

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00114
U.S. Patent No. 11,572,879

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,572,879**

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,572,879
1002	U.S. Patent No. 11,572,879 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 11 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 D-1 (Bourque-2001) of Supplemental Invalidity Contentions
1027	U.S. Patent No. 5,324,177
1028	Allaire, et al., <i>Prototype Continuous Flow Ventricular Assist Device</i> , J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690
1029	Kung and Hart, <i>Design Considerations for Bearingless Rotary Pumps</i> , J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis

CLAIM INDEX

Element	Claim language
[1PRE]	A system for assisting blood circulation of a heart, the system comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path aligned with a central axis;
[1B]	a magnetically driven rotor aligned with the central axis and
[1C]	that is rotatable about the central axis within a surrounding rotor housing to drive blood flowing from the inflow tube toward the magnetically driven rotor,
[1D]	the magnetically driven rotor being rigidly coupled and axially adjacent to a first magnetic device within the surrounding rotor housing;
[1E]	a second magnetic device axially aligned with the central axis
[1F]	and positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1G]	while both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap sized for passage of the blood during rotation of the magnetically driven rotor; and
[1H]	a blood outflow port positioned radially adjacent the magnetically driven rotor such that the blood driven by the magnetically driven rotor exits the surrounding rotor housing in a direction substantially perpendicular to the central axis,
[1I]	wherein the magneto coupling orients the magnetically driven rotor so that the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1J]	an external control unit configured to regulate operation of the second magnetic device, the external control unit being

	positionable exterior to a body when the heart assist pump device is delivered to the heart, wherein the external control unit is connectable to the heart assist pump device for operating the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.
[2]	The system of claim 1, wherein the magnetically driven rotor comprises: a guide surface to produce centrifugal flow components.
[4]	The system of claim 1, wherein the heart assist pump device further comprises a sealing wall positioned between the second magnetic device and the magnetically driven rotor.
[5]	The system of claim 4, wherein the sealing wall at least partially defines the gap sized for passage of the blood.
[7]	The system of claim 1, wherein the first magnetic device is positioned within a first chamber, the second magnetic device is positioned within a second chamber, and the first chamber is sealed from the second chamber.
[8]	The system of claim 7, wherein the heart assist pump device further comprises a wall separating the first chamber from the second chamber.
[11PRE]	A system for assisting blood circulation of a heart, the system comprising:
[11A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[11B]	one or more walls at least partially defining a chamber to receive blood from the inflow tube;
[11C]	a magnetically driven rotor axially aligned with the inflow axis
[11D]	and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis

[11E]	the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube;
[11F]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[11G]	and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device,
[11H]	the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device; and
[11I]	a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis
[11J]	wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor; and
[11K]	an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.
[12]	The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.
[14]	The system of claim 11, wherein the one or more walls and the magnetically driven rotor define a gap separating the magnetically driven rotor from the one or more walls, the gap configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor.
[15]	The system of claim 14, wherein the gap surrounds the magnetically driven rotor.

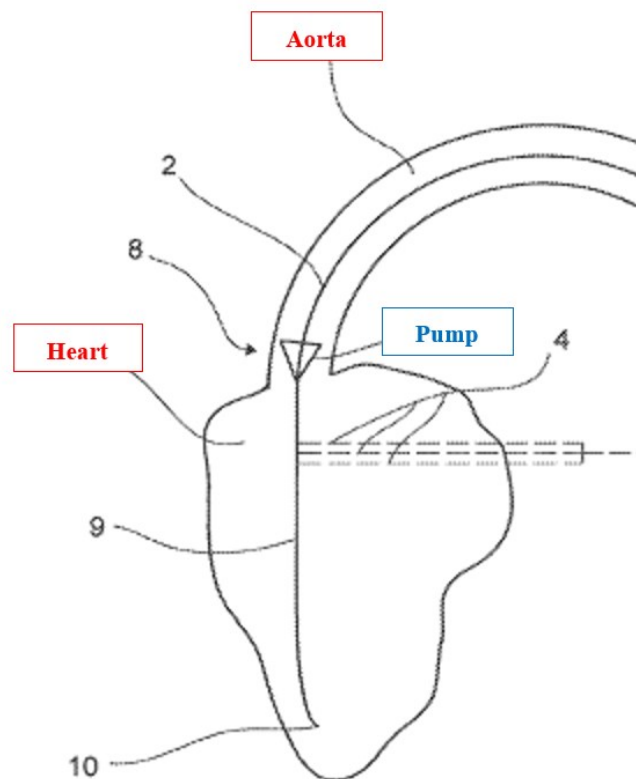
[16]	The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.
[18]	The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[19]	The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.
[20]	The system of claim 11, wherein the external control unit is configured to regulate operation of the second magnetic device based on a defined cardiac output.

I. INTRODUCTION

Abbott Laboratories (“Petitioner”) petitions for *Inter Partes* Review and cancellation of claims 1-2, 4-5, 7-8, 11-12, 14-16, 18-20 (“the Challenged Claims”) of U.S. Patent No. 11,572,879 (the “879 Patent” (Ex.1001)), assigned to Patent Owner, Miracor Medical SA (“Miracor” or “PO”).

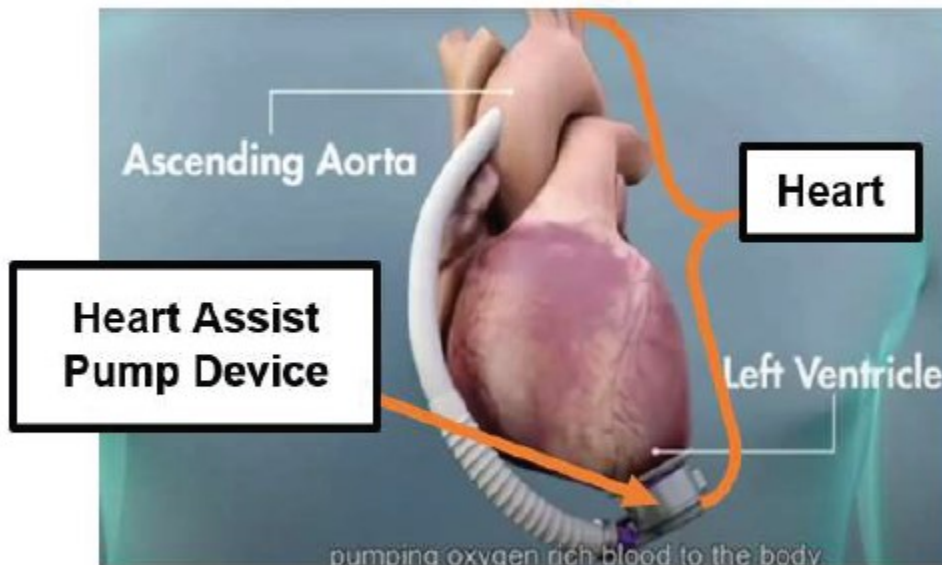
II. SUMMARY OF THE ARGUMENT

The 879 Patent discloses assisting the heart using an “intravasal” “catheter” blood pump placed **inside** a blood vessel like the aorta:



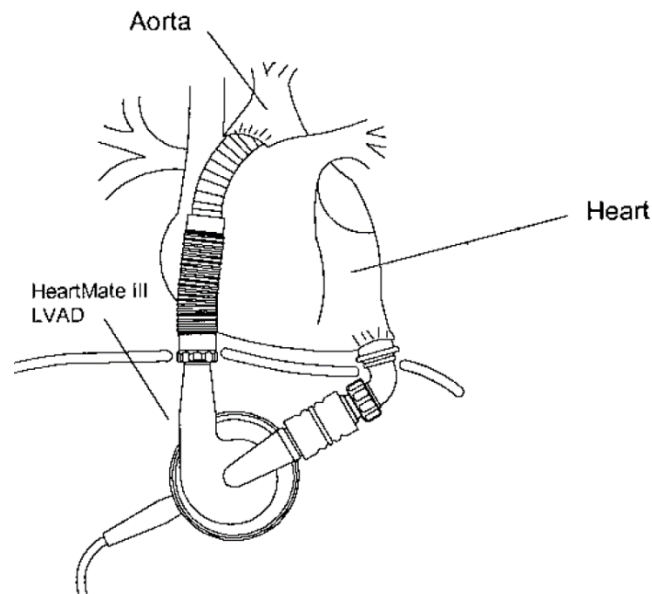
Ex.1001, Fig 1 (annotated), 2:29-38 (“the catheter according to the invention”); 3:48-57 (“according to the invention...an intravasal...catheter.”).

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, 3.

PO filed for the 879 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 879 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 MattersOffice Proceedings

Petitioner has filed a petition for *inter partes* review against the following related patents:

- U.S. Pat. No. 11,351,356 (see *Abbott Laboratories v. Miracor Medical SA*, IPR2025-00096 (Nov. 5, 2024);
- U.S. Pat. No. 11,351,357 (see *Abbott Laboratories v. Miracor Medical SA*, IPR2025-00112 (Nov. 26, 2024);
- U.S. Pat. No. 11,376,415 (see *Abbott Laboratories v. Miracor Medical SA*, IPR2025-00113 (Nov. 26, 2024);
- U.S. Pat. No. 11,674,517 (see *Abbott Laboratories v. Miracor Medical SA*, IPR2025-00115 (Nov. 26, 2024).

Petitioner will also be filing petitions for *inter partes* review against related U.S. Patent No. 11,754,077.

Litigation matters.

The 879 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 879 Patent is a continuation of and claims priority to U.S. application Ser. No. 16/282,948, filed on Feb. 22, 2019 (now

U.S. Pat. No. 11,123,540), which is a continuation of U.S. application Ser. No. 14/454,965, filed on Aug. 8, 2014 (now U.S. Pat. No. 10,251,984), which is a continuation of and claims priority to U.S. application Ser. No. 13/555,318, filed on Jul. 23, 2012 (now U.S. Pat. No. 8,801,590), which is a divisional of and claims priority to U.S. application Ser. No. 12/449,632, filed on Aug. 18, 2009 (now U.S. Pat. No. 8,255,050), which is the U.S. national phase of International Application PCT/IB2008/000421, filed on Feb. 27, 2008, which designated the U.S. and claims benefit of AT A 306/2007, filed Feb. 27, 2007.

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 879 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	1-2, 4-5, 7-8, 15, 11-12, 14, 16, 18-19, and 20	Wampler-169 (Ex.1008)
2	§103		Bourque-2001 (Ex.1007) and Wampler-169
3	§103		Akamatsu-1999 (Ex.1006)
4	§103		Schima (Ex.1005) and Akamatsu-1999

V. THE 879 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 879 Patent

The 879 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, 3:13-24.

VI. CLAIM CONSTRUCTION

PO's apparent Parallel Litigation constructions differ from the plain and ordinary meanings in the context of the 879 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 879 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, 2:28-52, 4:44-64, 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, 7; Ex.1003, ¶¶84-87.

B. By the Blood

Pump rotors can be suspended in at least two different ways—using hydrodynamic or magnetic bearings. Ex.1003, ¶¶57-60. The 879 patent explains that its rotor suspension results from “[t]he rotor produc[ing] flow...directed against the housing” causing “non-contact mounting and stabilizing 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—“*both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor*”—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*—meaningless by encompassing a magnetic bearing. Ex.1003, ¶95 (analyzing Ex.1019, 6).

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, 8 (showing the magnetic bearing in Abbott’s HeartMate 3 (left) versus a hydrodynamic bearing in another pump (right)).

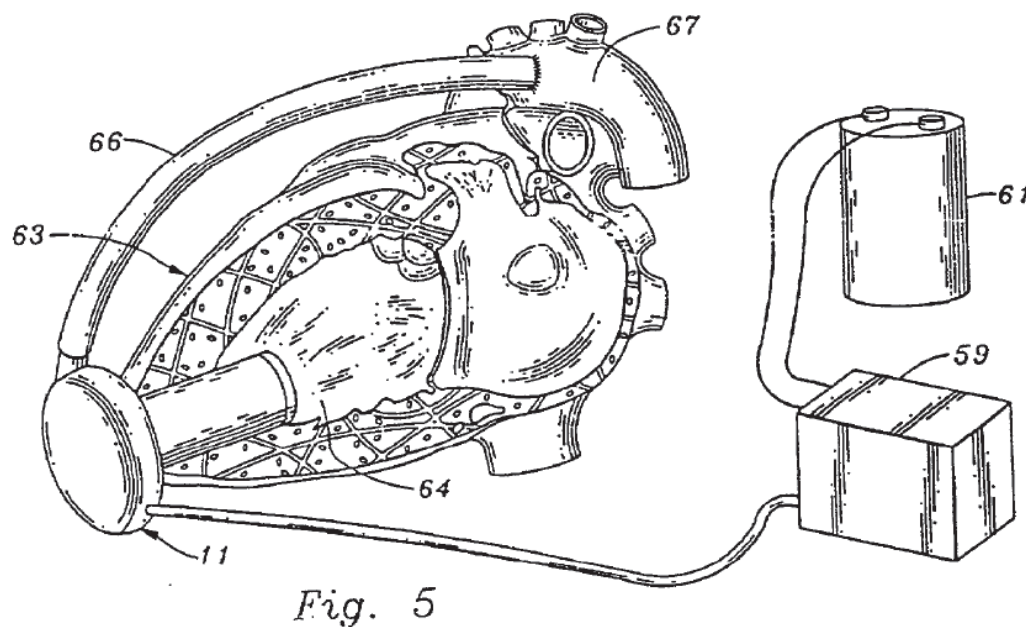
LVADs		Drive-type	
		Magneto coupling	Electromagnetic
Bearing-type	Hydrodynamic	<u>Schima</u>	<u>Wampler-169</u>
	Magnetic	<u>Akamatsu-1999</u>	<u>Bourque-2001</u>

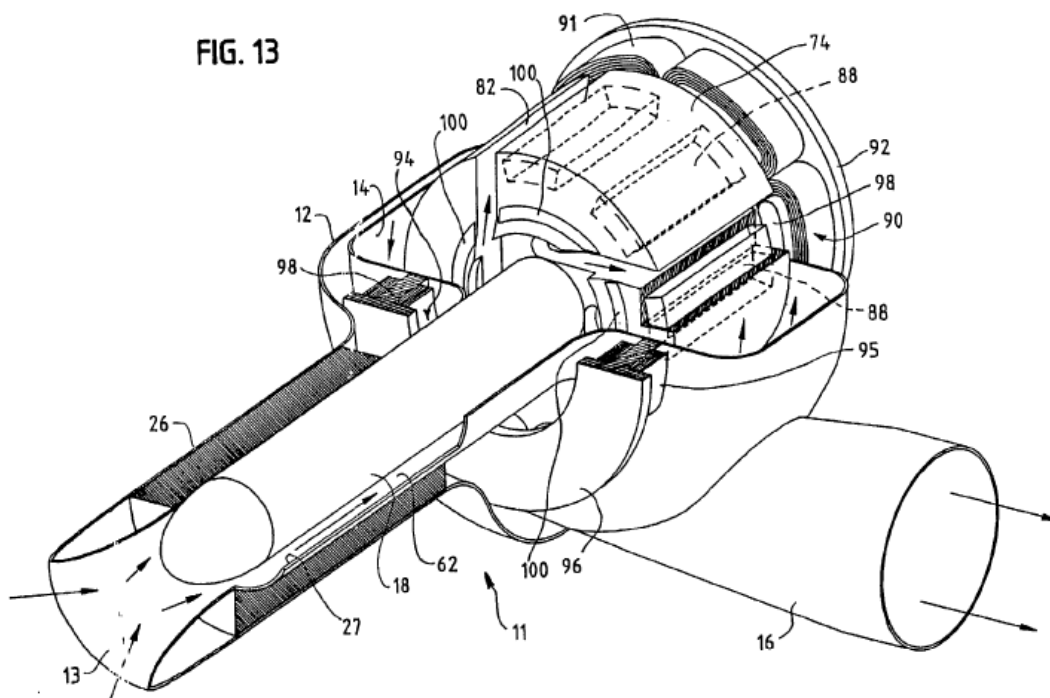
Ex.1003, ¶¶146-148.

A. Wampler-169

U.S. Pub. No. 2002/0102169A1 ("Wampler-169"), published **August 1, 2002**, is prior art to the 879 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, Bourque-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 879 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 879 Patent at least under 35 U.S.C. §102(b).

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

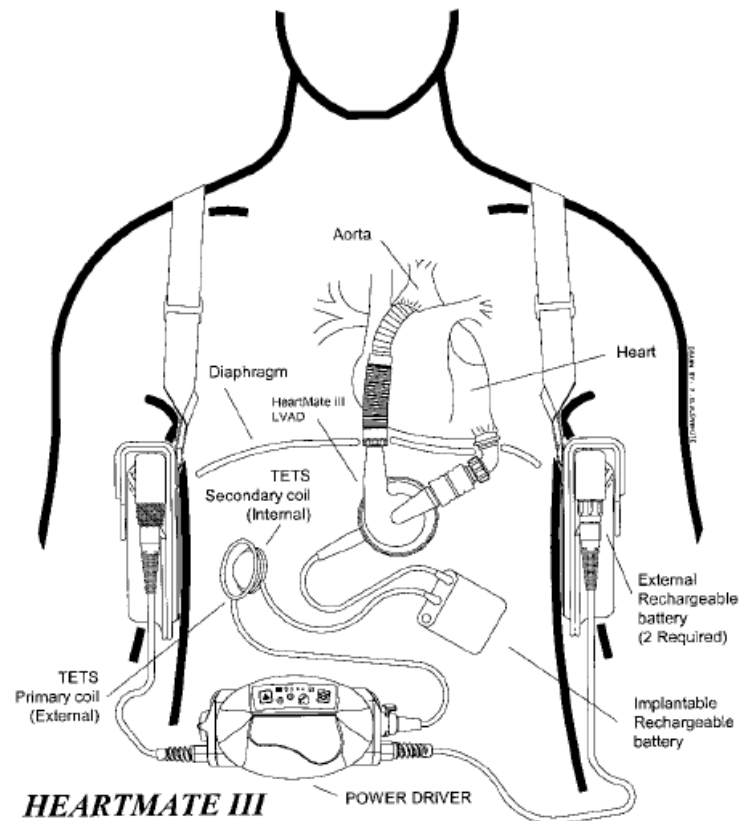


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

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 879 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 879 Patent at least under 35 U.S.C. §102(b).

The Akamatsu-1999 pump is shown below:

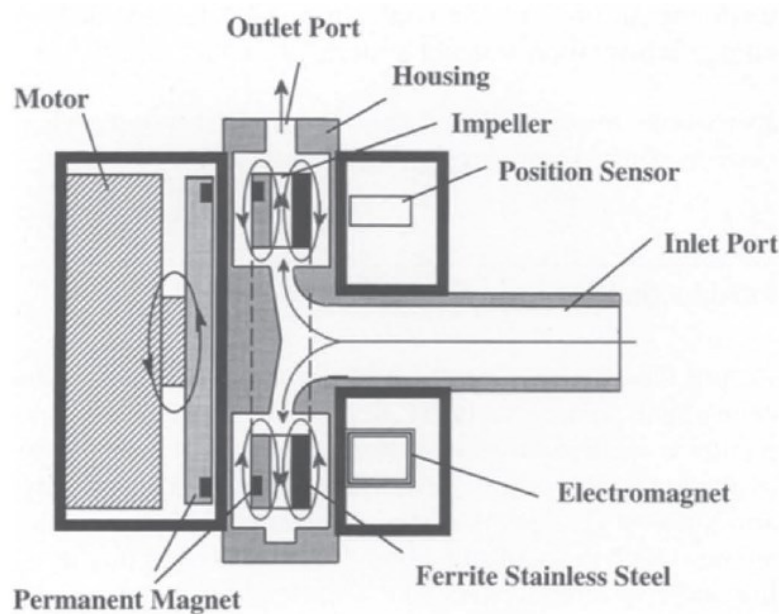


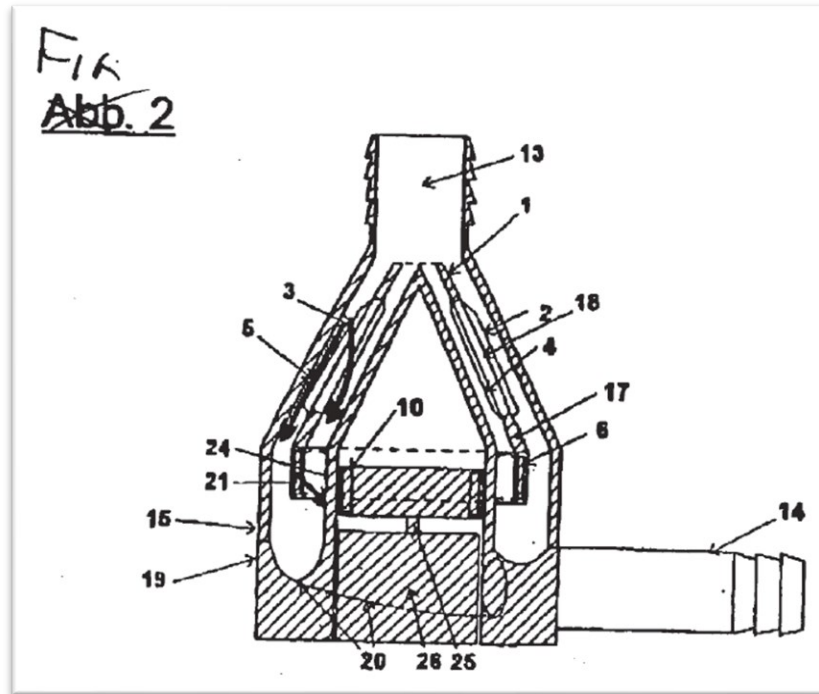
Fig. 2. Schematic cross section of the MSCP

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 879 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 879 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. THE CHALLENGED CLAIMS ARE UNPATENTABLE

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

1. Claim 11

i. [11PRE]³

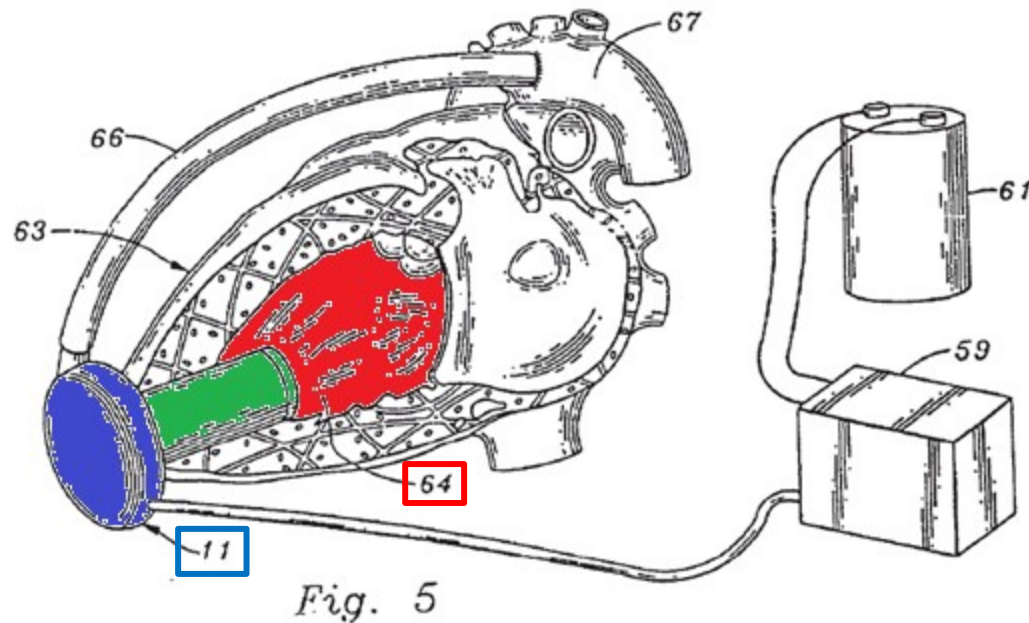
Wampler-169 discloses “implantation in humans” of “a left ventricular assist device (‘LVAD’)” “blood pump” “for chronic use” in patients with “heart failure” who “could benefit from cardiac transplantation,” but cannot receive a “donor heart.” Ex.1008, [0002]-[0003]. Ex.1003, ¶150.

Accordingly, Wampler-169 discloses “*a system for assisting blood circulation of a heart*” (“LVAD” for “heart failure”).” Ex.1003, ¶151.

ii. [11A]

Wampler-169 discloses that “**pump 11**” (“*a heart assist pump device*”) is “implanted” so that “**inlet tube [13] serves as the inflow cannula** and is placed into the apex of the **left ventricle 64**” (“*an inflow tube defining a blood inflow path ...and being insertable into a left ventricle*”) while the remainder of the “compact and disc-shaped [pump] fit[s] well between the apex of the heart and the adjacent diaphragm” (Ex.1008, [0075]-[0076]):

³ The claims of the 879 Patent are included in the Claim Index, *infra* pp. ix-xi.

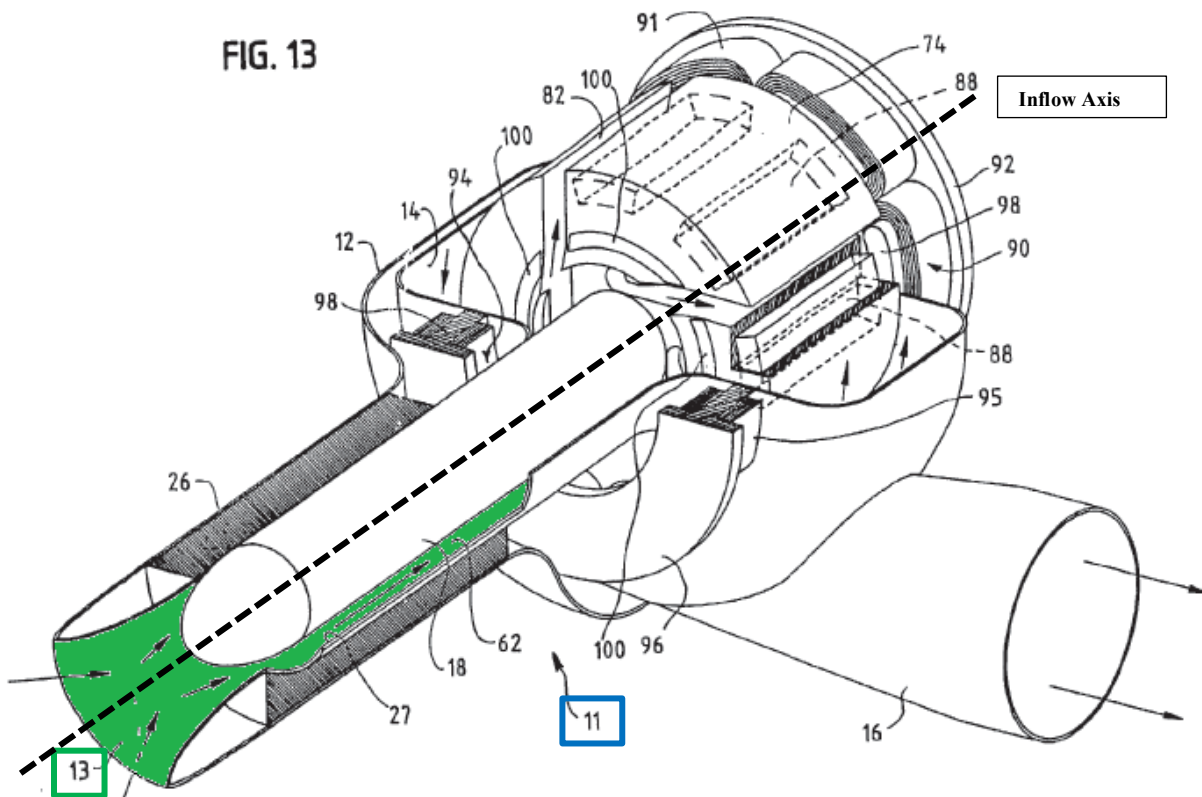


Ex.1008, Fig. 5 (annotated)⁴; *see also* Fig. 13 (showing blood suction through inlet tube, Ex.1003, ¶159)⁵; Ex.1003, ¶¶154-156.

Wampler-169 further discloses “axial inflow...of the blood” (“*an inflow axis*”) (Ex.1008, [0075]-[0076]; Ex.1003, ¶157) “to flow through **inlet tube 13** in the direction of the arrows 62” (Ex.1008, [0074]) towards “impeller 74,” which “rotat[es] about a[] longitudinal axis” (“*inflow axis*”) (Ex.1008, [0081]):

⁴ All figures annotated unless otherwise specified.

⁵ “Referring to FIGS. 11, 11a, 12, 13 and 14, the blood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGS. 1-8.” Ex.1008, [0080].



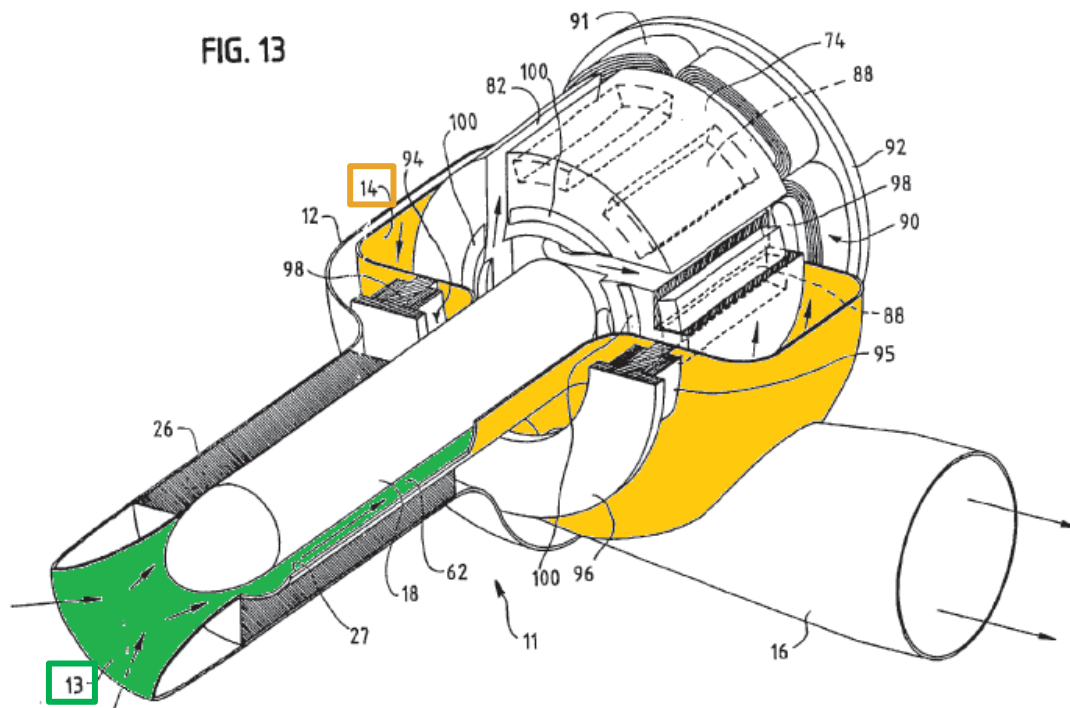
Ex.1008, Fig. 13; *see also* [0082] (explaining that the “longitudinal axis” of Fig. 13 is the same as the longitudinal axis of Figs. 1-8). Ex.1003, ¶159.

Accordingly, Wampler-169 discloses “a *heart assist pump device* (“pump 11”) deliverable to the *heart* and comprising: an *inflow tube* (“inlet tube 13”) defining a blood inflow path along an *inflow axis* (“axial inflow” along “longitudinal axis”) and being insertable into a *left ventricle* (“placed into the apex of the left ventricle 64”)” Ex.1003, ¶160.

iii. [11B]

Wampler-169 discloses a “housing” of the “rotary blood pump” that includes a “*casing 14*” (“a chamber”) with an “interior of the *casing*” (“one or more walls”)

(Ex.1008, [0074]) “enclosing the impeller” (Ex.1008, [0012]) and an “outer surface of impeller casing 14” (Ex.1008, [0070]) (“*one or more walls*”) for mounting the stator (*see* [11G]). Thus, “[b]lood ... flow[s] through **inlet tube 13** [*inflow tube*] in the direction of arrows 62 ... to the interior of casing 14” (“*to receive blood from the inflow tube*”) (Ex.1008, [0074]):



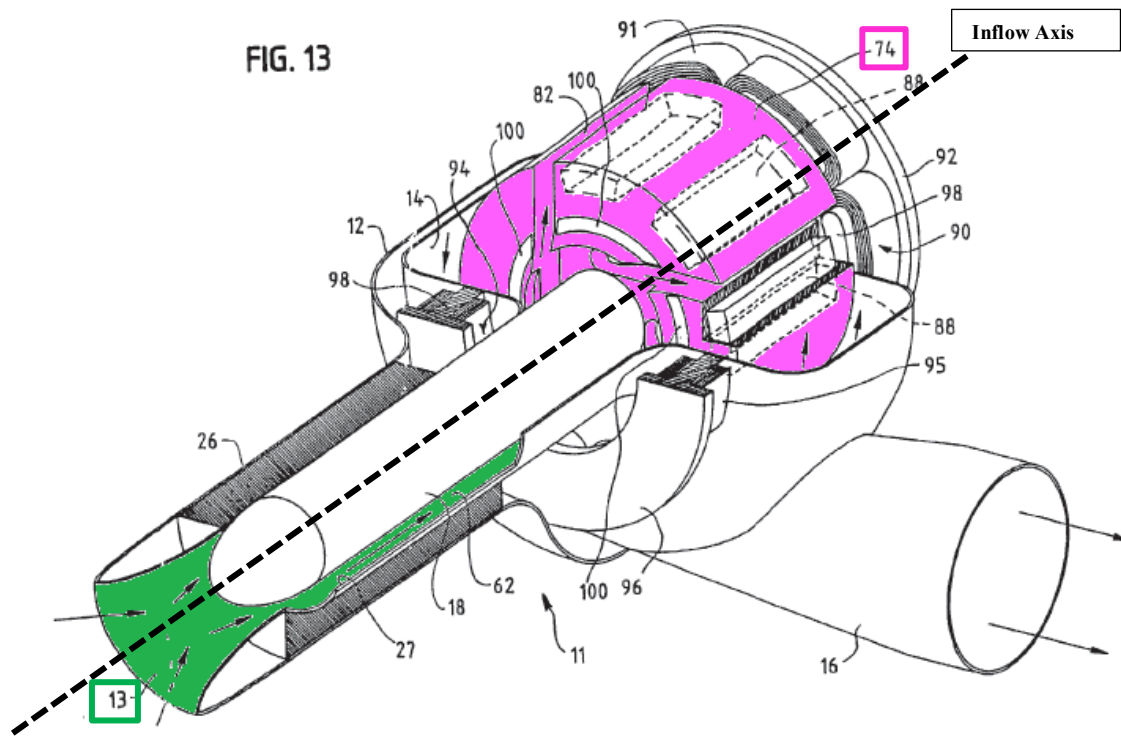
Ex.1008, Fig. 13 (annotated). Ex.1003, ¶164.

Accordingly, Wampler-169 discloses “*one or more walls* (“interior” and “outer surface”) *at least partially defining a chamber* (“casing 14”) *to receive blood from the inflow tube* (“inlet tube 13”).” Ex.1003, ¶165.

iv. *[11C]*

Wampler-169 discloses that the **pump's** “[t]orque drive is imparted to the **impeller 74** by magnetic interaction [*a magnetically driven rotor*] between...permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing.” Ex.1008, [0018]; *see also* [0070]-[0072] (describing magnets “effective to drive...the rotor.”); Ex.1003, ¶¶170-171. Mr. Crosby explains an “impeller” is a commonly used type of rotor used in a centrifugal pump. Ex.1003, ¶168 (citing Ex.1008, [0012], [0051], [0065]).

Wampler-169 further discloses that rotor 17, which includes **impeller 74**, “is mounted for rotation about a[] longitudinal axis” (“*inflow axis*”) Ex.1008, [0081], Ex.1003, ¶174. The “axial inflow...of the pump” (Ex.1008, [0075]-[0076]; Ex.1003, ¶175) allows for “blood to flow through **inlet tube 13** in the direction of [the] arrows 62” towards “**impeller 74**.” Ex.1008, [0074]. Mr. Crosby explains that for components to be “*axially aligned*,” they are configured to be colinear, or in the same line (or “axis”) in space. Ex.1003, ¶174. The “**impeller 74**” and the “**inlet tube 13**” are therefore *axially aligned* on the “longitudinal axis” (“*inflow axis*”) of the pump in the direction of arrows 62 (Ex.1008, [0074], [0081]):



Ex.1008, Fig. 13; Ex.1003, ¶174.

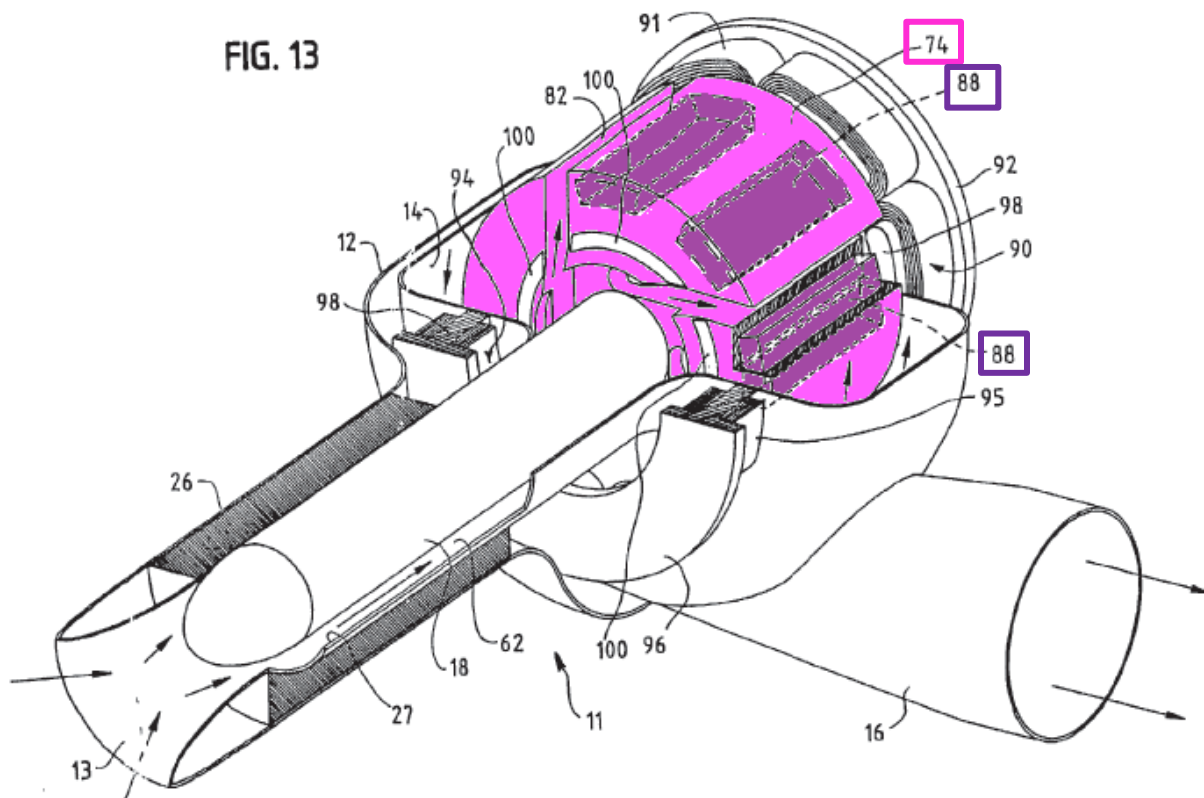
Accordingly, Wampler-169 discloses “a *magnetically driven rotor* (“impeller 74”) *axially aligned with the inflow axis* (“axial inflow” along “longitudinal axis”).”

Ex.1003, ¶176.

v. [11D]

Wampler-169 discloses that “torque drive is imparted to...*permanent magnetic segments [88]*” (“a *first magnetic device*”) “imbedded within [the]

impeller [74] (“*rigidly coupled*”).⁶ Ex.1008, [0018]; Ex.1003, ¶178. 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]):



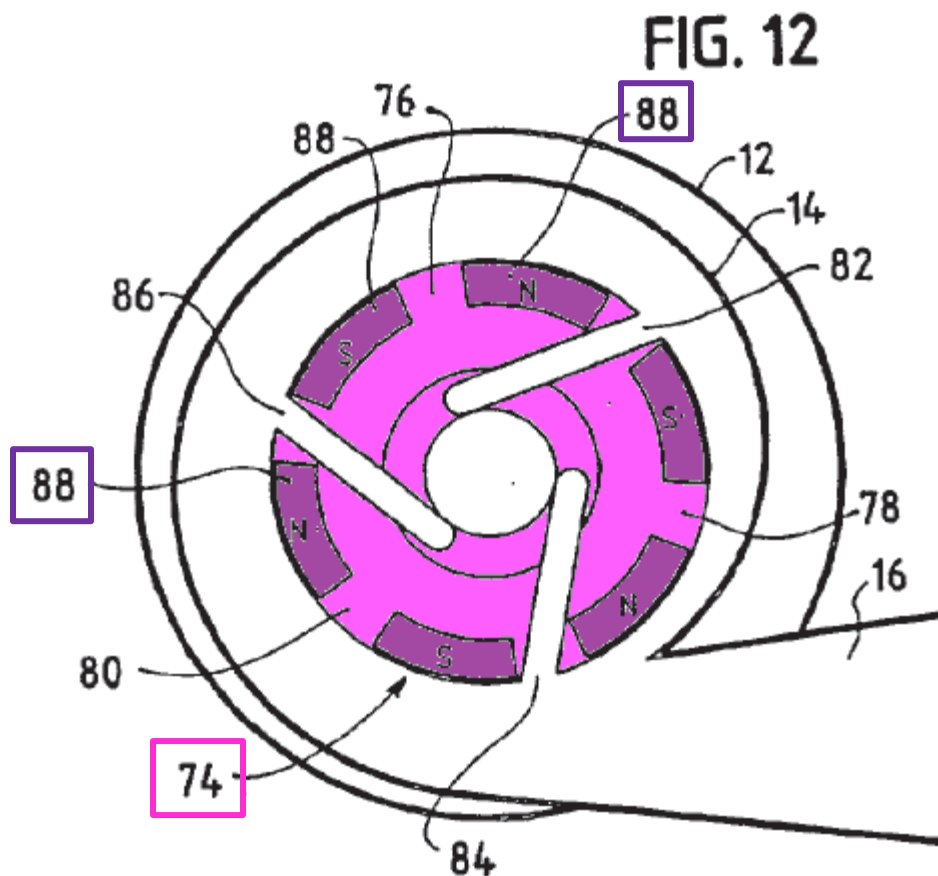
Ex.1008, Fig. 13. Ex.1003, ¶178. As will be discussed below, “segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56,” “to produce an electromagnetic field.” Ex.1008, [0070], [0072]; *see infra*

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

element [11F]. “This field is concentrated by pole pieces 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion.” Ex.1008, [0072]. *see also* Ex.1003, ¶179.⁷

Figure 12 of Wampler-169 is a cross-sectional view of the **impeller**’s **magnetic pieces** which “have alternating orientations in their polarities:”

⁷ Note, the interaction between the “magnetic segments 54” / “magnetic pieces 88” and the “motor stator 56” / “motor stators 90 and 94” to drive rotation of the impeller 74, is the same between the embodiment described in FIGs. 1-8 and the embodiment described in FIGs. 11-14. Ex.1003, ¶178.

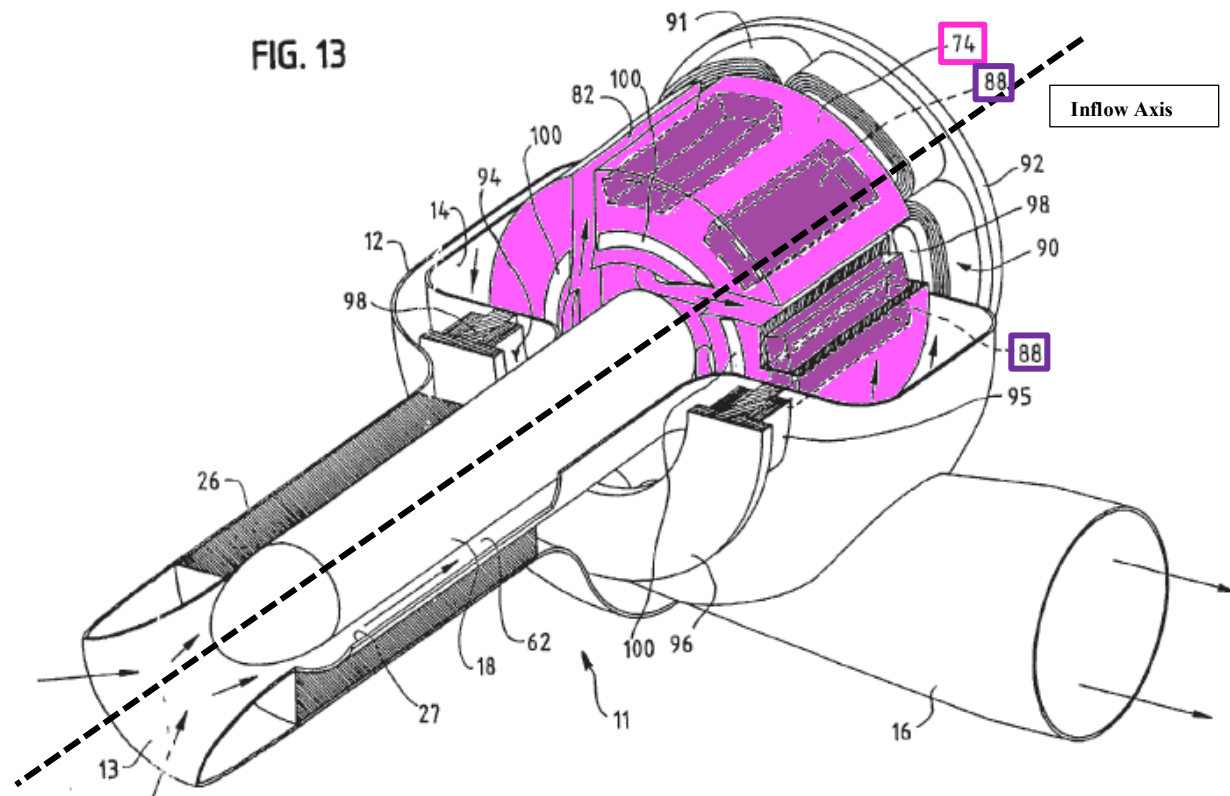


Ex.1008, Fig. 12, [0070]; Ex.1003, ¶185.

Mr. Crosby explains for components to be “*axially aligned*”, the components are configured such that they are colinear, or in the same line (or “axis”) in space. Ex.1003, ¶183. In addition, in Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is “*axially adjacent*” to the “*magnetically driven rotor.*” Ex.1019, 5.

Assuming that interpretation, Wampler-169 discloses that the “**permanent magnetic segments** [are] imbedded [‘*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 [‘axially adjacent’] in...the **impeller**” (Ex.1008, [0080]-[0081]; Ex.1003, ¶185). And as discussed for [11C], Wampler-169 discloses “axial inflow...of the blood” (Ex.1008, [0075]-[0076] towards “**impeller 74**,” which “rotat[es] about a[] longitudinal axis” (“axially aligned with the **inflow axis**”) (Ex.1008, [0081]):



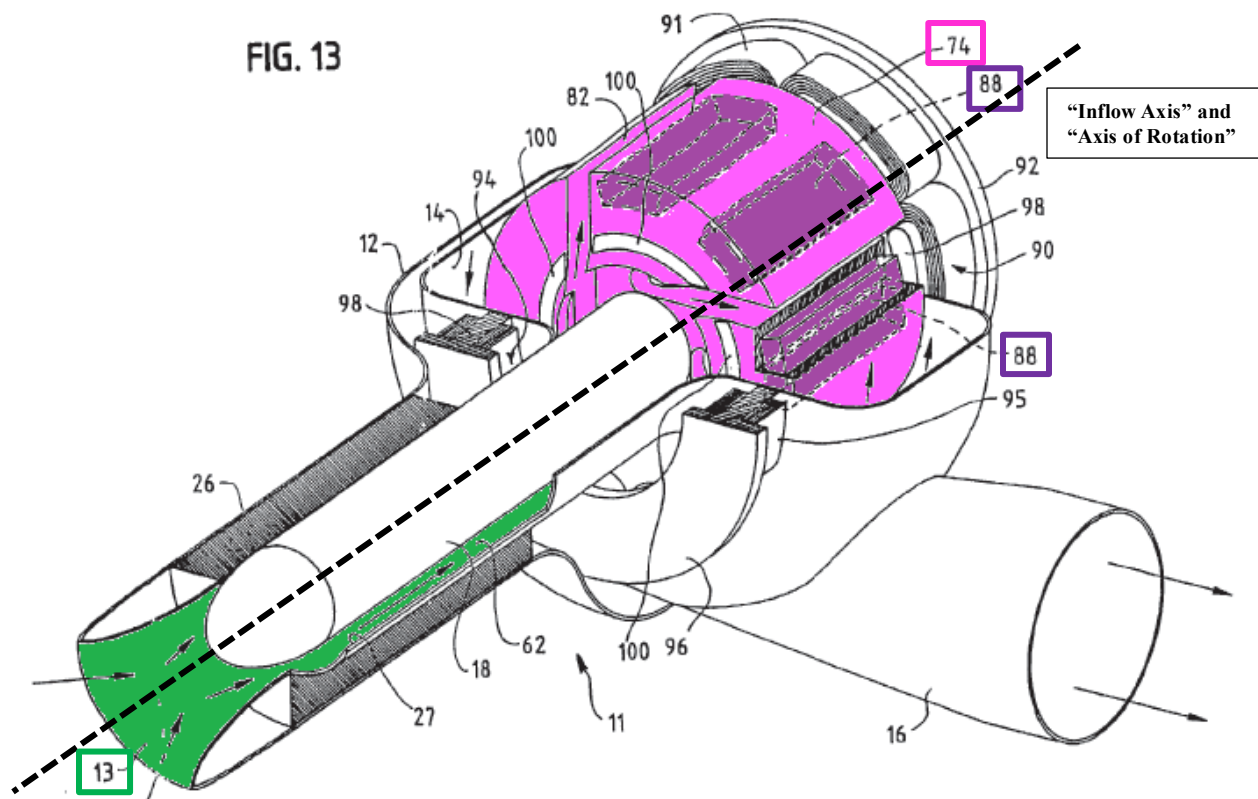
Ex.1008, Figs. 13; Ex.1003, ¶178.

Accordingly, Wampler-169 discloses the **magnetically driven rotor** (“impeller 74”) “being rigidly coupled and axially adjacent to a **first magnetic device**

(“magnetic pieces 88”) *that is axially aligned with the **inflow axis*** (“axial inflow” along “longitudinal axis”).” Ex.1003, ¶186.

vi. [11E]

Wampler-169 discloses that the “**impeller 74**” and its imbedded “**magnetic pieces 88**” are “mounted for rotation about a longitudinal axis” [‘*rotatable about an axis of rotation*’] (Ex.1008, [0081]; Ex.1003, ¶191) that is *aligned* with the “blood ... flow through **inlet tube 13** in the direction of arrows 62” [‘*aligned with the inflow axis*’] (Ex.1008, [0074]; Ex.1003, ¶191), after which “blood [is] expelled from the casing” [‘*to drive the blood flowing from the inflow tube*’] (Ex.1008, [0074]):



Ex.1008, Fig. 13. Ex.1003, ¶¶189-192.

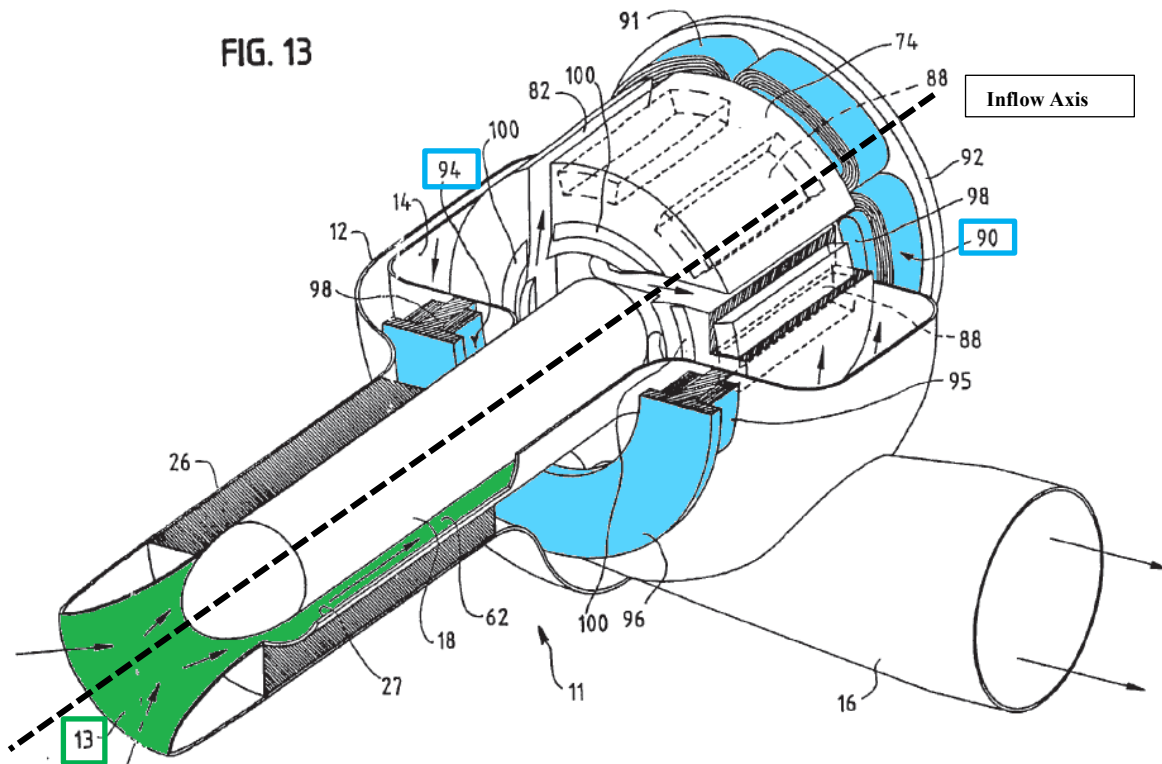
Accordingly, Wampler-169 discloses “*the magnetically driven rotor* (“impeller 74”) *and first magnetic device* (“magnetic pieces 88”) *being rotatable about an axis of rotation aligned with the inflow axis* (“longitudinal axis”) *to drive the blood flowing from the inflow tube* (“inlet tube 13”).” Ex.1003, ¶193.

vii. [11F]

In Parallel Litigation, PO asserts that a “motor and/or stator” is “*a second magnetic device.*” Ex.1019, 7-8 (cleaned up).

Assuming that interpretation, Wampler 169 discloses “a **first motor stator 90**, comprising conductive coils or motor windings 91, is located at the rear of **impeller 74**” and includes “a ring of back iron 92 [] located behind windings 91.” Ex.1008, [0083]. Ex.1003, ¶196. “A **second motor stator 94**, comprising windings 95, is positioned on the forward side of impeller 74” and “windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95.” Ex.1008, [0084]. Ex.1003, ¶196. Together, the “circular” “**motor stators 90 and 94**” comprise elements that “complete a magnetic circuit” in which “[t]orque drive is imparted to the impeller by magnetic interaction” between “**motor stators 90 and 94**” and permanent magnets in the impeller (Ex.1008, [0085], [0018]; Ex.1003, ¶¶195-197) [*a magnetic drive system comprising a second magnetic device*] and are *axially aligned* along the “**longitudinal axis**” [*inflow axis*] (Ex.1008, [0080]-[0081], Ex.1003, ¶ 200). Mr. Crosby explains components are “*axially aligned*” if they are

configured to be colinear, or in the same line (or “axis” of rotation) in space. Ex.1003, ¶199. The *axial align[ment]* of the “circular” “motor stators 90 and 94” along the “longitudinal axis,” through which “blood ... flows through the inlet tube 13 in the direction of arrows 62” (Ex.1008, [0074]) is shown in Figure 13:

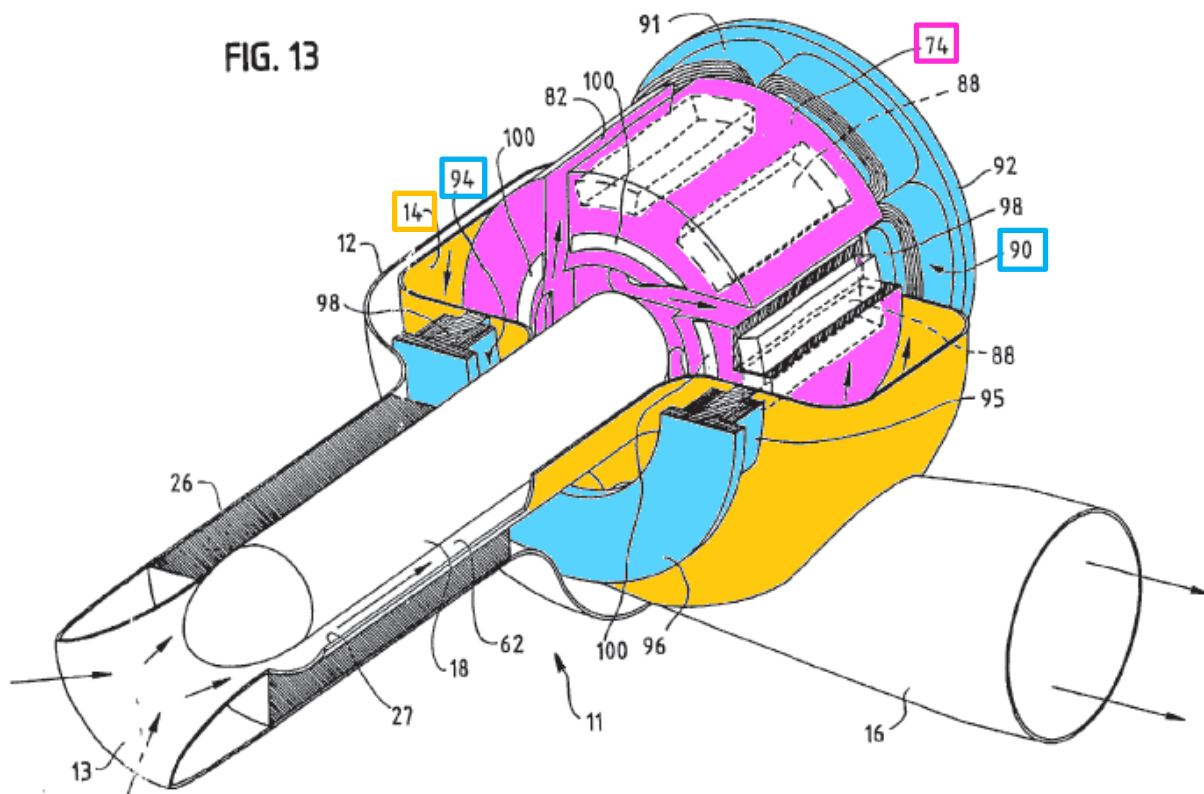


Ex.1008, Fig. 13; *see also* [0018] (referring to 90 and 94 as a “circular electromagnetic stator”), [0070]; *supra* [11C] (analyzing the “inflow axis”); Ex.1003, ¶202.

Accordingly, Wampler-169 teaches or suggests “a magnetic drive system comprising a *second magnetic device* (“motor stators 90 and 94”) axially aligned with the *inflow axis* (“longitudinal axis”).” Ex.1003, ¶203.

viii. *[11G]*

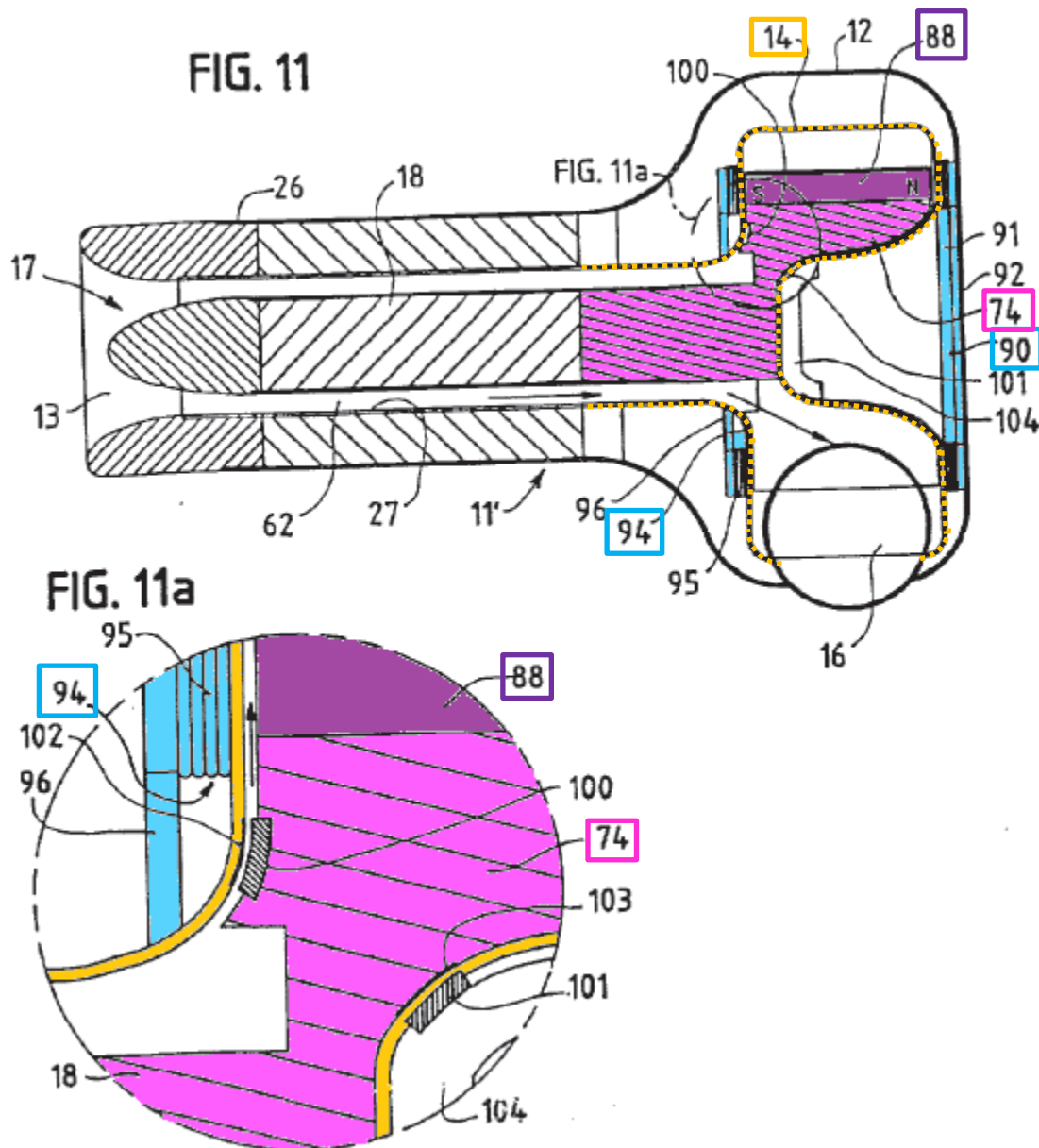
Wampler-169 discloses that the “**stator[s]**” [‘*second magnetic device*’] are fixed between housing 12 and **casing 14**” [‘*chamber*’] (Ex.1008, [0083]-[0084]; Ex.1003, ¶206) [‘*spaced apart*’] while the “**impeller**” [‘*magnetically driven rotor*’] is “enclos[ed]” within the **casing** [‘*chamber*’]. Ex.1008, [0012], Ex.1003, ¶205). The “**stator[s]**” may be “mounted on the outer surface [‘*a wall*’] of impeller **casing 14**” (Ex.1008, [0012], [0070], Ex.1003, ¶206):



Ex.1008, Fig. 13; Ex.1003, ¶209. While the “stator” being “mounted on the outer surface of impeller casing 14” is discussed for the embodiment of FIGs. 1-8, the “blood pump 11” of Fig. 3 “is similar in many respects to blood pump 11 illustrated

in FIGs. 1-8,” including in that the **stator[s]** are “fixed between housing 12 and **casing 14**” on an outer surface of the casing, shown in Figure 13. Ex.1008, [0080].

Figures 11-11a illustrate the “**stator[s]** fixed between housing 12 and **casing 14**” and that an “outer surface” [‘wall’] of the **casing** is positioned between the “**impeller**” (and its “**magnetic pieces 88**”) and the **stator[s]**:

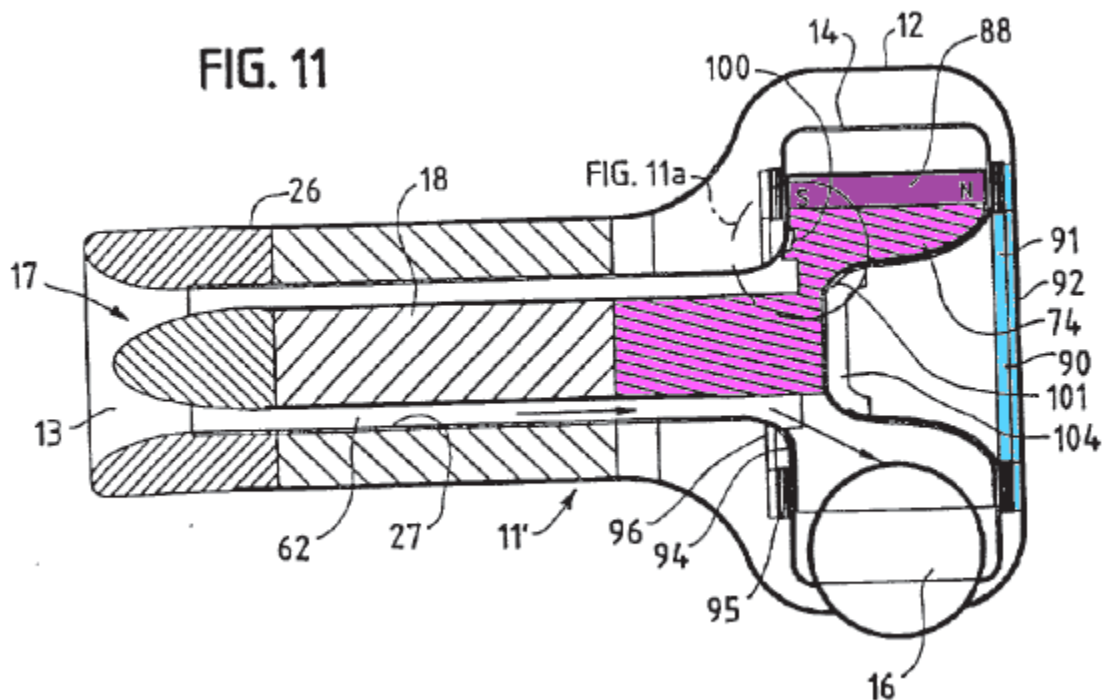


Ex.1008, Figs. 11-11a; Figs. 7-8b, [0070]; Ex.1003, ¶210.

Accordingly, Wampler-169 discloses that the “*second magnetic device*” (“motor stators 90 and 94”) is “*spaced apart from the magnetically driven rotor*” (“impeller 74”) *such that a wall* (“outer surface”) *of the one or more walls* (“interior” and “outer surface”) *defining the chamber* (“casing 14”) *is positioned between the magnetically driven rotor and the second magnetic device.*” Ex.1003, ¶211.

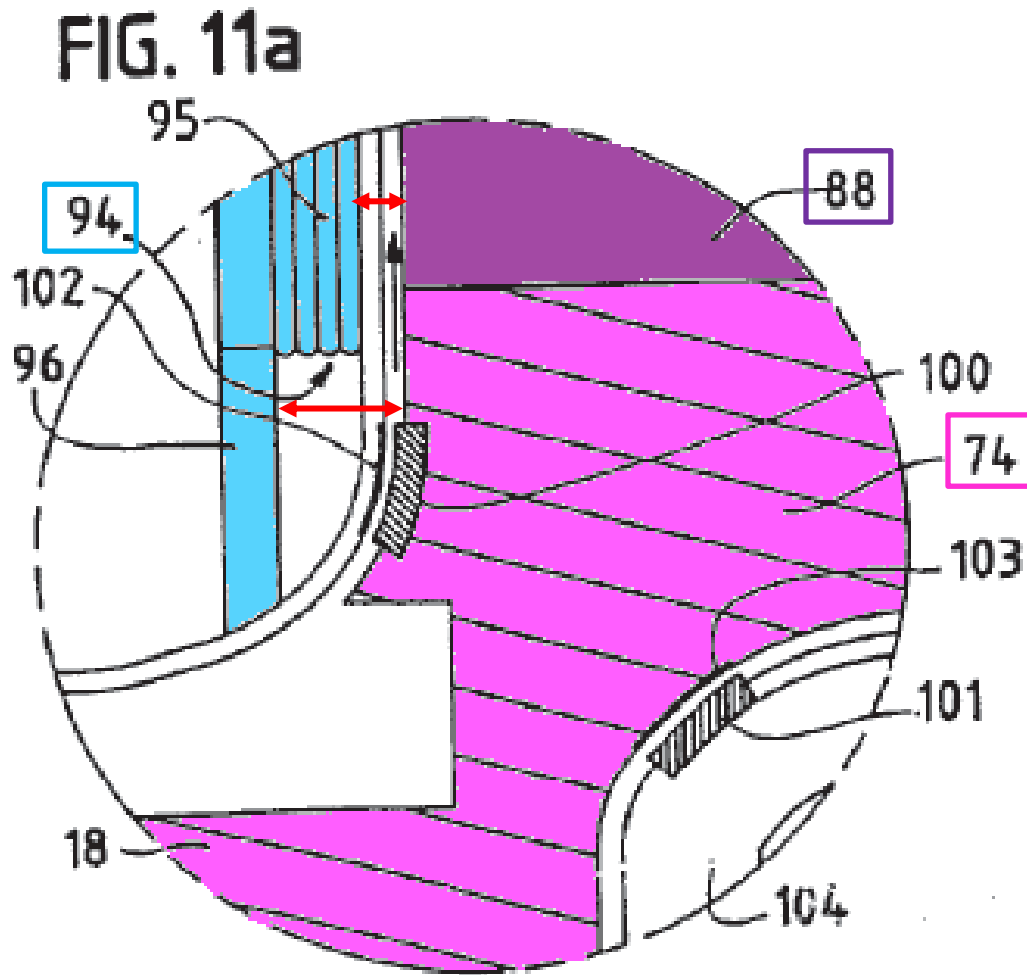
ix. [11H]

Wampler-169 discloses that **stator 90** is “adjacent to the pole faces of the **motor rotor magnets [88]**” and therefore *positioned axially closer to the motor rotor magnets 88* than to the **impeller 74**:



Ex.1008, [0085]; Ex.1003, ¶213.

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



Ex.1008, Fig. 11a; Ex.1003, ¶214 (analyzing the “*axially closer*” to effectively generate torque).⁸

In addition, in Parallel Litigation, PO alleges that a “stator” satisfies this limitation for “magnetically driv[ing] rotation of the magnetically driven rotor...via a magneto coupling.” Ex.1019, 9-11.

Assuming that interpretation, Wampler-169 discloses that there is a “magnetic interaction” [‘*magneto coupling*’] between arcuate, **permanent magnetic segments [88]** [‘*first magnetic device*’] imbedded within each **impeller** blade sector, and a **circular electromagnetic stator [90 and 94]** [‘*second magnetic device*’], and a “torque drive is imparted to the **impeller** by [this] magnetic interaction” [‘*magneto coupling...to drive rotation of the magnetically driven rotor*’]. Ex.1008, [0018]; Ex.1003, ¶¶218-220. Said another way, the **stator** and its “windings[] are energized...to produce an electromagnetic field [‘*to provide a magneto coupling*’]

⁸ The claimed relative locations of the “*first magnetic device*” and “*magnetically driven rotor*” to the “*second magnetic device*” would also have been an obvious design choice because the specification of the 879 Patent does not suggest that such relative locations are critical to the claimed invention. *See Ex Parte Spangler*, Appeal No. 2018-003800 2019 WL 1077598, at 5–6 (Patent Tr. & App. Bd. Feb. 15, 2019).

...[which] is effective to drive **magnets [88]** and the [**impeller**], in rotary fashion [*‘to drive rotation’*].” Ex.1008, [0072]; Ex.1003, ¶219 (explaining this description of electromagnetic drive referencing Figures 1-8 applies to the embodiment of Figures 11-14).

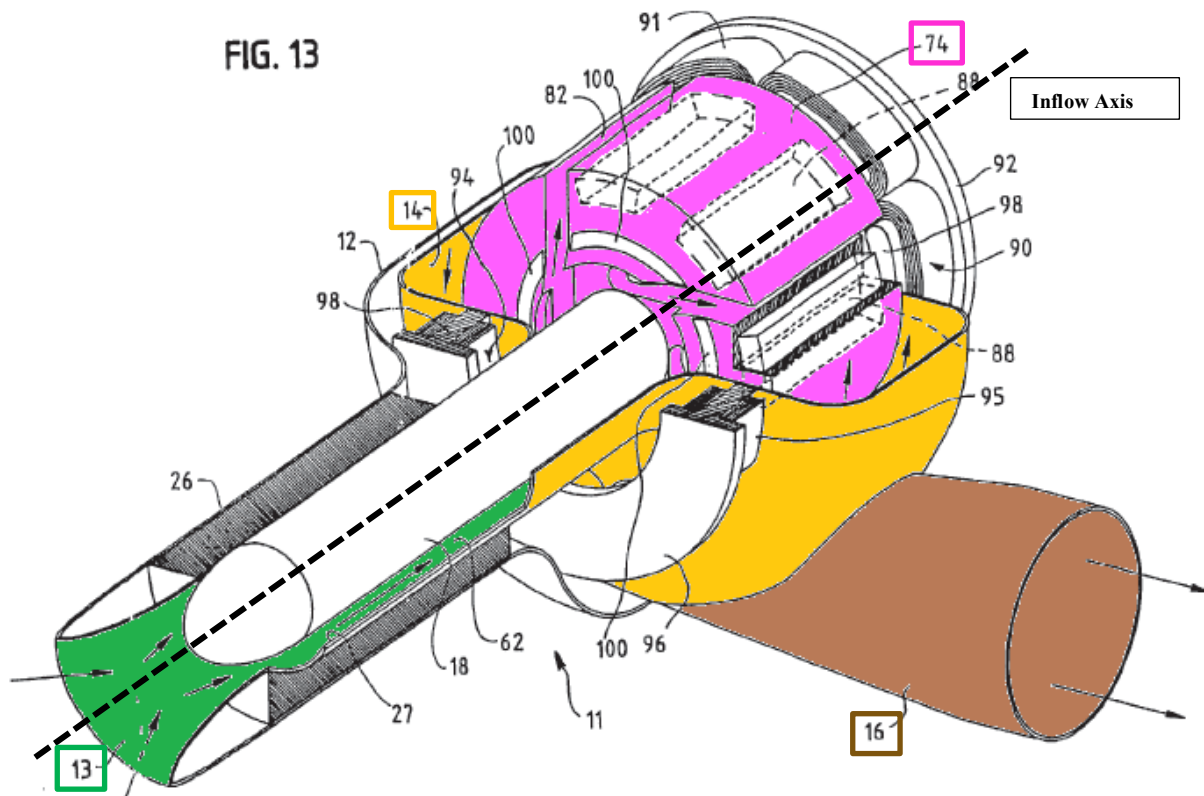
Finally, Wampler-169 discloses the “relative movement” during “rotation of the ... the **impeller**” [*‘rotation of the magnetically driven rotor’*] within the “interior of **casing 14**” [*‘relative to the one or more walls’*]. Ex.1008, [0092], [0074]. Ex.1003, ¶222.

Accordingly, Wampler-169 discloses or at least renders obvious the “**second magnetic device** positioned axially closer to the **first magnetic device** (“magnetic pieces 88”) *than to the magnetically driven rotor* (“impeller 74”) *so as to magnetically drive rotation of the magnetically driven rotor* (“impeller 74”) *relative to the one or more walls* (“interior” of “casing 14”) *via a magneto coupling with the first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶224.

x. [11I]

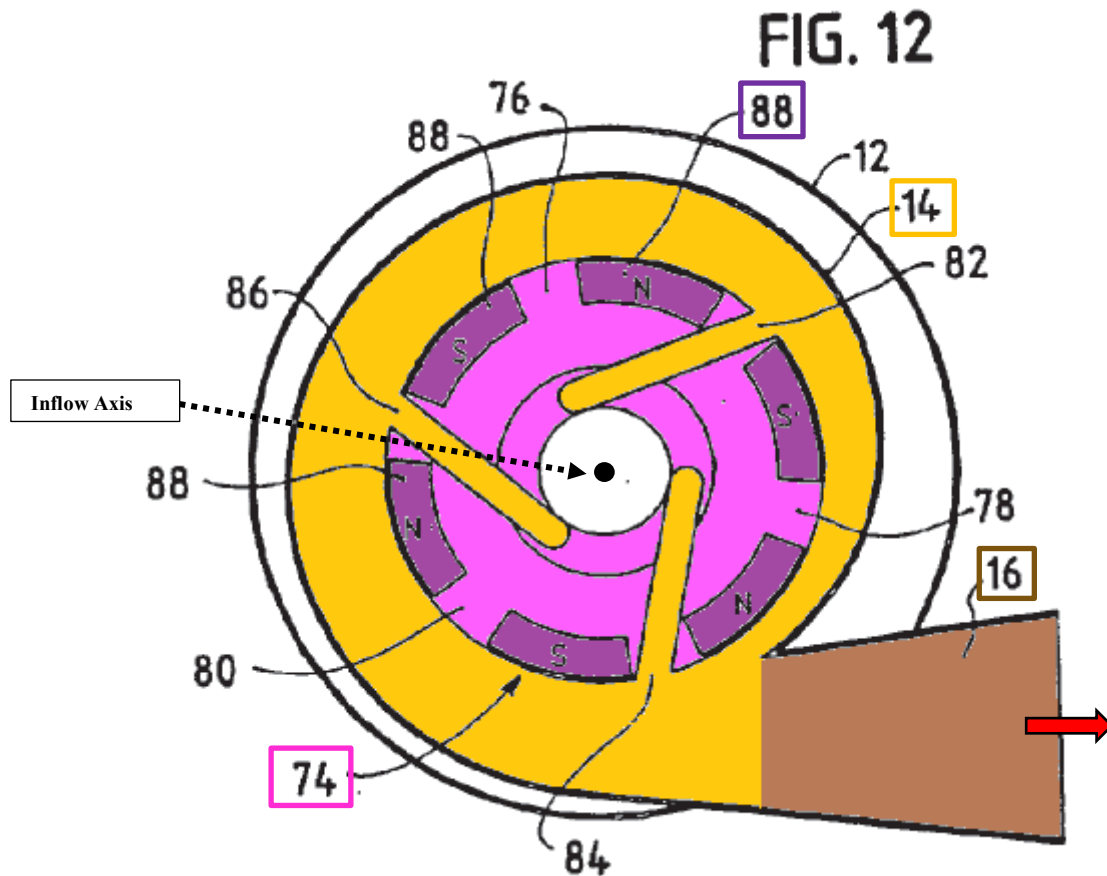
Wampler-169 discloses that “[r]otation of the...**impeller [74]**, causes blood to flow through **inlet tube 13** in the direction of arrows 62. The “blood continues its path from the...interior of **casing 14** and the...**[d]ischarge tube 16** [*‘a blood outflow port’*] allows the blood to be expelled from the **casing** an[d] into the user’s cardiovascular system” [*‘blood driven by the magnetically driven rotor’*]. Ex.1008,

[0074]; Ex.1003, ¶228. The “**discharge tube 16**” [‘*a blood outflow port*’] has “a tangential orientation with respect to a radius of the casing” that “enclose[s] the impeller” to allow “radial outflow [‘*exits the chamber*’] of the pump [in] a 90-degree redirection of the blood” [‘*in a direction substantially perpendicular to the inflow axis*’] (Ex.1008, [0074]-[0076], [0080]; Ex.1003, ¶229):



Ex.1008, Fig. 13; Ex.1003, ¶¶230.

Figure 12 illustrates a top view of the radial outflow (**red** arrow) in a direction *substantially perpendicular* from the **longitudinal axis** [*inflow axis*] of the **impeller**:



Ex.1008, Fig. 12; Ex.1003, ¶231.

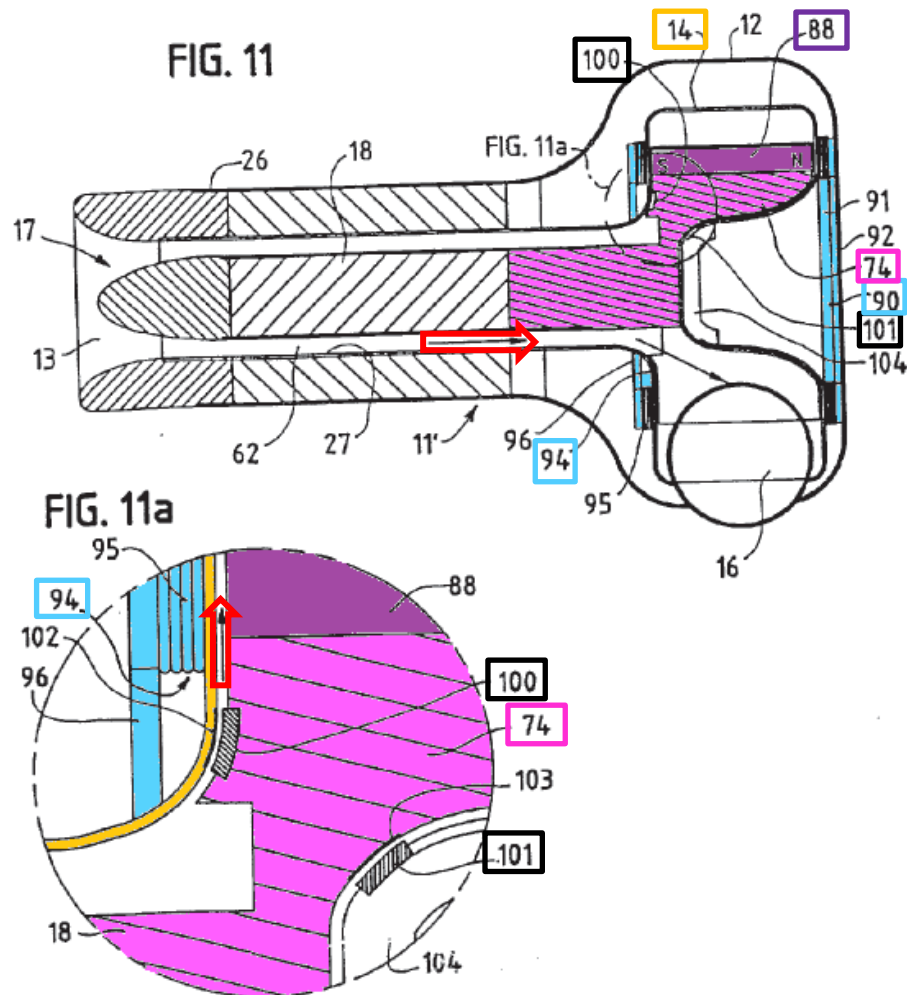
Accordingly, Wampler-169 discloses “a **blood outflow port** (“discharge tube 16”) positioned such that the blood driven by the **magnetically driven rotor** (“impeller 74”) exits the **chamber** (“casing 14”) in a direction substantially perpendicular to the **inflow axis** (“axial inflow” along “longitudinal axis”).”

Ex.1003, ¶232.

xi. [11J]

As demonstrated in [11H], Wampler-169 discloses that drive is imparted “*via a magneto coupling*” and that “the impeller [is] suspended within the housing.” Ex.1008, [0013]; *supra* [11H].

Wampler-169 further discloses that “[a]lthough at rest there may be contact between the impeller and the casing, 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’*; **red** arrows] produces increased pressure within the bearing gap which forces the [**impeller**] and the [**casing**] apart” [*‘is spaced apart from the one or more walls’*] (Ex.1008, [0092]; Ex.1003, ¶238):



Ex.1008, Figs. 11 and 11a; Ex.1003, ¶239.

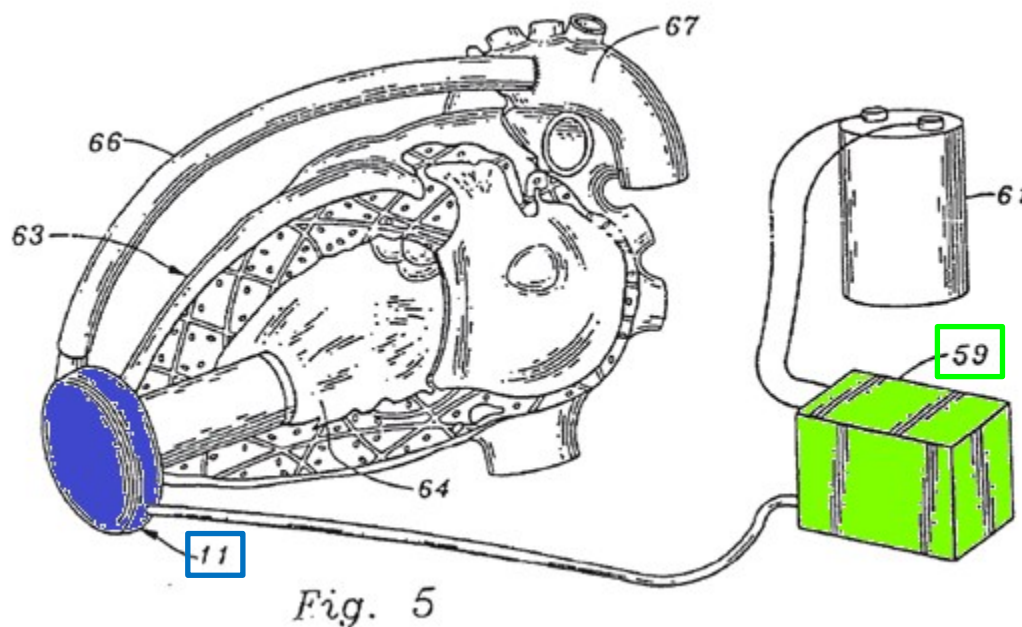
Said another way, Wampler-169 teaches that “hydrodynamic bearings are formed” “*in response to rotation of the [impeller]*”— “**once rotation begins...fluid film produces increased pressure...which forces**” (Ex.1008, [0020]) the “**impeller** [to be] separated from the casing by a fluid film.” Ex.1008, [0092]; Ex.1003, ¶238.

Accordingly, Wampler-169 discloses that “*the magneto coupling orients the magnetically driven rotor* (“impeller 74”) so that both the *magnetically driven rotor*

and the *first magnetic device* (“magnetic pieces 88”) remain spaced apart from the *one or more walls* (“interior of casing 14”) by the blood in response to rotation of the *magnetically driven rotor*.” Ex.1003, ¶241.

xii. [11K]

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 can be “manually adjusted or programmed to determine the running rate of pump” [*configured to regulate operation*] (Ex.1008, [0071]; Ex.1003, ¶243):



Ex.1008, Fig. 5; Ex.1003, ¶¶246-247.

The produced “electromagnetic field [*magneto coupling*]...is effective to drive **magnets [88]** [*first magnetic device*] and the **[impeller 74]**, [*magnetically*

driven rotor’] in a rotary fashion.” Ex.1008, [0072], Ex.1003, ¶243. “The back [electromagnetic field] resulting from the **magnets [88]** passing by the **windings** [‘*second magnetic device*’] is detected by the **controller**” which “uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor [‘*regulate operation of the second magnetic device... to thereby magnetically drive the rotation*’].” Ex.1008, [0072]; Ex.1003, ¶243).

In addition, Wampler-169 discloses that the “control unit allows the speed and drive cycle of the motor either ***to be programmed*** [‘*regulates operation...based on a fixed value*’] or interactively determined by the user’s physical activity or condition.” Wampler-169, [0018], [0071]. Ex.1003, ¶245.

Accordingly, Wampler-169 teaches or suggests “an **external control unit** (“controller 59”) *configured to control operation of the second magnetic device* (“motor stators 90 and 94”) *based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor* (“impeller 74”) *via the magneto coupling with the first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶248.

2. Claim 12

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

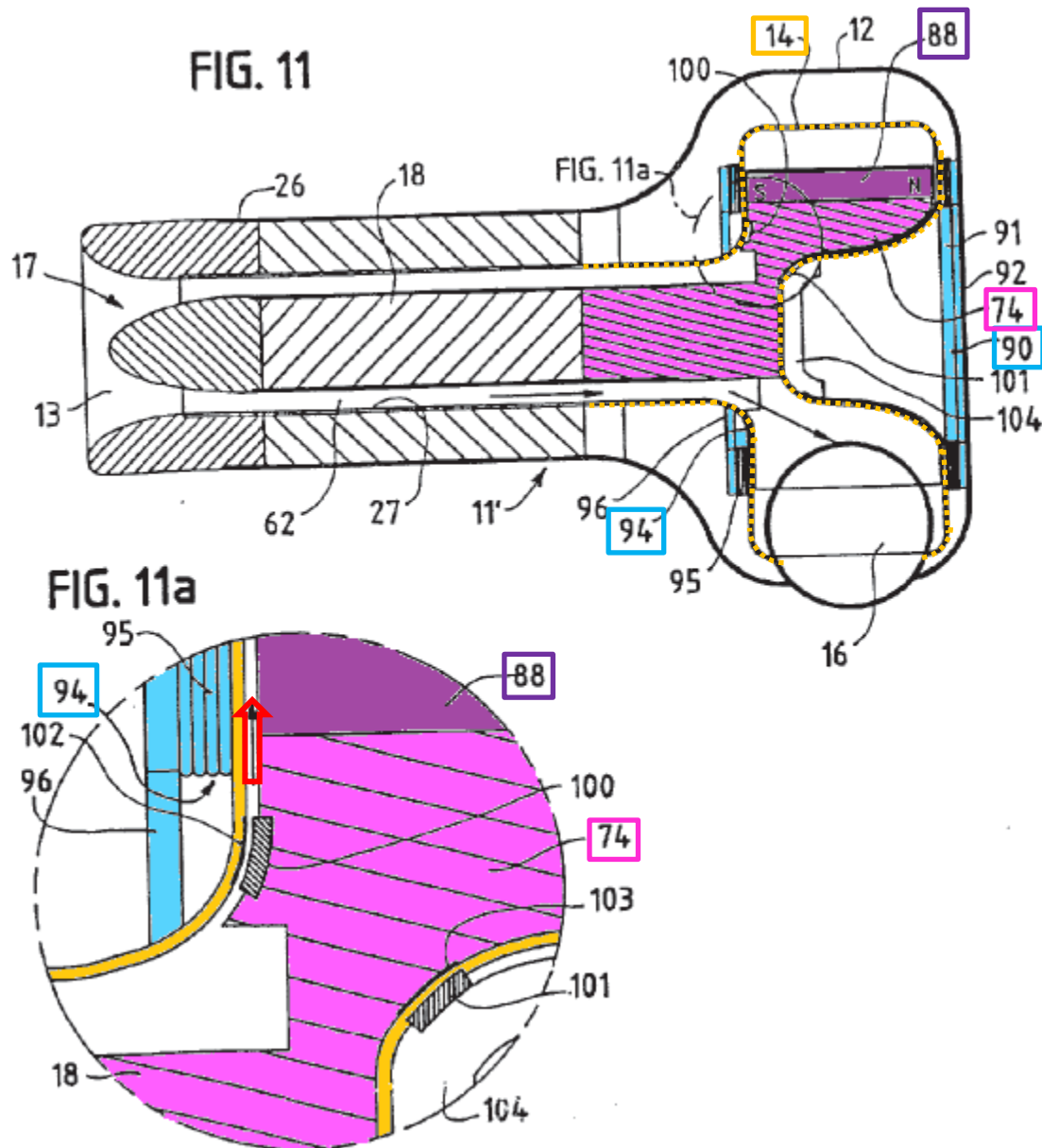
direction of arrows 62” (“*produce centrifugal flow components*”). Ex.1008, [0074], Fig. 6 (showing arrows 62); Ex.1003, ¶¶251-253.

Accordingly, Wampler-169 discloses that “*the magnetically driven rotor* (“impeller 74”) *includes a guide surface* (“blade sectors”) *to produce centrifugal flow components* (“arrows 62”).” Ex.1003, ¶254.

3. Claims 14-15

As demonstrated in [11H] and [11I], Wampler-169 discloses that once rotation [of the **impeller**] begins,” “relative movement between the [**impeller**] and...the hydrodynamic action of the fluid film [*‘a gap configured to be occupied by blood; red arrows*] produces increased pressure within the bearing gap which forces the [**impeller**] and the [**casing**] apart.” Ex.1008, [0092] (“The hydrodynamic bearings are formed by a raised pad spaced from a contact surface by the blood gap.”) Ex.1003, ¶260.

Figures 11 and 11*a* illustrate the “interior of the **casing**” and the **impeller** defining the “blood gap” (**red** arrow):



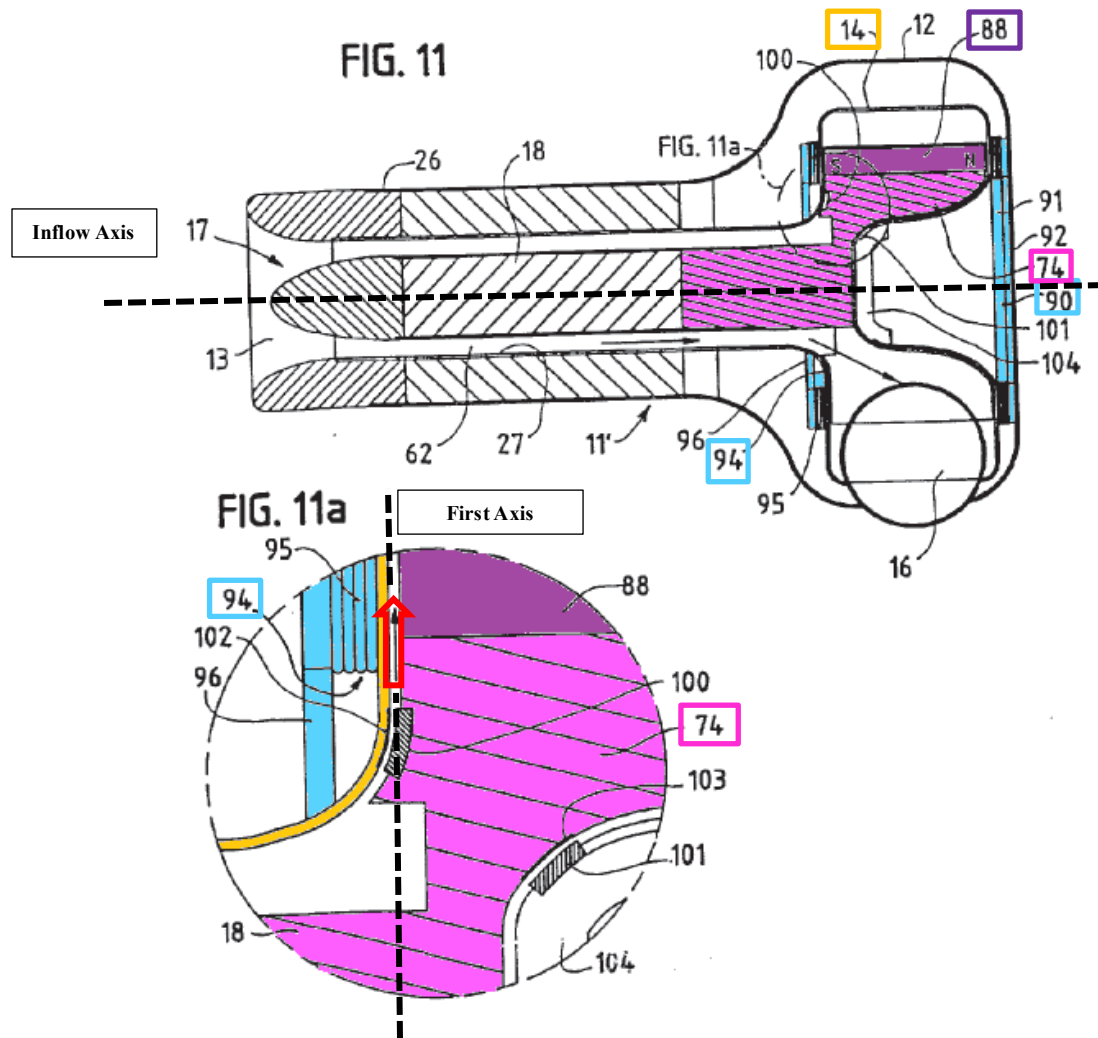
Ex.1008, Figs. 11-11a; Ex.1003, ¶260.

Accordingly, Wampler-169 discloses that “*one or more walls* (“interior of casing 14”) and the *magnetically driven rotor* (“impeller 74”) define a gap (“blood gap”) separating the *magnetically driven rotor* from the *one or more walls*, the gap configured to be occupied by the blood when the *second magnetic device* (“motor

stators 90 and 94”) *drives the rotation of the magnetically driven rotor...wherein the gap* (“blood gap”) *surrounds the magnetically driven rotor* (“impeller 74”).”
Ex.1003, ¶262.

4. Claim 16

Wampler-169 discloses that at least part of the “blood gap” [‘*the gap*’; **red** arrow], defined when the “**motor stators 90 and 94**” drive the rotation of the **impeller 74** via the magneto coupling with the “**magnetic pieces 88**” (*supra* [14]; Ex.1008, [0081], [0085]; Ex.1003, ¶265), extends along *a first axis substantially perpendicular to the “axial inflow” along the “longitudinal axis” [‘inflow axis’]*, (Ex.1008, [0081], [0092]; Ex.1003, ¶265) (in **black**):



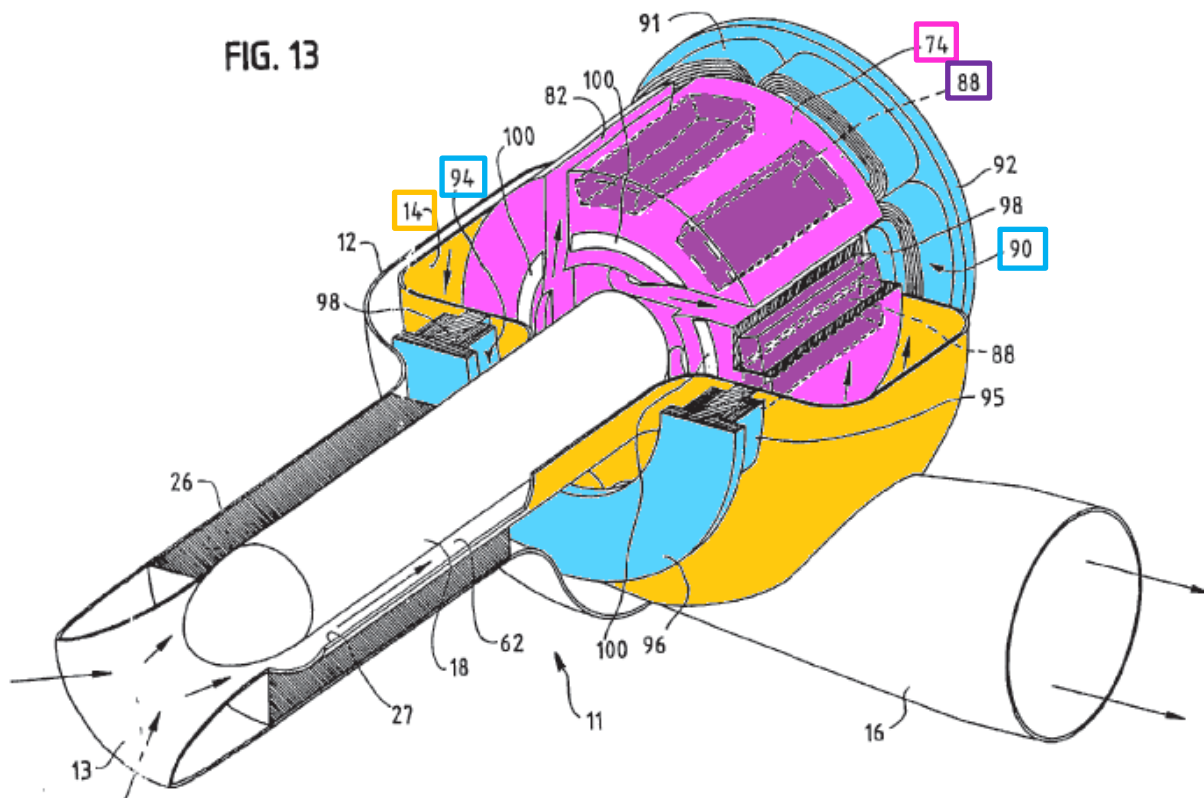
Ex.1008, Figs. 11 and 11a; Ex.1003, ¶266.

Accordingly, Wampler-169 discloses “at least part of the gap extends along a first axis substantially perpendicular to the **inflow axis** (“axial inflow” along “longitudinal axis”).” Ex.1003, ¶267.

5. Claim 18

As demonstrated in [11B], the “interior of **casing 14**” that “enclose[s] the impeller” [“within which the magnetically driven rotor is positioned”] (Ex.1008,

[0012]) is a ‘*chamber*’ at least partially defined by *one or more walls* (e.g., “interior,” “inner wall,” “outer surface,” Ex.1008, [0074], [0070], [0060]; Ex.1003, ¶270. Wampler-169 further discloses the “**motor stators 90 and 94**” [‘*magnetic drive system*’] (Ex.1008, [0085]) are positioned “between housing 12 and casing 14,” [‘*within a second chamber*’] (Ex.1008, [0083]) and sealed from the “interior of casing 14” that “enclos[es] the impeller” [‘*first chamber*’] (Ex.1008, [0074], [0012]):



Ex.1008, Fig. 13 (depicting a *first chamber* inside casing 14 and a *second chamber* outside casing 14). Ex.1003, ¶274.

Accordingly, Wampler-169 discloses that “*the **chamber** (“casing 14”) is a first chamber within which the **magnetically driven rotor** (“impeller 74”) is positioned, and the **magnetic drive system** (“motor stators 90 and 94”) is positioned within a second chamber (“between housing 12 and casing 14”) sealed from the first chamber.*” Ex.1003, ¶275.

6. Claim 19

As demonstrated in [18], because Wampler-169 discloses the “**motor stators 90 and 94**” [‘*magnetic drive system*’] (Ex.1008, [0085]) are “mounted on the outer surface of impeller casing 14,” while the “interior of the casing 14” [‘*first chamber*’] “encloses the impeller,” the “outer surface” is *a wall* that separates the “interior of **casing 14**” [‘*first chamber*’] (Ex.1008, [0074]) from the space “between housing 12 and casing 14,” [‘*second chamber*’] (Ex.1008, [0083]). Ex.1003, ¶¶279-280.

Accordingly, Wampler-169 discloses that “*the wall* (“outer surface”) *of the **one or more walls** separates the first chamber* (“interior of casing 14”) *from the second chamber* (“between housing 12 and casing 14”).” Ex.1003, ¶281.

7. Claims 1-2, 4-5, 7-8, 20

Claims 1, 2, 4-5, 7-8, and 20 recite elements that are identical or analogous in scope to the claims above, with exceptions noted below, and, except for the claim elements discussed below, thus, are rendered obvious for the same reasons, as incorporated below. Ex.1005, ¶¶282-284.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 1
[1PRE]	[11PRE]	§VIII.A.1.i
[1A]	[11A]	§VIII.A.1.ii
[1B]	[11C]	§VIII.A.5
[1C]	[11B], [11E]	§VIII.A.1.iii; §VIII.A.1.vi
[1D]	[11D]	§VIII.A.1.v
[1E]	[11F]	§VIII.A.1.vii
[1F]	[11H]	§VIII.A.1.ix
[1G]	[11G], [14]	§VIII.A.1.viii; §VIII.A.3
[1H]	[11I]	§VIII.A.1.x
[1I]	[11J]	§VIII.A.1.xi
[1J]	[11K]	§VIII.A.1.xii
[2]	[12]	§VIII.A.2
[4]	[11B], [18], [19]	§VIII.A.1.iii; §VIII.A.5-9

[5]	[14], [18]	§VIII.A.7.i; §VIII.A.3; §VIII.A.5
[7]	[18]	§VIII.A.5
[8]	[19]	§VIII.A.6
[20]	[11k]	§VIII.A.1.xii

i. Claim 4

See [11B], [18]-[19], above. Wampler-169 further discloses “a sealing wall positioned between the [‘motor stators 90 and 94’] and the [‘impeller 74’]” so that “a thin-walled non-magnetic jacket be placed over these portions, to prevent contact between the magnets and the blood.” Ex.1008, [0057]. Mr. Crosby explains a POSITA would have been motivated to do so because “[s]uch contact, if it were allowed, would likely cause an undesirable chemical reaction, to the detriment of the blood.” Ex.1008, [0057]; [0070]; Ex.1003, ¶283. *Supra* [11B] (analyzing “outer surface of impeller casing 14”); Ex.1008, [0070]).

ii. Claim 20

See [11K], [18]-[19], above. Wampler-169 further discloses the “controller” can be “manually adjusted or programmed to determine the running rate of pump...[and] may be interconnected to sensors on various organs...[to] automatically...tailor operation of the pump to the user's physical activity and condition” (“based on a defined cardiac output”). Ex.1008, [0071]; *see also* [0018]

(“The control unit allows the speed...to be...determined by the user’s physical activity”). Ex.1003, ¶284.

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

1. Claim 11

i. [11PRE]

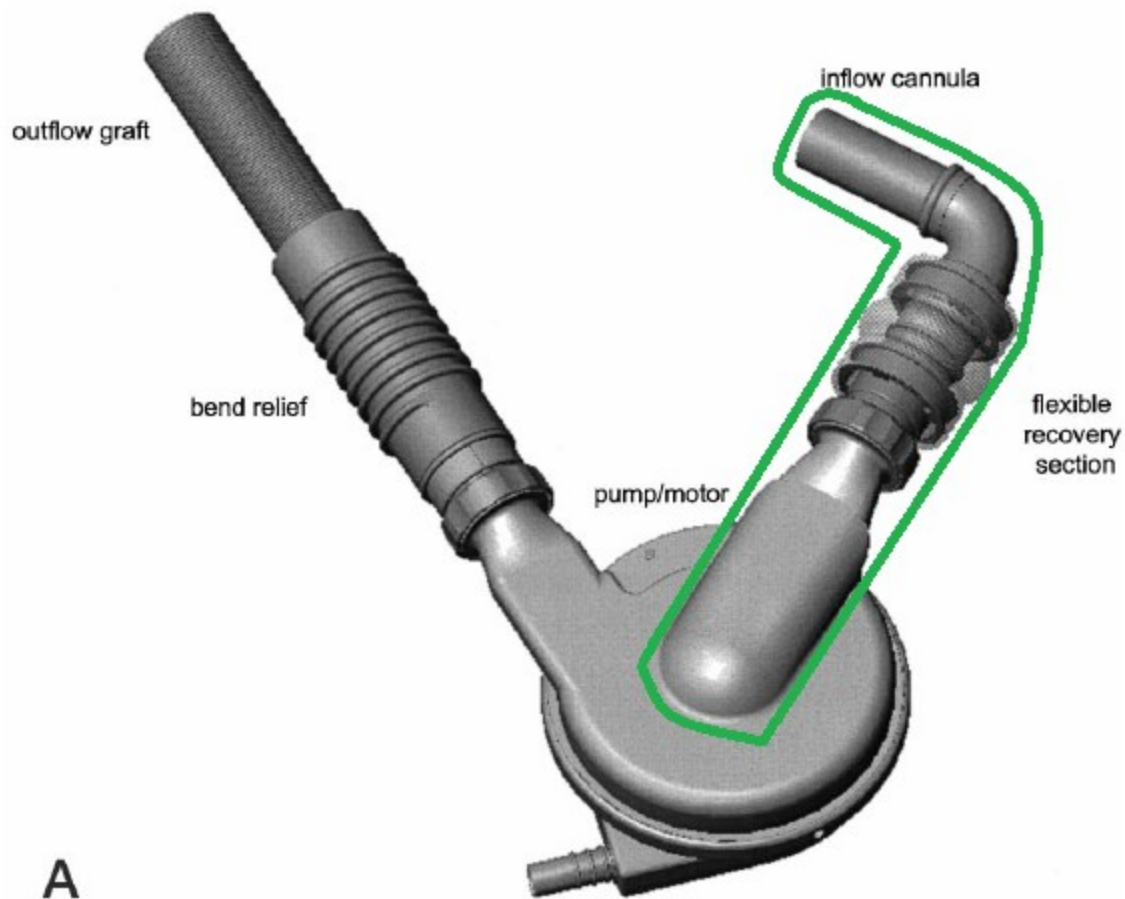
Bourque-2001 discloses the “HeartMate III”—“a centrifugal pump” that is a “long-term, compact left **ventricular** assist device (LVAD)” “to treat” “people...diagnosed with congestive heart failure” (“*a method for assisting the blood circulation of a heart in a body*”). Ex.1007, 401; Ex.1003, ¶286.

PO concedes that Bourque-2001 discloses this element. Ex.1026, D-1 31.

Accordingly, Bourque-2001 discloses “*a system for assisting the blood circulation of a **heart*** (“reliable device to treat CHF”).” Ex.1003, ¶287.

ii. [11A]

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



Ex.1007, Fig. 1A; Ex.1003, ¶293.

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

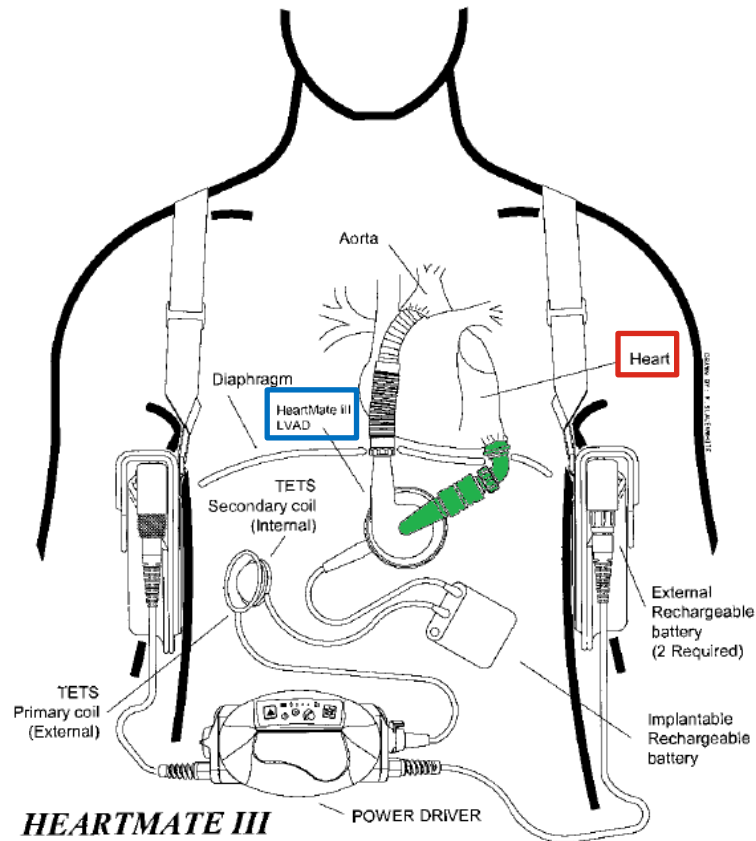
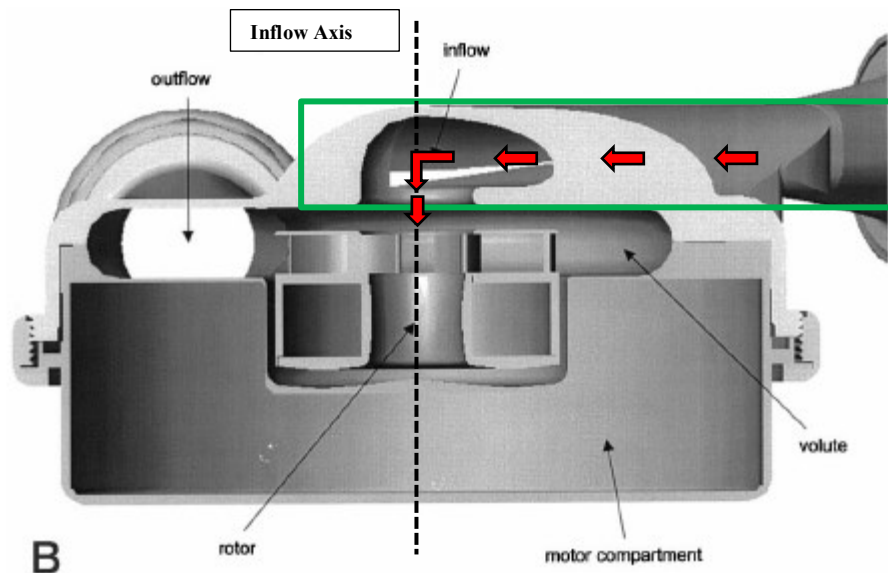


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. Ex.1003, ¶292.

Bourque-2001 further discloses that the “**inflow subassembly**” has an *inflow axis* to “permit...fluid leaving the inflow conduit to enter the impeller” (**red** arrows) along “the rotational axis of the pump’s rotor” (Ex.1007, 402):

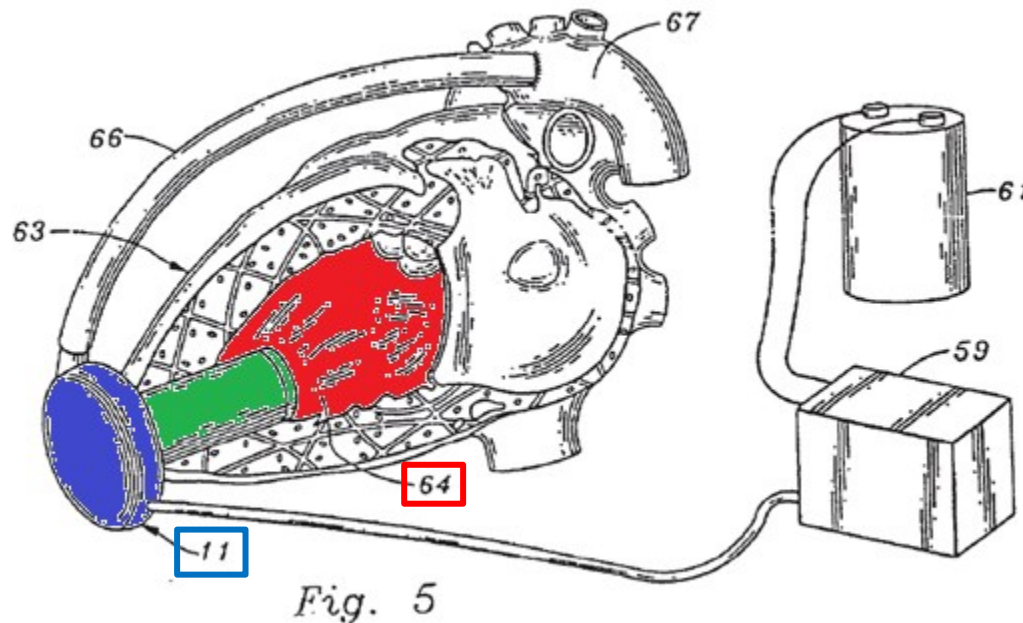


Ex.1007 at Fig. 1B (annotated). Ex.1003, ¶294.

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, ¶295. Nevertheless, by virtue of Bourque-2001’s device being “a centrifugal pump,” “**inflow subassembly**” defin[es] a blood inflow path along an inflow axis as flow “leav[es] the inflow conduit to enter the impeller.” Ex.1007, 402. Indeed, axial inflow is characteristic of centrifugal pumps. Ex.1003, ¶296.

To the extent one asserts that Bourque-2001 does not disclose this limitation, as detailed below (*infra* §VIII.B.8), it would have been obvious to modify Bourque-2001’s “inflow subassembly” to align the LV cannula along the “inflow axis” 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]:



Ex.1008, Fig. 5. Ex.1003, ¶¶298-299.

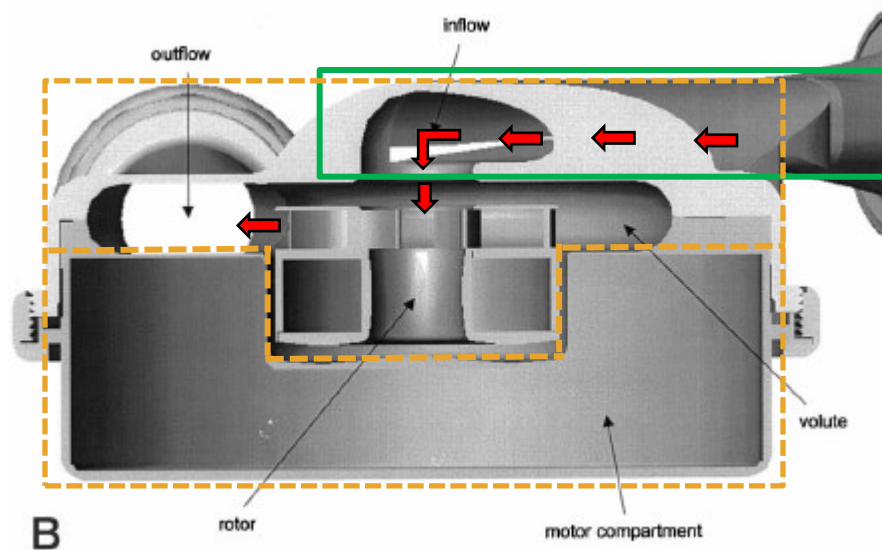
Mr. Crosby explains (*infra* §VIII.B.8) that a POSITA would have had a reasonable expectation of success to modify the pump’s “inflow subassembly” to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler-169, resulting in an “inflow tube defining a blood inflow path along an inflow axis.” Ex.1007, 402; Ex.1008, [0076], Fig. 5; Ex.1003, ¶299.

Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious “a heart assist pump device (“HeartMate III LVAD”) deliverable to the heart and comprising: an inflow tube (“an inflow subassembly that includes a left ventricular (LV) cannula,” Ex.1007; “inlet tube [13] serves as the

inflow cannula,” Ex.1008) *defining a blood inflow path along an **inflow axis** and being insertable into **a left ventricle*** (“left ventricular apical cannulation”).” Ex.1003, ¶300.

iii. [11B]

Bourque-2001 discloses an “**upper housing**” and “**lower housing**” [*‘one or more walls’*] that define the “**volute** and **a cavity** for the rotor” [*‘a chamber’*]. Ex.1007 at 401; Ex.1003, ¶302. Bourque-2001 further discloses “fluid leaving the **inflow conduit** [*‘inflow tube’*] ... enter[s] the impeller,” which is enclosed in the “**housing**,” (Ex.1007, 402):



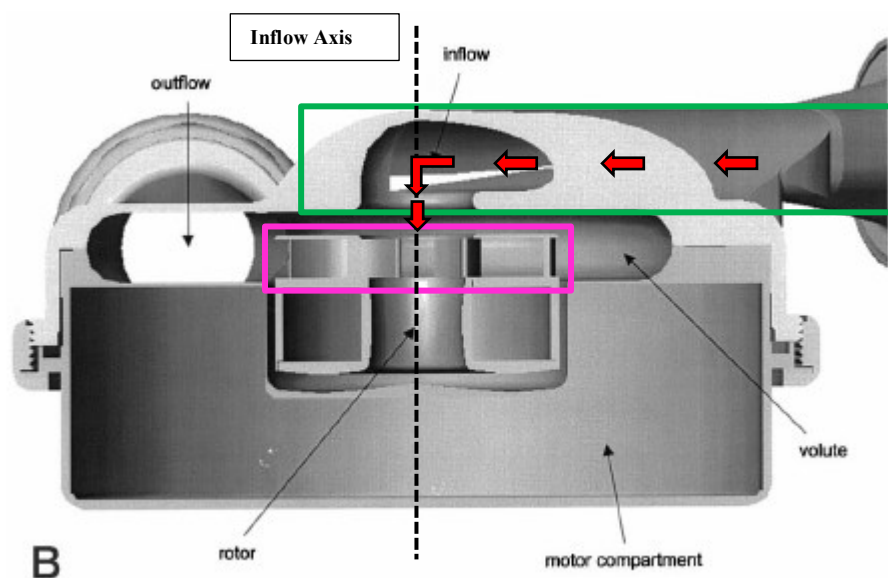
Ex.1007, Fig. 1B. Ex.1003, ¶305.

Accordingly, Bourque-2001 discloses “**one or more walls** at least partially defining **a chamber** (“upper housing” and “lower housing”) to receive blood from

the *inflow tube* (“an inflow subassembly that includes a left ventricular (LV) cannula”).” Ex.1003, ¶306.

iv. [11C]

Bourque-2001 discloses “a rotor that includes an *impeller* (“a magnetically driven rotor”)” (Ex.1007, 401; Ex.1003, ¶¶308-310) that rotates around a “rotational axis” (“axially aligned”) aligned with the inflow of “fluid leaving the inflow conduit to enter the impeller” (Ex.1007, 401-402):



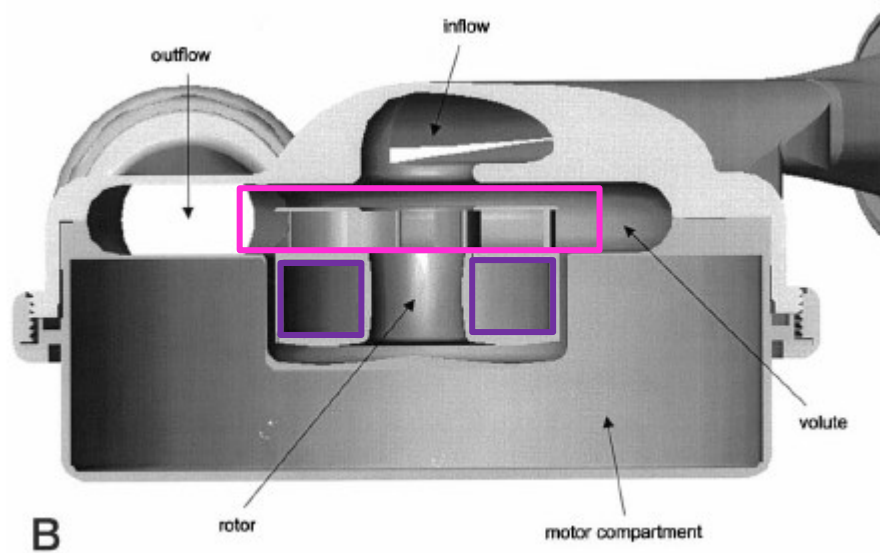
Ex.1007, Fig. 1B. Ex.1003, ¶312.

As demonstrated in [11A], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the “*impeller*” of the rotor is *axially aligned with the inflow axis*.

Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious “the **magnetically driven rotor** (“impeller”) is axially aligned with the **inflow axis**.” Ex.1003, ¶317.

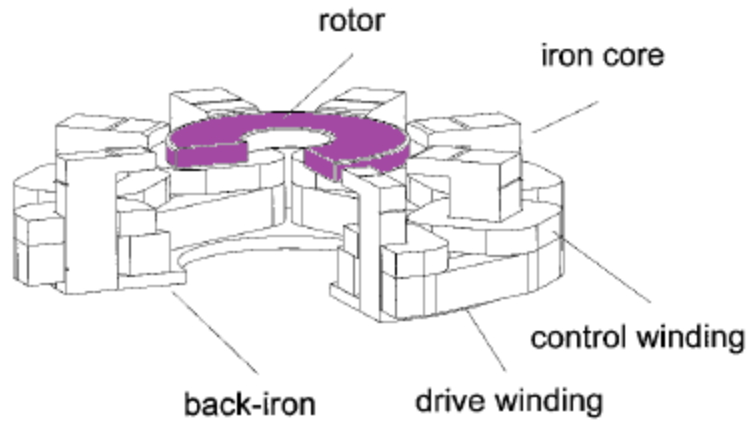
v. [11D]

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



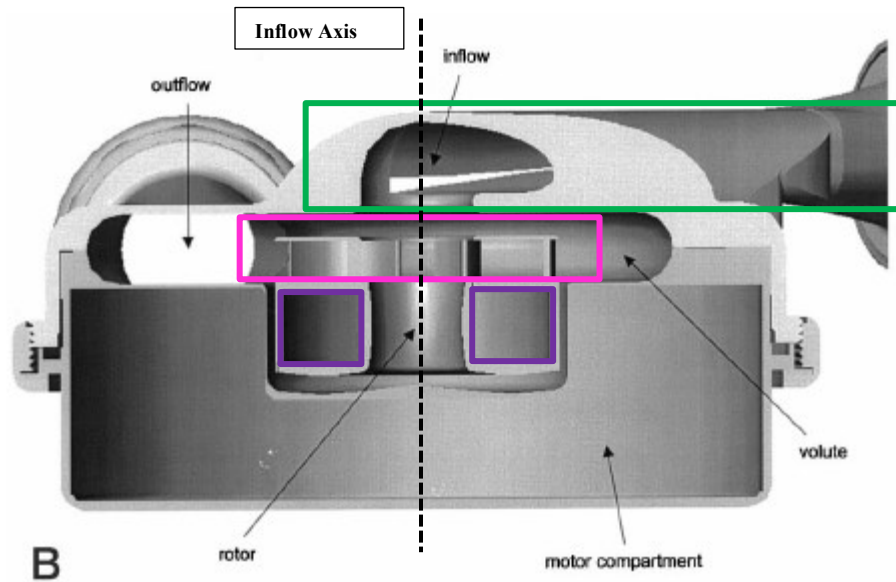
Ex.1007, Fig. 1B. Ex.1003, ¶322.

Figure 4 illustrates the “**passively magnetic elements**” of the rotor:



Ex.1007, Fig. 4, 402-403. Ex.1003, ¶321.

Mr. Crosby explains for components to be “*axially aligned*,” the components are configured such that they are colinear, or in the same line (or “axis”) in space. Ex.1003, ¶323. Bourque-2001 therefore discloses that the “rotor[’s] **impeller** and **passively magnetic elements**” are “*axially adjacent*” along “the rotational axis of the pump’s rotor” and “*axially aligned with the inflow axis*” of the “**inflow subassembly**” (Ex.1007, 401-402):



Ex.1007 at 401, Fig. 1B Ex.1003, ¶¶323-324.

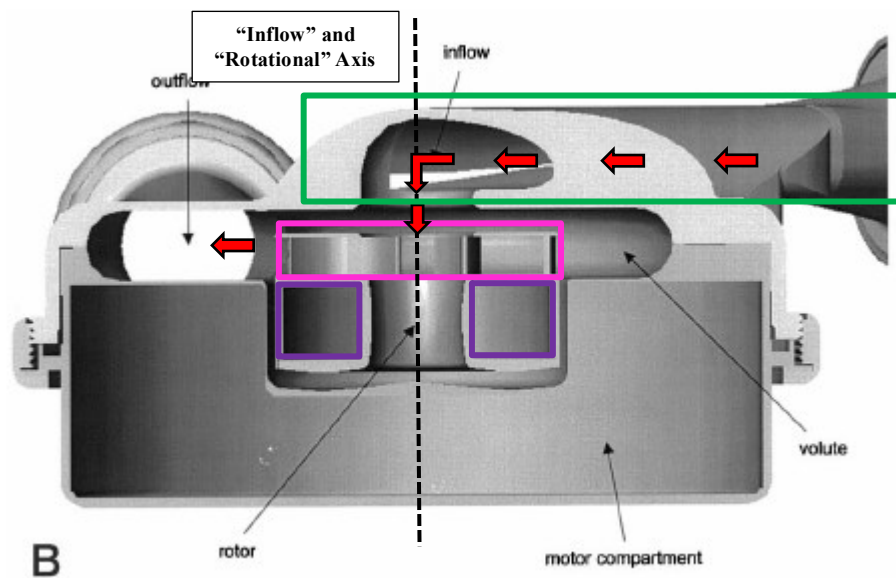
As demonstrated in [11A], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the “**passively magnetic elements**” of the rotor are *axially aligned with the inflow axis*. Ex.1003, ¶326.

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 and/or Bourque-2001 in view of Wampler-169 renders obvious the **magnetically driven rotor** (“impeller”) “*being rigidly coupled and axially adjacent to a **first magnetic device** (“passively magnetic elements”) that is axially aligned with the inflow axis.*” Ex.1003, ¶327.

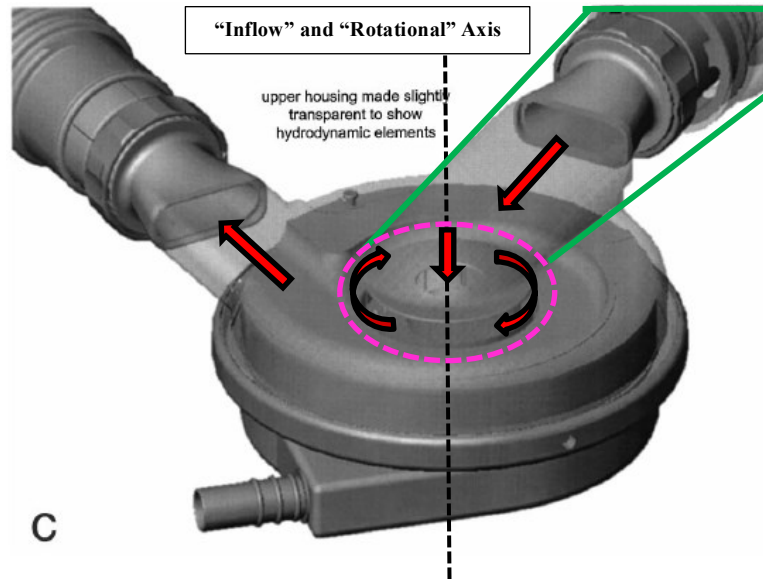
vi. [11E]

Bourque-2001 discloses that the “**impeller**” [‘*magnetically driven rotor*’] and “**passively magnetic elements**” [‘*first magnetic device*’] rotate about a “rotational axis” [‘*rotatable about an axis of rotation*’] that is *aligned with the inflow axis* such that “fluid leaving the inflow conduit [] enter[s] the impeller” and “exits the backswept blades of the impeller” [‘*to drive the blood flowing from the inflow tube*’]:



Ex.1007 at Fig. 1B; *see also* 402 (“rotational axis [is] perpendicular to the body’s long axis”). Ex.1003, ¶330.

Figure 1C shows the “flow paths” of blood (**red** arrows), and the **impeller’s** “rotational axis” aligned with the “inflow axis” *to drive the blood flowing from the inflow subassembly*:

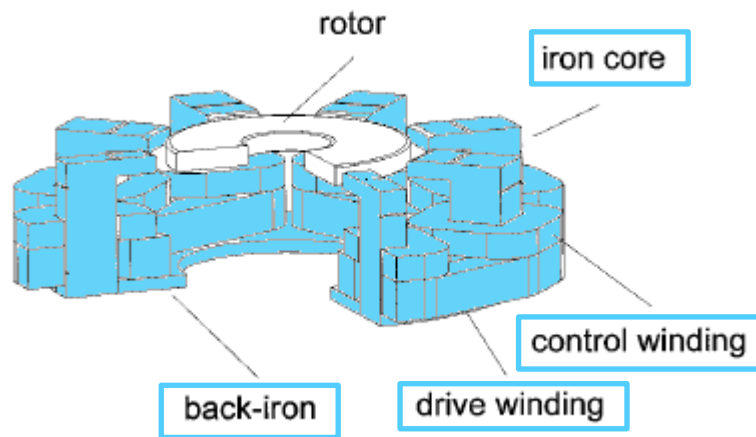


Ex.1007, Fig. 1B. Ex.1003, ¶331. As demonstrated in [11A], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that *the magnetically driven rotor and first magnetic device* be rotatable about an axis of rotation aligned with the *inflow axis* to drive the blood flowing from the *inflow tube*. Ex.1003, ¶332.

Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious discloses “*the magnetically driven rotor* (“impeller”) and *first magnetic device* (“passively magnetic elements”) being rotatable about an axis of rotation aligned with the *inflow axis* to drive the blood flowing from the *inflow tube* (“an inflow subassembly”).” Ex.1003, ¶333.

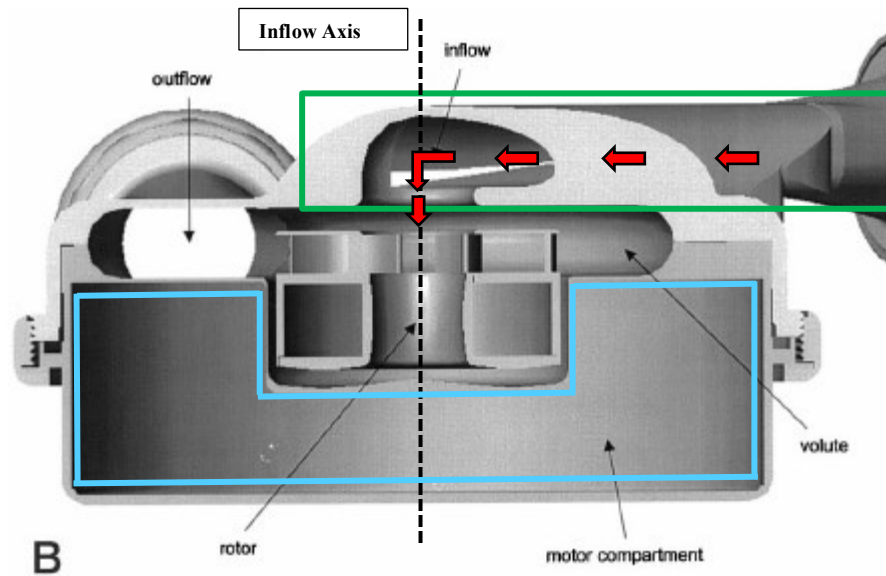
vii. [11F]

Bourque-2001 discloses that the pump’s “**motor** includes drive and levitation in a single magnetic structure” [*‘a magnetic drive system comprising a second magnetic device’*] (Ex.1007, 402-403; Ex.1003, ¶335):



Ex.1007, Fig. 4; Ex.1003, ¶336.

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 axis* of the “**inflow subassembly**” due to the “design to fit around the optimal hydrodynamic arrangement” (Ex.1007, 404):



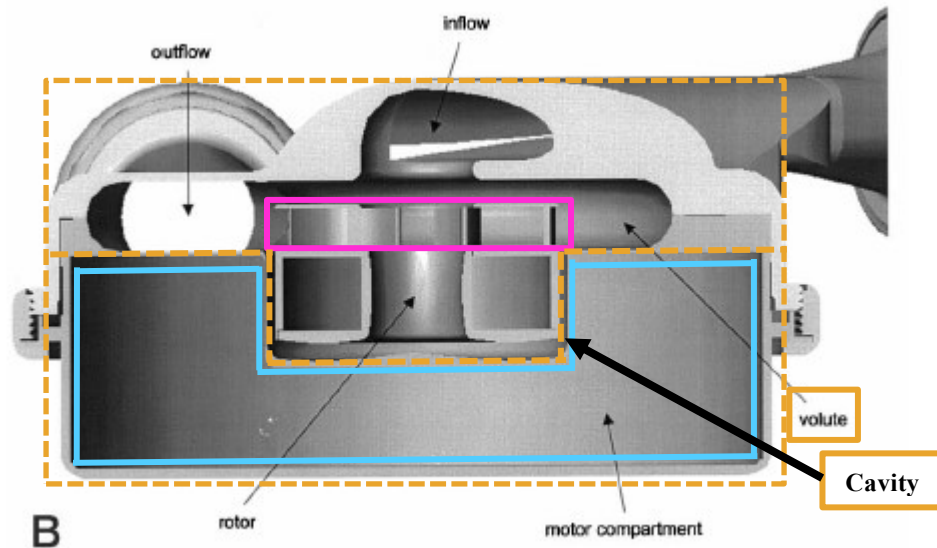
Ex.1007 at Fig. 1B, 401-403; Ex.1003, ¶338. As demonstrated in [11A], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the **motor** be *axially aligned with the inflow axis*. Ex.1003, ¶339.

Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious “a **magnetic drive system** comprising a **second magnetic device** (“motor” with drive windings) *axially aligned with the inflow axis*. Ex.1003, ¶340.

viii. [11G]

Bourque-2001 discloses that the pump has an “**upper housing**” and a “**lower housing**” in which “the **motor** is enclosed” (shown as “motor compartment” in Figure 1B) and that define the “volute and a cavity for the **rotor**.” Ex.1007, 401;

Ex.1003, ¶342. The **motor** is thus *spaced apart* from the **impeller** by the “volute” and “cavity” [*‘a wall...defining a chamber’*] formed by the **upper and lower housing** [*‘one or more walls’*] positioned between the **motor** and the **impeller** (Ex.1007, 401; Ex.1003, ¶345):

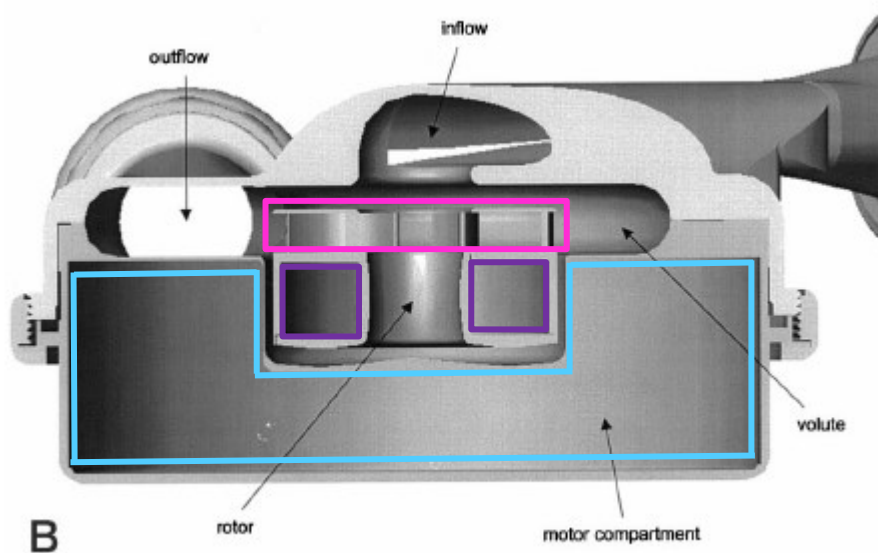


Ex.1007 at Fig. 1B; Fig. 5. Ex.1003, ¶346.

Accordingly, Bourque-2001 discloses the **second magnetic device** (“motor” with drive windings) “*spaced apart from the magnetically driven rotor* (“impeller”) *such that a wall of the one or more walls* (“upper and lower housing”) *defining the chamber* (“volute” and “cavity”) *is positioned between the magnetically driven rotor and the second magnetic device.*” Ex.1003, ¶348.

ix. [11H]

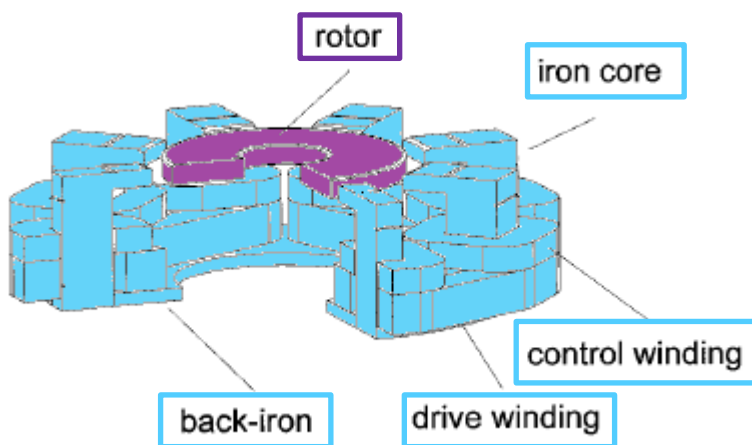
Mr. Crosby explains that for the *second magnetic device* to be “axially closer” to the *first magnetic device* than the *magnetically driven rotor*, each of the components are configured such that they are colinear, or in the same line (or “axis”) in space, and the *second magnetic device* is closer to the *first magnetic device* along that axis than it is to the *magnetically driven rotor*. Ex.1003, ¶355. Accordingly, as shown in Figure 1B, the *motor* [‘second magnetic device’] is *positioned axially closer to the passively magnetic elements* [‘first magnetic device’] than to the *impeller* so as to magnetically drive rotation:



Ex.1007 at Fig. 1B, 402-404; Ex.1003, ¶356.

In addition, in Parallel Litigation, PO alleges that the “stator” design of Abbott’s HeartMate 3 LVAD pump satisfies this limitation. Ex.1019, 9-11.

Assuming that interpretation, Bourque-2001 discloses this limitation because the HeartMate III pump has a similar “stator” design. The HeartMate III **motor** includes “drive windings” (Ex.1007, 402-403), and “the motor’s ‘J’ core configuration” (Ex.1007, 404) are *positioned to...drive rotation of the impeller via a magneto coupling* with the “**passively magnetic elements**”:



Ex.1007, Fig. 4, 402-404; Ex.1003, ¶354, *see also* ¶¶352-353 (discussing speed and flow rates).

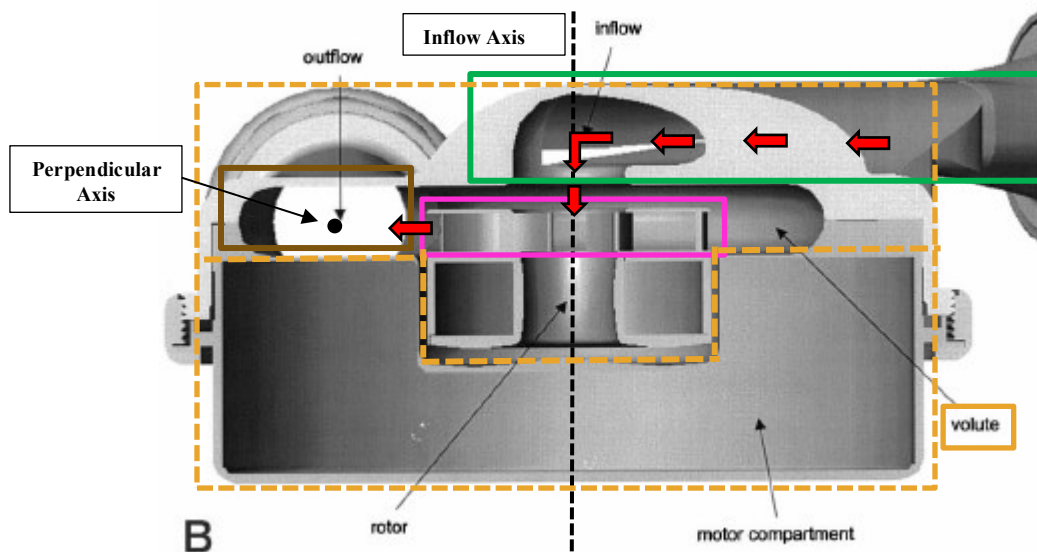
Finally, as discussed for [11E] and [11G], the **impeller** and the **passively magnetic elements** are rotatable about a “rotational axis,” within the “cavity for the rotor” formed by the “**upper housing**” and “**lower housing**” [*‘one or more walls’*].” *Supra* [11E], [11G]. Ex.1003, ¶357.

Accordingly, Bourque-2001 discloses “the **second magnetic device** (“motor” with drive windings) *positioned axially closer to the first magnetic device* (“passively magnetic elements”) *than to the magnetically driven rotor* (“impeller”)”

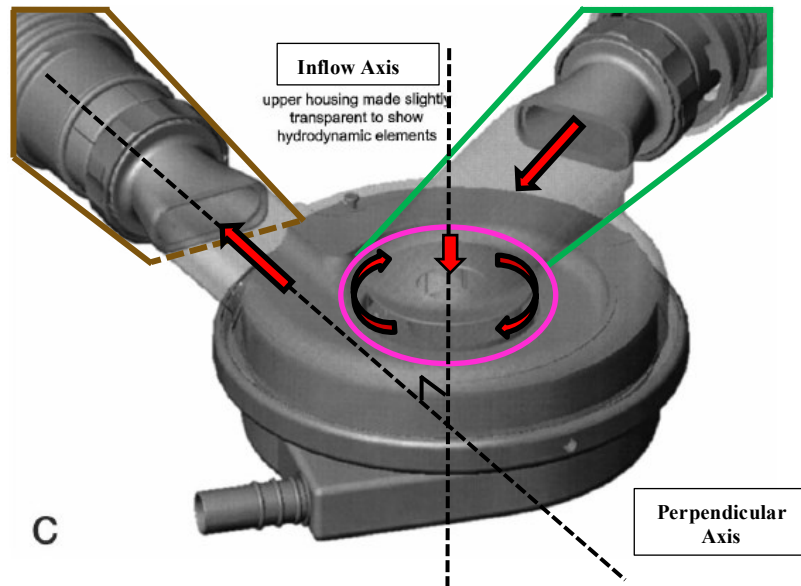
so as to magnetically drive rotation of the **magnetically driven rotor** relative to the **one or more walls** (“upper housing” and “lower housing”) via a magneto coupling with the **first magnetic device**” Ex.1003, ¶358.

x. [11I]

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 it “enters the **impeller**” (Ex.1007, 402) [‘blood driven by the magnetically driven rotor’], and “exits the backswept blades of the impeller into a **volute**,” which then “direct[s] [the flow] toward the **outflow**” [‘exits the chamber in a direction substantially perpendicular to the **inflow axis**’] (Ex.1007, 401-402; Ex.1003, ¶360) (**red** arrows):



Ex.1007, Fig. 1B. Ex.1003, ¶¶360-362.



Ex.1007, Fig. 1C; Ex.1003, ¶363.

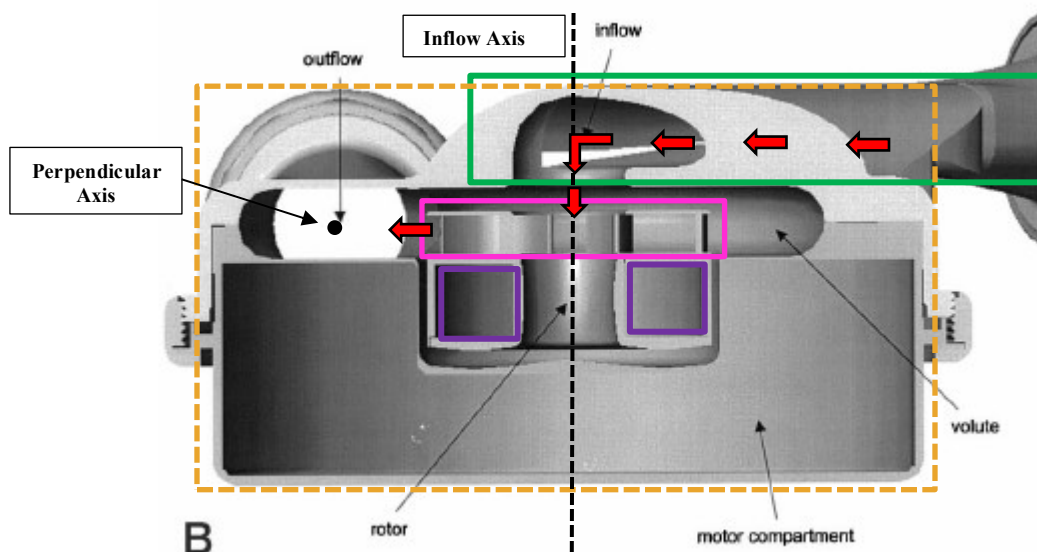
To the extent one asserts that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 for the same reasons discussed in [11A] that there would be “a 90-degree [*perpendicular*] redirection of the blood.” Ex.1003, ¶364; *infra* §VIII.B.8; Ex.1008, [0076].

Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious “a **blood outflow port** (“outflow channel”) *positioned such that the blood driven by magnetically driven rotor* (“impeller”) *exits the chamber* (“volute” and “cavity”) *in a direction substantially perpendicular to the inflow axis.*” Ex.1003, ¶365.

xi. [11J]

In Parallel Litigation, PO asserts that a magnetic bearing (“MagLev”) satisfies a similar limitation. *See e.g.*, Ex.1019, 10-11.

Assuming that interpretation, Bourque-2001 discloses that “the rotor” (which “includes an **impeller** and **passively magnetic elements**”) “is...magnetically levitated” (Ex.1007, 401-403) [*magneto coupling orients the magnetically driven rotor*] so that “gaps permit [movement] in any direction without contact between the [**impeller**] and **housing**” [*remain spaced apart from the one or more walls*] to allow “flow” “above and below the rotor” (Ex.1007, 402) [*by the blood*]:



Ex.1007, Fig. 1B; Ex.1003, ¶¶369-371.

Bourque-2001 further discloses that the pump’s “rotor is magnetically suspended, eliminating contact” [*remains spaced apart*].” Ex.1007 at 401. Ex.1003, ¶368.

Accordingly, Bourque-2001 discloses that “*the magneto coupling orients the magnetically driven rotor*” (“impeller”) so that both the **magnetically driven rotor**

and the *first magnetic device* (“passively magnetic elements”) remain spaced apart from the *one or more walls* (“upper housing” and “lower housing”) by the blood in response to rotation of the *magnetically driven rotor*.” Ex.1003, ¶372.

xii. [11K]

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

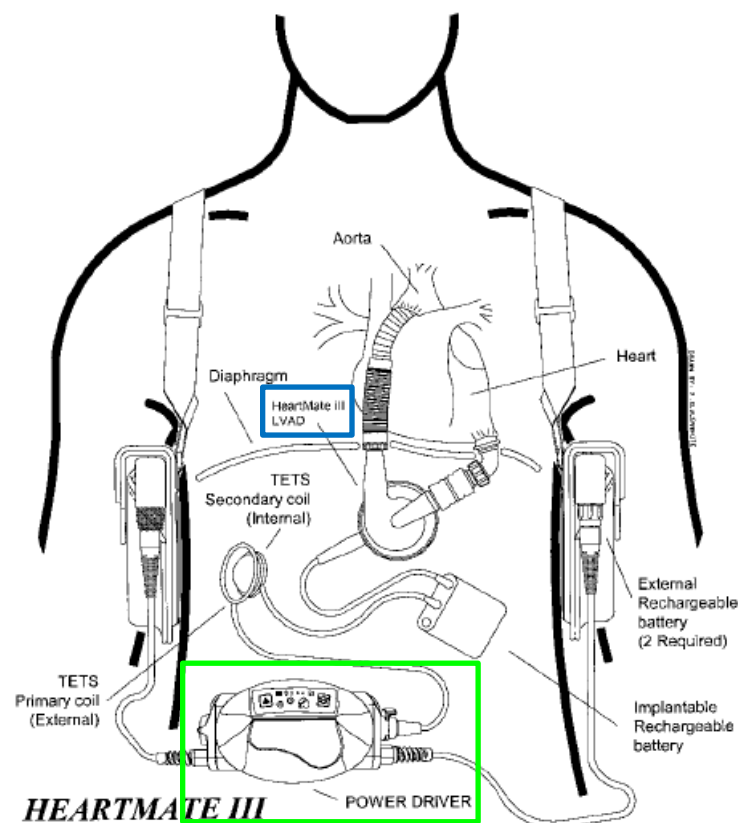


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶¶376-377.

Bourque-2001 further discloses that “[s]peed and motor parameters were set and controlled using software” [*‘configured to control operation of the second magnetic device’*] and that the “motor drive and control electronics” were *external*, because they had not been “incorporat[ed]...within the pump.” Ex.1007, 403, 405; Ex.1003, ¶378. For example, the “**electronics**” allowed for “[t]he pump to be prescribed to run at 3,500 rpm.” [*‘based on a fixed value’*] Ex.1007, 403.

Accordingly, Bourque-2001 discloses “an **external control unit** (“electronics for power and control”) *configured to control operation of the second magnetic device* (“motor”) *based on a fixed value 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, ¶380.

2. Claim 12

Bourque-2001 discloses that “blades of the impeller” (“*guide surfaces*”) “direct[] [the flow] toward the outflow” (“*produce centrifugal flow components*”). Ex.1007, 402. By virtue of its “centrifugal” design, the impeller produces *centrifugal flow components*. Ex.1007, 401; Ex.1003, ¶383.

Accordingly, Bourque-2001 discloses that “*the magnetically driven rotor* (“impeller”) *includes a guide surface to produce centrifugal flow components.*” Ex.1003, ¶385.

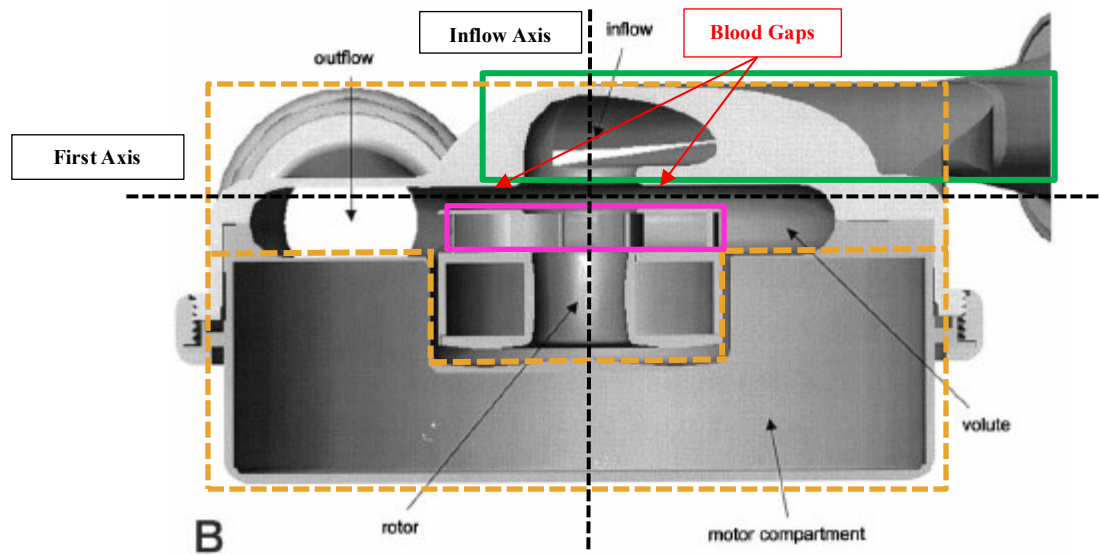
3. Claims 14–15

As demonstrated in [11H], Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (Ex.1007, 402-403) so that “*gaps* permit [movement] in any direction without contact between the [impeller] and housing” [*‘separating the magnetically drive rotor from the one or more walls’*] to allow “flow” “above and below the rotor” (Ex.1007, 402) [*‘gap...occupied by the blood’*] during rotation. Ex.1003, ¶388.

Accordingly, Bourque-2001 discloses that “*the one or more walls* (“housing”) and the *magnetically driven rotor* (“impeller”) define a gap (“gaps”) separating the *magnetically driven rotor* (“impeller”) from *the one or more walls* (“upper housing and lower housing”), *the gap configured to be occupied by the blood when the second magnetic device* (“motor”) *drives the rotation of the magnetically driven rotor...wherein the gap* (“blood gap”) *surrounds the magnetically driven rotor* (“impeller 74”).” Ex.1003, ¶391.

4. Claim 16

Bourque-2001 discloses that “*gaps* [red arrows] permit [movement] in any direction without contact between the [impeller] and housing” to allow “flow” “above and below the rotor” [*‘at least part of the gap extends along a first axis substantially perpendicular to the inflow axis’*] (Ex.1007, 402; Ex.1003, ¶¶394-395):

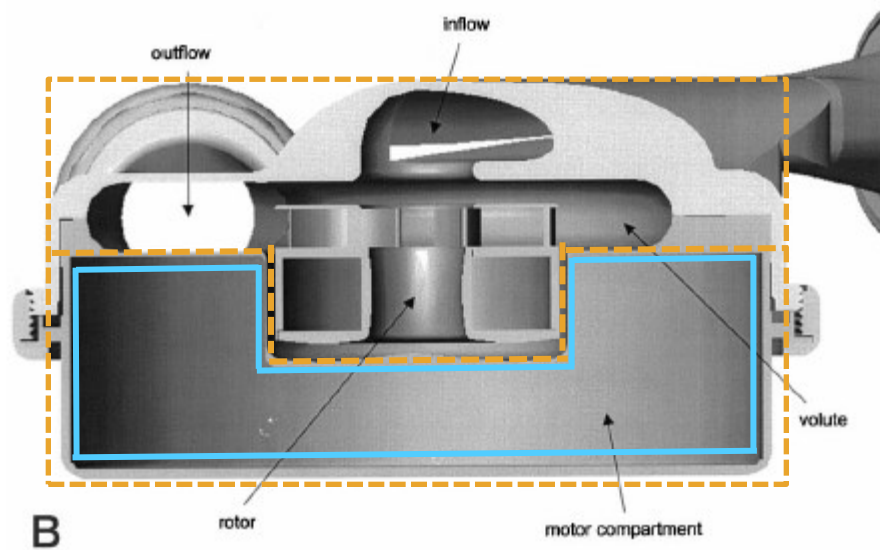


Ex.1007, Fig. 1B. Ex.1003, ¶396.

Accordingly, Bourque-2001 discloses that “at least part of the gap extends along a first axis substantially perpendicular to the *inflow axis*.” Ex.1003, ¶397.

5. Claim 18

As demonstrated in [11B], the “**volute**” and “**cavity for the rotor**” are a *first chamber* within which “**impeller**” of the rotor [‘*magnetically driven rotor*’] is positioned. Ex.1007, 401; Ex.1003, ¶304. Bourque-2001 further discloses the “**motor** [‘*second magnetic device*’] is enclosed” [‘*sealed*’] within a “motor compartment” [‘*a second chamber*’] formed by the walls of “lower housing,” Ex.1007 at 401-402, Fig. 1B; Ex.1003, ¶400):



Ex.1007, Fig. 1B. Ex.1003, ¶401.

Accordingly, Bourque-2001 discloses that “*the **chamber** (“upper housing and lower housing”) is a first chamber within which the **magnetically driven rotor** (“impeller”) is positioned, and the **magnetic drive system** (“motor” with drive windings) is positioned within a second chamber (“motor compartment”) sealed from the first chamber.*” Ex.1003, ¶403.

6. Claim 19

As demonstrated in [11B] and [18], Bourque-2001 discloses that “*the wall of the **one or more walls** separates the first chamber (“volute” and “cavity for the rotor”) from the second chamber (“motor compartment”).*” Ex.1003, ¶407.

7. Claims 1-2, 4-5, 7-8, 20

Claims 1, 2, 4-5, 7-8, and 20 recite elements that are identical or analogous in scope to the claims above, with exceptions noted below, and are rendered obvious for the same reasons, as incorporated below. Ex.1005, ¶¶408-410.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 2
[1PRE]	[11PRE]	§VIII.B.1.i
[1A]	[11A]	§VIII.B.1.ii
[1B]	[11C]	§VIII.B.5
[1C]	[11B], [11E]	§VIII.B.1.iii; §VIII.B.1.vi
[1D]	[11D]	§VIII.B.1.v
[1E]	[11F]	§VIII.B.1.vii
[1F]	[11H]	§VIII.B.1.ix
[1G]	[11G], [14]	§VIII.B.1.viii; §VIII.B.3
[1H]	[11I]	§VIII.B.1.x
[1I]	[11J]	§VIII.B.1.xi
[1J]	[11K]	§VIII.B.1.xii
[2]	[12]	§VIII.B.2
[4]	[18], [19]	§VIII.B.1.iii; §VIII.B.5-9
[5]	[14], [18]	§VIII.B.7.i; §VIII.B.3; §VIII.B.5

[7]	[18]	§VIII.B.5
[8]	[19]	§VIII.B.6
[20]	[11K]	§VIII.B.1.xii

i. Claim 4

See [11B], [18]-[19], *above*. Bourque-2001 further discloses “a sealing wall positioned between the [‘motor’] and the [‘impeller’]” so that “the motor is enclosed.” Ex.1007, 402. Ex.1003, ¶409. *Supra* [11B] (analyzing “lower housing”); Ex.1008, [0070]).

ii. Claim 20

See [11K], [18]-[19]. Bourque-2001 further discloses that “[s]peed and motor parameters [can be] set and controlled” for example, to be “prescribed to run at 3,500 rpm” and “gradually adjusted to maintain volume flow rates” including at “desired maximum flow (10 L/min at 135 mm Hg)” (“*based on a defined cardiac output*”). Ex.1007, 403 Ex.1003, ¶410.

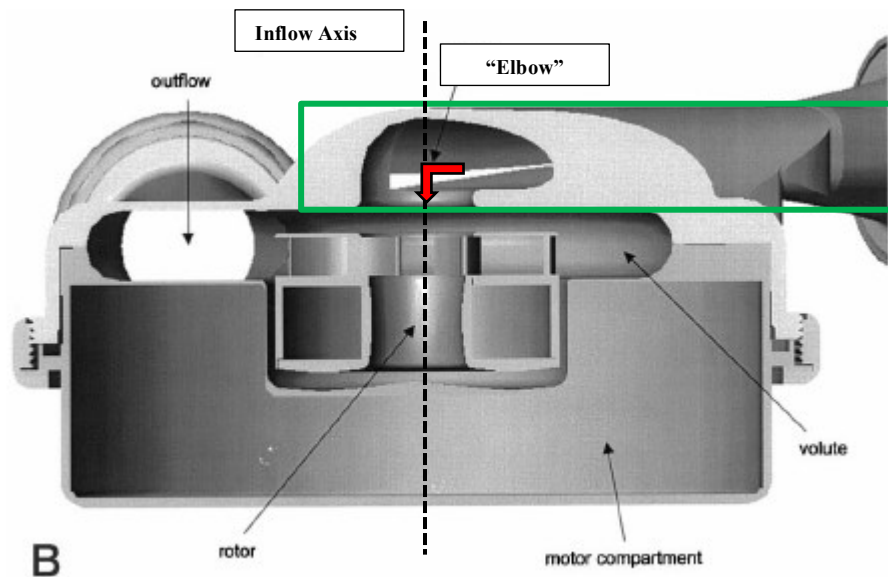
8. Motivation to Combine Bourque-2001 with Wampler-169

It would have been obvious to include Wampler-169’s techniques related to its use of *an inflow tube defining a blood inflow path along an inflow axis* in the Bourque-2001 HeartMate III as explained below. Ex.1003, ¶411.

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, ¶412; Ex.1008, [0075]-[0076]; Ex.1007, 402.

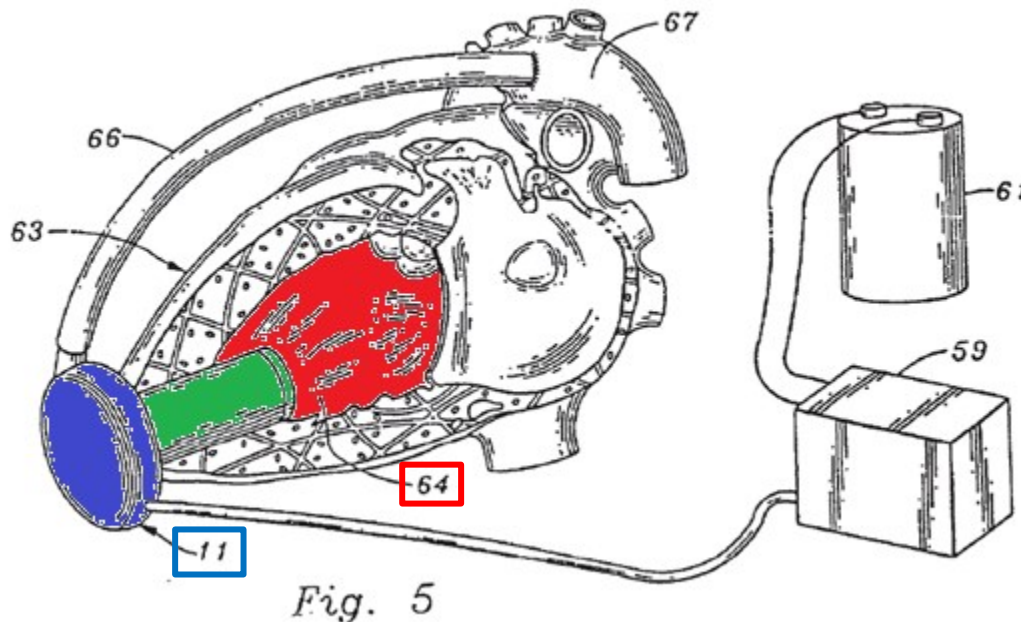
The HeartMate III’s *inflow tube* (“inflow subassembly”), however, also comprises an “elbow”—“a sharp bend in the flow before it enters the impeller”—as shown by **red** arrow:



Ex.1007, Fig. 1B, 402; Ex.1003, ¶¶416-417 (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:



Ex.1008, Fig. 5. Ex.1003, ¶417. 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 *along an inflow axis* as expressly taught by Wampler-169 for several reasons. Ex.1003, ¶423.

Bourque-2001 and Wampler-169 are analogous art to the 879 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; 3:47-48; Ex.1007, 401; Ex.1008, [0006], [0018]. Ex.1003, ¶419. Bourque-2001 and Wampler-169 are reasonably pertinent to a problem described by the 879 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:23-28; Ex.1007, 401; Ex.1008, [0101]. Ex.1003, ¶420.

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, ¶421.

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, ¶¶422-423; 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, ¶423.

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, ¶¶417-423; 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, ¶423.

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:

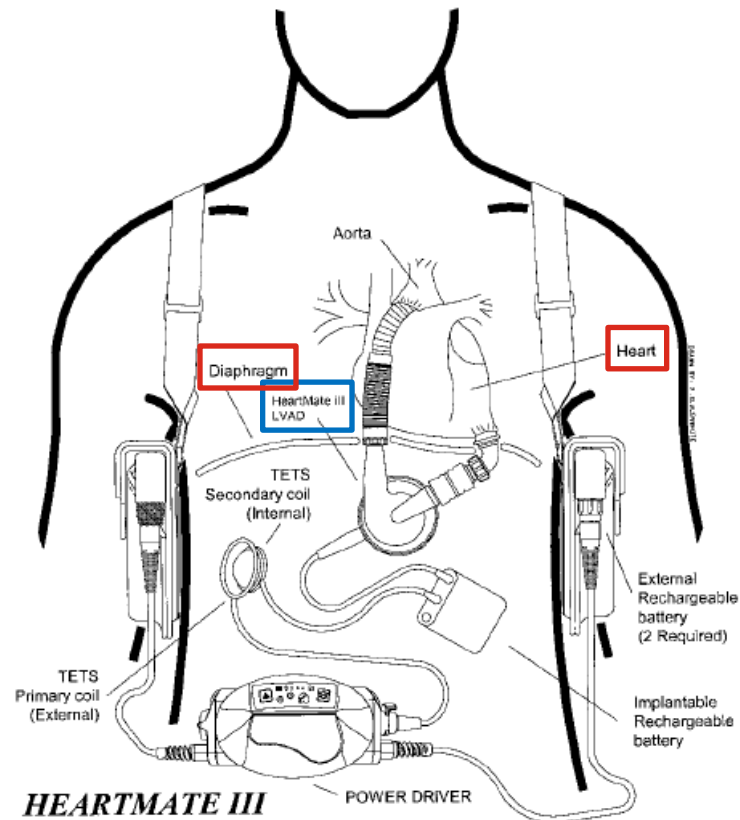


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶424. 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, ¶425.

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:

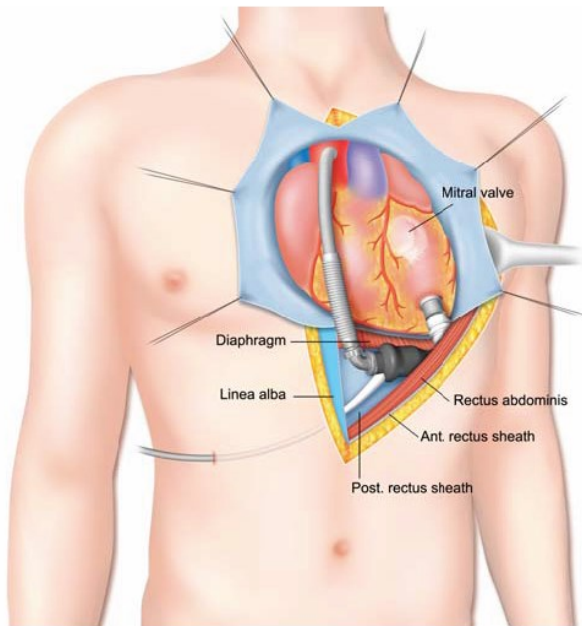


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

Ex.1013, 25; Ex.1003, ¶424 (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, ¶424. 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, ¶¶425-428.

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, ¶¶426-429 (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, ¶430. 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, ¶430.

Accordingly, it would have been obvious to modify Bourque-2001's pump to include Wampler's techniques to use of an *inflow tube defining a blood inflow path along an inflow axis* to yield the Bourque-2001/Wampler-169 combination. Ex.1003, ¶431; *see also* ¶¶411-430.

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

1. Claim 11

i. [11PRE]

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:

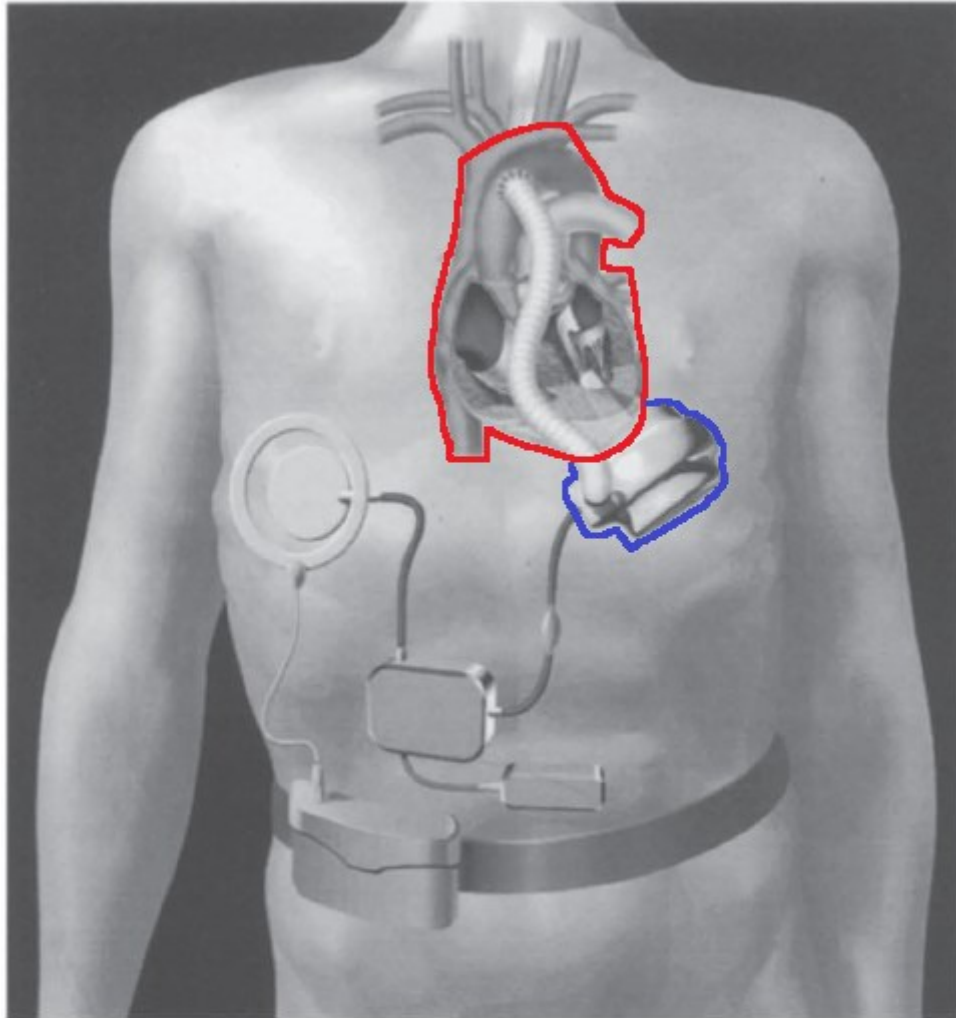


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶433.

Accordingly, Akamatsu-1999 discloses “a system for assisting blood circulation of a **heart** in a body.” Ex.1003, ¶434.

ii. [11A]

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

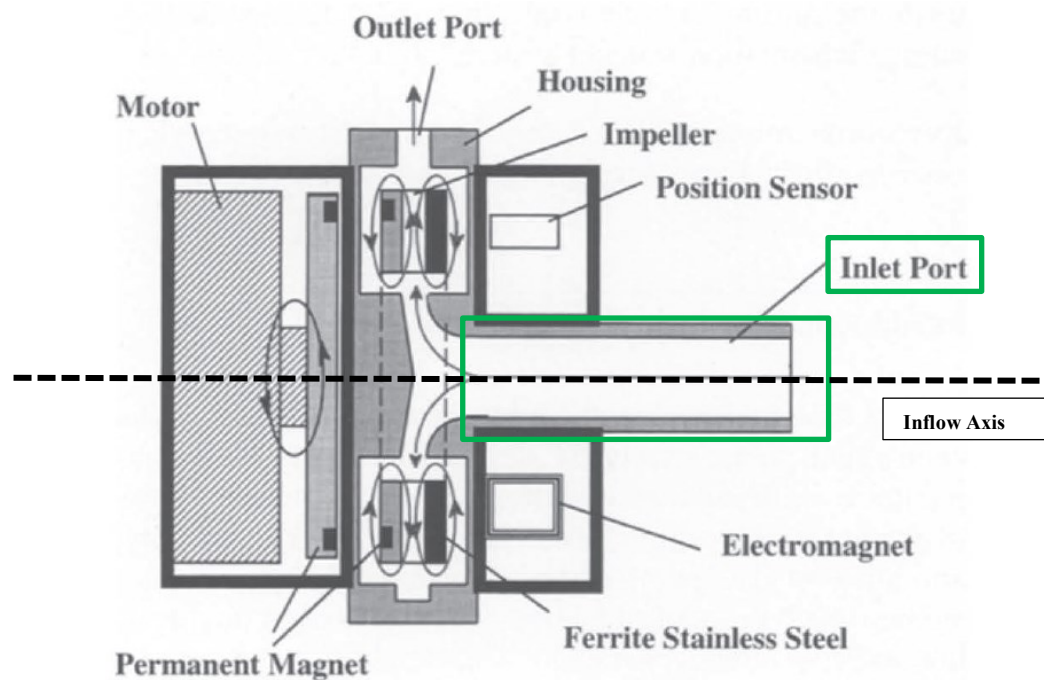


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶439.

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

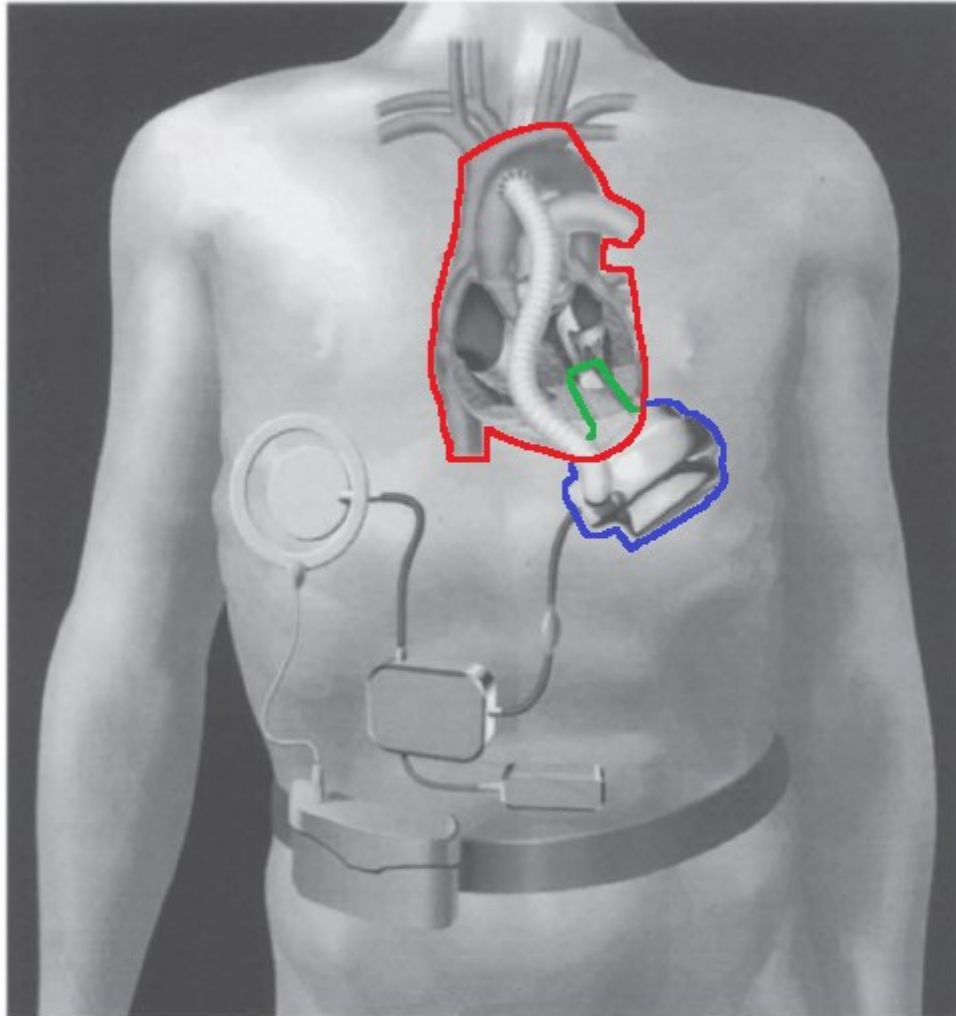


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶¶440.

Accordingly, Akamatsu-1999 discloses “a *heart assist pump device* (“centrifugal pump”) deliverable to the *heart* and comprising: an *inflow tube defining a blood inflow path* (“inlet port”) along an *inflow axis* and being insertable into a *left ventricle* (“inserted into the left ventricle”).” Ex.1003, ¶442.

iii. [11B]

Akamatsu-1999 discloses that its “**pump housing**” (“one or more walls”) defines a “**blood chamber**” (“a chamber”) (Ex.1006, 4) “to receive blood from the inflow tube”:

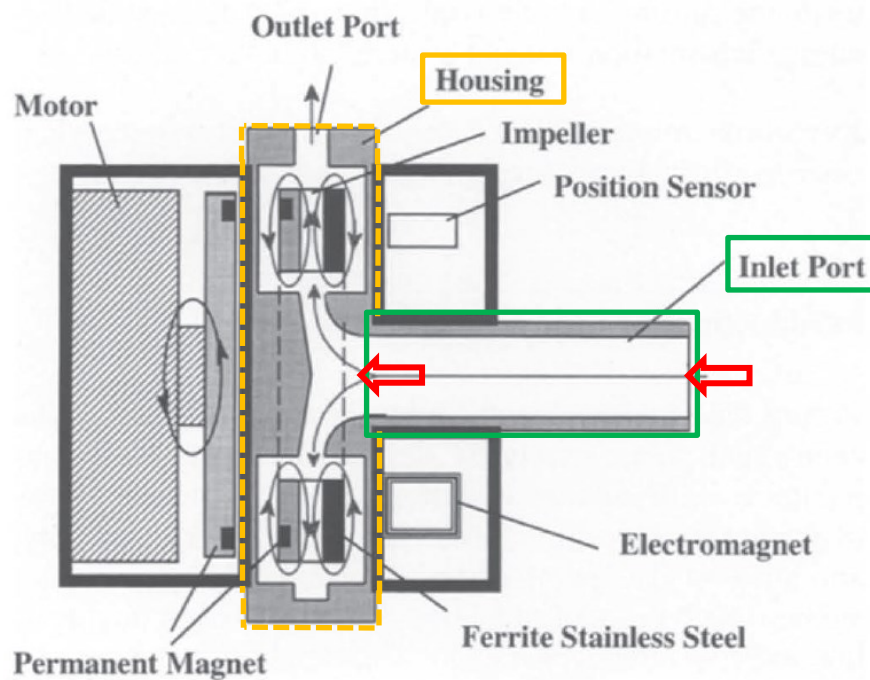
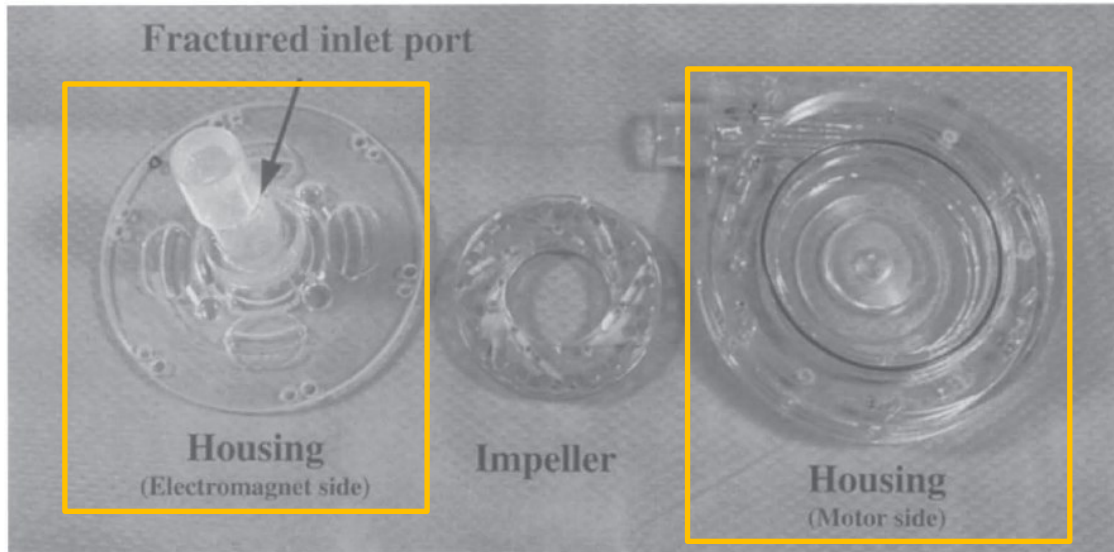


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶445.

Figure 5 depicts the impeller (*see* [11C]) and **pump housing**:



Ex.1006, Fig. 5.

Accordingly, Akamatsu-1999 discloses “*one or more walls at least partially defining a chamber* (“pump housing”) *to receive blood from the inflow tube* (“inlet port”).” Ex.1003, ¶448.

iv. [11C]

Akamatsu-1999 discloses that its pump comprises an “**impeller** inside the pump” (Ex.1006, 3), and that “the **impeller** rotates by a magnetic coupling” (“*a magnetically driven rotor*”). Ex.1006, 4. By virtue of Akamatsu-1999’s “centrifugal” design, its “**impeller**” is “*axially aligned with the*” “**inlet port**,” (Ex.1006, 3), as illustrated:

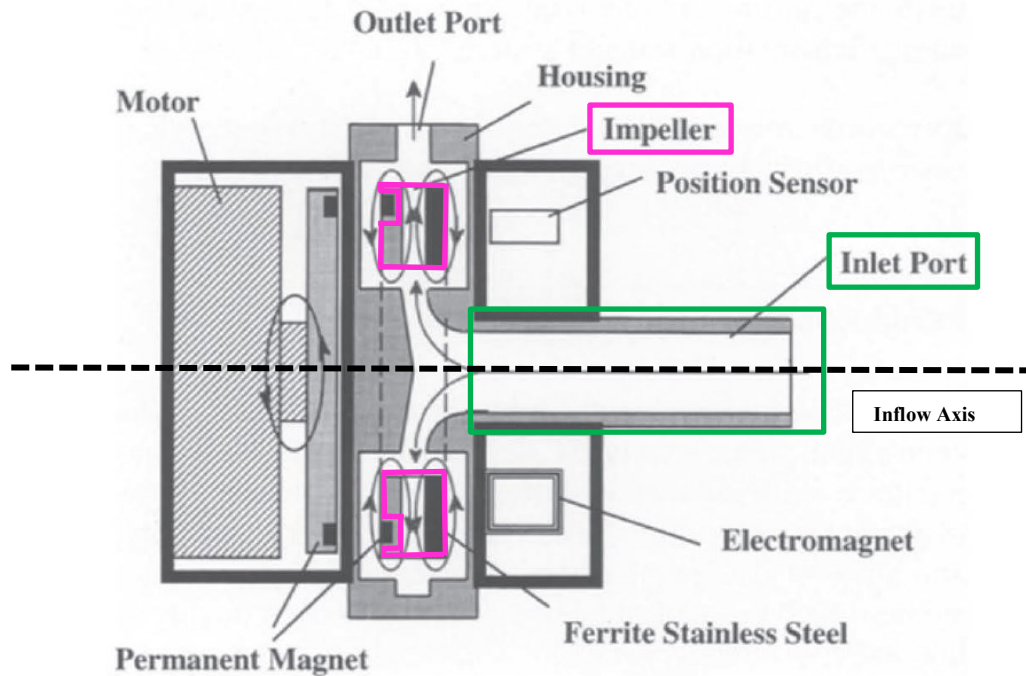


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2, Ex.1003, ¶457; Fig. 5 (photograph of “impeller”).

Accordingly, Akamatsu-1999 discloses a “*magnetically driven rotor*” (“impeller”) *axially aligned with the inflow axis* (“inlet port”)” Ex.1003, ¶459.

v. *[11D]*

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

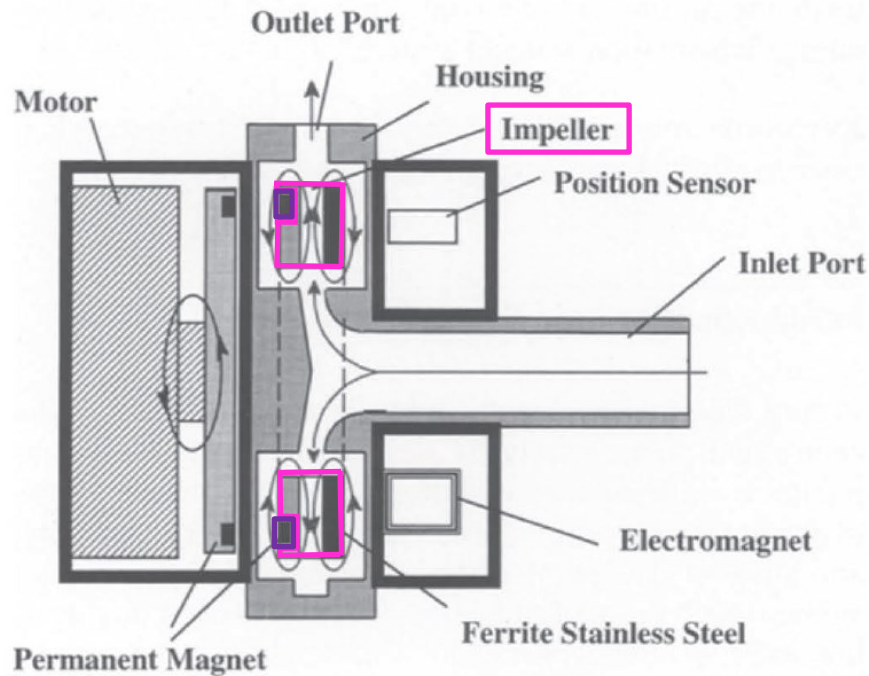


Fig. 2. Schematic cross section of the MSCP

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

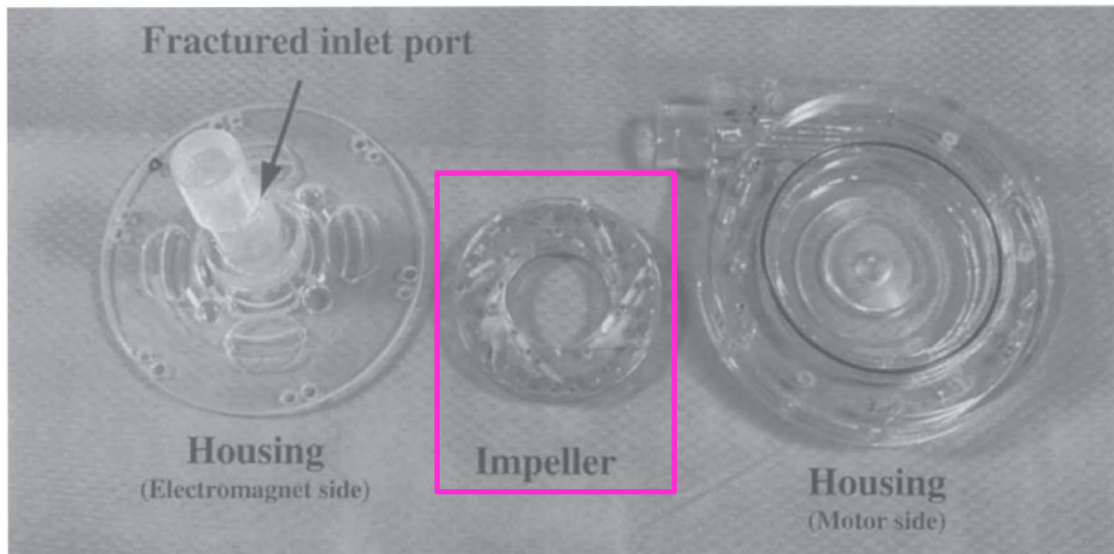


Fig. 5; Ex.1003, ¶¶463, 472.

Akamatsu-1999 further discloses that the “**impeller**” is “*axially adjacent*” to its “[p]ermanent [m]agnet,” which is “*axially aligned*” with the **inflow axis**:

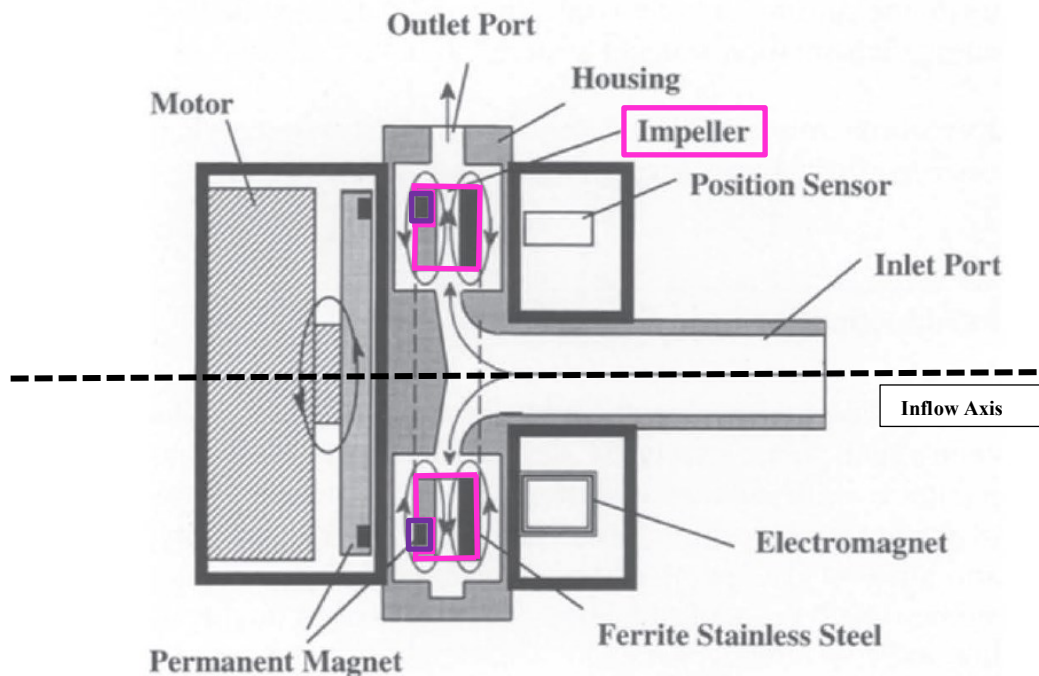


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; *see also* Figure 5 (impeller photo); Ex.1003, ¶463.

Accordingly, Akamatsu-1999 discloses the *magnetically driven rotor* (“impeller”) “*being rigidly coupled and axially adjacent to a first magnetic device* (impeller’s “permanent magnet”) *that is axially aligned with the inflow axis.*”

Ex.1003, ¶467.

vi. [11E]

Akamatsu-1999 discloses that the pump’s “**impeller** rotates” (“*being rotatable*”) “at the center” (“*about an axis of rotation aligned with the inflow axis*”)

to generate a “pump flow rate” (“*to drive the blood*”). Ex.1006, 4. Figure 2 illustrates the “*blood flowing from the*” “**inlet port**” (black arrows):

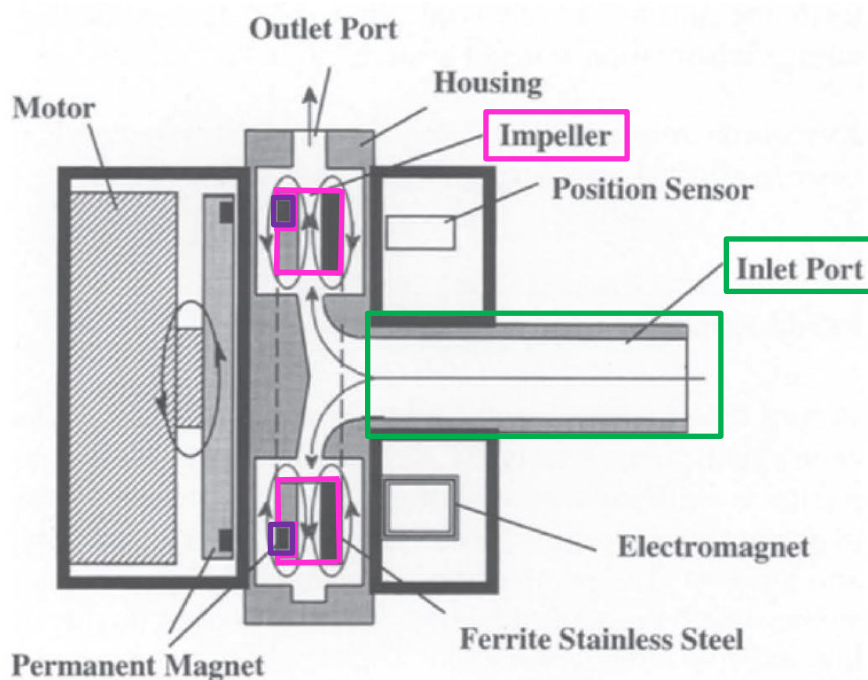


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶470-471.

Accordingly, Akamatsu-1999 discloses “*the magnetically driven rotor*” (“impeller”) and *first magnetic device* (impeller’s “permanent magnet”) being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the **inflow tube** (“inlet port”).” Ex.1003, ¶473.

vii. [11F]

Akamatsu-1999 discloses that its **pump** is “driven” (Ex.1006, 5) by a “**motor**” (“*magnetic drive system*”) that rotates “by a magnetic coupling” a “[p]ermanent

[m]agnet” (“a second magnetic device”), (Ex.1006, 4), which is also *axially aligned with the inflow axis of inlet port*”:

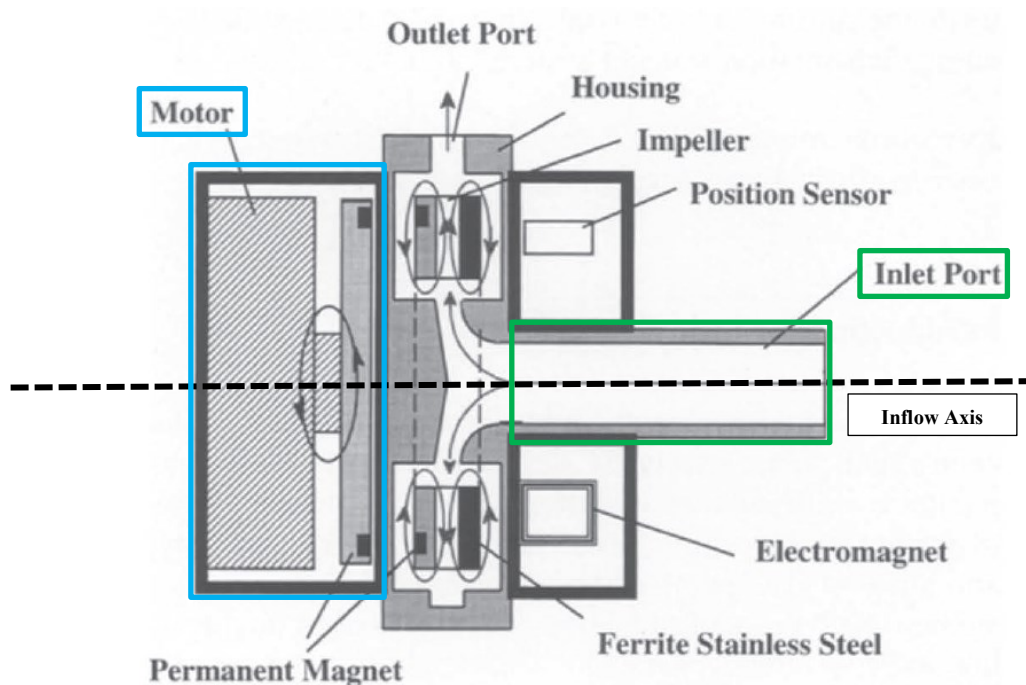


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶479.

Accordingly, Akamatsu-1999 teaches or suggests “a magnetic drive system (“motor”) comprising a **second magnetic device** (motor’s “permanent magnet”) *axially aligned with the inflow axis.*” Ex.1003, ¶480.

viii. [11G]

Akamatsu-1999 discloses that the **motor’s permanent magnet** and the “suspended **impeller**...operate[] completely contact-free” (“*spaced apart*”). Ex.1006, 6. As demonstrated in [11B], a wall of the “**pump housing**” defining the

“**blood chamber**” is “*positioned between*” the **motor** and **impeller** as indicated by the solid black line separating the two:

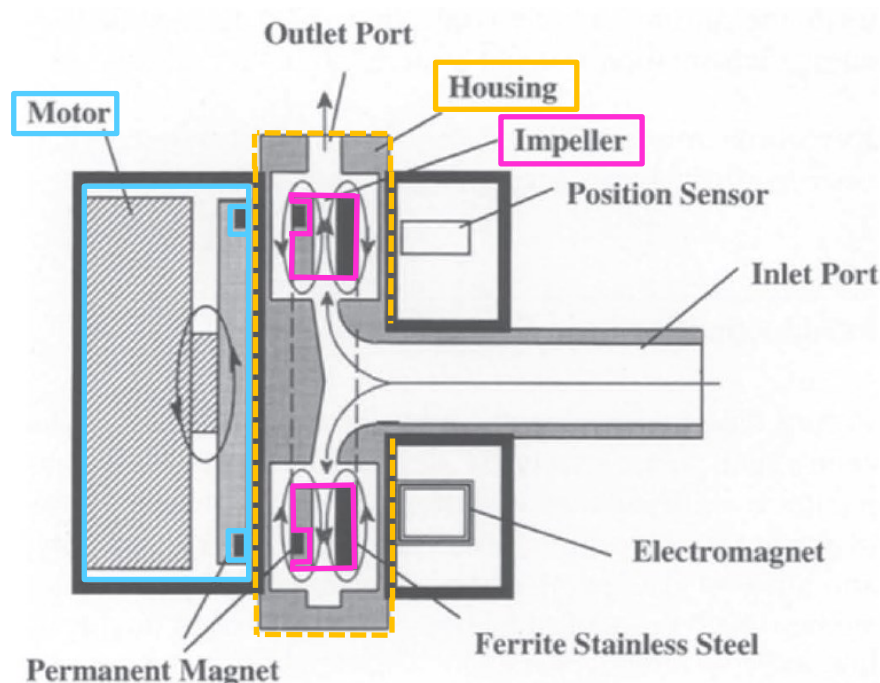


Fig. 2. Schematic cross section of the MSCP

Ex.1006, 4 Fig. 2; *see also* Fig. 5 (depicting motor housing); Ex.1003, ¶485. Akamatsu-1999 also discloses sealing the chamber to prevent “leakage of blood into the...motor.” Ex.1006, 5; Ex.1003, ¶537.

Accordingly, Akamatsu-1999 discloses the **second magnetic device** (motor’s “permanent magnet”) “*spaced apart from the magnetically driven rotor* (“impeller”) *such that a wall of the one or more walls defining the chamber* (“pump housing”) *is positioned between the magnetically driven rotor and the second magnetic device.*” Ex.1003, ¶486.

ix. [11H]

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. The “magnetic coupling between the impeller and the motor” (Ex.1006, 4) is achieved by positioning the motor’s “**permanent magnet**” “*axially closer*” to the impeller’s “**permanent magnet**” “*to magnetically drive rotation*” of the “**impeller**”:

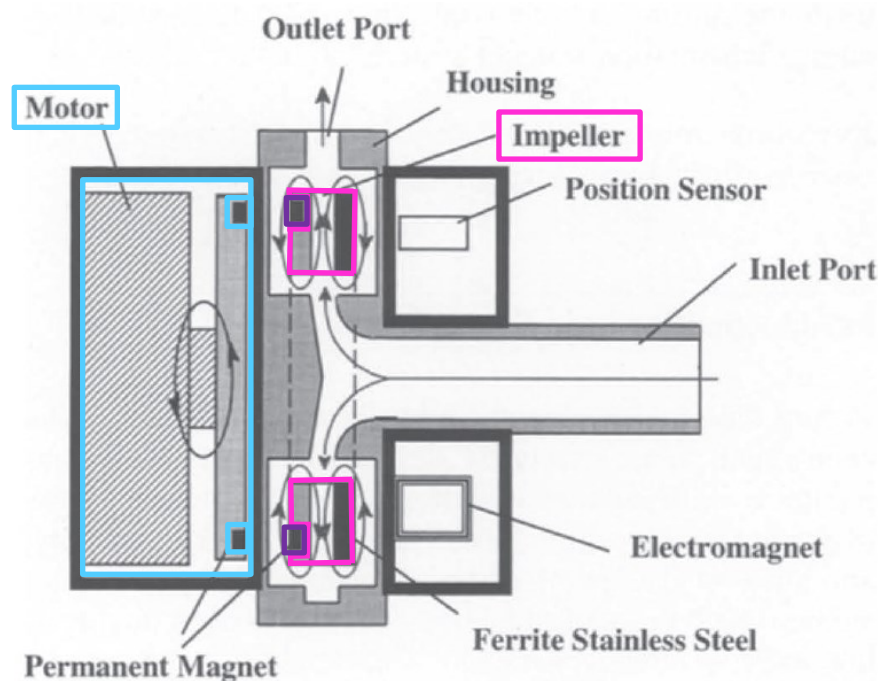


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶489-493. Thus, the **impeller** rotates “*relative to*” the “**pump housing**.” Ex.1006, 4.

Accordingly, Akamatsu-1999 discloses the “*second magnetic device* (motor’s “permanent magnet”) *positioned axially closer to the first magnetic device* (impeller’s “permanent magnet”) *than to the magnetically driven rotor* (“impeller”) *so as to magnetically drive rotation of the magnetically driven rotor* (“impeller”) *relative to the one or more walls* (“pump housing”) *via a magneto coupling with the first magnetic device* (impeller’s “permanent magnet”).” Ex.1003, ¶496.

x. [11I]

Akamatsu-1999 discloses an “outflow conduit” or “*outlet port*” (a blood outflow port), (Ex.1006, 4), which Figure 2 illustrates (black arrow) is *positioned such that blood driven by the impeller exits the “blood chamber”* formed by the *housing* in a direction substantially perpendicular to the *inlet port*:

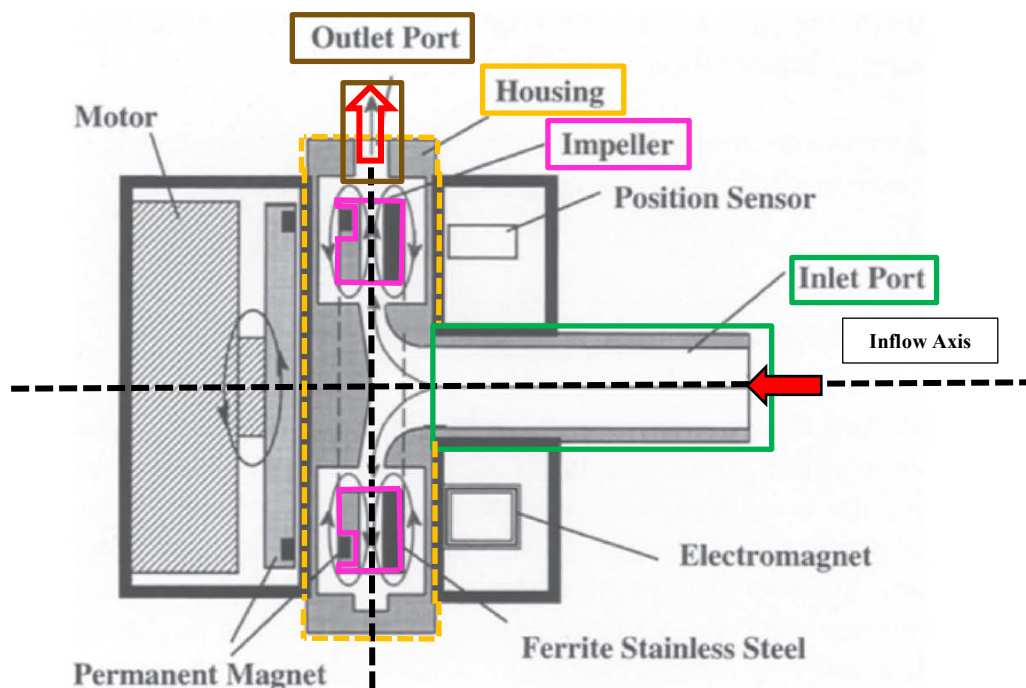


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2. Ex.1003, ¶502.

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

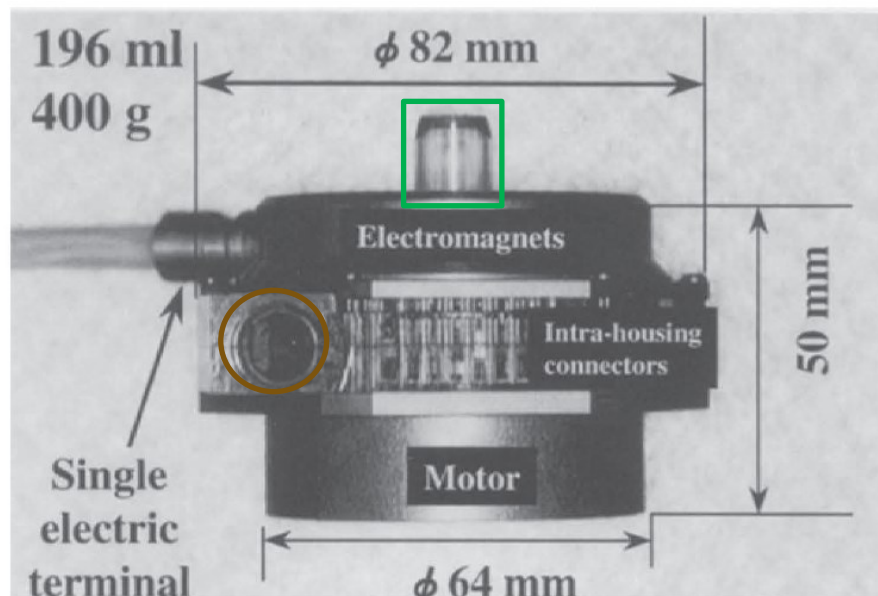


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3; Ex.1003, ¶¶503-504.

Accordingly, Akamatsu-1999 discloses “a **blood outflow port** (“outlet port”) positioned such that the blood driven by the **magnetically driven rotor** (“impeller”) exits the **chamber** (“housing”) in a direction substantially perpendicular to the **inflow axis**.” Ex.1003, ¶505.

xi. [11J]

In Parallel Litigation, PO asserts that a magnetic bearing (i.e., “MagLev”) satisfies this limitation. Ex.1019, 10-11.

Assuming that interpretation, as explained in [11H], Akamatsu-1999 discloses that the “**impeller** is suspended by a magnetic bearing” (“*magneto coupling orients the magnetically driven rotor*”) (Ex.1006, 3) and “rotates by a magnetic coupling,” thereby “providing contact-free rotation” from the **housing** (“*remain spaced apart from the one or more walls*”), (Ex.1006, 4), which Figure 2 illustrates (black arrow) allows for the “*the blood in response to rotation of the*” **impeller** to exit:

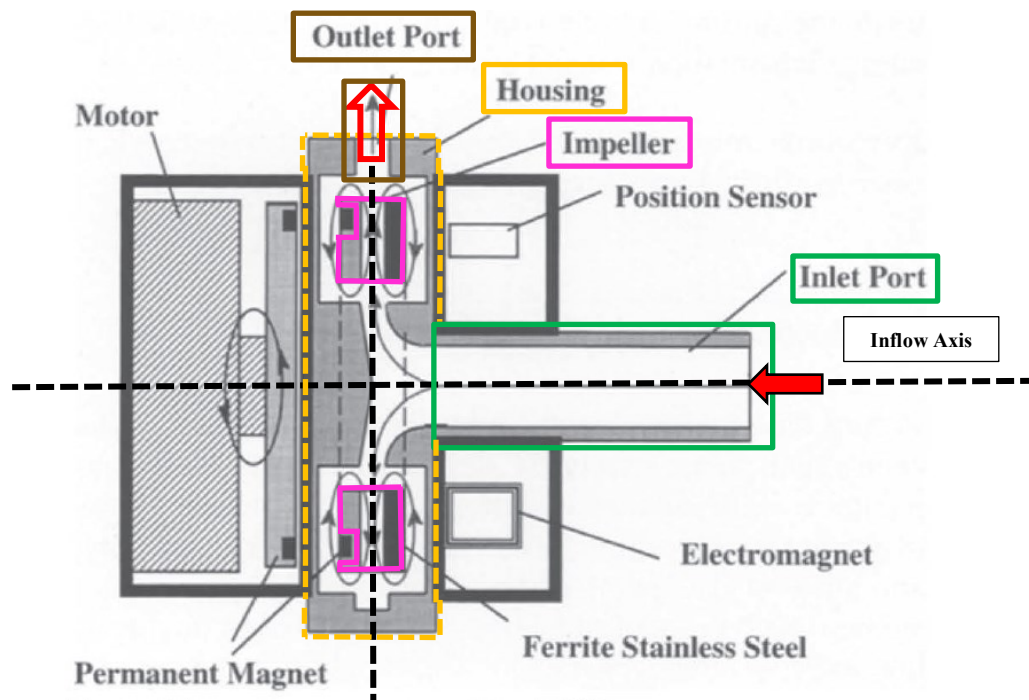


Fig. 2. Schematic cross section of the MSCP

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

Accordingly, Akamatsu-1999 discloses that “*the magneto coupling orients the magnetically driven rotor* (“impeller”) *so that both the magnetically driven rotor and the first magnetic device* (impeller’s “permanent magnet”) *remain spaced apart from the one or more walls* (“pump housing”) *by the blood in response to rotation of the magnetically driven rotor.*” Ex.1003, ¶512.

xii. [11K]

Akamatsu-1999 teaches or suggests a **controller** (worn externally in Figure 1) (“*an external control unit*”) so that “[t]he pump was operated at a fixed rotational speed” (“*to control operation...to thereby magnetically drive the rotation*”), (Ex.1006, 4):

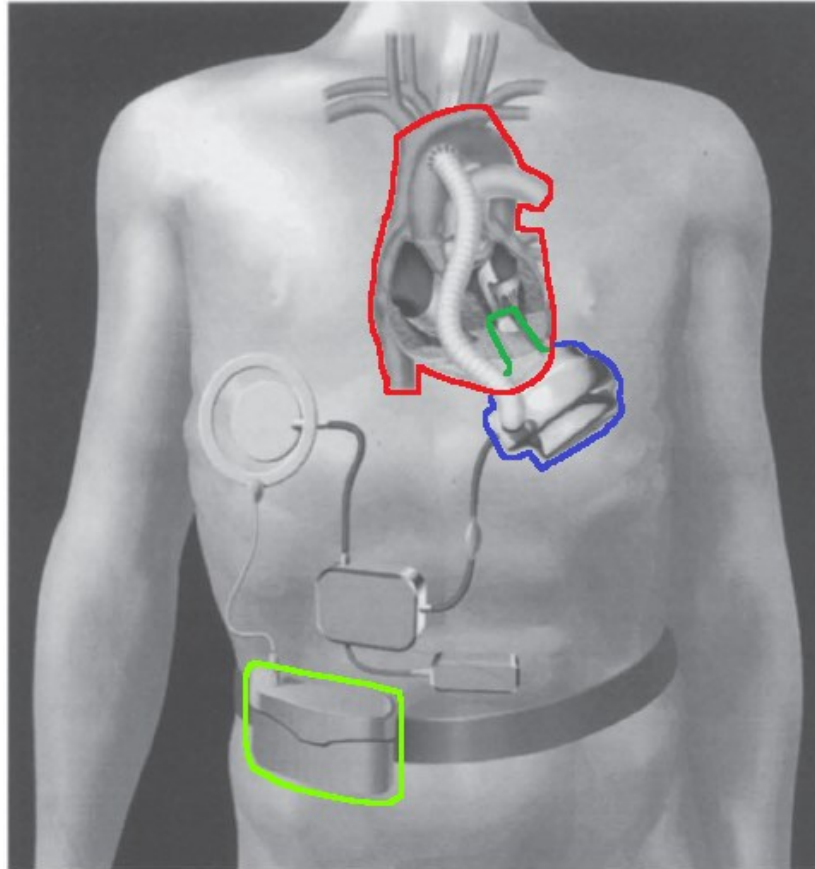


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶511.

Akamatsu-1999 discusses a “**next phase**” “**Model III** pump” with “an **implantable** controller and a transcutaneous energy/information transfer system.”

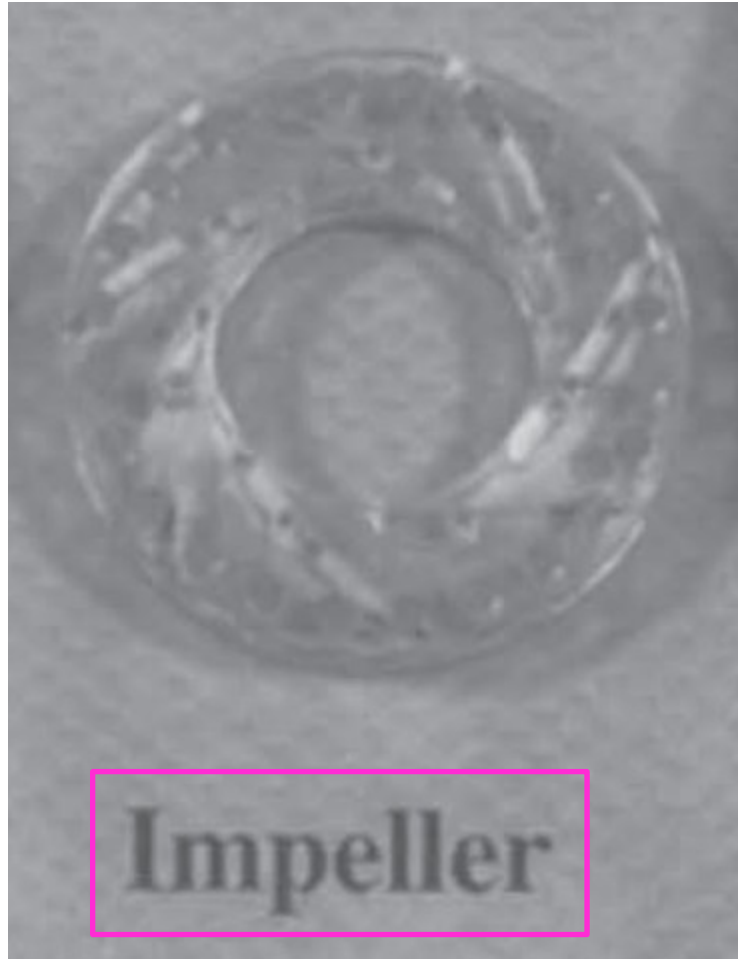
Ex.1006, 3. “The **Model II** pump,” however, which was the focus of the studies described in Akamatsu-1999, “was percutaneously driven” (i.e., externally controlled). Ex.1003, ¶665.

Akamatsu-1999 further discloses a “**controller**” to “*control operation of*” the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” (“*a fixed value*”). Ex.1006, 3-4; Ex.1003, ¶515.

Accordingly, Akamatsu-1999 teaches or suggests “*an external control unit* (‘‘controller’’) *configured to control operation of the second magnetic device* (motor’s ‘‘permanent magnet’’) *based on a fixed value* (‘‘fixed rotational speed’’) *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, ¶518.

2. Claim 12

Akamatsu-1999 discloses in Figure 5 that its “**impeller**” has blades or edges, which Mr. Crosby explains are *guide surfaces* (Ex.1003, ¶¶520-522):



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, ¶523.

Accordingly, Akamatsu-1999 teaches or suggests that the “*magnetically driven rotor*” (“impeller”) *includes a guide surface to produce centrifugal flow components.*” Ex.1003, ¶524.

3. Claims 14-15

As demonstrated in [11G] and [11J], the “suspended **impeller**...operates completely contact-free” from the **housing** and “*remain[s] spaced apart from the*

one or more walls by the blood.” *Supra* [11G] and [11J]; Ex.1006, 6. For the same reasons as “providing contact-free rotation” (Ex.1006, 3), a “gap configured to be occupied by the blood” separates the **impeller** from the **housing** “when the [**motor**] drives the rotation” of the **impeller**:

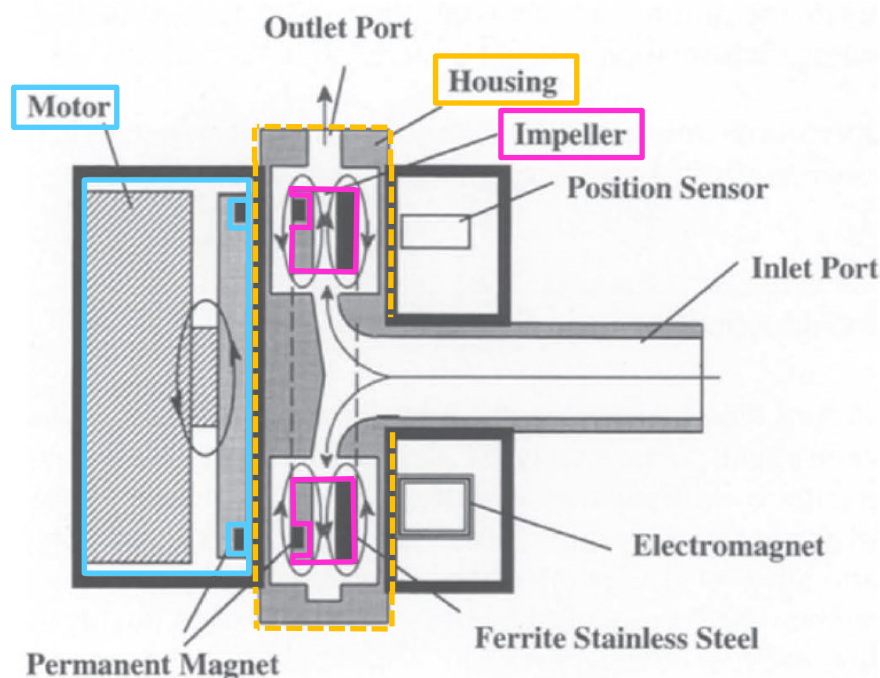


Fig. 2. Schematic cross section of the MSCP

Ex.1006, 4 Fig. 2. The black arrows leading from Figure 2’s inlet, around the **impeller**, and exiting the outlet illustrate the “gap...occupied by the blood.” Ex.1003 ¶529.

Accordingly, *Akamatsu-1999* discloses “*one or more walls* (“pump housing”) and the *magnetically driven rotor* (“impeller”) define a gap separating the *magnetically driven rotor* (“impeller”) from the *one or more walls*, the gap configured to be occupied by the blood when the *second magnetic device* (motor’s

“permanent magnet”) drives the rotation of the *magnetically driven rotor*...wherein the gap surrounds the *magnetically driven rotor* (“impeller”).” Ex.1003, ¶530.

4. Claim 16

As demonstrated in [11I] and [15], “at least part of the gap” that separates the *impeller* from the *housing* “extends along a first axis substantially perpendicular to the *inflow axis*,” allowing the blood to exit via the outlet port:

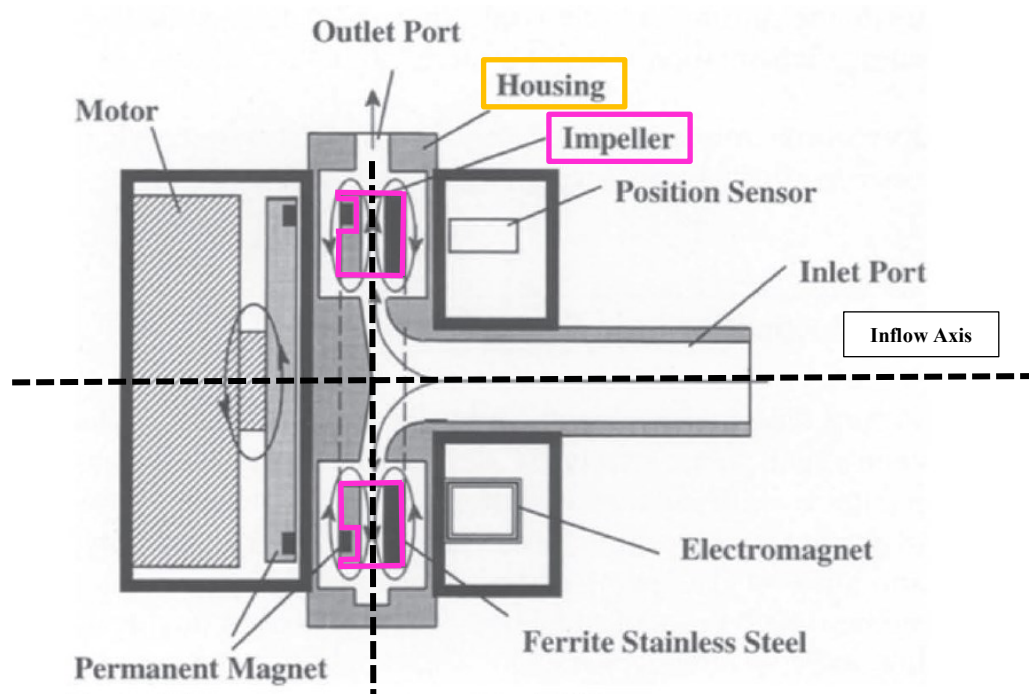


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶533.

Accordingly, Akamatsu-1999 discloses “at least part of the gap extends along a first axis substantially perpendicular to the *inflow axis* (“inlet port”).” Ex.1003, ¶534.

5. Claim 18

As demonstrated in [11B] and [11G], the **impeller** is positioned in the “**blood chamber**” (“a chamber”) of the “**pump housing**” (“one or more walls”), while the **motor** is positioned within a separate compartment (“a second chamber”), as indicated by the solid black line separating the below:

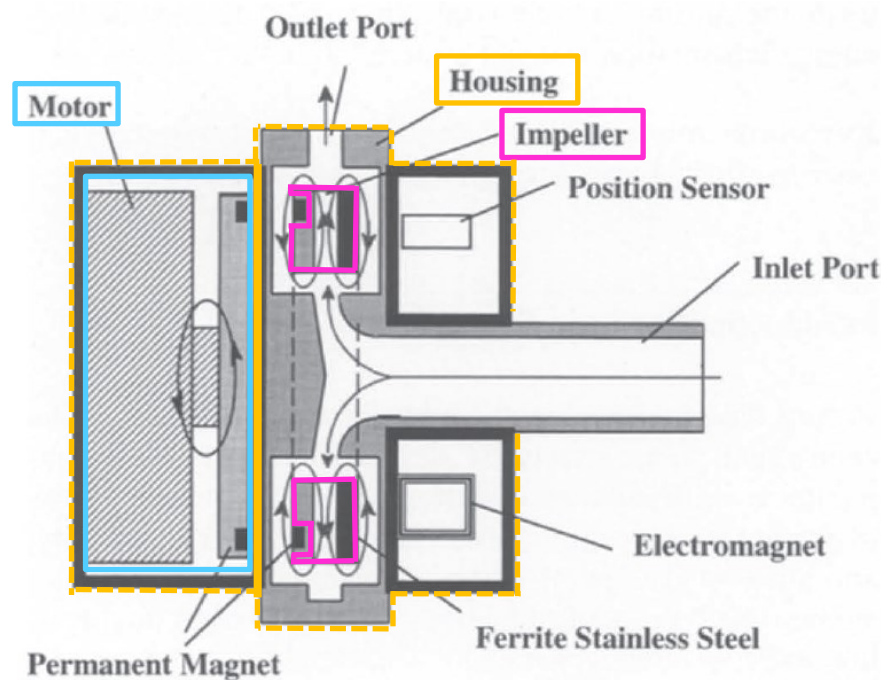


Fig. 2. Schematic cross section of the MSCP

Ex.1006, 4 Fig. 2; *see also* Fig. 5 (depicting motor housing); Ex.1003, ¶537. Akamatsu-1999 also discloses sealing the device to prevent “leakage of blood into the...motor.” Ex.1006, 5; Ex.1003, ¶537.

Accordingly, Akamatsu-1999 discloses “the **chamber** is a first chamber (“blood chamber”) within which the **magnetically driven rotor** (“impeller”) is positioned, and the **magnetic drive system** (motor’s “permanent magnet”) is

positioned within a second chamber (see Figure 2) sealed from the first chamber.”

Ex.1003, ¶538.

6. Claim 19

As demonstrated in [18], Akamatsu-1999 discloses that “*the wall of the **one or more walls** (“pump housing”) separates the first chamber from the second chamber.*” Ex.1003, ¶541.

7. Claims 1-2, 4-5, 7-8, 20

Claims 1, 2, 4-5, 7-8, and 20 recite elements that are identical or analogous in scope to the claims above, with exceptions noted below, and are except for the claim elements discussed below, thus, rendered obvious for the same reasons, as incorporated below. Ex.1005, ¶¶543-545.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 3
[1PRE]	[11PRE]	§VIII.C.1.i
[1A]	[11A]	§VIII.C.1.ii
[1B]	[11C]	§VIII.C.5
[1C]	[11B], [11E]	§VIII.C.1.iii; §VIII.C.1.vi
[1D]	[11D]	§VIII.C.1.v
[1E]	[11F]	§VIII.C.1.vii
[1F]	[11H]	§VIII.C.1.ix

[1G]	[11G], [14]	§ VIII.C.1.viii; § VIII.C.3
[1H]	[11I]	§ VIII.C.1.x
[1I]	[11J]	§ VIII.C.1.xi
[1J]	[11K]	§ VIII.C.1.xii
[2]	[12]	§ VIII.C.2
[4]	[18], [19]	§ VIII.C.1.iii; § VIII.C.5-9
[5]	[14], [18]	§ VIII.C.7.i; § VIII.C.3; § VIII.C.5
[7]	[18]	§ VIII.C.5
[8]	[19]	§ VIII.C.6
[20]	[11k]	§ VIII.C.1.i

i. Claim 4

See [11B], [18]-[19]. Akamatsu-1999 further discloses “a sealing wall positioned between the [‘motor’] and the [‘impeller’]” to prevent “leakage of blood into the...motor.” Ex.1006, 5; Ex.1003, ¶544.

ii. Claim 20

See [11K], [18]-[19]. Akamatsu-1999 further that “[t]he pump was operated at a fixed rotational speed” and that “[a]ortic pressure and pump flow rate were continuously measured” (“based on a defined cardiac output”). Ex.1006, 4, 5. Ex.1003, ¶545.

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

1. Claim 11

i. [11PRE]

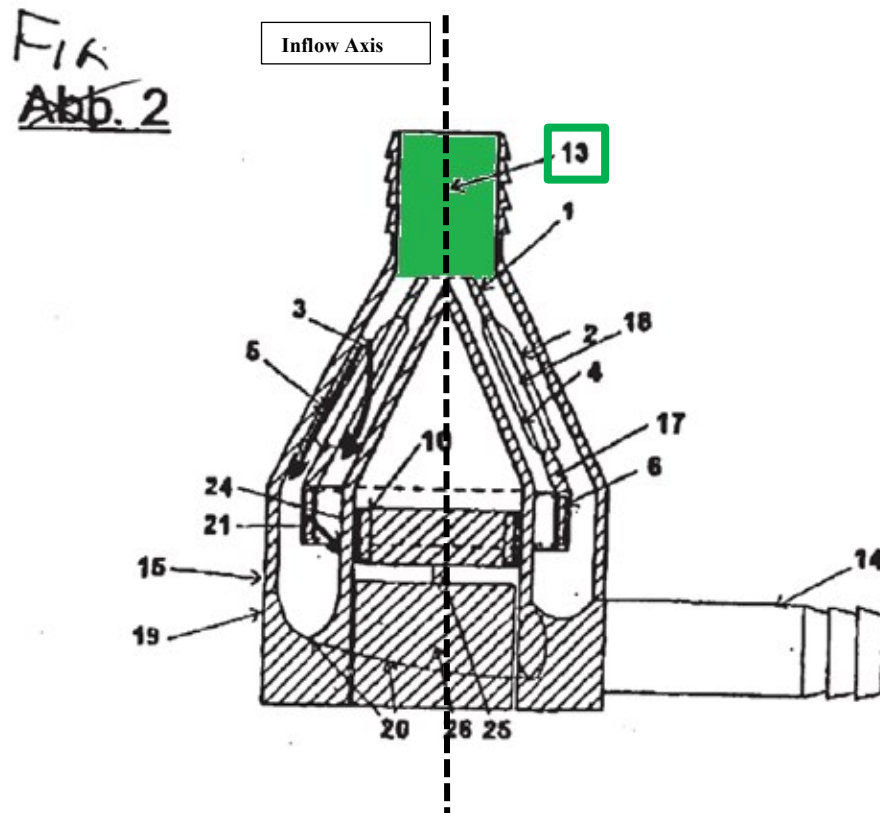
Schima discloses a “a rotary pump for moving blood [*“assisting blood circulation”*].” Ex.1005, [0001]; Ex.1003, ¶547.

Mr. Crosby explains a POSITA would recognize that Schima’s pump is “*for assisting ... a heart.*” *Infra* §VIII.D.8; Ex.1003, ¶548 (citing Ex.1005, [0004]-[0009]).

Accordingly, Schima teaches or suggests “*a system for assisting the blood circulation of a **heart** in a body.*” Ex.1003, ¶549.

ii. [11A]

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



Ex.1005, Fig. 2; Ex.1003, ¶552.

Mr. Crosby explains that the Schima/Akamatsu combination would have been obvious—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):

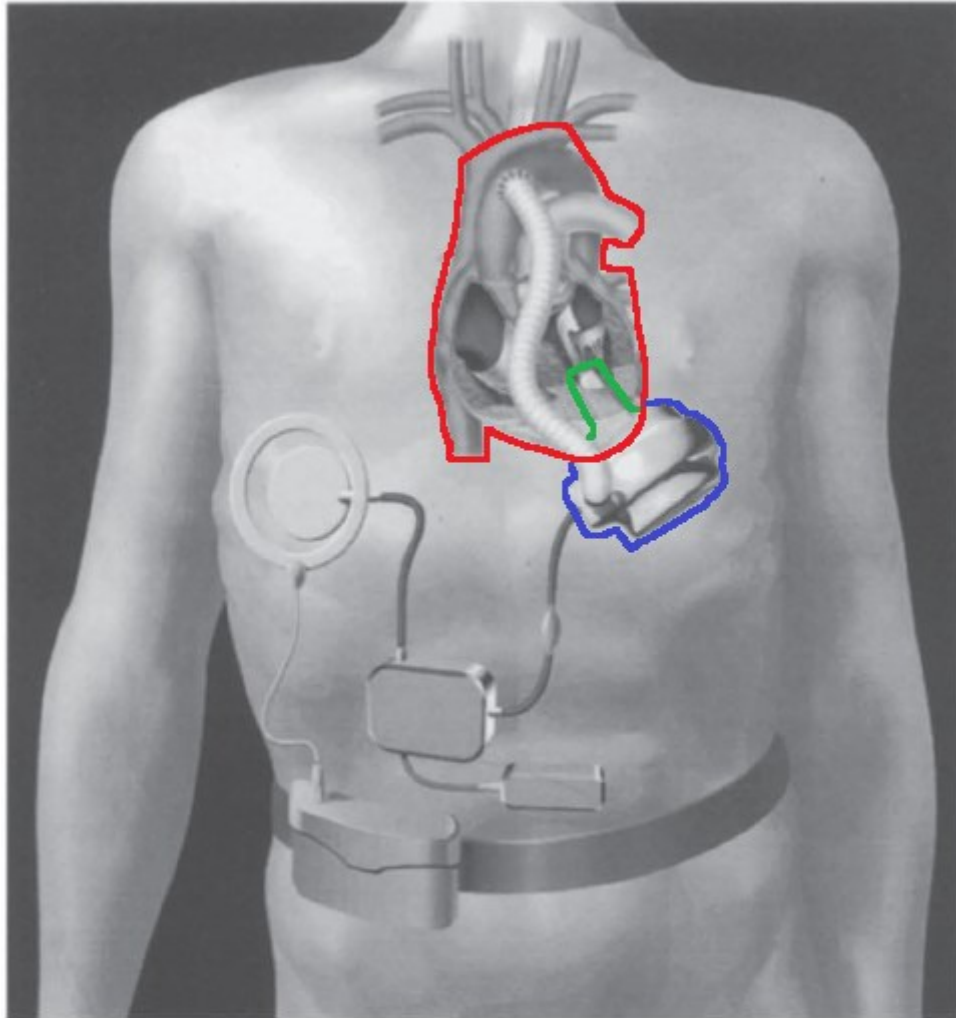


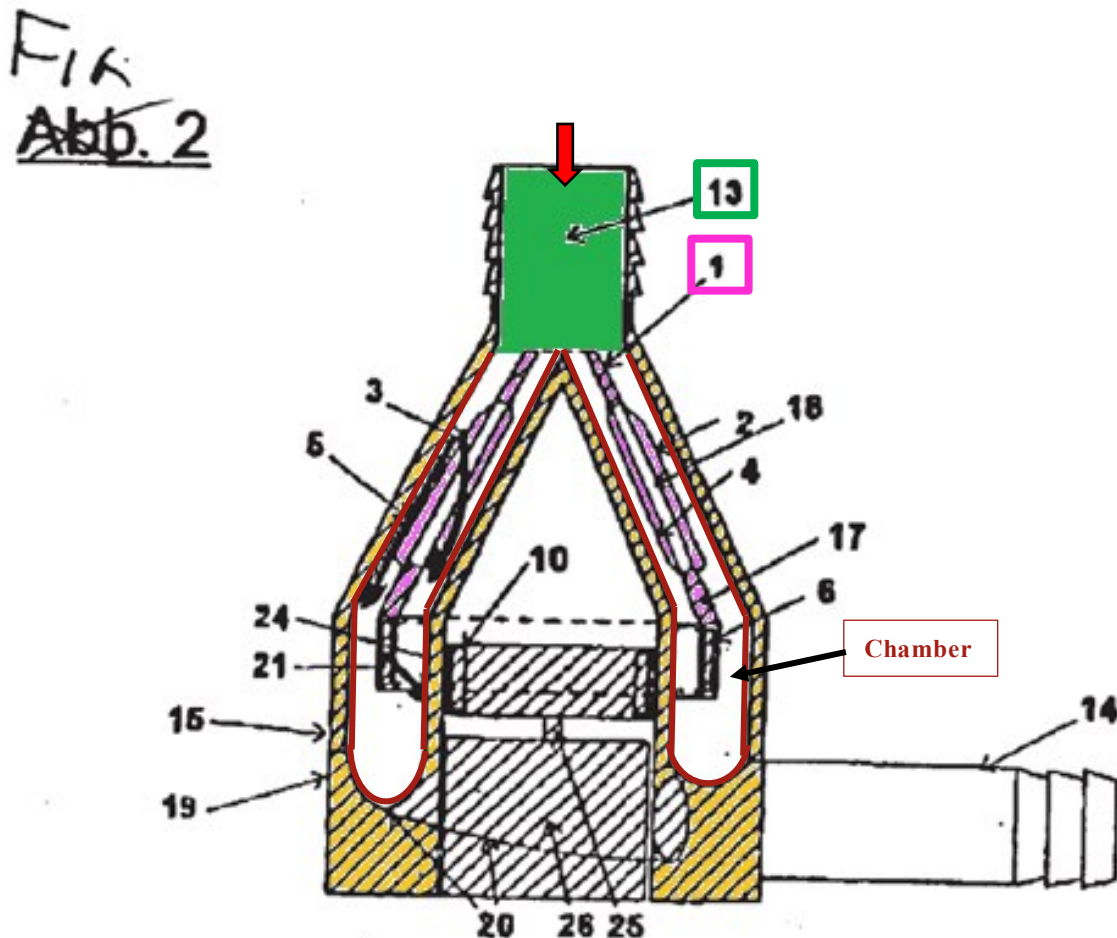
Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶562; *Infra* §VIII.D.8.

Accordingly, Schima, or Schima/Akamatsu-1999, renders obvious “a *heart assist pump device* (“pump”) deliverable to the *heart* and comprising: an *inflow tube defining a blood inflow path* (“inlet 13”) along an *inflow axis* and being insertable into a *left ventricle*.” Ex.1003, ¶564.

iii. [11B]

Schima discloses “a pump **housing 30** comprised of **a housing lower part 19** with **a conical middle part 16** and **a hollow conical upper part 15**” having **space** [‘one or more walls...defining a chamber’] “to receive blood from the” **inlet 13** (Ex.1005, [0012]):



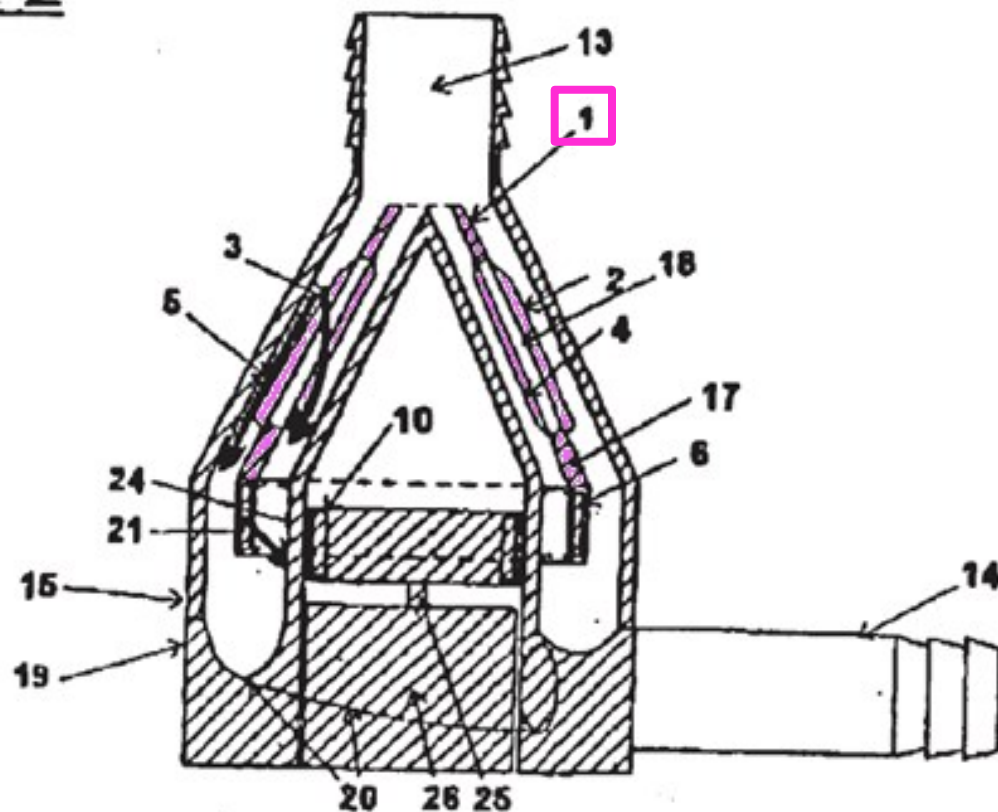
Ex.1005, Fig. 2 (conical middle part 16 labeled in Fig. 1); Fig. 1. Ex.1003, ¶567.

Accordingly, Schima discloses “*one or more walls* (“housing 30”) *at least partially defining a chamber* (space between “upper part 15” and “middle part 16”) *to receive blood from the inflow tube* (“inlet 13,” Ex.1005).” Ex.1003, ¶568.

iv. [11C]

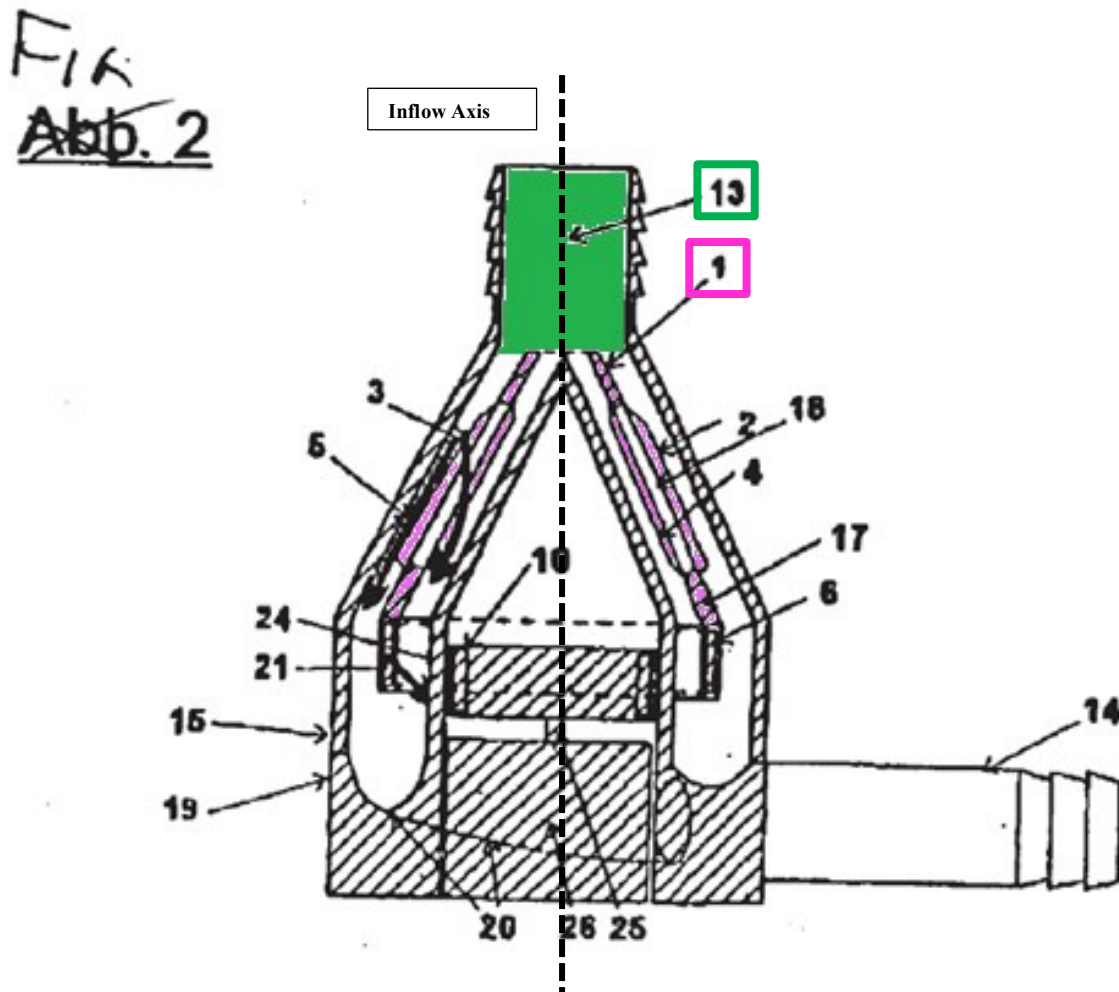
Schima discloses a “*rotor 1*” that “holds rotor magnets 6 that preferably transfer rotation energy” (“*magnetically driven rotor*”) (Ex.1005, [0012]; Ex.1003, ¶570):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶571.

Schima further discloses that its **rotor** is “axially aligned” with the **inflow axis** so that “flow [from *the inflow tube*]” is “preferably axially against” “the pump housing” which “serves to center the **rotor**” (Ex.1005, [0012]; Ex.1003, ¶573):

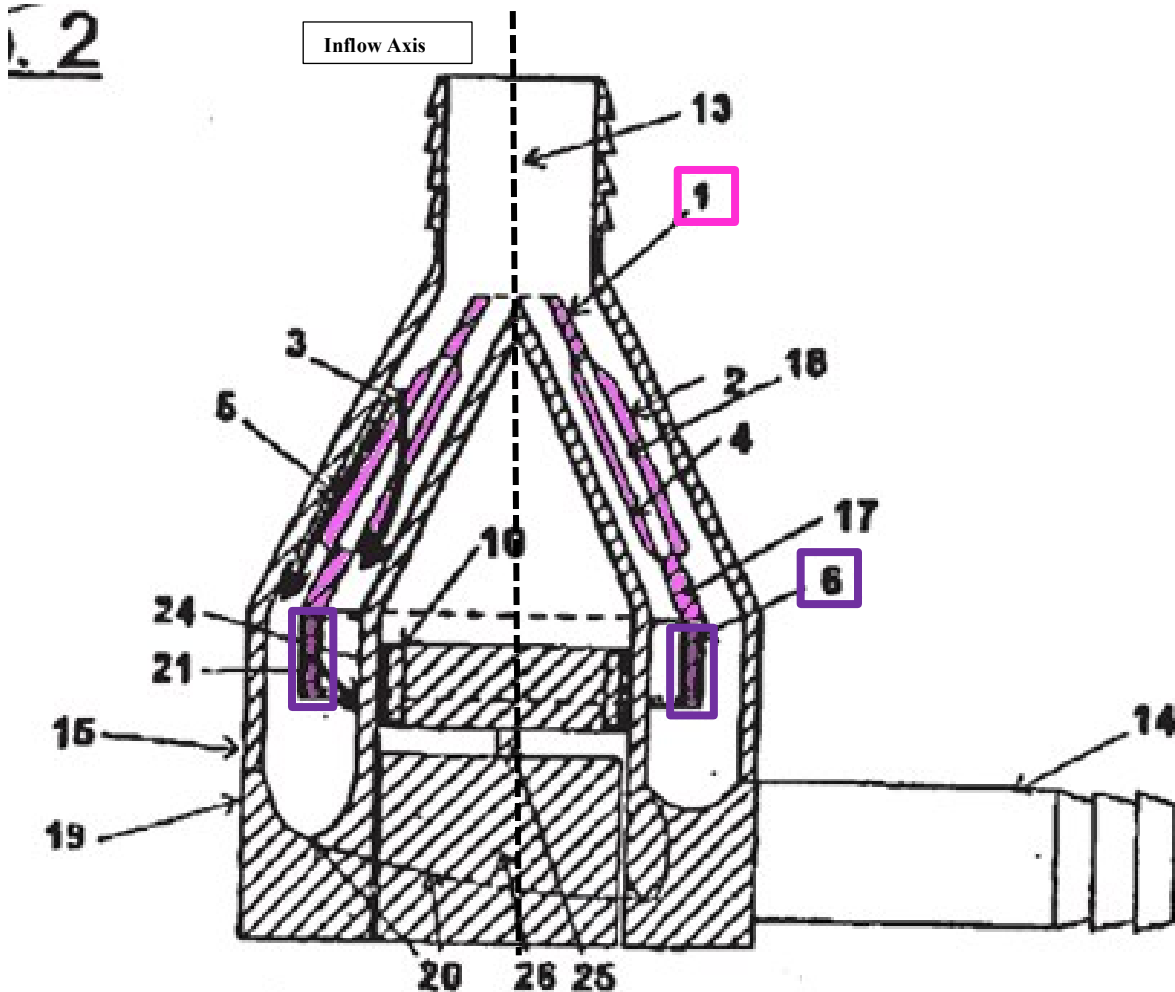


Ex.1005, Fig. 2; Ex.1003, ¶574.

Accordingly, Schima discloses “a **magnetically driven rotor** (“rotor 1”) axially aligned with the **inflow axis**.” Ex.1003, ¶576.

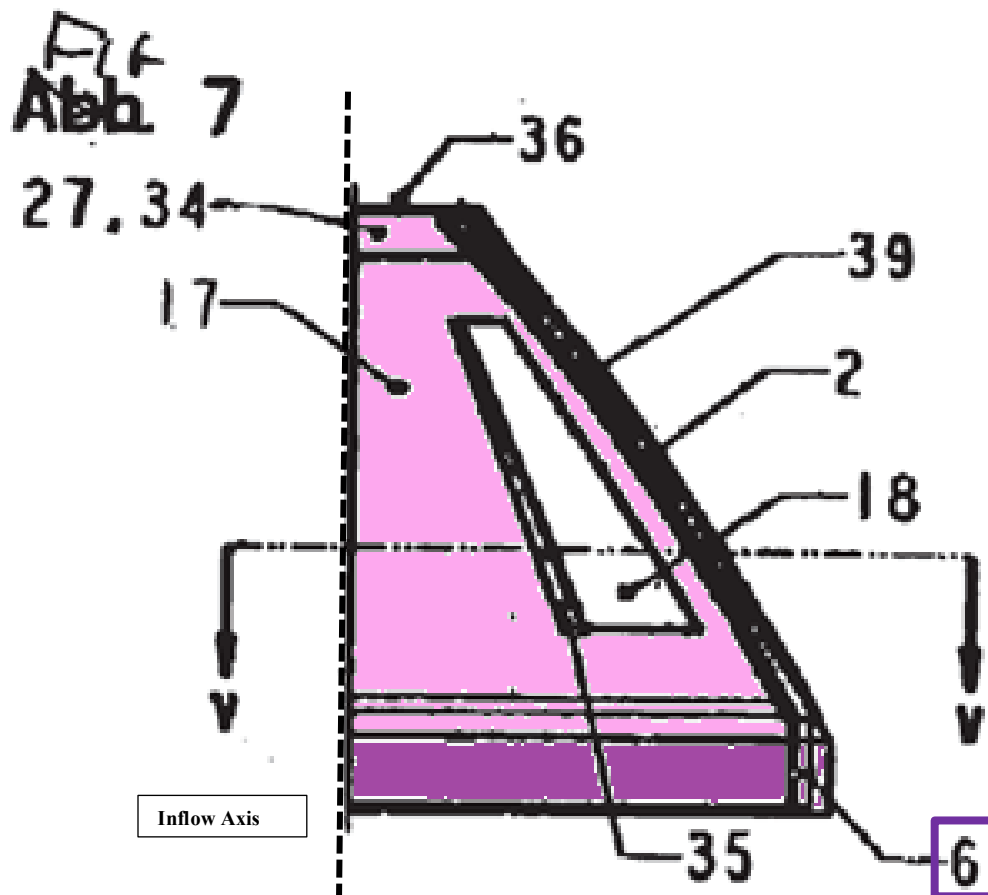
v. [11D]

Schima discloses that “[t]he **rotor** holds [*‘rigidly coupled to’*] **rotor magnets** 6 [*‘a first magnetic device’*]”:



Ex.1005, Fig. 2; Ex.1003, ¶580.

Figures 2 and 7 show that **rotor magnets 6** can be “formed by a continuous magnetic ring” (“*axially adjacent to...[and] axially aligned*”) centered with the *inflow axis*:



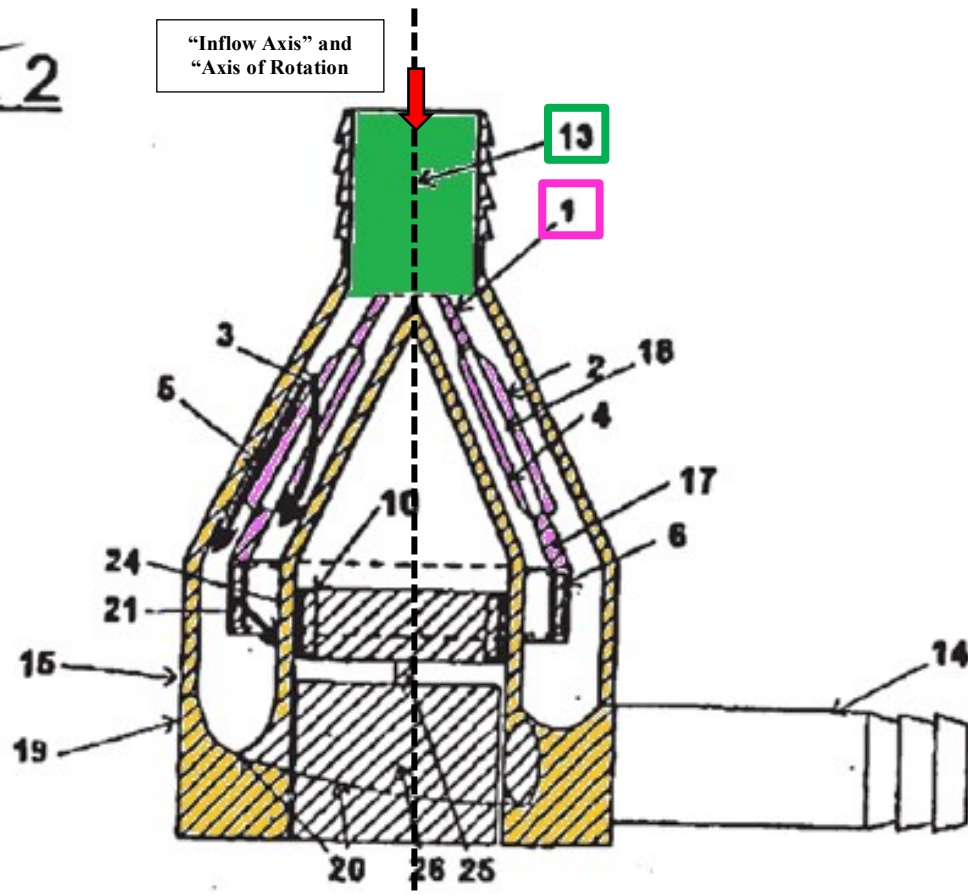
Ex.1005, [0012], Fig. 7; Ex.1003, ¶581.

Accordingly, Schima teaches or suggests the **magnetically driven rotor** (“rotor 1”) “being rigidly coupled and axially adjacent to a *first magnetic device* (“rotor magnets 6”) that is axially aligned with the *inflow axis*.” Ex.1003, ¶582.

vi. [11E]

Schima discloses that its “**rotor 1** rotates” (“rotatable about an axis of rotation”) and “**inlet 13**” “distributes the incoming liquid to both sides of the rotor” (“to drive the blood flowing from the inflow tube”) (Ex.1005, [0012]):

Fig.
Abb. 2



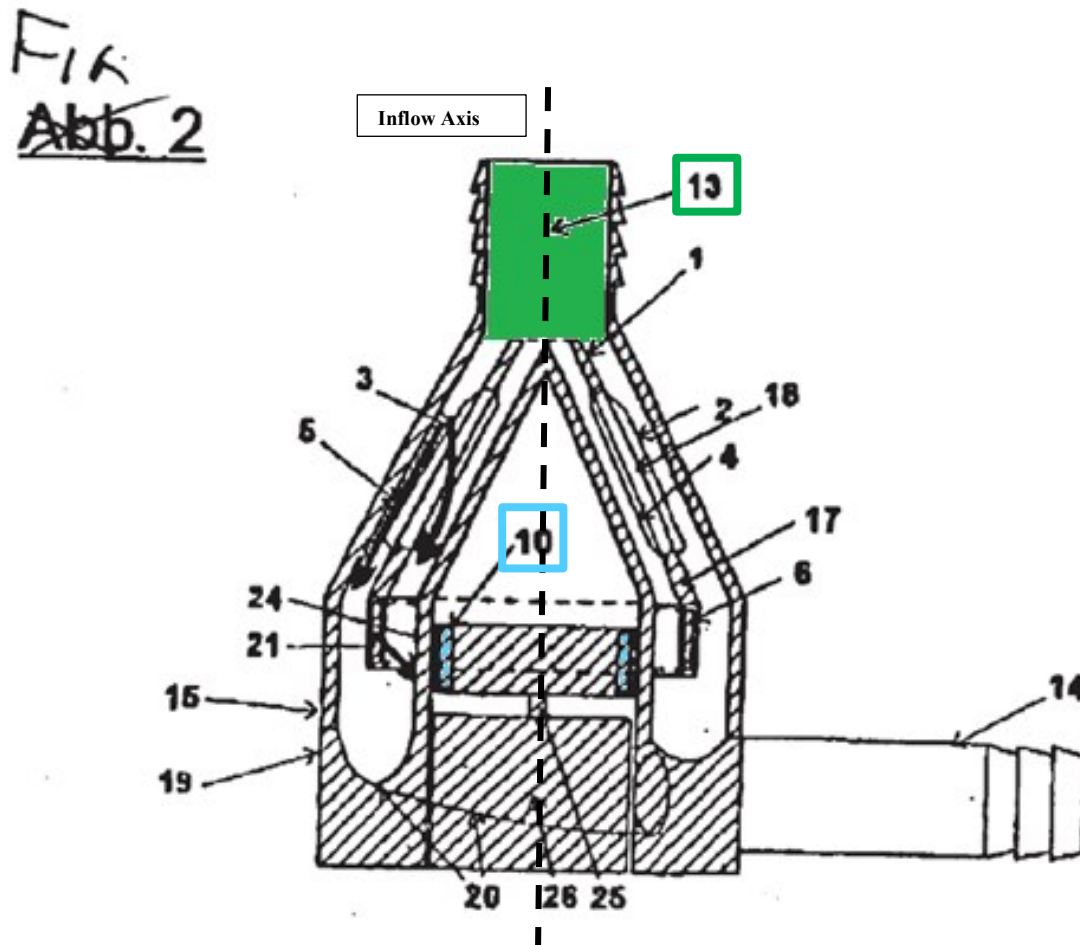
Ex.1005, Fig. 2; Fig. 1; Ex.1003, ¶585.

Accordingly, Schima teaches or suggests “the *magnetically driven rotor* (“rotor 1”) and *first magnetic device* (“rotor magnets 6”) being rotatable about an axis of rotation aligned with the *inflow axis* to drive the blood flowing from the *inflow tube* (“inlet 13”).” Ex.1003, ¶587.

vii. [11F]

Schima discloses “an *electric motor 26* [‘a magnetic drive system’] which drives a rotating disk 24 with *magnets 10* [‘a second magnetic device’].” Ex.1005,

[0013]. Further, Schima discloses that “**magnets 10**” have an “axial offset [that] ensures an axial component for the magnetic force” [*axially aligned with the inflow axis*] that “journal[s] the rotor” (Ex.1005, [0013]):



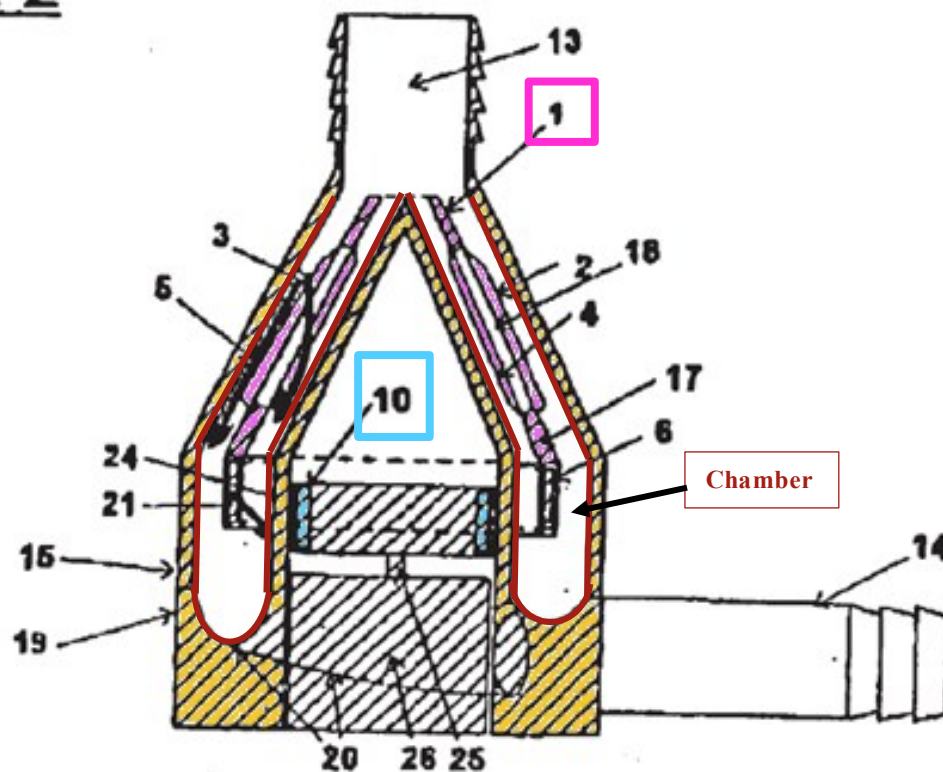
Ex.1005, Fig. 2; Ex.1003, ¶¶589, 592.

Accordingly, Schima discloses a “**magnetic drive system** (“electric motor 26”) comprising a **second magnetic device** (“magnets 10”) axially aligned with the **inflow axis** (“inlet 13”). Ex.1003, ¶593.

viii. [11G]

Schima discloses that “**magnets 10**” are *spaced apart* from the “**rotor 1**” such that “middle part 16” of the “**housing 30**” (“one or more walls”) is positioned between them (Ex.1005, [0010]; Ex.1003, ¶595):

Fig.
Abb. 2



Ex.1005, Fig. 2 (conical middle part 16 labeled in Fig. 1). Ex.1003, ¶598.

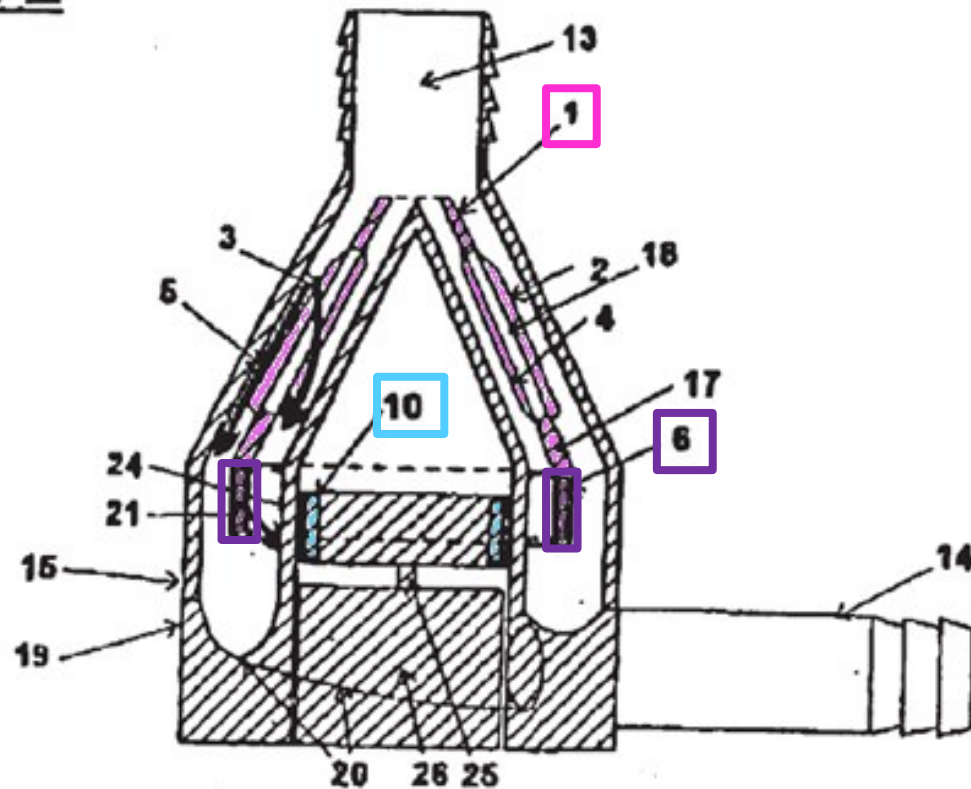
Accordingly, Schima discloses the **second magnetic device** (“magnets 10”) “*spaced apart* from the **magnetically driven rotor** (“rotor 1”) such that a wall of the **one or more walls** (“housing 30”) defining the **chamber** (space between “upper

part 15” and “middle part 16”) *is positioned between the magnetically driven rotor and the second magnetic device.*” Ex.1003, ¶599.

ix. [11H]

Schima discloses that “magnets 10” are positioned to “transfer rotation energy” (“*positioned axially...to provide magneto coupling...to drive rotation*”) to the “rotor magnets 6” of the “rotor.” Ex.1005, [0012]-[0013]; *see also* claim 9 (claiming a “magnetic drive”); Ex.1003, ¶601. The “magnets 10” are positioned *axially closer* to the rotor magnets 6 than to the rotor 1 so as to magnetically drive rotation via a “*magneto coupling*:”

FIG.
Abb. 2



Ex.1005, Fig. 2, [0013]; Ex.1003, ¶605. Schima also discloses that its “**rotor 1** rotates in a **pump housing 30**” [‘relative to the one or more walls’]. Ex.1005, [0012. Ex.1003, ¶603.

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,” as discussed above, “the drive can also” “work as shown in FIG. 1 with a **stator 12** [alternative *second magnetic device*]...creating a rotating

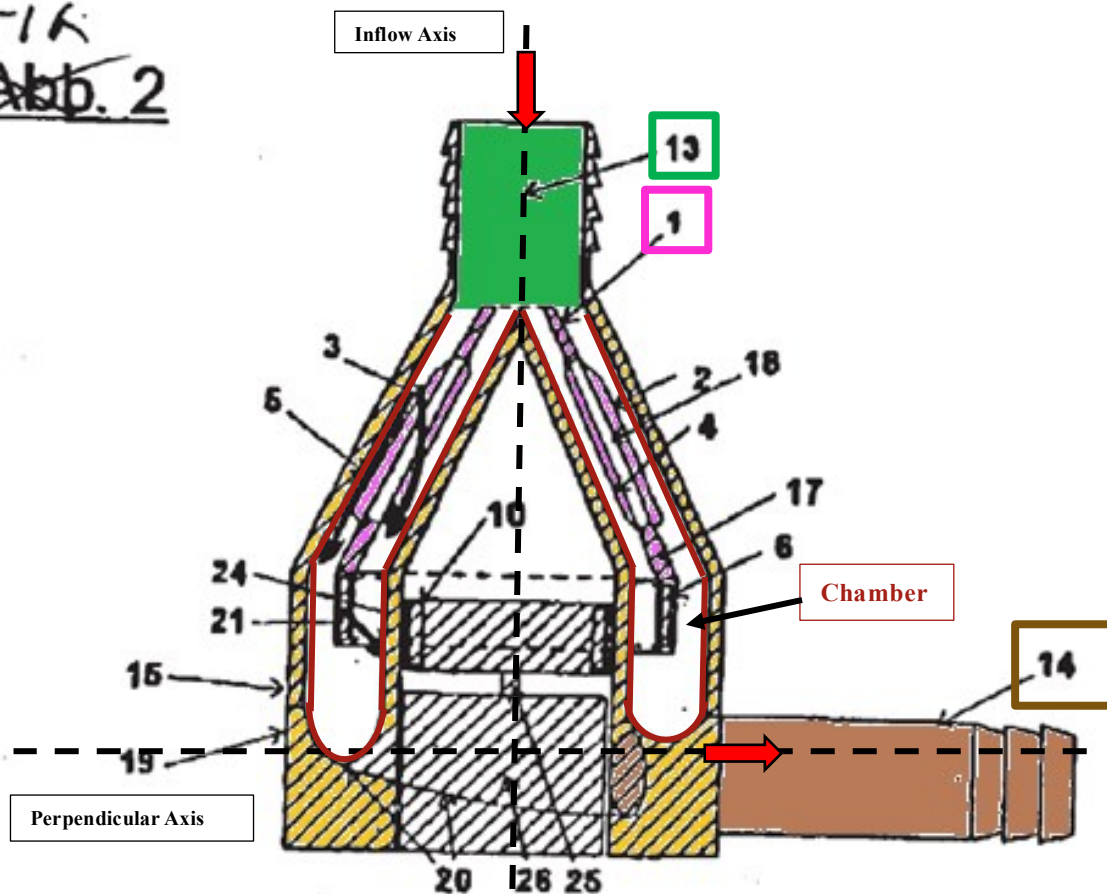
magnetic field” that “causes the coupling force [*‘drive rotation...via a magneto coupling’*]” “with **rotor magnets 6**.” Ex.1005, [0012]. Ex.1003, ¶607.

Thus, Schima teaches or suggests a **second magnetic device** (“magnets 10” or “stator 12”) is “*positioned axially closer to the first magnetic device* (“rotor magnets 6”) *than to the magnetically driven rotor* (“rotor 1”) *so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls* (“housing 30”) *via a magneto coupling* (“transfer rotation energy”).” Ex.1003, ¶¶608-610.

x. [111]

Schima discloses “[a] spiral-shaped **outlet passage 20**...[to] **outlet 14**” [*‘a blood outflow port’*]. Ex.1005, [0012]. The “**outlet 14**” is *positioned such that blood driven by the “rotor” exits the space between* “middle part 16 and upper part 15” of the “pump housing 30” of the “**housing 30**” *perpendicular to the inflow axis* (Ex.1003, ¶612) (see **red** arrows):

Fig.
Abb. 2



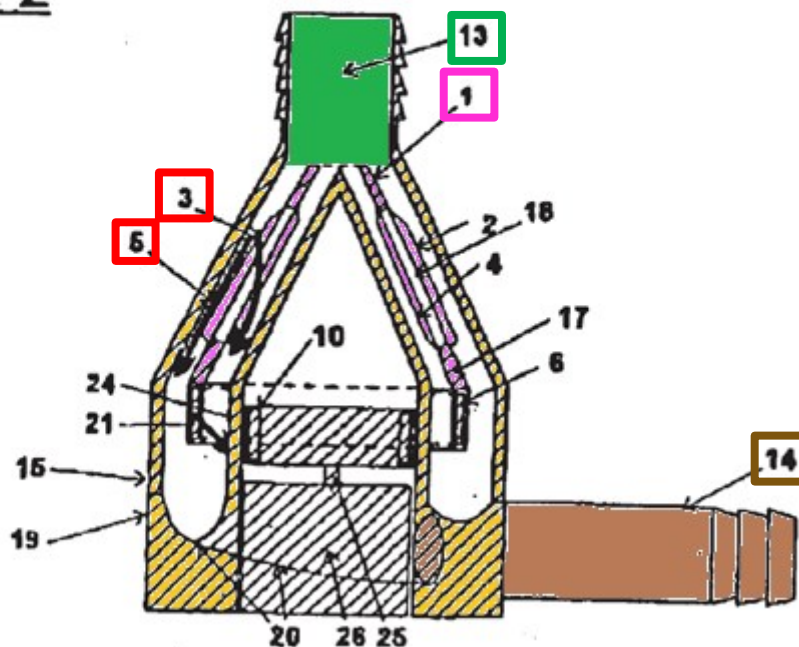
Ex.1005, Fig. 2; Ex.1003, ¶614.

Accordingly, Schima teaches or suggests a “a **blood outflow port** (“outlet 14”) positioned such that the blood driven by the **magnetically driven rotor** (“rotor 1”) exits the **chamber** (space between “middle part 16 and upper part 15” of the “pump housing 30”) in a direction substantially perpendicular to the **inflow axis**.” Ex.1003, ¶615.

xi. [11J]

As demonstrated in [11H], Schima discloses that the rotation [*in response to rotation*] “is used to journal the **rotor**” [*magneto coupling orients the magnetically driven rotor*] by “produc[ing] centrifugal flow components” (“*by the blood*”) “for contact-free journaling and stabilizing [or “centering”] of the rotor in the **housing**” (“*remain spaced apart*”) (Ex.1005, [0010]-[0013]; Ex.1003, ¶619):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶621.

Accordingly, Schima discloses that “the magneto coupling orients the **magnetically driven rotor** (“rotor 1”) so that both the **magnetically driven rotor** and the **first magnetic device** (“rotor magnets 6”) remain spaced apart from the **one or**

more walls (“pump housing 30”) *by the blood* (“centrifugal flow components 3 and 5”) *in response to rotation of the magnetically driven rotor* Ex.1003, ¶622.

xii. [11K]

Schima does not expressly disclose this element, however, using “*an external control unit...to control operation*” would have been obvious in view of Akamatsu-1999. Ex.1003, ¶623.

As discussed in Ground 3, Akamatsu-1999 discloses connecting an external control unit (**lime green**) to the centrifugal pump (**blue**):

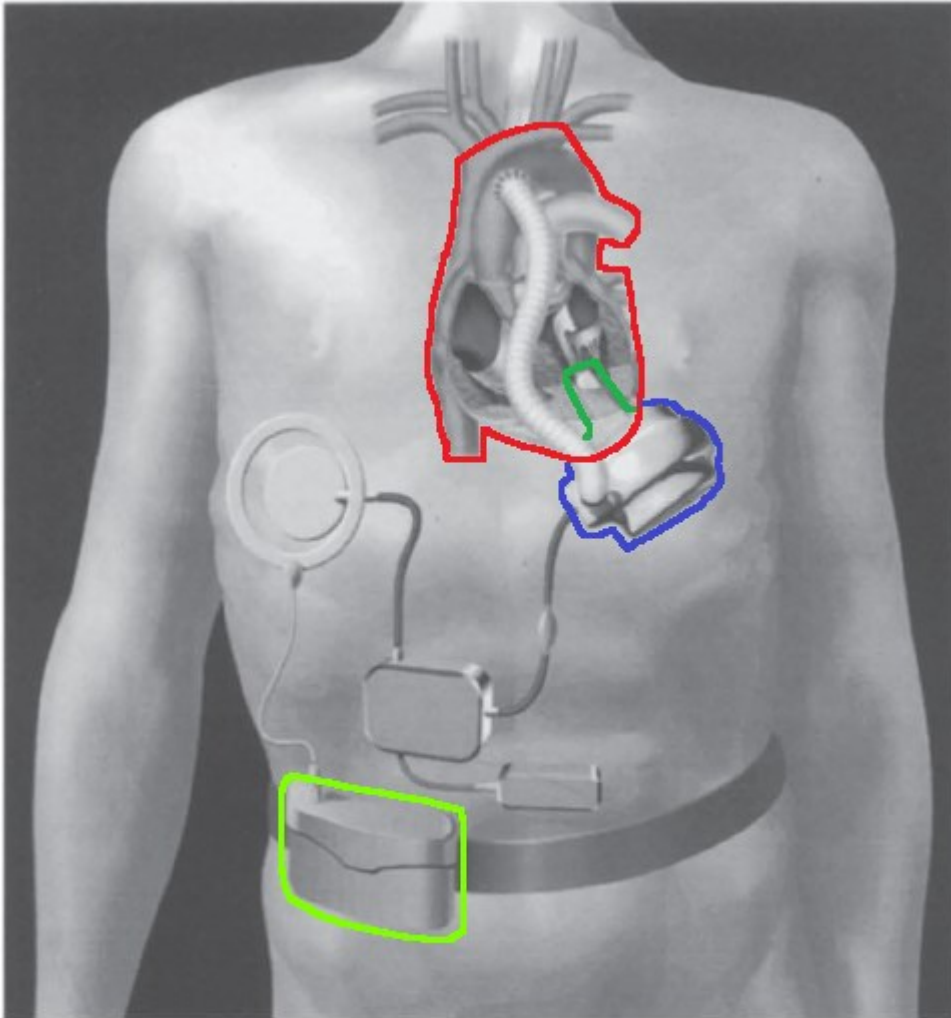


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Supra §VIII.C.1.xii.; Ex.1006, 3-4; Ex.1003, ¶624.

As detailed below (*infra* §VIII.X.D.8), in the Schima/Akamatsu-1999 combination, Akamatsu-1999’s “controller” would be connected “*for regulating operation*” of Schima’s “electric motor 26 which drives...magnets 10” (or “stator 12”) (“*the second magnetic device*”).”

It would also have been obvious to combine Schima's pump with Akamatsu-1999's *external control unit*...to control operation of the *second magnetic device* based on a fixed value. As demonstrated in Ground 3, Akamatsu-1999 discloses a “*controller*” to control the “*motor*” so that “[t]he pump was operated at a fixed rotational speed” (“*a fixed value*”). Ex.1006, 3-4; Ex.1003, ¶625.

Accordingly, Schima/Akamatsu-1999 renders obvious “*an external control unit*” (“controller,” Ex.1006, 3-4) configured to control operation of the *second magnetic device* (“magnets 10,” Ex.1005) based on a fixed value (“fixed rotational speed,” Ex.1006, 3-4) to thereby magnetically drive the rotation of the *magnetically driven rotor* (“rotor 1,” Ex.1005) via the magneto coupling with the *first magnetic device* (“rotor magnets 6,” Ex.1005).” Ex.1003, ¶626.

2. Claim 12

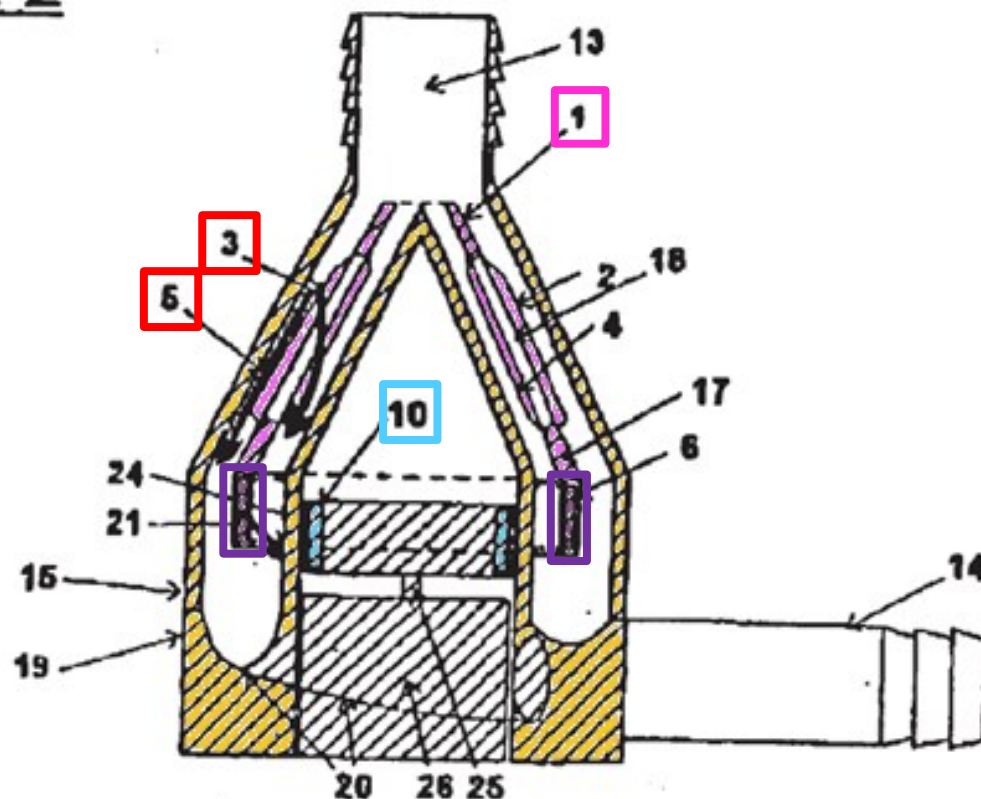
Schima further discloses that “[t]he *rotor* 1 has as flow surfaces 2 and 4 vanes” [‘*guide surfaces*’] “that produce centrifugal flow components” [‘*produce centrifugal flow components*’]. Ex.1005, [0012], [0010], Claim 1; Ex.1003, ¶628.

Accordingly, Schima teaches or suggests that “*the magnetically driven rotor*” (“rotor 1”) includes a guide surface to produce centrifugal flow components (“centrifugal flow components 3 and 5”).” Ex.1003, ¶632.

3. Claims 14-15

Schima discloses “contact-free...journaling and stabilizing of the **rotor** in the **housing** [‘a gap’]” “effectuated by the “**centrifugal flow components**” [‘configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor’] (Ex.1005, [0010]; Ex.1003, ¶635):

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶637.

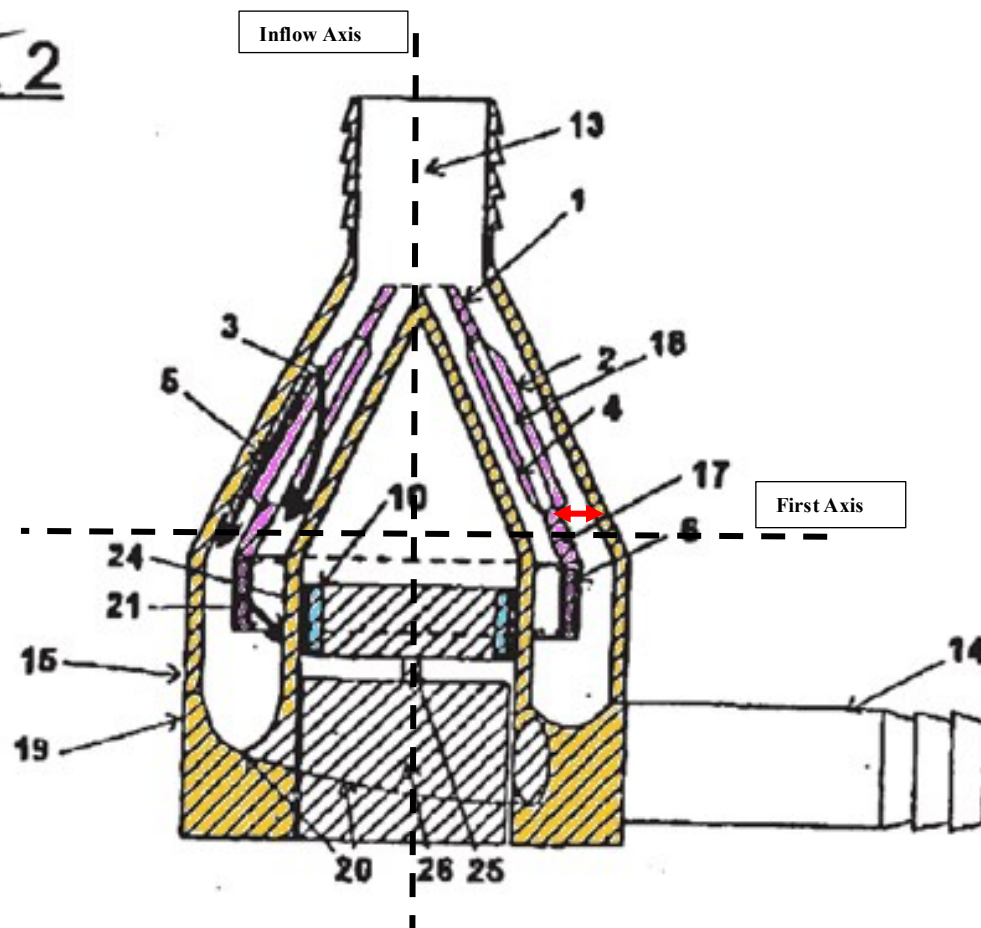
Accordingly, Schima teaches or suggests that “**one or more walls** and the **magnetically driven rotor** (“rotor 1”) define a gap separating the **magnetically**

driven rotor (“rotor 1”) *from the one or more walls, the gap configured to be occupied by the blood when the second magnetic device* (“magnets 10”; “stator 12”) *drives the rotation of the magnetically driven rotor...wherein the gap surrounds the magnetically driven rotor* (“rotor 1”).” Ex.1003, ¶638.

4. Claim 16

As demonstrated in [14], Schima discloses that the “contact-free...journaling and stabilizing of the rotor in the housing [‘a gap’]” is a result of “centrifugal flow components 3 and flow components 5 directed against the housing.” Therefore, at least part of the *gap occupied by the blood extends along an axis substantially perpendicular (red arrow) to the inflow axis* in the direction of the housing to effectuate the “journaling.” Ex.1005, [0012]; Ex.1003, ¶641.

Fig.
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶637.

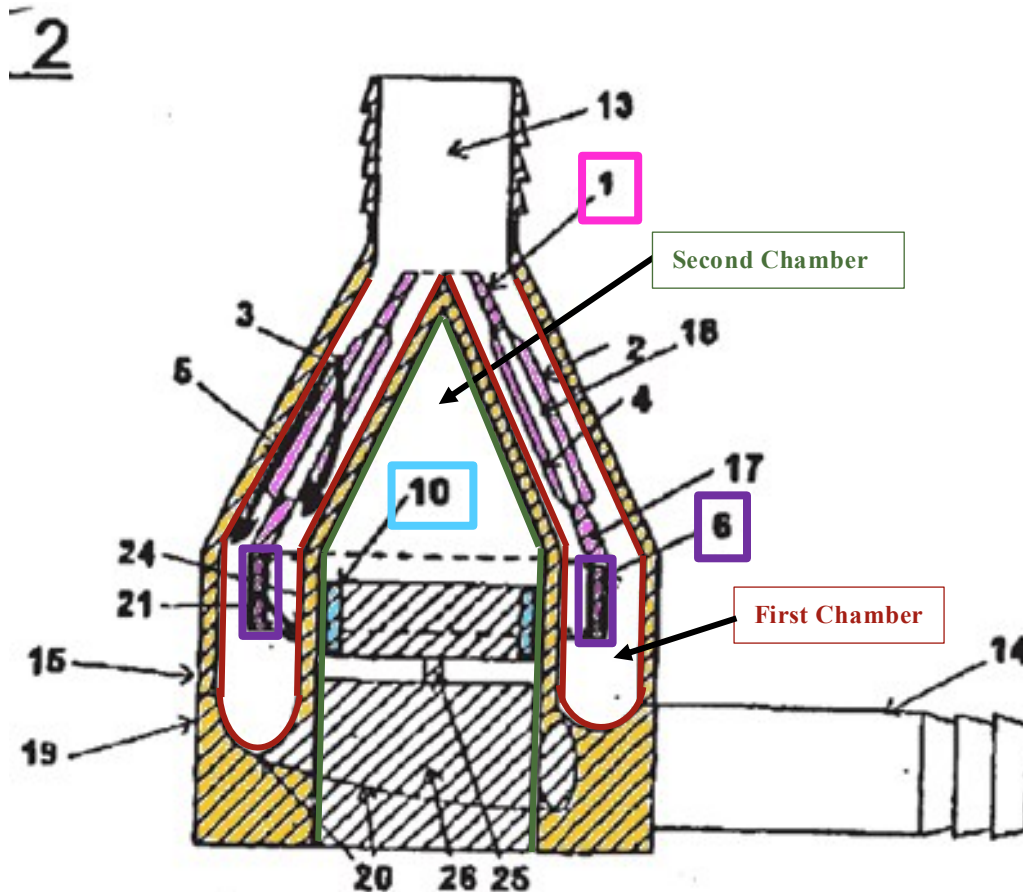
Accordingly, Schima teaches or at least renders obvious that “*at least part of the gap extends along a first axis substantially perpendicular to the **inflow axis**.*”

Ex.1003, ¶642.

5. Claim 18

As demonstrated in [11B], the **space** between the “conical middle part 16 and a hollow conical upper part 15” of the **housing** defines a *first chamber* within which “**rotor**” [‘*magnetically driven rotor*’] is “center[ed].” Ex.1005, [0012]; Ex.1003,

¶645. Schima further discloses the “**electric motor 26**” including “**magnets 10**” [‘*magnetic drive system*’] residing “**inside the housing lower part 19**” [‘*a second chamber*’] (Ex.1005, [0012], Fig. 2, Fig. 1; Ex.1003, ¶646):



Ex.1005, Fig. 2; *see also* Fig. 1 (“stator 12”); Ex.1003, ¶646.

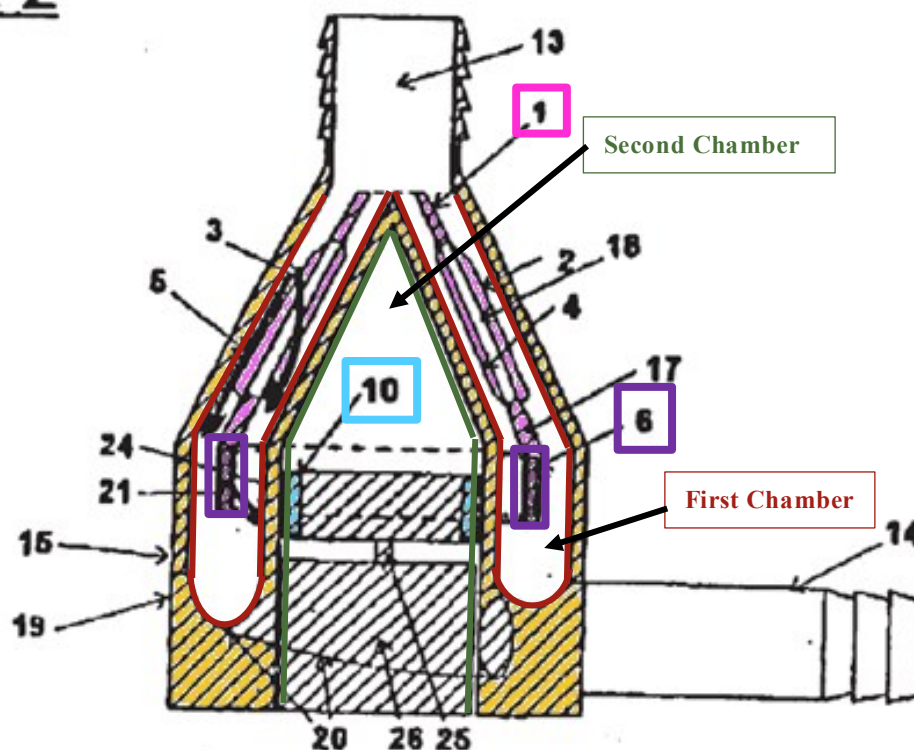
Schima teaches or suggests that “*the **chamber** (space between the “conical middle part 16 and a hollow conical upper part 15”) is **a first chamber** within which the **magnetically driven rotor** (“rotor 1”) is positioned, and the **magnetic drive***

system (“electric motor 26”) is positioned within a *second chamber* (“inside the housing lower part 19”) sealed from the first chamber.” Ex.1003, ¶647.

6. Claim 19

For the same reasons discussed for [11B] and [18], the “conical middle part 16” of the **housing 30** [‘the wall of the one or more walls’] separates the **spaces** between the “conical middle part 16 and a hollow conical upper part 15” [‘first chamber’] from the “inside [of] the housing lower part 19” [‘second chamber’] in which the “drive” components, e.g., **magnets 10 or “stator 12”**, reside, (Ex.1005, [0011]-[0012]; Ex.1003, ¶650):

Fig.
Abb. 2



Ex.1005, Fig. 2; *see also* Fig. 1 (showing stator 12); Ex.1003, ¶650.

Accordingly, Schima discloses that “the wall of the *one or more walls* (“conical middle part 16” of the housing 30”) *separates the first chamber* (space between the “conical middle part 16 and a hollow conical upper part 15”) *from the second chamber* (“inside the housing lower part 19”).” Ex.1003, ¶651.

7. Claims 1-2, 4-5, 7-8, 20

Claims 1, 2, 4-5, 7-8, and 20 recite elements that are identical or analogous in scope to the claims above, with exceptions noted below, and are except for the claim elements discussed below, thus, rendered obvious for the same reasons, as incorporated below. Ex.1005, ¶¶652-655.

Claims 1-2, 4-5, 7-8, 20	Analogous Claim Limitations	Analogous Sections of Ground 4
[1PRE]	[11PRE]	§VIII.D.1.i
[1A]	[11A]	§VIII.D.1.ii
[1B]	[11C]	§VIII.D.5
[1C]	[11B], [11E]	§VIII.D.1.iii; §VIII.D.1.vi
[1D]	[11D]	§VIII.D.1.v
[1E]	[11F]	§VIII.D.1.vii
[1F]	[11H]	§VIII.D.1.ix
[1G]	[11G], [14]	§VIII.D.1.viii; §VIII.D.3

[1H]	[11I]	§VIII.D.1.x
[1I]	[11J]	§VIII.D.1.xi
[1J]	[11K]	§VIII.D.1.xii
[2]	[12]	§VIII.D.2
[4]	[18], [19]	§VIII.D.1.iii; §VIII.D.5-9
[5]	[14], [18]	§VIII.D.7.i; §VIII.D.3; §VIII.D.5
[7]	[18]	§VIII.D.5
[8]	[19]	§VIII.D.6
[20]	[11k]	§VIII.D.1.i

i. Claim 4

See [11B], [18]-[19]. For the same reasons, Schima discloses “a sealing wall positioned between the [“magnets 10” or “stator 12”] and the [‘rotor].” Ex.1005, [0012]; Ex.1003, ¶653.

ii. Claim 20

See [11K], [18]-[19]; *see also* [20] from Ground 3 (Akamatsu-1999). Ex.1003, ¶654.

8. 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.8.

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.8.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.8.a.

Akamatsu-1999 and Schima are analogous art to the 879 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; 3:47-48; Ex.1006, 3; Ex.1008, [0001]. Ex.1003, ¶¶657, 666. *Second*, Akamatsu-1999 and Schima are reasonably pertinent to a problem described by the 879 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:23-28; Ex.1006, 8; Ex.1005, [0002], [0009]. Ex.1003, ¶¶658, 666.

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, ¶¶659-660 (discussing implantation), 667-671 (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, ¶662. Schima is silent as to pump implantation and control. Ex.1003, ¶664. 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, ¶672.

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, ¶¶672-673; 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, ¶663; 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 879 Patent as

Wampler-169, Bourque-2001 (or Bourque-2001/ Wampler-169), Akamatsu-1999, Schima⁹ (or Schima/Akamatsu-1999), were not cited or considered by the Examiner during prosecution of the 879 Patent. The Examiner also did not have Mr. Crosby's detailed expert testimony and the evidence of record.

B. 35 U.S.C. §314(a)

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

Trial: Factor 2 **weighs against** discretionary denial because there is no trial date. The most recent statistics¹⁰ 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.

⁹ A German-language version of Schima was cited in an IDS by the applicant during prosecution of the 879 Patent but was not relied on by the Examiner.

¹⁰ <https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2024/06/30-3>.

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 compelling—the prior art is robust, and each primary reference has strikingly similar disclosures to that of the 879 Patent, is directed at the same problem, and proposes the same solutions using nearly identical architecture.

X. CONCLUSION

The Challenged Claims are unpatentable as demonstrated.

Dated: November 27, 2024

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,987 words (as determined by the Microsoft Word word-processing system used to prepare the brief and including annotated figures), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

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

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