

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00116
U.S. Patent No. 11,754,077

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,754,077**

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,754,077
1002	U.S. Patent No. 11,754,077 File History
1003	Declaration of Peter Crosby
1004	CV of Peter Crosby
1005	U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled “ <i>Rotary Pump Comprising a Hydraulically Mounted Motor</i> ”
1006	Akamatsu et al., <i>Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump</i> , J Artif Organs 1999, Vol. 2, pp. 3-7
1007	Bourque et al., <i>HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor</i> , ASAIO Journal 2001
1008	U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled “ <i>Sealless rotary blood pump</i> ”
1009	Miracor’s Supplemental Initial Response to Invalidity Contentions, dated September 20, 2024
1010	Frazier et al. <i>Total Heart Replacement with Dual Centrifugal Ventricular Assist Devices</i> , ASAIO Journal 2005
1011	Schob, <i>Centrifugal pump without bearings or seals</i> , World Pumps Vol. 2002, No. 430, pp. 34-37
1012	Rose et al., <i>Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure</i> , N Engl J Med. 2001 Nov 15, Vol. 345, No. 20, pp. 1435-43
1013	HeartMate® II LVAS: Patient Management Guidelines, December 14, 2006
1014	Schulman et al., <i>Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices</i> , The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842

1015	LaRose et al., <i>Heartware – A novel miniaturized passive maglev centrifugal VAD</i> , ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137
1016	Qian et al., <i>Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump</i> , Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38
1017	Akamatsu et al., <i>Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump</i> , Artificial Organs 1997, Vol. 21, No. 7, pp. 645-638
1018	U.S. Patent No. 6,050,975
1019	Exhibit 13 of Complaint, dated November 27, 2023
1020	Bottone et al., <i>Magnetos for automobilists, how made and how used</i> , Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up)
1021	“Ignition magneto,” accessed via https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024)
1022	Masuzawa et al. <i>Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor</i> , Artificial Organs 2003, Vol. 27, No. 7, pp. 631-638
1023	U.S. Patent No. 6,152,704
1024	U.S. Patent No. 6,589,030
1025	European Patent No. 0 834 326
1026	Miracor’s Response to Exhibit F-1 (Bourque-2001) of Supplemental Invalidity Contentions, dated September 20, 2024
1027	U.S. Patent No. 5,324,177
1028	Allaire, et al., <i>Prototype Continuous Flow Ventricular Assist Device</i> , J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690
1029	Kung and Hart, <i>Design Considerations for Bearingless Rotary Pumps</i> , J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis

CLAIM INDEX

Element	Claim language
[1PRE]	A system for assisting the blood circulation of a heart, comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart;
[1B]	a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle,
[1C]	the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor
[1D]	[the rotor] having guide surfaces to produce centrifugal flow components
[1E]	the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor
[1F]	while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;
[1G]	a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device
[1H]	while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly,
[1I]	the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor;
[1K]	a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the

	surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly
[1L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and
[1M]	an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,
[2]	The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.
[3]	The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.
[4]	The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.
[5]	The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.
[7]	The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[10]	The system of claim 1, wherein the heart assist pump device is a catheter device.
[16PRE]	A system for assisting blood circulation of a heart, the system comprising:

[16A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[16B]	chamber walls at least partially defining a chamber to receive blood from the inflow tube;
[16C]	a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device
[16D]	that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor
[16E]	[the rotor] having guide surfaces to produce centrifugal flow components,
[16F]	the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation
[16G]	[the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;
[16H]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[16I]	and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,
[16J]	the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and
[16K]	a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,
[16L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically

	driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and
[16M]	an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output
[16N]	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.
[17]	The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.
[18]	The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.
[19]	The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.
[20]	The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.
[21]	The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.
[22]	The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[23]	The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.
[24]	The system of claim 16, wherein the first magnetic device comprises a permanent magnet.

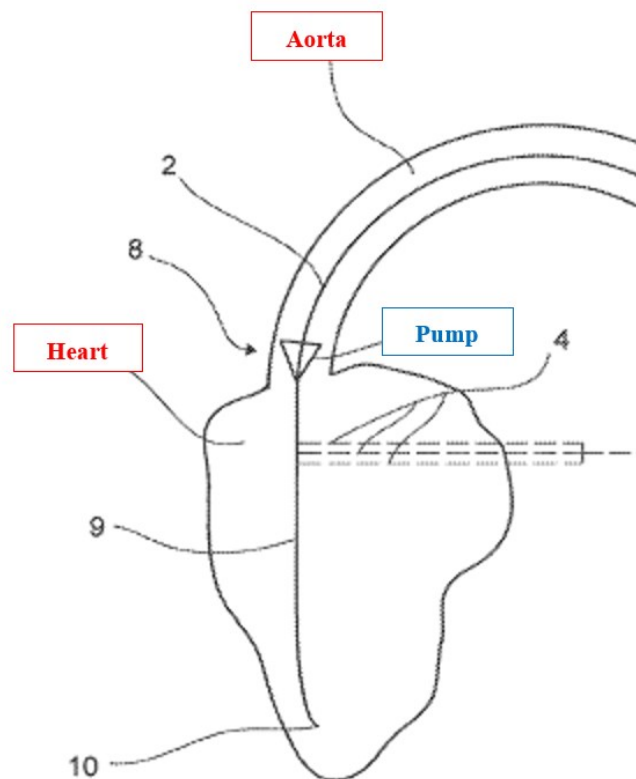
[26]	The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[28]	The system of claim 16, wherein the heart assist pump device is a catheter device.

I. INTRODUCTION

Abbott Laboratories (“Petitioner”) petitions for *Inter Partes* Review and cancellation of claims 1-5, 7, 10, 16-24, 26, and 28 (“the Challenged Claims”) of U.S. Patent No. 11,754,077, (the “077 Patent” (Ex. 1001)), assigned to Patent Owner, Miracor Medical SA (“Miracor” or “PO”).

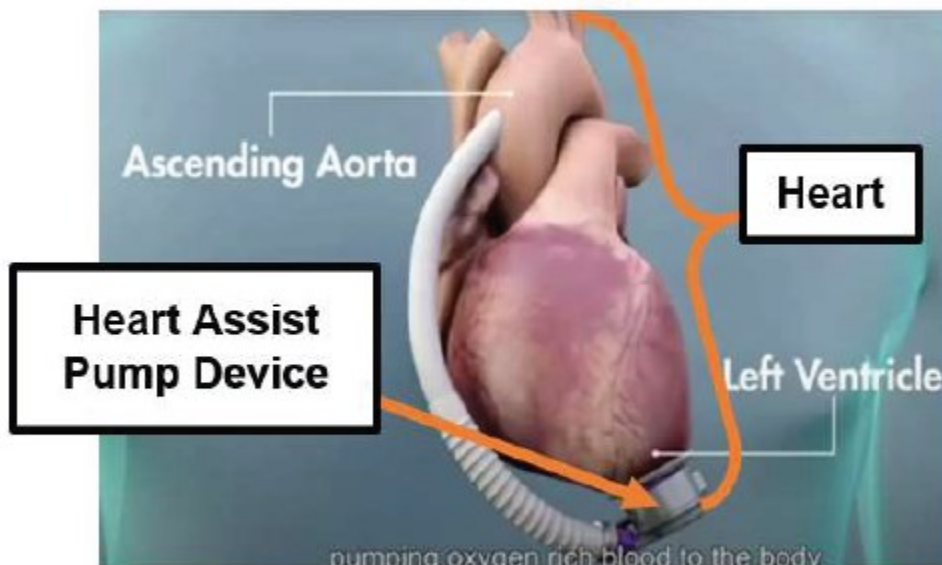
II. SUMMARY OF THE ARGUMENT

The 077 Patent discloses an “intravasal” “catheter” blood pump placed **inside** a blood vessel like the aorta:



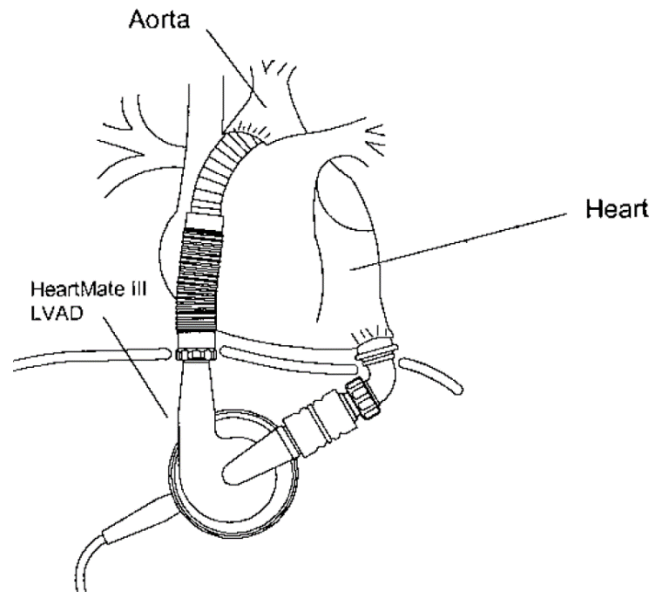
Ex.1001, Fig 1 (annotated), Ex.1001, 2:19-62 (“according to the invention...a heart ventricle catheter” “formed as an intravascular rotary pump...arranged inside the catheter”).

In co-pending litigation, PO accuses Abbott’s HeartMate 3 Left Ventricular Assist Device (“LVAD”) placed **outside** the heart, not an intravascular or a catheter device:



Ex.1019, 3.

PO filed the 077 Patent in 2023—five years after Abbott commercialized HeartMate 3—claiming priority to a 2007 application. Abbott disclosed centrifugal LVAD designs as early as 2001:



Ex.1007, Fig. 3 (annotated).

Ex.1007's magnetically levitated rotor eliminated mechanical bearings thought to cause clots. By 2007, similar centrifugal LVADs were in development. Ex.1006; Ex.1008. All employed magnetic rotors using different types of drive (e.g., magneto coupling and/or stators) and suspension (e.g., magnetic and/or hydrodynamic bearings). PO conflates which drive and suspension the 077 Patent claims, but all are disclosed by the references relied on herein.

III. MANDATORY NOTICES

A. Real Party-in-Interest

The real parties-in-interest for this Petition are Abbott Laboratories and Thoratec LLC.

B. Related Matters

Office Proceedings

Petitioner has already filed a petition for *inter partes* review against related U.S. Patent Nos. 11,351,356. *See* IPR2025-00096.

Petitioner will also be concurrently filing petitions for *inter partes* review against related U.S. Patent Nos. 11,351,357; 11,376,415; 11,674,517; and 11,572,879. *See* IPR2025-00112 – IPR2025-00115.

Litigation matters.

The 077 Patent is asserted by PO in the following matter:

- *Miracor Medical SA v. Abbott Laboratories and Thoratec LLC*, 1:23-cv-16257 (N.D. Ill. filed Nov. 27, 2023) (“Parallel Litigation”)

Continuity:

According to Patent Office records, the 077 Patent is a continuation of and claims priority to U.S. application Ser. No. 18/087,083 filed on Dec. 22, 2022, which is a continuation of and claims priority to U.S. application Ser. No. 17/446,046 filed on Aug. 26, 2021 (now U.S. Pat. No. 11,572,879), which is a continuation of U.S. application Ser. No. 16/282,948 filed on Feb. 22, 2019 (now U.S. Pat. No. 11,123,540), which is a continuation of U.S. application Ser. No. 14/454,965 filed on Aug. 8, 2014 (now U.S. Pat. No. 10,251,984), which is a continuation of U.S. application Ser. No. 13/555,318 filed on Jul. 23, 2012 (now U.S. Pat. No. 8,801,590), which is a divisional of U.S. application Ser. No. 12/449,632 filed on Aug. 18, 2009 (now U.S. Pat. No. 8,255,050), which is the U.S. national phase of International

Application PCT/IB2008/000421 filed on Feb. 27, 2008, which designated the U.S. and claims benefit of AT A 306/2007 filed Feb. 27, 2007.

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Petitioner consents to electronic service by email to the addresses listed above.

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing

Petitioner certifies that the 077 Patent is available for IPR and Petitioner is not barred or estopped from requesting this IPR on the grounds identified herein.

B. Challenged Claims

Ground	35 U.S.C.	Claims	Reference(s)
1	§103	1-5, 7, 10, 16-24, 26, and 28	Wampler-169 (Ex.1008)
2	§103		Bourque-2001 (Ex.1007) and Wampler-169 (Ex.1008)
3	§103		Akamatsu-1999 (Ex.1006)
4	§103		Schima (Ex.1005) and Akamatsu-1999 (Ex.1006)

V. THE 077 PATENT**A. Effective Filing Date**

Petitioner assumes for the purposes of this Petition a **February 27, 2007** effective filing date.

B. Person of Ordinary Skill in the Art

A Person of Ordinary Skill in The Art (“POSITA”) as of February 27, 2007, would have at least a bachelor’s degree in engineering; knowledge and experience in human circulatory system anatomy and physiology; and at least five years’ experience designing and developing implantable medical devices. Ex.1003, ¶18.

C. The 077 Patent

The 077 Patent concedes **the claimed pump design was known in the prior art:**

The rotor itself can follow design principles such as described for example in WO01/70300A1 [i.e., Schima].

Ex.1001, 2:29-30.

VI. CLAIM CONSTRUCTION

PO's apparent Parallel Litigation constructions differ from the plain and ordinary meanings in the context of the 077 Patent. Because a POSITA would find the Challenged Claims unpatentable under any interpretation, the Board need not construe the claim terms.

A. Magneto Coupling

“*[M]agneto coupling*” refers to a specific way to drive a pump's rotor, referred by the 077 Patent as a coupling between two rotating “bar magnets”—a drive wheel rotates one bar magnet, causing another bar magnet (connected to a rotor) to rotate. Ex.1003, ¶¶54-55 (analyzing Ex.1001, 2:60-62, 3:50-4:3, Fig.2). Contemporaneous art distinguished “*magneto coupling*” drives from another drive-type using stators—“[i]n both cases the torque is transmitted...onto the rotor by means of a rotating magnetic field. **In the magnetic coupling pump the rotating field is generated by rotating magnets**, in the [stator] pump, by electric stator windings.” Ex.1011, 1; Ex.1003, §VII.A.1 (analyzing “*magneto coupling*” described in Ex.1001, Ex.1011, Ex.1016, Ex.1022, Ex.1023, Ex.1024, Ex.1025). Thus, its plain meaning would be understood to be “a transfer of torque from one rotating permanent magnetic

component to another rotating permanent magnetic component via a magnetic field.”

Ex.1003, §VII.A.1.

PO conflates “*magneto coupling*” in Parallel Litigation with a stator drive using a **stationary electromagnet**, instead of a **rotating magnet**, to rotate the rotor magnet, and further alleges that a “stator” (a stationary element) achieves magneto coupling with a rotor. Ex.1019, 9-12; Ex.1003, ¶¶84-87.

B. By a gap sized for passage of the blood

Pump rotors can be suspended in at least two different ways—using hydrodynamic or magnetic bearings. Ex.1003, ¶¶57-60. The 077 Patent explains that its rotor suspension results from “[t]he rotor produc[ing] flow...directed against the housing” causing “non-contact...of the rotor in the housing.” Ex.1003, ¶92. The contemporaneous art referred to that type of suspension—which rotation produces a “fluid film”—as a “hydrodynamic bearing,” differentiating it from a “magnetic bearing” using “magnetic polarizations and repulsive forces.” Ex.1008, [0054], [0089]-[0092]; Ex.1003, ¶59.¹ A POSITA would have understood the phrase—“*by a*

¹ Even PO’s complaint distinguishes between the two. Ex.1019, 10 (showing the magnetic bearing in Abbott’s HeartMate 3 (left) versus a hydrodynamic bearing in another pump (right)).

gap sized for passage of the blood”—refers to a “hydrodynamic bearing.” Ex.1003, §VII.A.2 (analyzing definition of hydrodynamic bearing described in Ex.1001, Ex.1005, Ex.1016).

PO’s Parallel Litigation interpretation renders the claim language—*by a gap sized for passage of the blood*—meaningless by encompassing magnetic bearings. Ex.1003, ¶95 (analyzing Ex.1019, 7-8).

VII. PRIOR ART

The references disclose a centrifugal LVAD with a magnetically driven rotor, but these LVADs differ in how they (1) drive rotation (magnetic coupling drive or electromagnetic drive), and (2) suspend the rotor (hydrodynamic bearing or magnetic bearing):

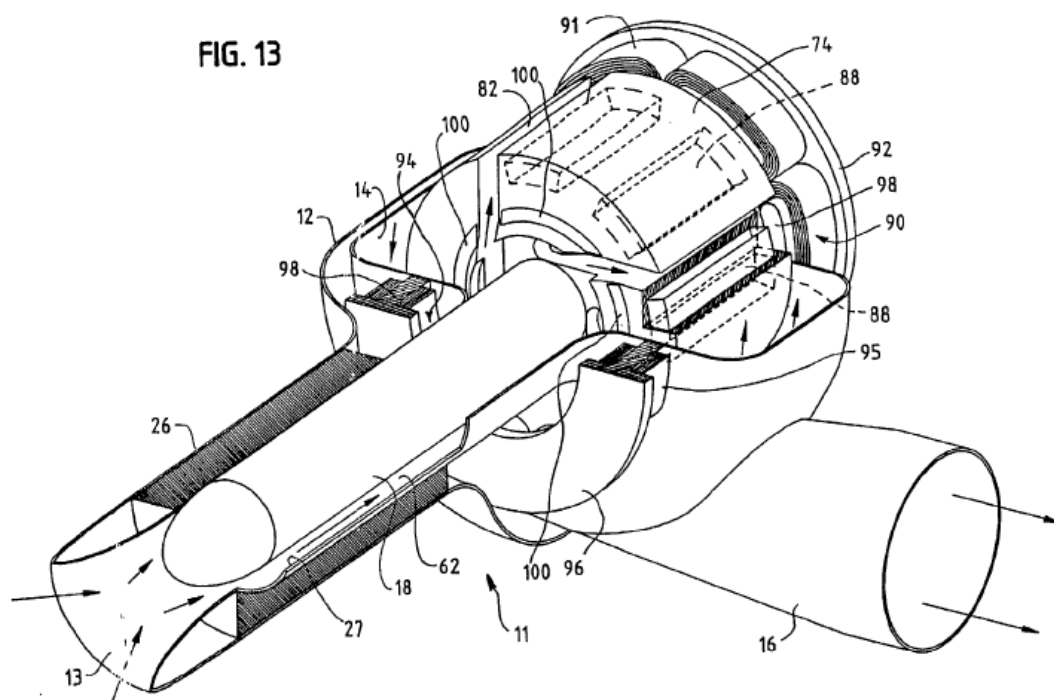
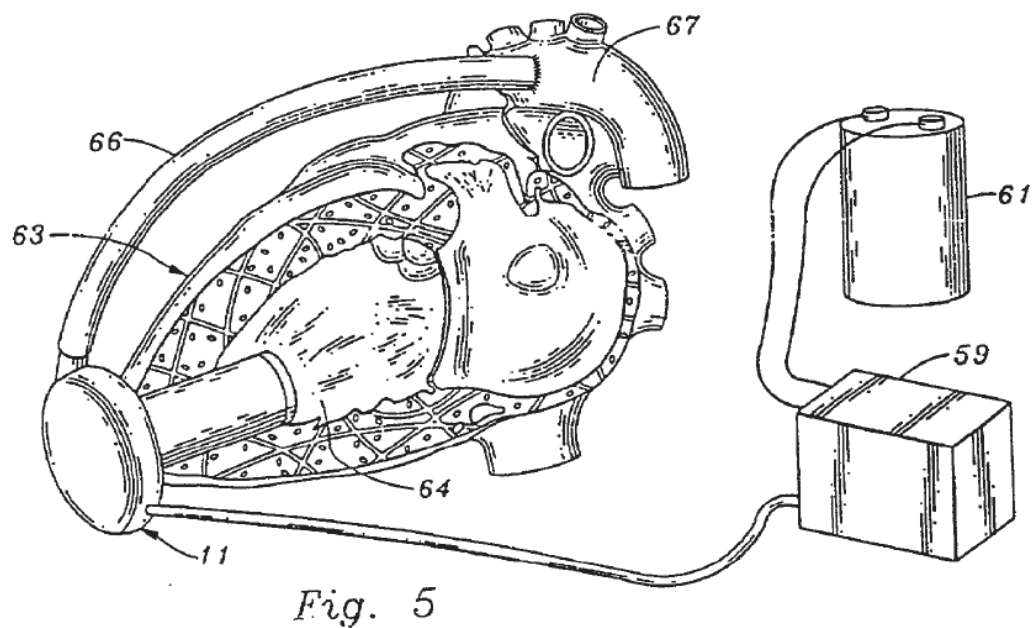
LVADs		Drive-type	
		Magneto coupling	Electromagnetic
Bearing-type	Hydrodynamic	<u>Schima</u>	<u>Wampler-169</u>
	Magnetic	<u>Akamatsu-1999</u>	<u>Bourque-2001</u>

Ex.1003, Ex.1003, ¶¶146-148.

A. Wampler-169

U.S. Pub. No. 2002/0102169A1 (“Wampler-169”), published **August 1, 2002**, is prior art to the 077 Patent at least under 35 U.S.C. §102(b).

The Wampler-169 pump is shown below:



Ex.1008, Fig. 5, 13.

B. Bourque-2001

Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD* (“Bourque-2001”), published in the **July 2001** issue of the ASAIO Journal. Boruque-2001 was a publicly accessible printed publication because it was printed and persons interested and ordinarily skilled in the art, exercising reasonable diligence, could have located it before the effective filing date of the 077 Patent. Ex.1030, ¶¶45-52 (explaining how the reference was found and indexed in the National Library of Medicine (among other places), including a description of how it could be located through its classification by interested members of the public); Ex.1003, ¶114 (Bourque-2001 cited 29 times before the effective filing date). Bourque-2001 is prior art to the 077 Patent at least under 35 U.S.C. §102(b).

The “HeartMate III” disclosed in Bourque-2001 is shown below:

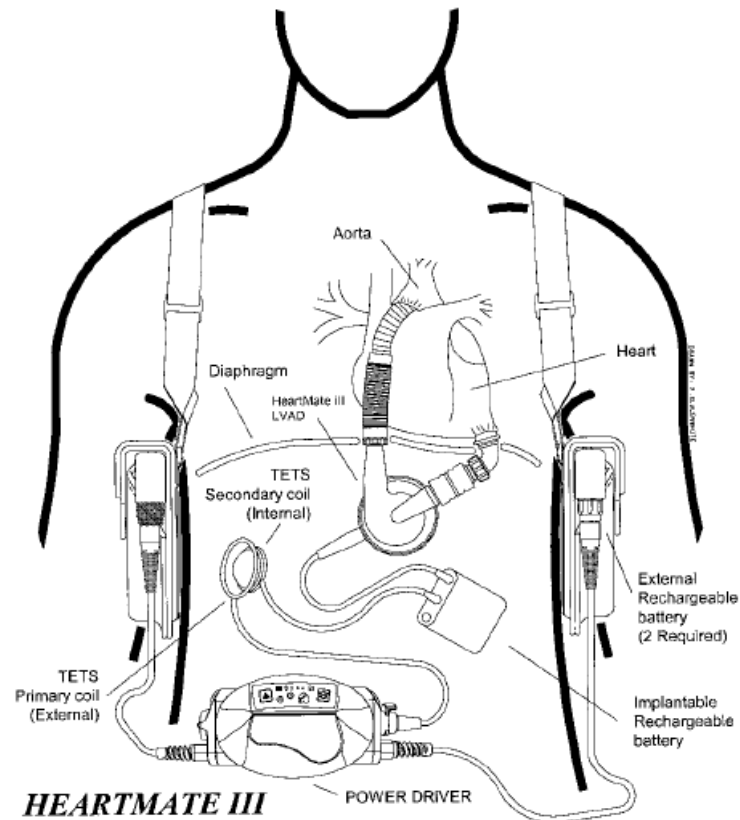


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3, 403; Ex.1003, ¶119.

C. Akamatsu-1999

Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS)* (“Akamatsu-1999”), was published in the **March 1999** issue of the Japanese Society for Artificial Internal Organs Journal. Further, Akamatsu-1999 was a publicly accessible printed publication because it was printed and persons interested and ordinarily skilled in the art, exercising reasonable diligence, could have located it before the effective filing date of the 077 Patent. Ex.1030, ¶¶53-60 (explaining how the reference was found and indexed in the National Library of

Medicine (among other places), including a description of how it could be located through its classification by interested members of the public); Ex.1003, ¶131 (Akamatsu-1999 cited 5 times before the effective filing date). Akamatsu-1999 is prior art to the 077 Patent at least under 35 U.S.C. §102(b).

The Akamatsu-1999 pump is shown below:

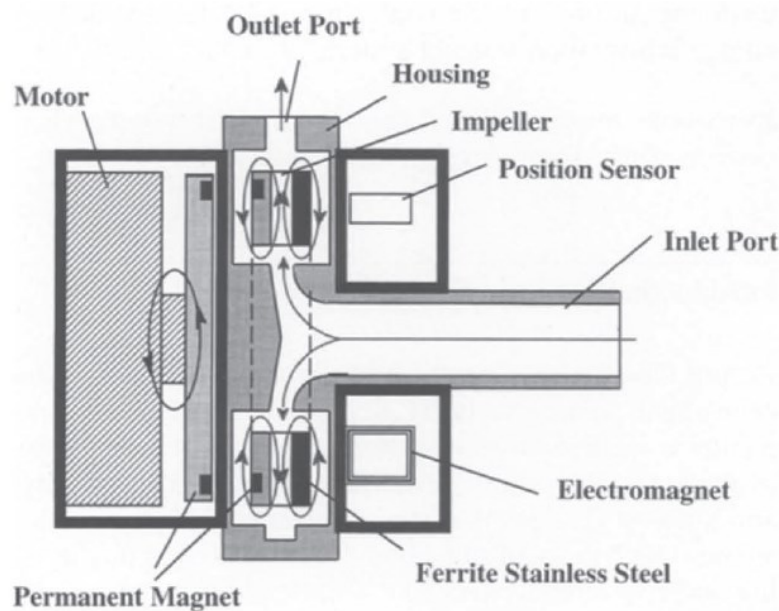


Fig. 2. Schematic cross section of the MSCP

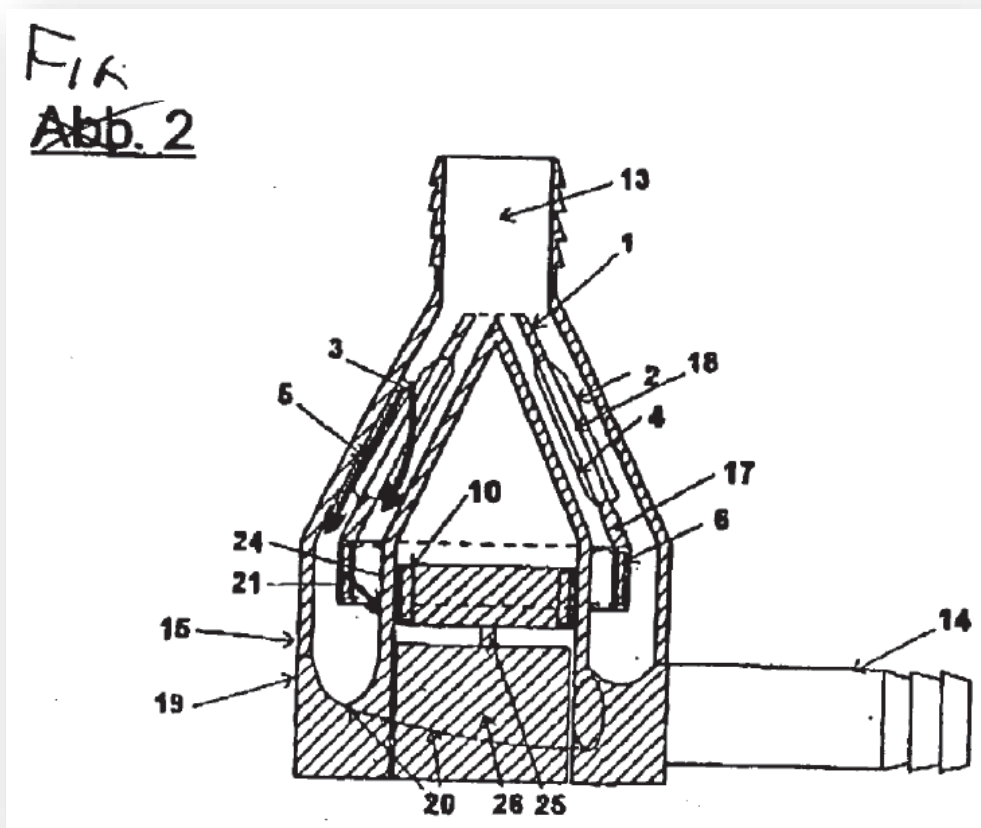
Ex.1006, Fig. 2; *see also* Ex.1003, ¶¶133-134.

D. Schima²

U.S. Pub. No. 2003/0124007A1 (“Schima”), published **July 3, 2003**, is prior art to the 077 Patent at least under 35 U.S.C. §102(b).

The Schima pump is shown below:

² In Parallel Litigation, PO argues that “WO01/70300A1” (Schima) provides §112 support for the claims. Ex.1009, 5, 7 (arguing the 077 Patent’s reference to WO 01/70300 A1 shows “possession of the full scope” “without undue experimentation”). If Schima provides §112 support for the claims, it renders them obvious because Schima is prior art.



Ex.1005, Fig. 2; Ex.1003, ¶¶137-145.

VIII. CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Wampler-169 Renders Obvious the Challenged Claims

1. Claim 1

i. [1PRE]³

Wampler-169 discloses “implantation in humans” of “a left ventricular assist device (‘LVAD’)” “blood pump” “for chronic use” in patients with “heart failure” who “could benefit from cardiac transplantation,” but cannot receive a “donor heart.” Ex.1008, [0002]-[0003]. Ex.1003, ¶150.

Accordingly, Wampler-169 discloses “a system for assisting the blood circulation of a **heart** (‘LVAD’ for ‘heart failure’).” Ex.1003, ¶151; *see also* Ex.1008, Fig. 13 (illustrating the blood pump).⁴

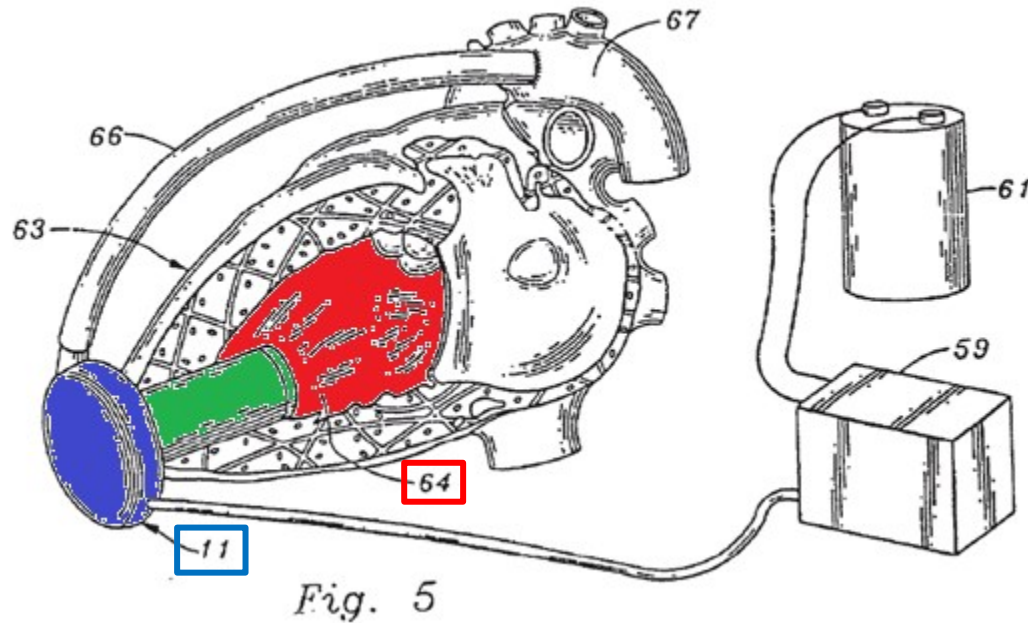
ii. [1A]

Wampler-169 discloses that “**pump 11**” (“a heart assist pump device”) is “implanted” so that “**inlet tube [13] serves as the inflow cannula** and is placed into the apex of the **left ventricle 64**” (“an inflow tube... insertable into a ventricle”) while the remainder of the “compact and disc-shaped [pump] fit[s] well between the

³ The claims of the 077 Patent are included in the Claim Index, *infra* pp. ix-xi.

⁴ “[B]lood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGS. 1-8.” Ex.1008, [80].

apex of the heart and the adjacent diaphragm” (“*deliverable to the heart*”) (Ex.1008, [0074]-[0076]), as shown:



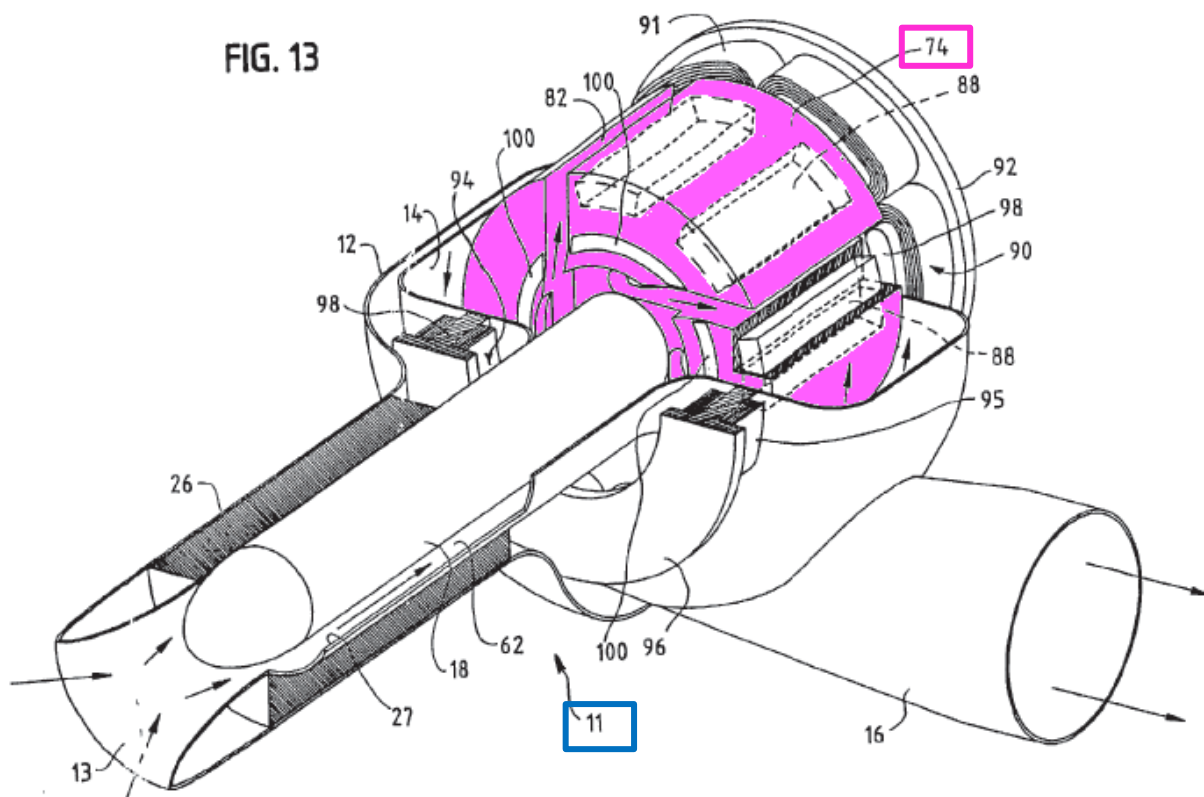
Ex.1008, Fig. 5 (annotated)⁵; *see also* Fig 13 (showing blood *suction* through inlet tube, Ex.1003, ¶155); Ex.1003, ¶154.

Accordingly, Wampler-169 discloses “*a heart assist pump device* (“pump 11”) *deliverable to the heart* and comprising: an *inflow tube defining a blood inflow path* (“inlet tube 13”) and having a suction end insertable into *a ventricle of the heart* (“placed into the apex of the left ventricle 64”). Ex.1003, ¶157.

⁵ All figures annotated unless otherwise specified.

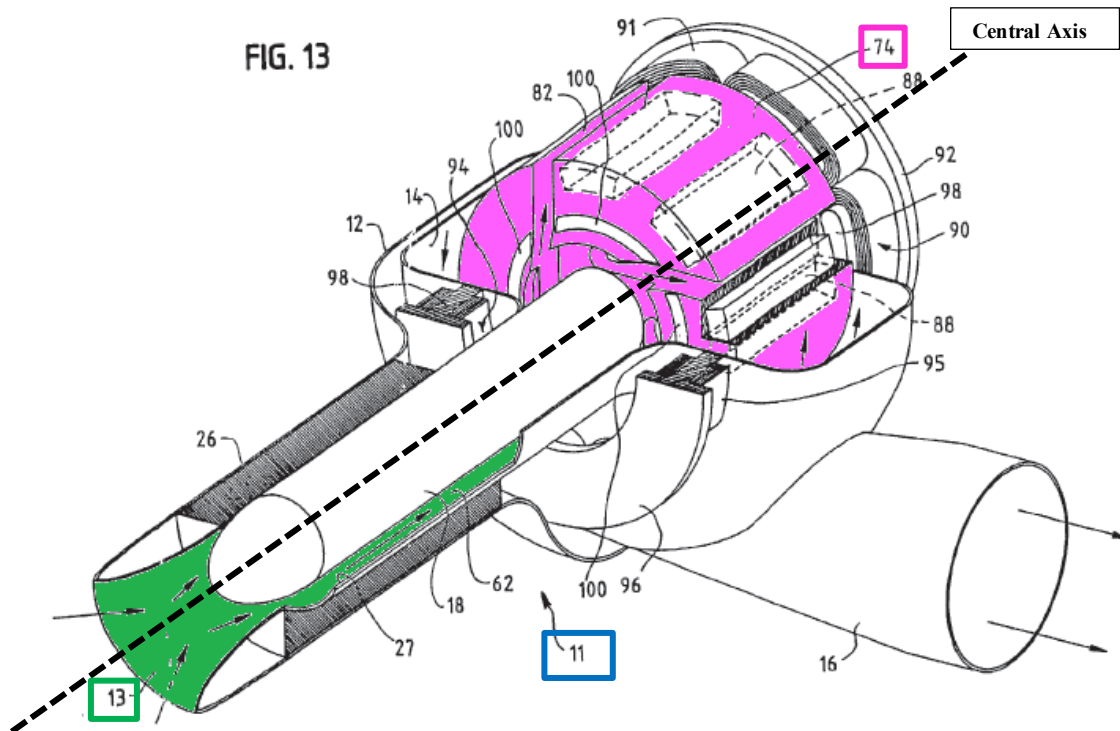
iii. [1B]

Wampler-169 discloses that the pump's "drive is imparted to [an] **impeller** [74] by magnetic interaction [*'a magnetically driven rotor assembly'*] between...permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator" (Ex.1008, [0018]; *see also* [0070]-[0072] (describing magnets "effective to drive...the rotor")), as shown:



Ex.1008, Fig.13. As demonstrated in [1A], inlet 13 "is placed into the apex" while the pump's "disc-shaped" portion, including its **impeller**, fits between the heart and diaphragm ("*spaced apart from the suction end*"). *Supra* [1A].

Wampler-169 discloses “axial inflow...of the blood” (Ex.1008, [0075]-[0076]; Ex.1003, ¶166) “to flow through **inlet tube 13** in the direction of the arrows” (Ex.1008, [0074]) towards “**impeller 74**,” which “rotat[es] about an longitudinal axis” (Ex.1008, [0081]), as shown:



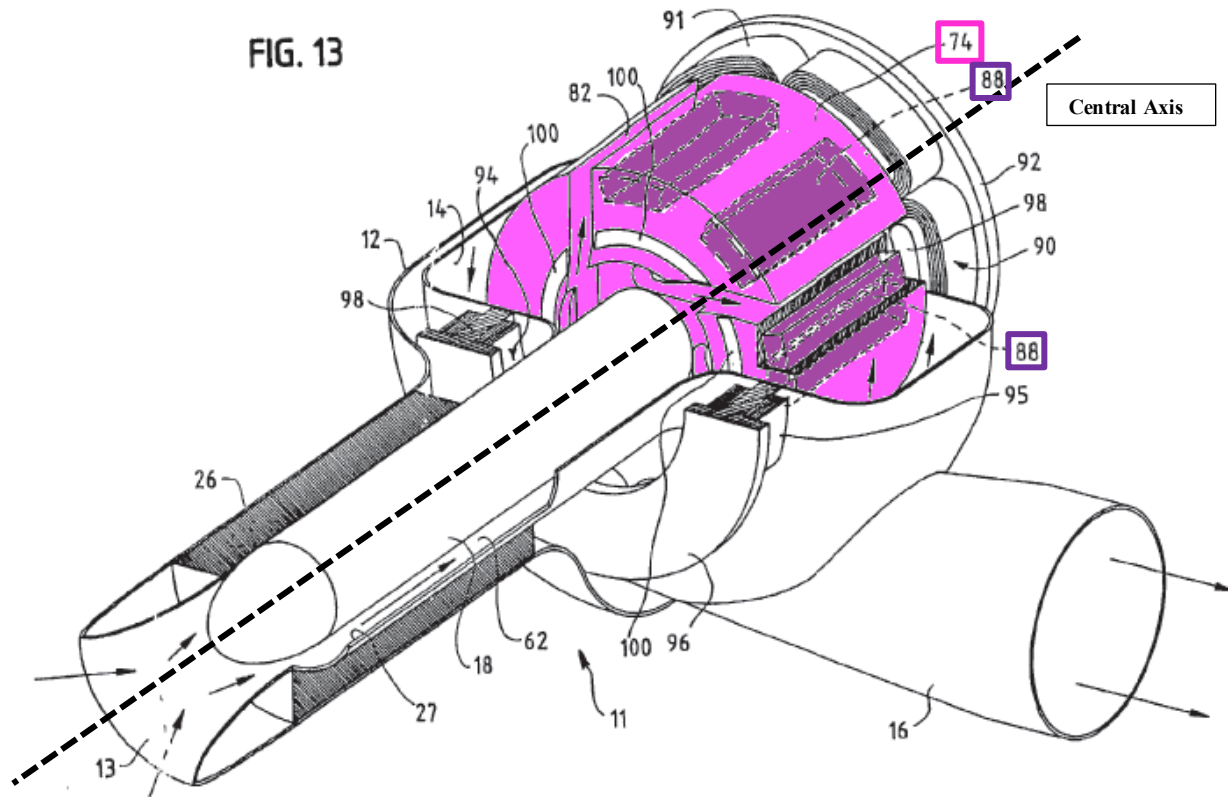
Ex.1008, Fig. 13; *see also* [0082] (explaining that Fig. 13’s “longitudinal axis...may be identical to...FIGS. 1-8”). Ex.1003, ¶165.

Accordingly, Wampler-169 discloses “a **magnetically driven rotor assembly** (“impeller 74”) configured to be axially aligned with the **inflow tube** (“inlet tube 13”) and to be spaced apart from the suction end when the **suction end of the inflow tube** is inserted into the **ventricle**.” Ex.1003, ¶168.

iv. [1C]

Wampler-169 discloses that “drive is imparted to...**permanent magnetic segments**” (“*a first magnetic device*”) “imbedded within...**impeller [74]**” (“*rigidly coupled*”).⁶ Ex.1008, [0018] *see also* [0070] (“magnetic segments...are encased in a jacket.”); Ex.1003, ¶171 (discussing that imbedded segments are *rigidly coupled*). Wampler-169 also refers to these “**segments**” as “**magnetic pieces 88**” (“*a first magnetic device*”), which “are inserted [*axially adjacent*] in...the **impeller**” (Ex.1008, [0080]), as shown:

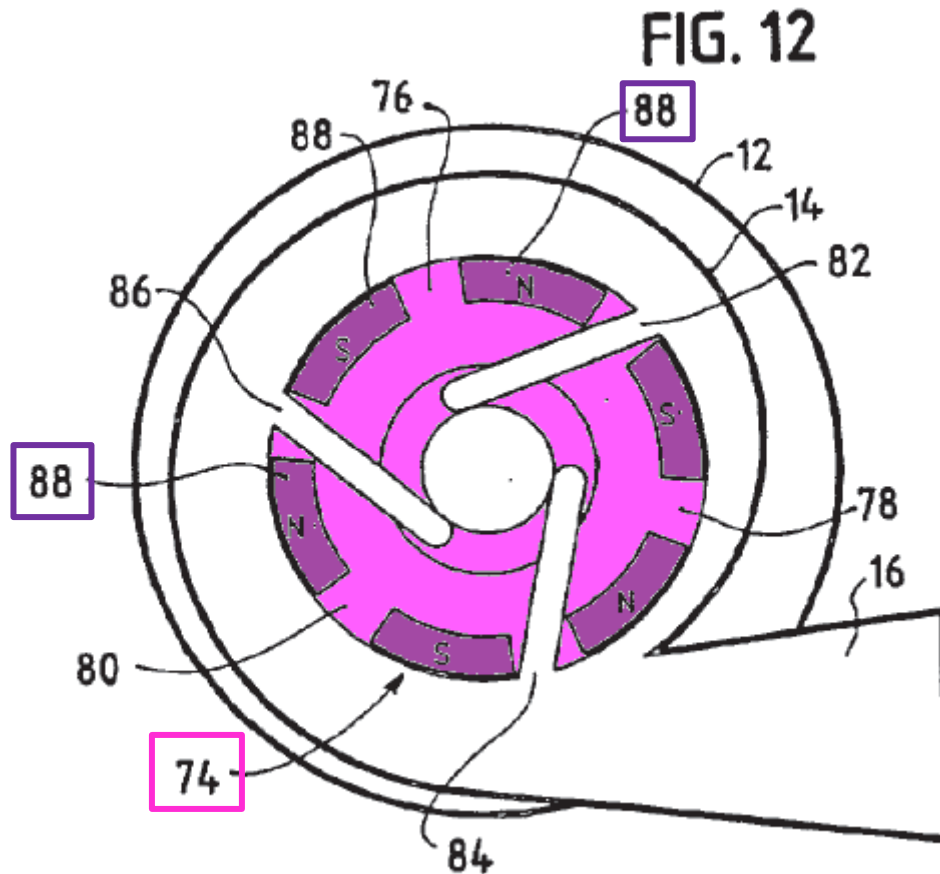
⁶ In Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is “*rigidly coupled*” and “*axially adjacent.*” Ex.1019, 5-7.



Ex.1008, Fig. 13. Ex.1003, ¶174. Further, Mr. Crosby explains the “impeller” and “magnetic pieces” are *axially adjacent*—situated next to each other on the same axis.

Ex.1003, ¶176

Figure 12 of Wampler-169 is a cross-section of the **impeller's magnetic pieces**:



Ex.1008, Fig. 12; Ex.1003, ¶175.

Accordingly, Wampler-169 discloses “the *magnetically driven rotor assembly* (“impeller 74”) comprising a *first magnetic device* (“magnetic pieces 88”) that is rigidly coupled to and axially adjacent to a *rotor* (“impeller 74”).” Ex.1003, ¶178.

v. *[1D]*

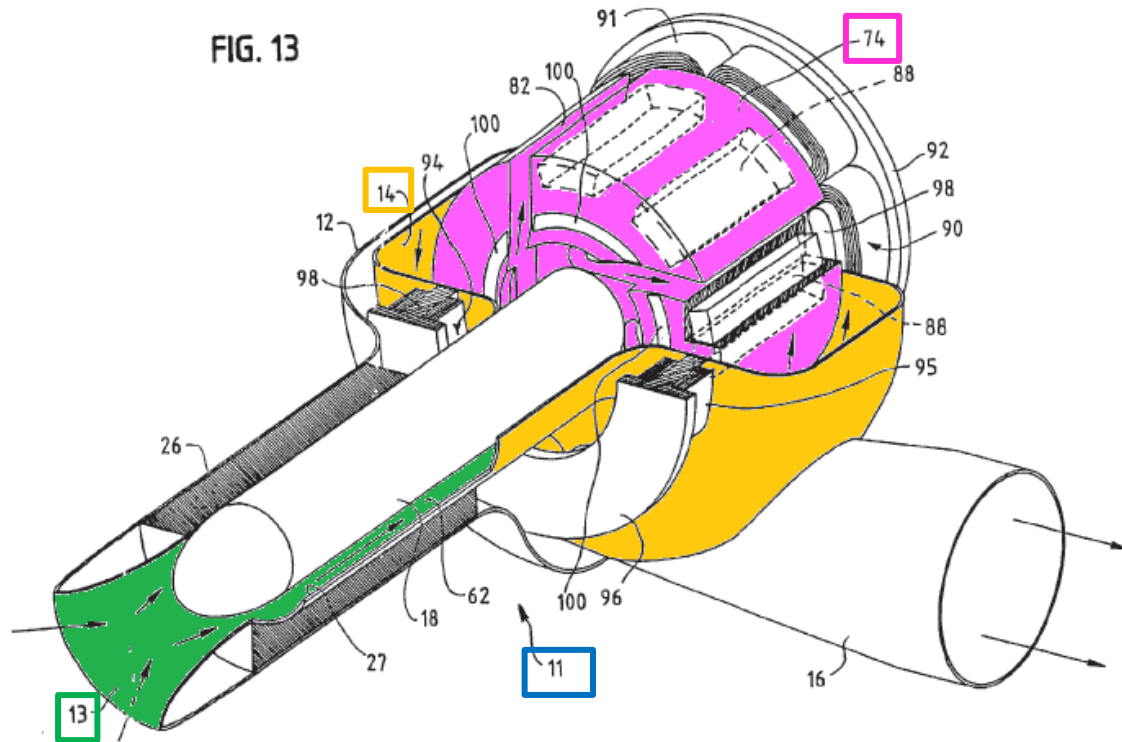
Wampler-169 discloses that the “centrifugal pump *impeller*” “includes...blade sectors” (Ex.1008, [0012]-[0013]) (“*guide surfaces*”) so that “[r]otation of...*impeller* 19, causes blood to flow through inlet tube 13 in the

direction of arrows 62” (“*produce centrifugal flow components*”). Ex.1008, [0074], Fig. 6 (showing arrows 62); Ex.1003, ¶¶180-181. As discussed *infra* [1J], the *centrifugal flow components* cause the blood to exit the pump.

Accordingly, Wampler-169 discloses that the **magnetically driven rotor** (“impeller 74”) “*having guide surfaces (“blade sectors”) to produce centrifugal flow components*” (“arrows 62”). Ex.1003, ¶187.

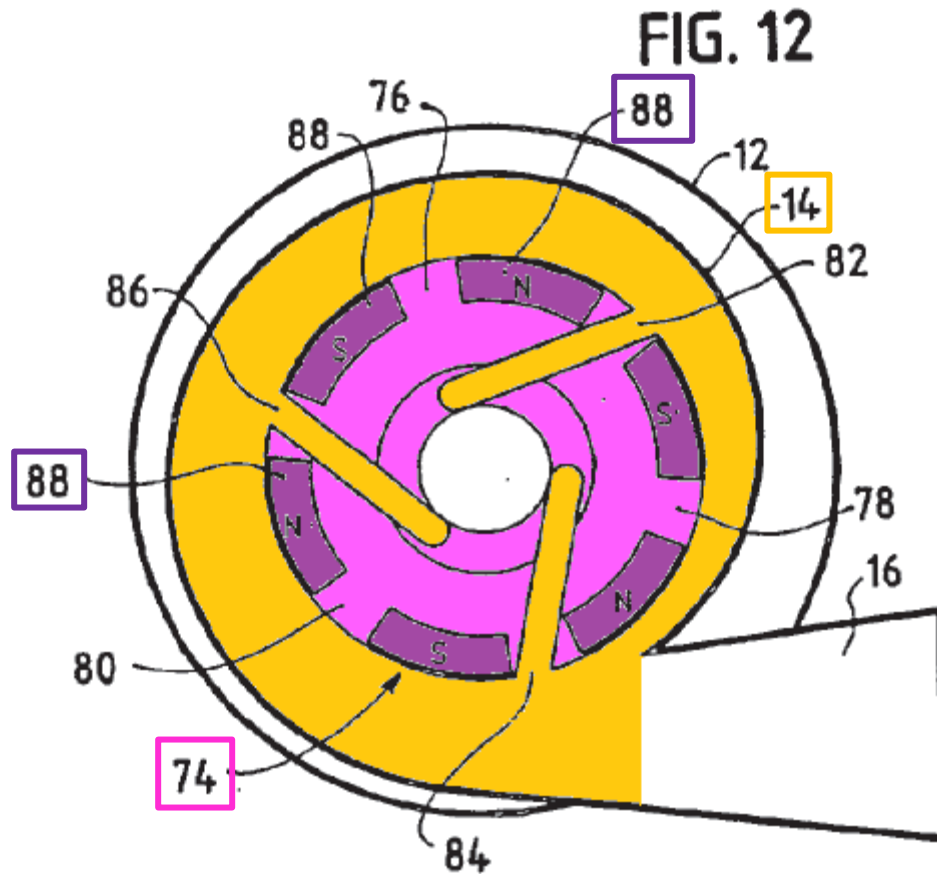
vi. [1E]

Wampler-169 discloses that “**impeller 74**[’s]” “rotation” “within housing 12, within **casing 14**” (Ex.1008, [0081], Ex.1003, ¶190) (“*rotatable...within a surrounding stationary housing*”) “causes blood to flow through **inlet tube 13** in the direction of arrows” (“*to act upon blood flowing from the inflow tube toward the rotor*”) (Ex.1008, [0074], Ex.1003, ¶192), as shown:



Ex.1008, Fig. 13. Ex.1003, ¶193. As demonstrated in [1B], “**impeller 74**,” “rotat[es] about an longitudinal axis” (“*rotatable about a central axis*”) (Ex.1008, [0081]). *Supra* [1B].

Figure 12 illustrates a cross-section of the **impeller** and **magnetic pieces** within **casing 14**:



Ex.1008, Fig. 12; Ex.1003, ¶194.

Accordingly, Wampler-169 discloses that the “*magnetically driven rotor assembly*” (“impeller 74”) being rotatable about a central axis within a *surrounding stationary housing* (“casing 14”) to act upon blood flowing from the *inflow tube* (“inlet tube 13”) to the *rotor*.” Ex.1003, ¶195.

vii. [1F]

Wampler-169 discloses that “once rotation begins,” the blood flowing produces a “fluid film...within the bearing gap” (“by a gap sized for passage of the blood”) (Ex.1008, [0092]), causing the “*impeller*” and its “*magnetic pieces*” to be

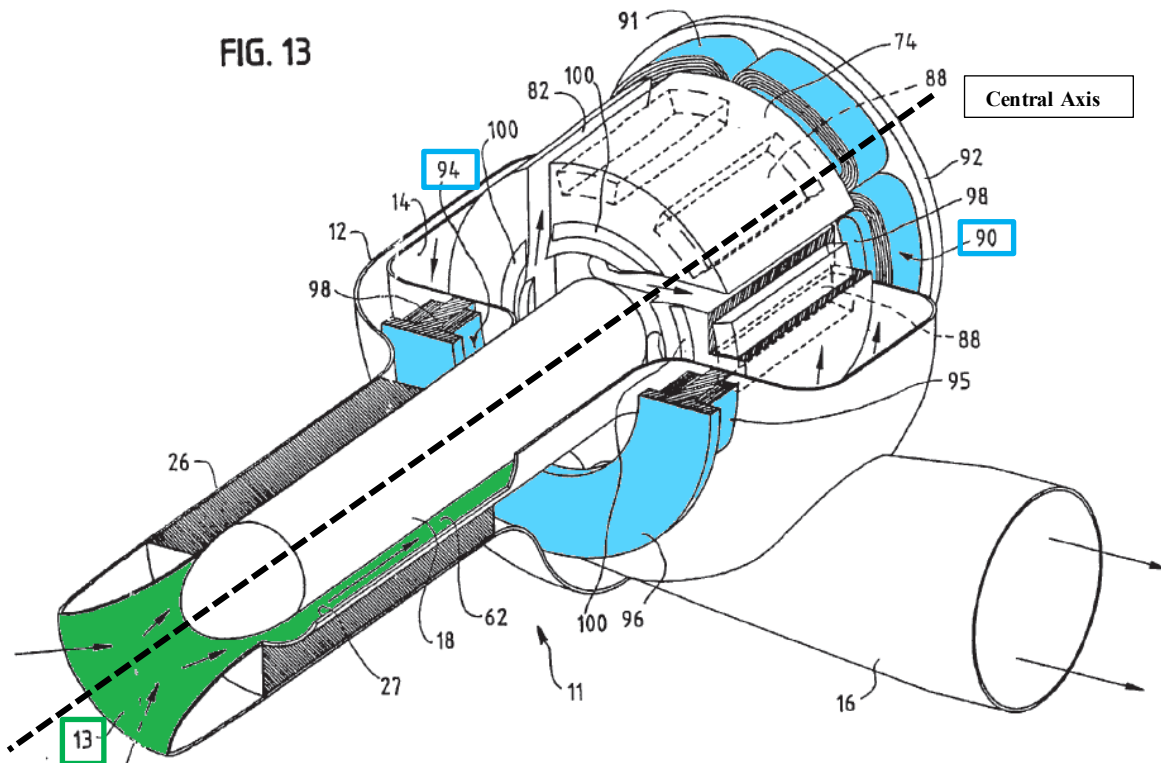
“suspended within the **housing**” (“*entirely spaced apart*”) (Ex.1008, [0013]; Ex.1003 ¶¶200-201). *See infra* [1K] (analyzing a “hydrodynamic bearing” that forms the “*gap*”).

Accordingly, Wampler-169 discloses that “*the magnetically driven rotor assembly* (“impeller 74”) *is entirely spaced apart from the stationary housing* (“casing 14”) *by a gap sized for passage of the blood.*” Ex.1003, ¶203.

viii. [1G]

In Parallel Litigation, PO alleges that a “motor and/or stator” satisfies this limitation. Ex.1019, 12 (cleaned up).

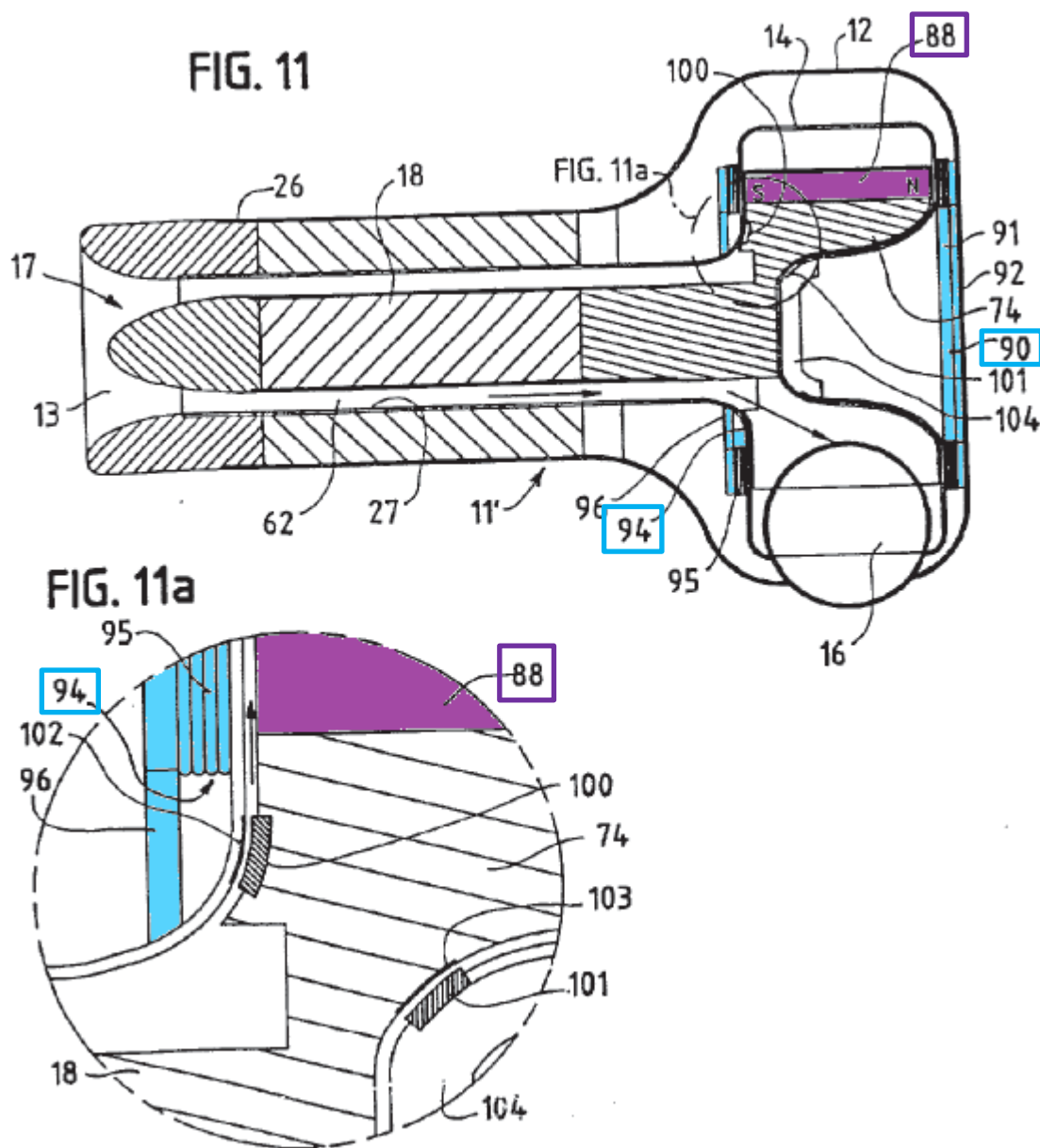
Assuming that interpretation, Wampler 169 discloses “**motor stators 90 and 94**” comprising elements “to complete a magnetic circuit” (Ex.1008, [0085]; Ex.1003 ¶206) (“*a second magnetic device*”) are “circular” (Ex.1008, [0018]) (“*axially aligned*”) and axially aligned with the “**inlet tube 13**” (“*inflow tube*”) (Ex.1008, [0080]), as shown:



Ex.1008, Fig. 13, *see also* [0070]; Ex.1003 ¶213.

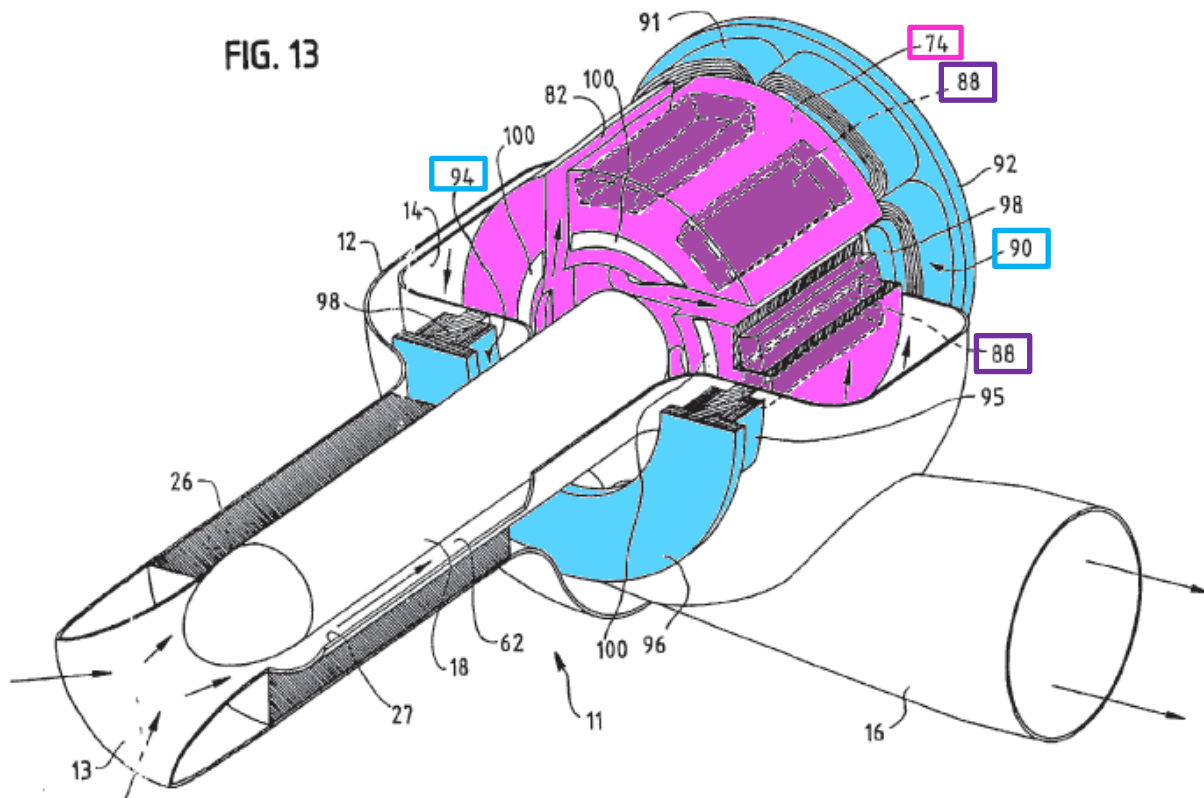
Further, Wampler-169 discloses that “drive is imparted to the **impeller** by magnetic interaction [‘*to magnetically drive...via a magneto coupling*’] between arcuate, **permanent magnetic segments [88]** imbedded within each **impeller** blade sector, and a **circular electromagnetic stator [90 and 94]**” (“*positioned to magnetically drive rotation*”). Ex.1008, [0018]; Ex.1003, ¶214. Said another way, the **stator** and its “windings[] are energized by the electrical output of [a] controller 59 to produce an electromagnetic field...[which] is effective to drive [‘*via a magneto coupling*’] **magnets [88]** and the [**impeller**], in rotary fashion.” Ex.1008, [0072];

Ex.1003, ¶212 (explaining this description of electromagnetic drive referencing Figures 1-8 applies to the embodiment of Figures 11-14).



Ex.1008, Figs 11-11*a*; Ex.1003, ¶215.

Figure 13 illustrates a perspective view of the **stators** “located at the rear” and “forward side of **impeller 74**” (Ex.1008, [0083]-0084]) to be “*positioned to magnetically drive rotation*” “*via a magneto coupling*” with the **impeller’s magnetic pieces 88**:



Ex.1008, Fig. 13; Ex.1003, ¶216.

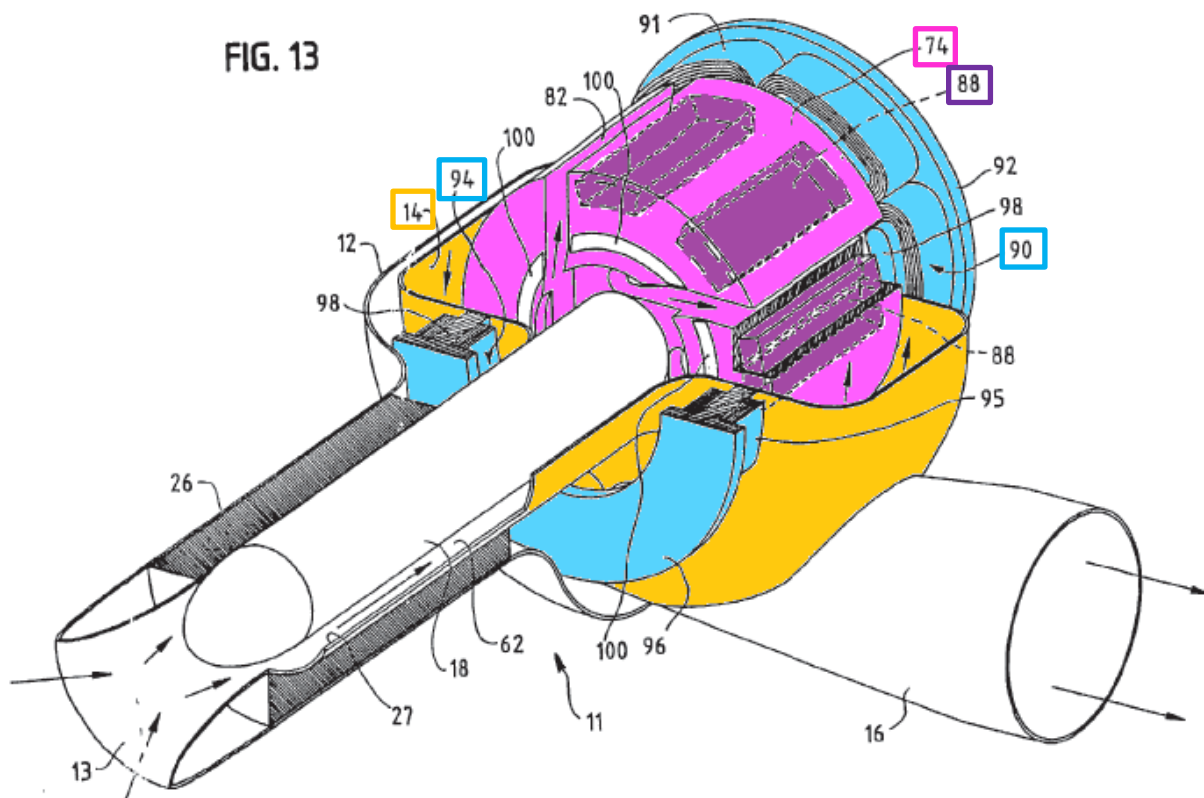
Accordingly, Wampler-169 discloses “a *second magnetic device* (“motor stators 90 and 94”) *axially aligned with the inflow tube* (“inlet 13”) and positioned to magnetically drive rotation of the *magnetically driven rotor assembly* (“impeller

74”) via a magneto coupling with the *first magnetic device* (“magnetic pieces 88”).”

Ex.1003, ¶217

ix. [1H]

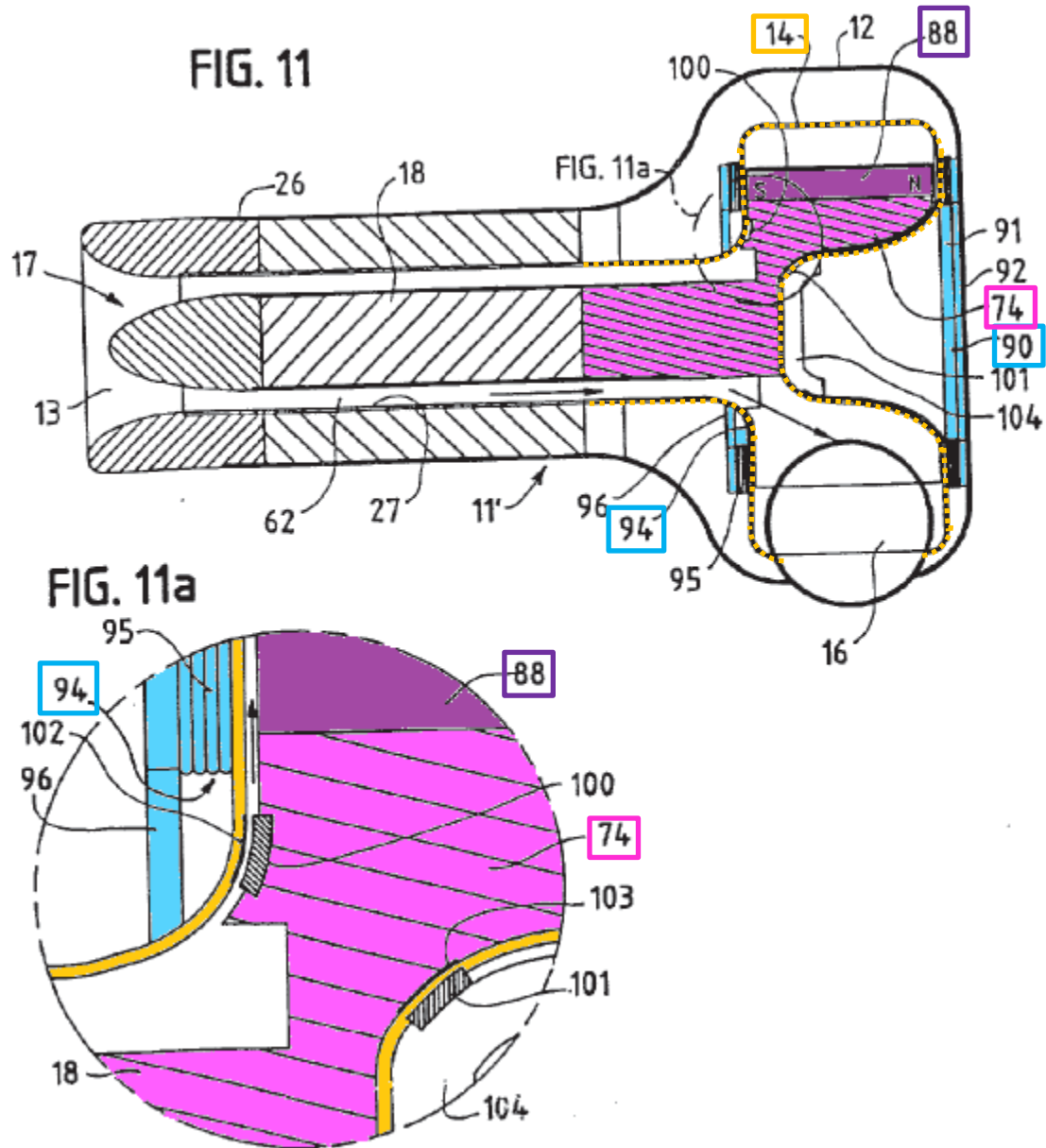
Wampler-169 discloses or at least renders obvious that the “*stator[s]*” are fixed between housing 12 and *casing 14*” (“*spaced apart*”) (Ex.1008, [0083]-[0084]; Ex.1003, ¶220) while the “*impeller*” and its “*magnetic pieces*” are “enclos[ed]” within the *casing* (“*sealed*”) (Ex.1008, [0012], Ex.1003, ¶221), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶222. Wampler-169 discloses that blood enters “the interior of the casing 14” (“*sealed...by at least one sealing wall*”) and is “expelled

from the casing” via a “discharge tube 16.” Ex.1008, [0074]; Ex.1003, ¶221. Mr. Crosby explains that it would have been obvious that “a thin-walled non-magnetic jacket be placed over these portions, to prevent contact between the magnets and the blood [*sealed...by at least one sealing wall*].” Ex.1008, [0057]; Ex.1003, ¶221 (analyzing sealing to avoid “undesirable chemical reaction”).

Figures 11-11*a* illustrate the “**stator[s]** fixed between housing 12 and **casing 14**” while the “**impeller**” and its “**magnetic pieces 88**” are within the **casing**:



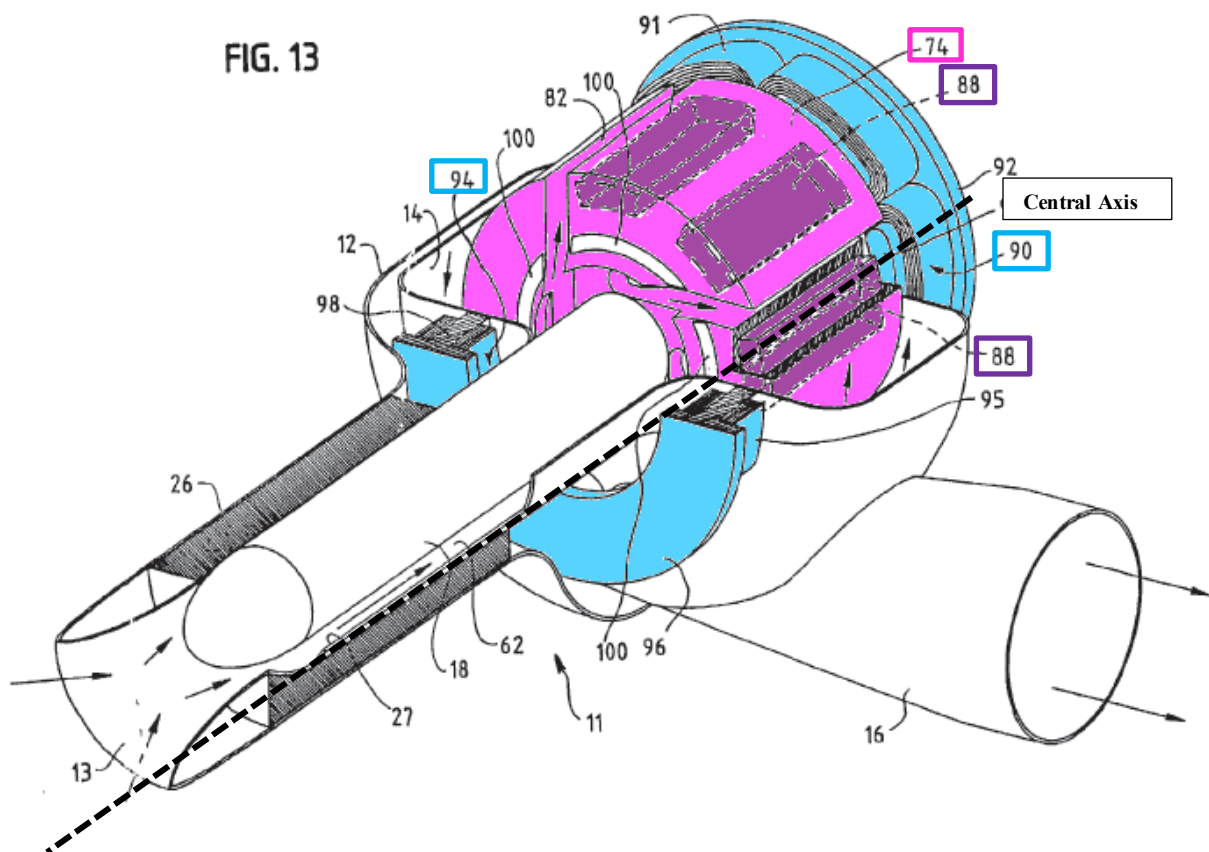
Ex.1008, Figs. 11-11a; Figs. 7-8b, [0070]; Ex.1003, ¶223.

Accordingly, Wampler-169 discloses or at least renders obvious that the “*second magnetic device* (“motor stators 90 and 94”) is positioned according to [1G] “while being spaced apart and sealed from both the *rotor* (“impeller 74”) and the

first magnetic device (“magnetic pieces 88”) of the *magnetically driven rotor assembly*.” Ex.1003, ¶224

x. [1I]

As demonstrated in [1D] and [1H], the “*stators*” are “*axially spaced apart*” from the “impeller 74” (supra [1H]), including its “blade sectors” (supra [1D]), as shown:

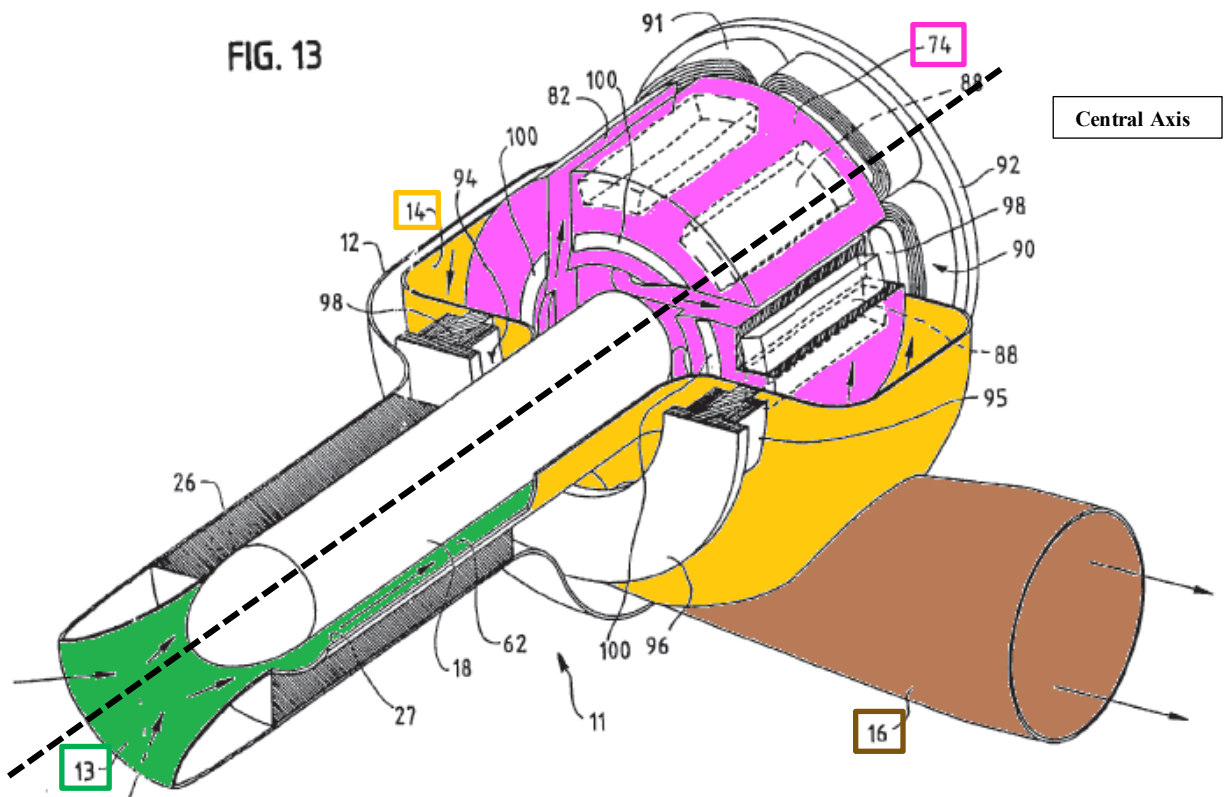


Ex.1008, Fig. 13; Ex.1003, ¶230.

Accordingly, Wampler-169 discloses “the *second magnetic device* (“motor stators 90 and 94”) being positioned axially spaced apart from the guide surfaces (“blade sectors”) of the *rotor* (“impeller 74”).” Ex.1003, ¶232.

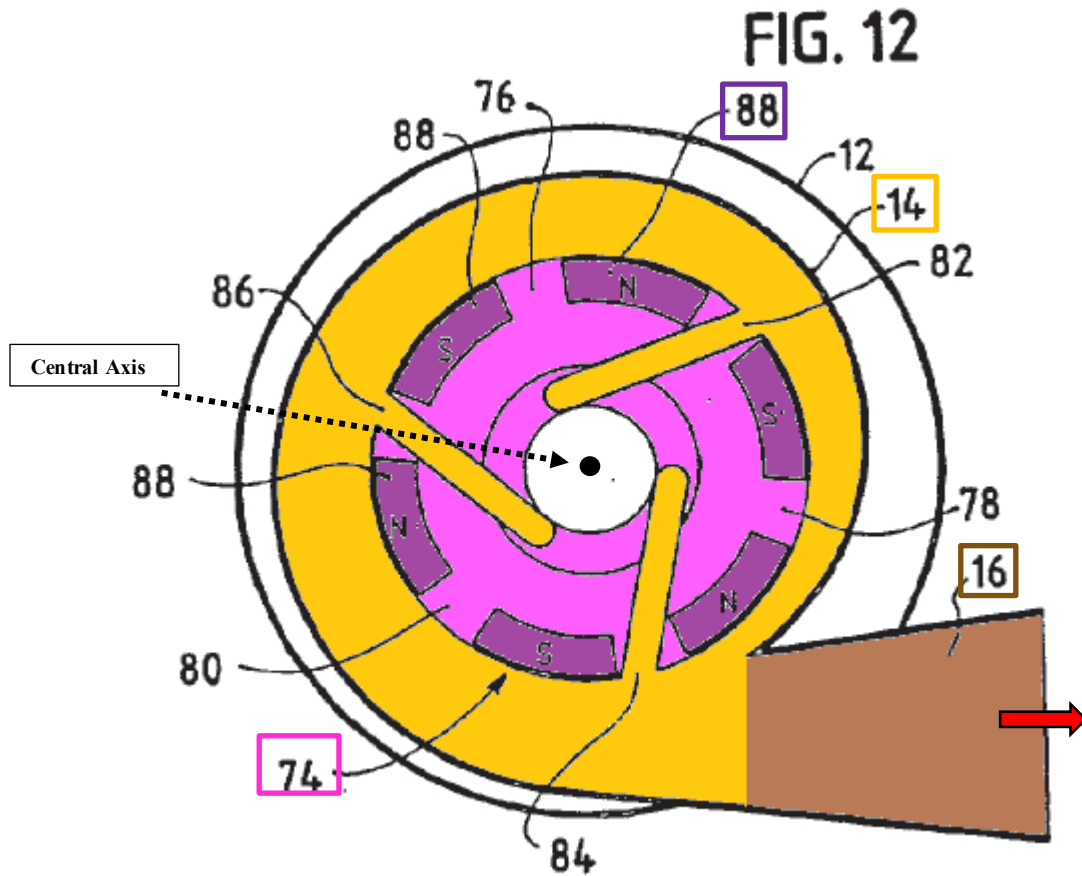
xi. [1J]

Wampler-169 discloses that “**discharge tube 16**” (“a blood outflow port”) has “a tangential orientation with respect to a radius of the casing” (“*positioned radially adjacent*”) to allow “radial outflow of the pump [in] a 90-degree redirection of the blood” (“*in a direction substantially perpendicular to the central axis*”) (Ex.1008, [0074]-[0076], [0080]; Ex.1003, ¶234), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶236.

Figure 12 illustrates a top view of the radial outflow (red arrow) “adjacent” to the “blade sectors”:

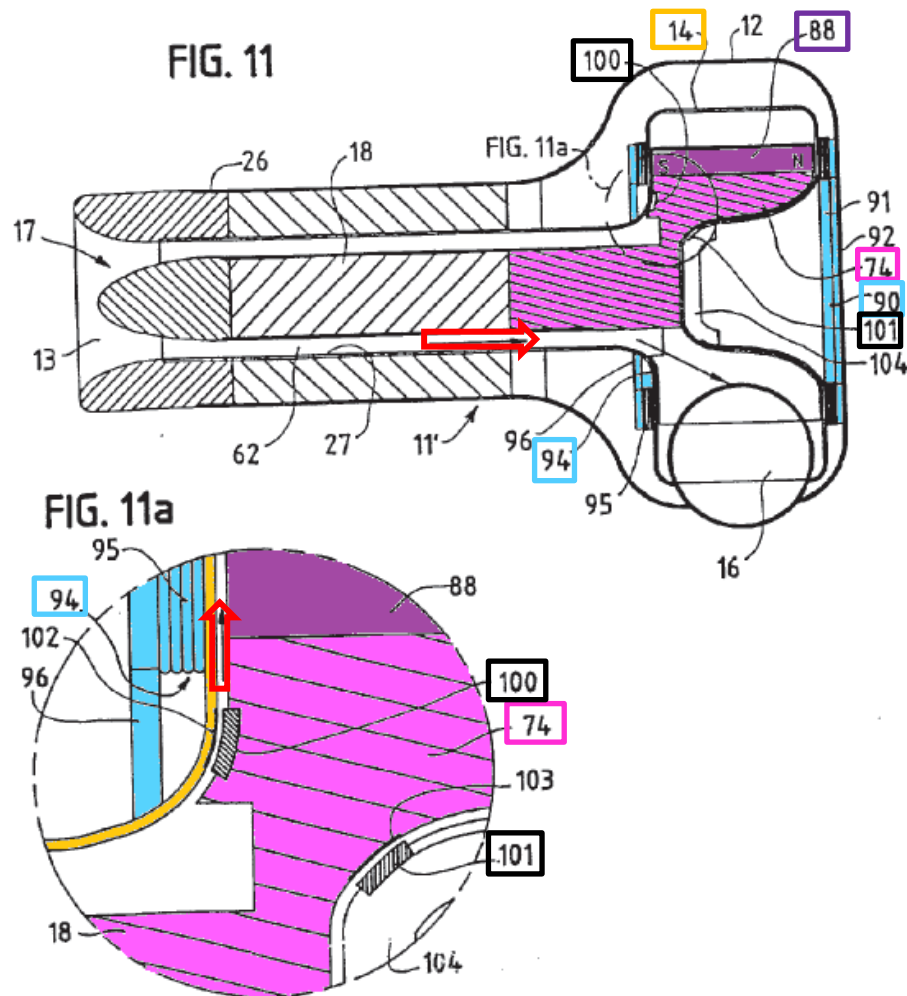


Ex.1008, Fig. 12; Ex.1003, ¶237.

Accordingly, Wampler-169 discloses “a **blood outflow port** (“discharge tube 16”) positioned radially adjacent the guide surfaces of the **rotor** (“impeller 74”) such that, when blood is driven by the **magnetically driven rotor assembly**, the blood exits the **surrounding stationary housing** (“casing 14”) in a direction substantially perpendicular (“a 90-degree redirection”) to the **central axis** of the **magnetically driven rotor assembly**.” Ex.1003, ¶238.

xii. [1K]

As demonstrated above, Wampler-169 discloses that drive is imparted “*via a magneto coupling*” (*supra* [1G]) and that “the impeller [is] suspended within the housing” (*supra* [1F]). Wampler-169 further discloses that “once rotation [of the **impeller**] begins” (“*magneto coupling is configured to both drive rotation...and orient the...rotor*”) “relative movement between the [**impeller**] and...the hydrodynamic action of the fluid film [(‘*by the blood flowing*’; **red** arrows)] produces increased pressure within the bearing gap which forces the [**impeller**] and the [**casing**] apart” (“*remains entirely spaced apart*”) (Ex.1008, [0092]; Ex.1003, ¶244), as shown:



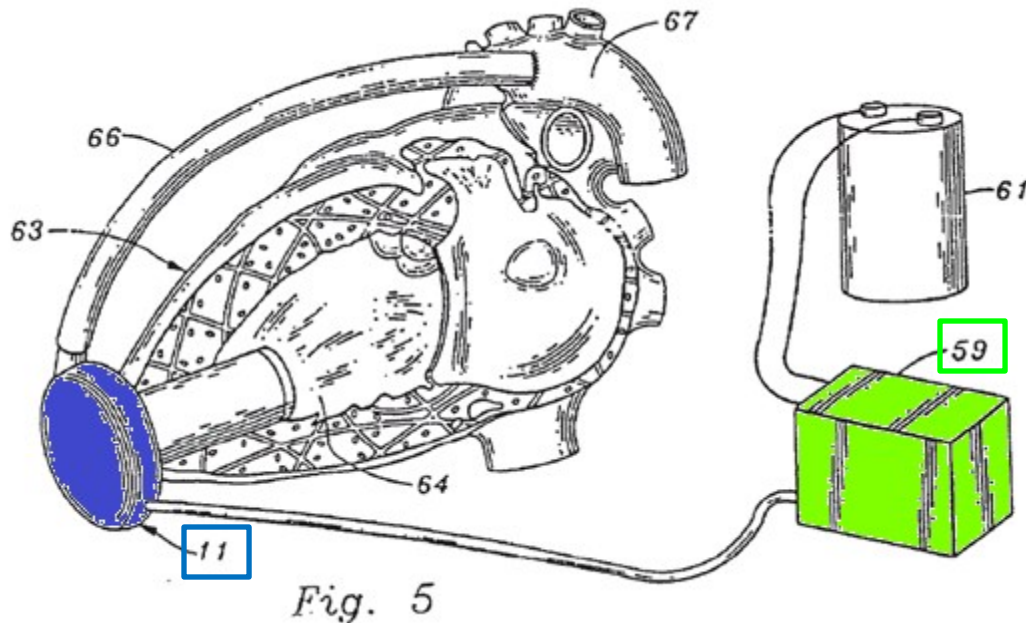
Ex.1008, Figs. 11-11a; Ex.1003, ¶245.

Said another way, Wampler-169 teaches that “hydrodynamic bearings are formed” in response “to rotation of the [impeller]”— “once rotation begins...fluid film produces increased pressure...which forces” (Ex.1008, [0020]) the “impeller [to be] separated from the casing by a fluid film” (“gap sized for passage of the blood”). Ex.1008, [0092]; Ex.1003, ¶244.

Accordingly, Wampler-169 discloses that “*the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly (“impeller 74”) and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing (“casing 14”) by the gap sized for passage of the blood.*” Ex.1003, ¶248.

xiii. [1L]

Wampler-169 discloses that the motor stators “are energized by the electrical output of **controller 59**” (Ex.1008, [0072]), which “may be worn externally by the user” (Ex.1008, [0070]) (“*an external control unit*”), and which can be “manually adjusted or programmed to determine the running rate of pump” (Ex.1008, [0071]; Ex.1003, ¶251) by “produc[ing] an electromagnetic field...to drive...the rotor” (“*regulate operation of the second magnetic device*”) (Ex.1008, [0072]; Ex.1003, ¶250), as shown:



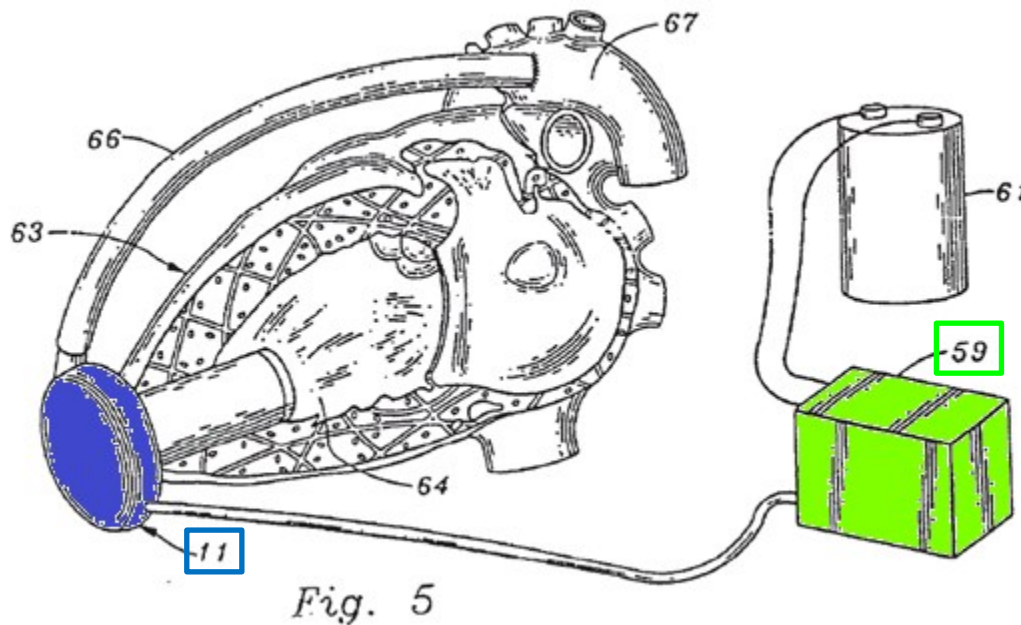
Ex.1008, Fig. 5; Ex.1003, ¶253; *see also* ¶¶250-252 (analyzing how the controller regulates operation).

The “external” **controller** can be “manually adjusted or programmed to determine the running rate of pump...[and] may be interconnected to sensors on various organs...[to] automatically...tailor operation of the pump to the user's physical activity and condition” (“*based upon a control value indicative of cardiac output*”). Ex.1008, [0071]; *see also* [0018] (“The control unit allows the speed...to be...determined by the user’s physical activity”). Ex.1003, ¶256.

Accordingly, Wampler-169 teaches or suggests that “an **external control unit** (“controller 59”) *configured to regulate the operation of the **second magnetic device** (“motor stators 90 and 94”) based upon a control value indicative of cardiac output (“user’s physical activity and condition”).*” Ex.1003, ¶258.

xiv. [1M]

As demonstrated in [1L], Wampler-169 discloses that the motor stators “are energized by...**controller 59**” which is *connectable* to the pump, “to produce an electromagnetic field...to drive...the rotor” (“*to thereby magnetically drive the rotation*”) (Ex.1008, [0072]; Ex.1003, ¶250), as shown:



Ex.1008, Fig. 5; Ex.1003, ¶253; *see also* ¶¶250-252 (analyzing how controller control[s]).

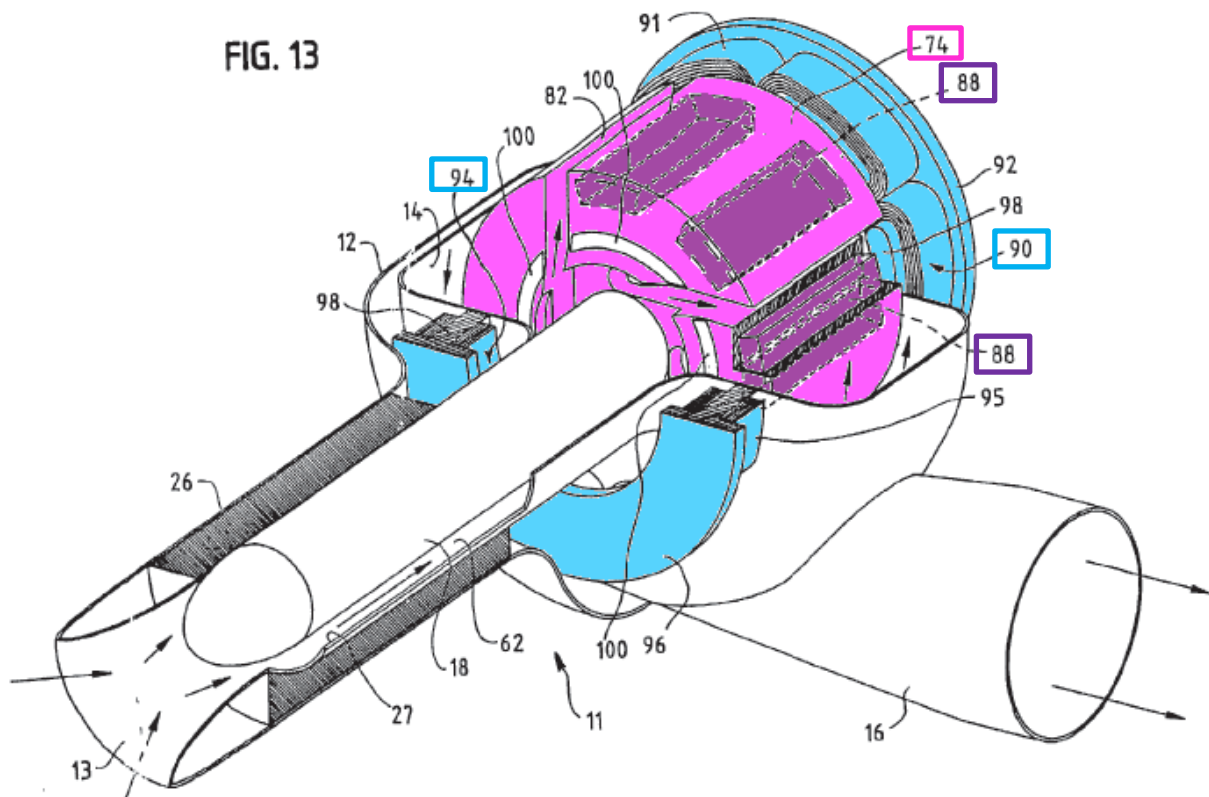
Accordingly, Wampler-169 teaches or suggests “the **external control unit** (“controller 59”) is *connectable* to the **heart assist pump device** (“pump 11”) for controlling (“to determine the running rate of pump”) the **second magnetic device** (“motor stators 90 and 94”) to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** (“impeller 74”) via the magneto coupling (as

demonstrated in 1[J]) *with the first magnetic device* (“magnetic pieces 88”).”
Ex.1003, ¶258.

Wampler-169 therefore renders obvious Claim 1. Ex.1003, ¶¶150-266.

2. Claim 2

As demonstrated in [1G], the **magnetic pieces 88** are “*positioned between*” the **motor stators 90 and 94**” and the **impeller 74** for the “produce[d] electromagnetic field” to be “effective to **magnetic pieces 88**” and thereby drive rotation of the **impeller 74**, as shown:



Ex.1008, [0072], [0085]. Ex.1003, ¶272

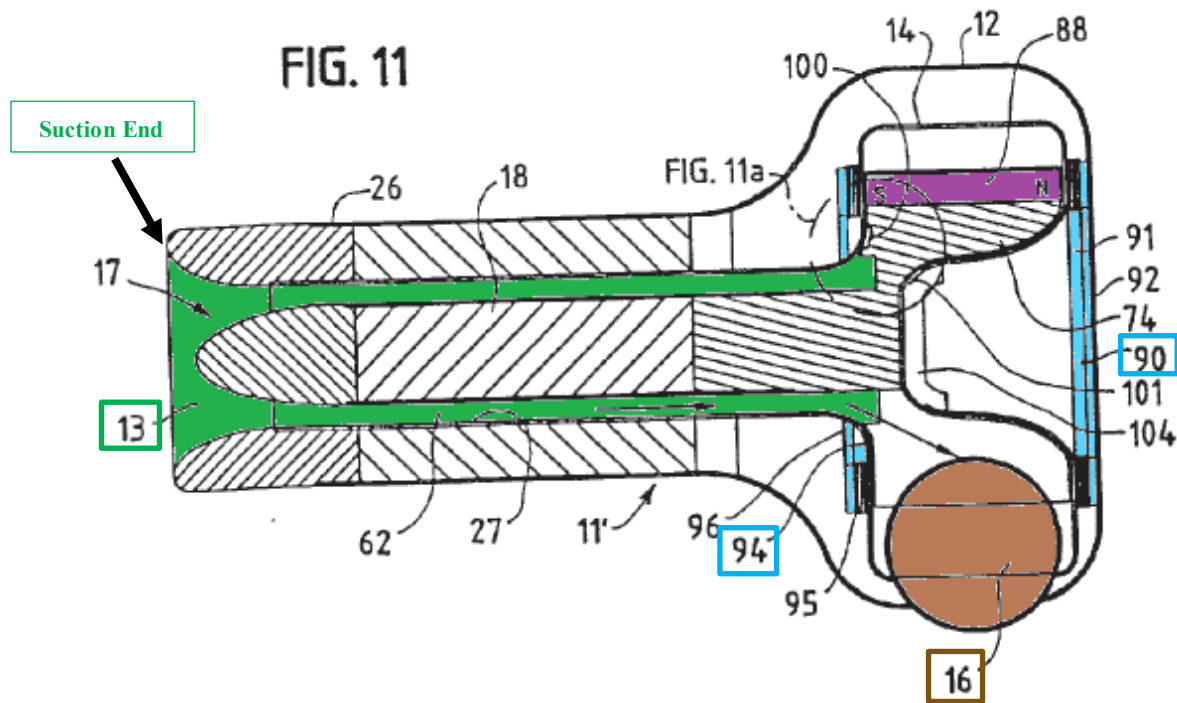
Accordingly, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *is configured to be positioned between the second magnetic device* (“motor stators 90 and 94”) *and the guide surfaces of the rotor of the magnetically driven rotor assembly* (“impeller 74).” Ex.1003, ¶273.

3. Claim 3

As demonstrated in [1C] that the “**impeller**” and “**magnetic pieces**” are *rigidly coupled*, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *is configured to rotate together with the rotor* (“impeller 74”) *relative to the surrounding stationary housing* (“casing 14”). *Supra* [1C] (analyzing Ex.1008, [0018], [0080]). Ex.1003, ¶¶276-277.

4. Claim 4

As demonstrated in [1A] and [1J], Wampler-169 discloses a “**discharge tube 16**” (Ex.1008, [0080]) that “extends through the housing...[and] casing” (Ex.1008, [0050]), “**stator[s]** [that] are fixed between housing 12 and casing” (Ex.1008, [0083]), and an “**inlet tube 13**,” as shown:



Ex.1008, Fig 11; Ex.1003, ¶¶282-283.

Accordingly, Wampler-169 discloses that “the *second magnetic device*” (“motor stators 90 and 94”) “is positioned closer to the *blood outflow port*” (“discharge tube 16”) “than the suction end of the *inflow tube*” (“inlet tube 13”).” Ex.1003, ¶284.

5. Claim 5

As demonstrated in [1H] and [1M] that the *second magnetic device* (“motor stators 90 and 94”) is “sealed” and the controller is “external,” Wampler-169 discloses “the *magnetically driven rotor assembly* (“impeller 74) is sealed from the *second magnetic device* (“motor stators 90 and 94”) and a drive source

(“controller 59”) *configured to regulate the operation of the second magnetic device.*” Ex.1003, ¶288.

6. Claim 7

As demonstrated in [1L]-[1M], the “external” “**controller**” “may be interconnected to sensors on various organs...to tailor operation of the pump to the user’s physical activity and condition.” Ex.1008, [0071]-[0072]; *supra* [1M]; Ex.1003, ¶292.

Accordingly, Wampler-169 teaches or suggests “*one or more sensors configured to deliver feedback signals to the **external control unit*** (“controller 59”).” Ex.1003, ¶293.

7. Claim 10

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Ex.1019, 3-4. Assuming that interpretation, because Wampler-169’s pump comprises an “inflow cannula” (Ex.1008, [0075]) it “*is a catheter device.*” Ex.1003, ¶¶294-297.

Accordingly, Wampler-169 discloses that “*the **heart assist pump device*** (“pump 11”) *is a catheter device.*” Ex.1003, ¶298.

8. Claim 16

Claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. Ex.1003, ¶299.

i. [16PRE]

See [1PRE]. Ex.1003, ¶¶301-302.

ii. [16A]

See [1A] and [1B] (analyzing axial inflow, i.e., an “*inflow path along an inflow axis*”). Ex.1003, ¶304.

iii. [16B]

See [1E] (analyzing a “*surrounding stationary housing*” (“casing 14”). Wampler-169 discloses “*walls...defining a chamber*” of [16B] for the reasons it discloses a “*surrounding stationary housing*” of [1E]. Ex.1003, ¶307.

iv. [16C]

See [1B] and [1C] (analyzing *magnetically driven rotor assembly* (“impeller 74”) axially aligned with the *inflow tube* (“inlet tube 13”) comprising “a *first magnetic device*” (“magnetic pieces 88”). Ex.1003, ¶310.

v. [16D]

See [1C]. Ex.1003, ¶313.

vi. [16E]

See [1D]. Ex.1003, ¶316.

vii. [16F]

See [1E]. Ex.1003, ¶319.

viii. [16G]

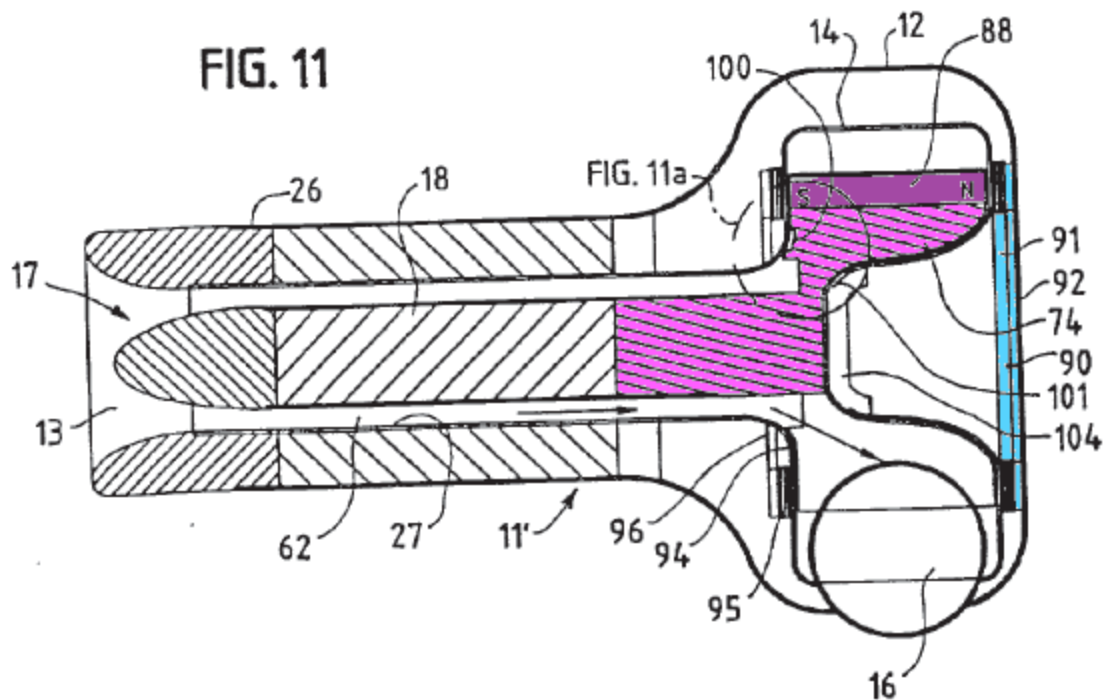
See [1B] and [1E]. Ex.1003, ¶322.

ix. [16H]

See [1G]. Wampler-169 discloses a “*magnetic drive system comprising a second magnetic device*” of [16H] for the reasons it discloses a “*second magnetic device*” (“motor stators 90 and 94”) of [1G]. Ex.1003, ¶325.

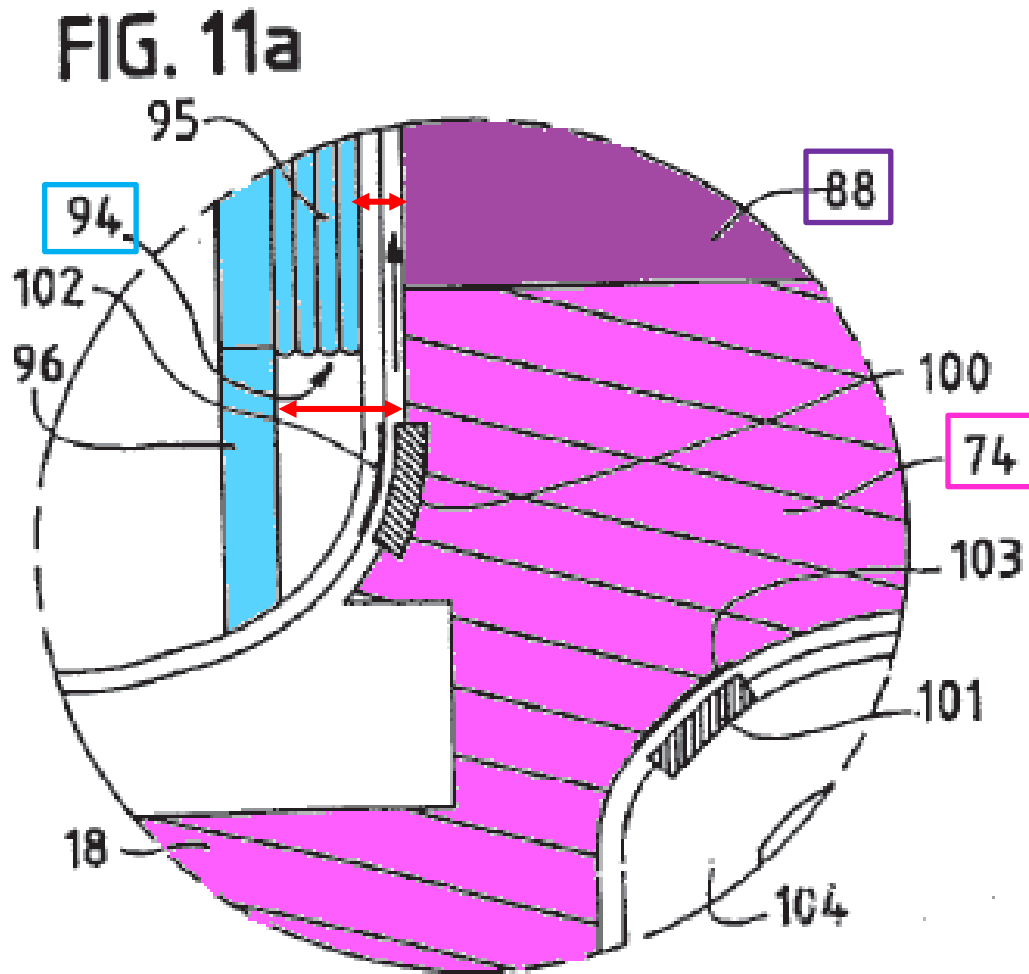
x. [16I]

See [1K] and [2]. Ex.1003, ¶328. Wampler-169 teaches or suggests that the *second magnetic device* is “*positioned axially closer*” to the *first magnetic device* of [16I] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor assembly* of [2]. Figure 11 illustrates that “*stator 90*” is “adjacent to the pole faces of the *motor rotor magnets [88]*” and therefore “*positioned axially closer to*” *motor rotor magnets [88]* than to the *impeller 74*:



Ex.1008, [0085]; Ex.1003, ¶328.

Additionally, Figure 11a illustrates that **stator 94**, including the “windings 95,” is *positioned axially closer to* the “**magnetic pieces 88**” than the “**impeller 74**” (shown by length of **red** arrows):



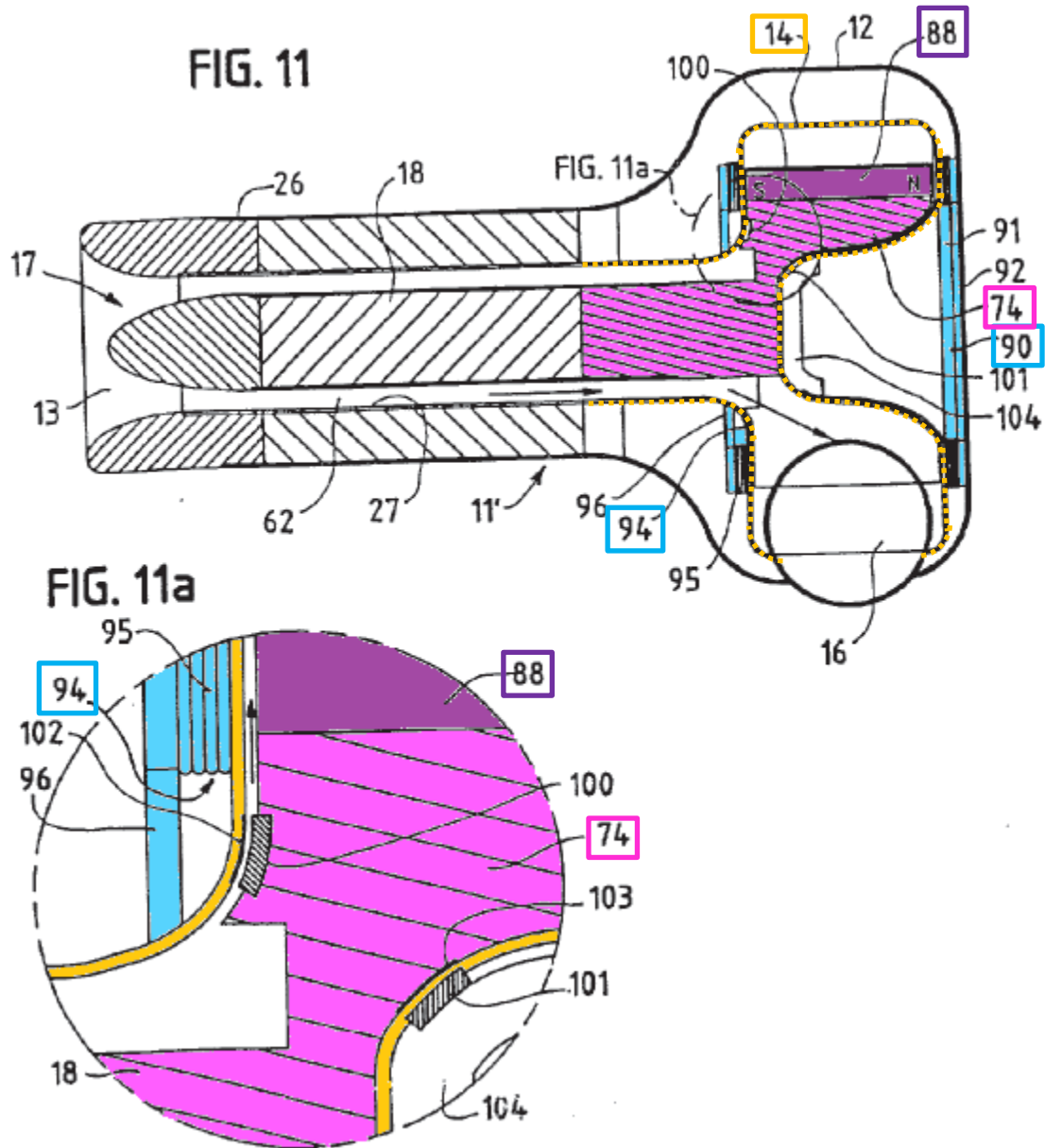
Ex.1008, Figs 11-11a; Ex.1003, ¶328 (analyzing the “*axially closer*” to effectively generate torque).⁷

⁷ The claimed relative locations of the “*first magnetic device*” and “*magnetically driven rotor*” to the “*second magnetic device*” would also have been an obvious design choice because the specification of the 077 Patent does not suggest that such

xi. [16J]

See [1H]. Ex.1003, ¶331. Wampler-169 discloses that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J] for the reasons it discloses a “*second magnetic device*” is “*sealed.*” Figures 11-11*a* illustrate the “*stator[s]* fixed between housing 12 and *casing 14*” while the “*impeller*” and its “*magnetic pieces 88*” are within the *casing*:

relative locations are critical to the claimed invention. *See Ex Parte Spangler*, Appeal No. 2018-003800 2019 WL 1077598, at 5–6 (Patent Tr. & App. Bd. Feb. 15, 2019).



Ex.1008, Figs. 11-11a; Figs. 7-8b, [0070].

xii. [16K]

See [1J]. Ex.1003, ¶334.

xiii. [16L]

See [1M]. Ex.1003, ¶337.

xiv. [16M]

See [1L]. Ex.1003, ¶340.

xv. [16N]

See [1M]. Ex.1003, ¶343.

9. Claim 17

See [2], [16D], and [16I] *above*. Ex.1003, ¶347.

10. Claims 18-21

See [1F], [1K]. Wampler-169 discloses a “gap...configured to be occupied by the blood” ([18]); that “surrounds” ([19]); “extends radially outward” ([20]) and “along a face...axially opposite from the inflow tube” ([21]) of “the magnetically driven rotor assembly” for the reasons Wampler-169 discloses “entirely spaced apart...by a gap sized for passage of the blood” of [1F] and [1K]—i.e., the gap extends entirely surrounding the *magnetically driven rotor assembly*. Ex.1003, ¶¶359, 364, 368, 372.

11. Claim 22-23

See [16J]. Wampler-169 discloses a “*wall of the...chamber* separates the first chamber from the second chamber” of [22]-[23] for the reasons that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J]. Ex.1003, ¶¶383-384, 390.

12. Claim 24

See [1C], [16C]. Ex.1003, ¶394.

13. Claim 26

See [7]. Ex.1003, ¶394.

14. Claim 28

See [10]. Ex.1003, ¶402.

Wampler-169 therefore renders obvious Claims 1-5, 7, 10, 16-24, 26, and 28. Ex.1003, ¶¶149-403.

B. Ground 2: Bourque-2001 and Wampler-169 Render Obvious the Challenged Claims

1. Claim 1

i. [1PRE]

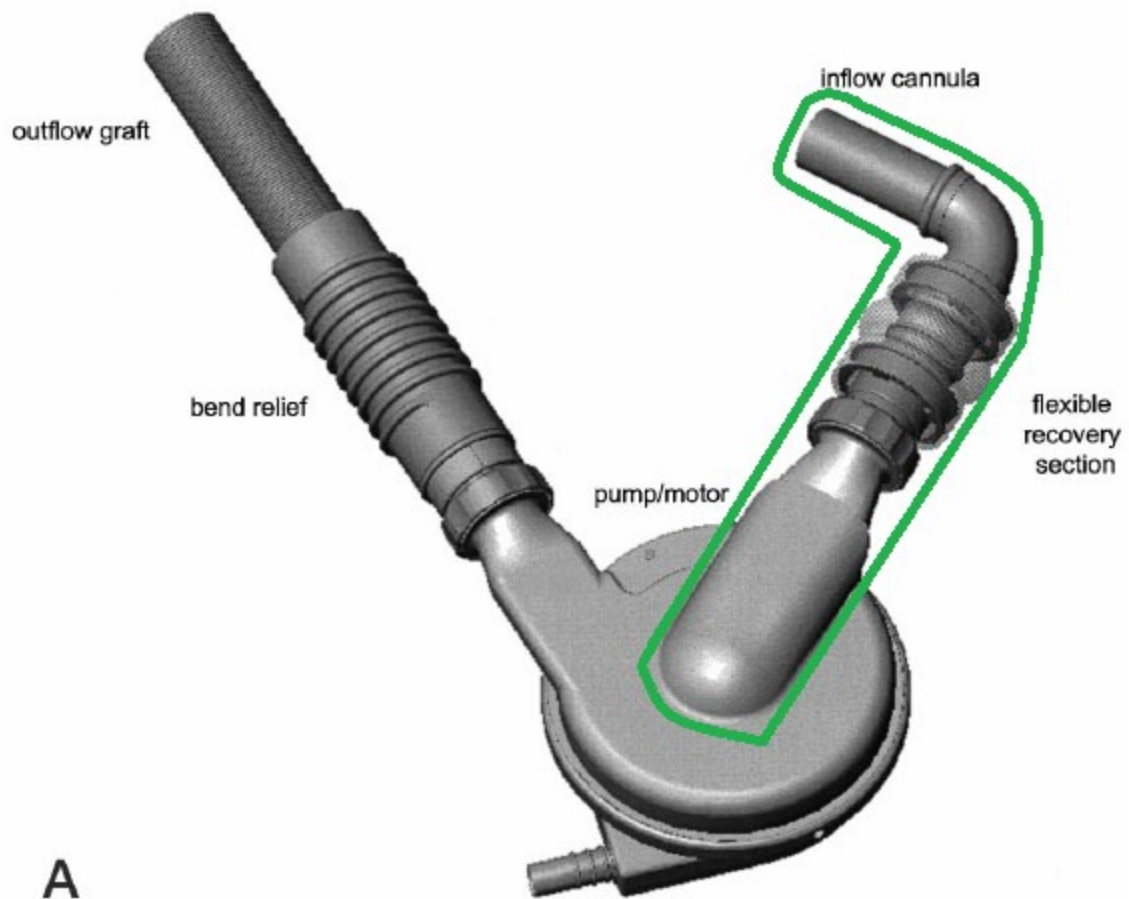
Bourque-2001 discloses the “HeartMate III”—“a centrifugal pump” that is a “long-term, compact left **ventricular** assist device (LVAD)” “to treat” “people...diagnosed with congestive heart failure” (“*a system for assisting the blood circulation of a heart*”). Ex.1007, 401; Ex.1003, ¶405.

PO concedes that Bourque-2001 discloses this element. Ex.1026, F-1 2.

Accordingly, Bourque-2001 discloses “*a system for assisting the blood circulation of a **heart*** (“reliable device to treat CHF”).” Ex.1003, ¶406.

ii. [1A]

Bourque-2001’s **HeartMate III LVAD** (“*a heart assist pump device*”) “comprises...**an inflow subassembly** [*‘an inflow tube’*] **that includes a left ventricular (LV) cannula** [*‘a suction end’*]” (Ex.1007, 401) as shown:



Ex.1007, Fig. 1A; Ex.1003, ¶412.

The “**HeartMate III LVAD**” is “*deliverable to the heart*” so that the “**inflow cannula**” is “implanted...via left ventricular apical cannulation” (Ex.1007, 403) *into a ventricle of the heart* as shown:

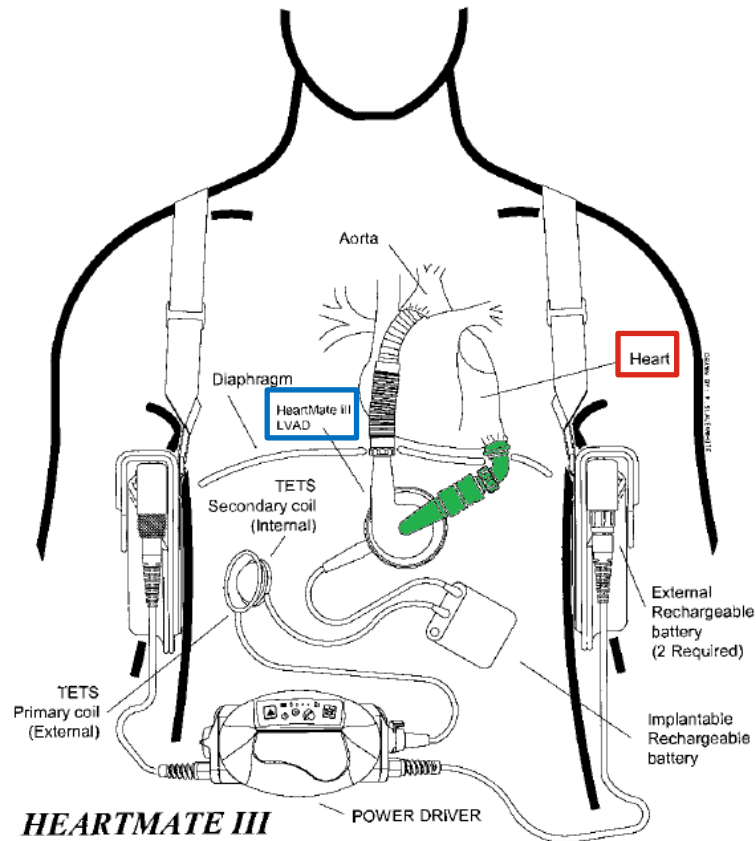


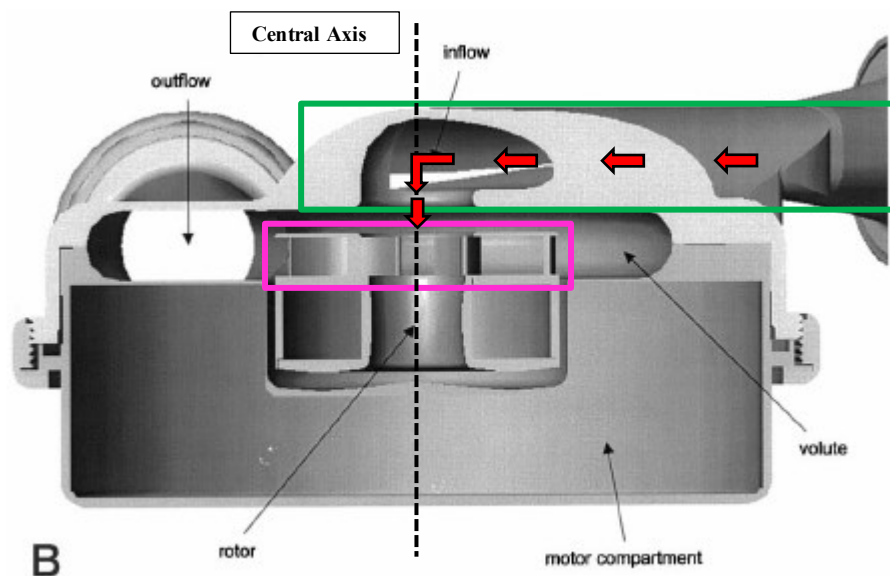
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. Ex.1003, ¶411.

Accordingly, Bourque-2001 discloses “*a heart assist pump device* (“HeartMate III LVAD”) deliverable to the *heart* and comprising: an *inflow tube defining a blood inflow path* (“an inflow subassembly that includes a left ventricular (LV) cannula”) and having a suction end insertable into *a ventricle of the heart* (“left ventricular apical cannulation”).” Ex.1003, ¶413.

iii. [1B]

Bourque-2001 discloses “a rotor that includes an **impeller** and passively magnetic elements” (“a magnetically driven rotor assembly”) that *is axially aligned with the “inflow subassembly”* to “permit...fluid leaving the inflow conduit to enter the **impeller**” (**red** arrows) at “the rotational axis of the pump’s rotor” (Ex.1007, 402) as shown:

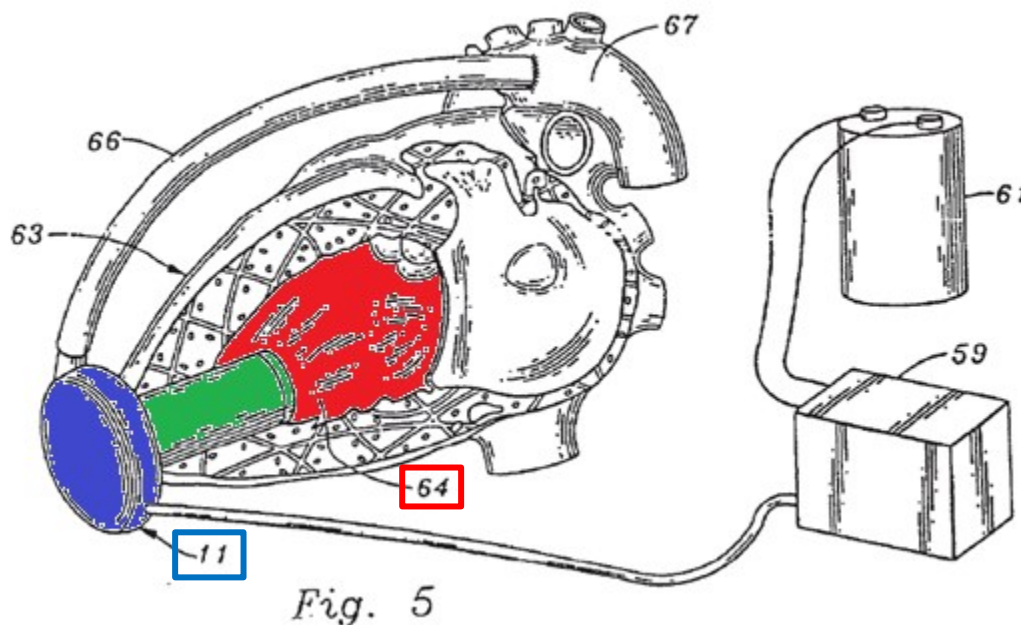


Ex.1007, Fig. 1B. Ex.1003, ¶419. Further, as demonstrated in [1A] and shown above in Fig. 1B, the **impeller** is “*spaced apart from the suction end*” of the **inflow subassembly**.

This inflow subassembly further comprises an “elbow” that “result[s] in a sharp bend in the flow before it enters the impeller.” Ex.1007, 402. Ex.1003, ¶420. Nevertheless, by virtue of Bourque-2001’s device being “a centrifugal pump,” its

“**impeller**” is axially aligned with the “**inflow subassembly**” as flow “leav[es] the inflow conduit to enter the impeller.” Ex.1007, 402. Indeed, axial inflow is characteristic of centrifugal pumps. Ex.1003, ¶421.

To the extent one asserts that Bourque-2001 does not disclose this limitation, as detailed below (*infra* §VIII.B.9), it would have been obvious to modify Bourque-2001’s “impeller” to “*be axially aligned with*” the “inflow subassembly” in view of Wampler-169. Bourque-2001 taught that the “elbow” of its “centrifugal pump” was **flow restrictive**. Ex.1007, 402. Wampler-169, however, appreciated that “[t]he centrifugal design of the pump allows...a 90 degree redirection of the blood [] **without the necessity of a flow-restrictive elbow fitting**” (Ex.1008, [0076], as shown:



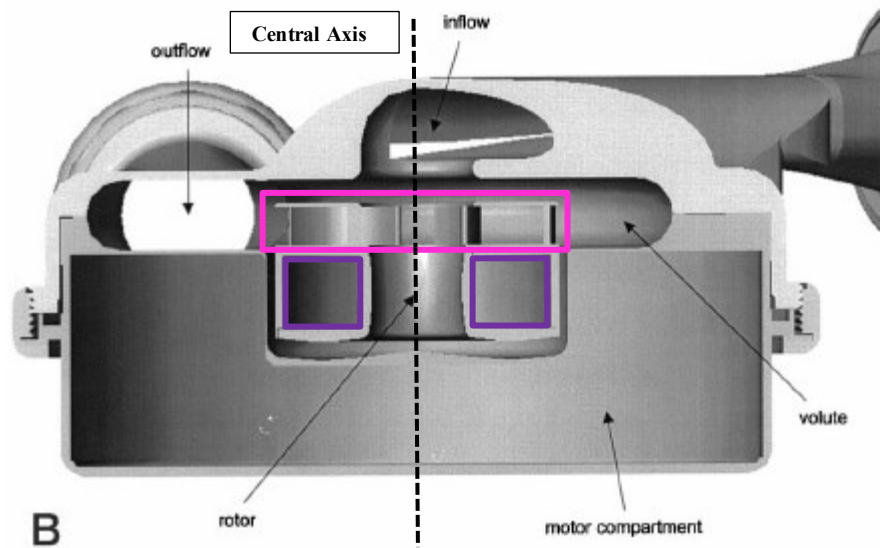
Ex.1008, Fig. 5. Ex.1003, ¶¶423-424.

Mr. Crosby explains (*infra* §X.B.13) that a POSITA would have been motivated with a reasonable expectation of success to modify the HeartMate III “inflow subassembly” to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler-169, resulting in an “*axially aligned...inflow tube*.” Ex.1007, 402; Ex.1008, [0076], Fig. 5; Ex.1003, ¶425.

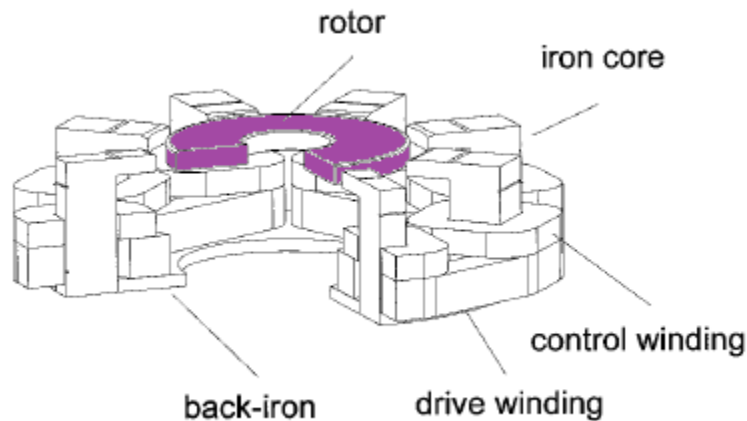
Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest a “*magnetically driven rotor assembly*” (“rotor includes an impeller and passively magnetic elements”) *configured to be axially aligned with the inflow tube* (“an inflow subassembly”; “inlet tube 16 [that] serves as the inflow cannula”) *and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle*.” Ex.1003, ¶426.

iv. [1C]

Bourque-2001 discloses that the “rotor includes an *impeller* and *passively magnetic elements*” (“*first magnetic device*”) (Ex.1007, 401) which are *rigidly coupled* and “*adjacent*” along “the rotational axis of the pump’s rotor” (Ex.1007, 401-402) as shown:



Ex.1007, Fig. 1B. Ex.1003, ¶431.



Ex.1007, Fig. 4, 402-403. Ex.1003, ¶430.

In Parallel Litigation, PO asserts that a similar arrangement of an impeller and magnetic elements satisfies this limitation. Ex.1019, 5-8.

Accordingly, Bourque-2001 discloses that “*the magnetically driven rotor assembly* (“impeller”) *comprising a first magnetic device* (“passively magnetic

elements”) *that is rigidly coupled to and axially adjacent to a rotor* (“impeller”).”

Ex.1007, 401-402; *supra* [1K]; Ex.1003, ¶433.

v. [1D]

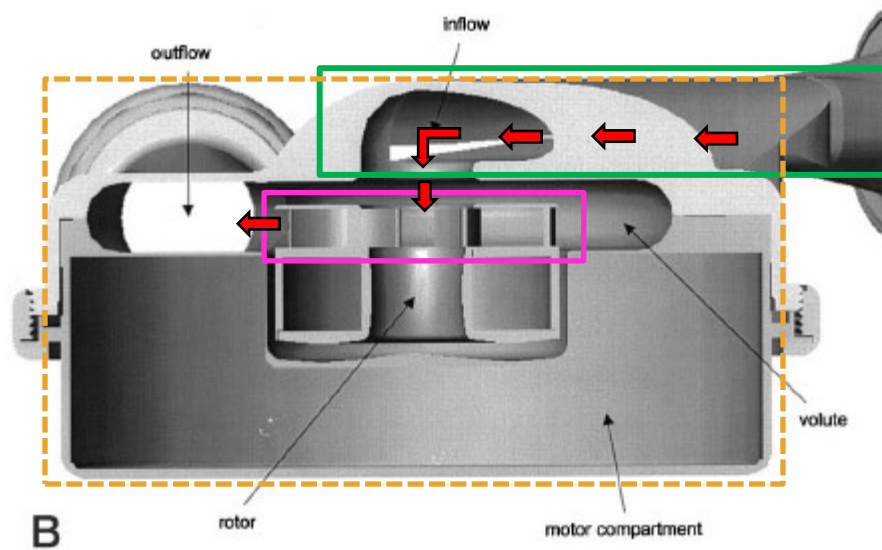
Bourque-2001 discloses that “blades of the impeller” (“*guide surfaces*”) “direct[] [the flow] toward the outflow” (“*produce centrifugal flow components*”).

Ex.1007, 402. Further, by virtue of its “centrifugal” design, the impeller produces centrifugal flow components. Ex.1007, 401; Ex.1003, ¶435.

Accordingly, Bourque-2001 discloses the *rotor* (“impeller”) “*having guide surfaces* (“blades”) *to produce centrifugal flow components.*” Ex.1003, ¶437.

vi. [1E]

Bourque-2001 discloses that its “HeartMate III...comprises an upper *housing*” that is clamped together by a “screw ring” with “a lower *housing* that includes...a cavity for the rotor” (“*rotatable...within a surrounding stationary housing*”) Ex.1007, 401. Bourque-2001 further discloses that “[a]n opening in the...rotor[] permits fluid [(red arrows)] leaving the *inflow conduit* to enter the *impeller*” (Ex.1007, 402) (“*to act upon blood flowing from the inflow tube to the rotor*”), as shown:

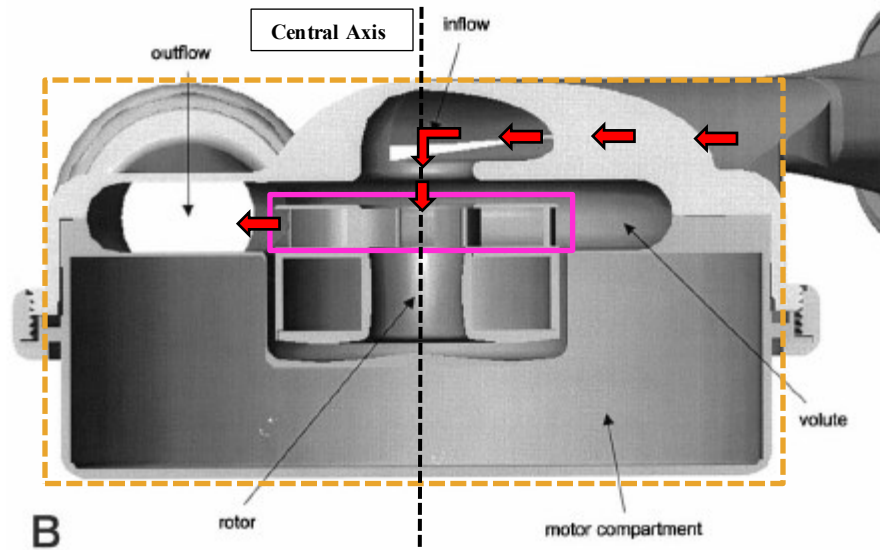


Ex.1007, Fig. 1B; *see also* Fig. 8 (showing flow measurements of impeller “act[ing] upon blood”). Ex.1003, ¶443443.

Accordingly, Bourque-2001 discloses that the “*the magnetically driven rotor assembly* (“impeller”) *being rotatable about a central axis within a surrounding stationary housing* (“upper housing and lower housing”) *to act upon blood flowing from the inflow tube* (“an inflow subassembly”) *to the rotor* (“impeller”).” Ex.1003, ¶445.

vii. [1F]

Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” so that “gaps permit [movement] in any direction without contact between the [impeller] and housing” (“spaced apart”) to allow “flow” “above and below the rotor” (Ex.1007, 402) (“gap sized for passage of the blood”), as shown:



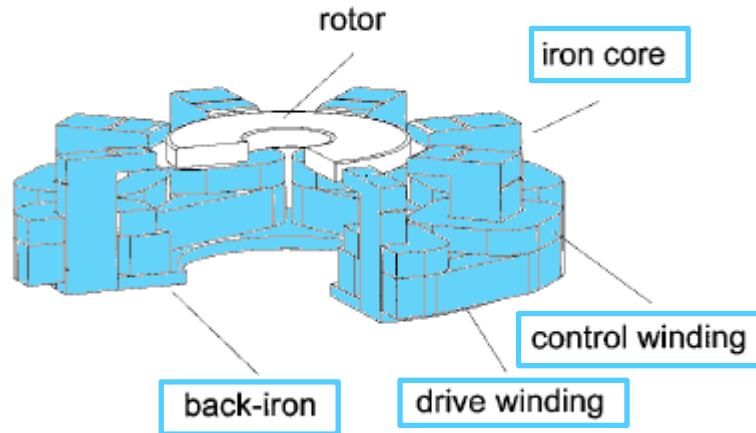
Ex.1007, Fig. 1B; Ex.1003, ¶448.

Accordingly, Bourque-2001 discloses that “the *magnetically driven rotor assembly* (“impeller”) is entirely spaced apart from the *stationary housing* (“upper housing and lower housing”) by a gap (“gaps”) sized for passage of the blood.”

Ex.1007, 401-402; Ex.1003, ¶450.

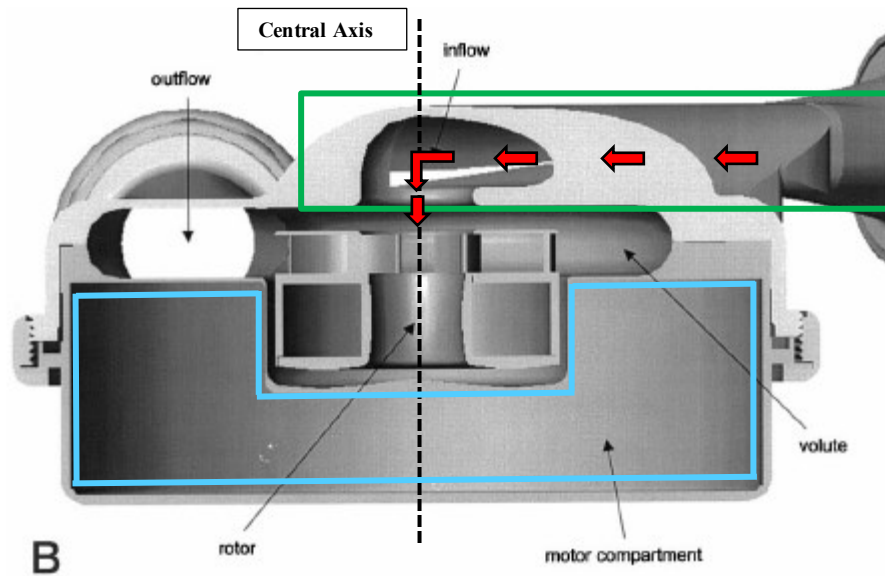
viii. [1G]

Bourque-2001 discloses that the “HeartMate III *motor* includes drive and levitation in a single magnetic structure as shown in Figure 4” (“a second magnetic device”) (Ex.1007, 402-403):



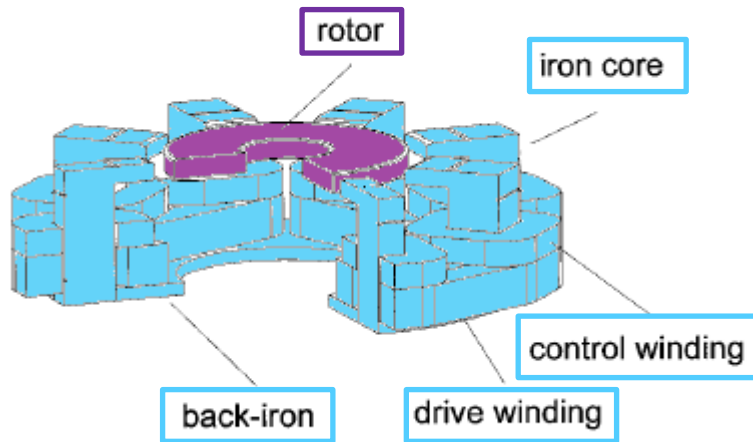
Ex.1007, Fig. 4; Ex.1003, ¶454.

Bourque-2001 discloses that “[t]he pump components were designed to achieve the desired flow paths [and] accommodate the **motor**” (Ex.1007, 402), which resulted in the **motor** being *axially aligned with the inflow subassembly* due to the “design to fit around the optimal hydrodynamic arrangement” (Ex.1007, 4024), as shown:



Ex.1007 at Fig. 1B, 401-403; Ex.1003, ¶455. As demonstrated in [1B], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the **motor** be *axially aligned with the inflow subassembly*. Ex.1003, ¶461.

As shown in Figure 4, “the motor’s ‘J’ core configuration (i.e., the stator laminations are J shaped)” (Ex.1007, 404) is *positioned to magnetically drive rotation...via a magneto coupling* with the “**passively magnetic elements**”:

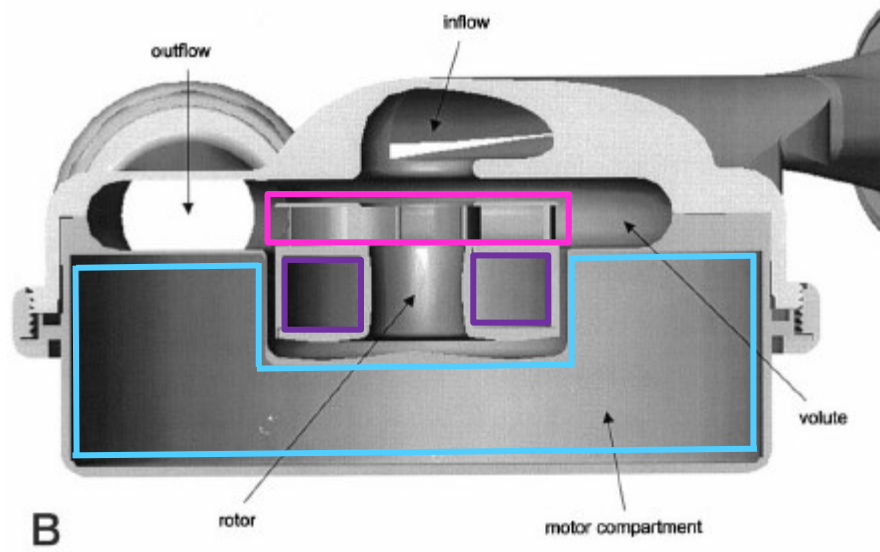


Ex.1007, Fig. 4, 402-404; Ex.1003, ¶457, *see also* ¶¶458-459 (discussing speed and flow rates).

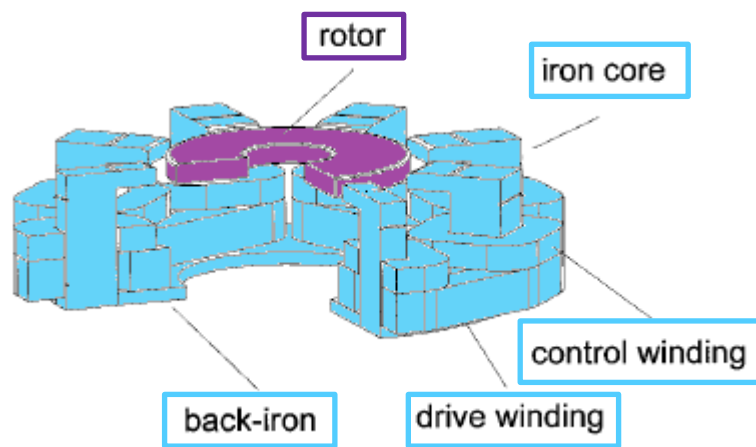
Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, discloses a **second magnetic device** (“motor”) is “axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** (“impeller”) via a magneto coupling with the **first magnetic device** (“passively magnetic elements”).” Ex.1003, ¶462.

ix. [1H]

Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (“*spaced apart*”) (Ex.1007, 402-403) to prevent “contact between the rotor and housing” “in which the motor is enclosed” (“*sealed*”) (Ex.1007, 402; *supra* [1J]) so that the **motor** is *spaced apart and sealed* from the rotor’s **impeller** and **magnetic elements** (Ex.1007, 402-403), as shown:



Ex.1007, Fig. 1B; Ex.1003, ¶467.



Ex.1007, Fig. 4; Ex.1003, ¶468.

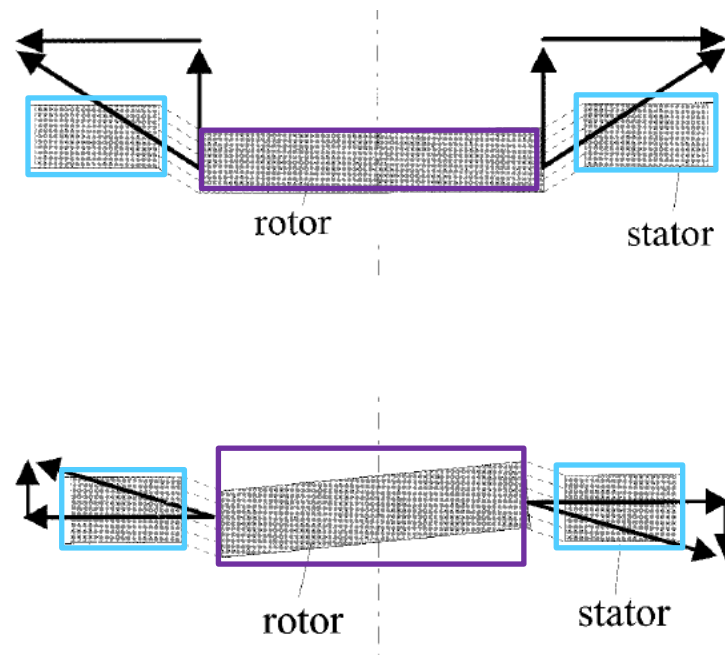


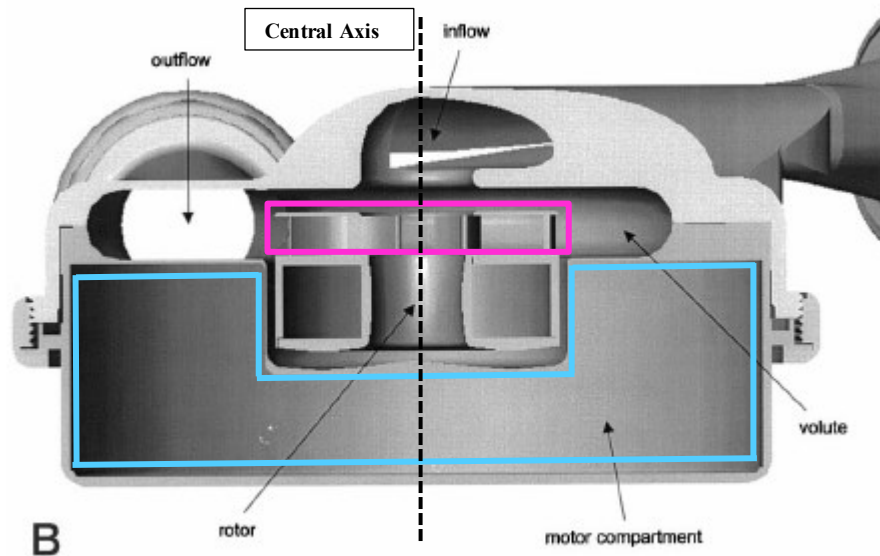
Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5, 401; Ex.1003, ¶468. Bourque-2001 discloses that “the pump components were designed to achieve the desired flow paths”—from the “inflow section,” through the impeller, “toward the outflow” (“sealed...by at least one sealing wall”). Ex.1007, 402; Ex.1003, ¶467.

Accordingly, Bourque-2001 discloses its **second magnetic device** (“motor”) is “spaced apart and sealed from both the **rotor** (“impeller”) and the **first magnetic device** (“passively magnetic elements”) of the **magnetically driven rotor assembly**.” Ex.1003, ¶469.

x. [1I]

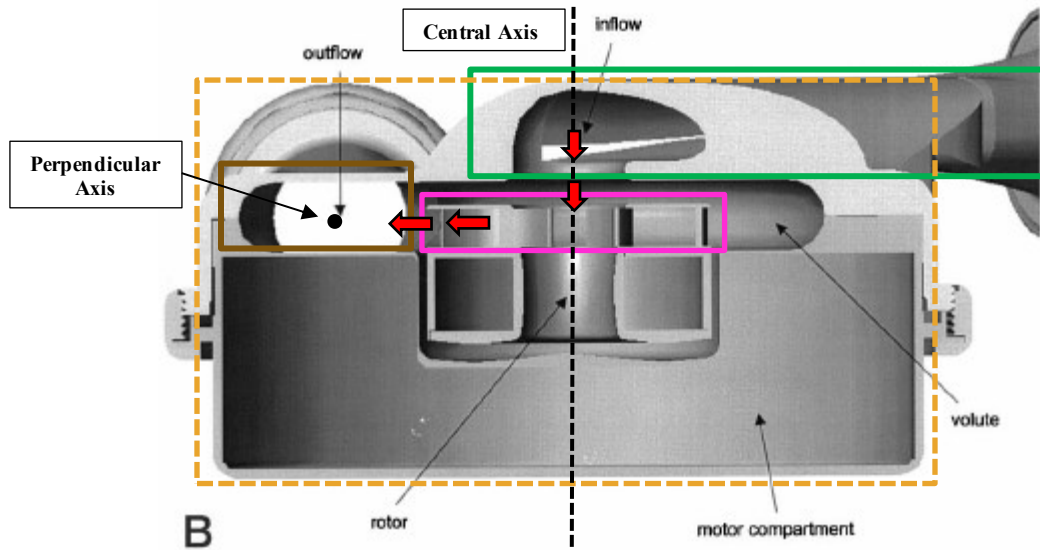
As demonstrated in [1H], Bourque-2001 discloses its **motor** is “*positioned axially spaced apart from the guide surfaces (“blades”) of the rotor (“impeller”),*” as shown:



Ex.1007, Fig. 1B; Ex.1003, ¶¶472-474.

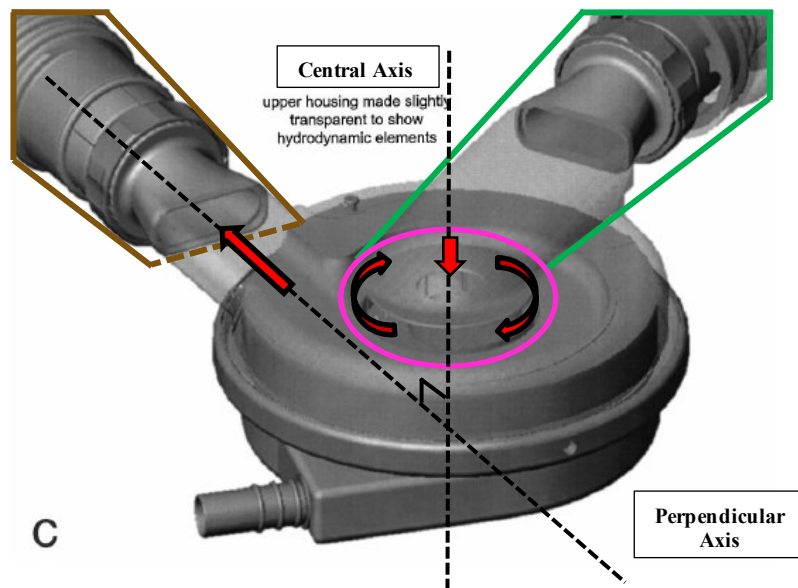
xi. [1J]

Bourque-2001 discloses that the pump comprises an “**outflow** channel” (Ex.1007, 401) (“*a blood outflow port*”) and that the blood’s “flow path is...through the **inflow** and **outflow** sections” so that “the flow...enters the **impeller**” (Ex.1007, 402) (“*blood is driven by the magnetically driven rotor assembly*”), which then “direct[s] [the flow] toward the **outflow**” (“*exits...in a direction substantially perpendicular to the central axis*”) (Ex.1007, 401-402), as shown (**red** arrows):



Ex.1007, Fig. 1B; Ex.1003, ¶480.

Figure 1C illustrates that the blood's “flow paths” (Ex.1007, 402; **red** arrows) are “*configured to exit...in a direction substantially perpendicular to the inflow*”:



Ex.1007, Fig. 1C; Ex.1003, ¶481.

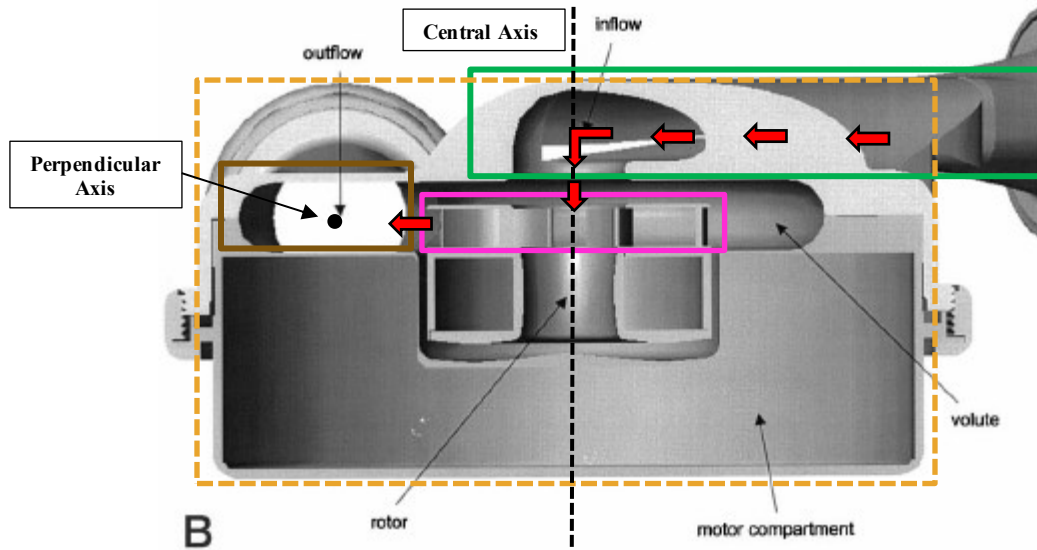
To the extent one asserts that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 for the same reasons discussed in [1B] that there would be “a 90-degree [*perpendicular*] redirection of the blood.” Ex.1003, ¶423; *infra* §[1B]; Ex.1008, [0076].

Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest that “a **blood outflow port** (“outflow channel”) *positioned radially adjacent the guide surfaces of the rotor* (“impeller”) *such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing* (“upper housing and lower housing”) *in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly.*” Ex.1003, ¶482.

xii. [1K]

In Parallel Litigation, PO asserts that a magnetic bearing (i.e., “MagLev”) satisfies this limitation. Ex.1019, 7-8.

Assuming that interpretation, as explained in [1F]-[1G], Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (Ex.1007, 402-403) (“*magneto coupling is configured to...orient*”) so that “gaps permit [movement] in any direction without contact between the [**impeller**] and **housing**” (“*entirely spaced apart from the surrounding stationary housing*”) to allow “flow” “above and below the rotor” (Ex.1007, 402) (“*by the gap sized for passage of the blood*”), as shown:



Ex.1007, Fig. 1B; *supra* [1J]-[1L].

Bourque-2001 further discloses that the HeartMate III’s “rotor is magnetically suspended, eliminating contact” (“*remains entirely spaced apart*”).” Ex.1007 at 401. Ex.1003, ¶485.

Accordingly, Bourque-2001 discloses that “*the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly (“impeller”) and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing (“upper housing and lower housing”) by the gap sized for passage of the blood.*” Ex.1003, ¶488.

xiii. [1L]

Bourque-2001 discloses connecting “**electronics for power and control** of the **LVAD**” (“*an external control unit*”) via an “electronic cable to be exteriorized percutaneously” (“*configured to regulate*”) (Ex.1007, 401, 403), as shown:

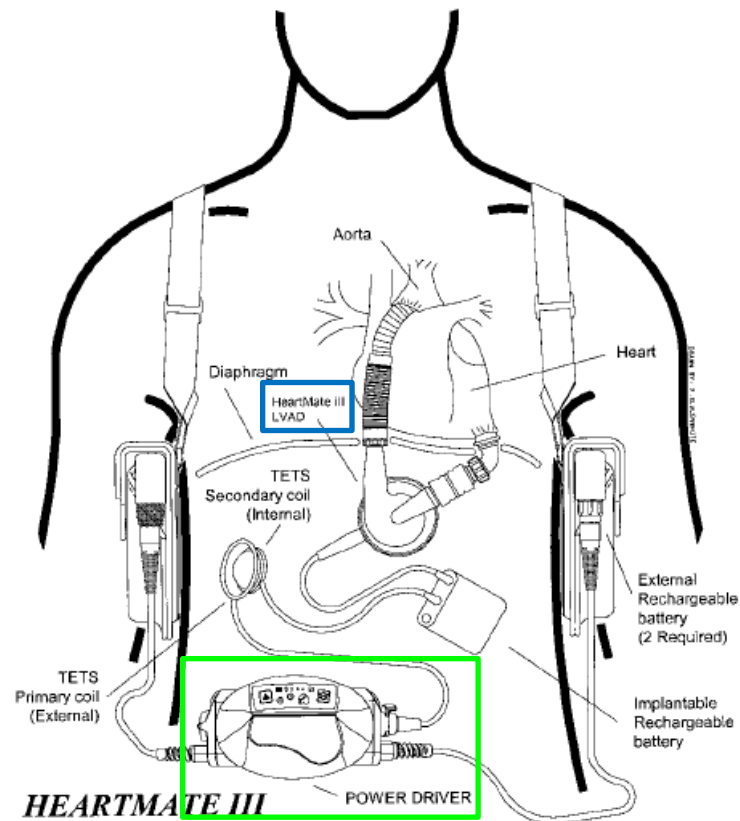


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶492.

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit (*e.g.* output as measured in liters of blood per minute) is a “*control value indicative of cardiac output.*” Ex.1019, 12. Assuming that interpretation, Bourque-2001 discloses

that “[s]peed and motor parameters [to be] set and controlled” for example, to be “gradually adjusted to maintain volume flow rates” including at “desired maximum flow (10 L/min at 135 mm Hg)” and “prescribed to run at 3,500 rpm” (“*control value*”). Ex.1003, ¶¶493-495.

Accordingly, Bourque-2001 discloses “an **external control unit** (“electronics for power and control”) *configured to regulate operation of the **second magnetic device** (“motor”) based upon a control value indicative of cardiac output* (“prescribed to run at 3,500 rpm”). ” Ex.1003, ¶497.

xiv. [1M]

See, [1G] and [1L]. Further, Bourque-2001 discloses connecting “**electronics for power and control**” to the **LVAD** via an “electronic cable to be exteriorized percutaneously” (“*connectable*”) (Ex.1007, 401, 403), as shown:

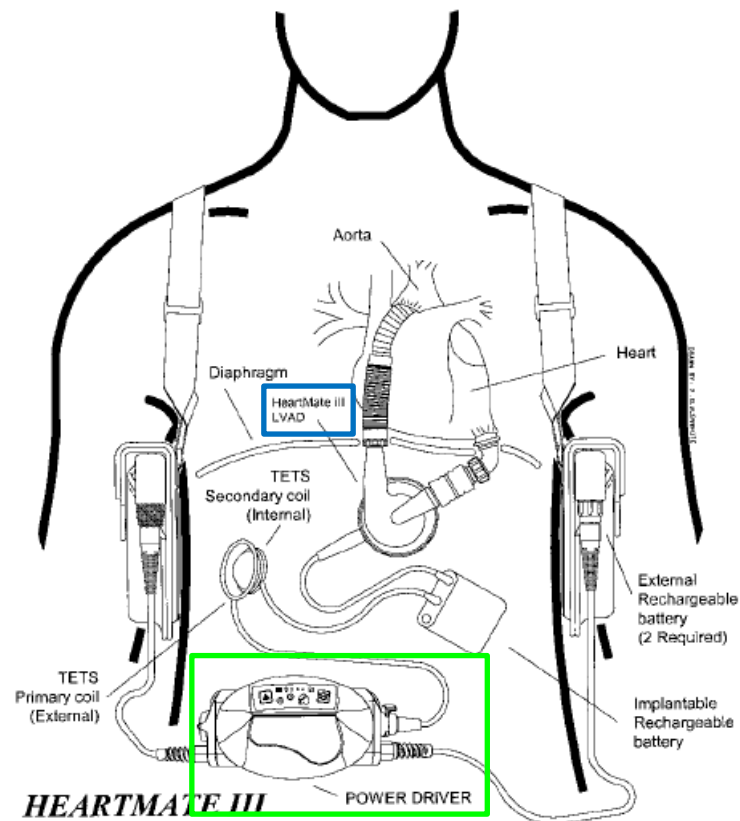


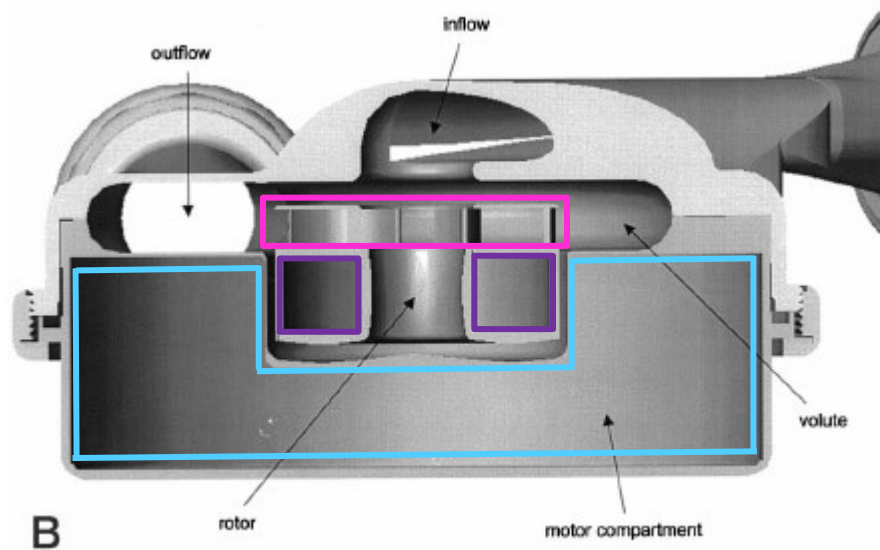
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶492.

Accordingly, Bourque-2001 discloses “the **external control unit** (“electronics for power and control”) is connectable to the **heart assist pump device** (“HeartMate III LVAD”) for controlling the **second magnetic device** (“motor”) to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** (“impeller”) via the magneto coupling with the **first magnetic device** (“passively magnetic elements”).” Ex.1003, ¶497.

2. Claim 2

As demonstrated in [1G], the rotor has “magnetic elements” “positioned between” the “impeller” and “motor” (Ex.1007, 401), as shown:



Ex.1007, Fig. 1B; *supra* [1G]; Ex.1003, ¶510.

Accordingly, Bourque-2001 discloses that “the *first magnetic device* (“passively magnetic elements”) is configured to be positioned between the *second magnetic device* (“motor”) and the guide surfaces (“blades”) of the *rotor* (“impeller”) of the *magnetically driven rotor assembly*.” Ex.1003, ¶511.

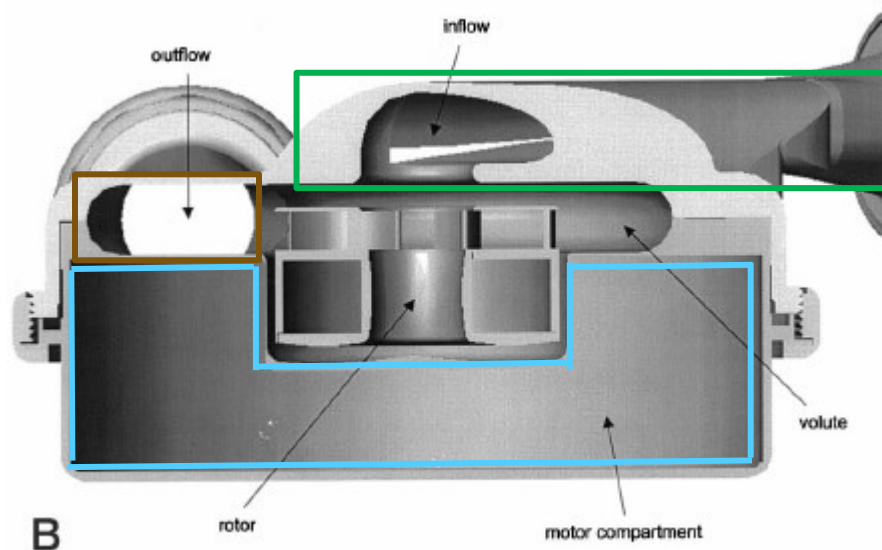
3. Claim 3

As demonstrated in [1C], the rotor’s “impeller” and “magnetic elements” are “rigidly coupled,” Bourque-2001 discloses that “the *first magnetic device* (“passively magnetic elements”) is configured to rotate together with the *rotor*

(“impeller”) *relative to the surrounding stationary housing* (“upper housing and lower housing”).” Ex.1007, 401; *supra* [1C]. Ex.1003, ¶¶515-516.

4. Claim 4

As demonstrated in [1A] and [1J], the “**left ventricular (LV) cannula**” is *insertable into a ventricle of the heart*, while the “**outflow**” is “*radially adjacent*” to the impeller which is aligned with the **motor**, as shown:



Ex.1007, Fig. 1B, 401-402; Ex.1003, ¶519.

Accordingly, Bourque-2001 discloses that “the **second magnetic device** (“motor”) is positioned closer to the **blood outflow port** (“outflow channel”) than to the suction end of the **inflow tube** (“an inflow subassembly that includes a left ventricular (LV) cannula”).” Ex.1003, ¶521.

5. Claim 5

As demonstrated in [1H] and [1M] that the *second magnetic device* (“motor”) is “*sealed*” and the electronics are “*external*,” Bourque-2001 discloses “*the magnetically driven rotor assembly* (“impeller”) *is sealed from the second magnetic device* (“motor”) *and a drive source* (“electronics for power and control”) *configured to regulate the operation of the second magnetic device.*” Ex.1003, ¶¶524-526.

6. Claim 7

Bourque-2001 discloses that “measurements were made with an ultrasonic flow probe...[and] catheter-type pressure transducers,” which Mr. Crosby explains are *sensors that deliver feedback signals* to the “**electronics for power and control.**” Ex.1007 at 403; Ex.1003, ¶¶529.

Accordingly, Bourque-2001 discloses “*one or more sensors configured to deliver feedback signals to the external control unit* (“electronics for power and control”).” Ex.1003, ¶532.

7. Claim 10

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Assuming that interpretation, because Bourque-2001’s LVAD comprises “a left ventricular (LV) cannula” (Ex.1007, 401), it “*is a catheter device.*” Ex.1003, ¶536536.

Accordingly, Bourque-2001 discloses that “*the heart assist pump device* (“HeartMate III LVAD”) *is a catheter device.*” Ex.1003, ¶537.

8. Claim 16

Claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. Ex.1003, ¶538.

i. [16PRE]

See [1PRE]. Ex.1003, ¶¶540-541.

ii. [16A]

See [1A] and [1B] (analyzing axial inflow, i.e., an “*inflow path along an inflow axis*”). Ex.1003, ¶543.

iii. [16B]

See [1E] (analyzing a “*surrounding stationary housing*” (“upper housing and lower housing”). Bourque-2001 discloses “*walls...defining a chamber*” of [16B] for the reasons it discloses a “*surrounding stationary housing*” of [1E]. Ex.1003, ¶546.

iv. [16C]

See [1B] and [1C]. Ex.1003, ¶549.

v. [16D]

See [1C]. Ex.1003, ¶552.

vi. [16E]

See [1D]. Ex.1003, ¶555.

vii. [16F]

See [1E]. Ex.1003, ¶558.

viii. [16G]

See [1B] and [1E]. Ex.1003, ¶561.

ix. [16H]

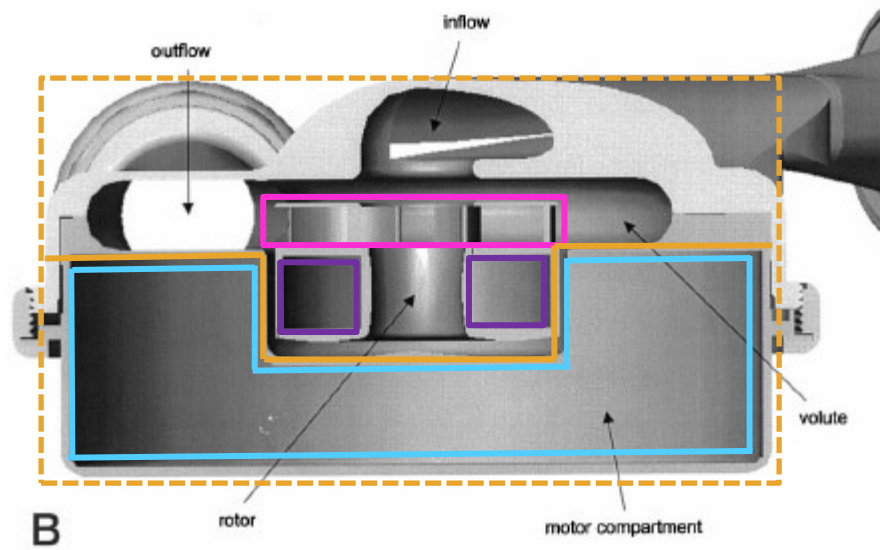
See [1G]. Ex.1003, ¶564. Bourque-2001, or Bourque-2001/Wampler-169, discloses a “*magnetic drive system comprising a second magnetic device*” of [16H] for the reasons it discloses a “*second magnetic device*” (“motor”) of [1G].

x. [16I]

See [1K] and [2]. Ex.1003, ¶567. Bourque-2001 teaches or suggests that the *second magnetic device* is “*positioned axially closer*” to the *first magnetic device* of [16I] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor assembly* of [2].

xi. [16J]

See [1H]. Ex.1003, ¶570. Bourque-2001 discloses that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J] for the reasons it discloses a “*second magnetic device*” is “*sealed*”—the lower housing’s motor compartment is sealed from the upper housing:



Ex.1007, Fig. 1B, 401.

xii. [16K]

See [1J]. Ex.1003, ¶573.

xiii. [16L]

See [1M]. Ex.1003, ¶576.

xiv. [16M]

See [1L]. Ex.1003, ¶579.

xv. [16N]

See [1M]. Ex.1003, ¶582.

9. Claim 17

See [2], [16D], and [16I]. Ex.1003, ¶586.

10. Claims 18-21

See [1F], [1K]. Bourque-2001 discloses a “gap...configured to be occupied by the blood” ([18]); that “surrounds” ([19]); “extends radially outward” ([20]) and “along a face...axially opposite from the inflow tube” ([21]) of “the magnetically driven rotor assembly” for the reasons Bourque-2001 discloses “entirely spaced apart...by a gap sized for passage of the blood” of [1F] and [1K]—i.e., the gap extends entirely surrounding the *magnetically driven rotor assembly*. Ex.1003, ¶¶595, 599, 603, 607.

11. Claim 22-23

See [16J]. Bourque-2001 discloses a “*wall of the...chamber* separates the first chamber from the second chamber” of [22]-[23] for the reasons that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J]. Ex.1003, ¶¶617-618, 622.

12. Claim 24

See [1C], [16C]. Ex.1003, ¶627.

13. Claim 26

See [7]. Ex.1003, ¶631.

14. Claim 28

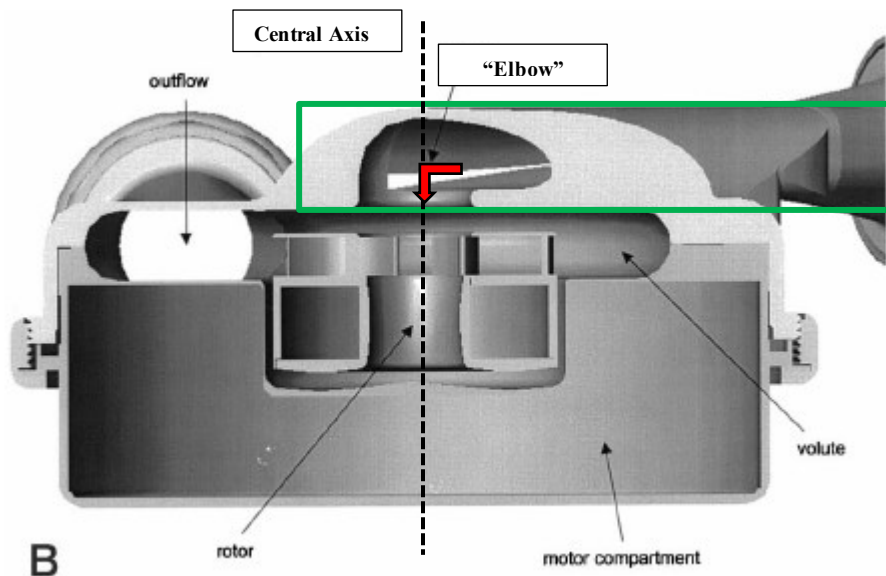
See [10]. Ex.1003, ¶635.

15. Motivation to Combine Bourque-2001 with Wampler-169

It would have been obvious to include Wampler-169's techniques related to its *axially aligned inflow tube* in the Bourque-2001 HeartMate III for the reasons explained below. Ex.1003, ¶637.

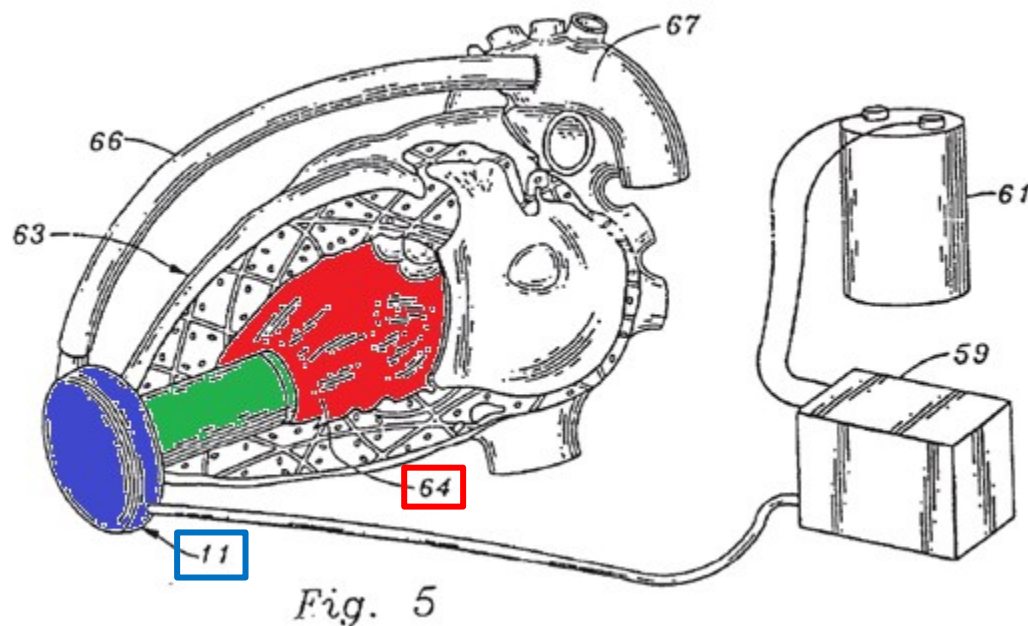
A POSITA would have recognized that, by virtue of the “centrifugal design,” both Bourque-2001's HeartMate III and Wampler-169's pump comprise “axial inflow and radial outflow” that result in “a 90 degree redirection of the blood.” Ex.1003, ¶638; Ex.1008, [0075]-[0076]; Ex.1007, 402.

The HeartMate III's *inflow tube* (“inflow subassembly”), however, also comprises an “elbow”—“a sharp bend in the flow before it enters the impeller”—as shown by **red** arrow:



Ex.1007, Fig. 1B, 402; Ex.1003, ¶¶642-643 (discussing a different “elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans”).

Wampler-169 expressly teaches that “[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation” because “a 90-degree redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting.**” Ex.1008, [0076]. As demonstrated in Ground 1, Wampler-169’s **pump** has an “**inlet tube 16** [that] serves as the inflow cannula and is placed into the apex of the **left ventricle 64**,” thereby eliminating the need for any elbow or additional inflow assembly, as shown:



Ex.1008, Fig. 5. Ex.1003, ¶643. With this design, “[g]ood anatomic compatibility is possible...fitting well between the apex of the heart and the adjacent diaphragm.” Ex.1008, [0076].

A POSITA would have been motivated to apply the teachings of Wampler-169 to Bourque-2001 to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex of the left ventricle as expressly taught by Wampler-169 for several reasons. Ex.1003, ¶648.

Bourque-2001 and Wampler-169 are analogous art to the 077 Patent because both are directed toward the same field of endeavor—“to assist the performance of a heart with...a rotary pump and driven via magneto coupling.” Ex.1001, Abstract; 3:50-51; Ex.1007, 401; Ex.1008, [0006], [0018]. Ex.1003, ¶645. Bourque-2001 and Wampler-169 are reasonably pertinent to a problem described by the 077 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:27-32; Ex.1007, 401; Ex.1008, [0101]. Ex.1003, ¶646.

A POSITA would have recognized that the Bourque-2001/Wampler-169 combination would have been the arrangement of old elements (an inflow subassembly, inlet tube, and inflow cannula) with each performing the same function it has been known to perform (allowing blood to flow from the ventricle to the pump) and yielding no more than one would expect from such an arrangement (blood

flowing from the ventricle to the pump) as Wampler-169 demonstrates. Ex.1007, 401; Ex.1008, [0075]; Ex.1003, ¶647.

Bourque 2001 itself confirms that a POSITA would recognize that its “elbow” was **flow restrictive**—the flow had to be “accelerated through this elbow” “[t]o minimize the losses in this transition.” Ex.1007, 402. Because Wampler-169 expressly teaches that this type of elbow was unnecessary (Ex.1003, ¶¶648-649; Ex.1008, [0075]-[0076]), a POSITA would have recognized Wampler-169’s teachings that an axial inflow can also serve as the inflow cannula to be complimentary to Bourque 2001 to improve blood flow. Ex.1003, ¶649.

A POSITA would have been further motivated for several reasons.

Bourque 2001 itself recognized that peripheral hardware, such as its “inflow...components” and “recovery section,” “account for most of the...clinical troubles.” Ex.1007, 405. Wampler-169 taught how to eliminate these components that caused clinical troubles—using the inlet to also “serve[] as the inflow cannula.” Ex.1003, ¶¶643-649; Ex.1008, [0075]-[0076]. A POSITA would have recognized Wampler-169’s dual-functioning inlet to be complimentary to Bourque 2001’s “fundamental goal” and been motivated to “design” the pump “in the simplest possible way.” Ex.1007, 401. Ex.1003, ¶649.

A POSITA would have further been motivated to reduce rates of infection by adhering to Wampler-169’s focus on “[g]ood anatomic compatibility” over Bourque-

2001's focus on “borrowing” from “presently available Heart-Mate systems” like the “HeartMate II.” Ex.1007, 403, 405. The HeartMate III’s “elbow” “resulted” from a design “decis[ion]” “[t]o orient the pump” below the “diaphragm” in a preperitoneal pocket position, as shown:

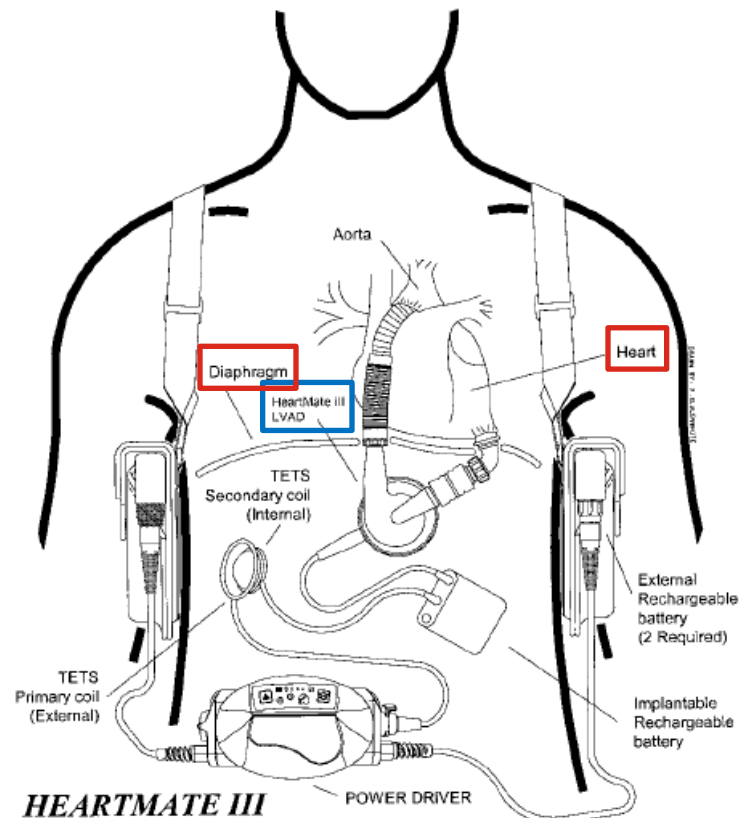


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶650. This pocket position (below the diaphragm) resulted from Bourque-2001's aim to utilize the “peripheral hardware (i.e., inflow and outflow components)” of its predecessor “Heart-Mate systems.” Ex.1003, ¶651.

In addition to “borrowing” “inflow and outflow components” from the predecessor systems, Bourque-2001 also used similar “surgical techniques” for a “pump pocket dissection” as used to implant the “HeartMate II” below the diaphragm in a “preperitoneal pocket,” as shown:

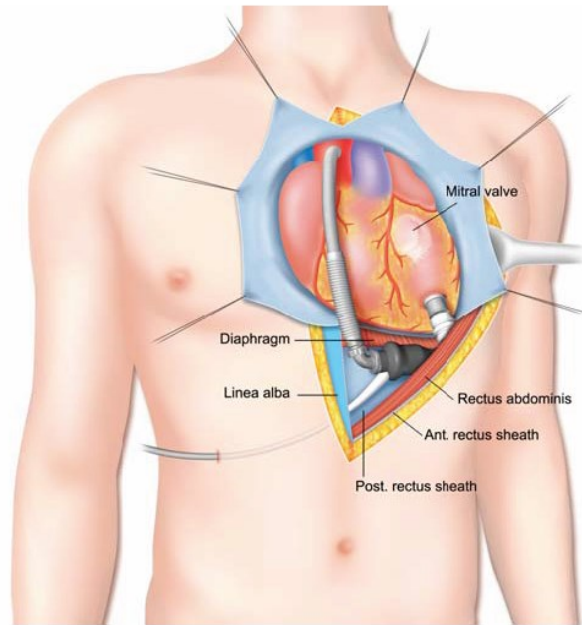


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

Ex.1013, 25; Ex.1003, ¶650 (citing Ex.1007, Ex.1013; discussing that both HeartMate II and III were “implanted...via left ventricular apical cannulation and anastomosis to the descending aorta.”).

But the prior art taught, and a POSITA would have recognized, the “disadvantage[]” of a “preperitoneal pocket position” due to the “increased risk of infection.” Ex.1014, 1442; Ex.1013, 25-26; Ex.1003, ¶650. Instead of borrowing

parts from predecessor systems, a POSITA would have adhered to the express teachings of Wampler-169, which focused on “[g]ood anatomic compatibility” so that the device “fit[s] well between the apex of the heart and the adjacent diaphragm,” eliminating the need for a peritoneal pocket dissection associated with increased rates of infection. Ex.1008, [0076]. Ex.1003, ¶¶651-654.

Further, Mr. Crosby explains a POSITA would have had a reasonable expectation that Bourque-2001/ Wampler-169 would be successful because the authors of Bourque-2001 specifically taught that modifying the HeartMate III with “an inflow cannula apical tube 45, which is inserted into the apex of the left ventricle,” like the Wampler-169 technique, is “not complex” and is “well-known in the art.” Ex.1018, 6:62-7:5. A POSITA would also have had a reasonable expectation of success that the Bourque-2001/ Wampler-169 combination would “fit[] well between the apex of the heart and the adjacent diaphragm” due to the pump’s “development as a compact” device and the existence of several similar LVADs that fit well at that position. Ex.1007, 405; Ex.1003, ¶¶652-655 (analyzing LVADs that fit at the apex of the heart, including Wampler-169, Akamatsu-1999, and HVAD).

Moreover, the Bourque-2001/ Wampler-169 combination would have been obvious to try. At the time of the claimed invention, it was within the general knowledge of a POSITA that there were a finite number (i.e., two) options for LVAD implantation: the device would be implanted at a preperitoneal pocket, or at the

cardiac apex. Ex.1003, ¶656. To implant the device at the cardiac apex, a POSITA would have used the Bourque-2001/Wampler-169 combination, because that technique was common for implanting at that position. Ex.1006, Fig. 1; Ex.1008, [0075]-[0076]; Ex.1015. A POSITA would thus have had a reasonable expectation of success in view of several similar LVADs that fit well at that position. Ex.1006, Fig. 1; Ex.1008, [0075]-[0076]; Ex.1015. Ex.1003, ¶656.

Accordingly, it would have been obvious to modify Bourque-2001's pump to include Wampler's techniques to use an *axially aligned inflow tube* to yield the Bourque-2001/Wampler-169 combination. Ex.1003, ¶657; *see also* ¶¶637-656.

C. Ground 3: Akamatsu-1999 Renders Obvious the Challenged Claims

1. Claim 1

i. [IPRE]

Akamatsu-1999 discloses a “left ventricular assist system (T-ILVAS),” which is a “**centrifugal pump**,” for “an implantable circulatory assist system” for the heart (**red**) (Ex.1006, 1), as illustrated in Figure 1:

ii. [1A]

Akamatsu-1999 discloses its “centrifugal pump” (“*heart assist pump device*”) has an “**inlet port**” or “inflow conduit” (“*an inflow tube defining a blood inflow path and having a suction end*”) (Ex.1006, 2):

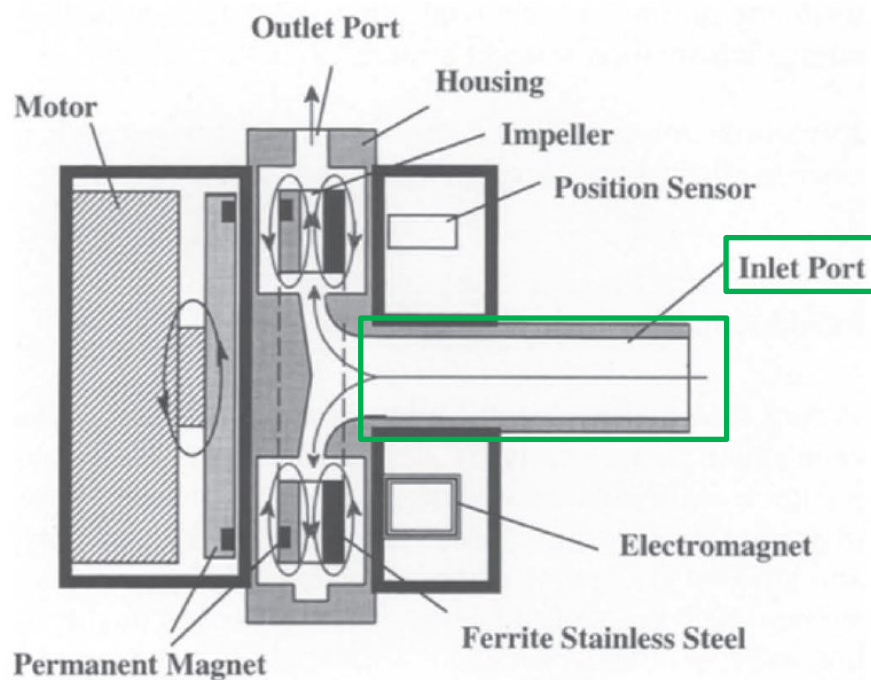


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶664.

The **pump** is “*deliverable to the heart*” so that its **inlet port** is “inserted into the left ventricle” (“*insertable into a ventricle of the heart*”):

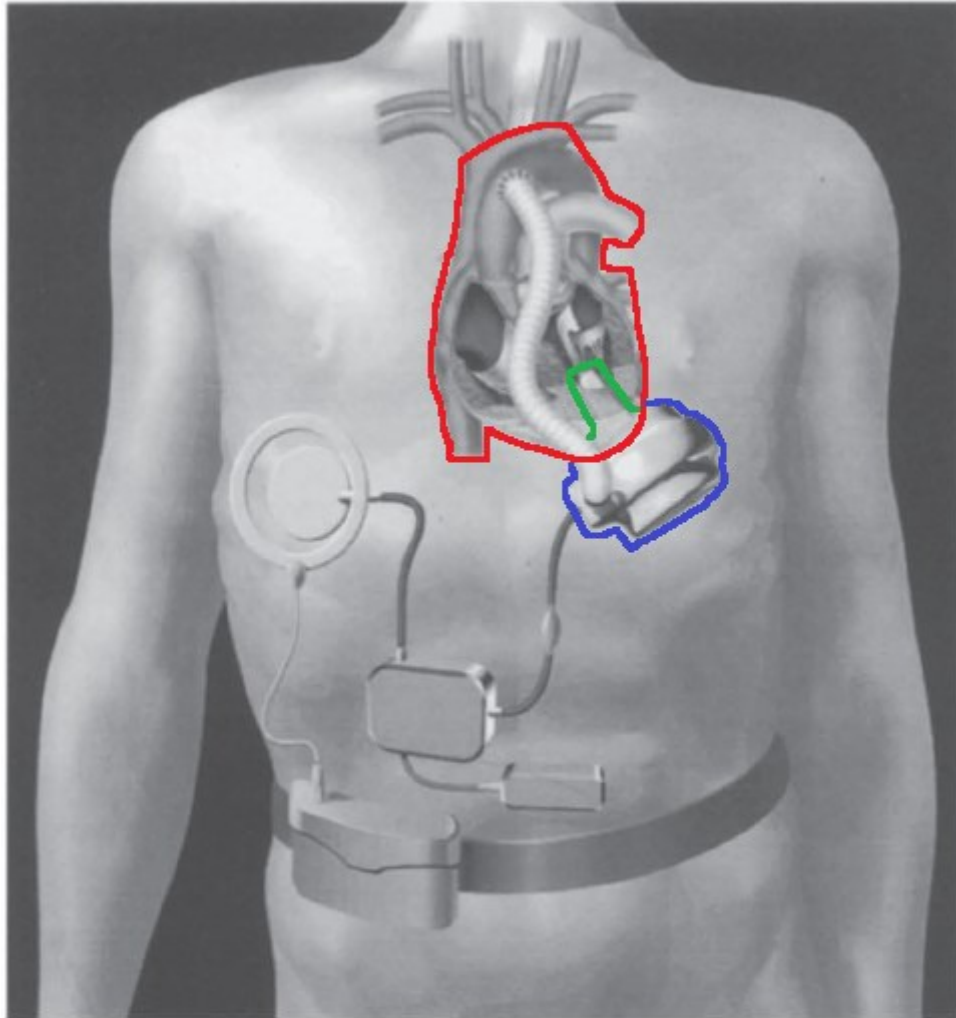


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶665.

Accordingly, Akamatsu-1999 discloses “*a heart assist pump device* (“centrifugal pump”) *deliverable to the heart* and comprising: an *inflow tube defining a blood inflow path* (“inlet port”) and having a suction end insertable into *a ventricle of the heart* (“inserted into the left ventricle”).” Ex.1003, ¶666.

iii. [1B]

Akamatsu-1999 discloses that its pump comprises an “**impeller** [that] rotates by a magnetic coupling” (“*a magnetically driven rotor assembly*”) and that the “**impeller** [is] inside the pump” (“*spaced apart from the suction end*”) Ex.1006, 2. By virtue of Akamatsu-1999’s “centrifugal” design, its “**impeller**” is “*axially aligned with the*” “**inlet port**,” (Ex.1006, 2), as illustrated:

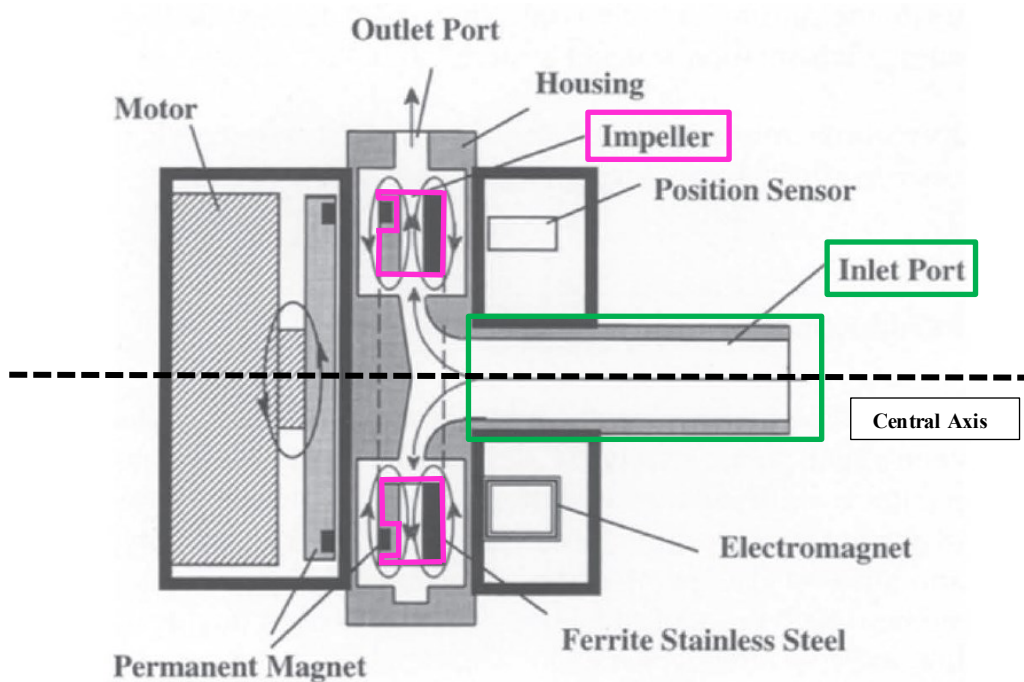


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶673; *see also* Ex.1006, Fig. 5 (photograph of “impeller”).

Accordingly, Akamatsu-1999 discloses that a “**magnetically driven rotor assembly** (“impeller”) *configured to be axially aligned with the inflow tube* (“inlet port”) and to be spaced apart from the suction end when the *suction end of the inflow tube* is inserted into the **ventricle**.” Ex.1003, ¶677677.

iv. [1C]

Akamatsu-1999 discloses that its “**impeller**” is “*rigidly coupled*” and “*axially adjacent to*” a “[p]ermanent [m]agnet” (“a first magnetic device”), as illustrated in Figure 2:

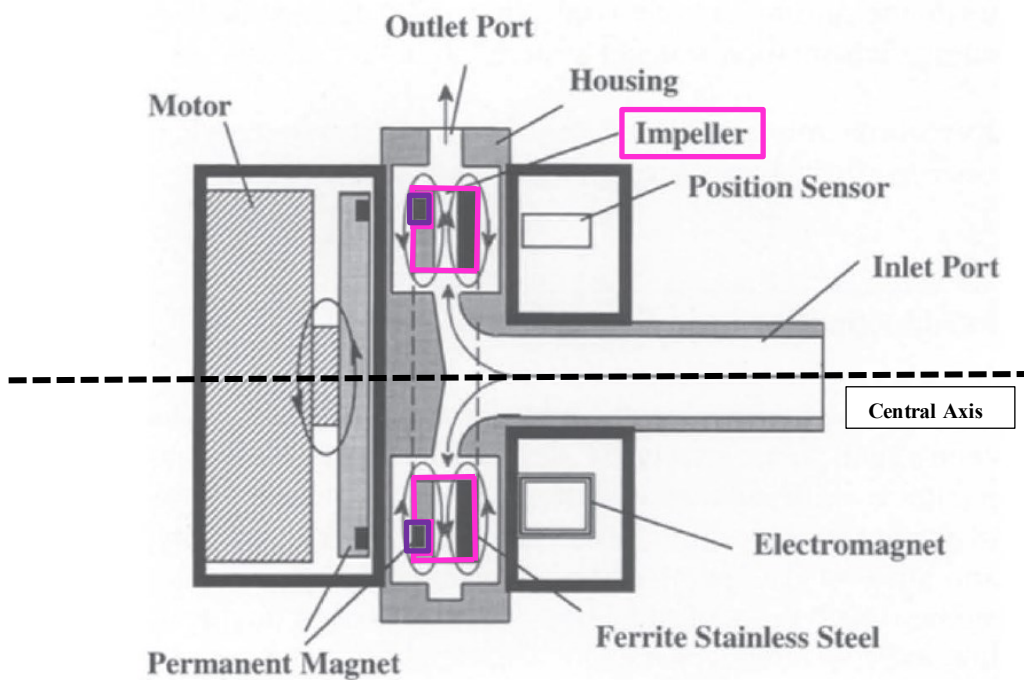
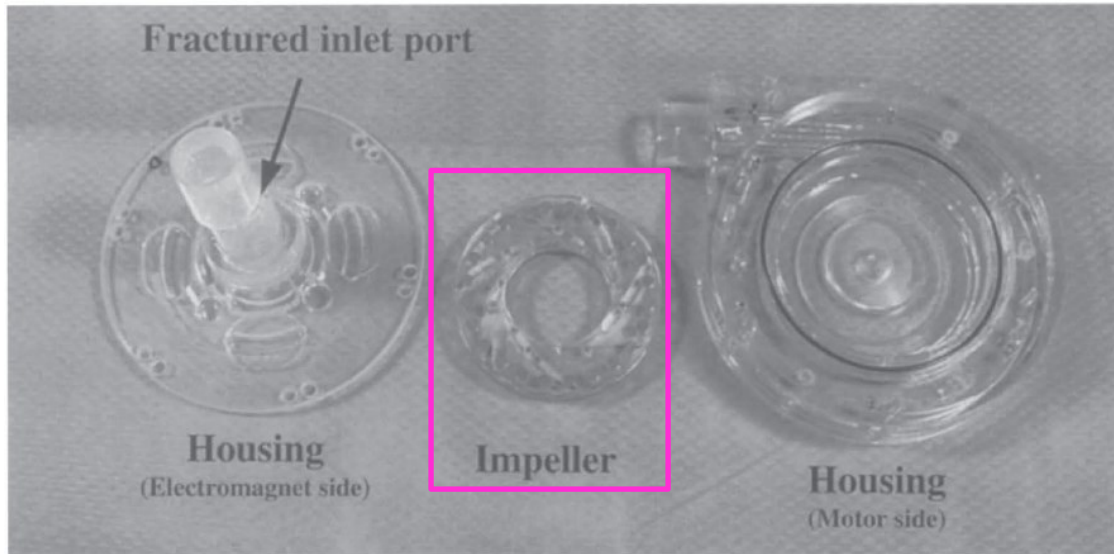


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶682. As Mr. Crosby explains, Figures 2 and 5 show that the “permanent magnet” is *rigidly coupled* to the impeller:

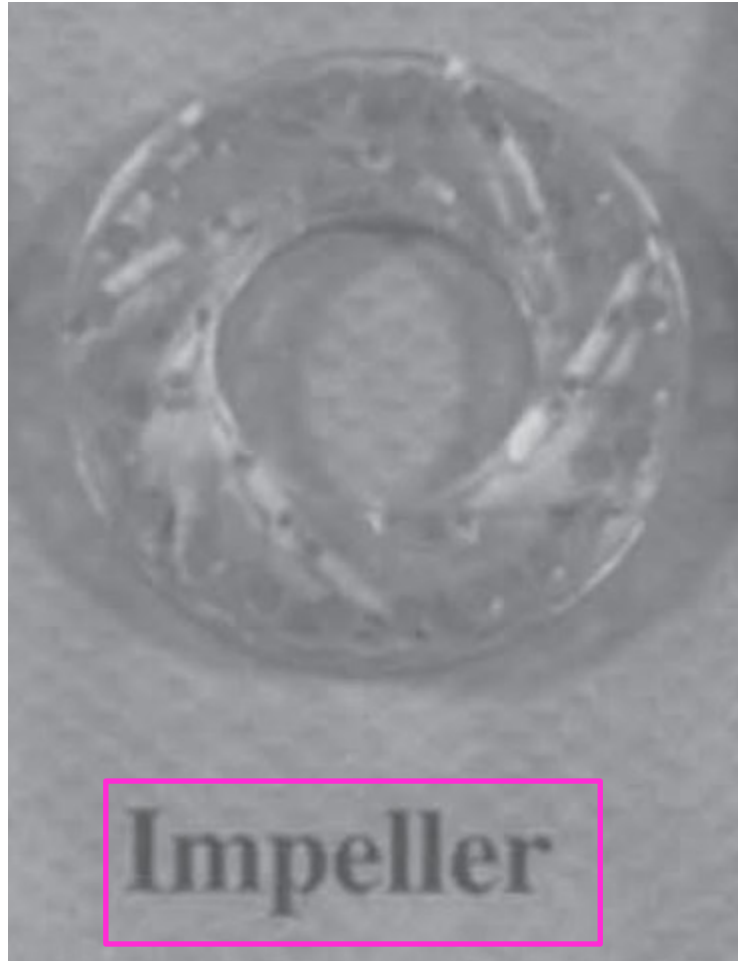


Ex.1006, Fig. 5; Ex.1003, ¶¶675, 682.

Accordingly, Akamatsu-1999 discloses that “the *magnetically driven rotor* (“impeller”) comprising a *first magnetic device* (“permanent magnet”) that is rigidly coupled to and axially adjacent to a *rotor*.” Ex.1003, ¶683.

v. [1D]

Akamatsu-1999 discloses that the “*impeller*” has blades or edges, which Mr. Crosby explains are *guide surfaces* (Ex.1003, ¶686):



Ex.1006, Fig. 5; Ex.1003, ¶685. By virtue of being “a centrifugal pump,” the rotor and guide surfaces *produce centrifugal flow components*. Ex.1006, 3; Ex.1003, ¶686.

Accordingly, Akamatsu-1999 teaches or suggests that the **rotor** (“impeller”) “*having guide surfaces to produce centrifugal flow components.*” Ex.1003, ¶687.

vi. [1E]

Akamatsu-1999 discloses that the pump’s “**impeller** rotates” (“*is rotatable*”) “at the center” (“*about a central axis*”) “of the pump **housing**” (“*within a surrounding stationary housing*”) to generate a “pump flow rate” (“*to act upon*

blood”). Ex.1006, 4. Figure 2 illustrates that the “blood [is] flowing from the” “inlet port” “toward the” “impeller” (black arrows):

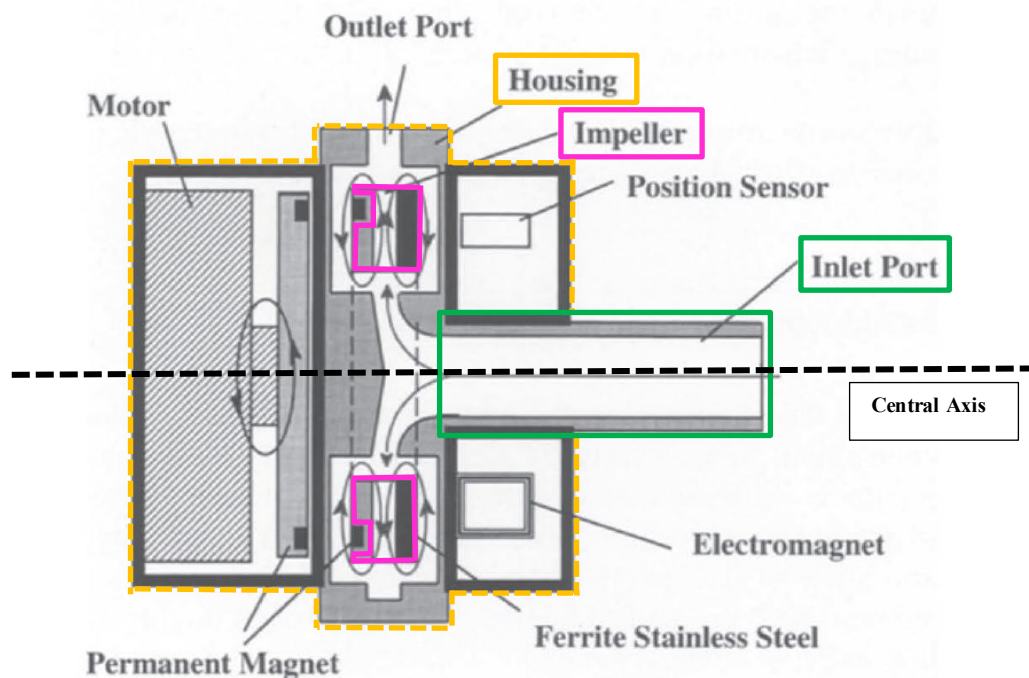


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶693.

Accordingly, Akamatsu-1999 discloses that the *magnetically driven rotor assembly* “being rotatable about a central axis within *a surrounding stationary housing* (“housing”) to act upon blood flowing from the *inflow tube* (“inlet port”) to the *rotor* (“impeller”).” Ex.1003, ¶695.

vii. [1F]

Akamatsu-1999 discloses that the “*impeller* is suspended by a magnetic bearing” (Ex.1006, 1), thereby “providing contact-free rotation” (“*is entirely spaced apart*”) from the *housing*, as shown:

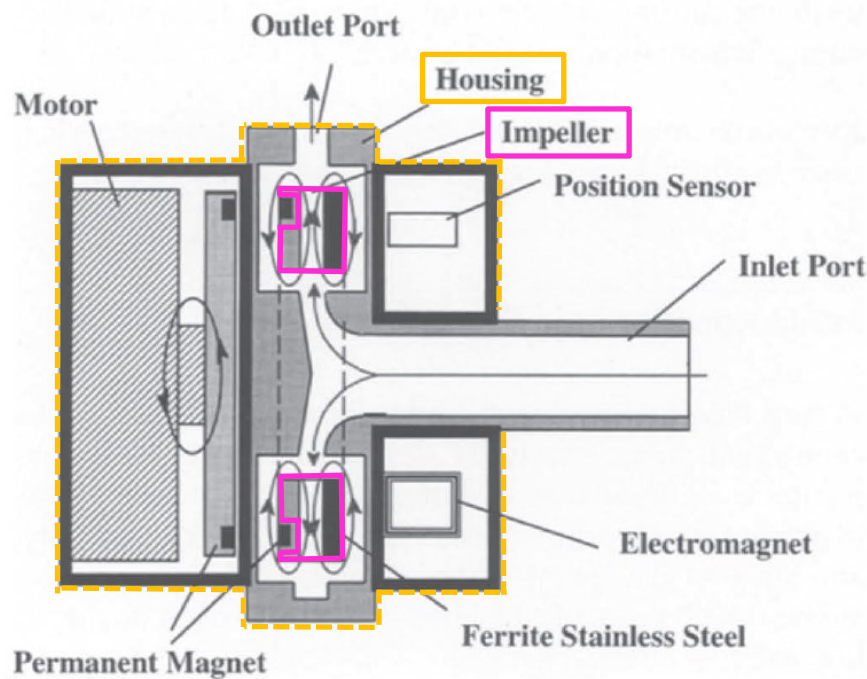


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶699. Indeed, the Akamatsu-1999 “magnetic suspension system” reported “excellent hydrodynamic performance with a low rate of hemolysis” (“*for passage of the blood*”). Ex.1006, 1.

Accordingly, Akamatsu-1999 discloses that “*the magnetically driven rotor assembly* (“impeller”) *is entirely spaced apart from the stationary housing* (“housing”) *by a gap sized for passage of the blood.*” Ex.1003, ¶433.

viii. [1G]

Akamatsu-1999 discloses that its **pump** has a “motor” which rotates a “[p]ermanent [m]agnet” (“*a second magnetic device*”), (Ex.1006, 2), which is also “*axially aligned with the inlet port,*” as shown:

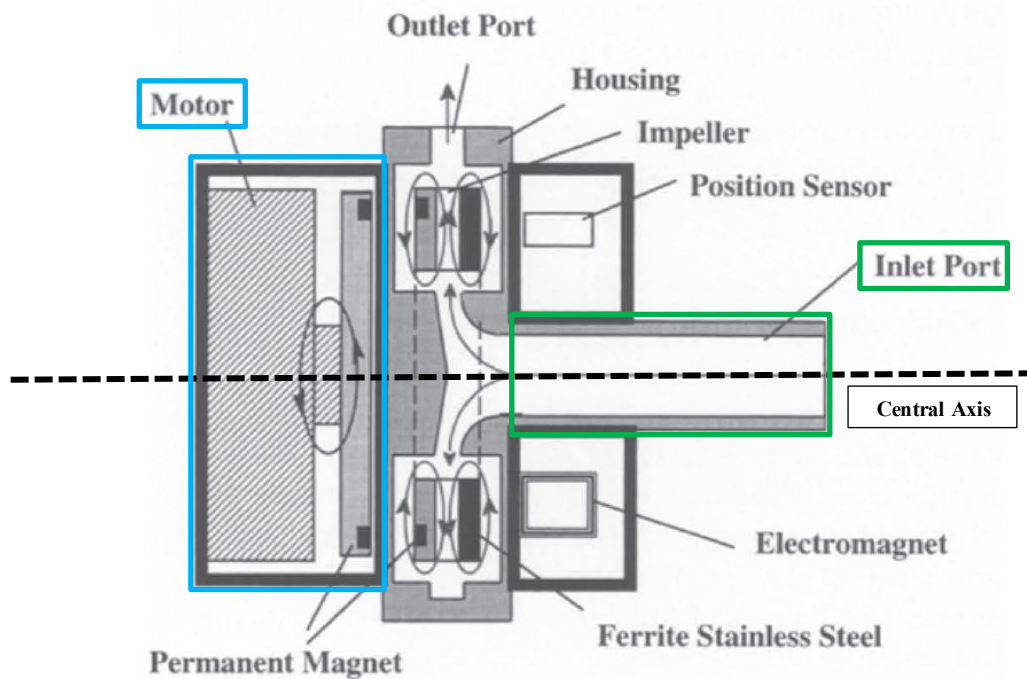


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶706.

Further, Akamatsu-1999 discloses that the “**impeller** rotates by a magnetic coupling” (“*via a magneto coupling*”) “between the **impeller**’s **permanent magnet**] and the motor’s **permanent magnet**],” thereby “providing contact-free rotation” (“*positioned to magnetically drive rotation*”) (Ex.1006, 1–2):

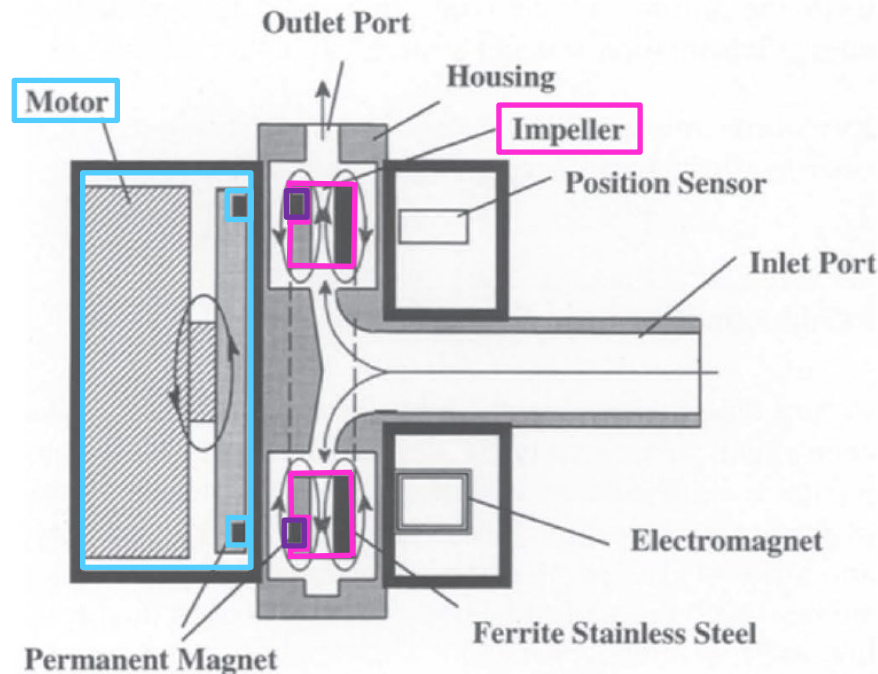


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶709, 711.

Accordingly, Akamatsu-1999 discloses that the **second magnetic device** (motor’s “permanent magnet”) is “axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** (“impeller”) via a magneto coupling with the **first magnetic device** (impeller’s “permanent magnet”).” Ex.1003, ¶713.

ix. [1H]

Akamatsu-1999 discloses that the “motor” and its **permanent magnet** “operate[] completely contact-free” (“while being spaced apart”) and are sealed from both the **impeller** and its **permanent magnet**, (Ex.1006, 4), as indicated by the solid black line surrounding the motor:

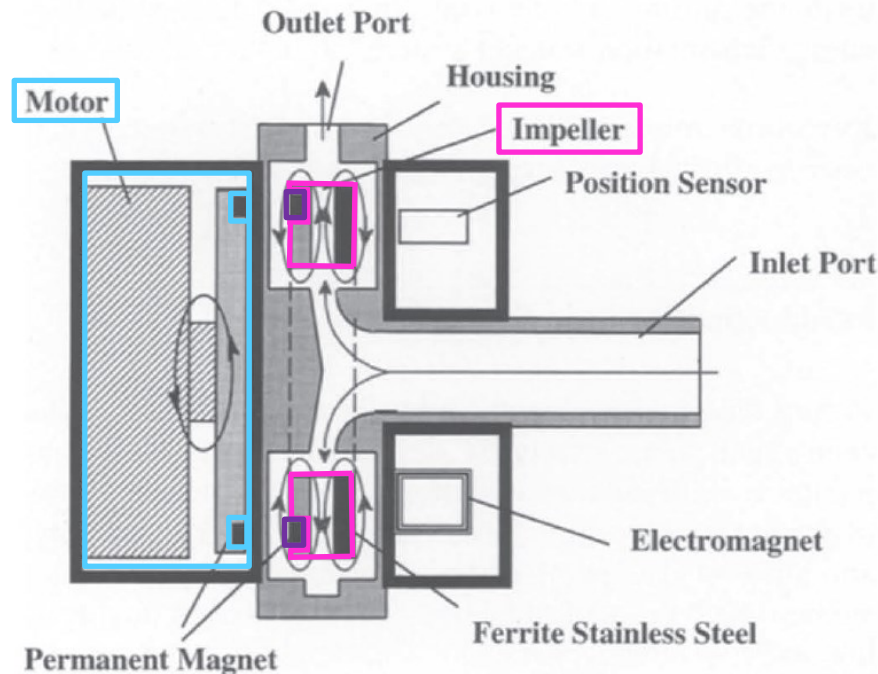


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2. Akamatsu-1999 also discloses sealing the device to prevent “leakage of blood into the...motor.” Ex.1006, 3; Ex.1003, ¶¶716–718.

Accordingly, Akamatsu-1999 discloses the *second magnetic device* (motor’s “permanent magnet”) “being spaced apart and sealed from both the *rotor* (“impeller”) and the *first magnetic device* (impeller’s “permanent magnet”) of the *magnetically driven rotor assembly* (“impeller”).” Ex.1003, ¶719.

x. [1I]

As demonstrated in [1H], Akamatsu-1999 discloses the motor’s *permanent magnet* is “positioned axially spaced apart from the guide surfaces (“blades”) of the *rotor* (“impeller”),” as shown:

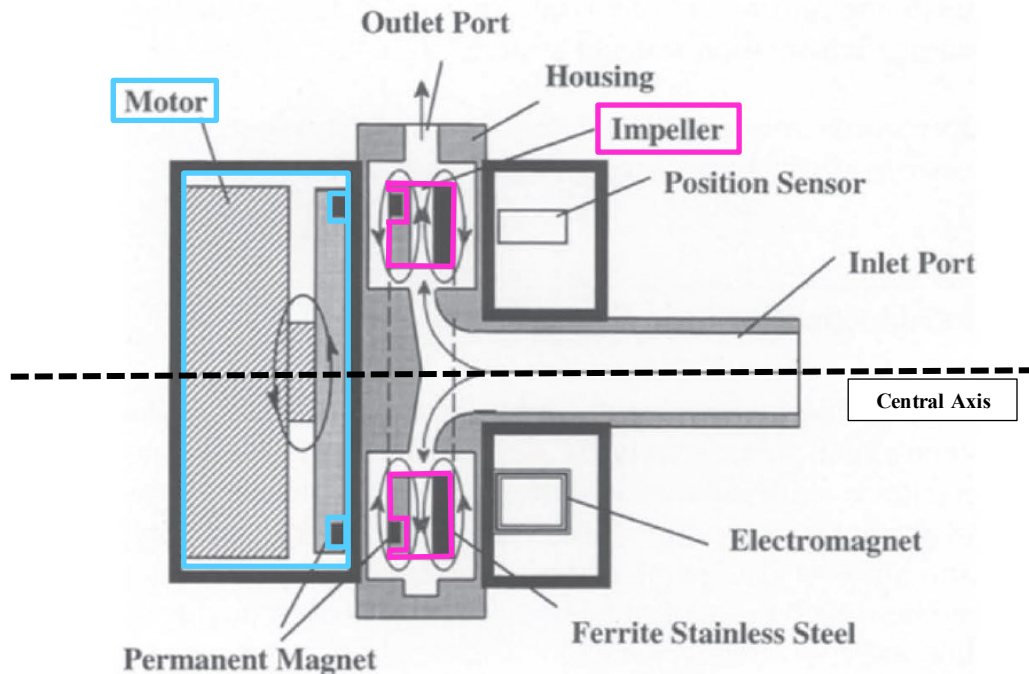


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶723–725/16718.

Accordingly, Akamatsu-1999 discloses a **second magnetic device** (motor’s “permanent magnet”) “being positioned axially spaced apart from the guide surfaces of the **rotor** (“impeller”).” Ex.1003, ¶726.

xi. [1J]

Akamatsu-1999 discloses an “outflow conduit” or “**outlet port**” (a blood outflow port), (Ex.1006, 2), which Figure 2 illustrates (black arrow) is positioned radially adjacent the [] **impeller** such that, when the blood is driven by the **impeller** the blood exits the **housing** in a direction substantially perpendicular to the **central axis** of the **impeller**:

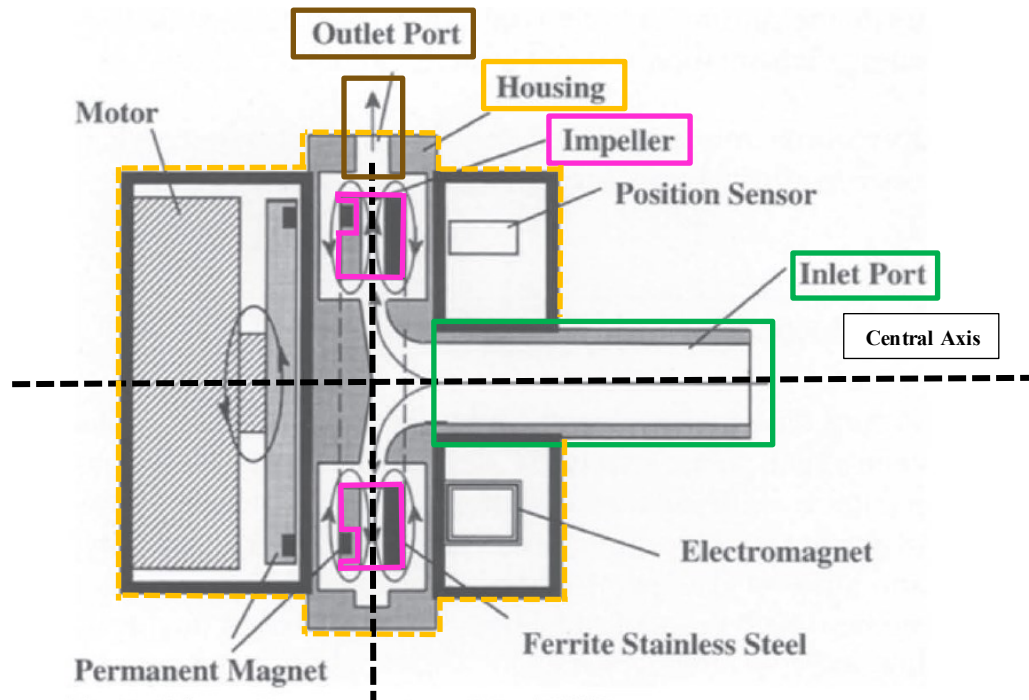


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶733.

Figure 3 illustrates the **outlet port** *substantially perpendicular* to the **inlet port**:

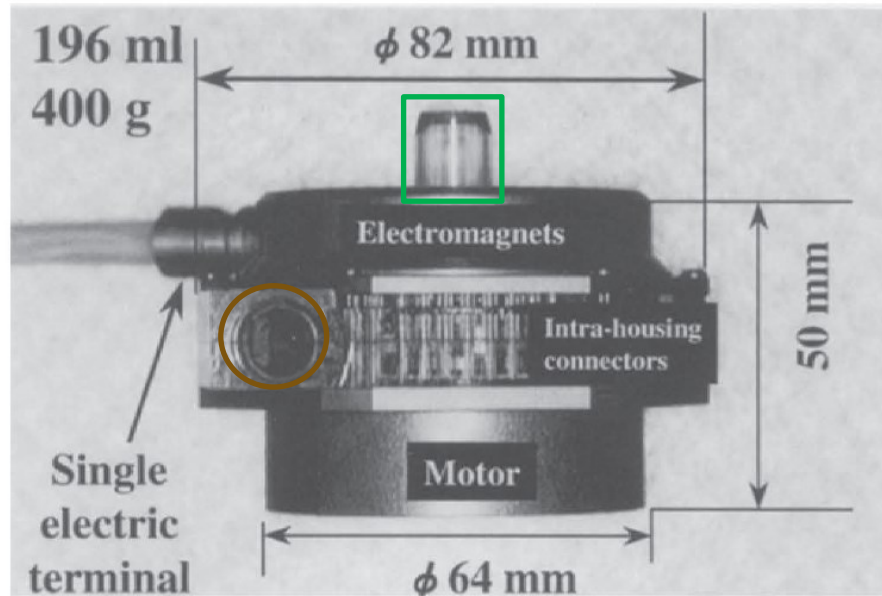


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3; Ex.1003, ¶¶734–735.

Accordingly, Akamatsu-1999 discloses that “a **blood outflow port** (“outlet port”) positioned radially adjacent the guide surfaces of the **rotor** (“impeller”) such that, when the blood is driven by the **magnetically driven rotor assembly**, the blood exits the **surrounding stationary housing** (“housing”) in a direction substantially perpendicular to the **central axis** of the **magnetically driven rotor assembly**.”

Ex.1003, ¶736.

xii. [1K]

In Parallel Litigation, PO asserts that a magnetic bearing (i.e., “MagLev”) satisfies this limitation. Ex.1019, 7–8.

Assuming that interpretation, as explained in [1F]-[1G], Akamatsu-1999 discloses that the “**impeller** is suspended by a magnetic bearing” (Ex.1006, 1) and

“rotates by a magnetic coupling,” thereby “providing contact-free rotation”
 (“*remains entirely spaced apart from the surrounding stationary housing*”),
 (Ex.1006, 1–2):

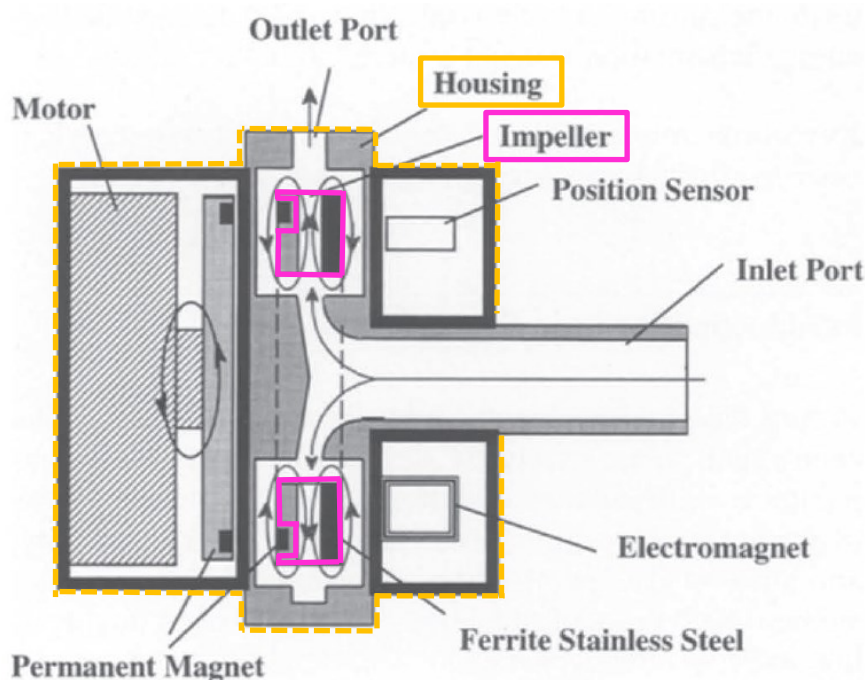


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶742. Indeed, the Akamatsu-1999 “magnetic suspension system” reported “excellent hydrodynamic performance with a low rate of hemolysis” (“*spaced apart...by the gap sized for passage of the blood*”). Ex.1006, 1, 4.

Accordingly, Akamatsu-1999 discloses that “the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** (“impeller”) and orient the **magnetically driven rotor assembly** such that the

magnetically driven rotor assembly remains entirely spaced apart from the *surrounding stationary housing* (“housing”) by the gap sized for passage of the blood.” Ex.1003, ¶743.

xiii. [1L]

Akamatsu-1999 teaches or suggests a **controller** (worn externally in Figure 1) (“an external control unit”) so that “[t]he pump was operated at a fixed rotational speed” (“to regulate operation”) (Ex.1006, 2):

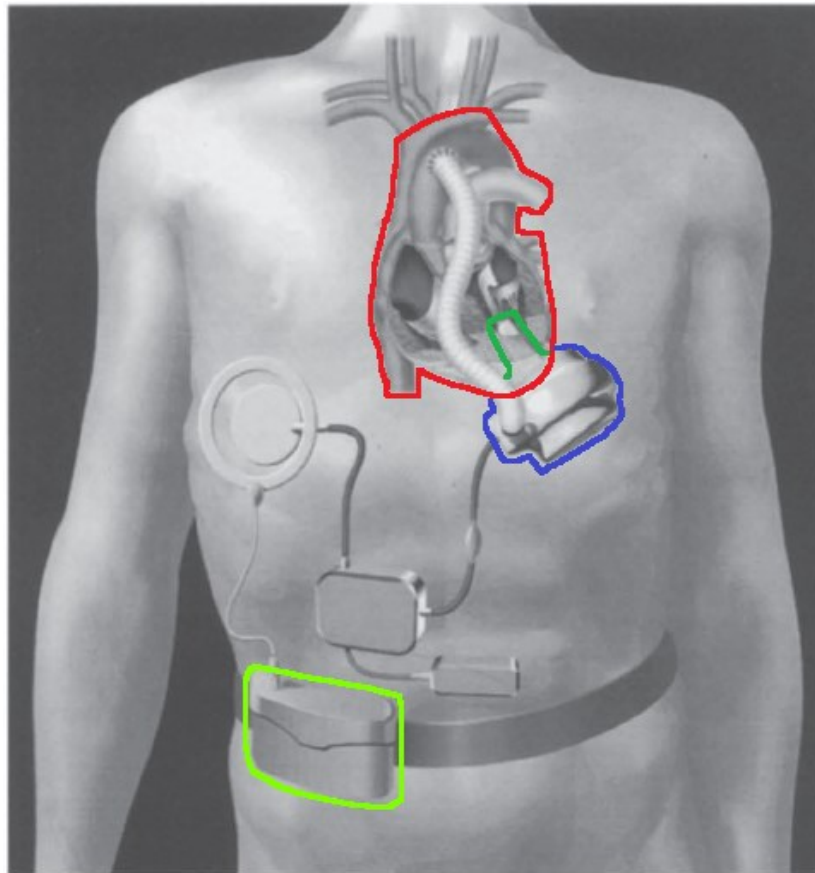


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶748.

Akamatsu-1999 discusses a “**next phase**” “Model **III** pump” with “an **implantable** controller” and “a transcutaneous...system.” Ex.1006, 5. “The Model **II** pump,” however, which was the focus of the studies described in Akamatsu-1999, “was percutaneously driven” (i.e., “*external*”). Ex.1006, Fig. 3, 3; Ex.1003, ¶747.

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit is a “*control value indicative of cardiac output.*” Assuming that interpretation, Akamatsu-1999 discloses that “[t]he pump was operated at a fixed rotational speed” Ex.1006, 2.

Accordingly, Akamatsu-1999 teaches or suggests “an **external control unit** (“controller”) *configured to regulate the operation of the **second magnetic device** (motor’s “permanent magnet”) based upon a control value indicative of cardiac output (“operated at a fixed rotational speed”).*” Ex.1003, ¶753.

xiv. [1M]

As demonstrated in [1L], Akamatsu-1999 teaches or suggests a **controller** that “was percutaneously driven” (“*to thereby magnetically drive the rotation*”) by “a single electric wire” with “intra-housing connectors” (“*connectable*”) from the “motor” to a controller:

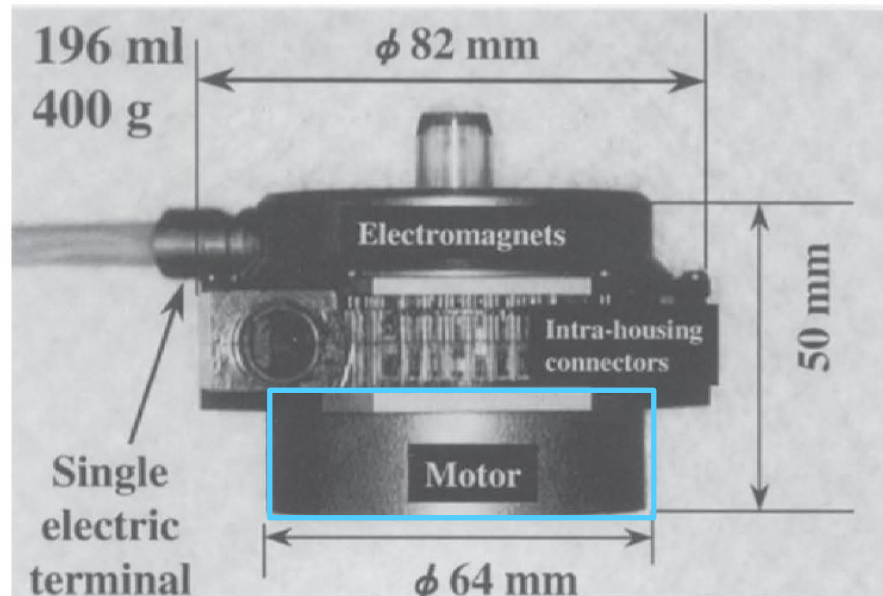


Fig. 3. Implantable Model II MSCP with intrahousing connectors
Ex.1006, Fig. 3, 3; Ex.1003, ¶756.

Accordingly, Akamatsu-1999 teaches or suggests “the **external control unit** (“controller”) connectable to the **heart assist pump device** (“centrifugal pump”) for controlling the **second magnetic device** (motor’s “permanent magnet”) to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** (“impeller”) via the magneto coupling with the **first magnetic device** (impeller’s “permanent magnet”).” Ex.1003, ¶758753.

2. Claim 2

As demonstrated in [1G], the impeller’s “**permanent magnet**” is positioned between the “**impeller**” and the motor’s “**permanent magnet**”:

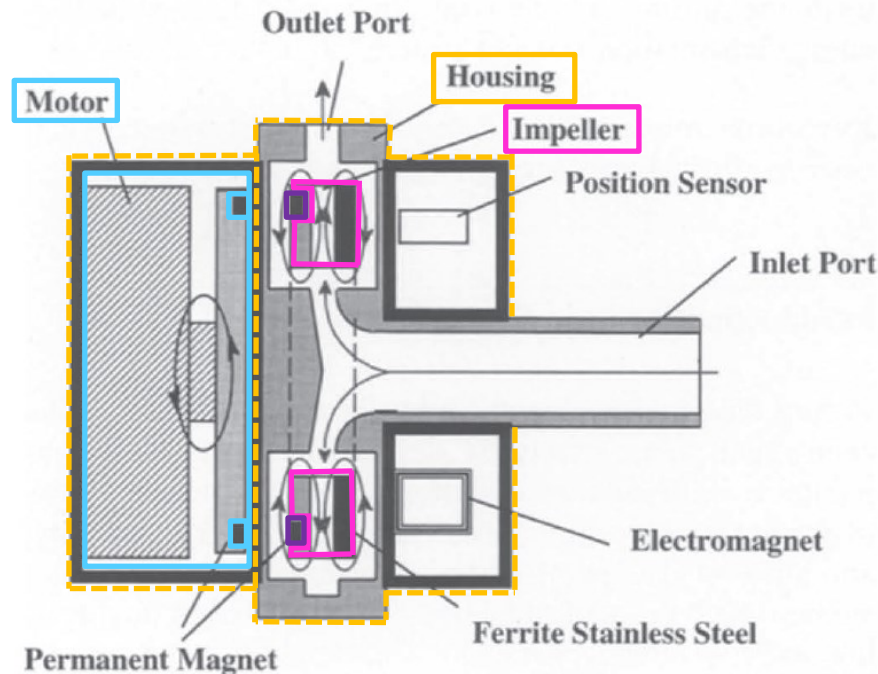


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶763.

Accordingly, Akamatsu-1999 discloses that “*the first magnetic device* (“permanent magnet”) *is configured to be positioned between the second magnetic device* (motor’s “permanent magnet”) *and the guide surfaces of the rotor* (“impeller”) *of the magnetically driven rotor assembly.*” Ex.1003, ¶764.

3. Claim 3

As demonstrated in [1C], the “impeller” and its “permanent magnet” are “rigidly coupled,” thus, Akamatsu-1999 discloses “*the first magnetic device* (“permanent magnet”) *is configured to rotate together with the rotor* (“impeller”) *relative to the surrounding stationary housing* (“housing”).” Ex.1003, ¶¶767, 769.

4. Claim 4

As demonstrated in [1A] and [1J], the suction end of the “inlet port” is insertable into a ventricle of the heart, while the “outflow” is radially adjacent to the impeller which is aligned with the motor:

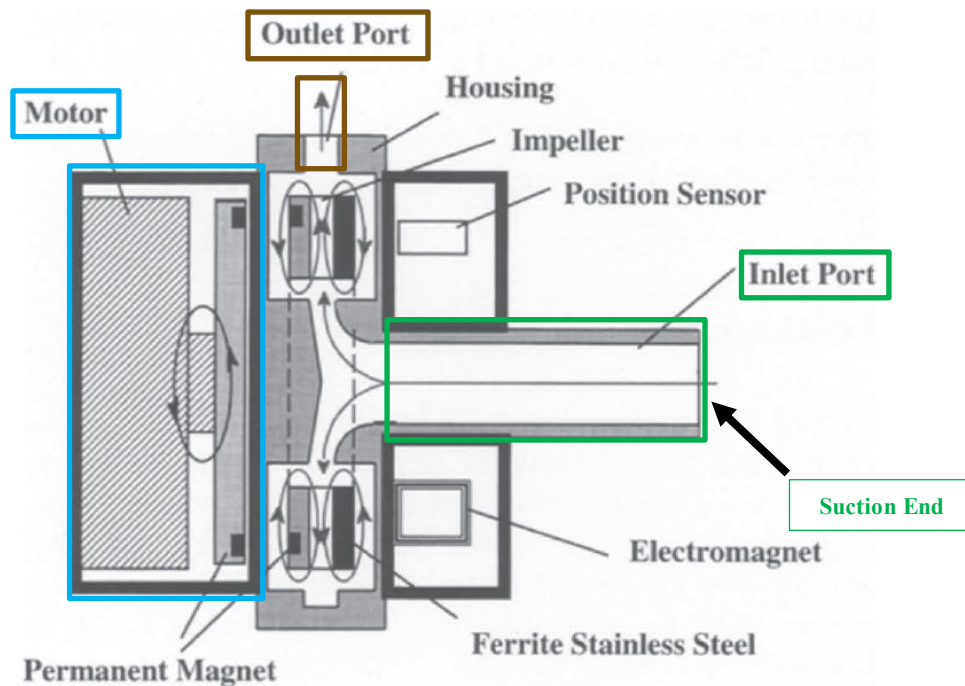


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶772.

Accordingly, Akamatsu-1999 discloses that “the *second magnetic device* (motor’s “permanent magnet”) is positioned closer to the *blood outflow port* (“outlet port”) than to the suction end of the *inflow tube* (“inlet port”).” Ex.1003, ¶773.

5. Claim 5

As demonstrated in [1H] and [1M], the *second magnetic device* is “sealed” and the controller is “external,” thus, Akamatsu-1999 discloses “the *magnetically*

driven rotor assembly (“impeller”) is sealed from the *second magnetic device* (motor’s “permanent magnet”) and a drive source (“controller”) configured to regulate the operation of the second magnetic device.” Ex.1003, ¶¶776–777.

6. Claim 7

Akamatsu-1999 discloses that “[t]he electric current of the electromagnet is controlled by using three position sensors [‘one or more sensors’].” Ex.1006, 2. Mr. Crosby explains that these “sensors” “deliver feedback signals” to the “**controller**,” which provides the “electric current.” Ex.1006, 2; Ex.1003, ¶781.

Accordingly, Akamatsu-1999 teaches or suggests “one or more sensors configured to deliver feedback signals to the **external control unit** (“controller”).” Ex.1003, ¶782.

7. Claim 10

In Parallel Litigation, PO asserts that a pump device with an inflow cannula is a catheter device. Assuming that interpretation, because Akamatsu-1999’s *heart assist pump device* comprises “an inlet port” “inserted into the left ventricle” (Ex.1006, 2–3), it “is a catheter device.” Ex.1003, ¶786.

8. Claim 16

Claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. Ex.1003, ¶788.

i. [16PRE]

See [1PRE]. Ex.1003, ¶790.

ii. [16A]

See [1A] and [1B] (analyzing axial inflow—an “*inflow path along an inflow axis*”). Ex.1003, ¶793.

iii. [16B]

See [1E] (analyzing a “*surrounding stationary housing*” (“housing”). Akamatsu-1999 discloses “*walls...defining a chamber*” for the reasons it discloses a “*surrounding stationary housing*” of [1E]. Ex.1003, ¶796.

iv. [16C]

See [1B] and [1C]. Ex.1003, ¶799.

v. [16D]

See [1C]. Ex.1003, ¶802.

vi. [16E]

See [1D]. Ex.1003, ¶805.

vii. [16F]

See [1E]. Ex.1003, ¶808.

viii. [16G]

See [1B] and [1E]. Ex.1003, ¶811.

ix. [16H]

See [1G]. Ex.1003, ¶814. Akamatsu-1999 discloses a “*magnetic drive system comprising a second magnetic device*” of [16H] for the reasons it discloses a “*second magnetic device*” (motor’s “permanent magnet”) of [1G].

x. [16I]

See [1K] and [2]. Ex.1003, ¶817. Akamatsu-1999 teaches or suggests that the “*second magnetic device*” is “*positioned axially closer*” to the *first magnetic device* of [16I] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor assembly* of [2].

xi. [16J]

See [1H]. Ex.1003, ¶820. For the same reasons Akamatsu-1999 discloses a “*second magnetic device*” is “*sealed,*” as Figure 2 illustrates, Akamatsu-1999 discloses a “*wall...positioned between the magnetically driven rotor assembly and the second magnetic device*”:

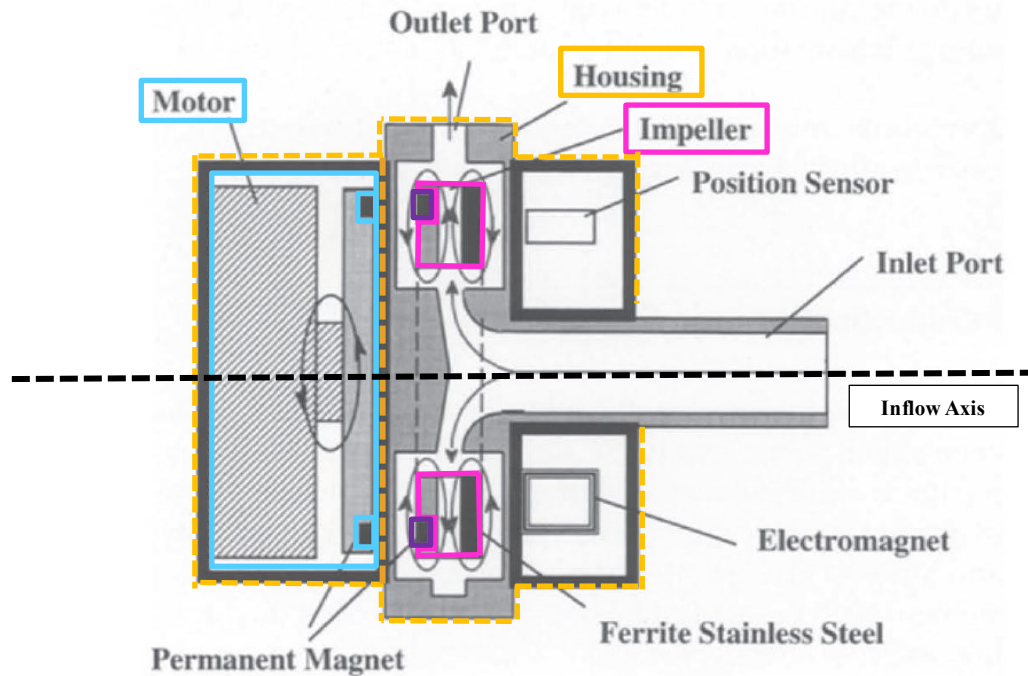


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

xii. [16K]

See [1J]. Ex.1003, ¶823.

xiii. [16L]

See [1M]. Ex.1003, ¶826.

xiv. [16M]

See [1L]. Ex.1003, ¶829.

xv. [16N]

See [1M]. Ex.1003, ¶832.

9. Claim 17

See [2], [16D], and [16I] *above*. Ex.1003, ¶837.

10. Claims 18-21

See [1F], [1K]. Akamatsu-1999 discloses a “gap...*configured to be occupied by the blood*” ([18]); that “*surrounds*” ([19]); “*extends radially outward*” ([20]) and “*along a face...axially opposite from the inflow tube*” ([21]) of “*the magnetically driven rotor assembly*” for the reasons Akamatsu-1999 discloses “*entirely spaced apart...by a gap sized for passage of the blood*” of [1F] and [1K]—i.e., the gap extends entirely surrounding the *magnetically driven rotor assembly*. Ex.1003, ¶¶842, 851, 855, 859.

11. Claim 22-23

See [16J]. Akamatsu-1999 discloses a “*wall of the...chamber separates the first chamber from the second chamber*” of [22]-[23] for the reasons that a “*wall of the...chamber is positioned between the magnetically driven rotor assembly and the second magnetic device*” of [16J]. Ex.1003, ¶864, 872.

12. Claim 24

See [1C], [16C]. Ex.1003, ¶878.

13. Claim 26

See [7]. Ex.1003, ¶882.

14. Claim 28

See [10]. Ex.1003, ¶888.

D. Ground 4: Schima and Akamatsu-1999 Render Obvious the Challenged Claims

1. Claim 1

i. [1PRE]

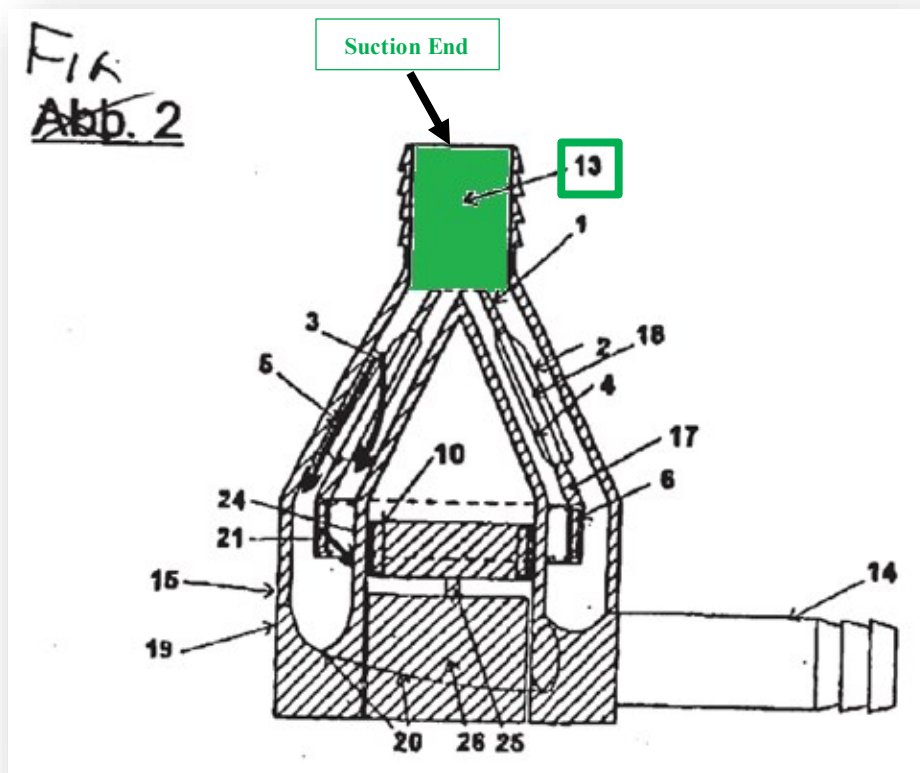
Schima discloses a “a rotary pump for moving blood” (“*assisting the blood circulation*”). Ex.1005, [0001]; Ex.1003, ¶891.

Schima does not expressly state where its pump is placed, but Mr. Crosby explains *infra* §X.D.1.i, it would have been obvious that Schima’s pump is “*for assisting ... a heart.*” Ex.1003, ¶892 (citing Ex.1005, [0004]–[0009]).

Accordingly, Schima teaches or suggests “*a system for assisting the blood circulation of a heart.*” Ex.1003, ¶893.

ii. [1A]

Schima explains that its “pump” has “**inlet 13**” (“*an inflow tube defining a blood inflow path*”) (Ex.1005, [0012]):



Ex.1005, Fig. 2; Ex.1003, ¶896.

Mr. Crosby explains (*infra* VIII.D.15) that Schima suggests that its pump is an LVAD designed to be “*deliverable to the heart*” so that inlet tube 13 (“*an inflow tube...having a suction end:*”) “*insertable into a ventricle of the heart.*” Ex.1003, ¶897.

Further, Mr. Crosby explains that it would have been obvious to implant Schima’s device in the configuration described by Akamatsu-1999 (i.e., “*an inflow tube... insertable into a ventricle*”), at least because Schima’s pump is designed to

solve the same problem as Akamatsu's pump. Ex.1003, ¶903; *see also* Ex.1005, [0001]-[0004] (explaining problems).

In the Schima/Akamatsu combination, Schima's **pump** is "*deliverable to the heart*" so that its **inlet 13** is "inserted into the **left ventricle**," as taught by Akamatsu-1999 (Ex.1006, 4) and illustrated:

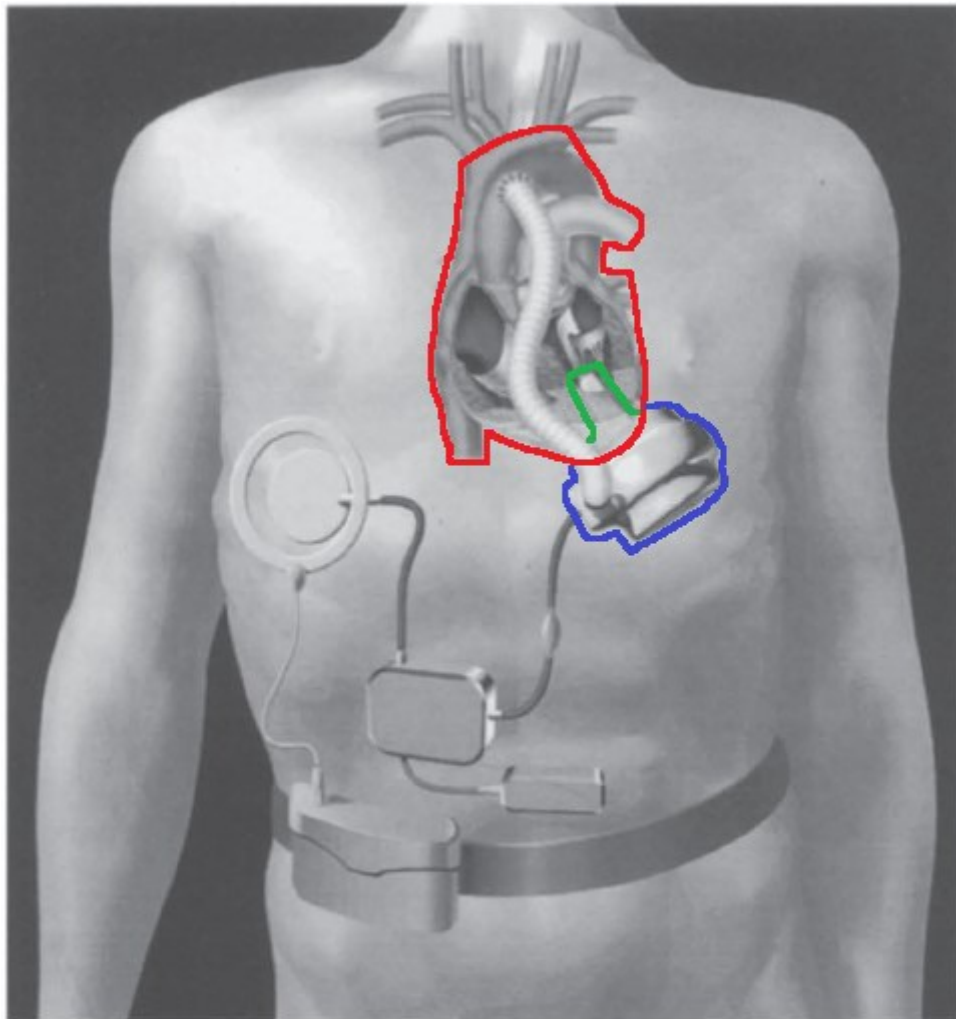


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

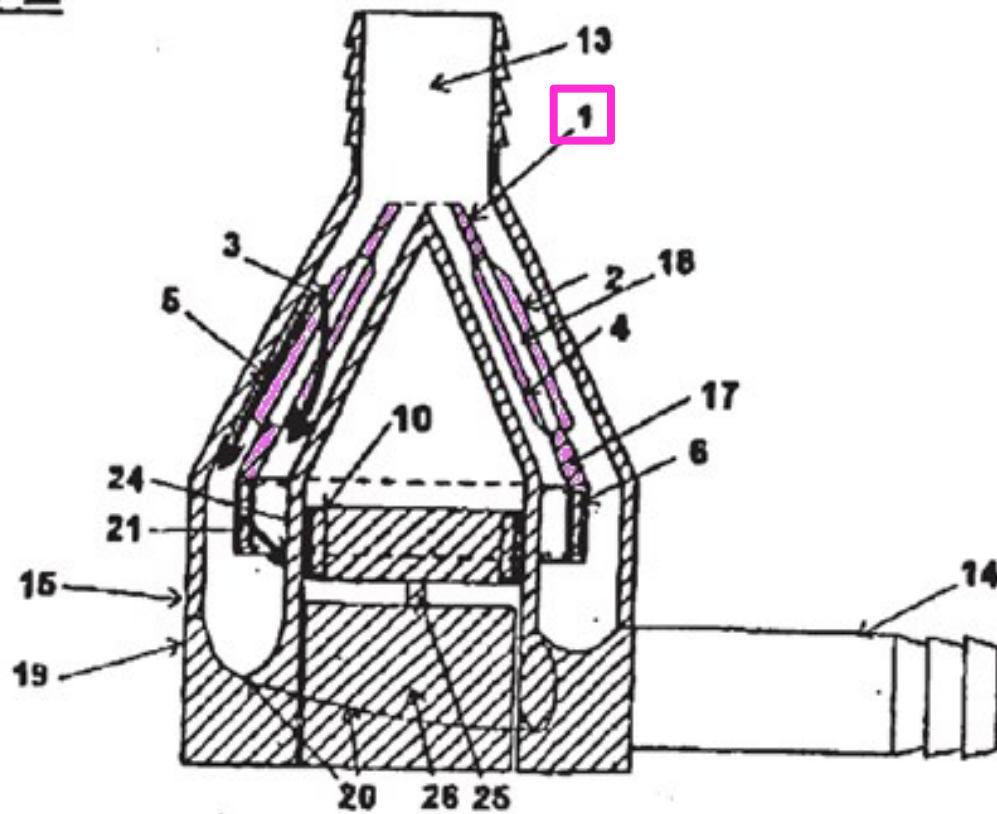
Ex.1006, Fig. 1; Ex.1003, ¶906.

Accordingly, Schima, or Schima/Akamatsu-1999, renders obvious “*a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart.*” Ex.1003, ¶908.

iii. [1B]

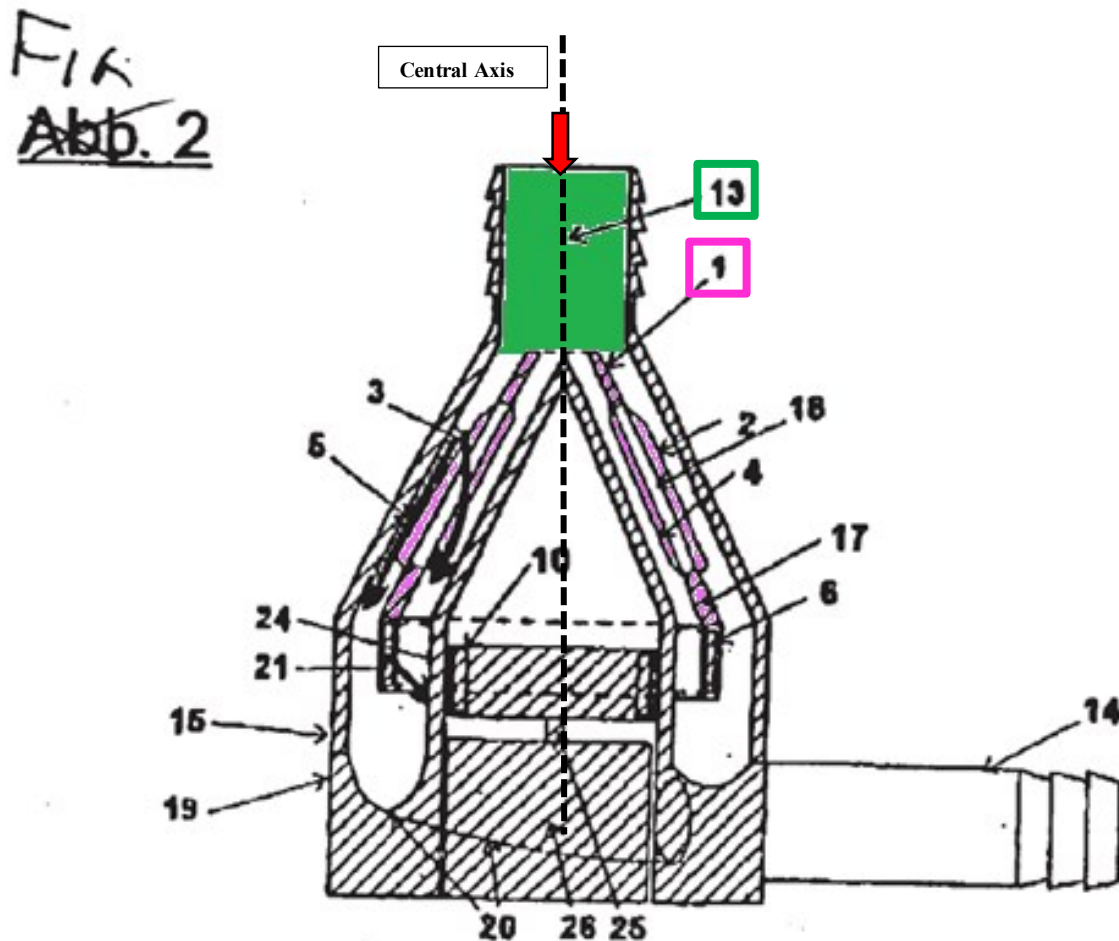
Schima discloses that its “pump” includes “rotor 1” which “holds rotor magnets 6 that preferably transfer rotation energy” (“magnetically driven rotor”) (Ex.1005, [0012]; Ex.1003, ¶910):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶¶910-911.

Schima discloses that its **rotor** is “axially” *aligned* with **inlet 13** so that the inlet’s “flow [is] preferably axially against” “the pump housing” which “serves to center the **rotor** (Ex.1005, [0012]). As demonstrated in [1A], the **rotor** is also “*spaced apart from the suction end*” of inlet 13 and the flow path of the blood from the left ventricle of the heart is demonstrated by the **red** arrow, as shown:

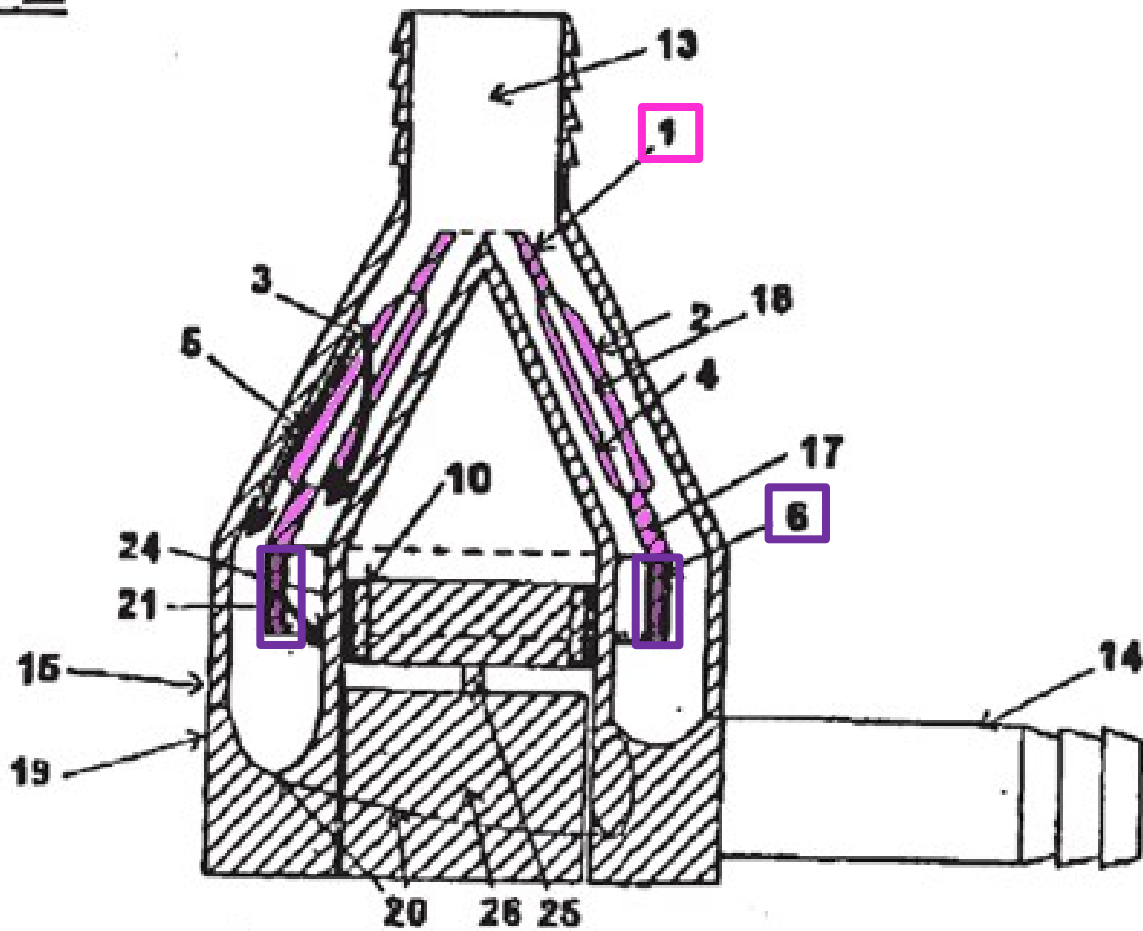


Ex.1005, Fig. 2; Ex.1003, ¶914.

Accordingly, Schima teaches or suggests that a “*magnetically driven rotor*” (“rotor 1”) *configured to be axially aligned with the inflow tube* (“inlet 13”) *and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle.*” Ex.1003, ¶916.

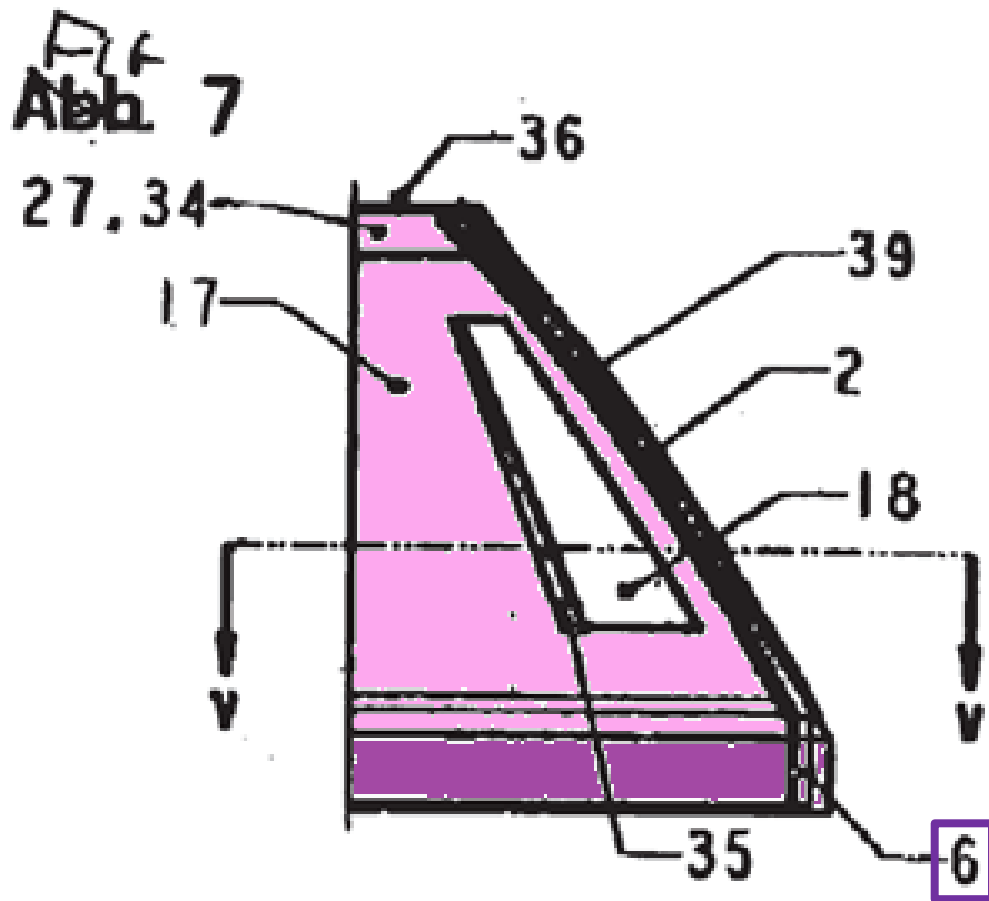
iv. [1C]

Schima discloses that “[t]he rotor holds [*is rigidly coupled to*] rotor magnets 6 [*a first magnetic device*].” Ex.1005, [0012]; Ex.1003, ¶919. Figure 2 illustrates the rigid coupling between rotor magnets 6 and the rotor:

2

Ex.1005, Fig. 2; Ex.1003, ¶922.

Figure 7 shows that “**rotor magnets 6**” can form “a continuous magnetic ring” at the base of (“*axially adjacent*”) the **rotor**:



Ex.1005, [0012], Fig. 7; Ex.1003, ¶923.

Accordingly, Schima teaches or suggests the *magnetically driven rotor assembly* (“rotor 1”) “comprising a *first magnetic device* (“rotor magnets 6”) that is rigidly coupled to and axially adjacent to a *rotor* (“rotor 1”).” Ex.1003, ¶924.

v. [1D]

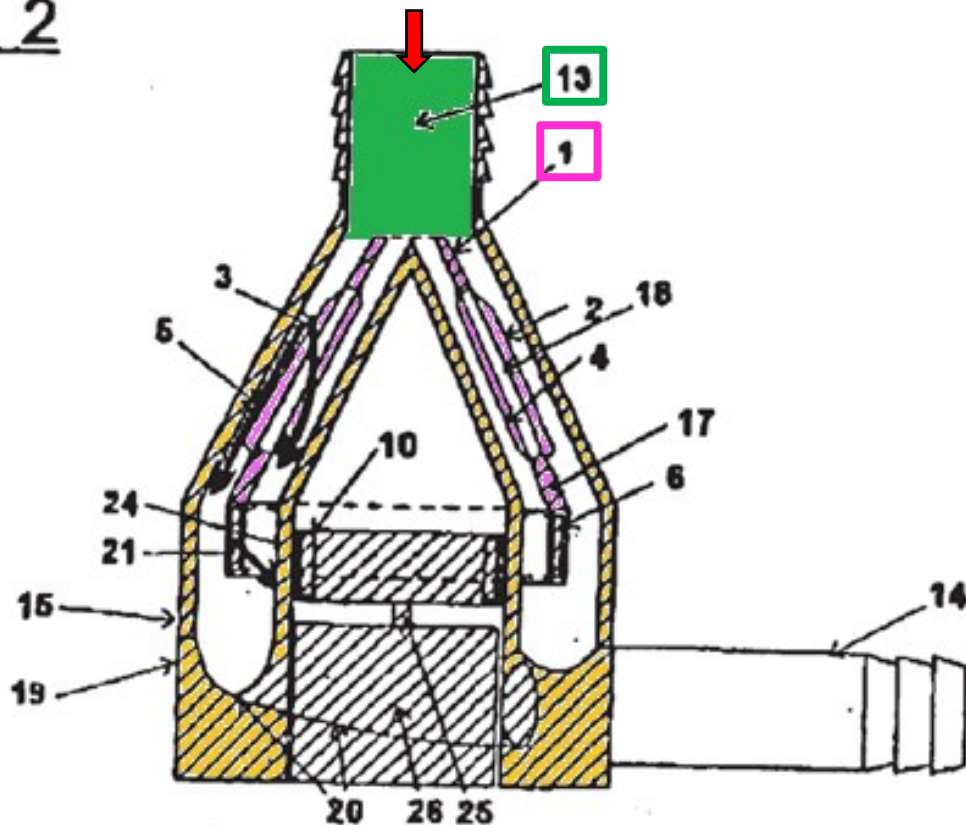
Schima discloses that “[t]he *rotor* 1 has as flow surfaces 2 and 4 vanes” (“*guide surfaces*”) “that produce centrifugal flow components.” Ex.1005, [0012], [0010], Claim 1; Ex.1003, ¶926.

Accordingly, Schima teaches or suggests the **rotor** (“rotor 1”) “*having guide surfaces* (“flow surfaces 2 and 4 vanes”) *to produce centrifugal flow components* (“centrifugal flow components”).” Ex.1003, ¶929.

vi. [1E]

Schima discloses that its “**rotor 1** rotates in a **pump housing 30**” (“*is rotatable...within a surrounding stationary housing*”) and “*distributes the incoming liquid*” (“*to act upon blood flowing from the inflow tube*”) (Ex.1005, [0012]):

Fig.
Abb. 2



Ex.1005, Fig. 2; Fig. 1; Ex.1003, ¶934.

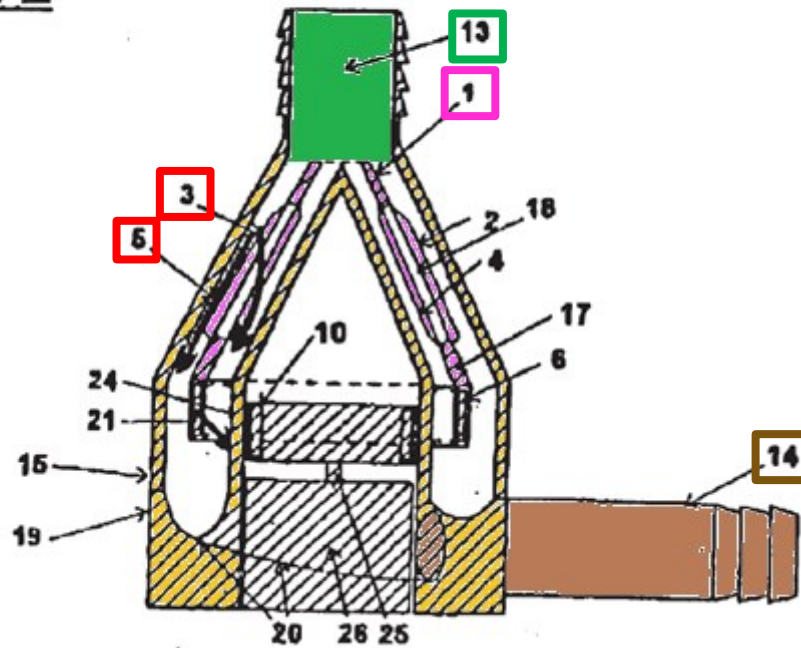
Indeed, Schima describes that its “contact-free journaling and stabilizing of the rotor in the housing” is achieved by “*act[ing] upon the blood*” to “produce centrifugal flow components.” Ex.1005, [0012]. Ex.1003, ¶932.

Accordingly, Schima teaches or suggests that *the magnetically driven rotor assembly* (“rotor 1”) “*being rotatable about a central axis within a surrounding stationary housing*” (“pump housing 30”) *to act upon blood flowing from the inflow tube* (“inlet 13”) *to the rotor* (“rotor 1”).” Ex.1003, ¶939.

vii. [1F]

Schima discloses “contact-free” (“*by a gap sized for passage of the blood*”) “journaling and stabilizing of the **rotor** in the **housing**.” Ex.1005, [0010]. Figure 2 illustrates the “centering of the...rotor ...by the **flow components** directed against the housing” (“*entirely spaced apart*”):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶942980.

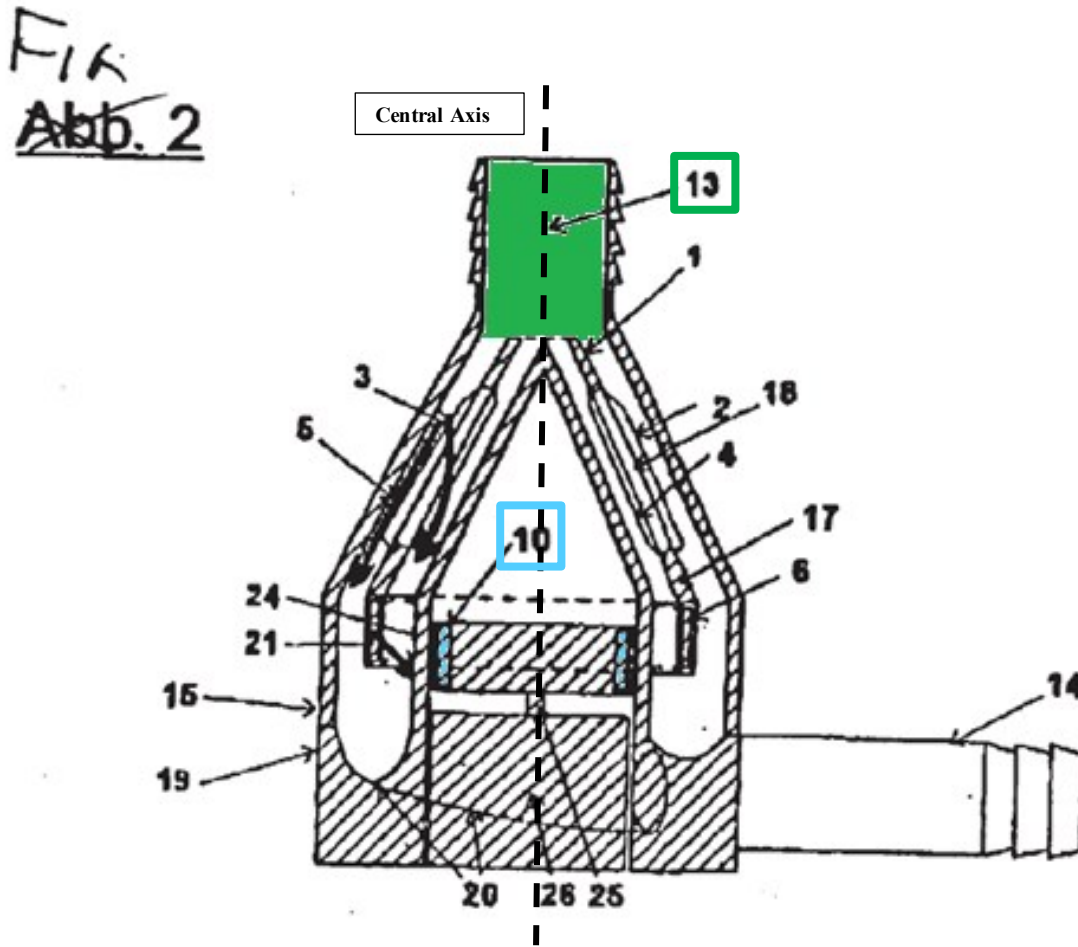
Accordingly, Schima teaches or suggests that “the *magnetically driven rotor assembly* (“rotor 1”) is entirely spaced apart from the *stationary housing* (“pump housing 30”) by a gap (“contact-free journaling”) sized for passage of the blood.”

Ex.1003, ¶943.

viii. [1G]

Schima discloses that the rotor’s “drive can...be an electric motor 26 which drives a rotating disk 24 with *magnets 10*” (“a second magnetic device”). Ex.1005, [0013]. Further, Schima discloses that “*magnets 10*” have an “axial offset

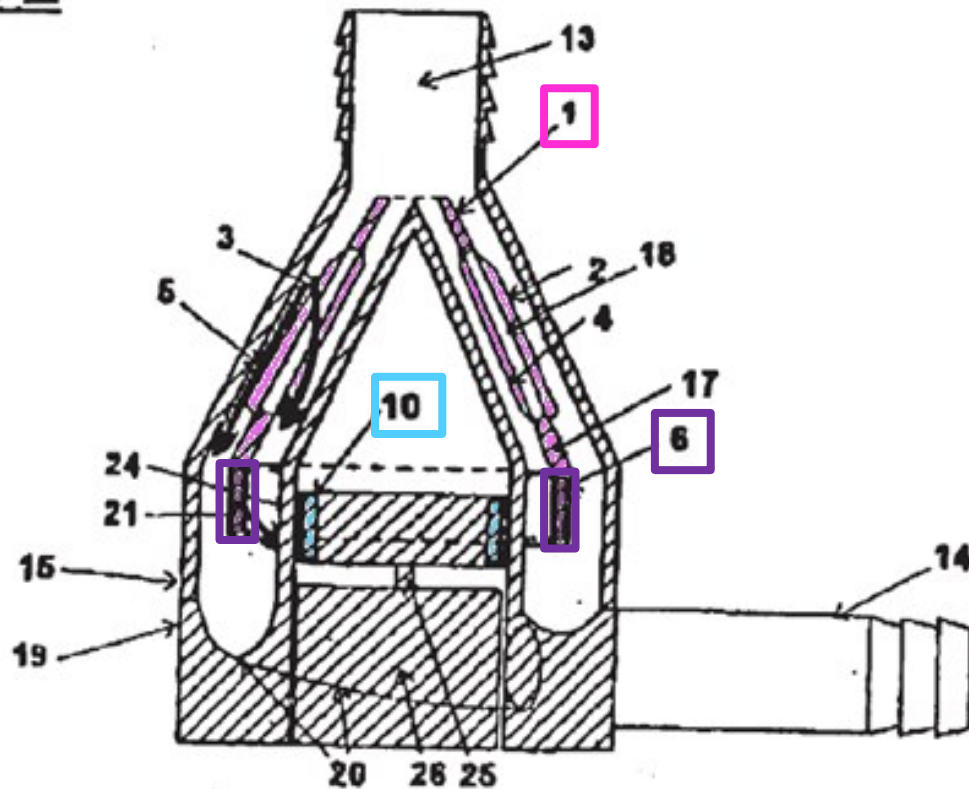
[that] ensures an axial component for the magnetic force” (“*axially aligned*”) that journals the rotor (Ex.1005, [0013]):



Ex.1005, Fig. 2; Ex.1003, ¶948.

Schima further discloses that “**magnets 10**” are positioned to “transfer rotation energy” (“*positioned to magnetically drive rotation...via a magneto coupling*”) to “**rotor magnets 6**” of the “**rotor.**” Ex.1005, [0012]-[0013]; *see also* claim 9 (claiming a “magnetic drive”).

FIG.
Abb. 2



Ex.1005, Fig. 2, [0013]; Ex.1003 ¶952.

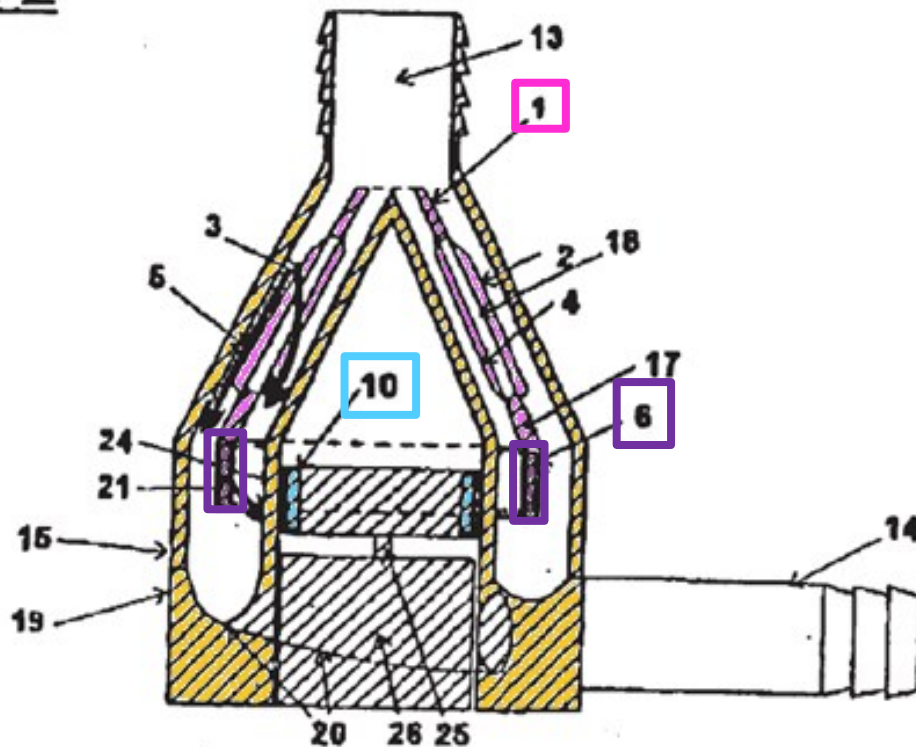
Schima also discloses “*magneto coupling*” under PO’s apparent construction. See §VI.A. Instead of using “a rotating disk 24 with magnets 10,” discussed above; “the drive can also” “work as shown in FIG. 1 with a **stator 12** [alternative ‘*second magnetic device*’]...creating a rotating magnetic field” that “causes the coupling force” (“*drive rotation...via a magneto coupling*”) “with **rotor magnets 6.**” Ex.1005, [0012]-[0013]. Ex.1003, ¶954.

Accordingly, Schima teaches or suggests “a *second magnetic device* (“magnets 10” or “stator 12”) *axially aligned with the inflow tube* and positioned to *magnetically drive rotation of the magnetically driven rotor assembly* (“rotor 1”) *via a magneto coupling* (“transfer rotation energy”) *with the first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶¶955-956.

ix. [1H]

Schima discloses that the pump’s “drive” components, e.g., *magnets 10 or “stator 12”*, reside “inside the *housing* lower part 19” while the “*rotor* rotates in...a hollow conical upper part” of “*pump housing* 30.” Ex.1005, [0011]-[0012]; Ex.1003, ¶958. Figure 2 illustrates that “*housing walls*” “*space[] apart and seal[]*” *second magnetic device* from both *rotor* and *rotor magnets 6*:

Fig.
Abb. 2



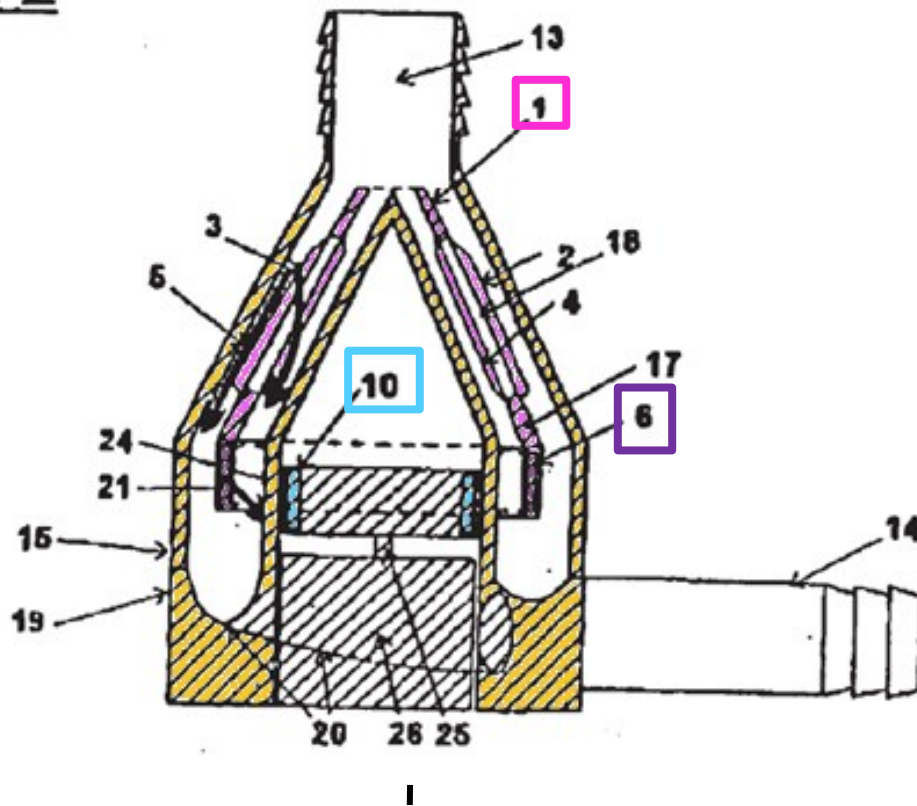
Ex.1005, Fig. 2; *see also* Fig. 1 (showing stator 12); Ex.1003, ¶961.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) “*being spaced apart and sealed from both the rotor* (“rotor 1”) *and the first magnetic device* (“rotor magnets 6”) of the *magnetically driven rotor assembly*.” Ex.1003, ¶962.

x. [1I]

As demonstrated in [1H], Schima discloses its *second magnetic device* is “*positioned axially spaced apart*” from the *rotor*’s *guide surfaces*, as shown:

Fig.
Abb. 2



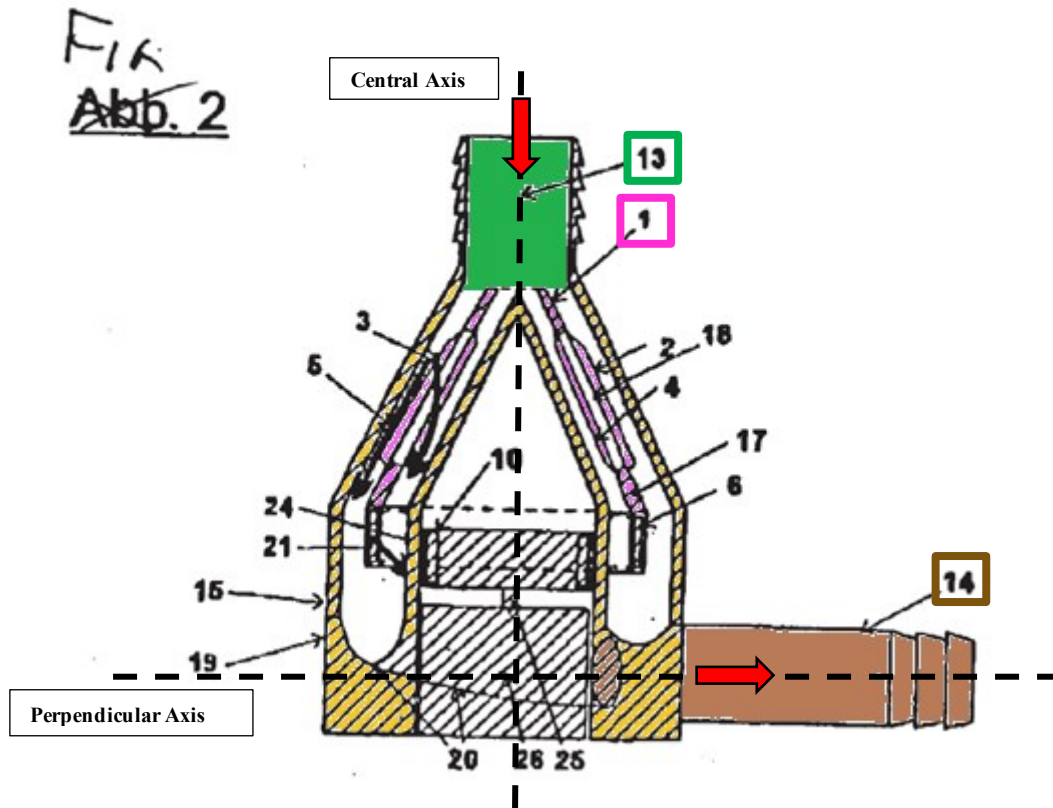
Ex.1005, Fig. 2, [0013]; Ex.1003 ¶968.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) “being positioned axially spaced apart from the guide surfaces (“flow surfaces”) of the *rotor* (“rotor 1”).” Ex.1003, ¶969.

xi. [1J]

Schima discloses “[a] spiral-shaped **outlet passage 20**...[to] **outlet 14**” (“a blood outflow port”). Ex.1005, [0012]. Given its “spiral-shape,” the “**outlet 14**” is “positioned radially adjacent the” *rotor*. Ex.1003, ¶971. Figure 2 illustrates that

“**outlet 14**” allows the “flow of the liquid” (“*blood is driven by the magnetically driven rotor assembly*”) to exit the “**pump housing**” in a direction substantially perpendicular from “**inlet 13**”:

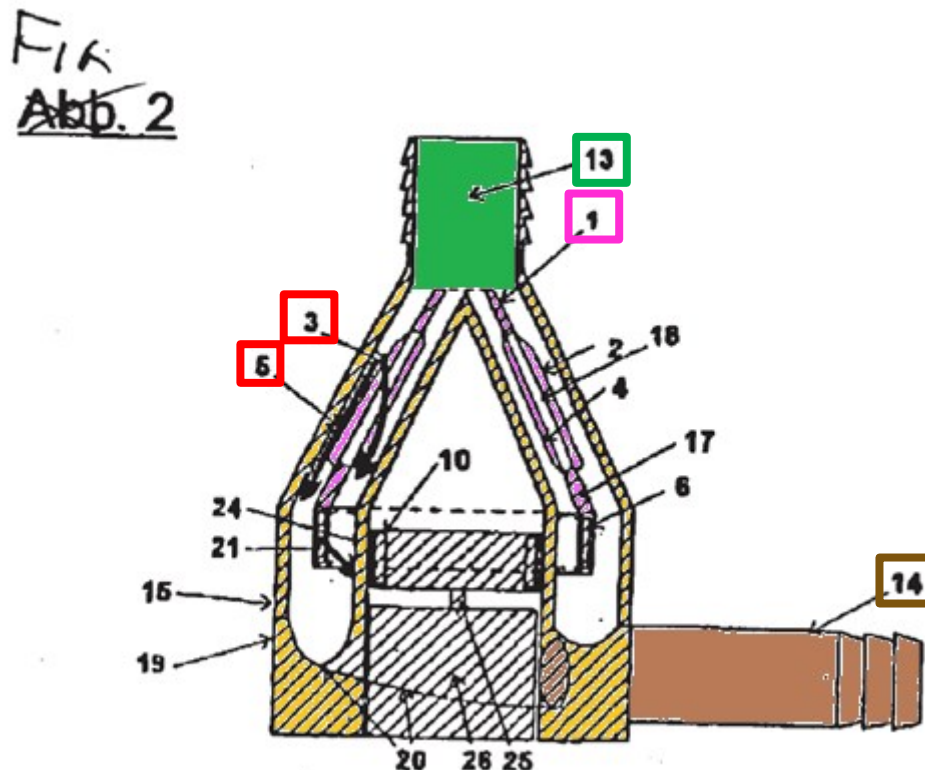


Ex.1005, Fig. 2; Ex.1003, ¶973.

Accordingly, Schima teaches or suggests that “**blood outflow port** (“outlet 14”) positioned radially adjacent the guide surfaces of the **rotor** (“rotor 1”) such that, when the blood is driven by the **magnetically driven rotor assembly**, the blood exits the **surrounding stationary housing** (“pump housing 30”) in a direction substantially perpendicular to the central axis of the **magnetically driven rotor assembly**.” Ex.1003, ¶974.

xii. [1K]

As demonstrated in [1F]-[1G], Schima teaches or suggests that “**magnets 10 or stator 12**” “drive rotation of” the “**rotor**” “via a magneto coupling” with “**rotor magnets 6**.” Schima further teaches or suggests that this rotation “journal[s] the **rotor**” (“orient[s] the magnetically driven rotor assembly”) by “produc[ing] centrifugal flow components 3 and flow components 5,” “mainly for contact-free journaling and stabilizing of the rotor in the **housing**” (“remains entirely spaced apart”). Ex.1005, [0010]-[0013]; Ex.1003, ¶978. Figure 2 illustrates the “centering of the...rotor ...by the **flow components** directed against the housing” (“by the gap sized for passage of the blood”):



Ex.1005, Fig. 2; Ex.1003, ¶980.

Accordingly, Schima teaches or suggests that “*the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly* (“rotor 1”) and orient the *magnetically driven rotor assembly* such that the *magnetically driven rotor assembly* remains entirely spaced apart from the *surrounding stationary housing* (“pump housing 30”) by the gap sized for passage of the blood.” Ex.1003, ¶981.

xiii. [1L]

Schima does expressly disclose this element, however “*an external control unit configured to regulate operation*” to Schima’s pump would have been obvious in view of Akamatsu-1999. Ex.1003, ¶982.

As demonstrated in Ground 3, Akamatsu-1999 expressly discloses this limitation—Figure 1 of Akamatsu-1999 illustrates the connection of the external control unit (**lime green**) to the centrifugal pump (**blue**):

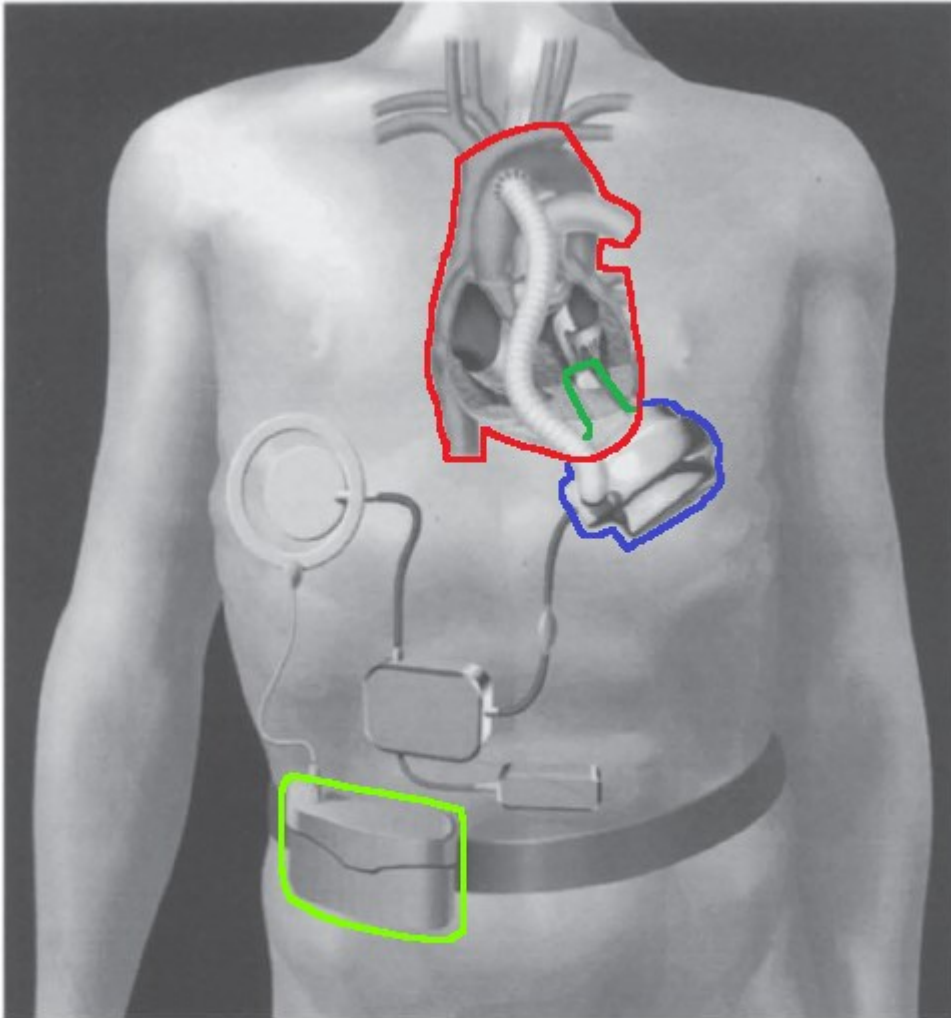


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Supra §VIII.C.1.xiii; Ex.1006, 3-4; Ex.1003, ¶983.

As detailed below (*infra* §VIII.D.15), in the combination, Akamatsu-1999's "controller" would be "*configured to regulate operation*" of Schima's "electric motor 26 which drives...magnets 10" (or "stator 12") ("*the second magnetic device*")." Moreover, Mr. Crosby explains a POSITA would have found it obvious

to try, because the location of a pump’s controller presented a finite number (i.e., two) options—a controller could be external or implanted. Ex.1003, Ex.1003, ¶983.

Further, as demonstrated in Ground 3, Akamatsu-1999 discloses that “[t]he pump was operated at a fixed rotational speed” (“*a control value*”). Ex.1006, 3-4; Ex.1003, ¶¶983–984.

Accordingly, Schima/Akamatsu-1999 render obvious “*an external control unit* (“controller”) *configured to regulate operation of the second magnetic device* (“magnets 10”; “stator 12”) *based upon a control value indicative of cardiac output.*” Ex.1003, ¶988.

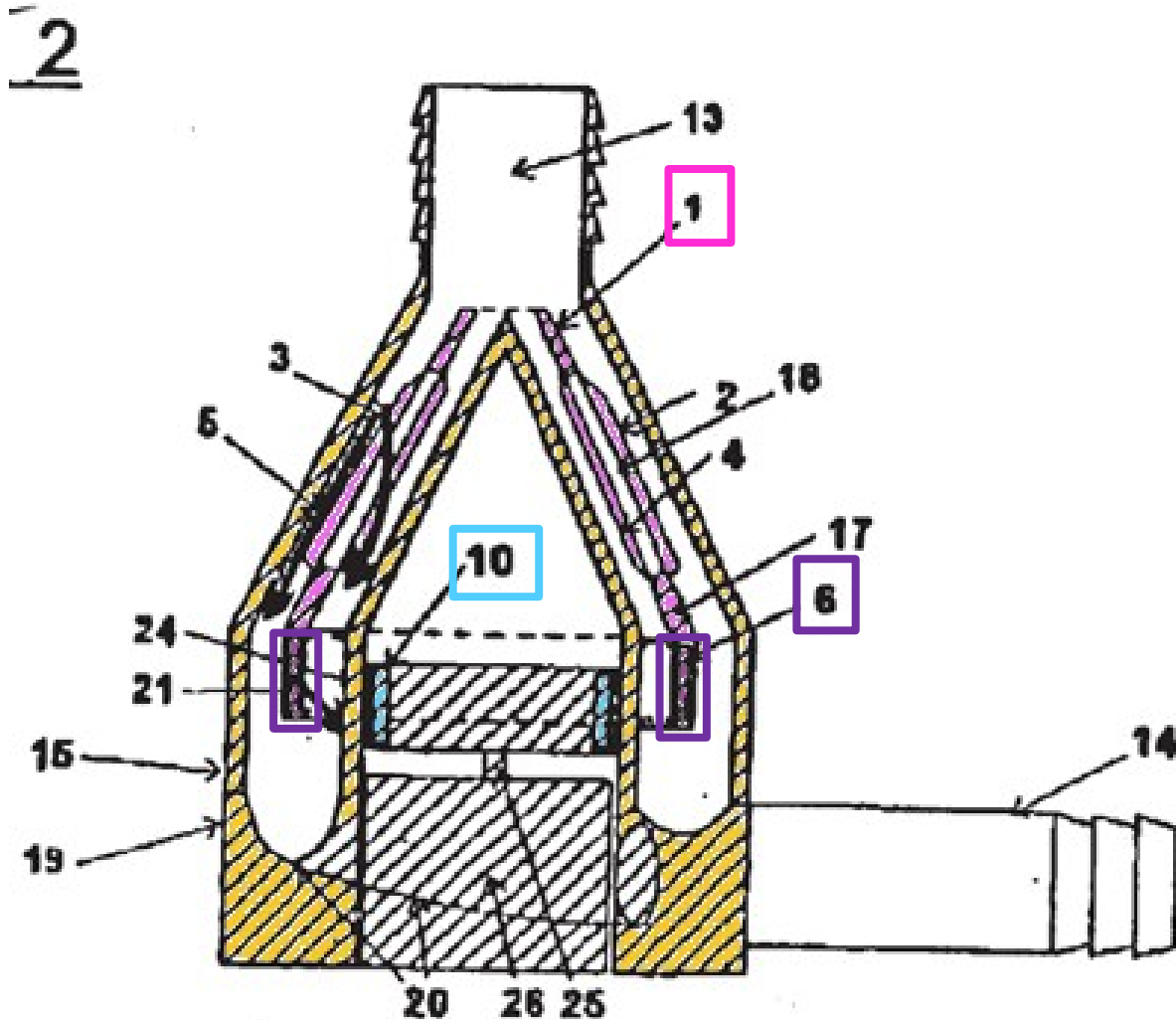
xiv. [1M]

As described in [1L], Schima does expressly disclose this element, however “[*an external control unit is connectable...for controlling*]” Schima’s pump would have been obvious in view of Akamatsu-1999. Ex.1003, ¶989.

Accordingly, for the reasons in [1L] and *infra* §VIII.D.15, Schima/Akamatsu-1999 renders obvious “*the external control unit* (“controller”) *is connectable to the heart assist pump device* (“pump”) *for controlling the second magnetic device* (“magnets 10” or “stator 12”) *to thereby magnetically drive the rotation of the magnetically driven rotor assembly* (“rotor 1”) *via the magneto coupling with the first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶991.

2. Claim 2

As explained in [1G], Schima discloses **rotor magnets 6** at the base of the **rotor**—“positioned between” the **rotor** and the **second magnetic device**, as shown:



Ex.1005, Fig. 2; *see also* Fig. 1 (“stator 12”); Ex.1003, ¶996.

Accordingly, Schima teaches or suggests that “the **first magnetic device** (“rotor magnets 6”) is configured to be positioned between the **second magnetic**

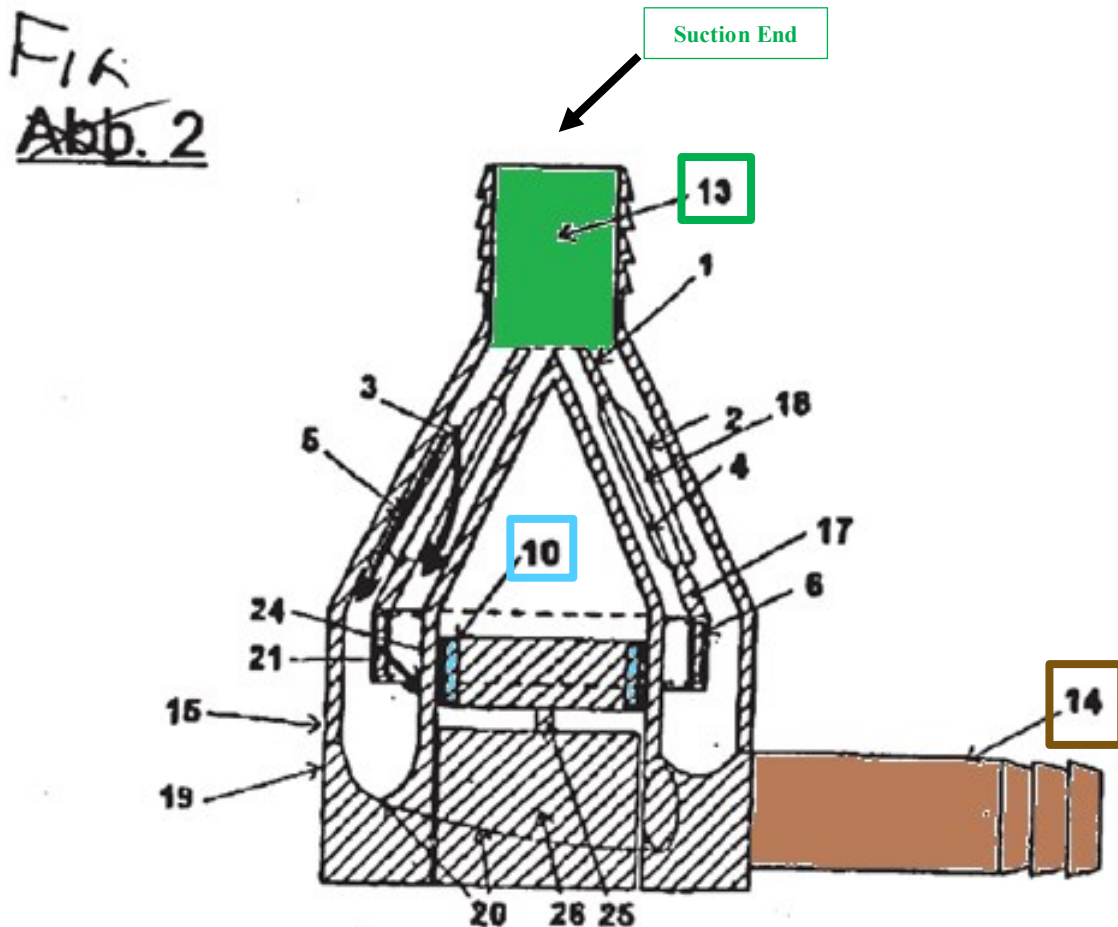
device (“magnets 10”; “stator 12”) and the guide surfaces of the *rotor* (“rotor 1”) of the *magnetically driven rotor assembly*.” Ex.1003, ¶997.

3. Claim 3

For the reasons discussed in [1C], that the “*rotor*” and “*rotor magnets*” are “*rigidly coupled*,” Schima teaches or suggests that “*the first magnetic device* (“rotor magnets 6”) rotates together with the *magnetically driven rotor* (“rotor 1”) relative to the *surrounding rotor housing* (“pump housing 30”).” Ex.1003, ¶1000

4. Claim 4

As demonstrated in [1A] and [1J], the suction end of the “inlet” is insertable into a ventricle of the heart, while the “outlet” is radially adjacent to the impeller which is aligned with the magnets 10 (or “stator 12”):



Ex.1005, Fig. 2; Ex.1003, ¶1004. Further, Schima discloses that, unlike Figure 2 above, “the outlet...[can] be set higher, generally in the plane...of the rotor”), which would make the outlet “positioned closer” to the *second magnetic device*. Ex.1005, [0026]; Ex.1003, ¶1004.

Accordingly, Schima discloses that “*the second magnetic device* (“magnets 10” or “stator 12”) *is positioned closer to the blood outflow port* (“outlet 14”) *than to the suction end of the inflow tube* (“inlet 13”).” Ex.1003, ¶1005.

5. Claim 5

As demonstrated in [1H] and [1M] that the *second magnetic device* is “sealed” and the controller is “external,” Schima/ Akamatsu-1999 renders obvious “*the magnetically driven rotor assembly* (“rotor 1”) *is sealed from the second magnetic device* (“magnets 10”; “stator 12”) *and a drive source* (“controller”) *configured to regulate the operation of the second magnetic device.*” Ex.1003, ¶¶1008–1009.

6. Claim 7

As demonstrated in [1M] and Ground 3, Akamatsu-1999 discloses a “**controller**” using “position sensors” (“*one or more sensors*”) that “*provid[e] feedback signals*” to the “**controller**.” Ex.1006, 3-4; *supra* Ground 3, claim 33; Ex.1003, ¶¶1013–1014.

Accordingly, Schima in view of Akamatsu-1999 renders obvious “*providing feedback signals to the external control unit* (“controller,” Ex.1006) *from one or more sensors* (“position sensors,” Ex.1005).” Ex.1003, ¶1016.

7. Claim 10

In Parallel Litigation, PO asserts that a pump device with an inflow cannula “*is a catheter device*.” Assuming that interpretation, as explained in [1A], because Schima’s pump comprises an “inlet port,” it “*is a catheter device*.” Ex.1003, ¶¶1020–1021.

8. Claim 16

Claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. Ex.1003, ¶1022.

i. [16PRE]

See [1PRE]. Ex.1003, ¶¶1024.

ii. [16A]

See [1A] and [1B] (analyzing axial inflow, i.e., an “*inflow path along an inflow axis*”). Ex.1003, ¶1027.

iii. [16B]

See [1E] (analyzing a “*surrounding stationary housing*” (“pump housing 30”). Schima discloses “*walls...defining a chamber*” of [16B] for the reasons it discloses a “*surrounding stationary housing*” of [1E]. Ex.1003, ¶1030.

iv. [16C]

See [1B] and [1C]. Ex.1003, ¶1033.

v. [16D]

See [1C]. Ex.1003, ¶1036.

vi. [16E]

See [1D]. Ex.1003, ¶1039.

vii. [16F]

See [1E]. Ex.1003, ¶1042.

viii. [16G]

See [1B] and [1E]. Ex.1003, ¶1045.

ix. [16H]

See [1G]. Ex.1003, ¶1048. Schima discloses a “*magnetic drive system comprising a second magnetic device*” of [16H] for the reasons it discloses a “*second magnetic device*” (“magnets 10” or “stator 12”) of [1G].

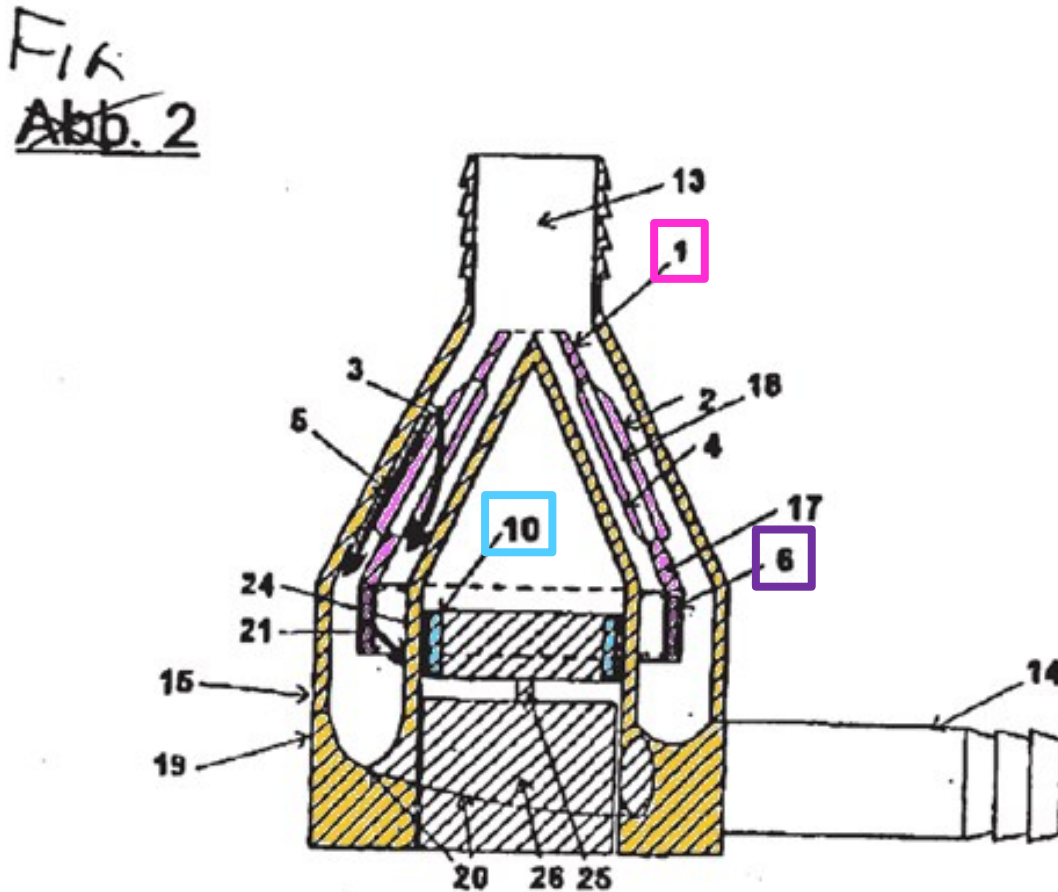
x. [16I]

See [1K] and [2]. Ex.1003, ¶1051. Schima teaches or suggests that the *second magnetic device* is “*positioned axially closer*” to the *first magnetic device* of [16I] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor assembly* of [2].

xi. [16J]

See [1H]. Ex.1003, ¶1054. Schima discloses that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J] for the reasons it discloses a “*second magnetic device*” is “*sealed.*”

Figure 2 illustrates the *second magnetic device* is in a separate section of the housing 30 that is sealed from the *rotor*:



Ex.1005, Fig. 2.

xii. [16K]

See [1J]. Ex.1003, ¶1057.

xiii. [16L]

See [1M]. Ex.1003, ¶1060.

xiv. [16M]

See [1L]. Ex.1003, ¶1063.

9. Claim 17

See [2], [16D], and [16I] *above*. Ex.1003, ¶1070.

10. Claims 18-21

See [1F], [1K]. Schima discloses a “gap...configured to be occupied by the blood” ([18]); that “surrounds” ([19]); “extends radially outward” ([20]) and “along a face...axially opposite from the inflow tube” ([21]) of “the magnetically driven rotor assembly” for the reasons Schima discloses “entirely spaced apart...by a gap sized for passage of the blood” of [1F] and [1K]—i.e., the gap extends entirely surrounding the *magnetically driven rotor assembly*. Ex.1003, ¶1073, 1080, 1084, 1088.

11. Claim 22-23

See [16J]. Schima discloses a “*wall of the...chamber* separates the first chamber from the second chamber” of [22]-[23] for the reasons that a “*wall of the...chamber* is positioned between the *magnetically driven rotor assembly* and the *second magnetic device*” of [16J]. Ex.1003, ¶1099, 1101.

12. Claim 24

See [1C], [16C]. Ex.1003, ¶1107.

13. Claim 26

See [7]. Ex.1003, ¶1114.

14. Claim 28

See [10]. Ex.1003, ¶1119.

15. Motivation to Combine Schima with Akamatsu-1999

It would have been obvious to control (using an “*an external control unit*”) and implant (“*insert[] into a ventricle of the heart*”) Schima’s pump in the configuration per Akamatsu-1999. Ex.1003, §X.D.13.

In the Schima/Akamatsu-1999 combination, an external controller would regulate operation of Schima’s “motor 26 which drives...magnets 10,” as taught by Akamatsu-1999. Ex.1003, §X.D.13.a. For implantation of Schima/Akamatsu-1999, Schima’s “inlet 13” would be “inserted into the left ventricle” as taught by Akamatsu-1999. Ex.1003, §1120.

Akamatsu-1999 and Schima are analogous art to the 077 Patent for several reasons. *First*, Akamatsu-1999 and Schima are directed toward the same field of endeavor—“to assist the performance of a heart with...a rotary pump and driven via magneto coupling.” Ex.1001, Abstract; 3:50-51; Ex.1006, 3; Ex.1008, [0001]. Ex.1003, ¶¶1122, 1132. *Second*, Akamatsu-1999 and Schima are reasonably pertinent to a problem described by the 077 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:27-32; Ex.1006, 8; Ex.1005, [0002], [0009]. Ex.1003, ¶¶1123, 1132.

The Schima/Akamatsu-1999 combination would have been an arrangement of old elements (inlet tube; and external controller) with each performing the same function it has been known to perform (allowing blood flow from the ventricle to the

pump; and allowing a user to regulate operation) and yielding no more than one would expect from such an arrangement (blood flowing from the ventricle to the pump; and user control of a pump) as Akamatsu-1999, Bourque-2001, and Wampler-169 all demonstrate. Ex.1005, [0012]; Ex.1006, 4; Ex.1007, 401-402; Ex.1008 [0072]-[0075]; Ex.1003, ¶¶1124-1126 (discussing implantation), 1133-1138 (discussing controller).

A POSITA would have been motivated to control and implant Schima's pump according to Akamatsu-1999 because the teachings are complimentary—Schima focuses on pump design alone, while Akamatsu-1999 focuses on pump design, control, and implantation. Ex.1003, ¶1128. Schima is silent as to pump implantation and control. Ex.1003, ¶1130. Thus, a POSITA would have been motivated to use Schima's advantageous pump design while using Akamatsu-1999's teachings as to pump control (regulating operation via external controller) and implantation (inserted into the left ventricle). Ex.1003, ¶1139.

Further, a POSITA would have had a reasonable expectation of success that Schima's pump would be controlled and implanted according to Akamatsu-1999's teachings. External controllers were commonly employed to regulate operation of LVADs. Ex.1003, ¶¶1139-1140; Ex.1008, [0072]; Ex.1007, 401, 403. LVADs were routinely delivered to the heart with a suction end inserted into the left ventricle. Ex.1003, ¶1129; Ex.1008, [0075]; Ex.1007, 401-402; Ex.1006, 4.

IX. BOARD DISCRETION

A. 35 U.S.C. §325(d)

Denial under §325(d) is not warranted. The challenges presented herein are not cumulative or redundant to the prosecution of the 077 Patent as Wampler-169, Bourque-2001 (or Bourque-2001/ Wampler-169), Akamatsu-1999, Schima⁸ (or Schima/Akamatsu-1999), were not cited or considered by the Examiner during prosecution of the 077 Patent. The Examiner also did not have Mr. Crosby's detailed expert testimony and the evidence of record.

B. 35 U.S.C. §314(a)

Stay: Factor 1 is **neutral or weighs against** discretionary denial because Petitioner intends to request a stay after filing.

Trial: Factor 2 **weighs against** discretionary denial because there is no trial date. The most recent statistics⁹ on median time-to-trial for civil actions in NDIL was 53.7 months. Trial can be expected in approximately July 2028, about two years after a FWD.

⁸ A German-language version of Schima was cited in an IDS by the applicant during prosecution of the 077 Patent but was not relied on by the Examiner.

⁹ <https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2024/06/30-3>.

Investment: Factor 3 **weighs against** discretionary denial because the Parallel Litigation is in its early stages of discovery and the parties' investment has been relatively minimal.

Overlapping Issues and Parties: Factors 4-5 are **neutral** for discretionary denial because the issues and parties are the same here as in the Parallel Litigation.

Other Considerations: Factor 6 **weighs against** discretionary denial. The merits of this petition are particularly compelling—the prior art is robust in this field, and each primary reference has strikingly similar disclosures to that of the 077 Patent, is directed at the same problem, and proposes the same solutions as the 077 Patent using nearly identical architecture.

X. CONCLUSION

Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent are unpatentable for the reasons demonstrated above.

Dated: November 27, 2024

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,911 words (as determined by the Microsoft Word word-processing system used to prepare the brief and including annotated figures), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on November 27, 2024, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by priority mail on the following:

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