, "Clinical results of Hemopump support in surgical cases," 1991. ("Jegaden")
1034	[RESERVED]
1035	[RESERVED]
1036	[RESERVED]
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	[RESERVED]
1041	Library of Congress, Catalog Record of *Textbook of Medical Physiology* by Arthur C. Guyton and John E. Hall, 9th Edition (1996)
1042	[RESERVED]
1043	[RESERVED]
1044	[RESERVED]
1045	DE19821307
1046	Colombo, Selection of Coronary Stents, Journal of the American College of Cardiology, 2002. ("Colombo")
1047	[RESERVED]
1048	[RESERVED]
1049	U.S. Patent No. 5,061,256 ("Wampler '256)
1050	D. Loisance et al., Prophylactic Intraventricular Pumping in High-Risk

	Coronary Angioplasty, The Lancet (Feb 24, 1990) "Loisance")
1051	R. Wampler et al., The Sternotomy Hemopump: A Second Generational Intraarterial Ventricular Assist Device, Wolters Kluwer (Jul.-Sep. 1993) ("Wampler ASAIO")
1052	K. Scholz et al., Mechanical Left Ventricular Unloading During High Risk Coronary Angioplasty: First Use of a New Percutaneous Transvalvular Left Ventricular Assist Device, Wiley-Liss, Inc (1994) ("Scholz")
1053	S. Seldinger, Catheter Replacement of the Needle in Percutaneous Arteriography, Sage Publications (May 1953);
1054	Hemopump®: Temporary Cardiac Assist System, Nimbus Medical, Inc. (1988) ("Hemopump Manual")
1055	[RESERVED]
1056	IPR2017-01025 POPR
1057	[RESERVED]
1058	[RESERVED]
1059	U.S. Patent No. 4,944,722 ("Carriker")
1060	Leupold Declaration
1061	IPR2017-01201 POPR
1062	Certified translation of DE19821307 ("Sammler")

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 8,845, 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 (EX1001-1062)
- Exhibits 1001-1062
- Power of Attorney

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

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

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

__/s/ *Daniel Shults*
Daniel Shults