

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00096
U.S. Patent No. 11,351,356

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,351,356**

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,351,356
1002	U.S. Patent No. 11,351,356 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 7 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 A-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 method for assisting the blood circulation of a heart in a body, comprising:
[1A]	delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart
[1B]	while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart
[1C]	wherein the magnetically driven rotor is axially aligned with the inflow tube,
[1D]	and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor
[1E]	the magnetically driven rotor being rotatable about a central axis
[1F]	and [the magnetically driven rotor] being rigidly coupled to a first magnetic device
[1G]	that [the first magnetic device] is located within the surrounding rotor housing
[1H]	[the first magnetic device is] at a position axially adjacent to the magnetically driven rotor
[1I]	wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube
[1J]	and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1K]	while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device
[1L]	and a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the

	magnetically driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor,
[1M]	wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1N]	connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,
[1O]	the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.
[2]	The method of claim 1, wherein in response to the rotation of the magnetically driven rotor via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.
[3A]	The method of claim 2, wherein the surrounding rotor housing comprises at least one sealing wall between the first magnetic device and the second magnetic device
[3B]	and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.
[4]	The method of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.
[5]	The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.
[6]	The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.

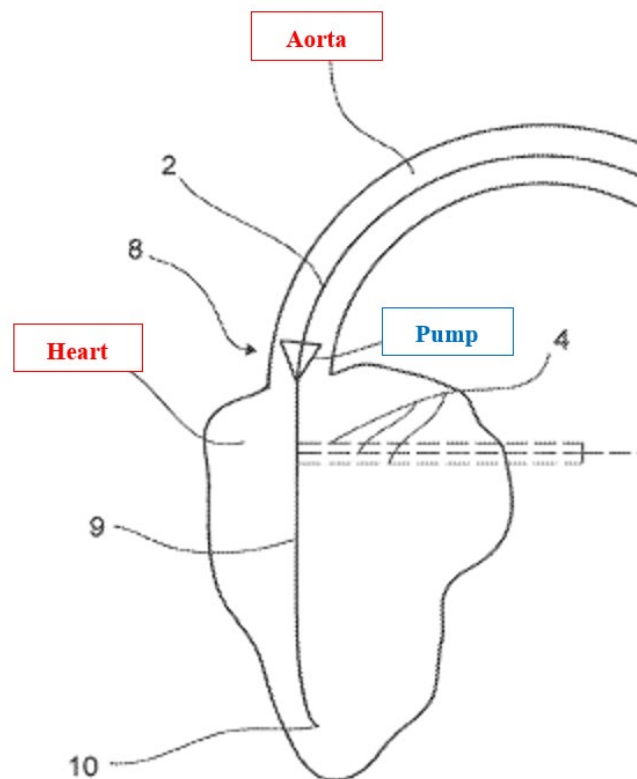
[7]	The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.
[10]	The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.
[12]	The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube.
[13]	The method of claim 1, wherein the heart assist pump device is a catheter device.

I. INTRODUCTION

Abbott Laboratories (“Petitioner”) petitions for *Inter Partes* Review and cancellation of claims 1-7, 10, and 12-13 (“the Challenged Claims”) of U.S. Patent No. 11,351,356 (the “356 Patent” (Ex.1001)), assigned to Patent Owner, Miracor Medical SA (“Miracor” or “PO”).

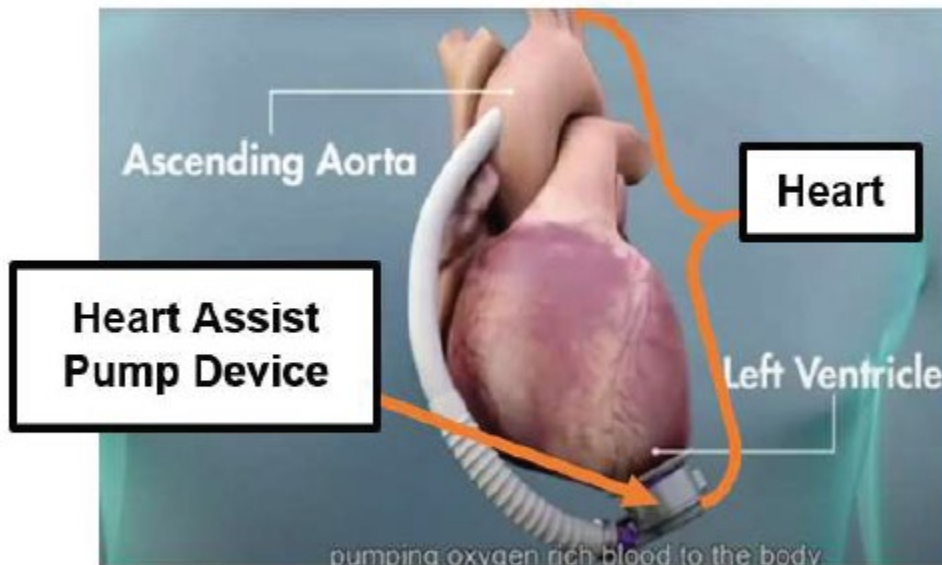
II. SUMMARY OF THE ARGUMENT

The 356 Patent discloses assisting the heart using an “intravasal” “catheter” blood pump placed **inside** a blood vessel like the aorta:



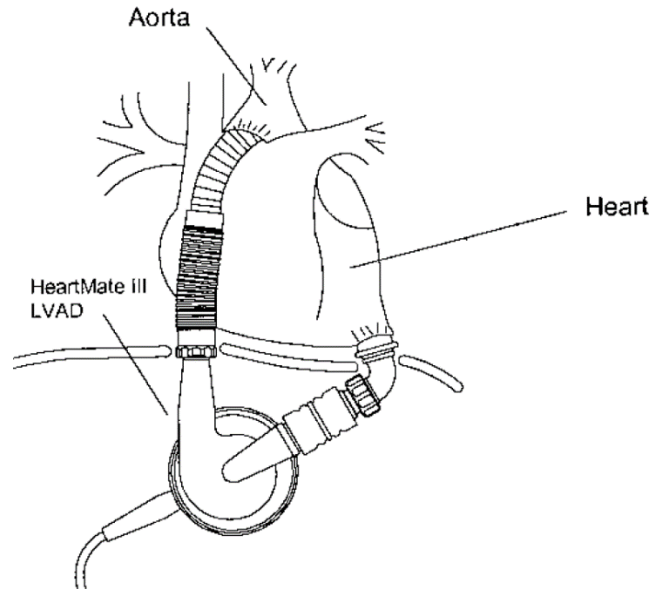
Ex.1001, Fig 1 (annotated), 2:32-42 (“the catheter according to the invention”); 3:50-60 (“according to the invention...an intravasal...catheter.”).

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



Ex.1019 (Miracor's complaint), 5.

PO filed for the 356 Patent in 2021—three years after Abbott commercialized HeartMate 3—but claimed priority to a 2007 application. Abbott had disclosed designs for its centrifugal LVAD as early as 2001:



Ex.1007, Fig. 3 (annotated).

Ex.1007 featured a magnetically levitated rotor, eliminating 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 356 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 will also be filing petitions for *inter partes* review against related U.S. Patent Nos. 11,351,357; 11,376,415; 11,572,879; 11,674,517; and 11,754,077.

Litigation matters.

The 356 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 356 Patent is a continuation and claims priority to U.S. App. No. 17/558,979, filed on Dec. 22, 2021, which is a continuation of U.S. App. No. 17/446,046, filed on Aug. 26, 2021, which is a continuation of U.S. App. No. 16/282,948, filed on Feb. 22, 2019 (issued as U.S. Pat. No. 11,123,540), which is a continuation of U.S. App. No. 14/454,965, filed on Aug. 8, 2014 (issued as U.S. Pat. No. 10,251,984), which is a continuation of U.S. App. No. 13/555,318, filed on July 23, 2012 (issued as U.S. Pat. No. 8,801,590), which is a divisional of U.S. App. No. 12/449,632 filed on Aug. 18, 2009 (issued as 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 the benefit of AT A 306/2007 filed Feb. 27, 2007.

C. Lead and Back-Up Counsel and Service Information

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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 356 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	1-7, 10, and 12-13	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 356 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 356 Patent

The 356 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].

...**The known design** namely assumes that centrifugal flow components and flow components directed against a housing are present, in which the flow components directed against the housing serve primarily for the non-contact mounting and stabilizing of the rotor in the housing.

Ex.1001, 3:17-27.

VI. CLAIM CONSTRUCTION

PO's apparent Parallel Litigation constructions differ from the plain and ordinary meanings in the context of the 356 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, as is referred by the 356 Patent as a coupling between two rotating “bar magnets”—a drive wheel rotates one bar magnet which causes another bar magnet (connected to a rotor) to rotate. Ex.1003, ¶¶54-55 (analyzing Ex.1001, 2:32-56, 4:47-67, 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, 12; Ex.1003, ¶¶84-87.

B. By the Blood Flowing

Pump rotors can be suspended in at least two different ways—using hydrodynamic or magnetic bearings. Ex.1003, ¶¶57-60. The 356 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—“*in response to rotation, ...[the] rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing*”—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 the blood flowing*—meaningless by encompassing a magnetic bearing. Ex.1003, ¶95 (analyzing Ex.1019, 12).

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):

¹ Even PO’s complaint distinguishes between the two. Ex.1019, 6 (showing the magnetic bearing in Abbott’s HeartMate 3 (left) versus a hydrodynamic bearing in another pump (right)).

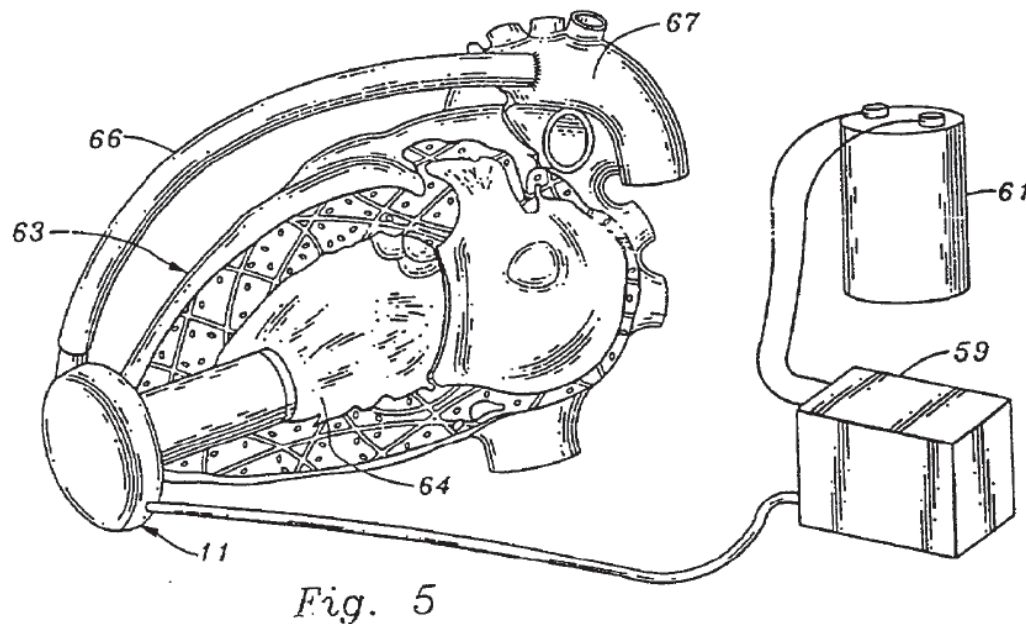
LVADs		Drive-type	
		Magneto coupling	Electromagnetic
Bearing-type	Hydrodynamic	<u>Schima</u>	<u>Wampler-169</u>
	Magnetic	<u>Akamatsu-1999</u>	<u>Bourque-2001</u>

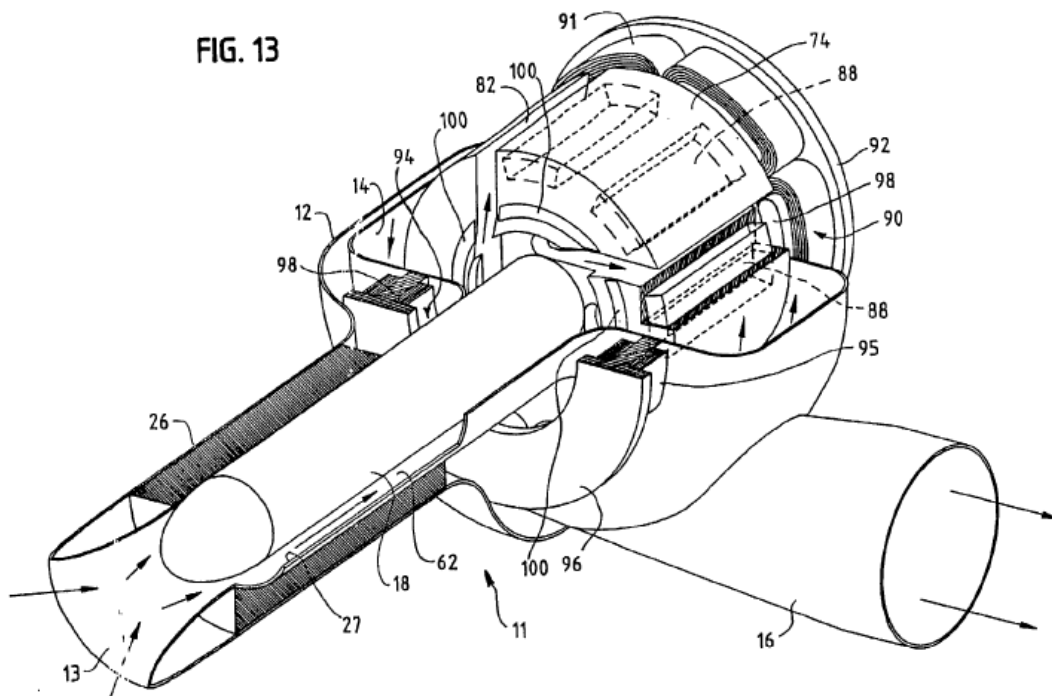
Ex.1003, Ex.1003, ¶¶146-148.

A. Wampler-169

U.S. Pub. No. 2002/0102169A1 (“Wampler-169”), published **August 1, 2002**, is prior art to the 356 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. As Dr. Hall-Ellis explains, 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 356 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 356 Patent at least under 35 U.S.C. §102(b).

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

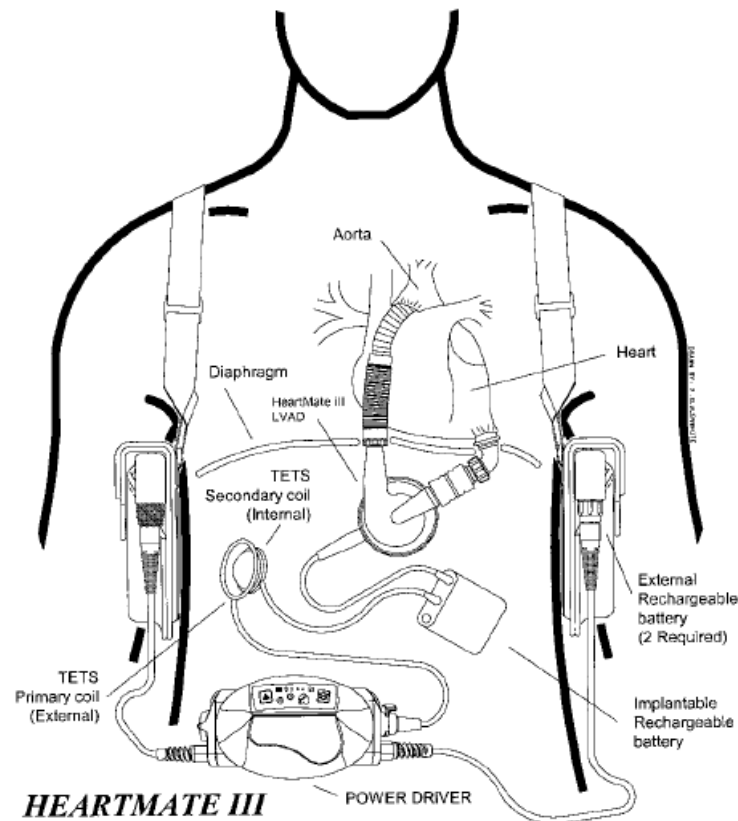


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

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, as Dr. Hall-Ellis explains, 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 356 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 356 Patent at least under 35 U.S.C. §102(b).

The Akamatsu-1999 pump is shown below:

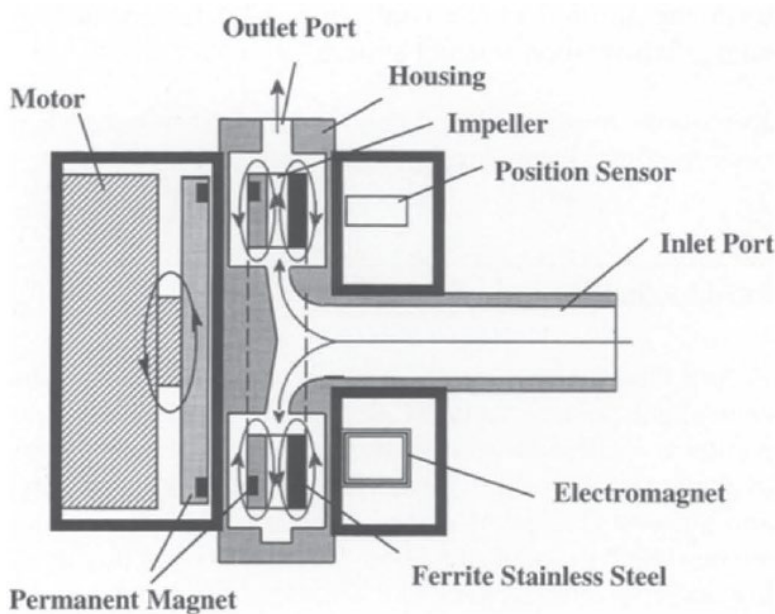


Fig. 2. Schematic cross section of the MSCP

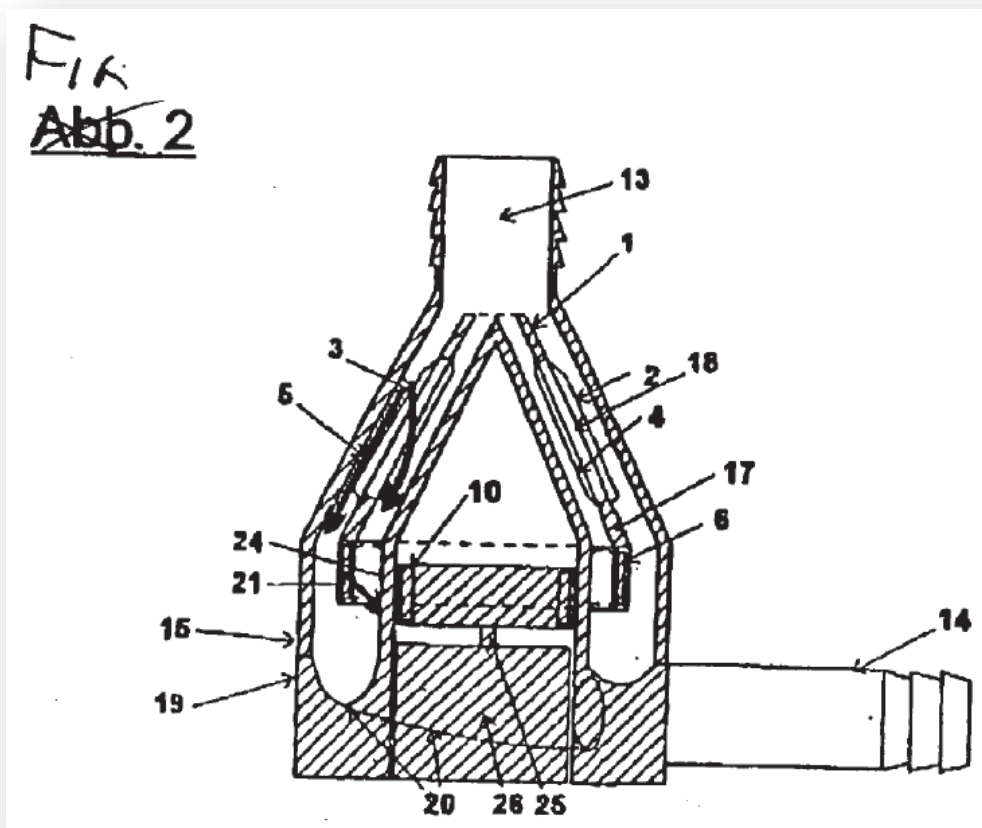
Ex.1006, Fig. 2; *see also* Ex.1003, ¶¶133-134.

D. Schima²

U.S. Pub. No. 2003/0124007A1 (“Schima”), published **July 3, 2003**, is prior art to the 356 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 356 Patent’s specification’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. CLAIMS 1-7, 10, AND 12-13 ARE UNPATENTABLE

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

1. Claim 1

i. [1PRE]³

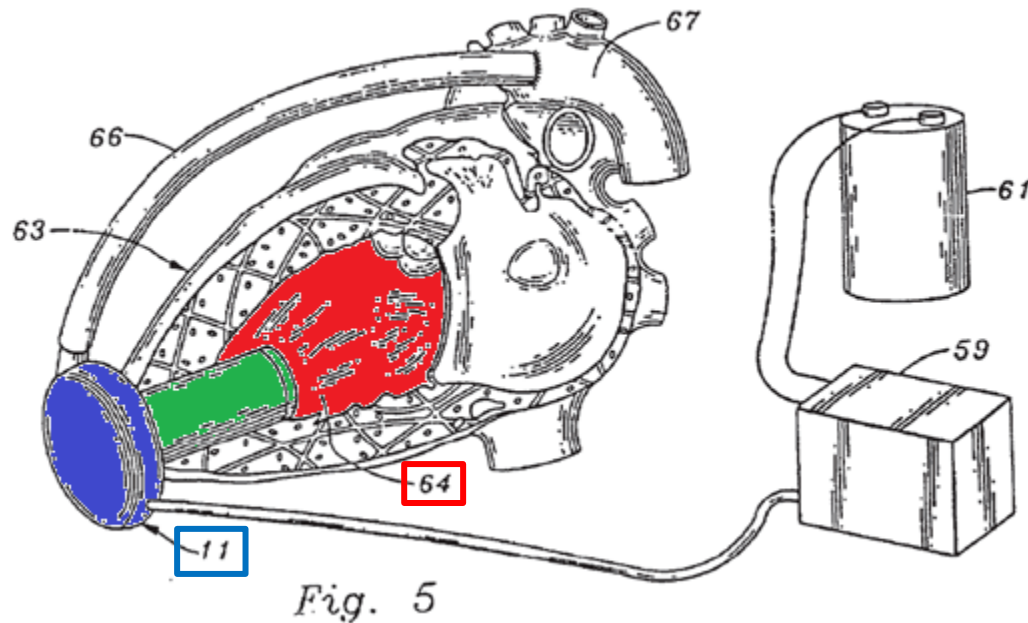
Wampler-169 discloses “implantation in humans” of “a left ventricular assist device (‘LVAD’)” “blood pump” “for chronic use” in patients with “heart failure” who “could benefit from cardiac transplantation,” but cannot receive a “donor heart.” Ex.1008, [0002]-[0003]. Ex.1003, ¶150.

Accordingly, Wampler-169 discloses “*a method for assisting the blood circulation of a **heart** in a body* (‘LVAD’ for ‘heart failure’).” Ex.1003, ¶151.

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**” (“*so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart*”) while the remainder of the “compact and disc-shaped [pump] fit[s] well between the apex of the heart and the adjacent diaphragm” (“*delivering...to the heart*”) (Ex.1008, [0075]-[0076]), as shown:

³ The claims of the 356 Patent are included in the Claim Index, *infra* pp. ix-xi.



Ex.1008, Fig. 5 (annotated)⁴; *see also* Fig 13 (showing blood suction through inlet tube, Ex.1003, ¶155); Ex.1003, ¶154.

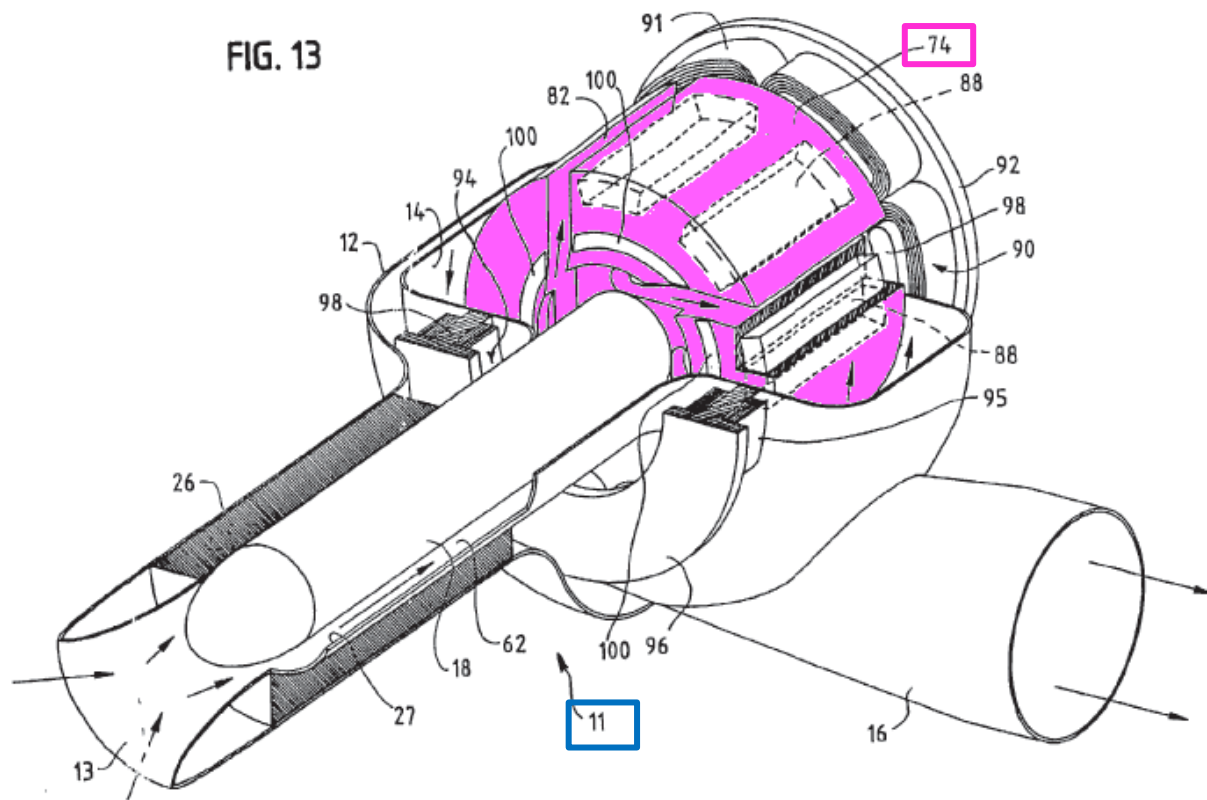
Accordingly, Wampler-169 discloses “delivering *a heart assist pump device* (“pump 11”) to the *heart* so that *a suction end of an inflow tube* (“inlet tube 13”) of the *heart assist pump device* is inserted into *a ventricle of the heart* (“placed into the apex of the left ventricle 64”). Ex.1003, ¶157.

iii. [1B]

Wampler-169 discloses that the *pump’s* “drive is imparted to the *impeller* [74] by magnetic interaction [‘*a magnetically driven rotor*’] between...permanent

⁴ All figures annotated unless otherwise specified.

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:



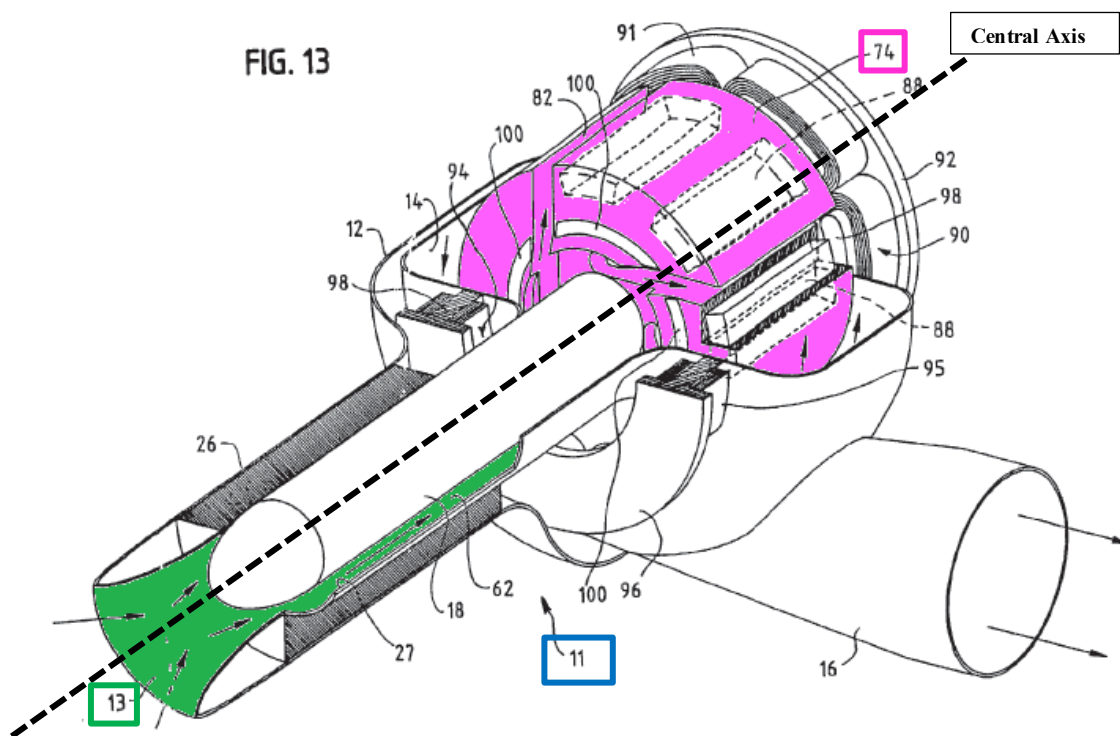
Ex.1008, Fig. 13; Ex.1003, ¶163; *see also id.*, ¶¶159, 162. As demonstrated in [1A], inlet 13 “is placed into the apex” while the “disc-shaped” portion of the pump, including its **impeller**, fit between the heart and diaphragm (“*positioned outside the ventricle*”). *Supra* [1A].

Accordingly, Wampler-169 discloses that a suction end of an inflow tube of the heart assist pump device is inserted into the ventricle of the heart “*while a*

magnetically driven rotor (“impeller 74”) of the *heart assist pump device* (“pump 11”) is positioned outside the ventricle of the *heart*.” Ex.1003, ¶166.

iv. [1C]

Wampler-169 discloses “axial inflow...of the blood” (Ex.1008, [0075]-[0076]; Ex.1003, ¶169) “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:

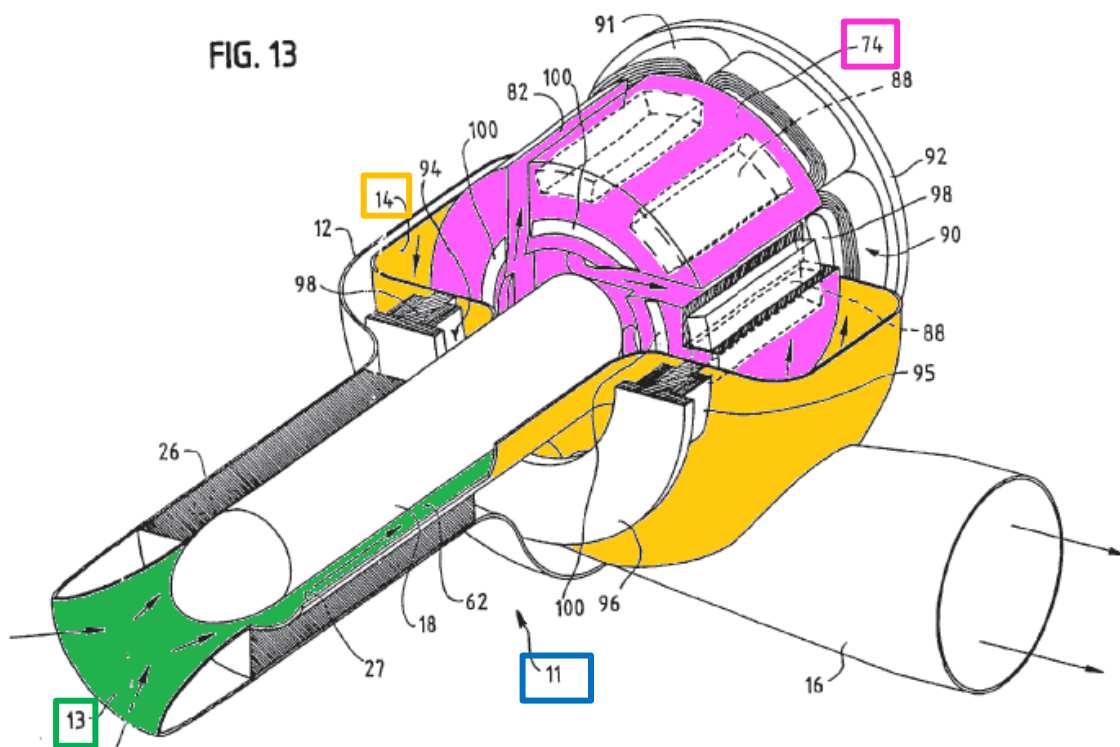


Ex.1008, Fig. 13; *see also* [0082] (explaining that “longitudinal axis...may be identical to...FIGS. 1-8”). Ex.1003, ¶168.

Accordingly, Wampler-169 discloses that “*the magnetically driven rotor (“impeller 74”) is axially aligned with the inflow tube (“inlet tube 13”).*” Ex.1003, ¶170.

v. [1D]

Wampler-169 discloses that the “*impeller 74[’s] “rotation” is “within housing 12, within casing 14” (Ex.1008, [0081], Ex.1003, ¶172) (“rotatable within a surrounding rotor housing”), and that “[r]otation of the...impeller...causes blood to flow through inlet tube 13 in the direction of arrows” (“to act upon blood flowing from the inflow tube toward the magnetically driven rotor”) (Ex.1008, [0074], Ex.1003, ¶174), as shown:*

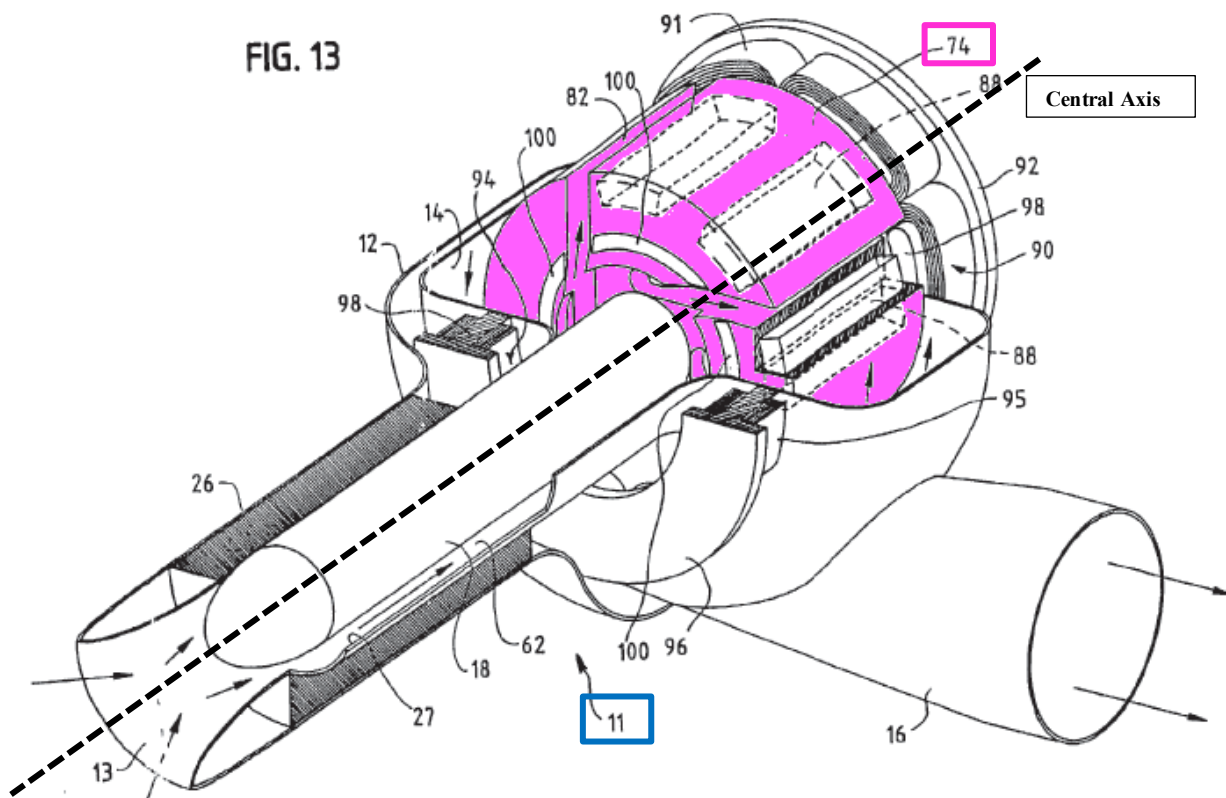


Ex.1008, Fig. 13. Ex.1003, ¶175.

Accordingly, Wampler-169 discloses that the magnetically driven rotor “is rotatable within **a surrounding rotor housing** (“casing 14”) of the **heart assist pump device** (“pump 11”) to act upon blood flowing from the **inflow tube** (“inlet tube 13”) toward the **magnetically driven rotor** (“impeller 74).” Ex.1003, ¶176.

vi. *[1E]*

As demonstrated in [1B]-[1C], “drive is imparted to [rotate] the **impeller** [74]” (Ex.1008, [0018]) “about a rotational axis” (Ex.1008, [0013]; Ex.1003, ¶172), as shown:



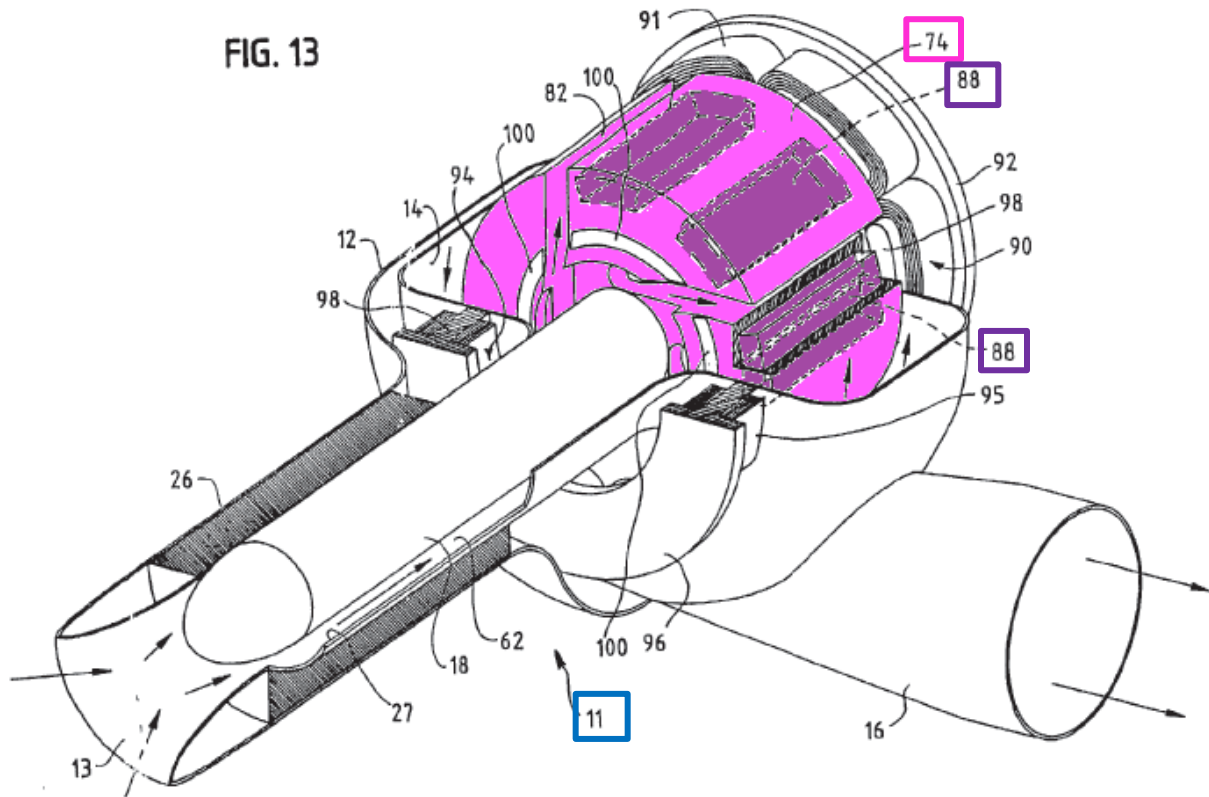
Ex.1008, Fig. 13; *see also* [0081]-[0082] (explaining “rotation about a[] longitudinal axis...may be identical to...FIGS. 1-8”); *supra* [1B]-[1C]; Ex.1003, ¶180.

Accordingly, Wampler-169 discloses “*the magnetically driven rotor* (“impeller 74”) *being rotatable about a central axis.*” Ex.1003, ¶181.

vii. [1F]

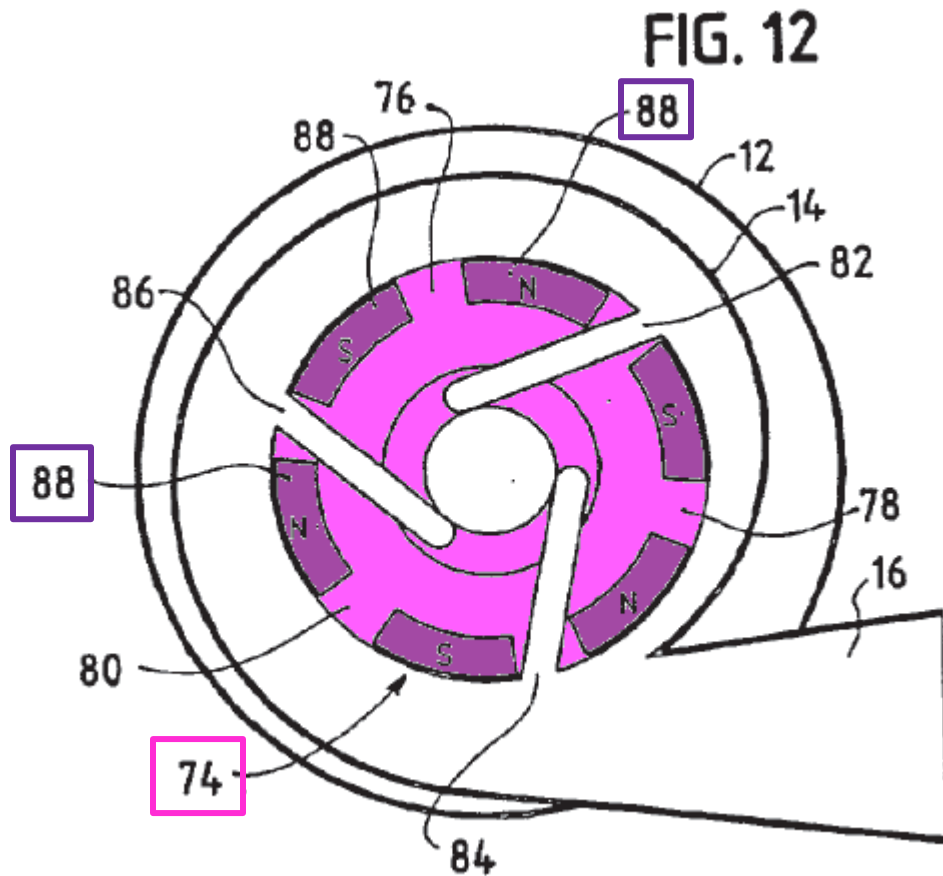
Wampler-169 discloses that “drive is imparted to...**permanent magnetic segments**” (“*a first magnetic device*”) “imbedded within [the] **impeller [74]**” (“*rigidly coupled*”).⁵ Ex.1008, [0018] *see also* [0070] (“magnetic segments...are encased in a jacket.”); Ex.1003, ¶183 (discussing that imbedded segments are *rigidly coupled*). Wampler-169 also refers to these “**segments**” as “**magnetic pieces 88**” (“*a first magnetic device*”), which “are inserted [*‘rigidly coupled’*] in...the **impeller**” (Ex.1008, [0080]), as shown:

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



Ex.1008, Fig. 13. Ex.1003, ¶187; *see also* Ex.1003, ¶¶184-186 (analyzing interaction between “magnetic pieces 88” and “motor stators 90 and 94”).

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

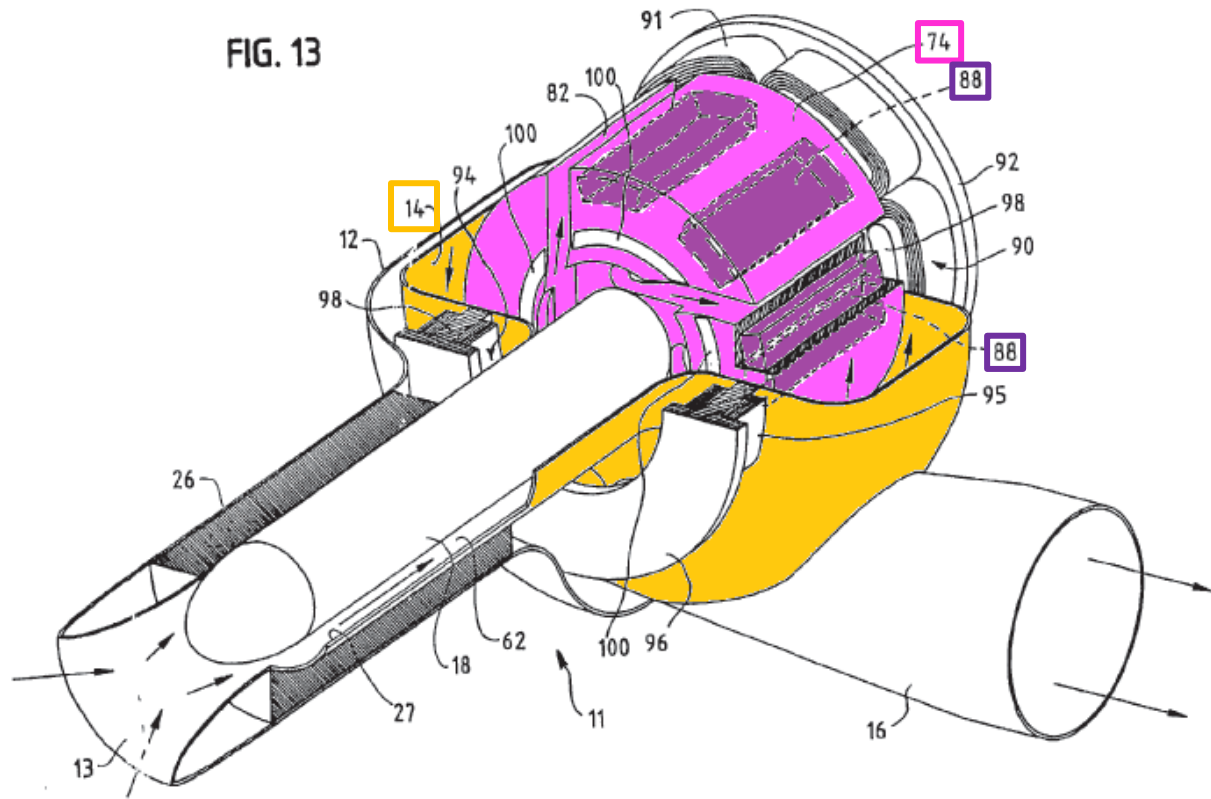


Ex.1008, Fig. 12; Ex.1003, ¶188.

Accordingly, Wampler-169 teaches or suggests the *magnetically driven rotor* (“impeller 74”) “being rigidly coupled to a *first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶189.

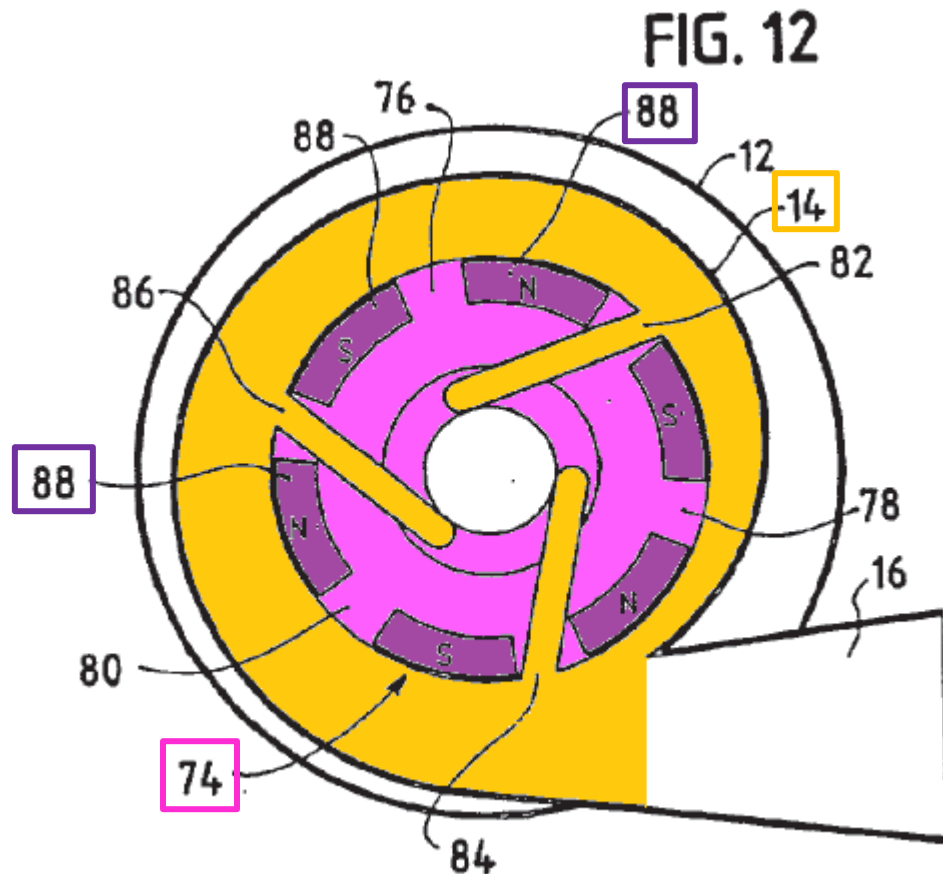
viii. [1G]

As demonstrated in [1D] and [1F], Wampler-169 discloses that the *impeller 74*, which has *magnetic pieces 88*, is “located within housing 12, within *casing 14*” (“within the surrounding rotor housing”) (Ex.1008, [0080]-[0081], Ex.1003, ¶191), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶194; *supra* [1D], [1F].

Figure 12 illustrates a cross-sectional view of the **impeller's magnetic pieces** within **casing 14**:



Ex.1008, Fig. 12; Ex.1003, ¶193.

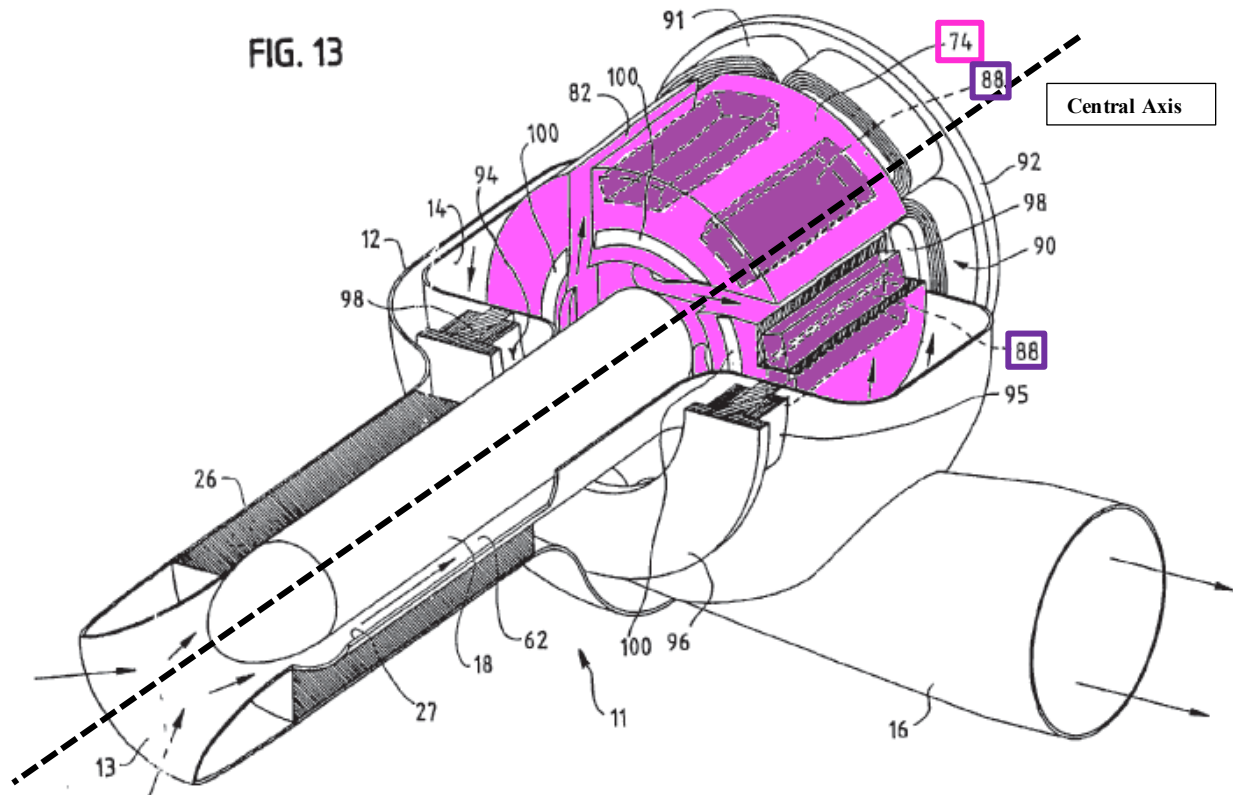
Accordingly, Wampler-169 discloses that the **first magnetic device** (“magnetic pieces 88”) “*is located within the **surrounding rotor housing*** (“casing 14”).” Ex.1003, ¶195.

ix. $[1H]$

In Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is “*at a position axially adjacent to the magnetically driven rotor.*” Ex.1019, 5-7.

Assuming that interpretation, as demonstrated in [1F], Wampler-169 discloses that the “**permanent magnetic segments** [are] imbedded [*‘at a position axially*

adjacent’] within [the] **impeller**.” Ex.1008, [0080]; *see also* [0070] (“magnetic segments...are encased in a jacket.”). Wampler-169 also refers to these “**segments**” as “**magnetic pieces 88**” which “are inserted [‘*at a position axially adjacent*’] in...the **impeller**” (Ex.1008, [0080]-[0081]; Ex.1003, ¶197), as shown:



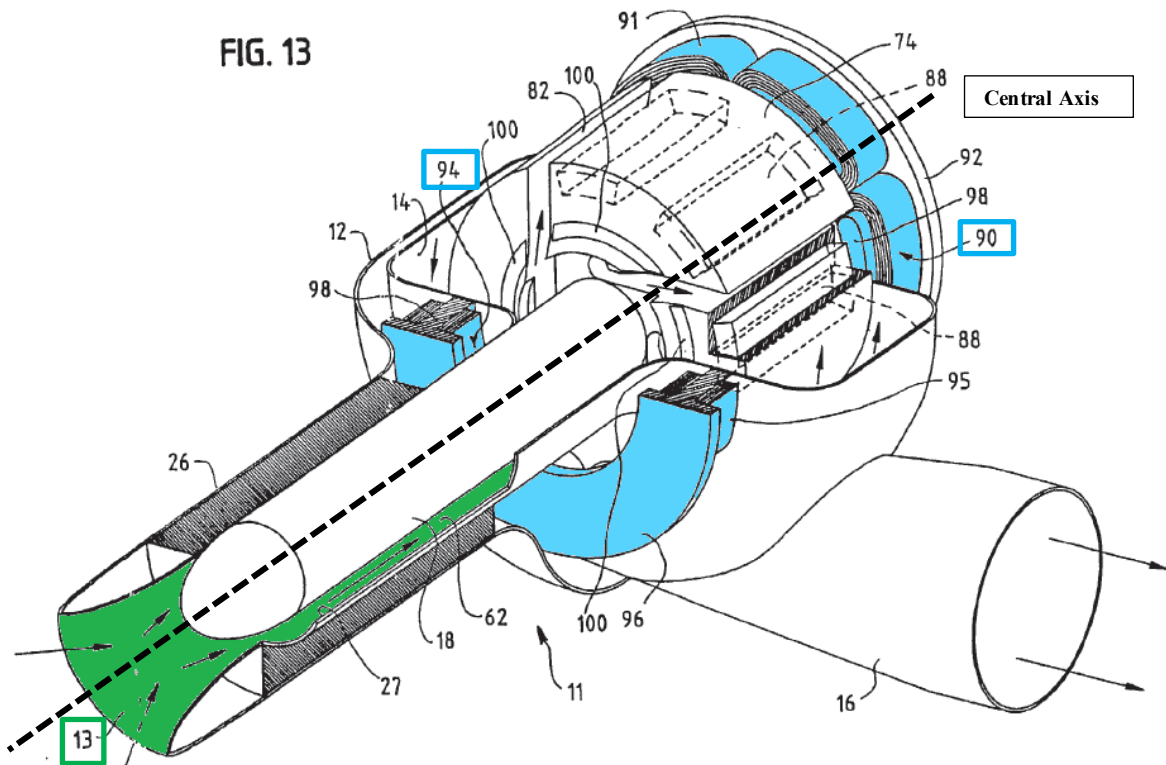
Ex.1008, Figs. 13; *supra* [1F]; Ex.1003, ¶198. Further, Mr. Crosby explains the “impeller” and “magnetic pieces” are axially adjacent—situated next to each other on the same axis. Ex.1003, ¶199, ¶355.

Accordingly, Wampler-169 teaches or suggests that the **first magnetic device** (“magnetic pieces 88”) is “*at a position axially adjacent to the magnetically driven rotor.*” Ex.1003, ¶200.

x. [II]

In Parallel Litigation, PO asserts that a “motor and/or stator” is “*a second magnetic device.*” Ex.1019, 8 (cleaned up).

Assuming that interpretation, Wampler 169 discloses “**motor stators 90 and 94**” that comprise elements “to complete a magnetic circuit” (Ex.1008, [0085]; Ex.1003 ¶203) (“*a second magnetic device*”); are “circular” (Ex.1008, [0018]) (“*axially aligned*”); and are axially aligned with the “**inlet tube 13**” (“*inflow tube*”) (Ex.1008, [0080], ¶¶206-207), as shown:



Ex.1008, Fig. 13, *see also* [0018] (referring to 90 and 94 as a “circular electromagnetic stator”), [0070]; Ex.1003, ¶209.

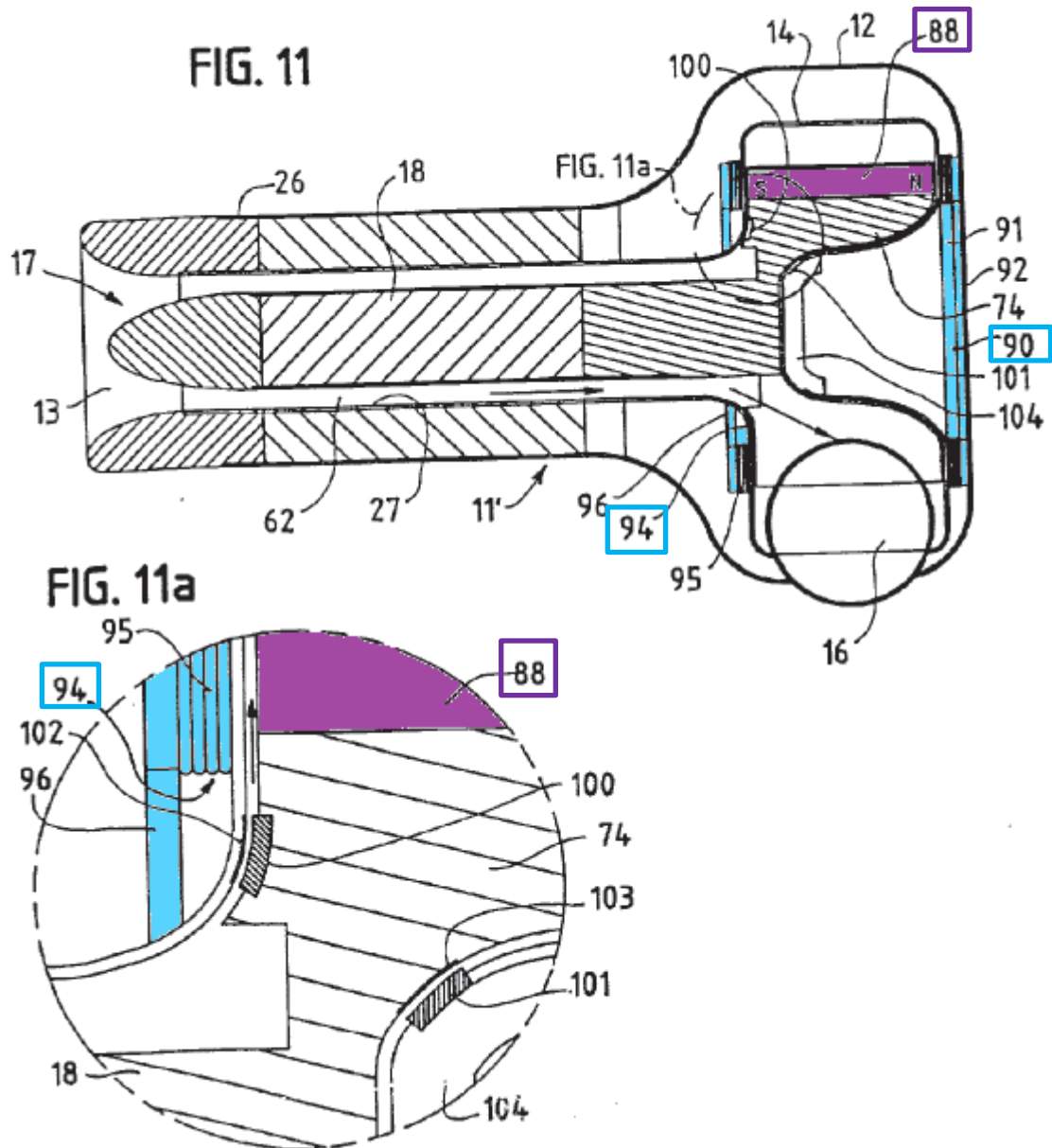
Accordingly, Wampler-169 discloses that “*the heart assist pump device* (“pump 11”) *further includes: a second magnetic device* (“motor stators 90 and 94”) *axially aligned with the inflow tube* (“inlet tube 13”).” Ex.1003, ¶210.

xi. [1J]

In Parallel Litigation, PO alleges that a “stator” satisfies this limitation. Ex.1019, 12.

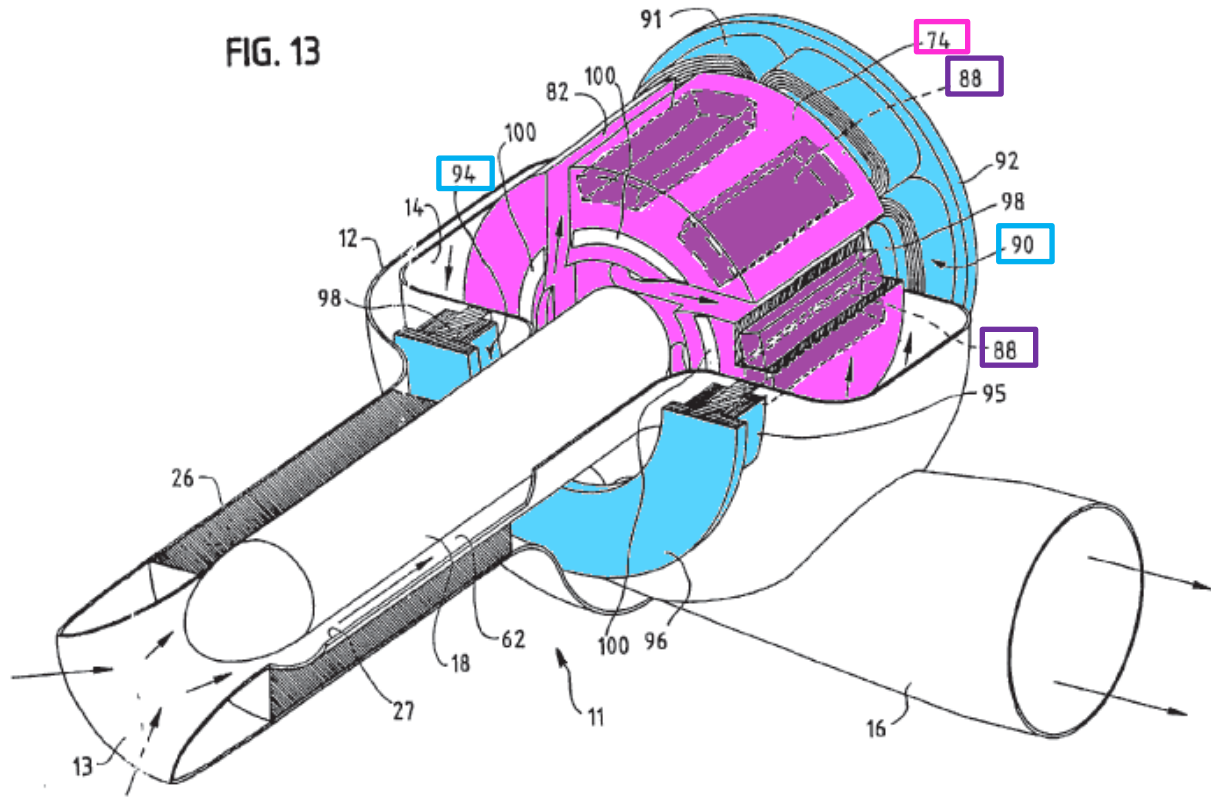
Assuming that interpretation, Wampler-169 discloses that “drive is imparted to the **impeller** by magnetic interaction [*to magnetically drive...via a magneto*

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, ¶¶214-215. 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, ¶214 (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, ¶216.

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**:

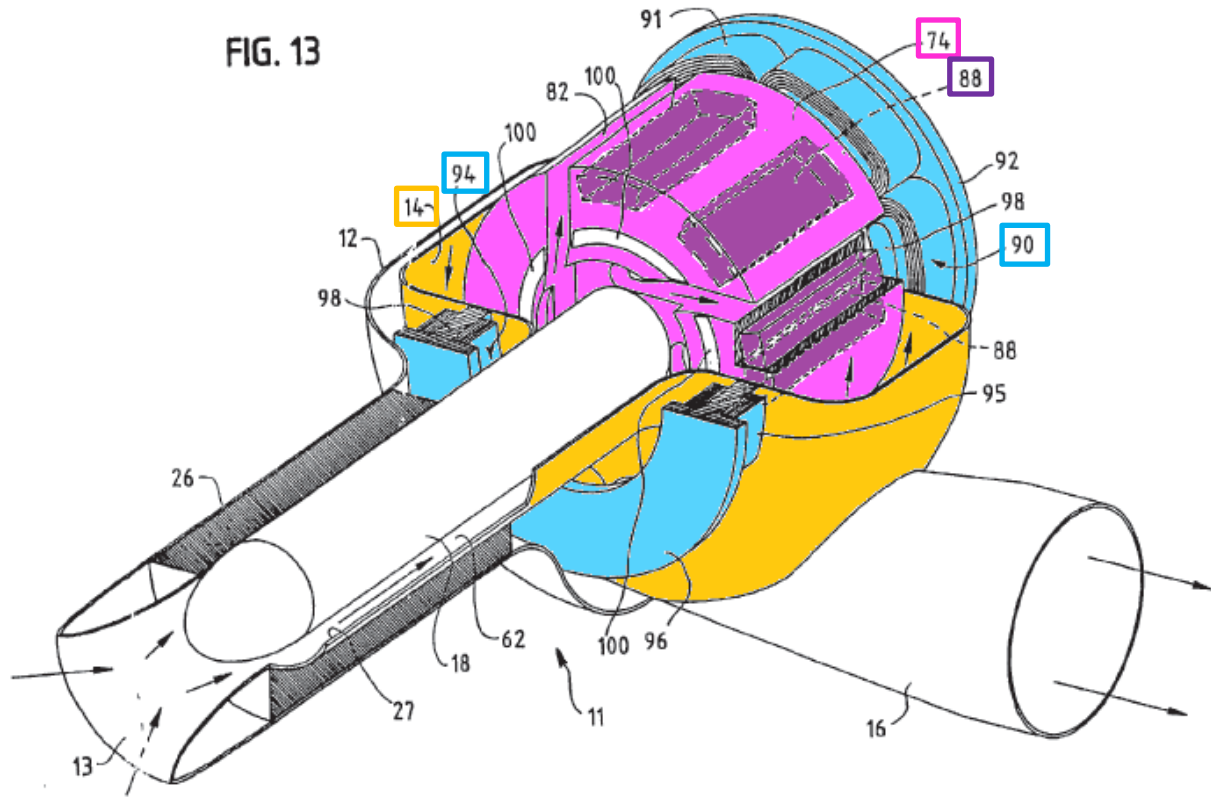


Ex.1008, Fig. 13; Ex.1003, ¶217.

Accordingly, Wampler-169 discloses that the **second magnetic device** (“motor stators 90 and 94”) is “*positioned to magnetically drive rotation of the magnetically driven rotor*” (“impeller 74”) *via a magneto coupling with the first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶218.

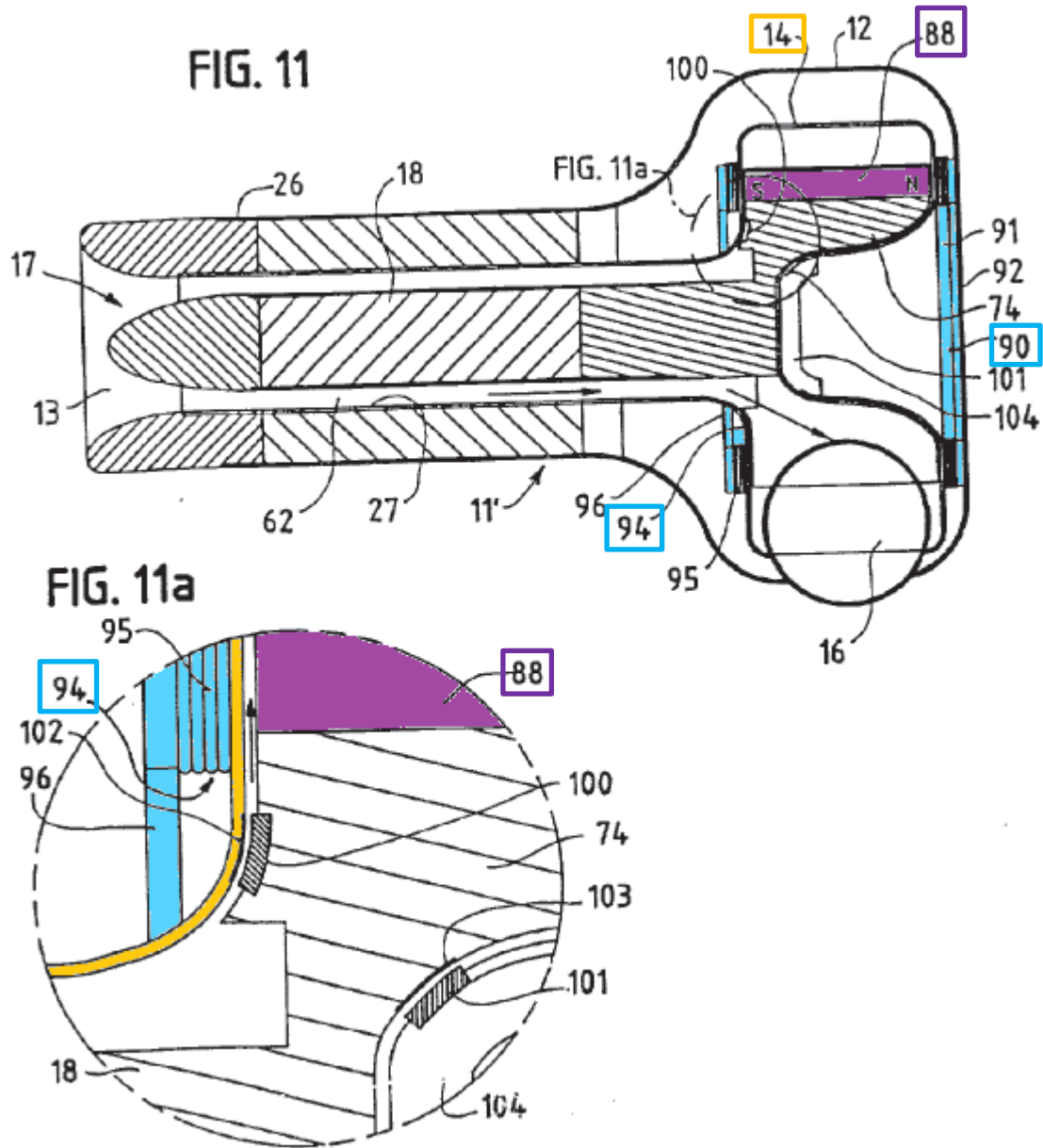
xii. [1K]

Wampler-169 discloses that the “**stator[s]**” are fixed between housing 12 and **casing 14**” (Ex.1008, [0083]-[0084]; Ex.1003, ¶221) (“*spaced apart and sealed*”) while the “**impeller**” and its “**magnetic pieces**” are “*enclos[ed]*” within the **casing** (Ex.1008, [0012], Ex.1003, ¶222), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶223.

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

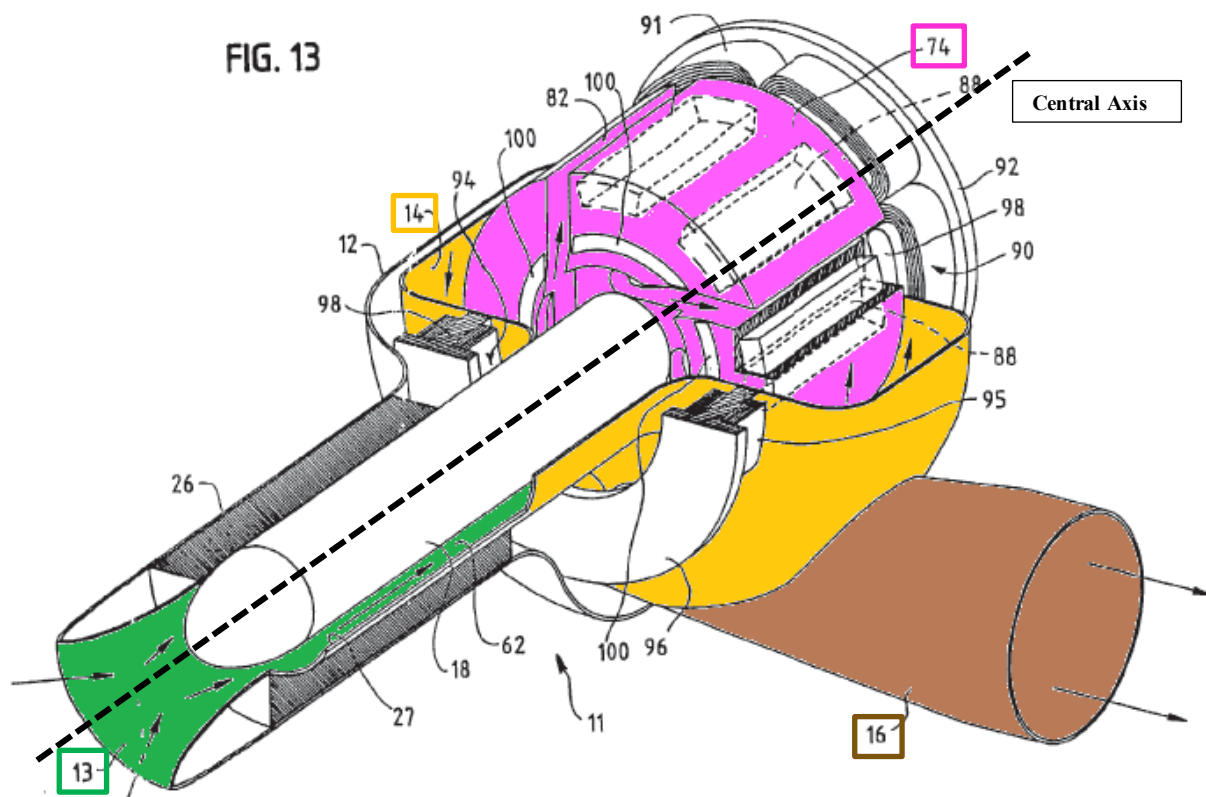


Ex.1008, Figs. 11-11a; Figs. 7-8b, [0070]; Ex.1003, ¶224.

Accordingly, Wampler-169 discloses that the *second magnetic device* (“motor stators 90 and 94”) is positioned according to [1K] “*while being spaced apart and sealed from both the magnetically driven rotor* (“impeller 74”) *and the first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶225.

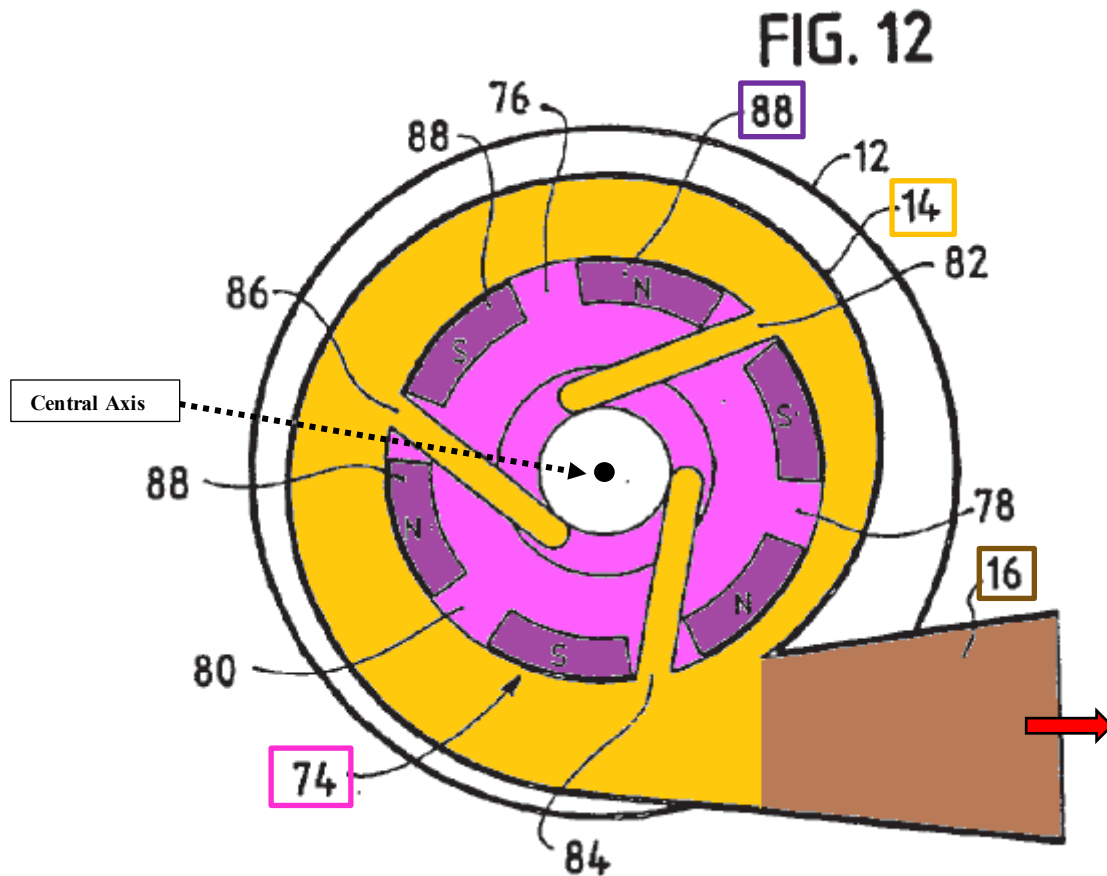
xiii. [1L]

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 from the inflow tube*”) (Ex.1008, [0074]-[0076], [0080]; Ex.1003, ¶227), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶229.

Figure 12 illustrates a top view of the radial outflow (**red** arrow):



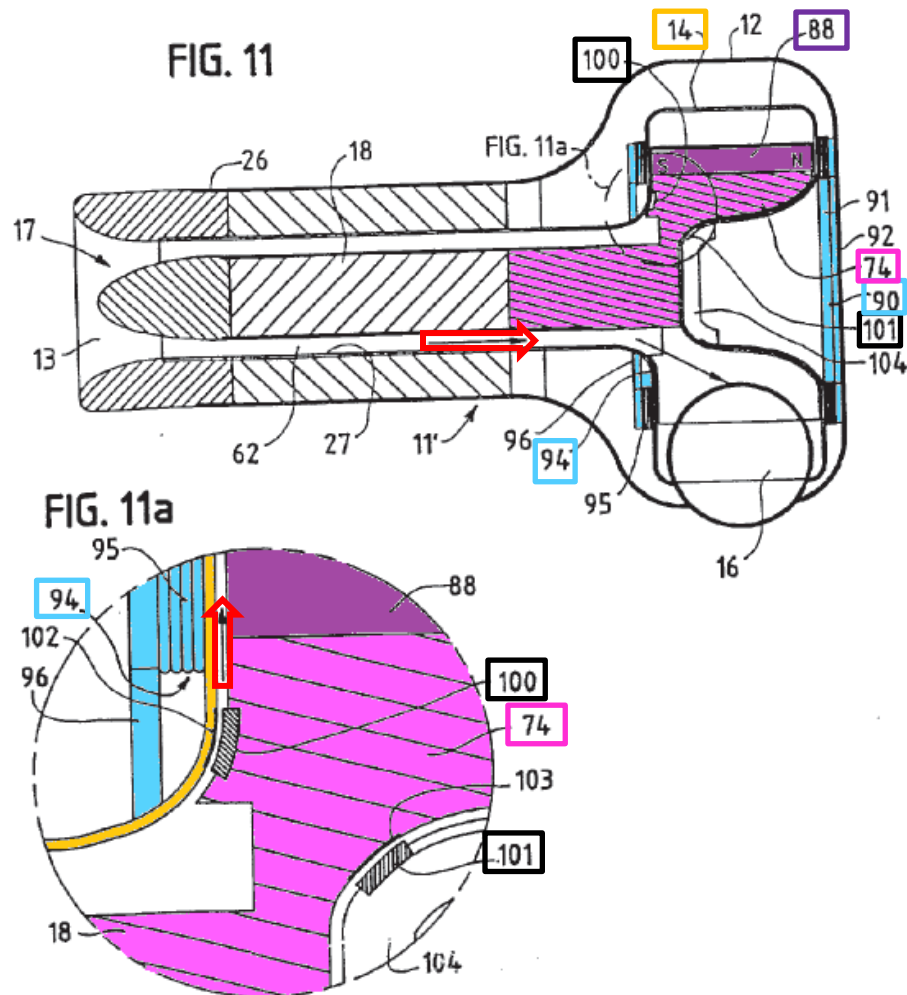
Ex.1008, Fig. 12; Ex.1003, ¶230.

Accordingly, Wampler-169 discloses “a **blood outflow port** (“discharge tube 16”) positioned radially adjacent the **magnetically driven rotor** (“impeller 74”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“casing 14”) in a direction substantially perpendicular (“a 90-degree redirection”) from the **inflow tube** (“inlet tube 13”) and the **central axis** of the **magnetically driven rotor**.” Ex.1003, ¶231.

xiv. [1M]

As demonstrated in [1J], Wampler-169 discloses that drive is imparted “*via a magneto coupling*” and that “the impeller [is] suspended within the housing.” Ex.1008, [0013]; *supra* [1J].

Wampler-169 further discloses that “once rotation [of the **impeller**] begins” (“*in response to rotation of the magnetically driven 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, ¶237), as shown:



Ex.1008, Figs. 11-11a; Ex.1003, ¶238.

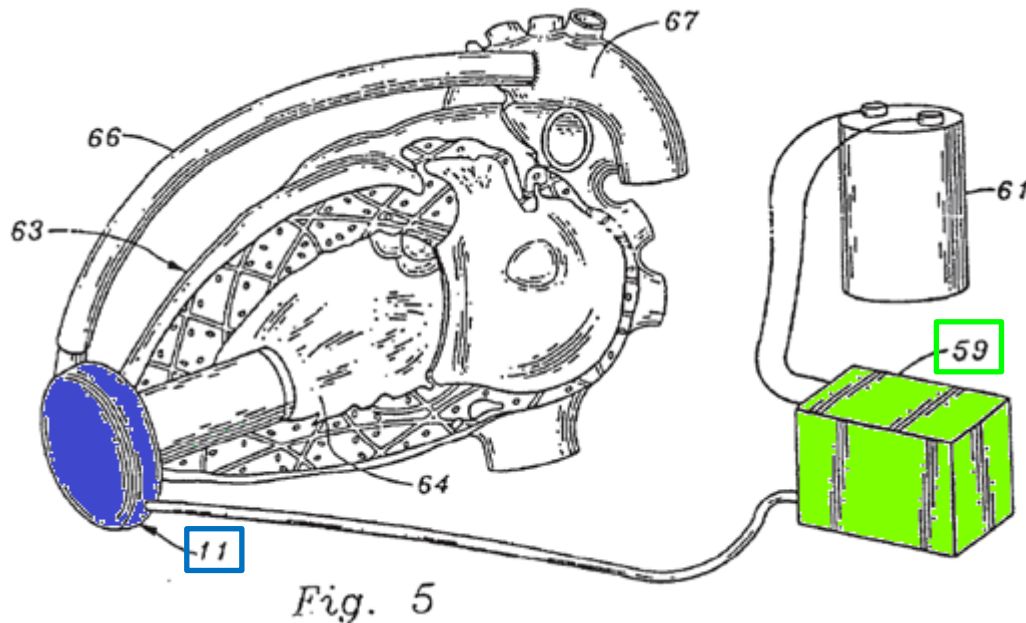
Said another way, Wampler-169 teaches that “hydrodynamic bearings are formed” “*in response to rotation of the [impeller]*”—“**once rotation begins...** fluid film produces increased pressure...which forces” (Ex.1008, [0020]) the “**impeller** [to be] separated from the casing by a fluid film.” Ex.1008, [0092]; Ex.1003, ¶239.

Accordingly, Wampler-169 discloses that “*the magneto coupling orients the magnetically driven rotor* (“impeller 74”) so that, in response to rotation of the

magnetically driven rotor (“once rotation...begins”), the *magnetically driven rotor* remains entirely spaced apart (“force[d] apart”), from the *surrounding rotor housing* (“casing 14”) by the blood flowing (“fluid film”) from the *inflow tube* (“inlet tube 13”) and to the *blood outflow port* (“discharge tube 16”).” Ex.1003, ¶240.

xv. [1N]

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, ¶243) (“*for regulating operation*”) by “produc[ing] an electromagnetic field...to drive...the rotor” (“*to thereby magnetically drive the rotation*”) (Ex.1008, [0072]; Ex.1003, ¶242), as shown:



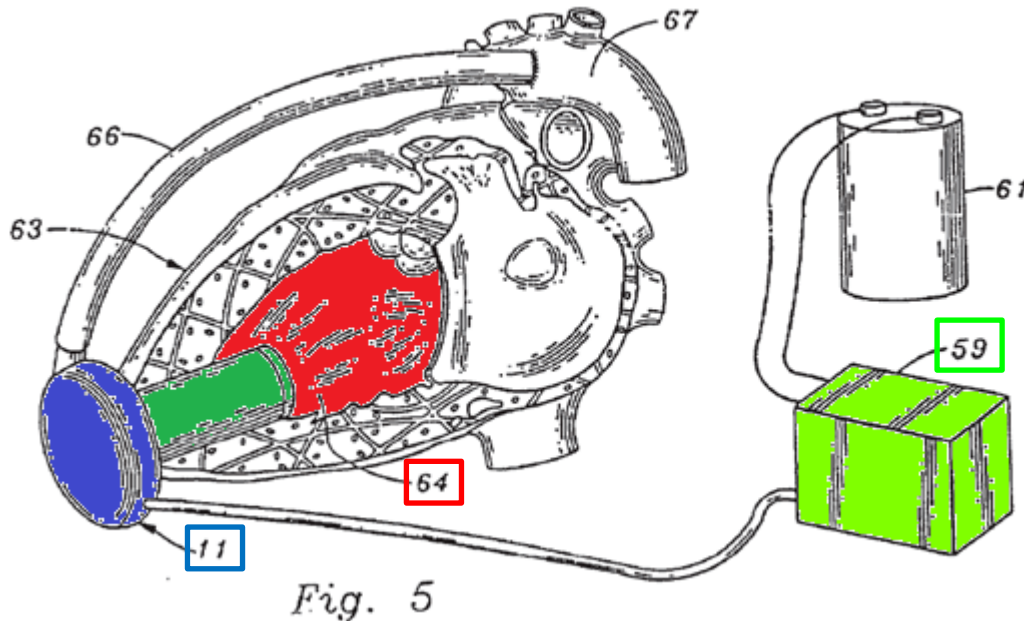
Ex.1008, Fig. 5; Ex.1003, ¶245; *see also* ¶¶242-244 (analyzing how controller regulat[es] operation).

Accordingly, Wampler-169 teaches or suggests “connecting an **external control unit** (“controller 59”) to the **heart assist pump device** (“pump 11”) for regulating operation (“to determine the running rate of pump”) of the **second magnetic device** (“motor stators 90 and 94”) to thereby magnetically drive the rotation of the **magnetically driven rotor** (“impeller 74”) via the magneto coupling (as demonstrated in 1[J]) with the **first magnetic device** (“magnetic pieces 88”).” Ex.1003, ¶246.

xvi. [10]

As explained in [1N], Wampler-169 discloses “that **controller 59**...may be worn externally by the user” (Ex.1008, [0070]) (*positioned exterior to the body*); and

as explained in [1A], an “inlet tube 16...is placed into the apex of the left ventricle” (Ex.1008, [0075], Ex.1003, ¶249), as shown:



Ex.1008, Fig. 5; *supra* [1A]; Ex.1003, ¶249.

Accordingly, Wampler-169 discloses “the external control unit (“controller 59”) being positioned exterior to the body while the inflow tube (“inlet tube 13”) of the heart assist pump device (“pump 11”) is in the heart.” Ex.1003, ¶250.

Wampler-169 therefore renders obvious Claim 1. Ex.1003, ¶¶150-251.

2. Dependent Claims 2, 3, and 4

i. [2]

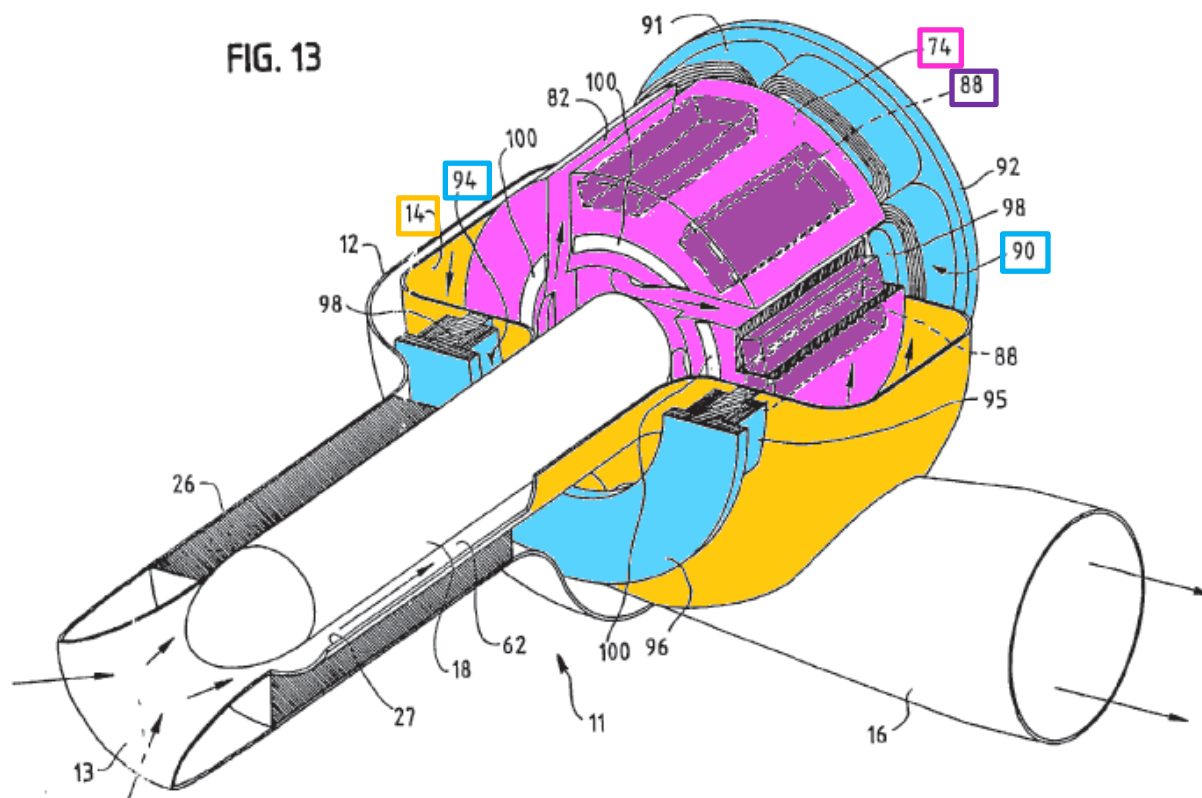
Wampler-169 discloses that the “centrifugal pump impeller” “includes...blade sectors” (Ex.1008, [0012]-[0013]) (“guide surfaces”) so that “[r]otation of...impeller 19, causes blood to flow through inlet tube 13 in the

direction of arrows 62” (“*produce centrifugal flow components*”). Ex.1008, [0074], Fig. 6 (showing arrows 62); Ex.1003, ¶¶255-256.

Accordingly, Wampler-169 discloses that “*in response to the rotation of the magnetically driven rotor* (“impeller 74”) *via the magneto coupling, guide surfaces* (“blade sectors”) *of the magnetically driven rotor produce centrifugal flow components*” (“arrows 62”). Ex.1003, ¶258.

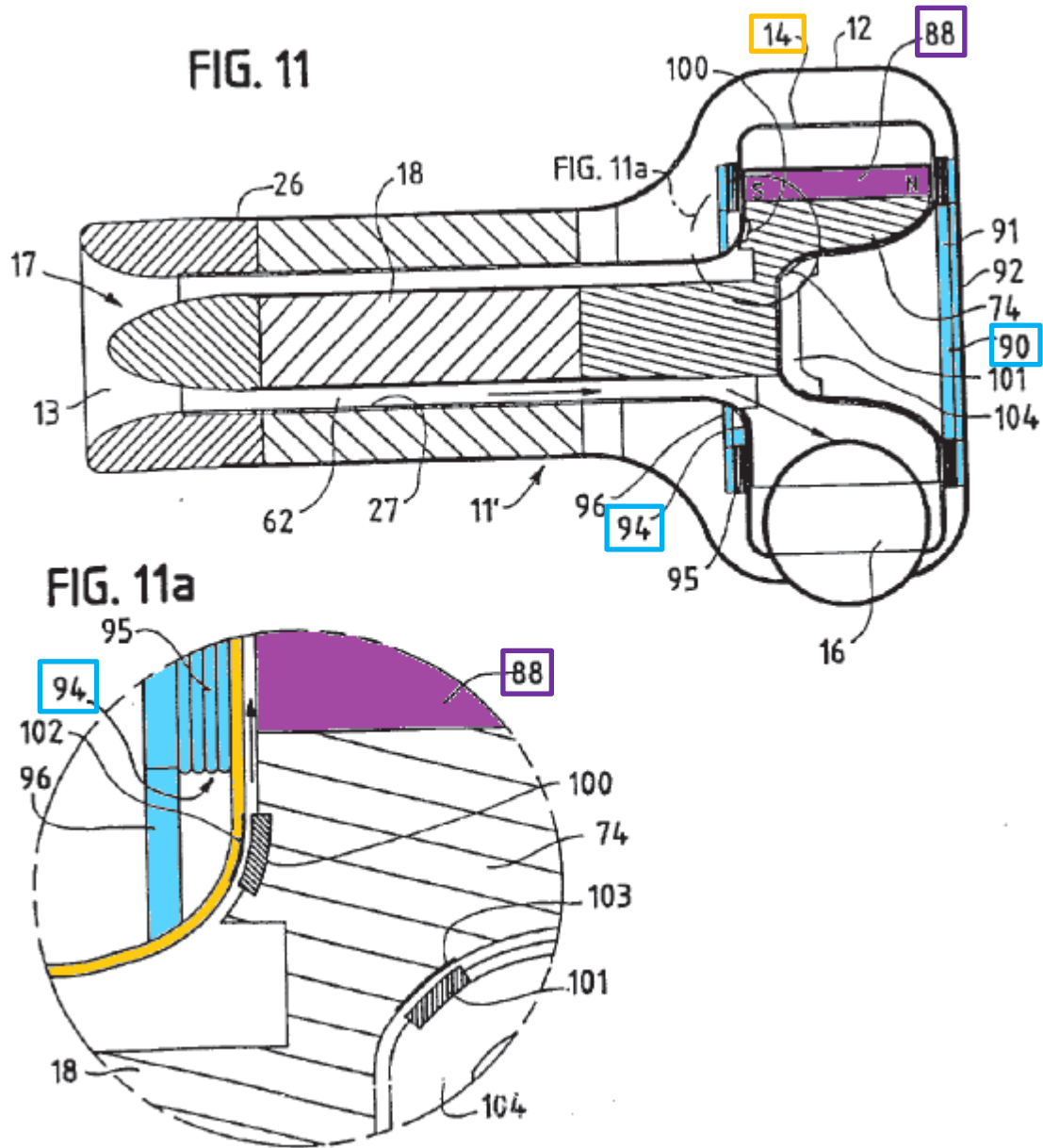
ii. [3A]

As demonstrated in [1K], Wampler-169 discloses that the “**stator[s]** are fixed between housing 12 and **casing 14**” (Ex.1008, [0083]) while the “**impeller**” and its “**magnetic pieces**” are “enclos[ed]” within the casing (Ex.1008, [0012]; Ex.1003, ¶261), as shown:



Ex.1008, Fig. 13; *supra* [1K]; Ex.1003, ¶263.

Figures 11 and 11a illustrate the **casing** forming a “*sealing wall*”:



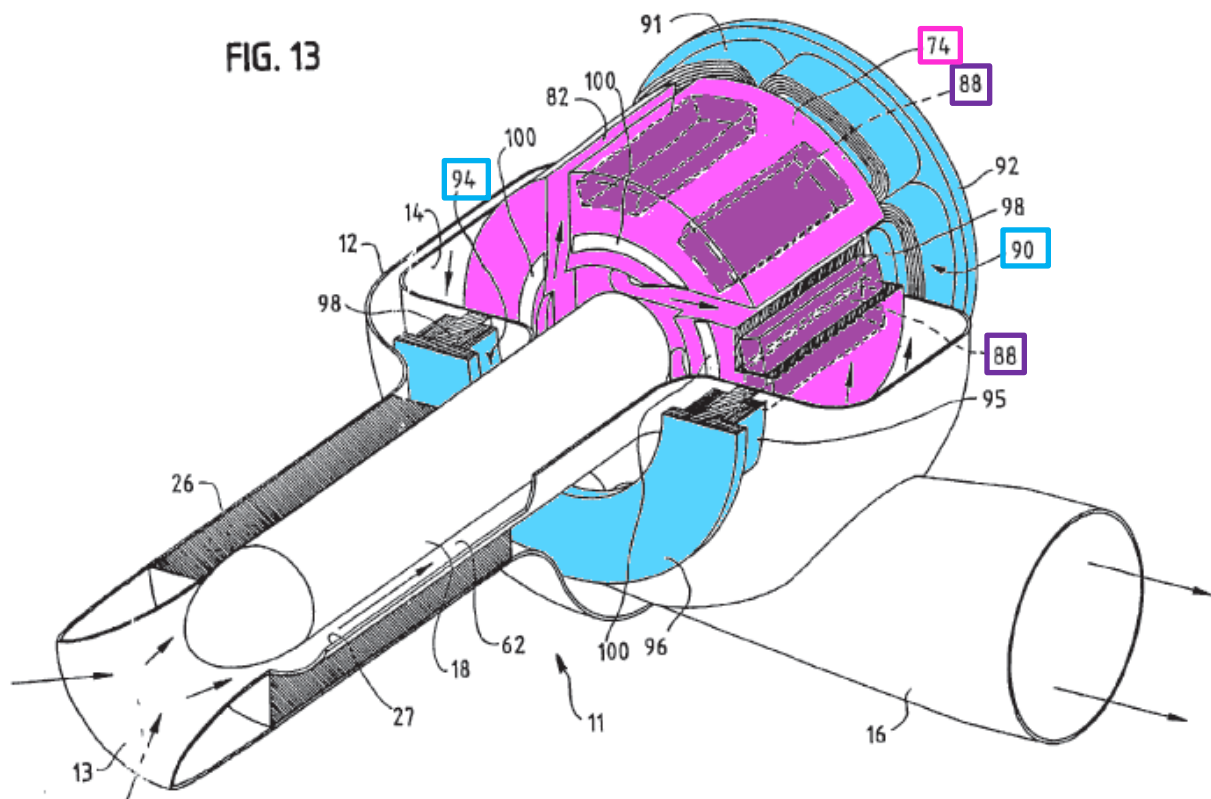
Ex.1008, Figs. 11-11a; Ex.1003, ¶263.

Accordingly, Wampler-169 discloses that “the *surrounding rotor housing* (“casing 14”) comprises at least one sealing wall between the *first magnetic device* (“magnetic pieces 88”) and the *second magnetic device* (“motor stators 90 and 94”).” Ex.1003, ¶264.

iii. [3B]

In Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is “is positioned between the second magnetic device and the magnetically driven rotor.” Ex.1019, 5-7.

Assuming that interpretation, as demonstrated in [1H]-[1J], the rotor has “imbedded” “magnetic pieces 88” (Ex.1008, [0018]; Ex.1003, ¶267) “positioned between the “impeller 74” and “motor stators 90 and 94” (Ex.1008, [0080]; Ex.1003, ¶268), as shown:



Ex.1008, Fig. 13; *supra* [1H]-[1J] (analyzing axially adjacent position).

Accordingly, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *is positioned between the second magnetic device* (“motor stators 90 and 94”) *and the magnetically driven rotor* (“impeller 74).” Ex.1003, ¶269.

iv. [4]

For the reasons demonstrated in [1F] that the “*impeller*” and “*magnetic pieces*” are *rigidly coupled*, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *rotates together with the magnetically driven rotor* (“impeller 74”) *relative to the surrounding rotor housing* (“casing 14”). *Supra* [1F] (analyzing Ex.1008, [0018], [0080]). Ex.1003, ¶¶272-273.

3. Claim 5

As demonstrated in [1N], 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.” Ex.1008, [0071]; *see also* [0018] (“The control unit allows the speed...to be...determined by the user’s physical activity”); *supra* [1N]; Ex.1003, ¶280.

Accordingly, Wampler-169 teaches or suggests that “*the external control unit* (“controller 59”) *controls the second magnetic device* (“motor stators 90 and 94”) *in response* (“automatically...tailor operation”) *to measurement values* (“sensors on

various organs”) *indicative of cardiac output of the heart* (“user’s physical activity and condition”).” Ex.1003, ¶282.

4. Claim 6

For the reasons demonstrated in [1K] and [1M] that the “**impeller**” and its “**magnetic pieces**” are “suspended within the **housing**” (Ex.1008, [0013]) and “*remain[] entirely spaced...by the blood flowing*” (*supra* [1M] (analyzing Ex.1008, [0083]-[0084])), Wampler-169 discloses that “*both the **magnetically driven rotor*** (“impeller 74”) *and **first magnetic device*** (“magnetic pieces 88”) *are entirely spaced apart from the **surrounding rotor housing*** (“casing 14”) *by a gap during rotation of the **magnetically driven rotor***.” Ex.1003, ¶285.

5. Claim 7

As demonstrated in [5], 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* [5]; Ex.1003, ¶290.

Accordingly, Wampler-169 teaches or suggests “*providing feedback signals to the **external control unit*** (“controller 59”) *from one or more sensors*.” Ex.1003, ¶291.

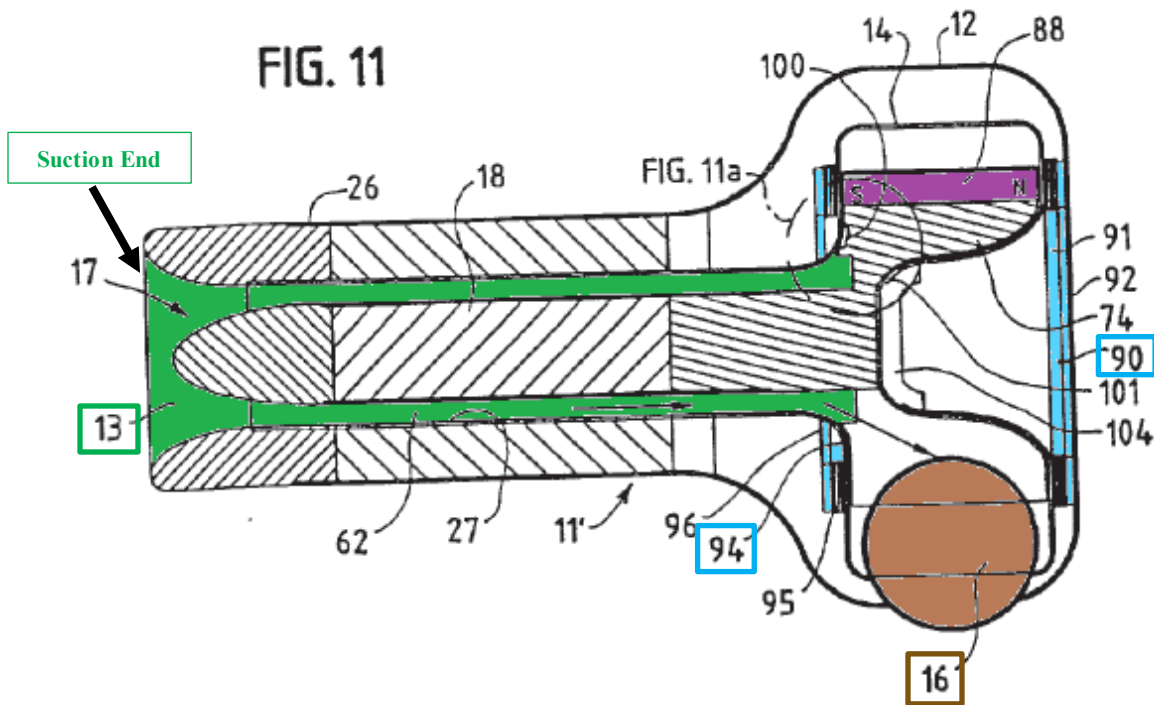
6. Claim 10

As demonstrated in [5], the “*external*” “**controller**” may be “manually adjusted or programmed to determine the running rate of pump.” Ex.1008, [0071], [0018]; Ex.1003, ¶294.

Accordingly, Wampler-169 teaches or suggests that “*the external control unit* (“controller 59”) *is configured to regulate operation of the second magnetic device* (“motor stators 90 and 94”) *based on a fixed control value.*” Ex.1003, ¶296.

7. Claim 12

As demonstrated in [1A] and [1K]-[1L], 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, ¶¶299-300.

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 *second magnetic device* is positioned relative to the suction end of the *inflow tube*” (“inlet tube 13”).” Ex.1003, ¶301.

8. Claim 13

In Parallel Litigation, PO asserts that a pump device with an inflow cannula is a catheter device. Ex.1019, 4. Assuming that interpretation, because Wampler-169’s pump comprises an “inflow cannula” (Ex.1008, [0075]) it “is a catheter device.” Ex.1003, ¶¶302-305.

Accordingly, Wampler-169 discloses that “*the heart assist pump device* (“pump 11”) *is a catheter device.*” Ex.1003, ¶306.

Wampler-169 therefore renders obvious Claims 2-7, 10, and 12-13. Ex.1003, ¶¶252-306.

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

1. Claim 1

i. [1PRE]

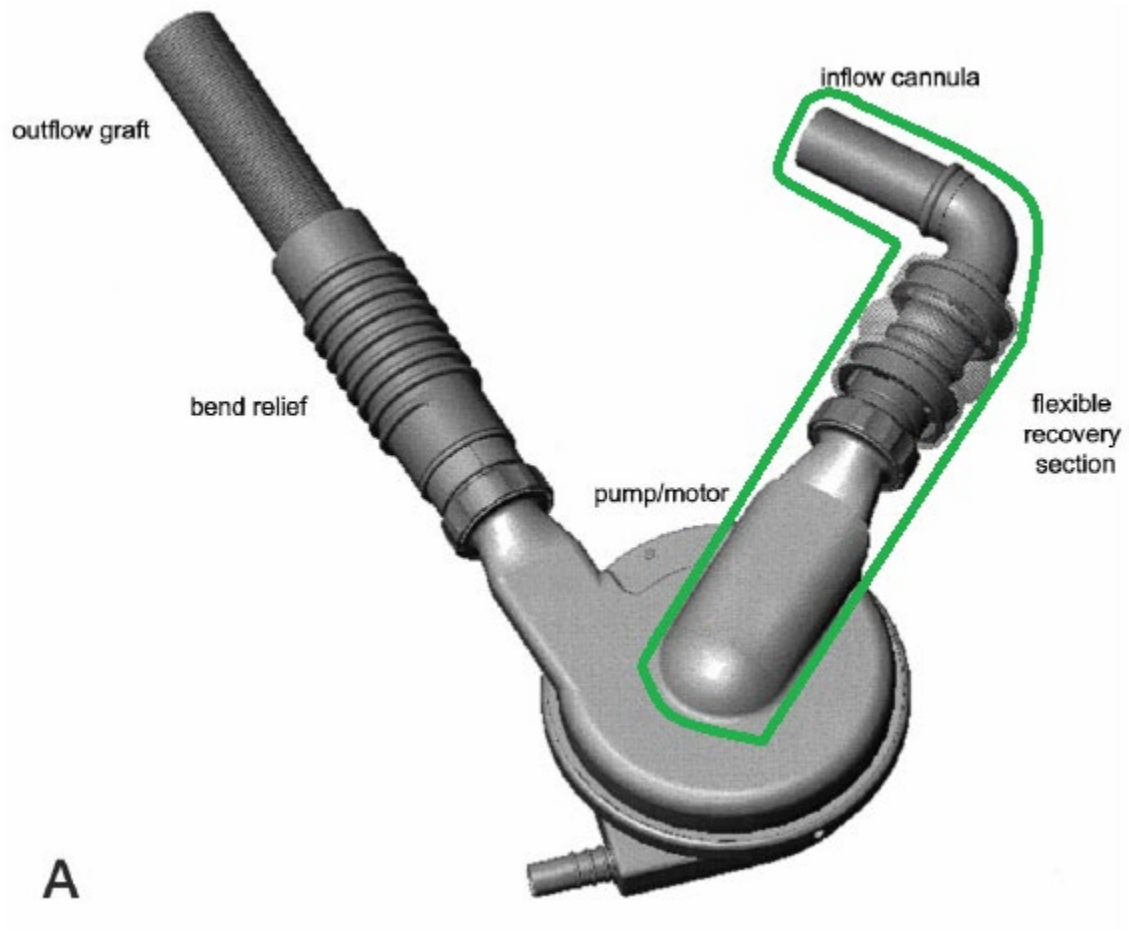
Bourque-2001 discloses the “HeartMate III”—“a centrifugal pump” that is a “long-term, compact left **ventricular** assist device (LVAD)” “to treat” “people...diagnosed with congestive heart failure” (“*a method for assisting the blood circulation of a heart in a body*”). Ex.1007, 401; Ex.1003, ¶308.

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

Accordingly, Bourque-2001 discloses “*a method for assisting the blood circulation of a heart in a body* (“reliable device to treat CHF”).” Ex.1003, ¶309.

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, ¶315.

The “**HeartMate III LVAD**” is “*deliver[ed] ...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:

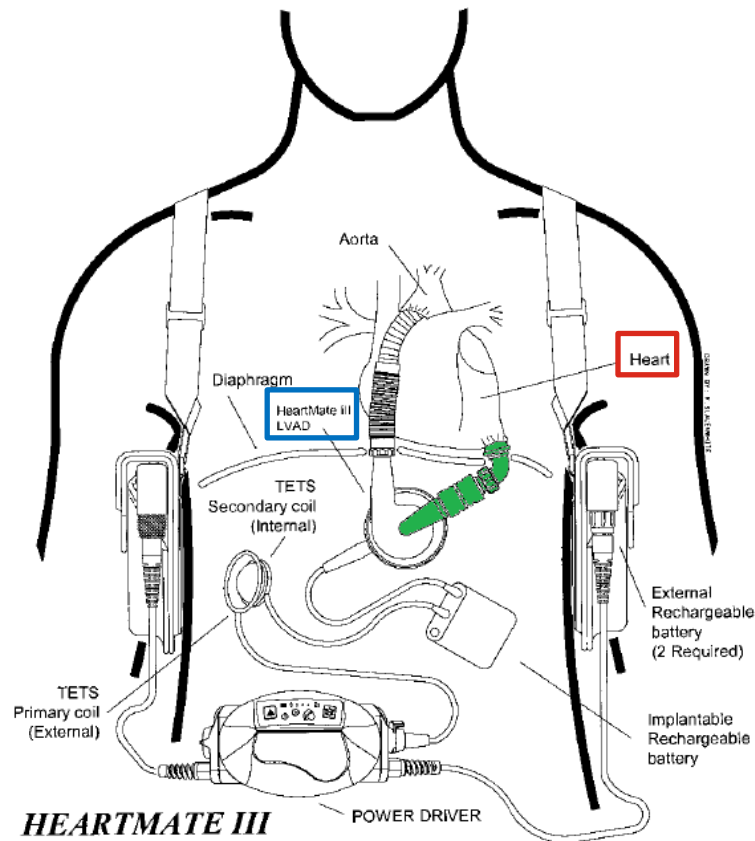


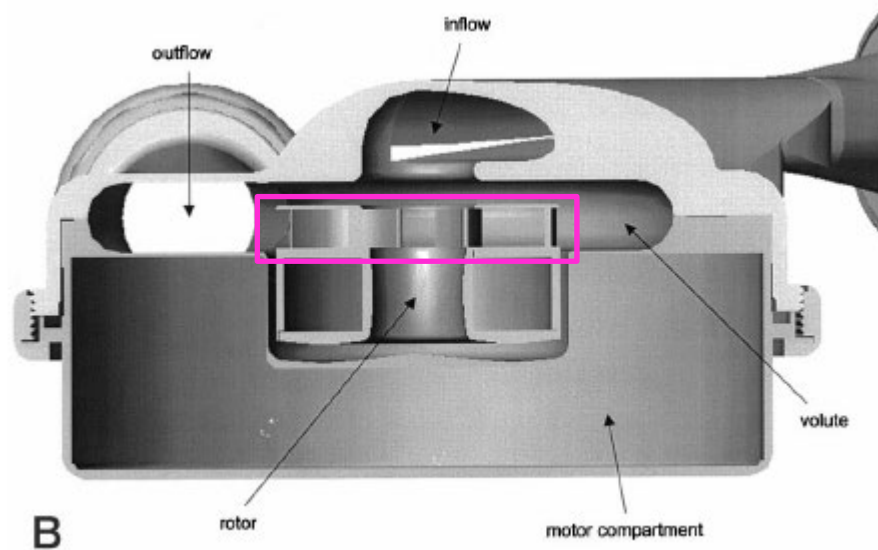
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. Ex.1003, ¶314.

Accordingly, Bourque-2001 discloses “delivering *a heart assist pump device* (“HeartMate III LVAD”) to the *heart* so that *a suction end of an inflow tube* (“an inflow subassembly that includes a left ventricular (LV) cannula”) of the *heart assist pump device* is inserted into *a ventricle of the heart* (“left ventricular apical cannulation”).” Ex.1003, ¶316.

iii. [1B]

Bourque-2001 discloses “a rotor that includes an **impeller** and passively magnetic elements” (“a magnetically driven rotor”) (Ex.1007, 401) as shown:



Ex.1007, Fig. 1B, 401-402; Ex.1003, ¶321. As demonstrated in [1A], aside from the suction end of the inflow tube, the pump, including its **impeller**, is *positioned outside the ventricle of the heart* as shown:

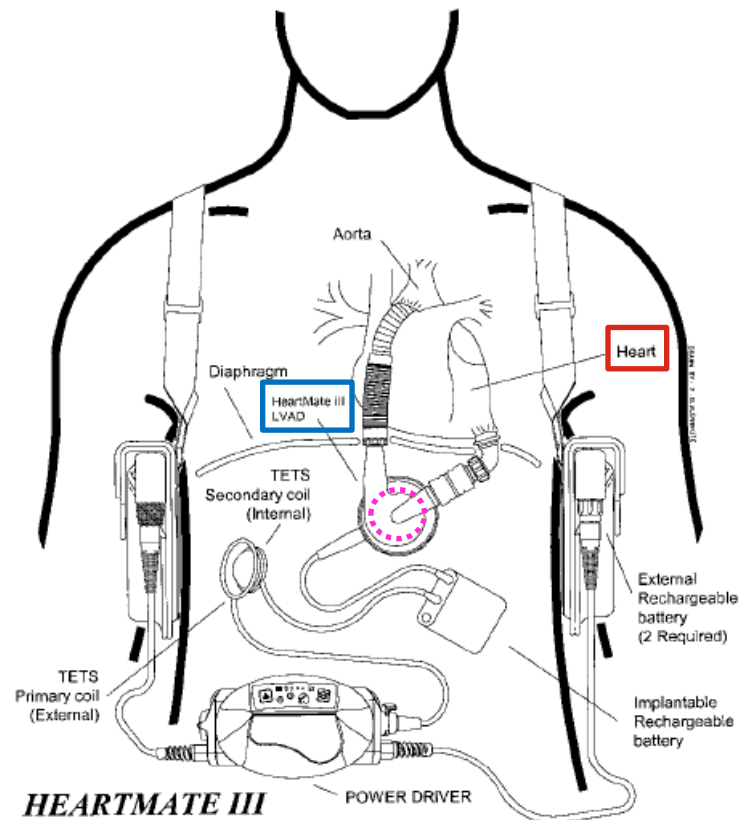


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

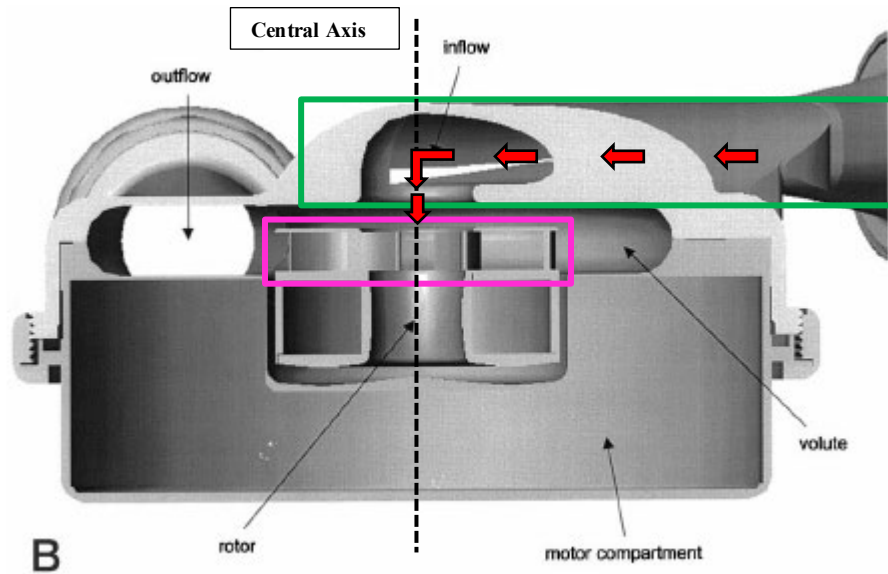
Ex.1007, Fig. 3, 403; *supra* [1A]; Ex.1003, ¶322.

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

Accordingly, Bourque-2001 discloses “while a *magnetically driven rotor* (“impeller”) of the *heart assist pump device* (“HeartMate III LVAD”) is positioned outside the ventricle of the *heart*.” Ex.1003, ¶323.

iv. [1C]

Bourque-2001 discloses that its “*impeller*” 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:

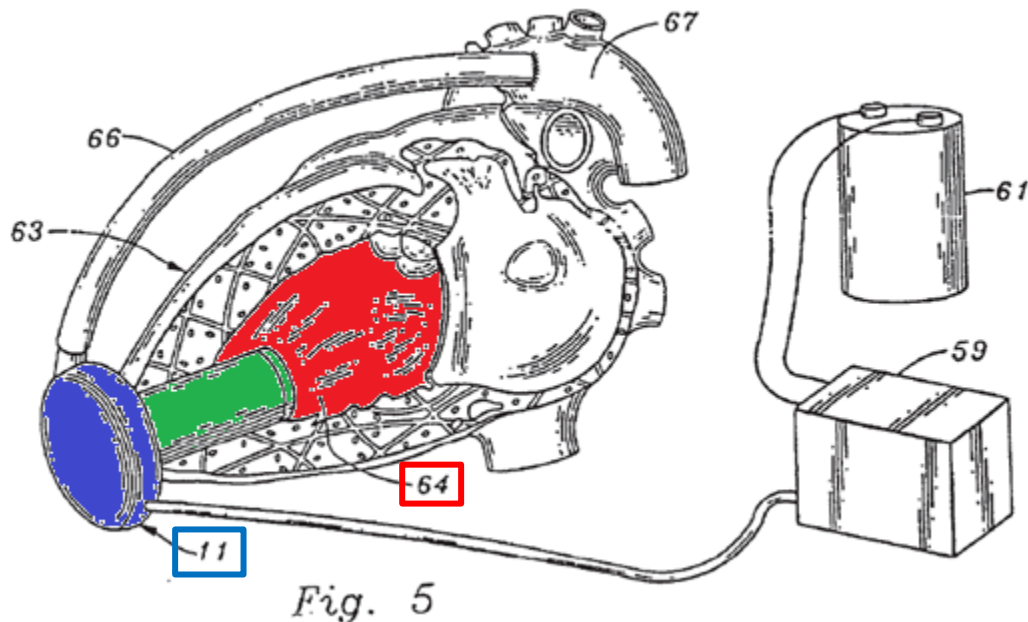


Ex.1007, Fig. 1B. Ex.1003, ¶326.

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, ¶327. 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, ¶328.

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, ¶¶330-331.

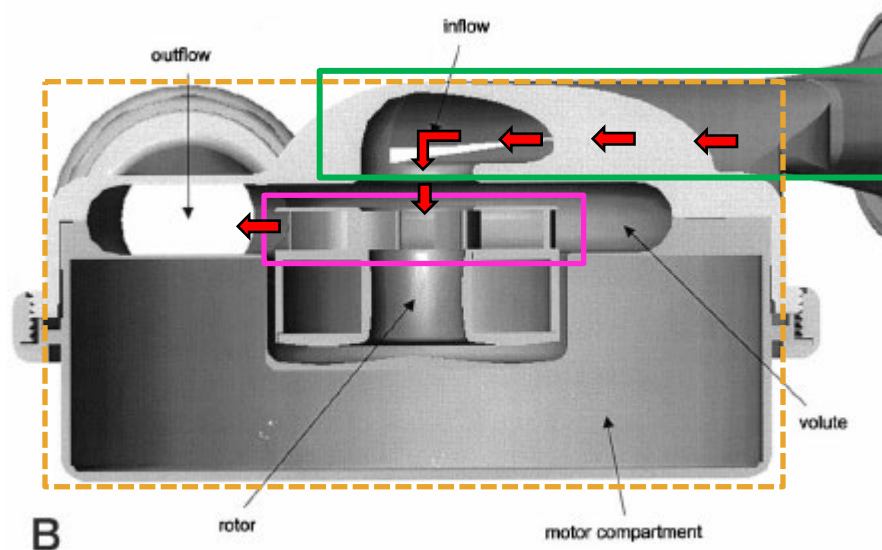
Mr. Crosby explains (*infra* §VIII.B.9) that a POSITA would have been motivated with a reasonable expectation of success to modify the HeartMate III “inflow subassembly” to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler-169, resulting in an “*axially aligned...inflow tube*.” Ex.1007, 402; Ex.1008, [0076], Fig. 5; Ex.1003, ¶331.

Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest that “*the magnetically driven rotor* (“impeller”) *is axially aligned with the*

inflow tube (“an inflow subassembly”; “inlet tube 16 [that] serves as the inflow cannula”).” Ex.1003, ¶332.

v. [1D]

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 rotor 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 toward the magnetically driven rotor*”), as shown:

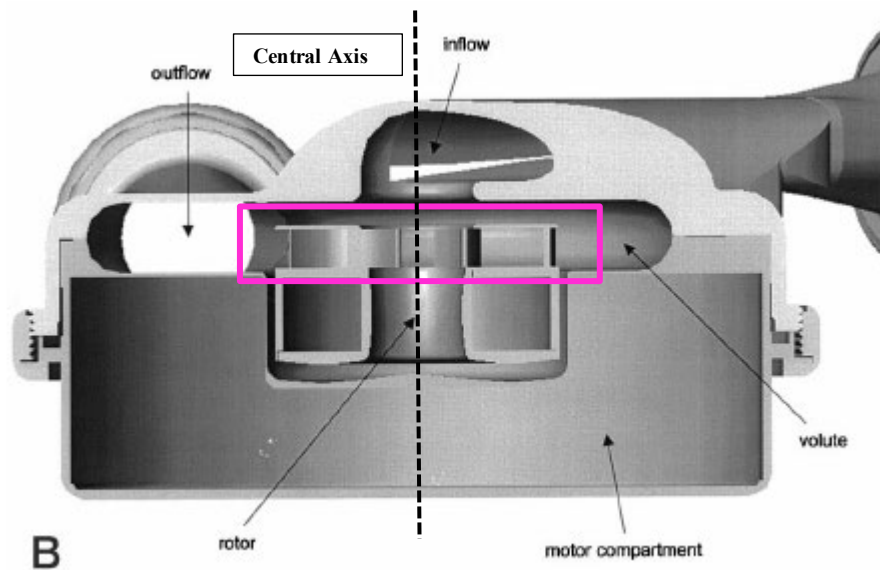


Ex.1007, Fig. 1B; *see also* Fig. 8 (showing flow measurements of impeller “act[ing] upon blood”). Ex.1003, ¶337.

Accordingly, Bourque-2001 discloses that the magnetically driven rotor “*is rotatable within a surrounding rotor housing* (“upper housing and lower housing”) of the *heart assist pump device* (“HeartMate III LVAD”) to act upon blood flowing from the *inflow tube* (“an inflow subassembly”) toward the *magnetically driven rotor* (“impeller”).” Ex.1003, ¶338.

vi. [1E]

Bourque-2001 discloses “the rotational axis of the pump’s rotor” (“*being rotatable about a central axis*”) in which the rotor’s *impeller* rotates (Ex.1007, 402), as shown:

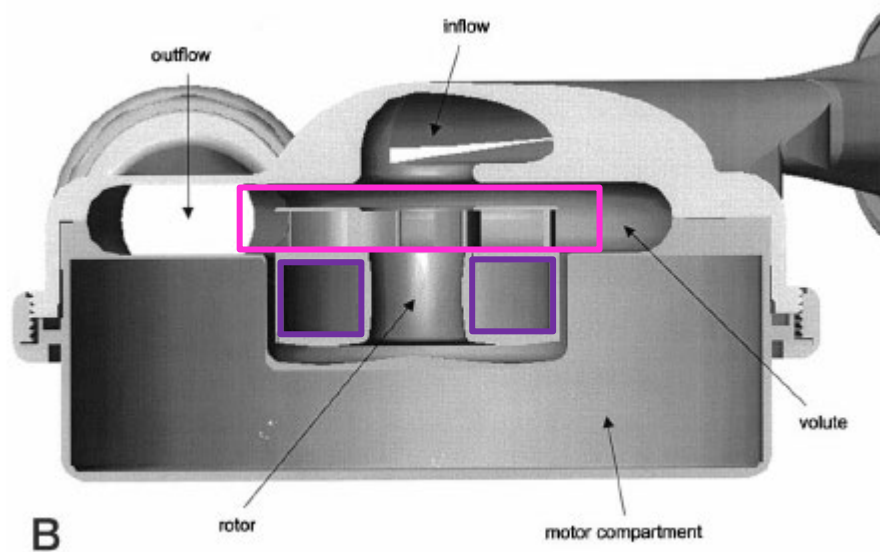


Ex.1007, Fig. 1B; *see also* 402 (“rotational axis [is] perpendicular to the body’s long axis”). Ex.1003, ¶340.

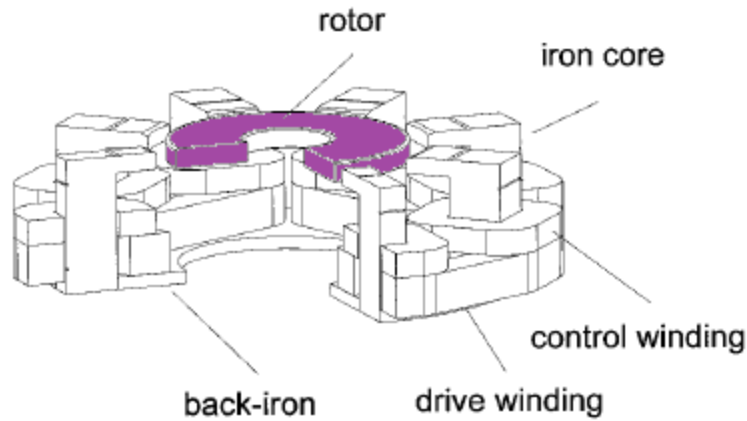
Accordingly, Bourque-2001 discloses “the *magnetically driven rotor* (“impeller”) *being rotatable about a central axis* (“rotational axis”).” Ex.1003, ¶342.

vii. [1F]

Bourque-2001 discloses that the “rotor includes an *impeller* and *passively magnetic elements*” (Ex.1007, 401) (“*being rigidly coupled to a first magnetic device*”), which are *rigidly coupled* as illustrated in Figure 1B:



Ex.1007, Fig. 1B. Ex.1003, ¶347.



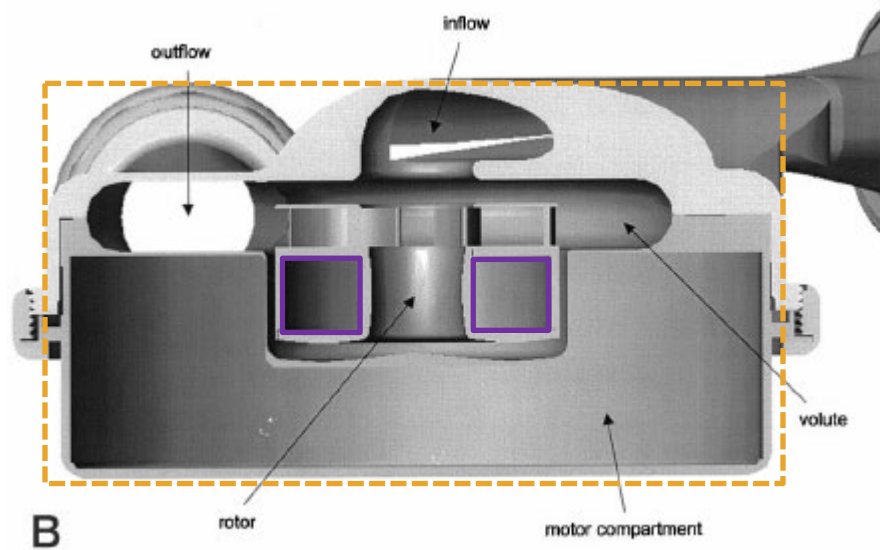
Ex.1007, Fig. 4, 402-403. Ex.1003, ¶346.

In Parallel Litigation, PO asserts that a similar arrangement of an impeller and magnetic elements satisfies this limitation. Ex.1019, 5-7.

Accordingly, Bourque-2001 discloses the *magnetically driven rotor* (“impeller”) “*being rigidly coupled to a first magnetic device* (“passively magnetic elements”).” Ex.1003, ¶348.

viii. [1G]

For the reasons described in [1D], Bourque-2001 discloses that its “*housing*...includes...a cavity for the rotor” (Ex.1007, 401), and as described in [1F], the “rotor includes...*passively magnetic elements*” (Ex.1007, 401), as shown:

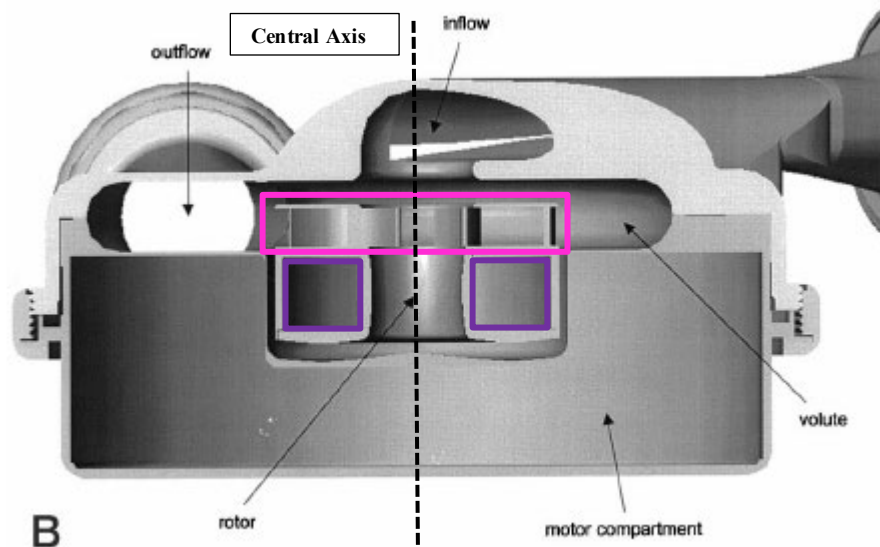


Ex.1007, Fig. 1B; *see also* 403 (discussing rotation “without contact between the rotor and housing”); *supra* [1D]; Ex.1003, ¶352.

Accordingly, Bourque-2001 discloses that the **first magnetic device** (“passively magnetic elements”) “*is located within the surrounding rotor housing* (“upper housing and lower housing”).” Ex.1003, ¶353.

ix. [1H]

Bourque-2001 discloses that the “rotor[’s] **impeller** and **passively magnetic elements**” are “*adjacent*” along “the rotational axis of the pump’s rotor” (Ex.1007, 401-402) as shown:

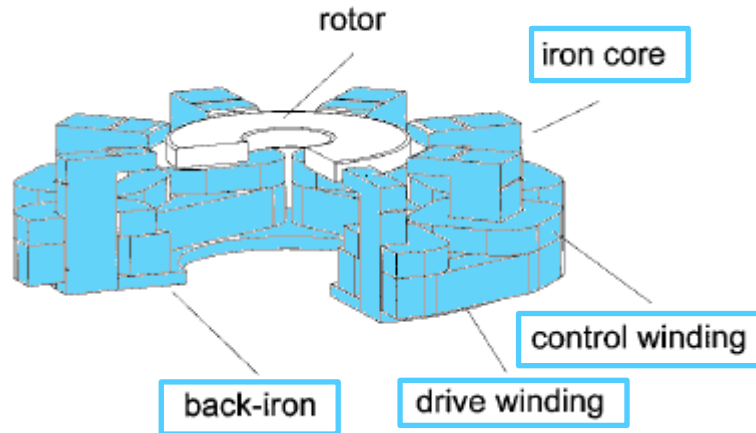


Ex.1007, Fig. 1B; Ex.1003, ¶355.

Accordingly, Bourque-2001 discloses that the *first magnetic device* (“passively magnetic elements”) is “*at a position axially adjacent to the magnetically driven rotor* (“impeller”).” Ex.1003, ¶356.

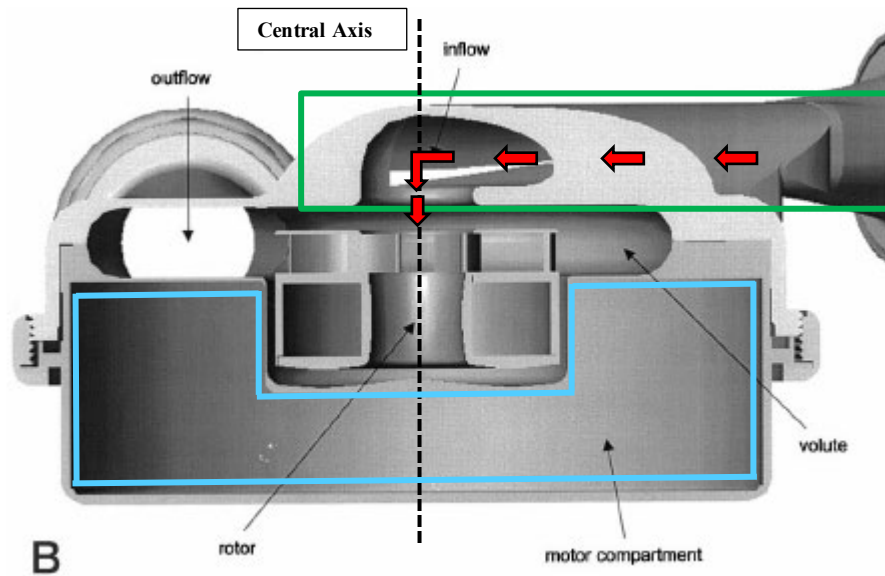
x. *[II]*

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, ¶359.

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:



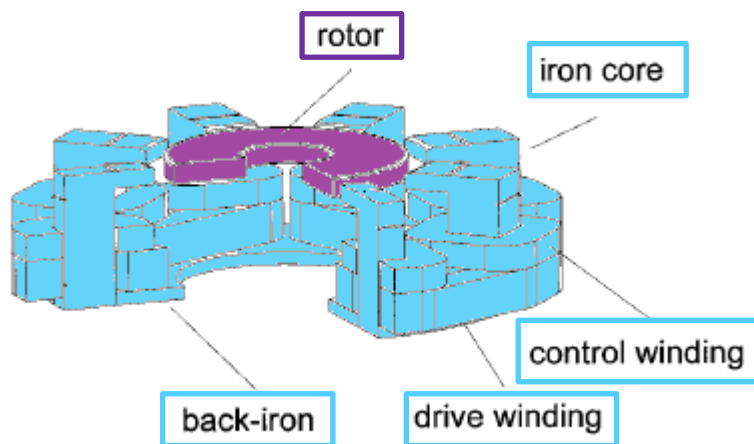
Ex.1007 at Fig. 1B, 401-403; Ex.1003, ¶361. As demonstrated in [1C], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the **motor** be *axially aligned with the inflow subassembly*. Ex.1003, ¶363.

Accordingly, Bourque-2001 or Bourque-2001/Wampler-169 teach or suggest that “*the heart assist pump device* (“HeartMate III LVAD”) *further includes: a second magnetic device* (“motor” with drive windings) *axially aligned with the inflow tube* (“an inflow subassembly” of Bourque-2001 or “inlet tube 13” of Wampler-169).” Ex.1003, ¶364.

xi. [1J]

In Parallel Litigation, PO alleges that the “stator” design of Abbott’s HeartMate 3 LVAD pump satisfies this limitation. Ex.1019, 12.

Assuming that interpretation, as demonstrated in [11], Bourque-2001 discloses this limitation because the HeartMate III pump has a similar “stator” design. The “HeartMate III **motor** includes drive” (Ex.1007, 402-403), and as shown in Figure 4, “the motor’s ‘J’ core configuration (i.e., the stator laminations are J shaped)” (Ex.1007, 404) are *positioned to magnetically drive rotation of the rotor via a magneto coupling* with the “**passively magnetic elements**”:

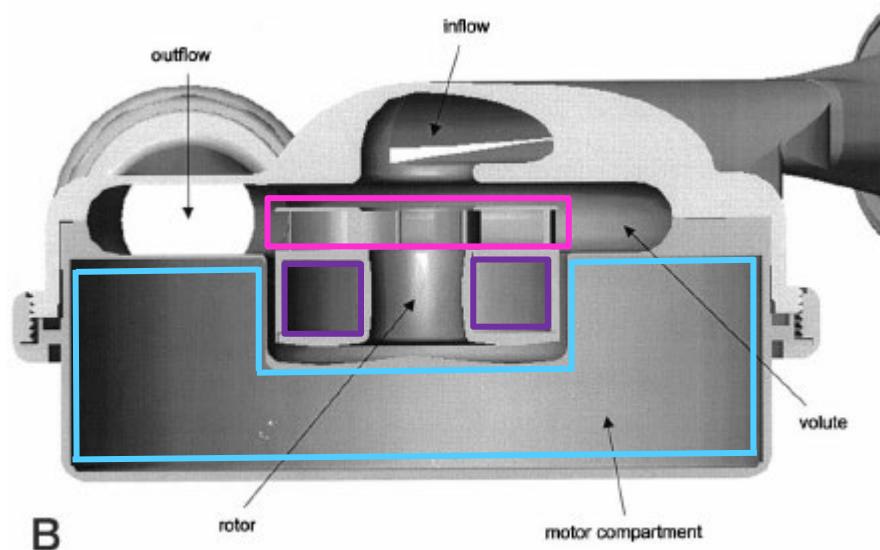


Ex.1007, Fig. 4, 402-404; Ex.1003, ¶367, *see also* ¶¶368-369 (discussing speed and flow rates).

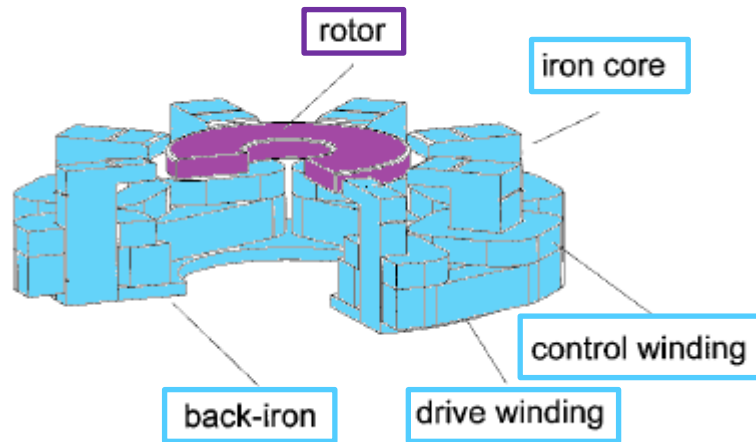
Accordingly, Bourque-2001 discloses that the **second magnetic device** (“motor” with drive windings) is “*positioned to magnetically drive rotation of the magnetically driven rotor* (“impeller”) *via a magneto coupling with the first magnetic device* (“passively magnetic elements”).” Ex.1003, ¶370.

xii. [1K]

Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (“*spaced apart*”) (Ex.1007, 402-403) using “control windings” and “J shaped” “stator laminations” shown in Figure 4 (Ex.1007, 404) 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 in Figures 1B and 4-5:



Ex.1007, Fig. 1B; Ex.1003, ¶375.



Ex.1007, Fig. 4; Ex.1003, ¶376.

Figure 5 illustrates how “[t]he rotor is magnetically suspended, eliminating contact between [the motor]” (“*spaced apart*”):

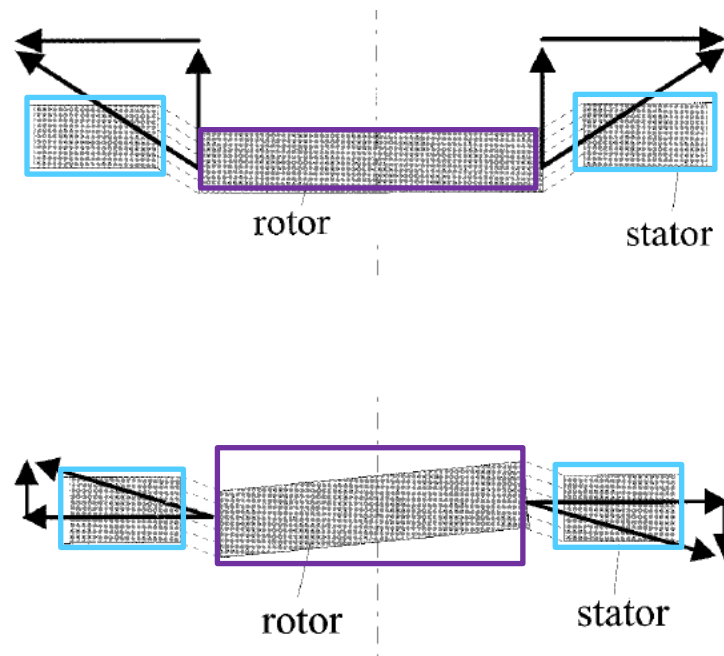


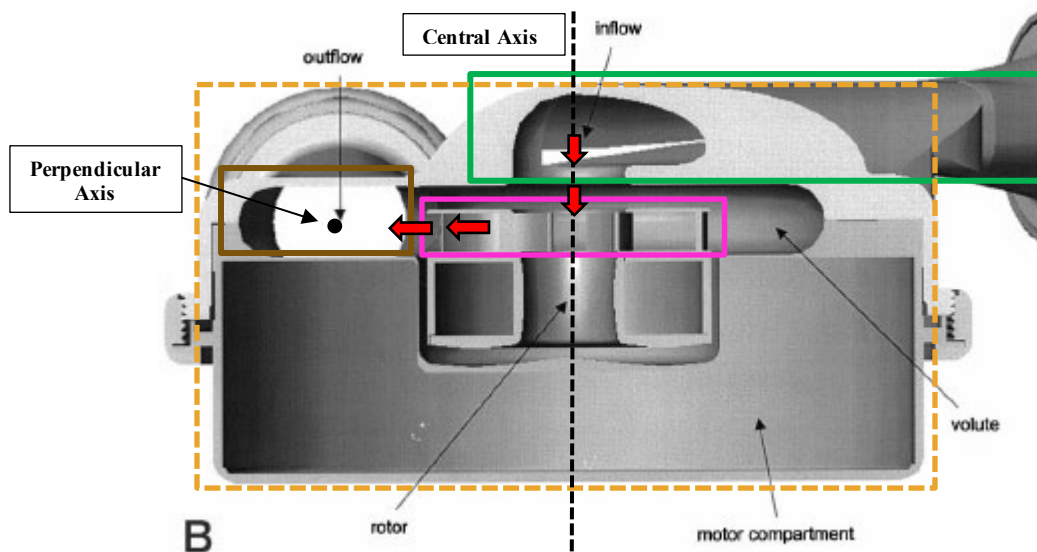
Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5, 401; Ex.1003, ¶376.

Accordingly, Bourque-2001 discloses its **motor** is “*spaced apart and sealed from both the magnetically driven rotor (“impeller”) and the first magnetic device (“passively magnetic elements”).*” Ex.1003, ¶377.

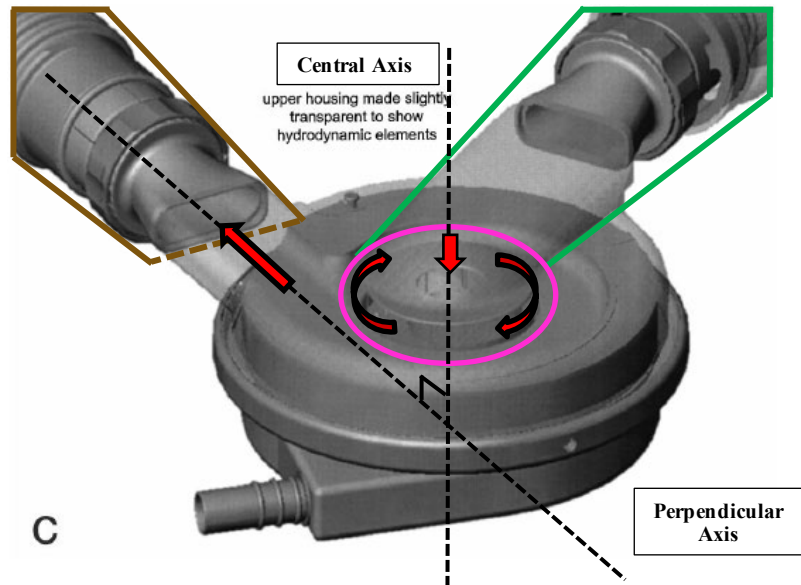
xiii. [1L]

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 driven by the magnetically driven rotor*”), which then “direct[s] [the flow] toward the **outflow**” (“*configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube*”) (Ex.1007, 401-402), as shown (**red** arrows):



Ex.1007, Fig. 1B; Ex.1003, ¶381.

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



Ex.1007, Fig. 1C; Ex.1003, ¶382.

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 [1C] that there would be “a 90-degree [*perpendicular*] redirection of the blood.” Ex.1003, ¶330; *infra* §VIII.B.9; Ex.1008, [0076].

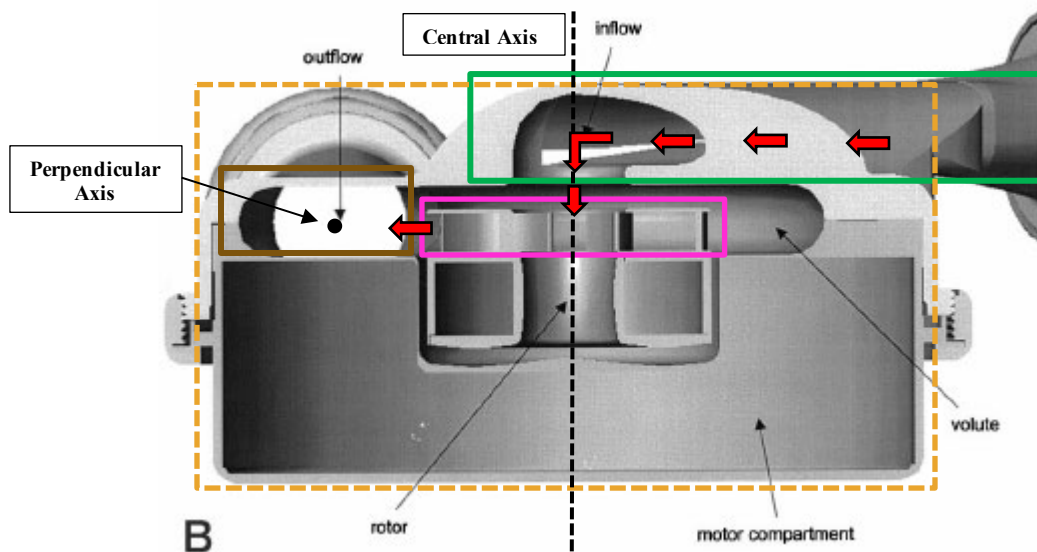
Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest that “a **blood outflow port** (“outflow channel”) positioned radially adjacent the **magnetically driven rotor** (“impeller”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“upper housing and lower housing”) in a direction substantially perpendicular from

the *inflow tube* (“an inflow subassembly”) and the *central axis* of the *magnetically driven rotor*.” Ex.1003, ¶383.

xiv. [1M]

In Parallel Litigation, PO asserts that a magnetic bearing (i.e., “MagLev”) satisfies this limitation. Ex.1019, 12-13.

Assuming that interpretation, as explained in [1J]-[1L], Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (Ex.1007, 402-403) (“*magneto coupling orients*”) so that “gaps permit [movement] in any direction without contact between the [impeller] and housing” (“*entirely spaced apart from the surrounding rotor housing*”) to allow “flow” “above and below the rotor” (Ex.1007, 402) (“*by the blood flowing*”), 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, ¶386.

Accordingly, Bourque-2001 discloses that "*the magneto coupling orients the magnetically driven rotor* ("impeller") *so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing* ("upper housing and lower housing") *by the blood flowing from the inflow tube* ("an inflow subassembly") *and to the blood outflow port* ("outflow channel")." Ex.1003, ¶390.

xv. [IN]

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

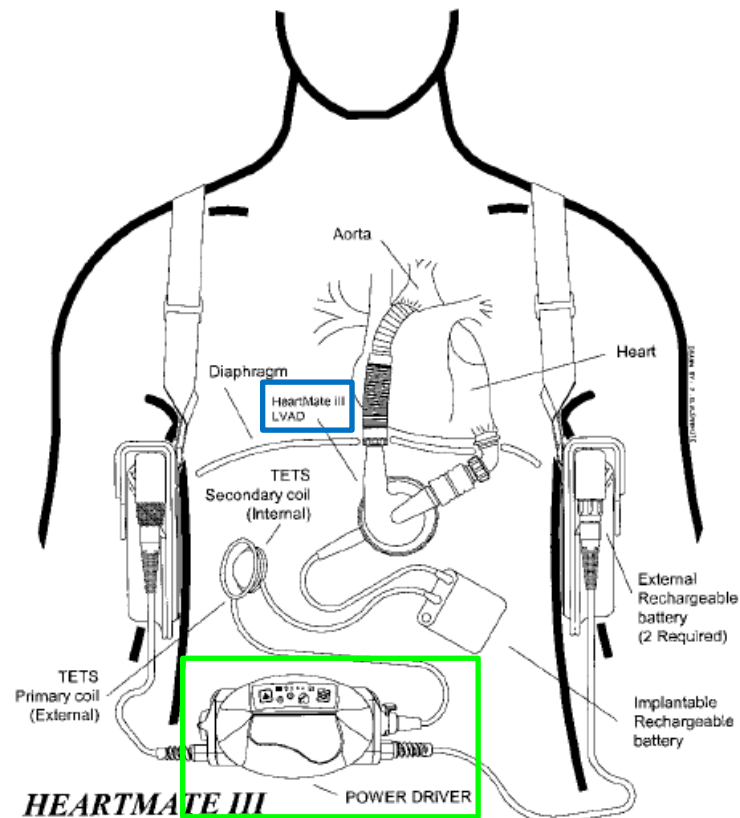


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶395.

Bourque-2001 further discloses that “[s]peed and motor parameters were set and controlled using software” (“*for regulating operation*”) and that the “motor drive and control electronics” were *external*, because they had not been “incorporat[ed]...within the pump.” Ex.1007, 405; Ex.1003, ¶392.

These “**electronics**” allowed the speed to be “gradually adjusted to maintain volume flow rates” (“*regulating operation*”) Ex.1007, 403.

Accordingly, Bourque-2001 discloses “connecting an **external control unit** (“electronics for power and control”) to the **heart assist pump device** (“HeartMate III LVAD”) for regulating operation of the **second magnetic device** (“motor”) to thereby magnetically drive the rotation of the **magnetically driven rotor** (“impeller”) via the magneto coupling with the **first magnetic device** (“passively magnetic elements”).” Ex.1003, ¶396.

xvi. [10]

As explained in [1N], Bourque-2001 discloses external (“positioned exterior to the body”) “**electronics for power and control** of the **LVAD**” (Ex.1007, 403); and explained in [1A], an “**inflow subassembly that includes a left ventricular (LV) cannula**” that “is in the **heart**” (Ex.1007, 403) as shown:

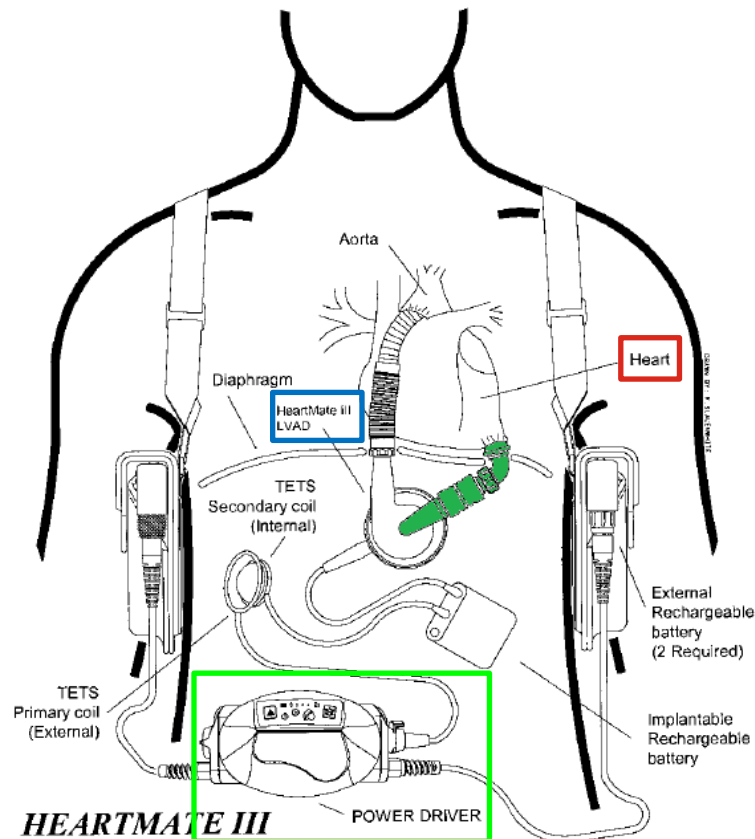


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; *supra* [1A]; Ex.1003, ¶402.

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 [1C] that the inflow subassembly be placed into the left ventricle. Ex.1003, ¶330; *infra* §VIII.B.9.

Bourque-2001/Wampler-169 therefore teaches or suggests that “*the external control unit* (“electronics for power and control”) *being positioned exterior to the*

body while the *inflow tube* (“an inflow subassembly”) of the *heart assist pump device* (“HeartMate III LVAD”) is in the *heart*.” Ex.1003, ¶403.

Borque-2001, or Bourque-2001/Wampler-169, therefore teach or suggest claim 1. Ex.1003, ¶404; *see also* ¶¶307-404.

2. Claims 2, 3, and 4

i. [2/

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, ¶408.

Accordingly, Bourque-2001 discloses that “*in response to the rotation of the magnetically driven rotor* (“impeller”) *via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.*” Ex.1003, ¶410.

ii. [3A/

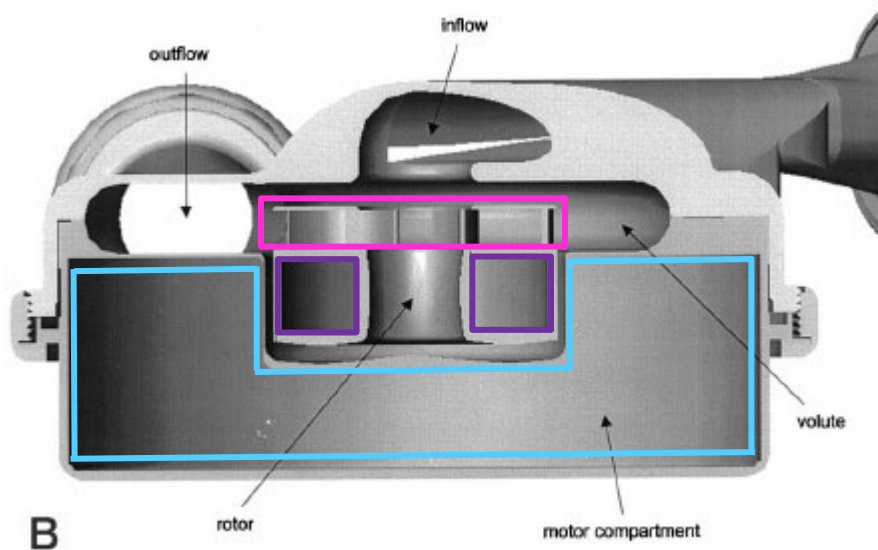
As explained in [1K], “the *motor* is enclosed” in the “*housing*,” thus, is *spaced apart and sealed*. Ex.1007, 401; Ex.1003, ¶414.

Accordingly, Bourque-2001 discloses that “*the surrounding rotor housing* (“upper housing and lower housing”) *comprises at least one sealing wall* (“motor is

enclosed”) *between the **first magnetic device*** (“passively magnetic elements”) *and the **second magnetic device*** (“motor”).” Ex.1003, ¶415.

iii. [3B]

As explained in [1H]-[1J], the rotor has “**magnetic elements**” “*positioned between*” the “**impeller**” and “**motor**” (Ex.1007, 401), as shown:



Ex.1007, Fig. 1B; *supra* [1H]-[1J]; Ex.1003, ¶418.

Accordingly, Bourque-2001 discloses that “*the **first magnetic device*** (“passively magnetic elements”) *is positioned between the **second magnetic device*** (“motor”) *and the **magnetically driven rotor*** (“impeller”).” Ex.1003, ¶419.

iv. [4]

As demonstrated in [1F], the rotor’s “**impeller**” and “**magnetic elements**” are “*rigidly coupled*,” Bourque-2001 discloses that “*the **first magnetic device*** (“passively magnetic elements”) *rotates together with the **magnetically driven rotor***

(“impeller”) *relative to the surrounding rotor housing* (“upper housing and lower housing”).” Ex.1007, 401; *supra* [1F]. Ex.1003, ¶422.

3. Claim 5

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit (e.g. output as measured in liters of blood per minute) are “*measurement values indicative of cardiac output of the heart.*” Ex.1019, 29. Assuming that interpretation, Bourque-2001 discloses this element. Ex.1003, ¶429.

As explained in [1N], the “**electronics for power and control** of the LVAD and for data acquisition” “*regulates operation*” of the **motor** (Ex.1007, 403, Fig. 3) and allows for “[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)” (“*in response to measurement values indicative of cardiac output of the heart*”). Ex.1007, 403; Ex.1003, ¶430.

Accordingly, Bourque-2001 discloses that “*the external control unit* (“electronics for power and control”) *controls the second magnetic device* (“motor”) *in response to measurement values indicative of cardiac output of the heart.*” Ex.1003, ¶431.

4. Claim 6

For the reasons demonstrated in [1M] that the magnetic levitation prevents “contact between the rotor and housing,” Bourque-2001 discloses that “*both the*

magnetically driven rotor (“impeller”) and *first magnetic device* (“passively magnetic elements”) are entirely spaced apart from the *surrounding rotor housing* (“upper housing and lower housing”) by a gap during rotation of the *magnetically driven rotor*.” Ex.1007, 401-402; *supra* [1M]; Ex.1003, ¶¶434-436.

5. 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 *provid[e] feedback signals* to the “**electronics for power and control**.” Ex.1007 at 403; Ex.1003, ¶¶439.

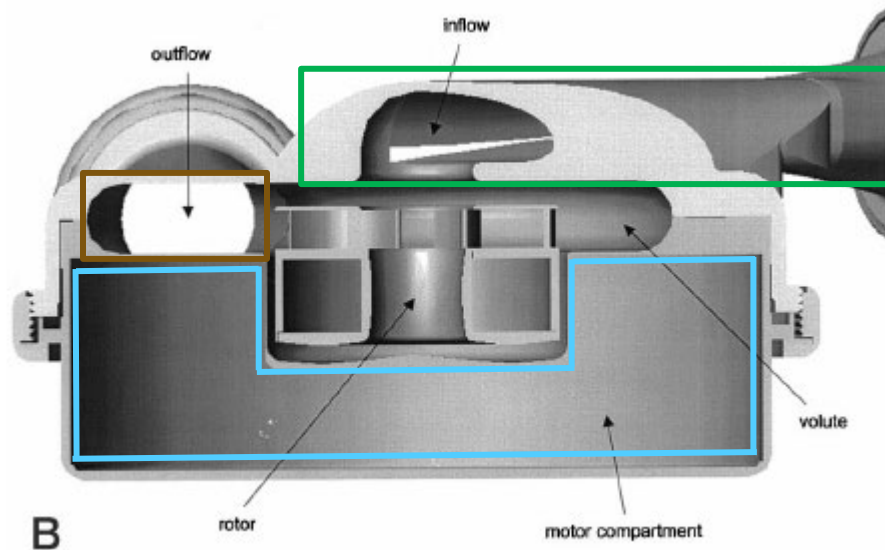
Accordingly, Bourque-2001 discloses “*providing feedback signals to the external control unit* (“electronics for power and control”) *from one or more sensors*.” Ex.1003, ¶442.

6. Claim 10

For the reasons discussed in [1N] that “[s]peed and motor parameters were set and controlled using software,” Bourque-2001 discloses that “*the external control unit* (“electronics for power and control”) *is configured to regulate operation of the second magnetic device* (“motor”) *based on a fixed control value*.” Ex.1007 at 403-404 (“pump was prescribed to run at 3,500 rpm”); *supra* [1N]; Ex.1003, ¶445.

7. Claim 12

As demonstrated in [1A] and [1L], the “**left ventricular (LV) cannula**” is inserted 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, ¶450.

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

Ex.1003, ¶452.

8. Claim 13

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, ¶456.

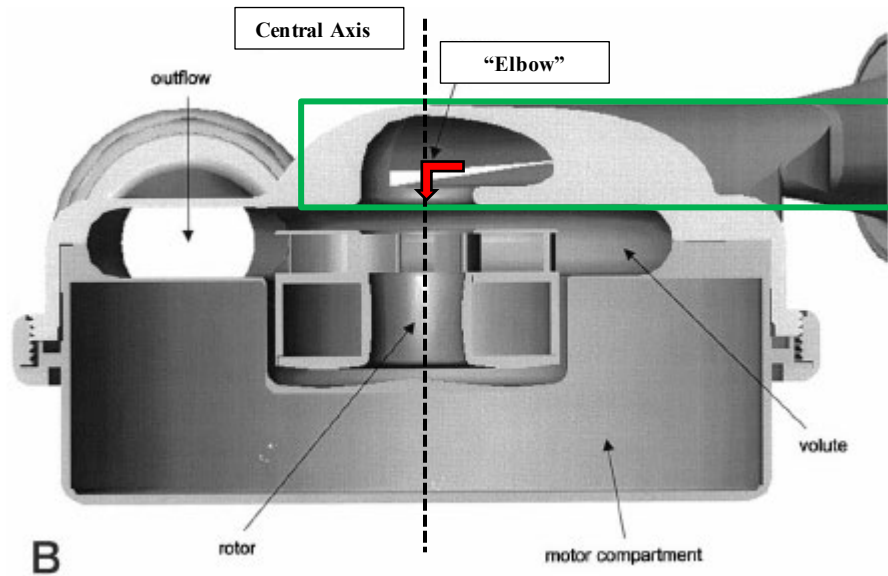
Accordingly, Bourque-2001 discloses that “*the heart assist pump device* (“HeartMate III LVAD”) *is a catheter device*.” Ex.1003, ¶457.

9. 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, ¶458.

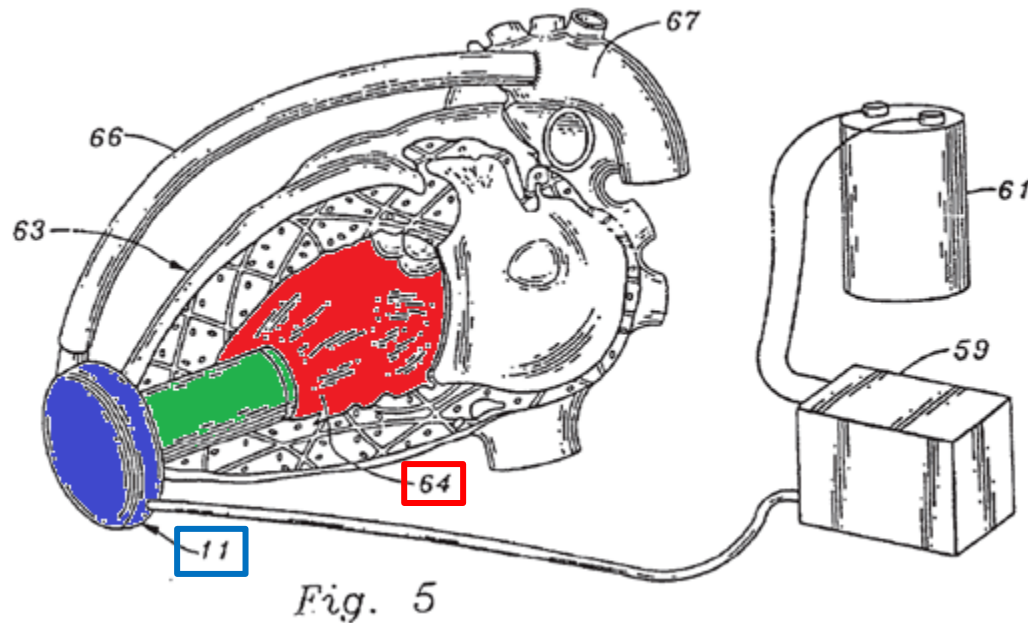
A POSITA would have recognized that, by virtue of the “centrifugal design,” both Bourque-2001's HeartMate III and Wampler-169's pump comprise “axial inflow and radial outflow” that result in “a 90 degree redirection of the blood.” Ex.1003, ¶459; Ex.1008, [0075]-[0076]; Ex.1007, 402.

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, ¶¶463-464 (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, ¶464. 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, ¶470.

Bourque-2001 and Wampler-169 are analogous art to the 356 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, ¶466. Bourque-2001 and Wampler-169 are reasonably pertinent to a problem described by the 356 Patent:

reducing mechanical stress on the blood during pumping. Ex.1001, 2:27-32; Ex.1007, 401; Ex.1008, [0101]. Ex.1003, ¶467.

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, ¶468.

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, ¶¶469-470; 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, ¶470.

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, ¶¶464-470; 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, ¶470.

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 “deci[sion]” “[t]o orient the pump” below the “diaphragm” in a preperitoneal pocket position, as shown:

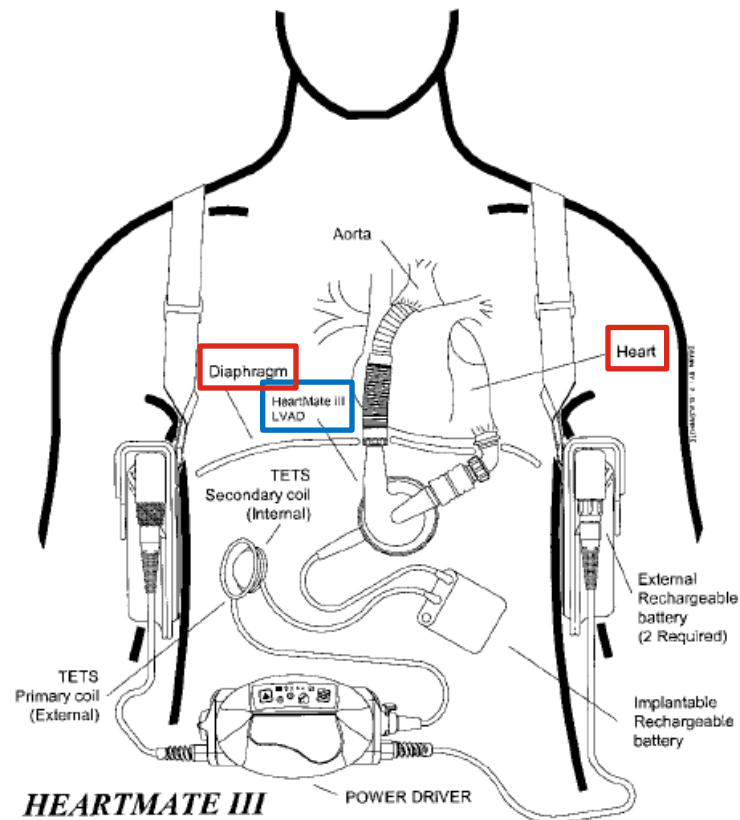


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶471. 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, ¶472.

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:

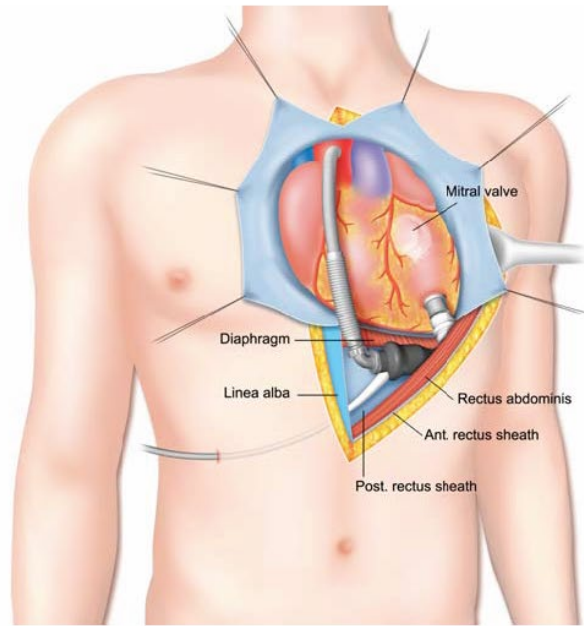


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

Ex.1013, 25; Ex.1003, ¶471 (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, ¶471. 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, ¶¶472-475.

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, ¶¶473-476 (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, ¶477. 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, ¶477.

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, ¶478; *see also* ¶¶458-477.

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, 3), as illustrated in Figure 1:

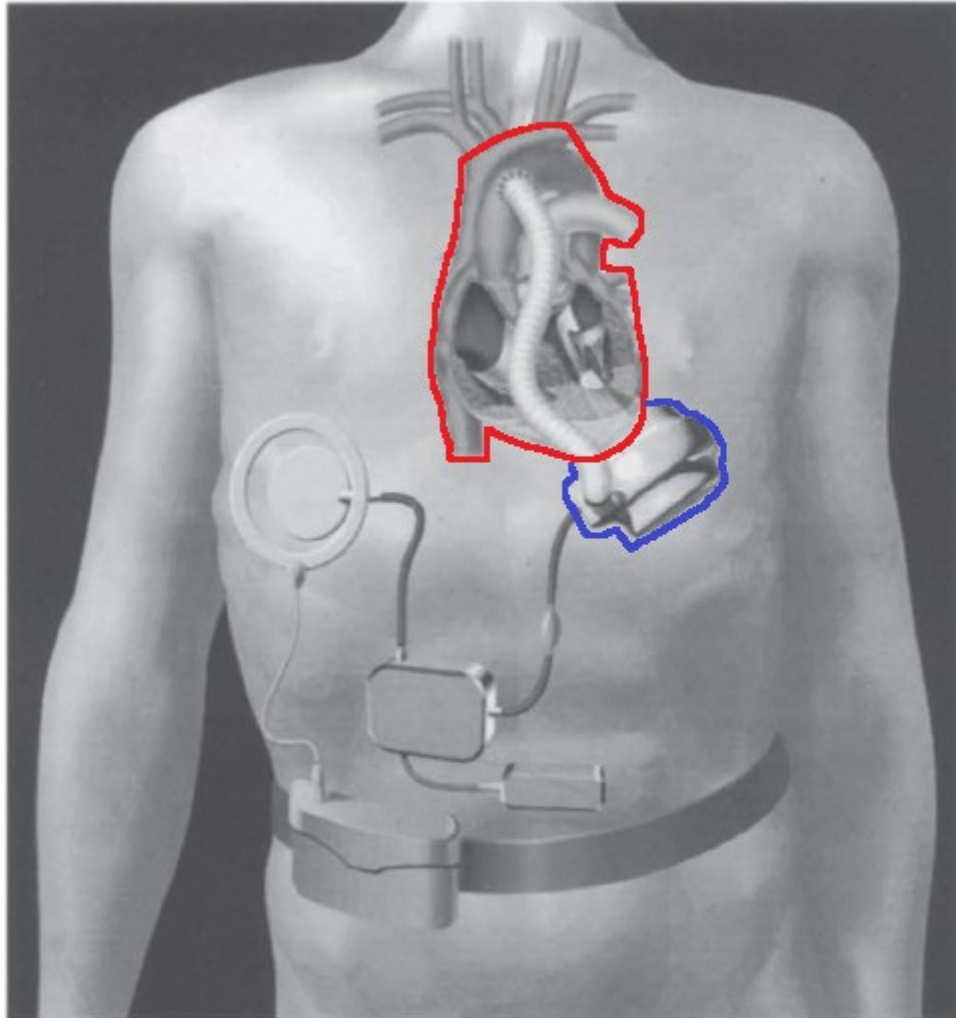


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶¶480-481.

Accordingly, Akamatsu-1999 discloses “a method for assisting the blood circulation of a **heart** in a body.” Ex.1003, ¶481.

ii. [1A]

Akamatsu-1999 discloses its “centrifugal pump” (“heart assist pump device”) has an “**inlet port**” or “inflow conduit” (Ex.1006, 4):

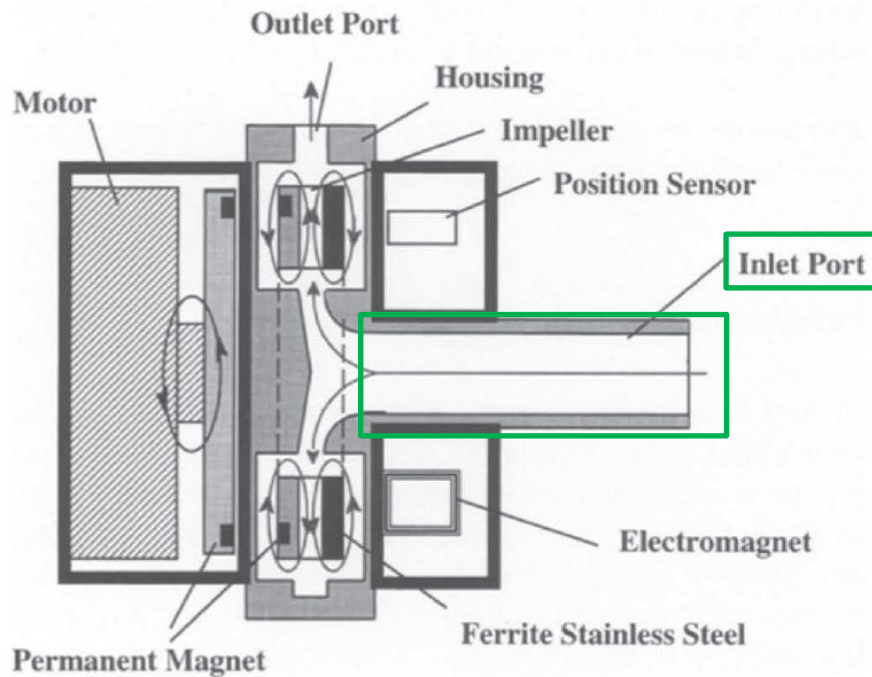


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶485.

The **pump** is “*deliver[ed] ...to the heart*” so that its **inlet port** is “inserted into the left ventricle [*so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart*],” but the remainder of the **pump** is *positioned outside the ventricle of the heart*:

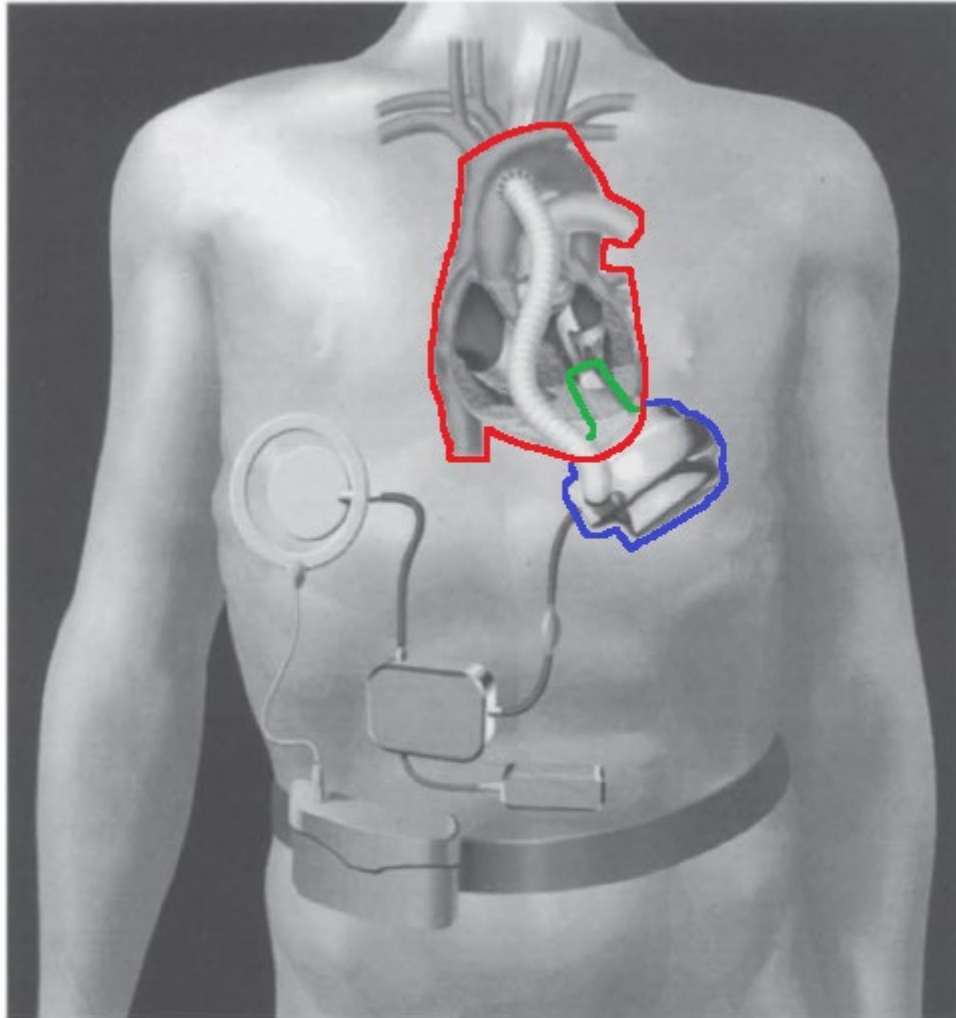


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶¶486-487.

Accordingly, Akamatsu-1999 discloses “*delivering a heart assist pump device* (“centrifugal pump”) *to the heart* so that *a suction end of an inflow tube* (“inlet port”) *of the heart assist pump device* is inserted into *a ventricle of the heart* (“inserted into the left ventricle”).” Ex.1003, ¶487.

iii. [1B]

Akamatsu-1999 discloses that pump comprises an “**impeller** [that] rotates by a magnetic coupling [‘a magnetically driven rotor’]” (Ex.1006, 4):

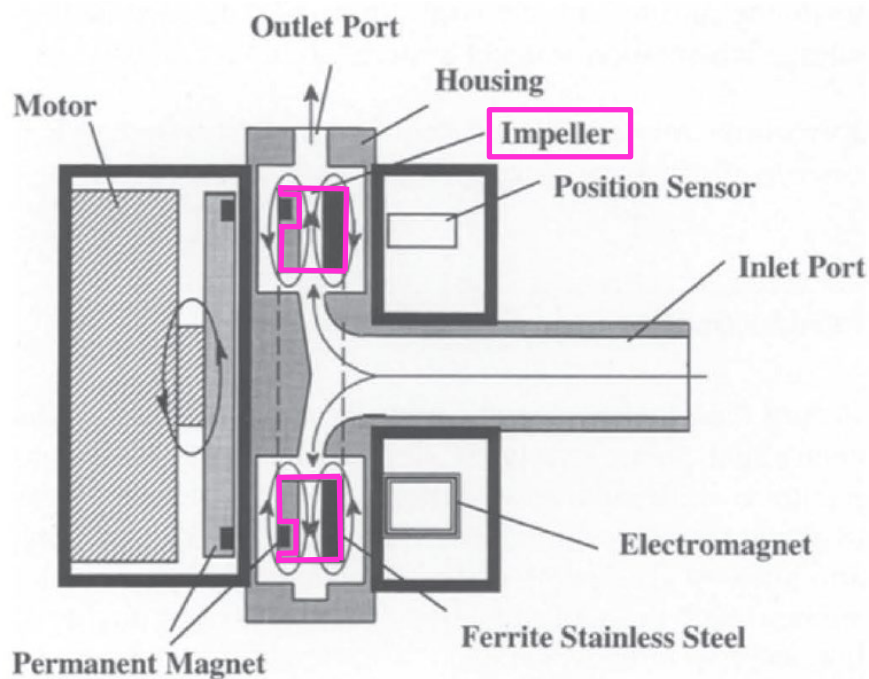


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; *see also* Fig. 5 (photograph of “impeller”); Ex.1003, ¶494.

As explained in [1A], the “**inlet port**” is *inserted into a ventricle* but the remainder of the “**pump**” including the “**impeller**,” is *positioned outside the ventricle of the heart*, as shown:

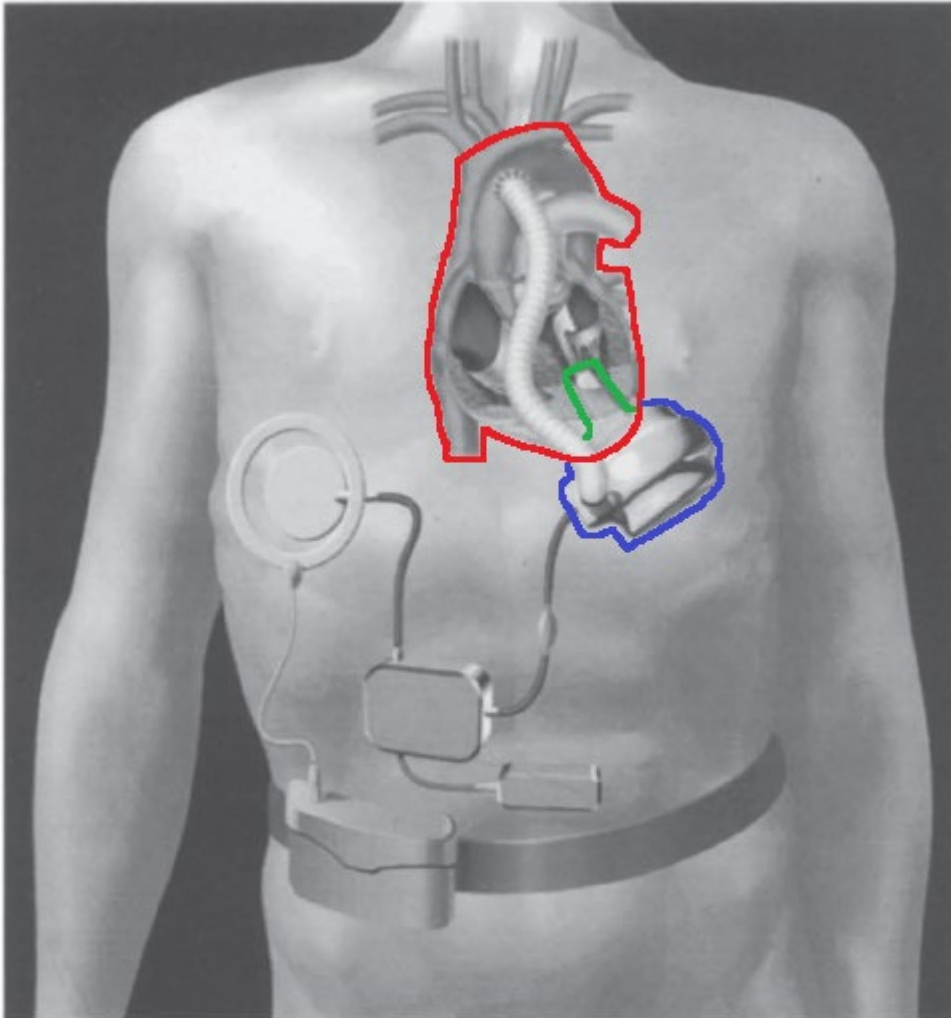


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶496.

Accordingly, Akamatsu-1999 discloses “while a *magnetically driven rotor* (“impeller”) of the *heart assist pump device* (“centrifugal pump”) is positioned outside the ventricle of the *heart*.” Ex.1003, ¶497.

iv. [1C]

By virtue of Akamatsu-1999's "centrifugal" design, its "**impeller**" is "*axially aligned with the*" "**inlet port**," (Ex.1006, 3), as illustrated:

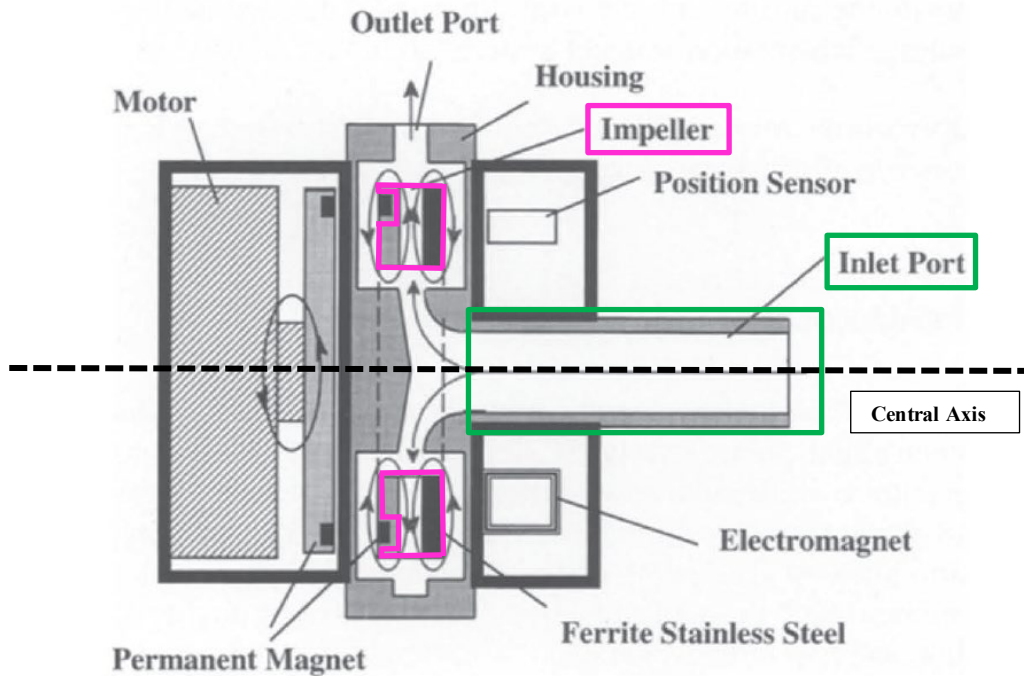


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2, Ex.1003, ¶499.

Accordingly, Akamatsu-1999 discloses that "*the magnetically driven rotor*" ("impeller") is *axially aligned with the inflow tube* ("inlet port")." Ex.1003, ¶501.

v. [1D]

Akamatsu-1999 discloses that the pump's "**impeller** rotates" ("*is rotatable*") "at the center of the pump **housing**" ("*within a surrounding rotor 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):

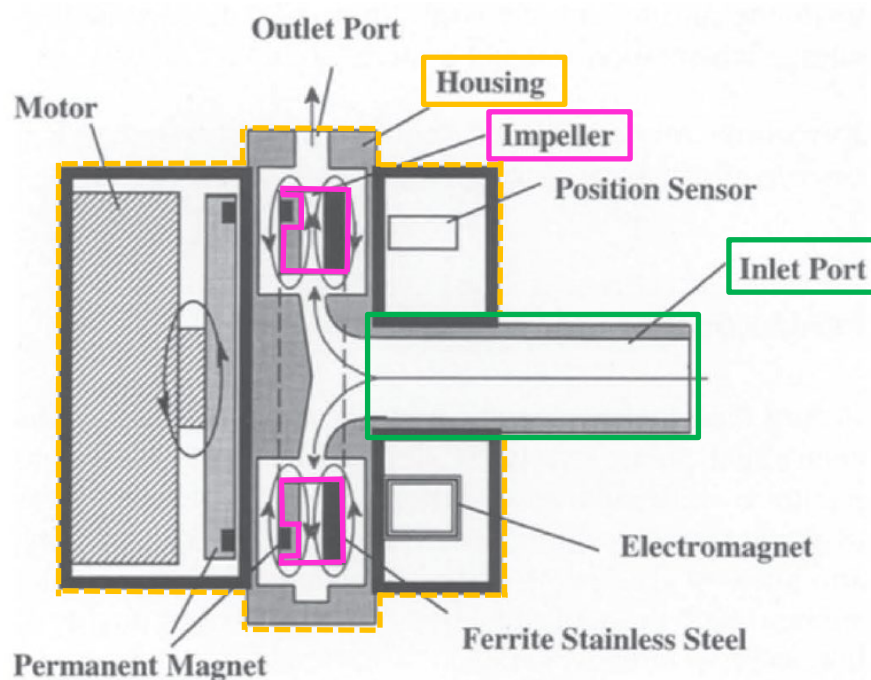


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶506.

Accordingly, Akamatsu-1999 discloses that the *magnetically driven rotor* “is rotatable within *a surrounding rotor housing* (“housing”) of the *heart assist pump device* (“centrifugal pump”) to act upon blood flowing from the *inflow tube* (“inlet port”) toward the *magnetically driven rotor* (“impeller”).” Ex.1003, ¶508.

vi. [1E]

As demonstrated in [1C], the *impeller* is axially aligned with the *inflow tube*, and in [1D], the “*impeller* rotates” “at the center [‘about a central axis’] of the pump housing” (Ex.1006, 4), as shown:

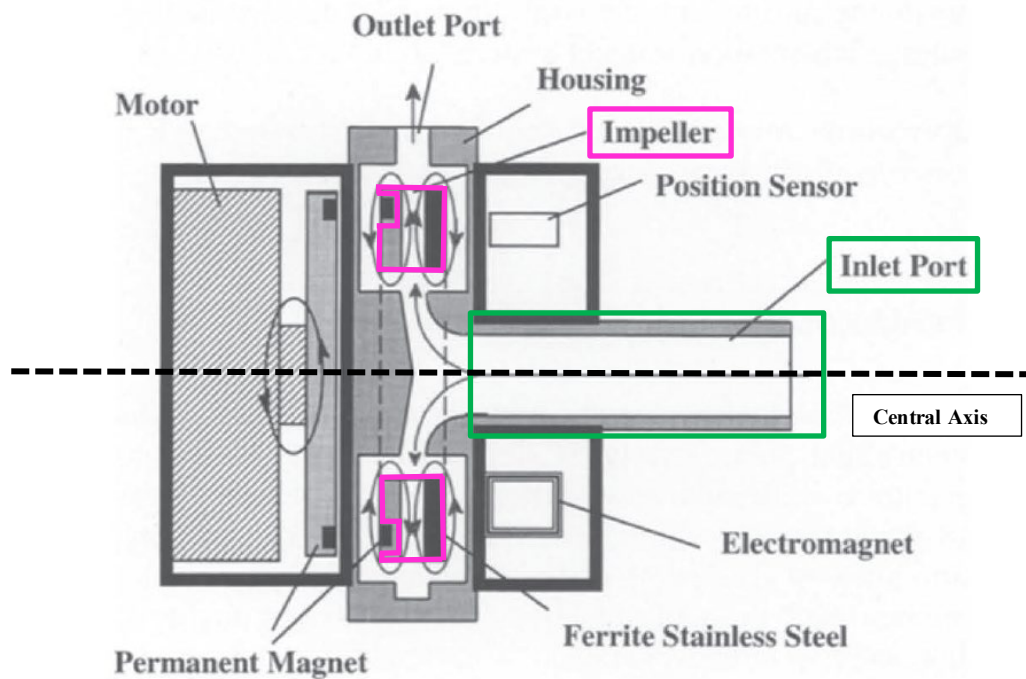


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶511-512.

Accordingly, Akamatsu-1999 discloses “*the magnetically driven rotor (“impeller”) being rotatable about a central axis (“at the center”).*” Ex.1003, ¶514.

vii. [1F]

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

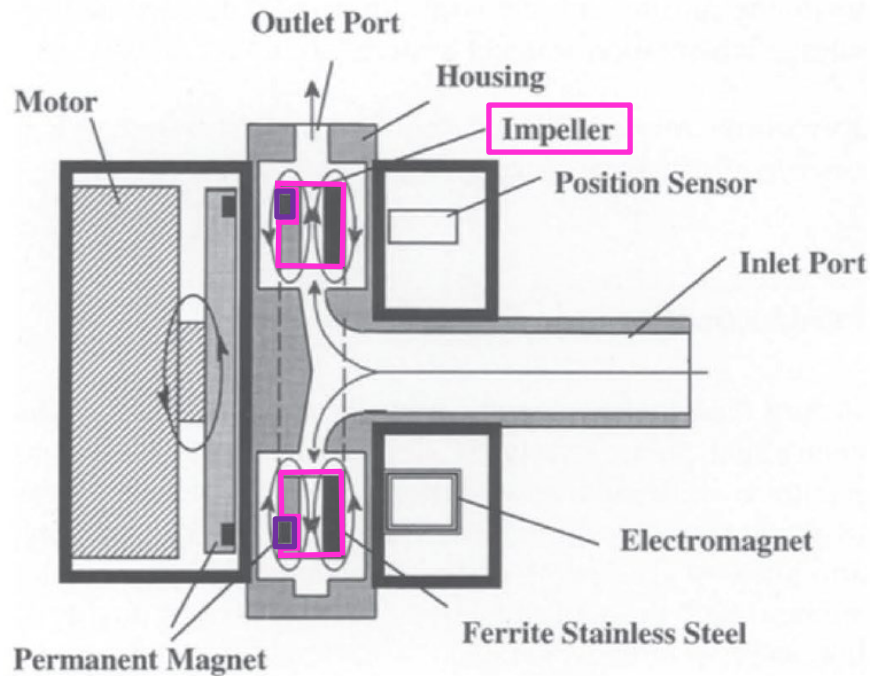


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2. As Mr. Crosby explains, Figure 2 and 5 both show that the “permanent magnet” is rigidly coupled to the impeller:

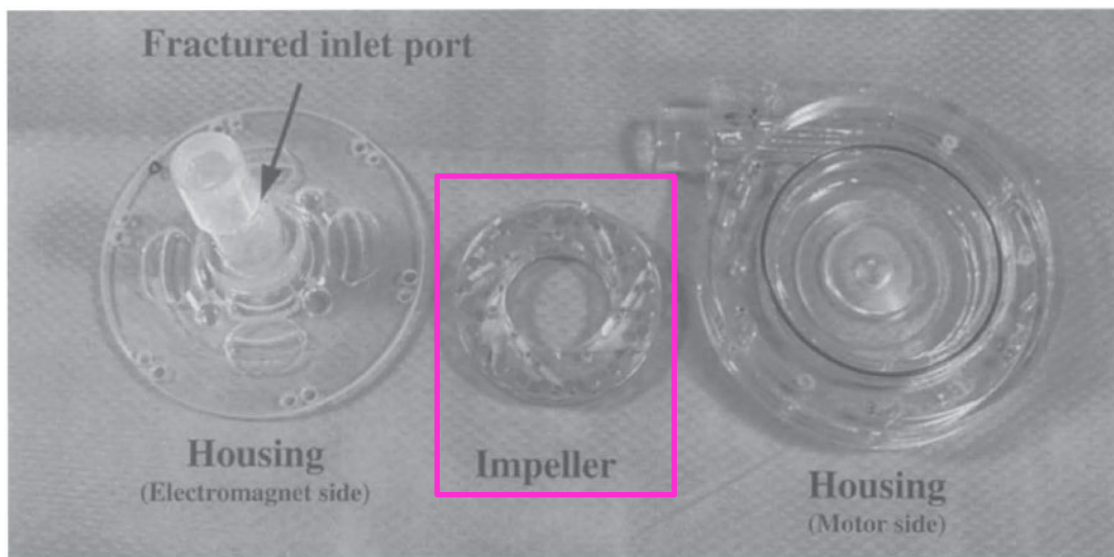


Fig. 5; Ex.1003, ¶¶516, 518.

Accordingly, Akamatsu-1999 teaches or suggests the **magnetically driven rotor** (“impeller”) “being rigidly coupled to a **first magnetic device** (impeller’s “permanent magnet”).” Ex.1003, ¶519.

viii. [1G]

As demonstrated for [1D], Akamatsu-1999 discloses that the “**impeller** rotates” with its “[p]ermanent [m]agnet” “at the center of the **pump housing**” (“is located within the surrounding rotor housing”) (Ex.1006, 3-4):

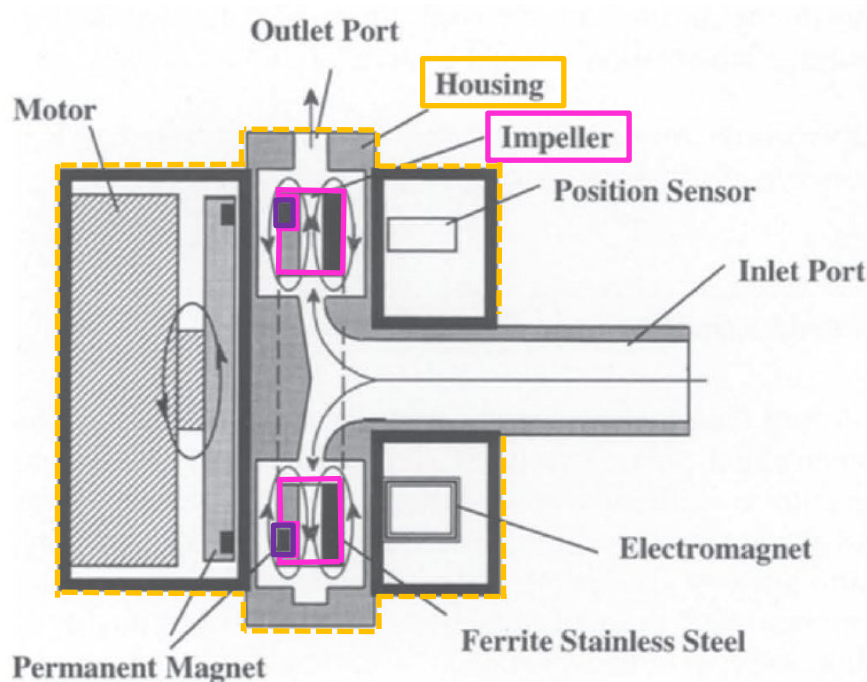


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶523.

Accordingly, Akamatsu-1999 discloses that the **first magnetic device** (impeller’s “permanent magnet”) “is located within the **surrounding rotor housing** (“housing”).” Ex.1003, ¶524.

ix. [1H]

Akamatsu-1999 discloses that the impeller's "[p]ermanent [m]agnet" is "at a position axially adjacent to the" the "impeller" (Ex.1006, 3-4):

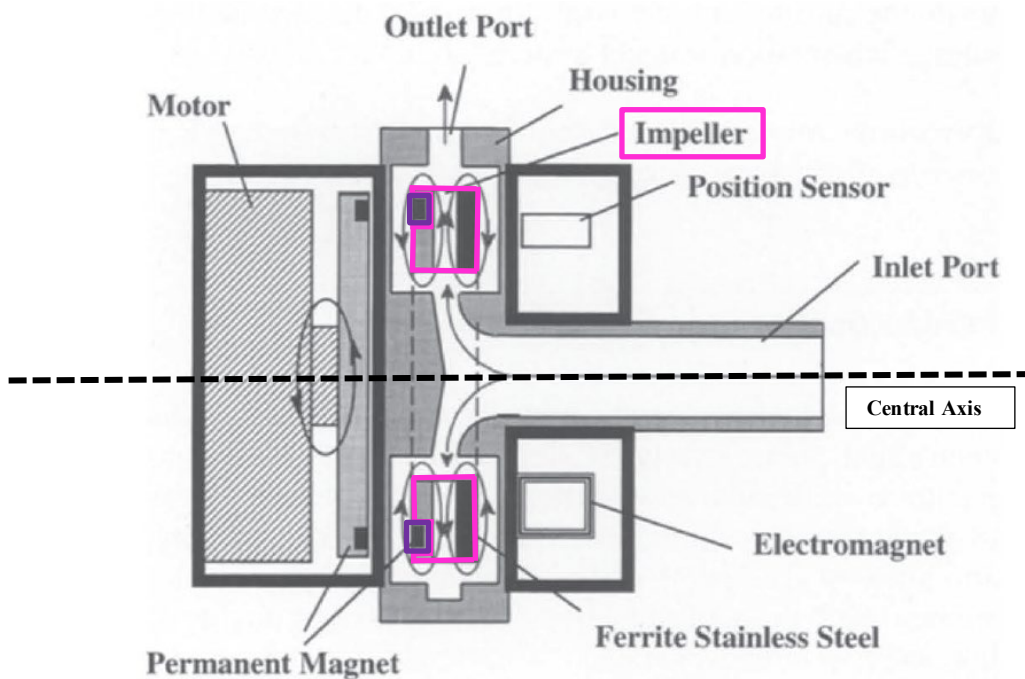


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; *see also* Figure 5 (impeller photo); Ex.1003, ¶528.

Accordingly, Akamatsu-1999 teaches or suggests that the **first magnetic device** is "at a position axially adjacent to the **magnetically driven rotor** ("impeller")." Ex.1003, ¶529.

x. [1I]

Akamatsu-1999 discloses that its **pump** has a "motor" which rotates a "[p]ermanent [m]agnet" ("a second magnetic device"), (Ex.1006, 4), which is also *axially aligned with the inlet port:*

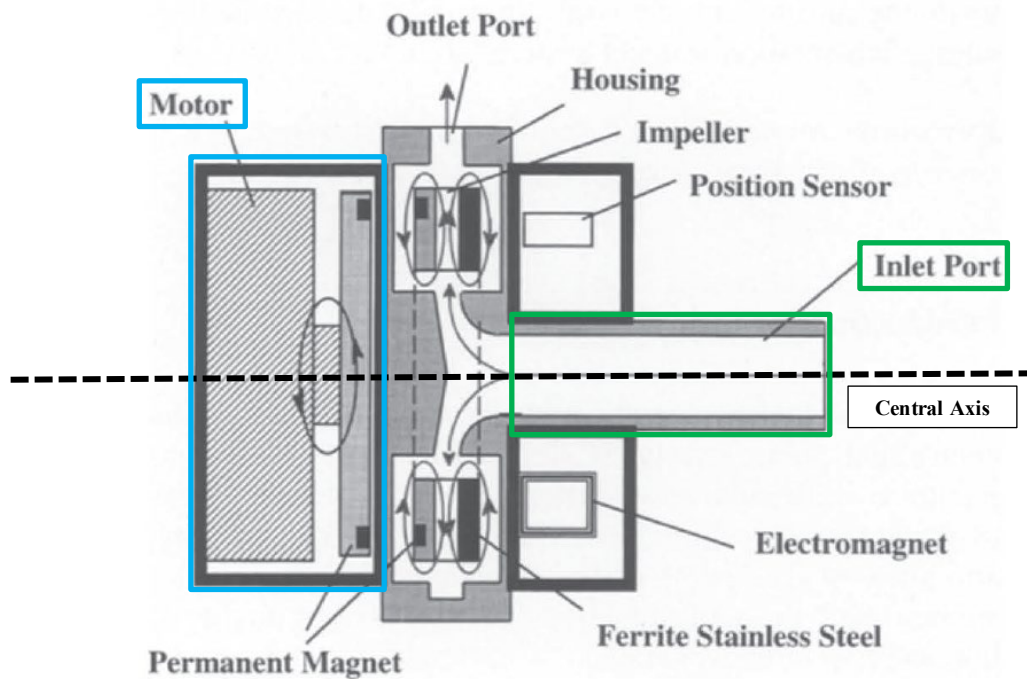


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶535.

Accordingly, Akamatsu-1999 discloses that “*the heart assist pump device* (“centrifugal pump”) *further includes: a second magnetic device* (motor’s “permanent magnet”) *axially aligned with the inflow tube* (“inlet port”).” Ex.1003, ¶536.

xi. [1J]

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, 3-4):

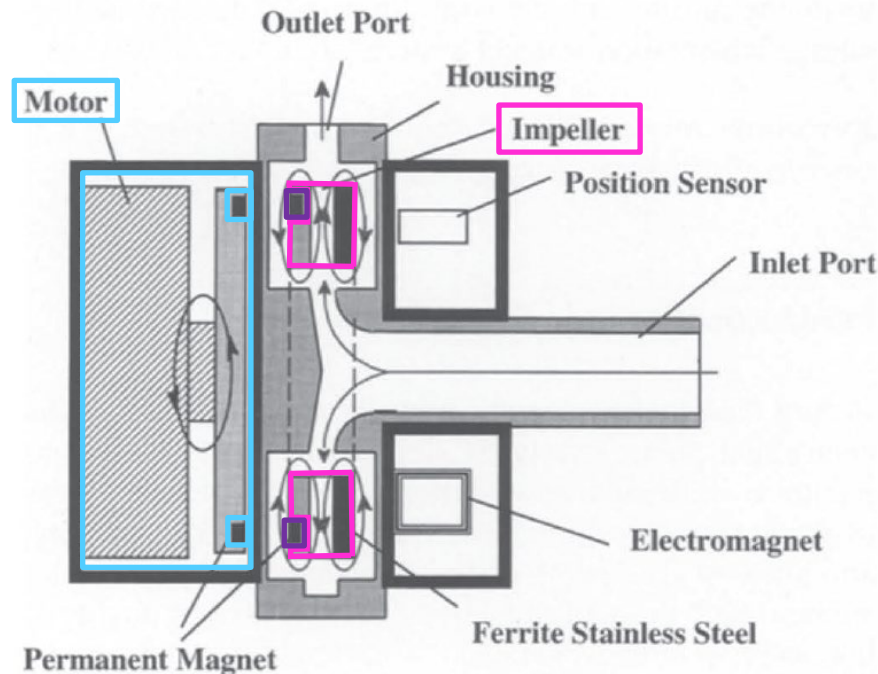


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶540, 542.

Accordingly, Akamatsu-1999 discloses that the **second magnetic device** (motor's "permanent magnet") is "*positioned to magnetically drive rotation of the magnetically driven rotor*" ("impeller") *via a magneto coupling with the first magnetic device* (impeller's "permanent magnet")." Ex.1003, ¶544.

xii. [1K]

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, 6), as indicated by the solid black line surrounding the motor:

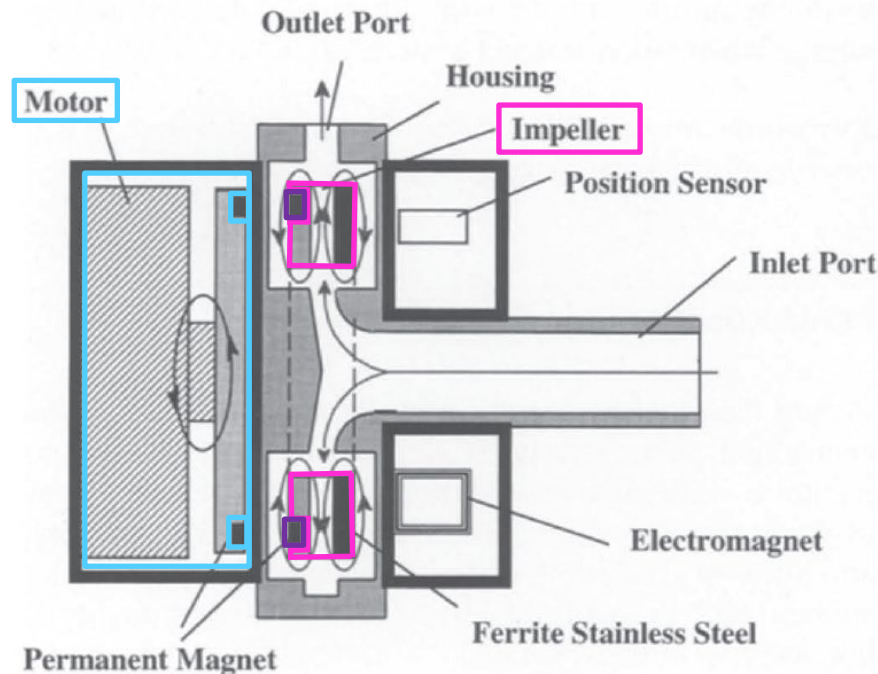


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2. Akamatsu-1999 also discloses sealing the device to prevent “leakage of blood into the...motor.” Ex.1006, 5; Ex.1003, ¶¶547-549.

Accordingly, Akamatsu-1999 discloses a **second magnetic device** (motor’s “permanent magnet”) “while being spaced apart and sealed from both the **magnetically driven rotor** (“impeller”) and the **first magnetic device** (impeller’s “permanent magnet”).” Ex.1003, ¶550.

xiii. [1L]

Akamatsu-1999 discloses an “outflow conduit” or “**outlet port**” (a blood outflow port), (Ex.1006, 4), which Figure 2 illustrates (black arrow) is positioned radially adjacent the **impeller** such that blood driven by the **impeller** is configured

to exit the **housing** in a direction substantially perpendicular from the **inlet port** and the central axis of the **impeller**:

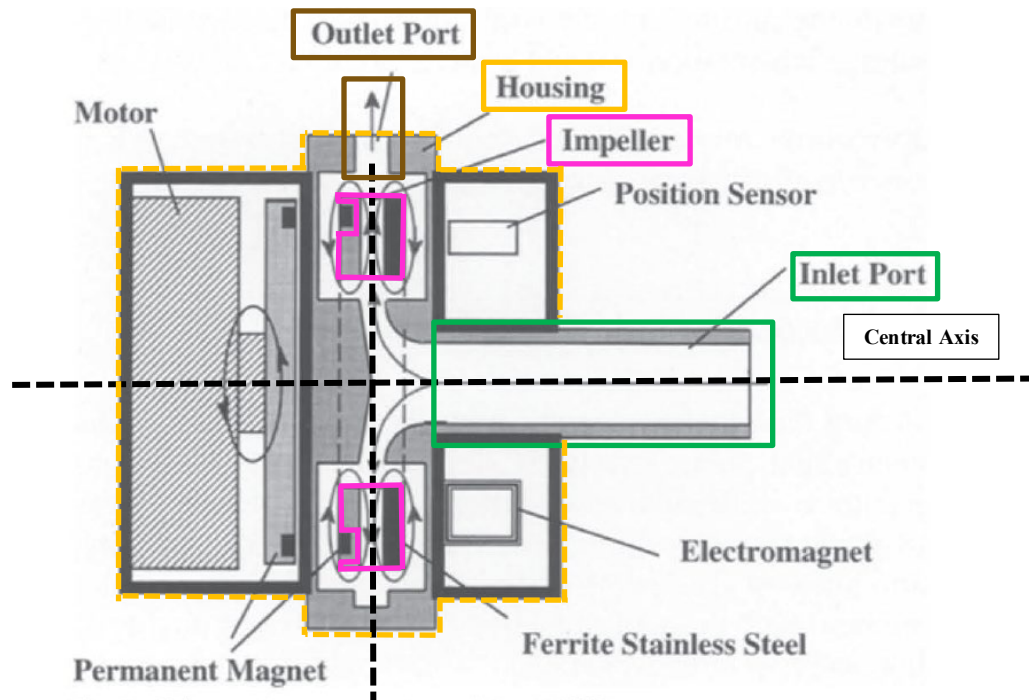


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶556.

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

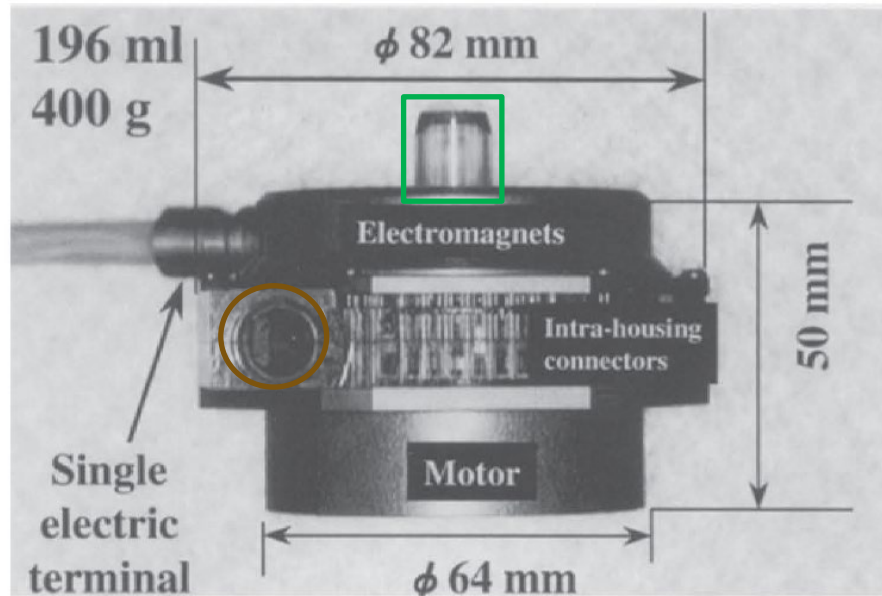


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3; Ex.1003, ¶¶557-558.

Accordingly, Akamatsu-1999 discloses that “a **blood outflow port** (“outlet port”) positioned radially adjacent the **magnetically driven rotor** (“impeller”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“housing”) in a direction substantially perpendicular from the **inflow tube** (“inlet port”) and the **central axis** of the **magnetically driven rotor**.” Ex.1003, ¶559.

xiv. [1M]

In Parallel Litigation, PO asserts that a magnetic bearing (i.e., “MagLev”) satisfies this limitation. Ex.1019, 12-13. Assuming that interpretation, as explained in [1J], Akamatsu-1999 discloses that the “**impeller** rotates by a magnetic coupling” (“*magneto coupling orients the magnetically driven rotor*”), thereby “providing

contact-free rotation” (“*remains entirely spaced apart from the surrounding rotor housing*”), (Ex.1006, 4), which Figure 2 illustrates (black arrow) allows for the “*blood flowing*”:

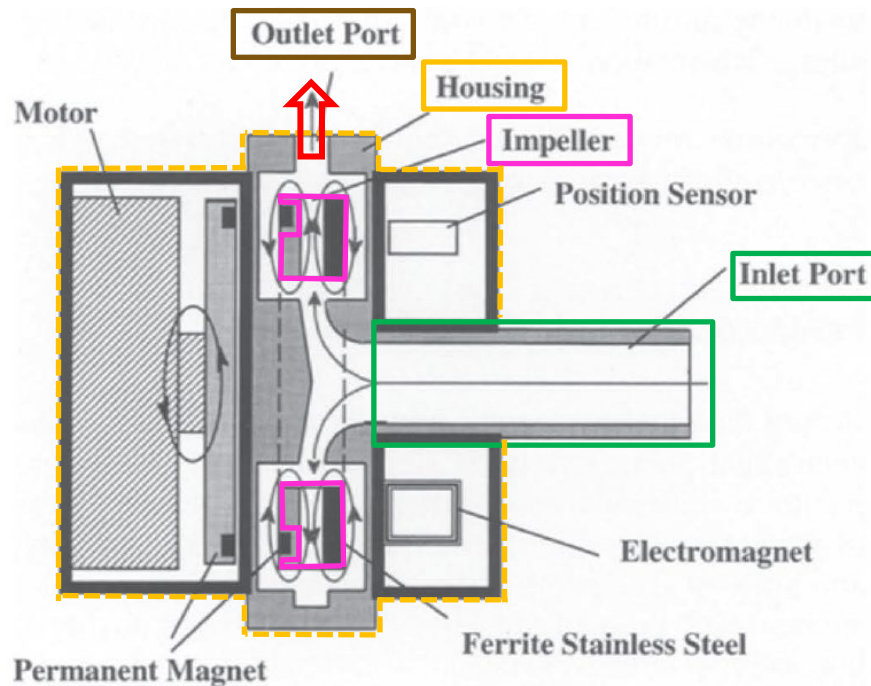


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶565. Indeed, the Akamatsu-1999 “magnetic suspension system” reported “excellent hydrodynamic performance with a low rate of hemolysis” (“*spaced apart...by the blood flowing*”). Ex.1006, 6.

Accordingly, Akamatsu-1999 discloses that “*the magneto coupling orients the magnetically driven rotor* (“impeller”) so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing (“housing”) by the blood flowing from

the *inflow tube* (“inlet port”) and to the *blood outflow port* (“outlet port”).” Ex.1003, ¶566.

xv. [1N]

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” (*regulating operation...to thereby magnetically drive the rotation*”), (Ex.1006, 4):

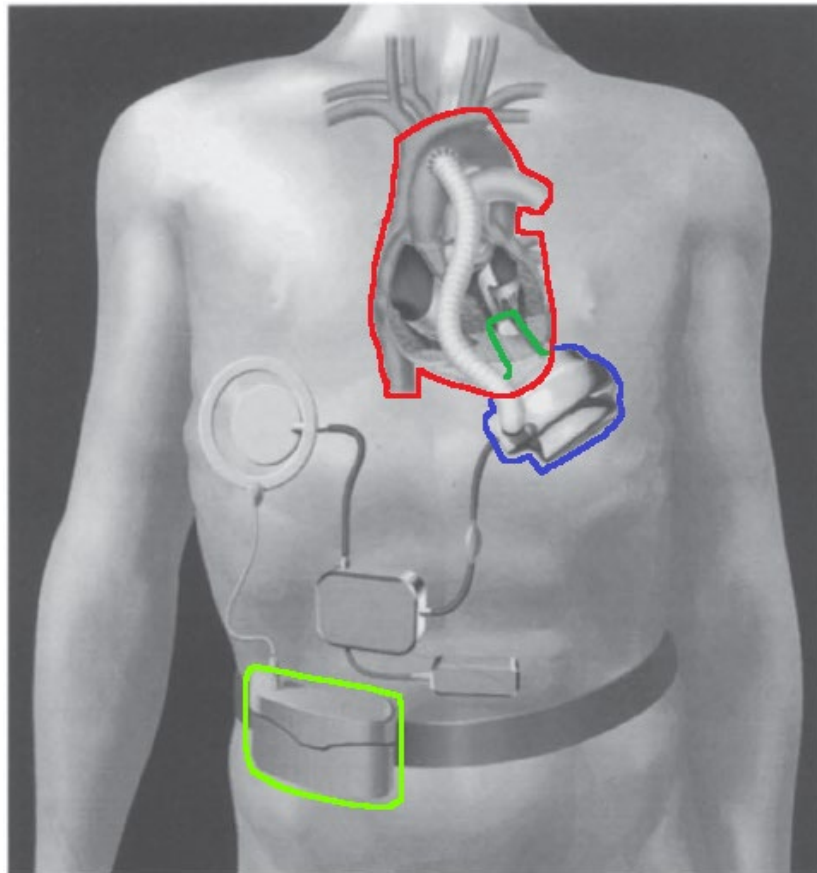


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶571.

Akamatsu-1999 discusses a “**next phase**” “**Model III** pump” with “an **implantable** controller and a transcutaneous energy/information transfer system.” Ex.1006, 3. “The **Model II** pump,” however, which was the focus of the studies described in Akamatsu-1999, “was percutaneously driven” by “a single electric wire” with “intra-housing connectors” (“*connecting*”) between the “motor” to a controller:

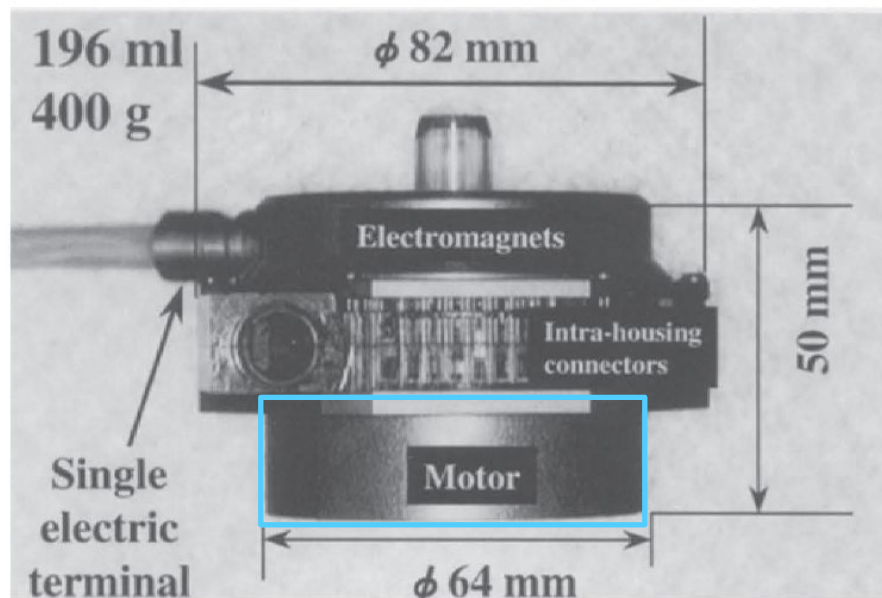


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3, 4-5; Ex.1003, ¶570.

Accordingly, Akamatsu-1999 teaches or suggests “*connecting an **external control unit** (“controller”) to the **heart assist pump device** (“centrifugal pump”) for regulating operation of the **second magnetic device** (motor’s “permanent magnet”) to thereby magnetically drive the rotation of the **magnetically driven rotor***”

(“impeller”) *via the magneto coupling with the **first magnetic device*** (impeller’s “permanent magnet”).” Ex.1003, ¶572.

xvi. [10]

As explained for [1N], Akamatsu-1999 discloses a **controller** worn externally and *positioned exterior to the body*, and as demonstrated for [1A], Akamatsu-1999 discloses an **inlet port** that “*is in the **heart***.”

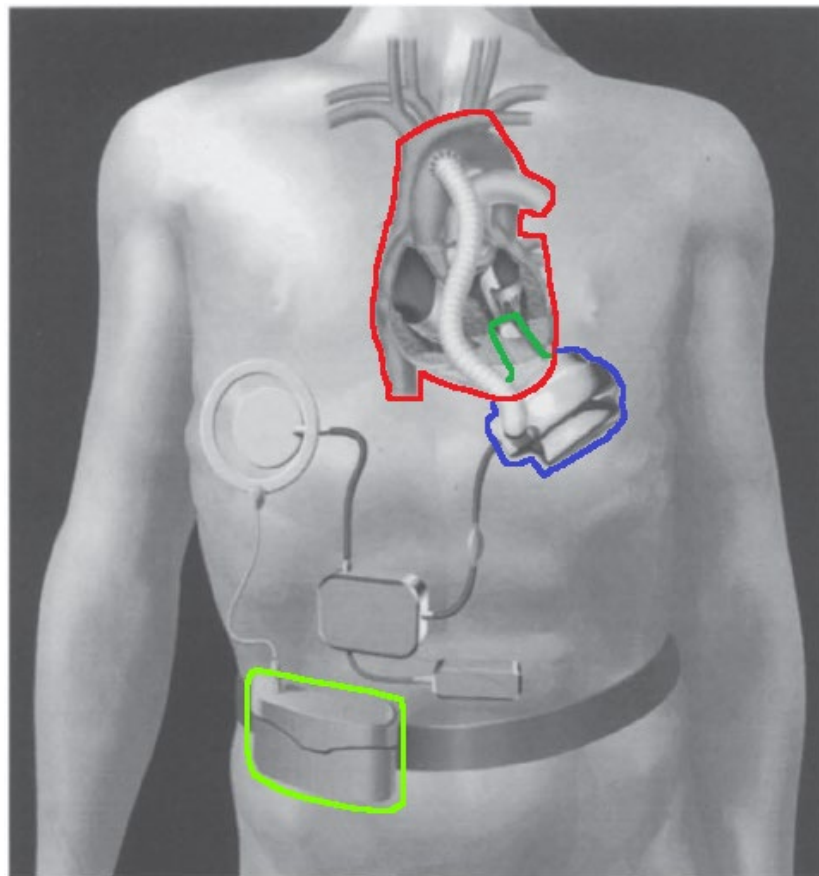


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

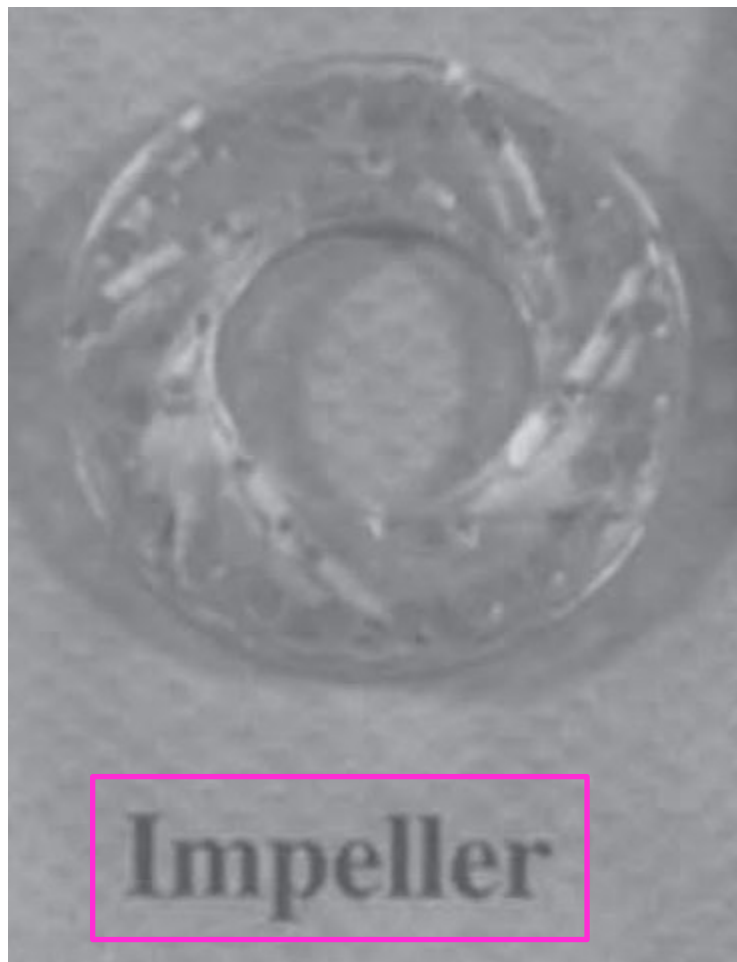
Ex.1006, Fig. 1; Ex.1003, ¶¶575-576.

Accordingly, Akamatsu-1999 discloses “the *external control unit* (“controller”) *being positioned exterior to the body while the inflow tube* (“inlet port”) *of the heart assist pump device* (“centrifugal pump”) *is in the heart.*” Ex.1003, ¶577; *see also* ¶¶479-627.

2. Claims 2, 3, and 4

i. [2]

Akamatsu-1999 discloses in Figure 5 that its “*impeller*” has blades or edges, which Mr. Crosby explains are *guide surfaces* (Ex.1003, ¶¶580-581):



Ex.1006, Fig. 5. By virtue of being “a centrifugal pump,” the rotor and guide surfaces *produce centrifugal flow components*. Ex.1006, 3; Ex.1003, ¶582.

Accordingly, Akamatsu-1999 teaches or suggests that “*in response to the rotation of the magnetically driven rotor (“impeller”) via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.*” Ex.1003, ¶583.

ii. [3A]

As demonstrated in [1K], the “motor” is *spaced apart and sealed from the “impeller”* (Ex.1006, 6):

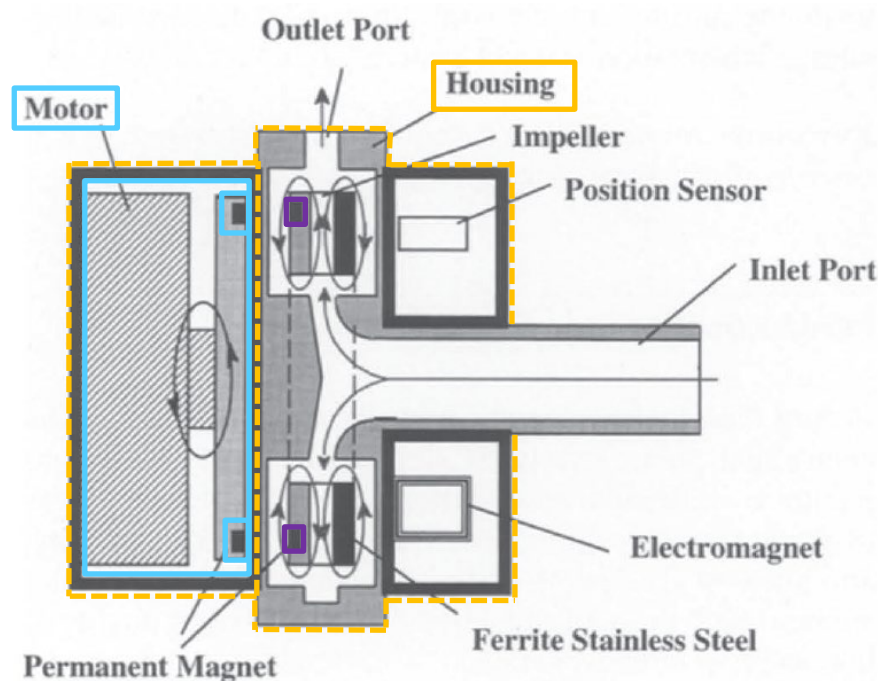


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶587.

Accordingly, Akamatsu-1999 discloses that “*the surrounding rotor housing* (“housing”) *comprises at least one sealing wall between the first magnetic device* (“permanent magnet”) *and the second magnetic device* (motor’s “permanent magnet”).” Ex.1003, ¶588.

iii. [3B]

As demonstrated in [1H]-[1J], the impeller’s “permanent magnet” is positioned between the “impeller” and the motor’s “permanent magnet” (Ex.1007, 401):

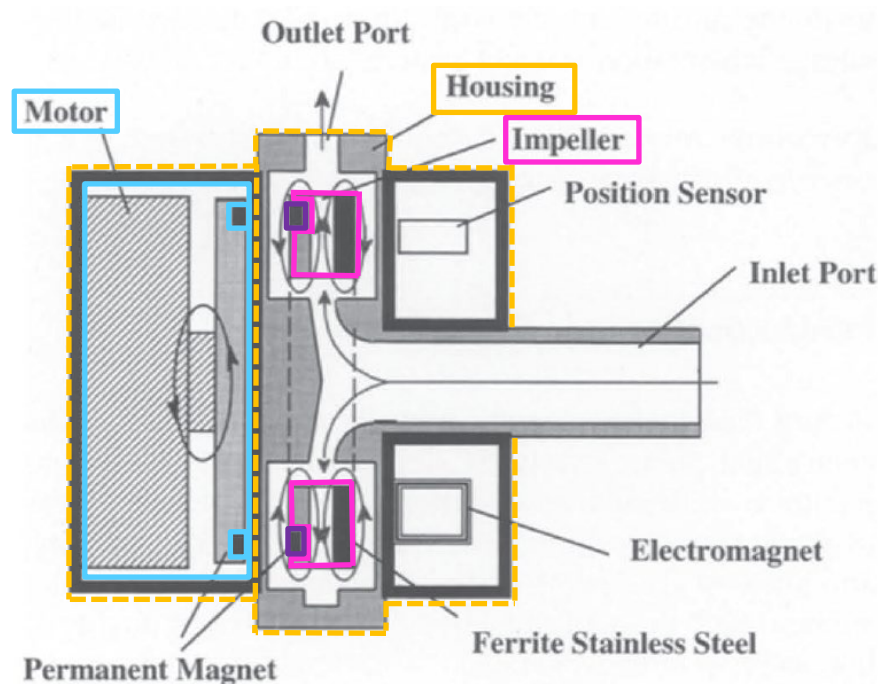


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶591.

Accordingly, Akamatsu-1999 discloses that “*the first magnetic device* (“permanent magnet”) *is positioned between the second magnetic device* (motor’s “permanent magnet”) *and the magnetically driven rotor* (“impeller”).” Ex.1003, ¶592.

iv. [4]

As demonstrated in [1F], the “impeller” and its “permanent magnet” are “rigidly coupled,” Akamatsu-1999 discloses “*the first magnetic device* (“permanent magnet”) *rotates together with the magnetically driven rotor* (“impeller”) *relative to the surrounding rotor housing* (“housing”).” Ex.1003, ¶595.

3. Claim 5

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit are “*measurement values indicative of cardiac output of the heart.*” Assuming that interpretation, Akamatsu-1999 discloses a “controller” to regulate the “motor” so that “[t]he pump was operated at a fixed rotational speed” Ex.1006, 3-4; Ex.1003, ¶600.

Accordingly, Akamatsu-1999 teaches or suggests “*wherein the external control unit* (“controller”) *controls the second magnetic device* (motor’s “permanent magnet”) *in response to measurement values indicative of cardiac output of the heart* (“operated at a fixed rotational speed”).” Ex.1003, ¶604.

4. Claim 6

As demonstrated in [1M], because the motor's **permanent magnet** “operates completely contact-free” (“*while being spaced apart*”) *from both the **impeller** and its **permanent magnet***, (Ex.1006, 6), Akamatsu-1999 discloses that “*both the **magnetically driven rotor** (“impeller”) and **first magnetic device** (“permanent magnet”) are entirely spaced apart from the **surrounding rotor housing** (“housing”) by a gap during rotation of the **magnetically driven rotor**.*” Ex.1003, ¶607.

5. 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, 3-4. Mr. Crosby explains that these “sensors” “*provid[e] feedback signals*” to the “**controller**,” which provides the “electric current.” Ex.1006, 4; Ex.1003, ¶612.

Accordingly, Akamatsu-1999 teaches or suggests “*providing feedback signals to the **external control unit** (“controller”) from one or more sensors (“position sensors”).*” Ex.1003, ¶613.

6. Claim 10

As demonstrated in [1N], Akamatsu-1999 discloses a “**controller**” to *regulate* the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” (“*a fixed control value*”). Ex.1006, 3-4; Ex.1003, ¶616.

Accordingly, Akamatsu-1999 teaches or suggests that “the **external control unit** (“controller”) is configured to regulate operation of the **second magnetic device** (motor’s “permanent magnet”) based on a fixed control value.” Ex.1003, ¶618.

7. Claim 12

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

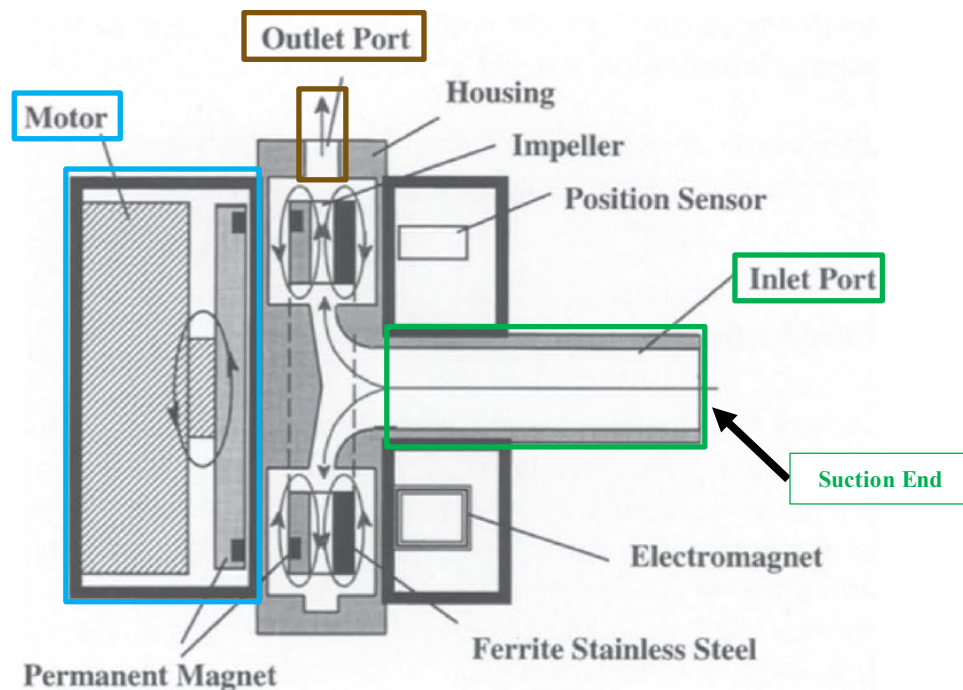


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶621.

Accordingly, Akamatsu-1999 discloses that “the **second magnetic device** (motor’s “permanent magnet”) is positioned closer to the **blood outflow port** (“outlet

port”) than the *second magnetic device* is positioned relative to the suction end of the *inflow tube* (“inlet port”).” Ex.1003, ¶622.

8. Claim 13

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Assuming that interpretation, because Akamatsu-1999’s *centrifugal pump* comprises “an inlet port” “inserted into the left ventricle” (Ex.1006, 4), it “*is a catheter device*.” Ex.1003, ¶626.

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

1. Claim 1

i. [1PRE]

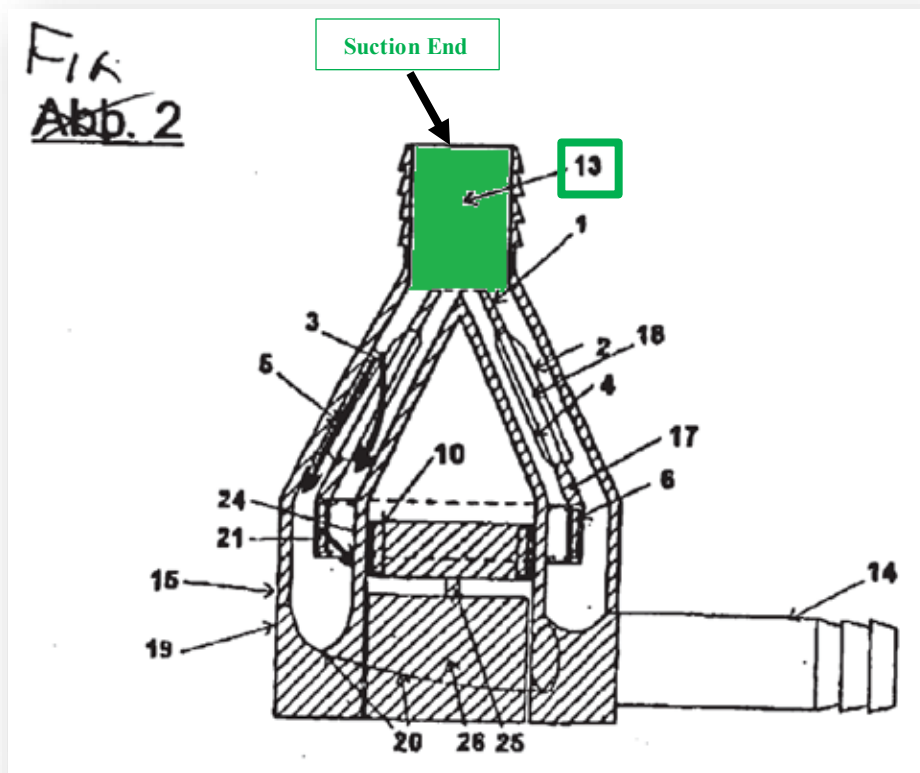
Schima discloses a “a rotary pump for moving blood [*“assisting the blood circulation”*].” Ex.1005, [0001]; Ex.1003, ¶629.

Schima does not expressly state where its pump is placed, but Mr. Crosby explains *infra* §VIII.D.9, it would have been obvious that Schima’s pump is “*for assisting ... a heart*.” Ex.1003, ¶630 (citing Ex.1005, [0004]-[0009]).

Accordingly, Schima teaches or suggests “*a method for assisting the blood circulation of a heart in a body*.” Ex.1003, ¶631.

ii. [1A]

Schima explains that its “pump” has “*inlet 13*” (“*an inflow tube of the heart assist pump device*”) (Ex.1005, [0012]):



Ex.1005, Fig. 2; Ex.1003, ¶634.

Mr. Crosby explains that Schima suggests that its pump is an LVAD designed to be “*delivered to a heart*” so that inlet tube 13 (“*a suction end of an inflow tube:*”) “*is inserted into a ventricle of the heart.*” Ex.1003, ¶635. 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 of the heart assist pump device is inserted into a ventricle of the heart*”), at least because Schima’s pump is designed to solve the same problem as Akamatsu’s pump. Ex.1003, ¶641; *see also* Ex.1005, [0001]-[0004] (explaining problems).

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

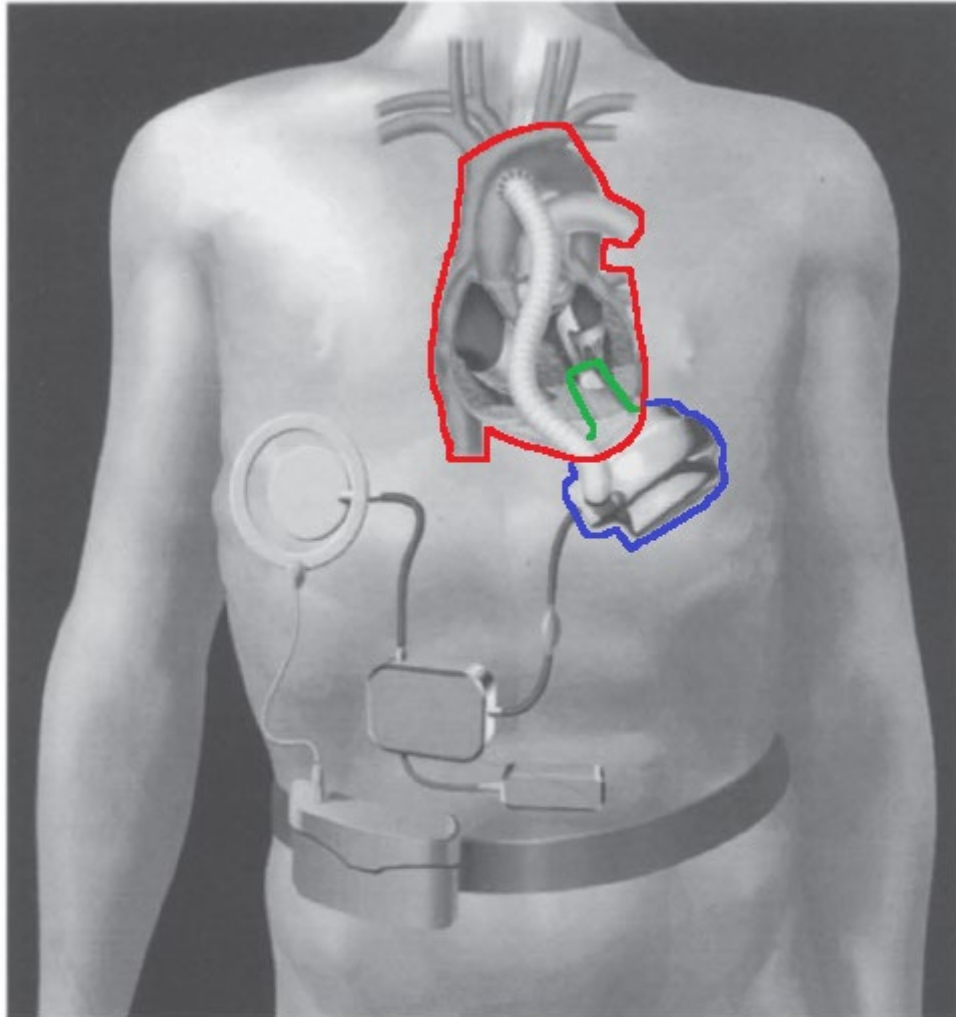


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶644.

A POSITA would have been motivated to implant Schima's **inlet 13** according to Akamatsu-1999, because the teachings are complimentary—Schima focuses on

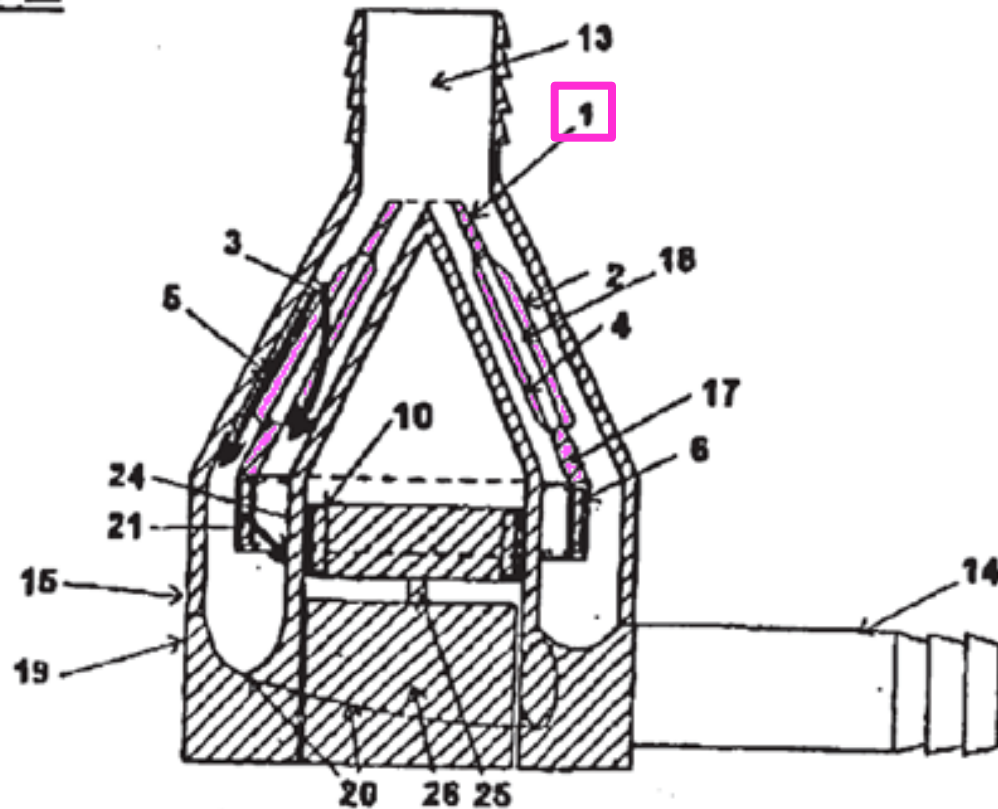
pump design alone, while Akamatsu-1999 focuses on pump design, control, and implantation. Ex.1003, ¶644. A POSITA would have been motivated to use Schima's advantageous pump design while using Akamatsu-1999's teachings as to pump implantation (inserted into the left ventricle) with a reasonable expectation of success, as detailed below. *Infra* §VIII.D.9.

Accordingly, Schima, or Schima/Akamatsu-1999, renders obvious “delivering *a heart assist pump device* to the *heart* so that *a suction end of an inflow tube* of the *heart assist pump device* is inserted into *a ventricle of the heart*.” Ex.1003, ¶646.

iii. [1B]

Schima discloses that its “**pump**” includes a “**rotor 1**” which “holds rotor magnets 6 that preferably transfer rotation energy” (“*magnetically driven rotor*”) (Ex.1005, [0012]; Ex.1003, ¶648):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶¶648-649.

Further, Schima discloses that “the drive can...be an electric motor 26 which drives a rotating disk 24 with magnets 10” (“*magnetically driven*”). Ex.1005, [0013]; Ex.1003, ¶648.

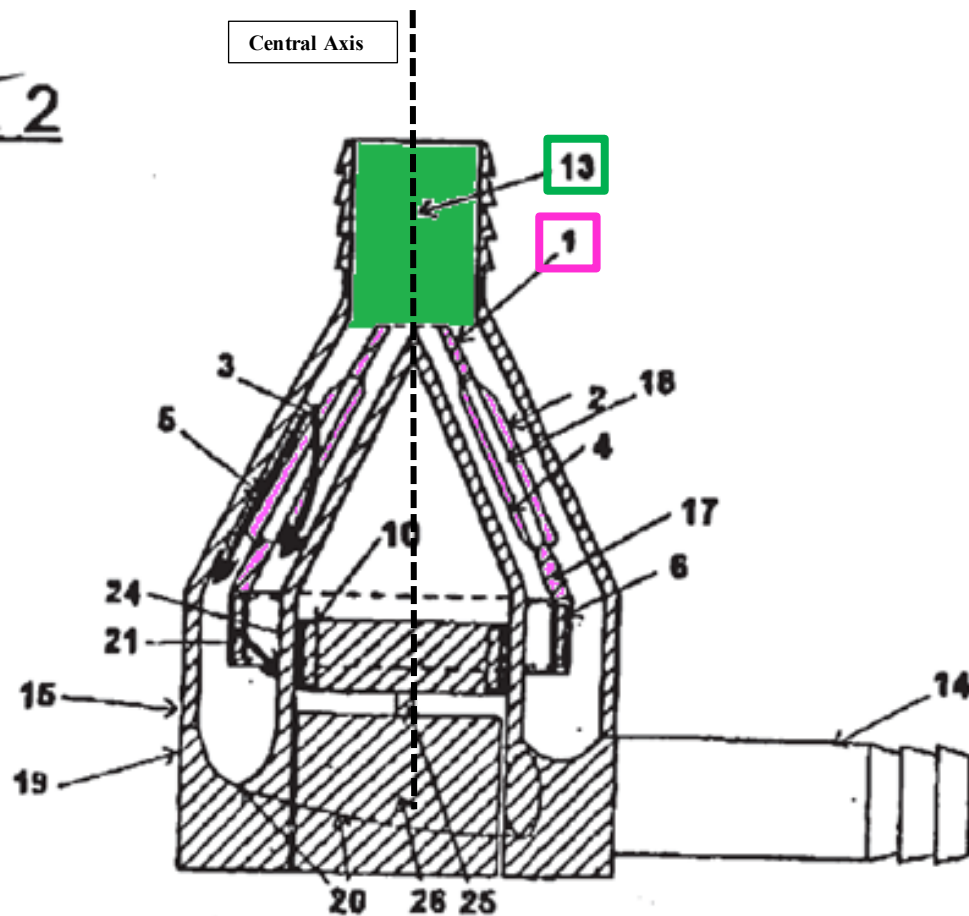
As demonstrated in [1A], the “*suction end of an inflow tube...is inserted into ... the heart,*” but the remainder of Schima’s “pump,” including its “**rotor 1**,” is “*positioned outside...the **heart**.*” Ex.1005, Fig. 2; Ex.1003, ¶651.

Accordingly, Schima teaches or suggests “*while a **magnetically driven rotor** of the **heart assist pump device** is positioned outside the ventricle of the **heart**.*” Ex.1003, ¶652.

iv. [1C]

Schima discloses that its **rotor** is “axially” *aligned* with “**inlet 13**” (“*the magnetically driven rotor is axially aligned with the inflow tube*”) so that the “flow [from *the inflow tube*]” is “preferably axially against” “the pump housing” which “serves to center the **rotor**.” Ex.1005, [0012]; Ex.1003, ¶654. Figure 2 illustrates the axial alignment of the **rotor** and **inlet 13**:

Fig.
Abb. 2



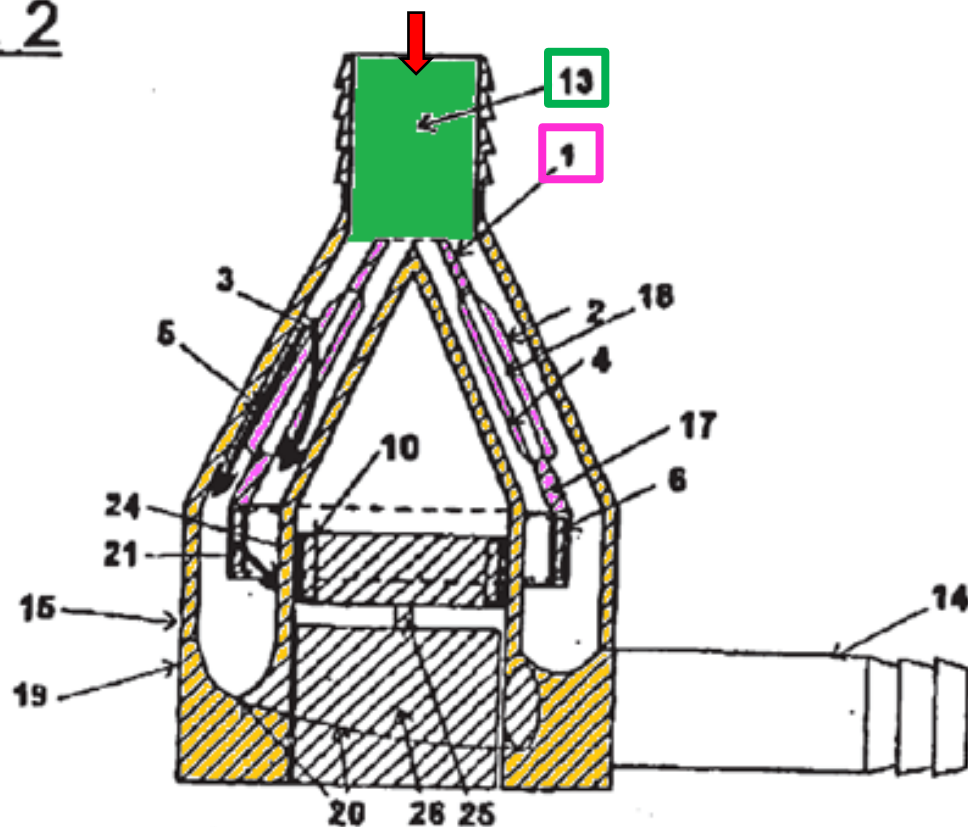
Ex.1005, Fig. 2; Ex.1003, ¶655.

Accordingly, Schima teaches or suggests that “the *magnetically driven rotor* (“rotor 1”) is axially aligned with the *inflow tube* (“inlet 13”).” Ex.1003, ¶656.

v. [1D]

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

FIG.
Abb. 2



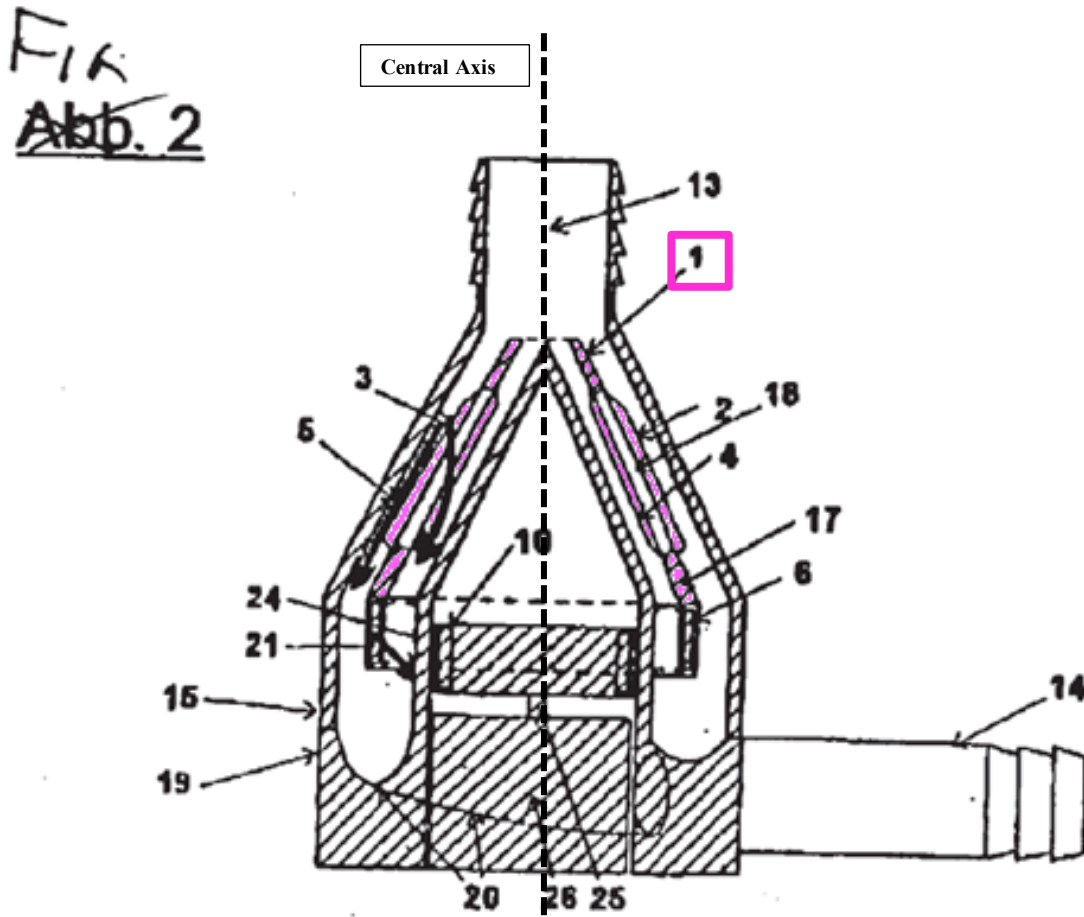
Ex.1005, Fig. 2; Fig. 1; Ex.1003, ¶661.

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, ¶659.

Accordingly, Schima teaches or suggests that the magnetically driven rotor “is rotatable within *a surrounding rotor housing* (“pump housing 30”) of the *heart assist pump device* (“pump”) to act upon blood flowing from the *inflow tube* (“inlet 13”) toward the *magnetically driven rotor* (“rotor 1”).” Ex.1003, ¶662.

vi. [1E]

Schima discloses that “**rotor** 1 rotates in a pump housing” and that there is “axial...stabilizing of the rotor,” and as Figure 2 illustrates the rotation is around the axis of the pump (“being rotatable about a central axis”) (Ex.1005, [0012]):



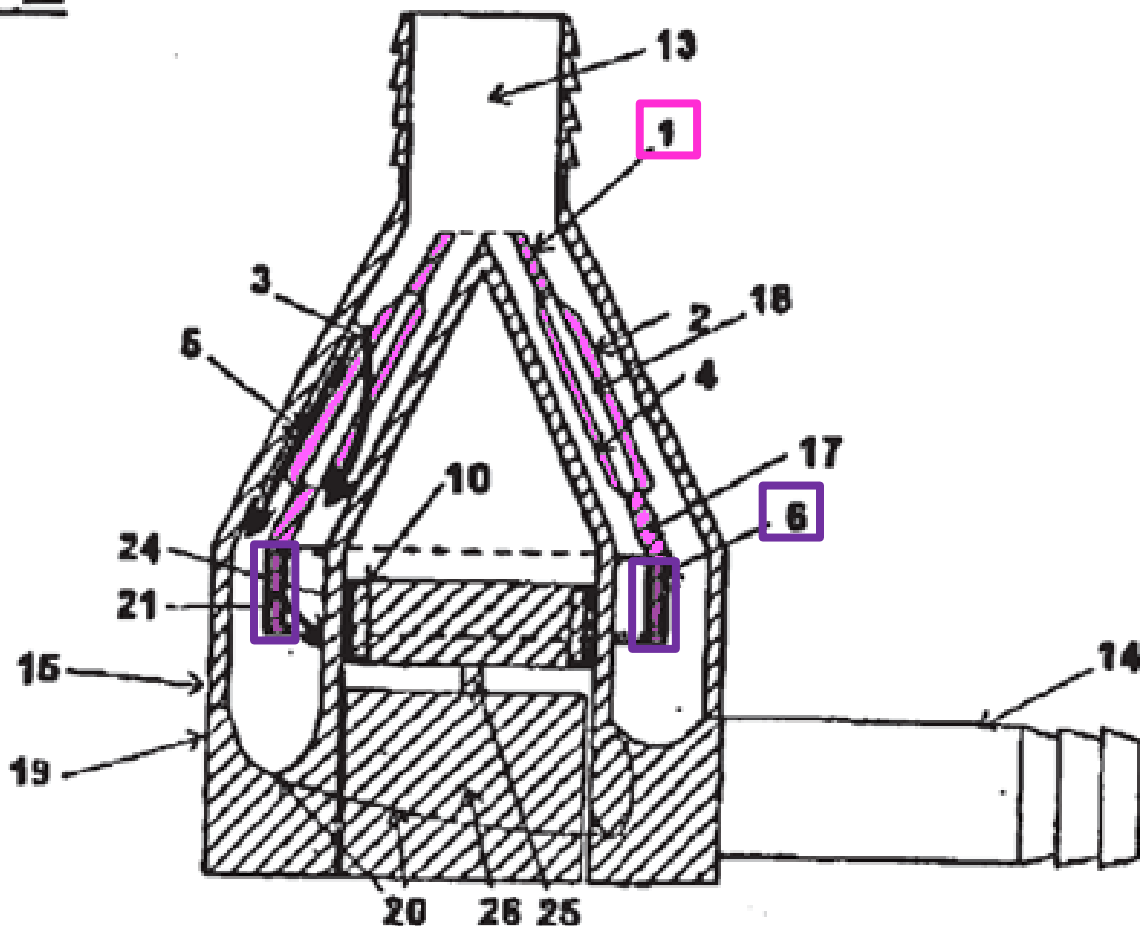
Ex.1005, Fig. 2; Ex.1003, ¶¶664-665. Further, because Schima is a “centrifugal blood pump[],” the rotor is by definition “*rotatable about a central axis.*” Ex.1003, ¶667.

Accordingly, Schima teaches or suggests “the *magnetically driven rotor* (“rotor 1”) *being rotatable about a central axis.*” Ex.1003, ¶668.

vii. [1F]

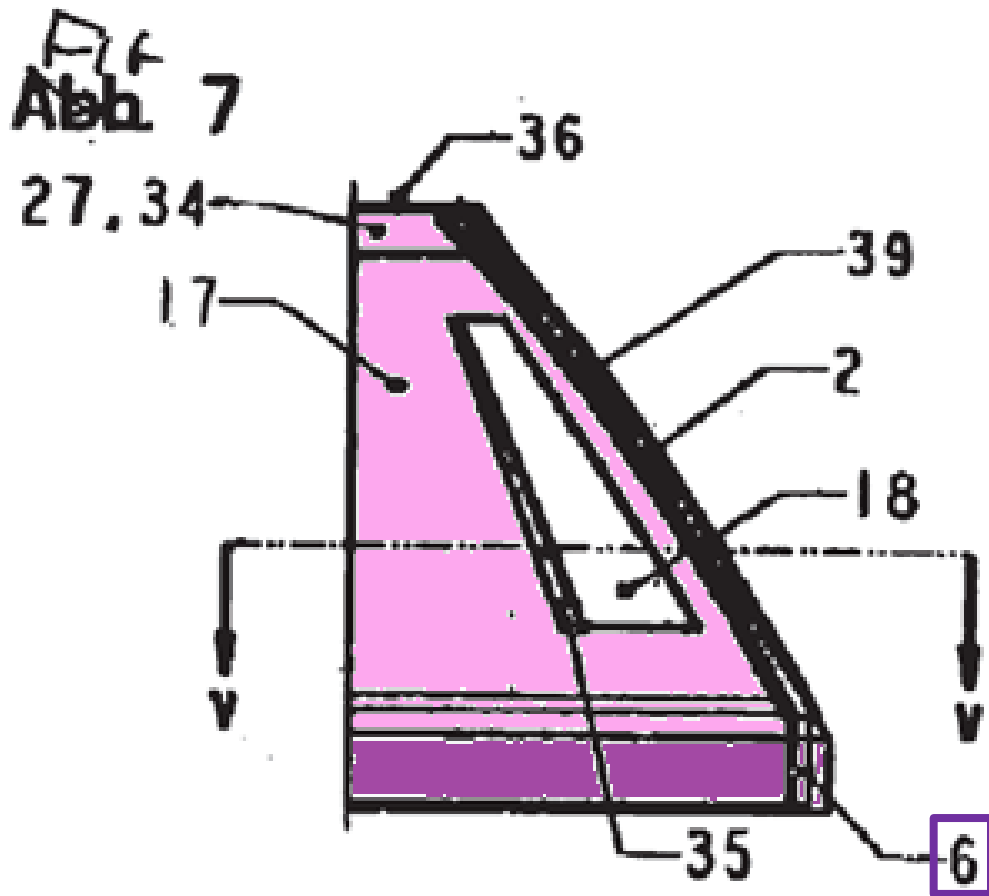
Schima discloses that “[t]he *rotor* holds [*being rigidly coupled to*] *rotor magnets 6* [*a first magnetic device*] that preferably transfer rotation energy.” Ex.1005, [0012]; Ex.1003, ¶671. Figure 2 illustrates the rigid coupling between *rotor magnets 6* and the *rotor*:

2



Ex.1005, Fig. 2; Ex.1003, ¶672.

Figure 7 shows that **rotor magnets 6** can be “formed by a continuous magnetic ring”:



Ex.1005, [0012], Fig. 7; Ex.1003, ¶673.

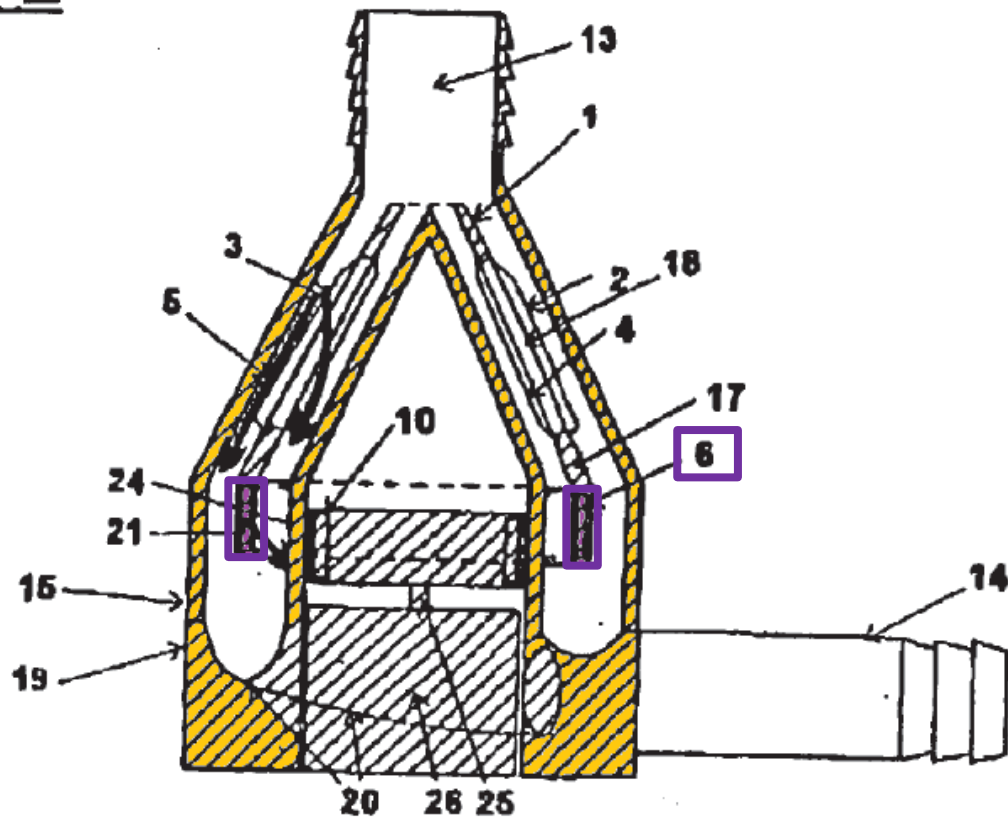
Accordingly, Schima teaches or suggests the **magnetically driven rotor** (“rotor 1”) “being rigidly coupled to a *first magnetic device* (“rotor magnets 6”).”

Ex.1003, ¶674.

viii. *[1G]*

Schima discloses that “**rotor magnets 6**” “rotate[] in a **pump housing**” (“*is located within the surrounding rotor housing*”)” (Ex.1005, [0012]; Ex.1003, ¶676):

Fik
Abb. 2

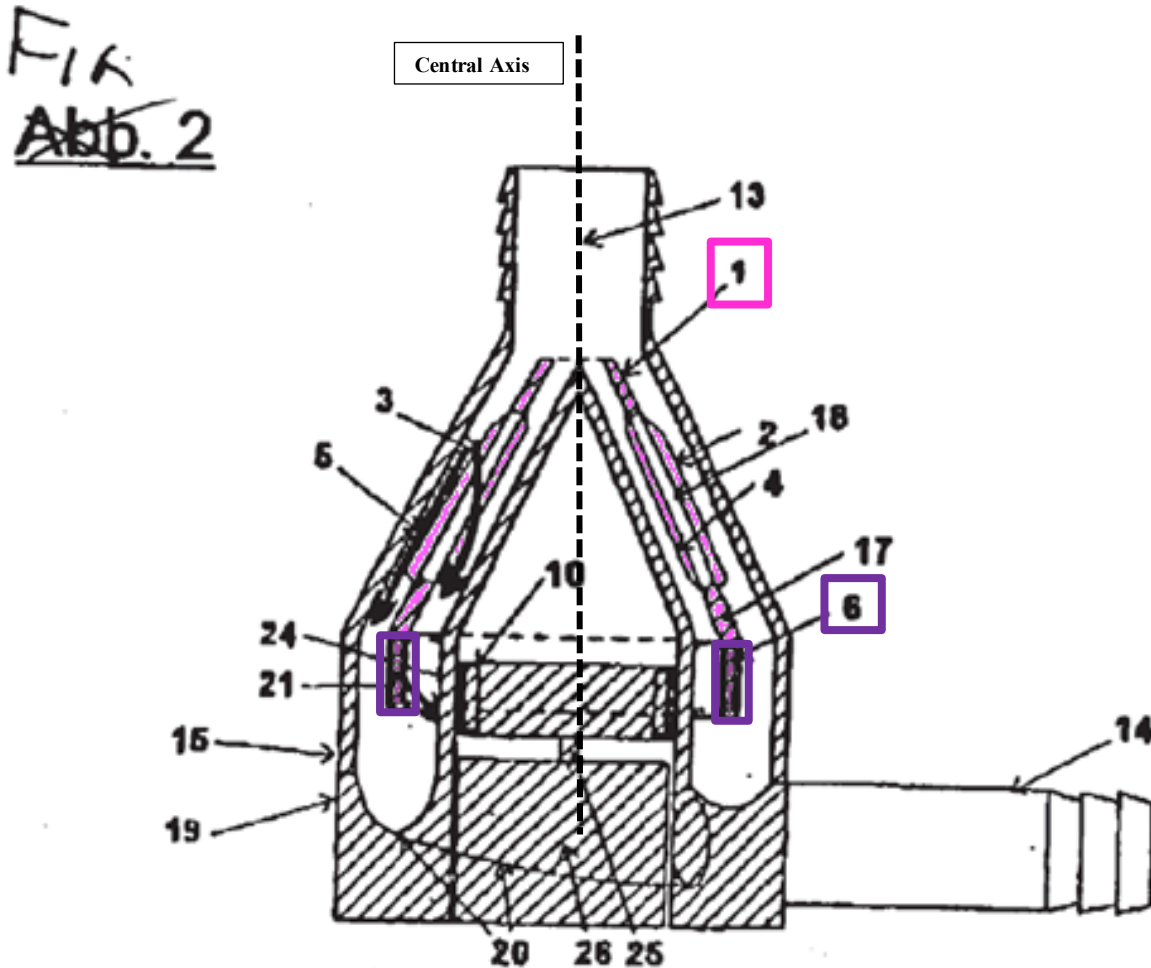


Ex.1005, Fig. 2; Ex.1003, ¶679.

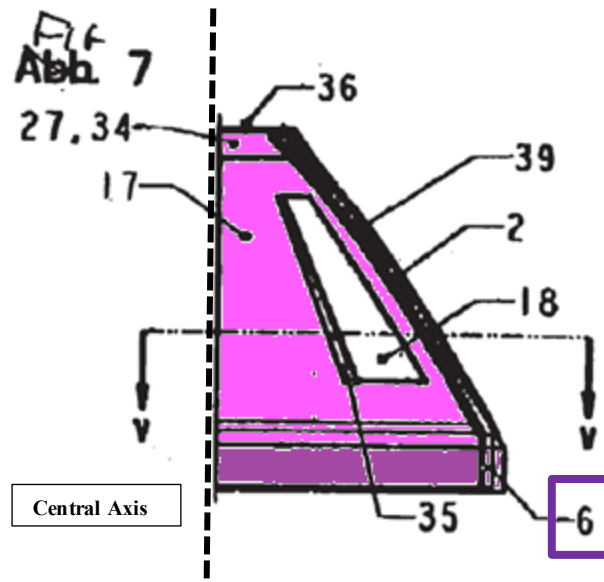
Accordingly, Schima teaches or suggests that the **first magnetic device** (“rotor magnets 6”) “*is located within the **surrounding rotor housing*** (“pump housing 30”).” Ex.1003, ¶680.

ix. [1H]

Schima discloses that “rotor magnets 6” can form “a continuous magnetic ring” at the base of (“at a position axially adjacent to”) the rotor, as illustrated in Figures 2 and 7:



Ex.1005, Fig. 2; Ex.1003, ¶¶682-683.



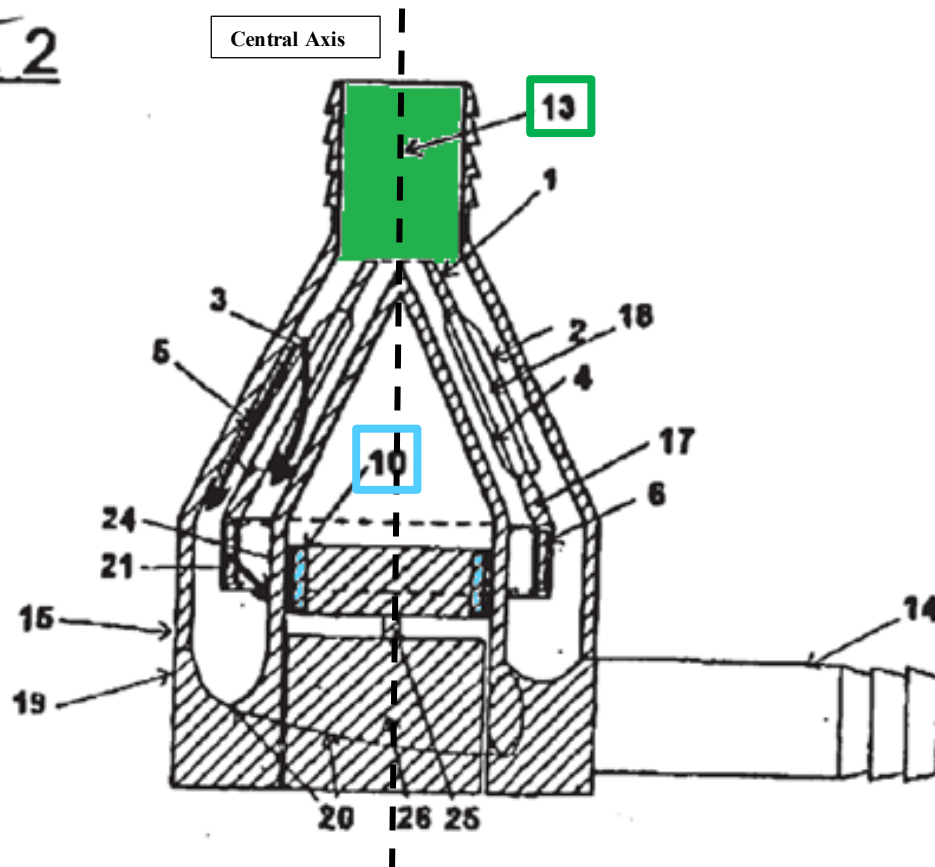
Ex.1005, Fig. 7; Ex.1003, ¶684.

Accordingly, Schima teaches or suggests that the *first magnetic device* (“rotor magnets 6”) is “at a position axially adjacent to the *magnetically driven rotor* (“rotor 1”).” Ex.1003, ¶685.

x. [11]

Schima discloses that the pump’s rotor can be driven by “an electric motor 26 which drives a rotating disk 24 with **magnets 10** [‘a second magnetic device’] by means of a shaft 25.” Ex.1005, [0013]. Further, Schima discloses that “rotating disk 24 with **magnets 10**” has an “axial offset [that] ensures an axial component for the magnetic force” (“*axially aligned*”) that journals the rotor (Ex.1005, [0013]):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶¶687, 690.

Accordingly, Schima teaches or suggests that “*the heart assist pump device* (“pump”) *further includes: a second magnetic device* (“magnets 10”) *axially aligned with the inflow tube* (“inlet 13”).” Ex.1003, ¶691.

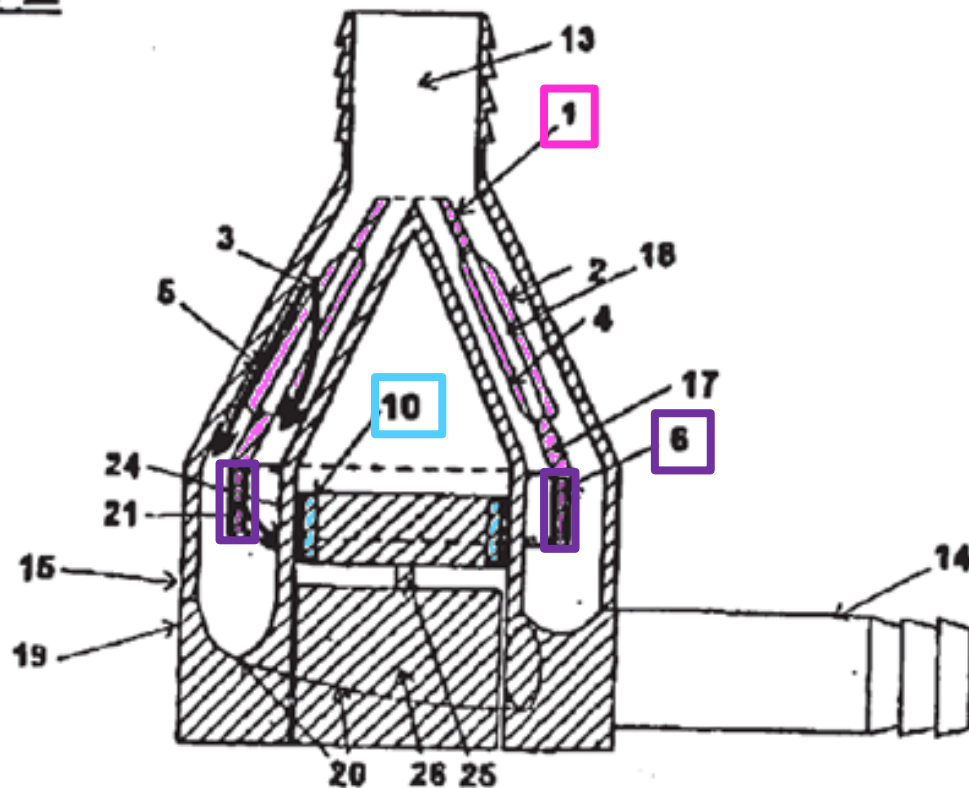
xi. [1J]

Schima discloses that “*magnets 10*” are positioned to “ensure[] an axial component for the magnetic force” and “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”).

Schima further discloses that “[a]s shown in FIG. 2, the drive [*‘magnetically drive rotation’*] can...be an electric motor 26 which drives a rotating disk 24 with **magnets 10:**”

Fig.
Abb. 2



Ex.1005, Fig. 2, [0013]; Ex.1003, ¶696.

Schima also discloses “*magneto coupling*” under PO’s apparent construction.

See §VI.A. Instead of using “an electric motor 26 which drives a rotating disk 24

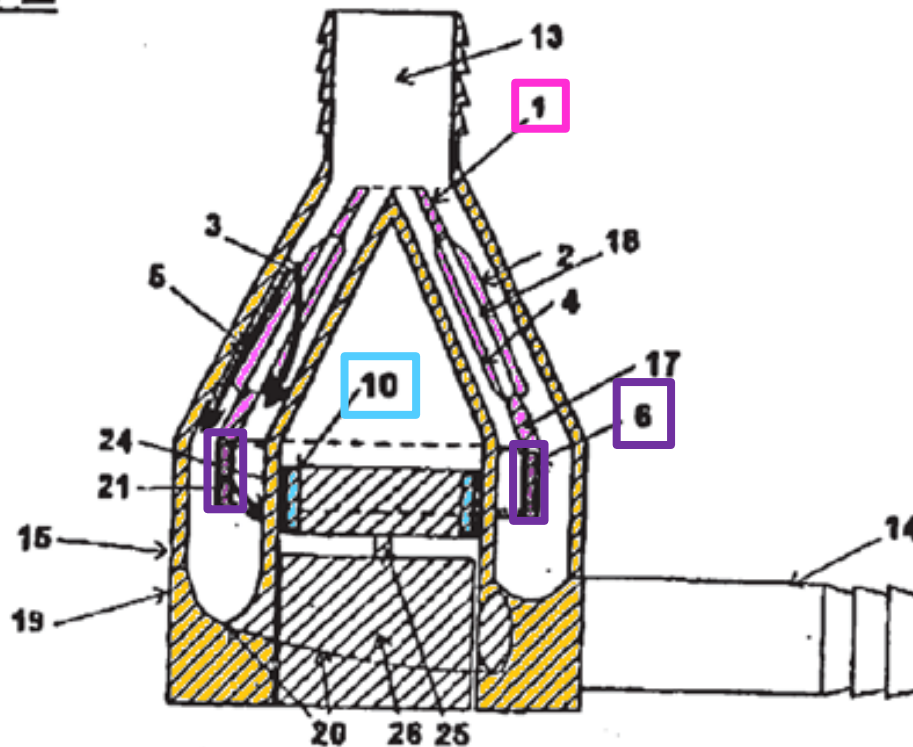
with magnets 10,” discussed above; “the drive can also” “work as shown in FIG. 1 with a **stator 12** [alternative *second magnetic device*]...creating a rotating magnetic field” that “causes the coupling force [to ‘*drive rotation...via a magneto coupling*’]” “with **rotor magnets 6**.” Ex.1005, [0012]. Ex.1003, ¶698.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) is “*positioned to magnetically drive rotation of the magnetically driven rotor*” (“rotor 1”) *via a magneto coupling* (“transfer rotation energy”) *with the first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶¶699-700.

xii. [1K]

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, ¶702. Figure 2 illustrates that “**housing walls**” “*space[] apart and seal[]*” **second magnetic device** from both **rotor** and **rotor magnets 6**:

Fig.
Abb. 2



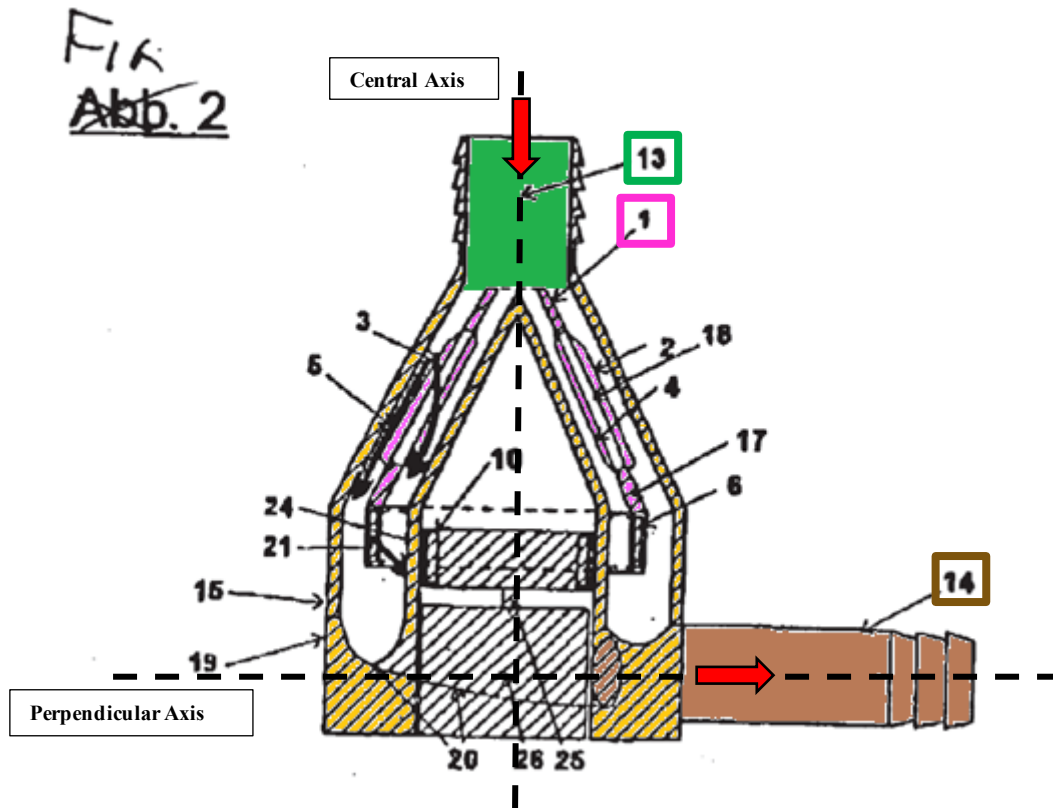
Ex.1005, Fig. 2; *see also* Fig. 1 (showing stator 12); Ex.1003, ¶705.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) “being spaced apart and sealed from both the *magnetically driven rotor* (“rotor 1”) and the *first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶706.

xiii. [1L]

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, ¶708. Figure 2 illustrates that

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



Ex.1005, Fig. 2; Ex.1003, ¶710.

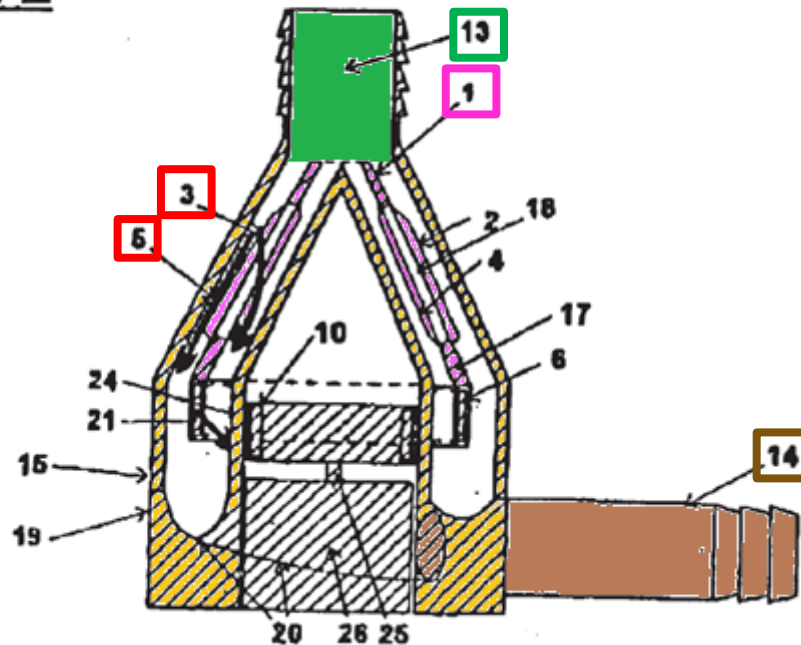
Accordingly, Schima teaches or suggests that “*blood outflow port* (“outlet 14”) positioned radially adjacent the *magnetically driven rotor* (“rotor 1”) such that blood driven by the *magnetically driven rotor* is configured to exit the *surrounding rotor housing* (“pump housing 30”) in a direction substantially perpendicular from the *inflow tube* (“inlet 13”) and the central axis of the *magnetically driven rotor*.”

Ex.1003, ¶711.

xiv. [1M]

As demonstrated in [1J], 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 (“*in response to rotation of the magnetically driven rotor*”) “is used to journal the **rotor**” (“*magneto coupling orients the magnetically driven rotor*”) by “produce[ing] centrifugal flow components 3 and flow components 5” (“*by the blood flowing*”) which are produced “mainly for contact-free journaling and stabilizing of the rotor in the **housing**” (“*the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing*”). Ex.1005, [0010]-[0013]; Ex.1003, ¶715. Figure 2 illustrates the “centering of the...rotor ...by the flow components 5 directed against the housing” (“*by the blood flowing*”):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶717.

Accordingly, Schima teaches or suggests that “the magneto coupling orients the *magnetically driven rotor* (“rotor 1”) so that, in response to rotation of the *magnetically driven rotor*, the *magnetically driven rotor* remains entirely spaced apart from the *surrounding rotor housing* (“pump housing 30”) *by the blood flowing* (“centrifugal flow components 3 and 5”) from the *inflow tube* (“inlet 13”) and to the *blood outflow port* (“outlet 14”).” Ex.1003, ¶718.

xv. [1N]

Schima does expressly disclose this element, however “*connecting an external control unit...for regulating operation*” to Schima’s pump would have been obvious in view of Akamatsu-1999. Ex.1003, ¶719.

As described above 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**):

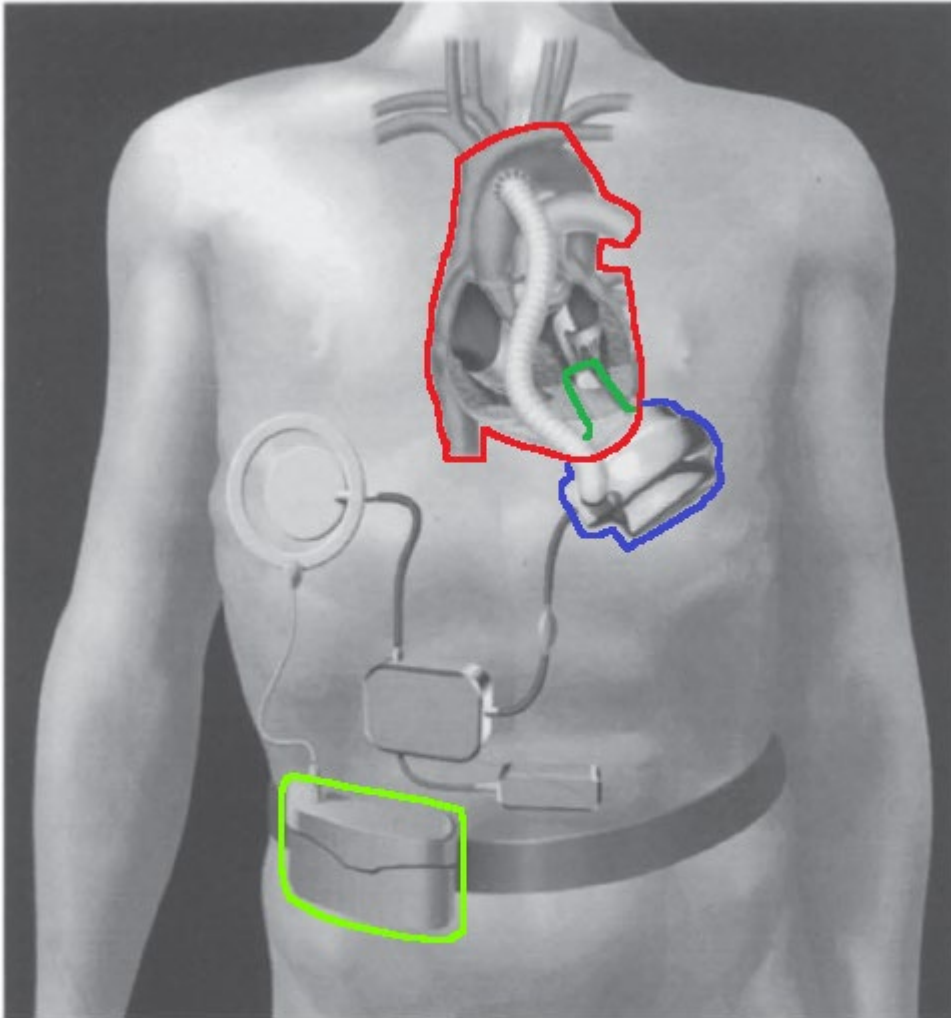


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Supra §VIII.C.1.xv; Ex.1006, 3-4; Ex.1003, ¶720.

As detailed below (*infra* §VIII.D.9), in the combination, Akamatsu-1999’s “controller” would be “connect[ed]...for regulating 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, ¶720.

Accordingly, Schima/Akamatsu-1999 renders obvious “*connecting an external control unit* (“controller”) *to the heart assist pump device* (“pump”) *for regulating operation of the second magnetic device* (“magnets 10” or “stator 12”) *to thereby magnetically drive the rotation of the magnetically driven rotor* (“rotor 1”) *via the magneto coupling with the first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶721.

xvi. [10]

As explained in [1N], Akamatsu-1999’s “controller” is *external* (“*positioned exterior to the body*”), and as explained in [1A], “inlet 13” is *inserted into a ventricle of the heart*, (“*is in the heart*”). Ex.1003, ¶¶723-724

Accordingly, Schima/Akamatsu-1999 renders obvious “*the external control unit* (“controller”) *being positioned exterior to the body while the inflow tube* (“inlet 13”) *of the heart assist pump device* (“pump”) *is in the heart*.” Ex.1003, ¶¶726-727; *see also* ¶¶628-801.

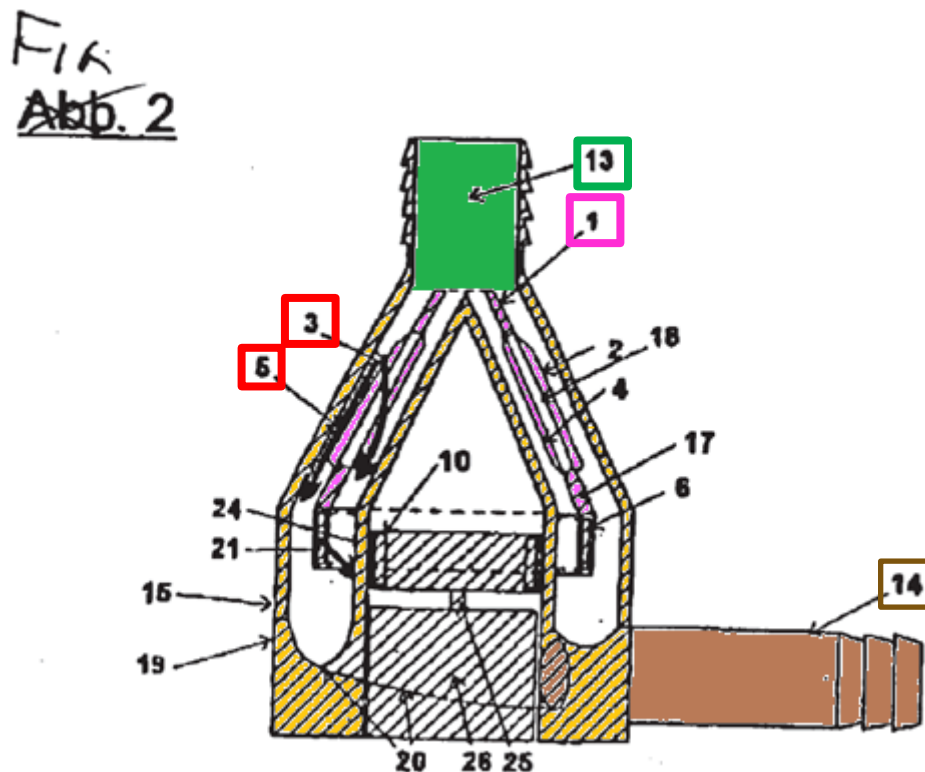
2. Claims 2, 3, and 4

i. [2]

Schima further discloses that “[t]he rotor 1 has as flow surfaces 2 and 4 vanes” (“*guide surfaces*”) “that produce centrifugal flow components 3 and flow

components 5 directed against the housing” (“*produce centrifugal flow components*”). Ex.1005, [0012], [0010], Claim 1; Ex.1003, ¶730.

As Mr. Crosby explains, a POSITA would understand the “flow surfaces 2 and 4 vanes” are “*guide surfaces of the magnetically driven rotor*” as recited in Claim 2, that “*produce centrifugal flow components 3 and flow components 5 directed against the housing.*” Ex.1005, [0012]. Ex.1003, ¶732. Figure 2 illustrates the *centrifugal flow components 3 and 5 (red)* produced “*in response to the rotation of the*” **rotor** and directed against the **housing** to create a “contact free journaling and stabilizing of the rotor in the housing”:



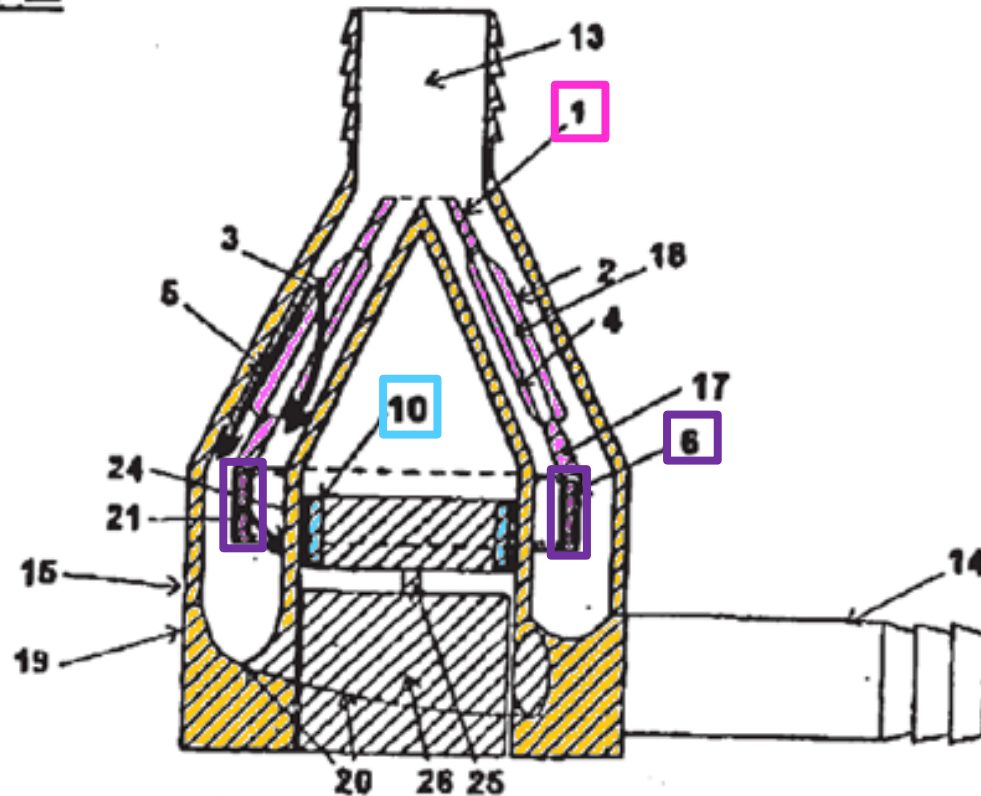
Ex.1005, Fig. 2, [0012]; Ex.1003, ¶733.

Accordingly, Schima teaches or suggests that “*in response to the rotation of the magnetically driven rotor* (“rotor 1”) *via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components (“centrifugal flow components 3”).*” Ex.1003, ¶734.

ii. [3A]

As demonstrated in [1K], Schima discloses that the *second magnetic device* resides “inside the housing lower part 19” while the “rotor rotates in...a hollow conical upper part” of “pump housing 30.” Ex.1005, [0012]. Figure 2 illustrates *at least one sealing wall* between magnets 10 and the rotor magnets 6:

Fig.
Abb. 2

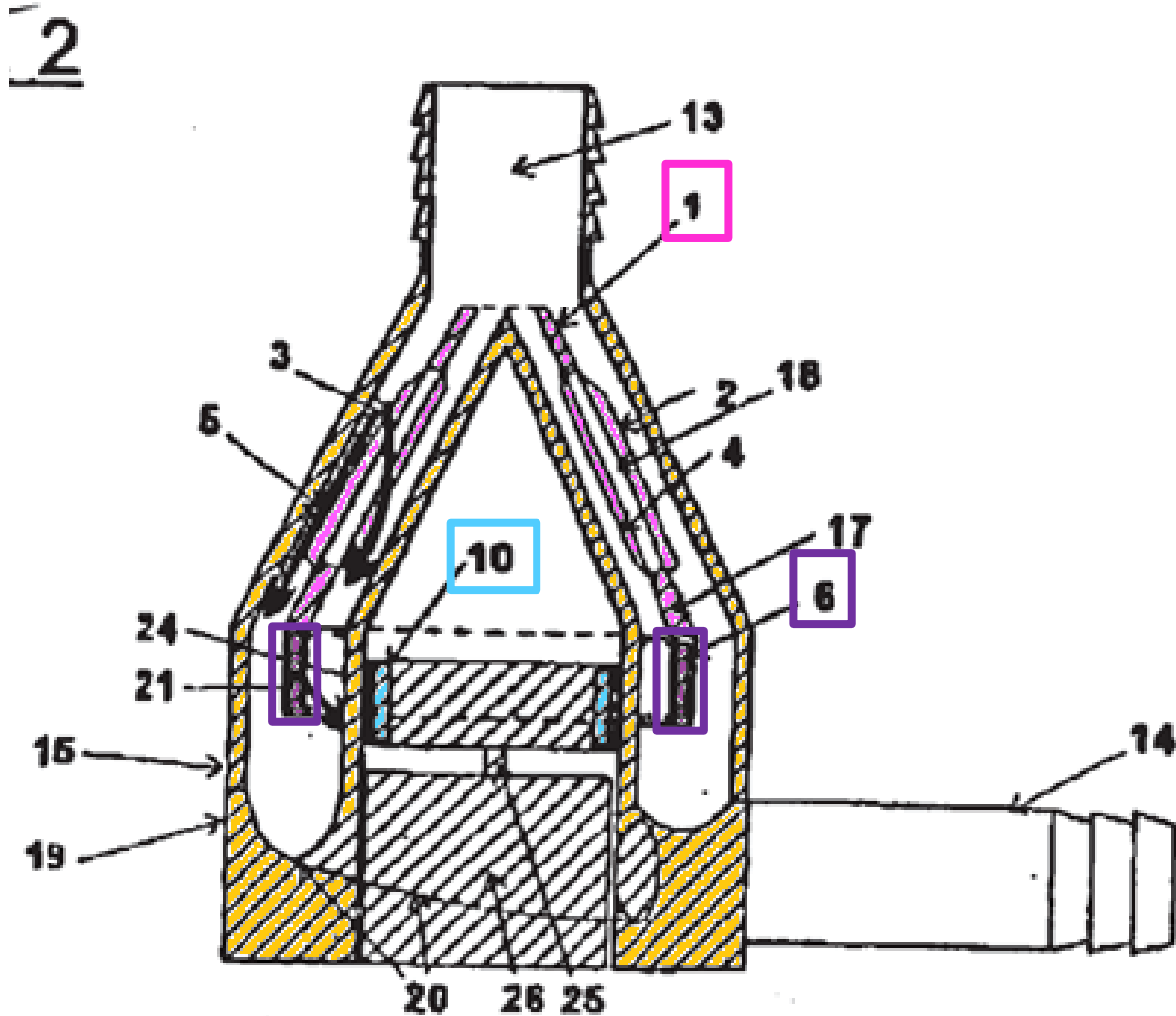


Ex.1005, Fig. 2; *see also* Fig. 1 (sealing “stator 12”); Ex.1003, ¶738.

Accordingly, Schima teaches or suggests that “the *surrounding rotor housing* (“pump housing 30”) *comprises at least one sealing wall between the first magnetic device* (“rotor magnets 6”) *and the second magnetic device* (“magnets 10” or “stator 12”).” Ex.1003, ¶739.

iii. [3B]

As explained in [1H]-[1J], Schima discloses “**rotor magnets 6**” at the base of (“at a position axially adjacent to”) the **rotor**, while the **second magnetic device**, resides “inside the **housing** lower part 19” (Ex.1005, [0012]-[0013]; Ex.1003, ¶741):



Ex.1005, Fig. 2; *see also* Fig. 1 (“stator 12”); Ex.1003, ¶742.

Accordingly, Schima teaches or suggests that “*the first magnetic device* (“rotor magnets 6”) *is positioned between the second magnetic device* (“magnets 10”; “stator 12”) *and the magnetically driven rotor* (“rotor 1”).” Ex.1003, ¶743.

iv. [4]

For the reasons discussed in [1F], 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, ¶746.

3. Claim 5

As demonstrated in [1N], it would have been obvious to combine Schima’s pump with Akamatsu-1999’s **external control unit**,...to regulat[e] operation of the **second magnetic device**. As discussed in Ground 3 ([5]), Akamatsu-1999 discloses a “**controller**” to regulate the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” Ex.1006, 3-4; Ex.1003, ¶750.

For the same reasons as [1N] and Ground 3, Schima/Akamatsu-1999 render obvious that “*the external control unit* (“controller”) *controls the second magnetic device* (“magnets 10”; “stator 12”) *in response to measurement values indicative of cardiac output of the heart*.” Ex.1003, ¶754.

4. Claim 6

As demonstrated in [1M], Schima discloses “contact-free” (“*by a gap*”) “journaling and stabilizing of the **rotor** in the **housing**,” which discloses this limitation. Ex.1005, [0010]; Ex.1003, ¶757.

Accordingly, Schima/Akamatsu-1999 renders obvious that “*both the magnetically driven rotor* (“rotor 1”) *and first magnetic device* (“rotor magnets 6”) *are entirely spaced apart from the surrounding rotor housing* (“pump housing 30”) *by a gap* (“contact-free journaling”) *during rotation of the magnetically driven rotor.*” Ex.1003, ¶758.

5. Claim 7

As explained for [1N], it would have been obvious to combine Schima’s pump with Akamatsu-1999’s **external control unit**,...to regulat[e] operation of the **second magnetic device**. As demonstrated in Ground 3, Akamatsu-1999 discloses a “**controller**” and “position sensors” (“*one or more sensors*”) that “*provid[e] feedback signals*” to the “**controller**.” Ex.1006, 3-4; Ex.1003, ¶¶762-763.

For the same reasons discussed in [1N] and Ground 3, Schima/Akamatsu-1999 renders obvious “*providing feedback signals to the external control unit* (“controller”) *from one or more sensors* (“position sensors”).” Ex.1003, ¶764.

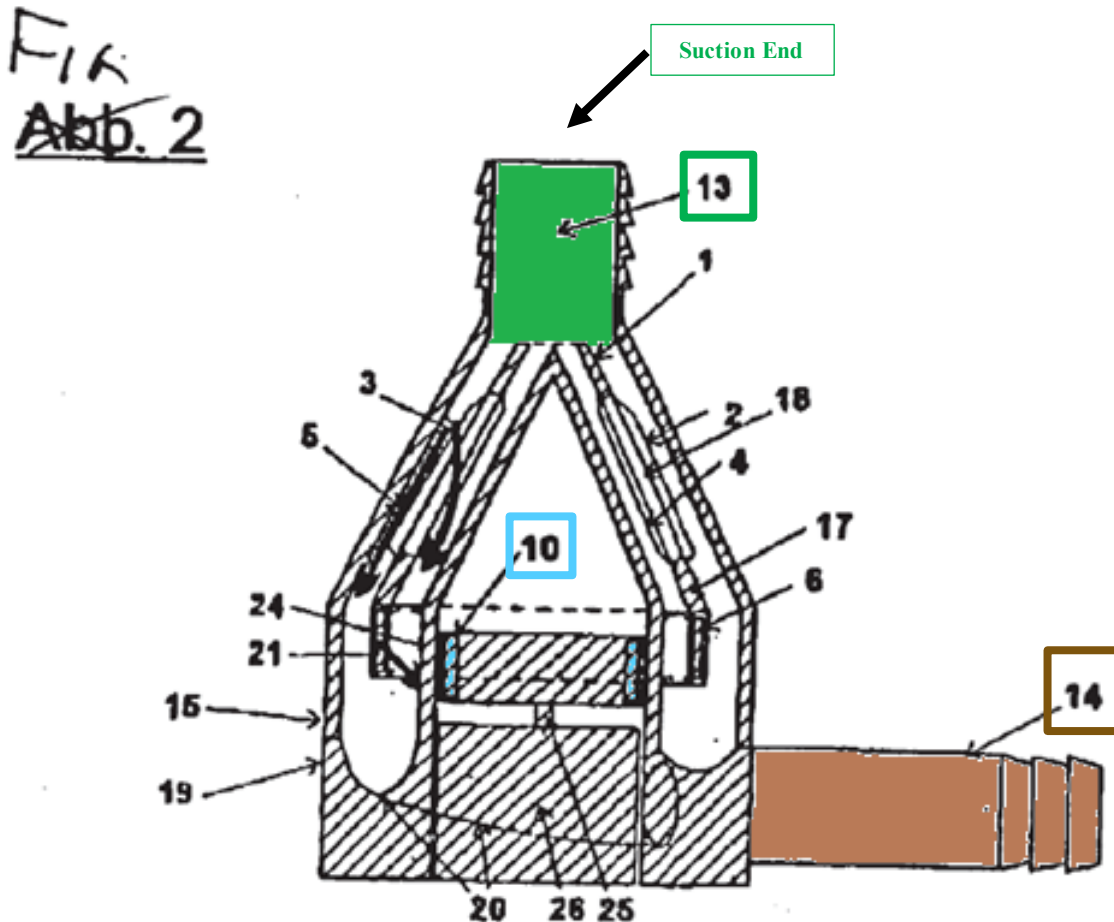
6. Claim 10

As explained in [1N], it would have been obvious to combine Schima's pump with Akamatsu-1999's *external control unit*,...to regulat[e] operation of the *second magnetic device*. As demonstrated in Ground 3, Akamatsu-1999 discloses a “*controller*” to regulate the “*motor*” so that “[t]he pump was operated at a fixed rotational speed” (“*a fixed control value*”). Ex.1006, 3-4; Ex.1003, ¶¶767-768.

Accordingly, Schima/Akamatsu-1999 renders obvious that “*the external control unit* (“controller”) is configured to regulate operation of the *second magnetic device* (“magnets 10”; “stator 12”) based on a fixed control value.” Ex.1003, ¶769.

7. Claim 12

As demonstrated in [1A] and [1L], *the suction end of the “inlet” is inserted 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, ¶772. 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, ¶772.

Accordingly, Schima/Akamatsu-1999 renders obvious that “the *second magnetic device* (“magnets 10” or “stator 12”) is *positioned closer* to the **blood outflow port** (“outlet 14”) than the *second magnetic device* (“magnets 10” or “stator

12”) *is positioned relative to the suction end of the inflow tube* (“inlet 13”).” Ex.1003, ¶773.

8. Claim 13

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, ¶¶777-778.

9. 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.9.

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.9.b. For implantation of Schima/Akamatsu-1999, Schima’s “inlet 13” would be “inserted into the left ventricle” as taught by Akamatsu-1999. Ex.1003, §X.D.9.a.

Akamatsu-1999 and Schima are analogous art to the 356 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, ¶¶781, 791. *Second*, Akamatsu-1999 and Schima are reasonably pertinent to a problem described by the 356 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:27-32; Ex.1006, 8; Ex.1005, [0002], [0009]. Ex.1003, ¶¶782, 791.

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, ¶¶783-785 (discussing implantation), 792-797 (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, ¶787. Schima is silent as to pump implantation and control. Ex.1003, ¶789. 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, ¶798.

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, ¶¶798-799; 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, ¶788; 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 in this Petition are not cumulative or redundant to the prosecution of the 356 Patent as Wampler-169, Bourque-2001 (or Bourque-2001/Wampler-169), Akamatsu-1999, Schima⁶ (or Schima/Akamatsu-1999), were not cited or considered by the Examiner during prosecution of the 356 Patent. The Examiner also did not have Mr. Crosby's detailed expert testimony and the evidence of record.

⁶ A German-language version of Schima was cited in an IDS by the applicant during prosecution of the 356 Patent but was not relied on by the Examiner.

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 statistics⁷ 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.

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 356 Patent, is directed at the same problem, and proposes the same solutions as the 356 Patent using nearly identical architecture.

⁷ <https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2024/06/30-3>.

X. CONCLUSION

Claims 1-7, 10, and 12-13 of the 356 Patent are unpatentable for the reasons demonstrated above.

Dated: November 5, 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 13,981 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.

Dated: November 5, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on November 5, 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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