

**UNITED STATES PATENT AND TRADEMARK OFFICE**

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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ABBOTT LABORATORIES,  
Petitioner,

v.

MIRACOR MEDICAL SA,  
Patent Owner.

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IPR2025-00115  
U.S. Patent No. 11,674,517

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**PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 11,674,517**

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**EXHIBIT LIST**

| No.  | Exhibit Description                                                                                                                                                                                                                                                              |
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| 1001 | U.S. Patent No. 11,674,517                                                                                                                                                                                                                                                       |
| 1002 | U.S. Patent No. 11,674,517 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                                                |

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| 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 12 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 <a href="https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up">https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up</a> ) |
| 1021 | “Ignition magneto,” accessed via <a href="https://en.wikipedia.org/wiki/Ignition_magneto">https://en.wikipedia.org/wiki/Ignition_magneto</a> (last accessed October 28, 2024)                                                                                                               |
| 1022 | Masuzawa et al. <i>Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor</i> , Artificial Organs 2003, Vol. 27, No. 7, pp. 631-638                                                                                                                                  |
| 1023 | U.S. Patent No. 6,152,704                                                                                                                                                                                                                                                                   |
| 1024 | U.S. Patent No. 6,589,030                                                                                                                                                                                                                                                                   |
| 1025 | European Patent No. 0 834 326                                                                                                                                                                                                                                                               |
| 1026 | Miracor’s Response to Exhibit A-1 (Bourque-2001) of Supplemental Invalidity Contentions, dated September 20, 2024                                                                                                                                                                           |
| 1027 | U.S. Patent No. 5,324,177                                                                                                                                                                                                                                                                   |
| 1028 | Allaire, et al., <i>Prototype Continuous Flow Ventricular Assist Device</i> , J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690                                                                                                                                                         |
| 1029 | Kung and Hart, <i>Design Considerations for Bearingless Rotary Pumps</i> , J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650                                                                                                                                                           |
| 1030 | Declaration of Sylvia Hall-Ellis                                                                                                                                                                                                                                                            |

**CLAIM INDEX**

| <b>Element</b> | <b>Claim language</b>                                                                                                                                                                                                                                                       |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [1PRE]         | A system for assisting the blood circulation of a heart, comprising:                                                                                                                                                                                                        |
| [1A]           | a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart;                                                                                          |
| [1B]           | a magnetically driven rotor axially aligned with the inflow tube and being spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle                                                                                         |
| [1C]           | the magnetically driven rotor being rotatable within a surrounding rotor housing to act upon blood flowing from the inflow tube toward the rotor,                                                                                                                           |
| [1D]           | the magnetically driven rotor being rotatable about a central axis                                                                                                                                                                                                          |
| [1E]           | and [the magnetically driven rotor] being rigidly coupled to [a first magnetic device]                                                                                                                                                                                      |
| [1F]           | and [the magnetically driven rotor is] axially adjacent to a first magnetic device                                                                                                                                                                                          |
| [1G]           | that [the first magnetic device] is located within the surrounding rotor housing                                                                                                                                                                                            |
| [1H]           | a second magnetic device axially aligned with the inflow tube                                                                                                                                                                                                               |
| [1I]           | and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device                                                                                                        |
| [1J]           | while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device by at least one sealing wall, the second magnetic device being positioned axially spaced apart from the magnetically driven rotor |
| [1K]           | a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding                                                                                               |

|      |                                                                                                                                                                                                                                                                                                                                                           |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | rotor housing in a direction transverse to the central axis of the magnetically driven rotor,                                                                                                                                                                                                                                                             |
| [1L] | wherein when the magnetically driven rotor is rotated, 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                                                                                                                 |
| [1M] | an external control unit configured to regulate operation of the second magnetic device, wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device. |
| [2]  | The system of claim 1, wherein the magnetically driven rotor comprises guide surfaces to produce centrifugal flow components.                                                                                                                                                                                                                             |
| [3A] | The system of claim 2, wherein the surrounding rotor housing comprises the at least one sealing wall,                                                                                                                                                                                                                                                     |
| [3B] | and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.                                                                                                                                                                                                                                         |
| [4]  | The system of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.                                                                                                                                                                                                   |
| [10] | The system of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.                                                                                                                                       |
| [11] | The system of claim 10, further comprising one or more sensors that deliver feedback signals to the external control unit.                                                                                                                                                                                                                                |
| [14] | The system of claim 10, wherein the external control unit is configured to regulate operation of the second magnetic device based on a control value.                                                                                                                                                                                                     |
| [15] | The system of claim 14, wherein the control value indicative of a defined cardiac output for control of the heart assist pump device.                                                                                                                                                                                                                     |

|         |                                                                                                                                                                                                                                                                                                                                                                |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [17]    | The system of claim 1, wherein heart assist pump device is a catheter device.                                                                                                                                                                                                                                                                                  |
| [21PRE] | A system for assisting blood circulation of a heart, the system comprising:                                                                                                                                                                                                                                                                                    |
| [21A]   | 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;                                                                                                                                                                               |
| [21B]   | one or more walls at least partially defining a chamber to receive blood from the inflow tube;                                                                                                                                                                                                                                                                 |
| [21C]   | a magnetically driven rotor axially aligned with the inflow axis and being rigidly coupled [to a first magnetic device]                                                                                                                                                                                                                                        |
| [21D]   | and [a magnetically driven rotor is] axially adjacent to a first magnetic device that is axially aligned with the inflow axis,                                                                                                                                                                                                                                 |
| [21E]   | 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;                                                                                                                                                                                |
| [21F]   | a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis                                                                                                                                                                                                                                                               |
| [21G]   | 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, the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor |
| [21H]   | so as to [the second magnetic device] magnetically drive rotation of the magnetically driven rotor within the chamber via a magneto coupling with the first magnetic device; and                                                                                                                                                                               |
| [21I]   | a blood outflow port positioned radially outward of the magnetically driven rotor such that the blood driven by the magnetically driven rotor exits the chamber in a direction transverse to the inflow axis                                                                                                                                                   |
| [21J]   | 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                                                                                                                                                                                                                                     |
| [21K] | an external control unit configured to control operation of the second magnetic device based on a control value indicative of a defined cardiac output,                                                                                                                                                        |
| [21L] | wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.                                               |
| [22]  | The system of claim 21, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.                                                                                                                                                                                 |
| [24]  | The system of claim 21, 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. |
| [26]  | The system of claim 24, wherein at least part of the gap extends along radially outward from the magnetically driven rotor.                                                                                                                                                                                    |
| [28]  | The system of claim 21, 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.                                                                                    |
| [29]  | The system of claim 28, wherein the wall of the one or more walls separates the first chamber from the second chamber.                                                                                                                                                                                         |
| [30]  | The system of claim 21, wherein the first magnetic device comprises a permanent magnet.                                                                                                                                                                                                                        |
| [32]  | The system of claim 21, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.                                                                                           |
| [33]  | The system of claim 21, further comprising one or more sensors that deliver feedback signals to the external control unit.                                                                                                                                                                                     |

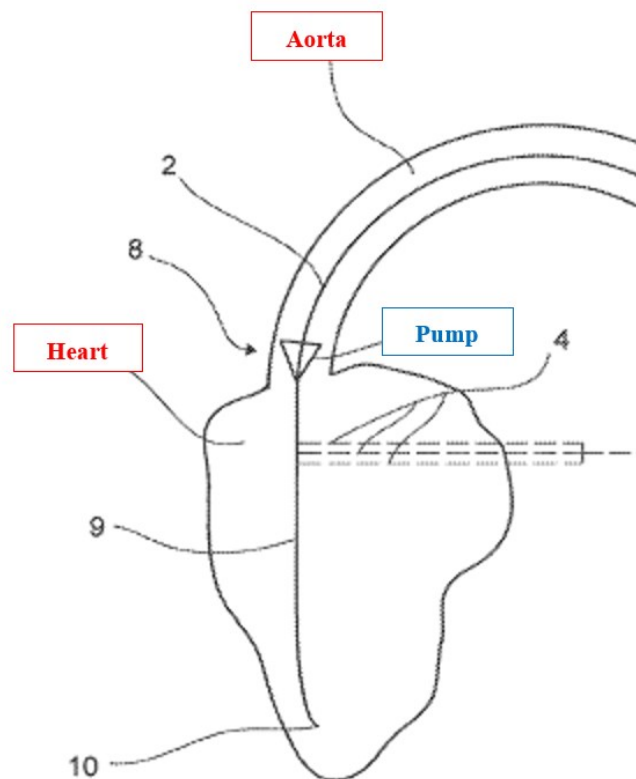
|      |                                                                                |
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| [35] | The system of claim 21, wherein heart assist pump device is a catheter device. |
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## I. INTRODUCTION

Abbott Laboratories (“Petitioner”) petitions for *Inter Partes* Review and cancellation of claims 1-4, 10-11, 14-15, 17, 21-22, 24, 26, 28-30, 32-33, 35 (“Challenged Claims”) of U.S. Patent No. 11,674,517 (“517 Patent” (Ex.1001)), assigned to Patent Owner, Miracor Medical SA (“Miracor” or “PO”).

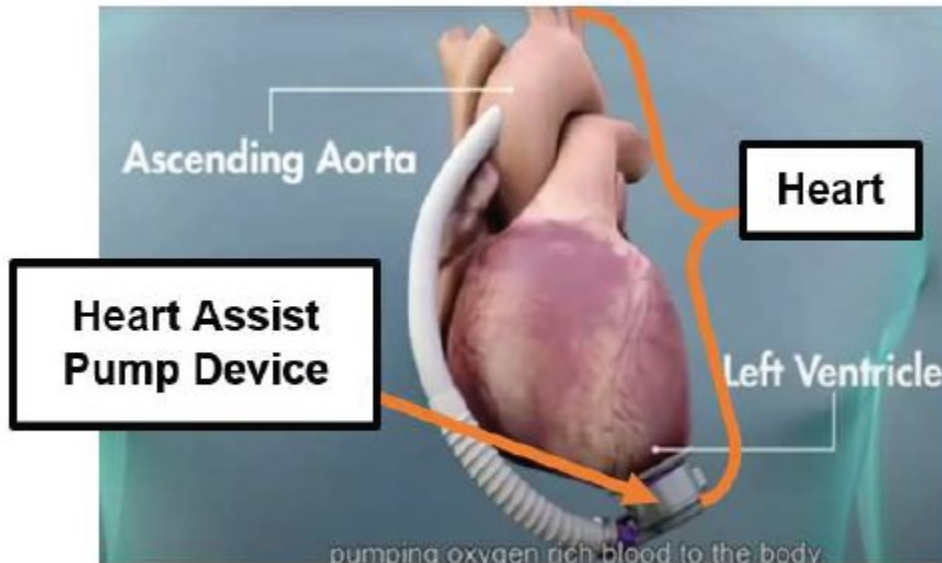
## II. SUMMARY OF THE ARGUMENT

The 517 Patent discloses assisting the heart using an “intravasal” “catheter” blood pump placed **inside** a blood vessel like the aorta:



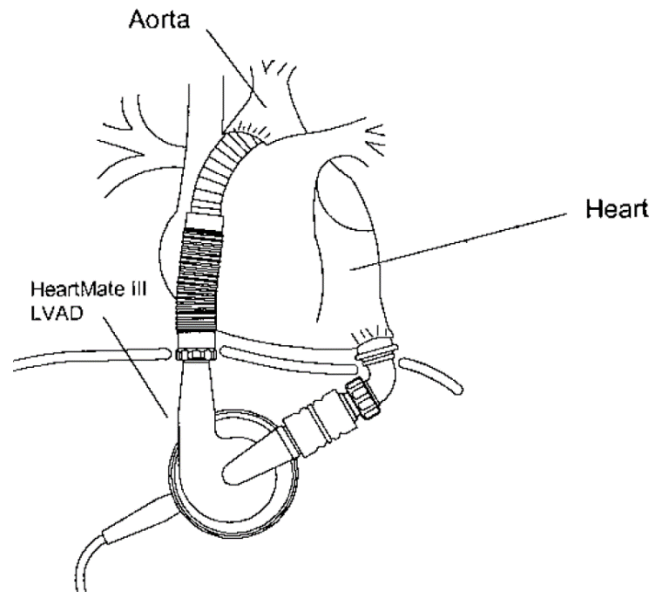
Ex.1001, Fig 1 (annotated), 2:52-62 (“according to the invention...a heart ventricle catheter” “formed as an intravasal rotary pump...arranged inside the catheter.”).

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



Ex.1019 (Miracor's complaint), 3.

PO filed for the 517 Patent in 2022—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 517 Patent claims, but all are disclosed by the references relied on herein.

### III. MANDATORY NOTICES

#### A. Real Party-in-Interest

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

#### B. Related Matters

##### Office Proceedings

Petitioner will also be filing petitions for *inter partes* review against related U.S. Patent Nos. 11,351,356 (IPR2025-00096 (Nov. 5, 2024)); 11,351,357 (IPR2025-00114 (Nov. 25, 2024)); 11,376,415; 11,572,879; and 11,754,077.

Litigation matters.

The 517 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 517 Patent is a continuation of and claims priority to U.S. application Ser. No. 17/446,046 filed on Aug. 26, 2021, which is a continuation of U.S. application Ser. No. 16/282,948 filed on Feb. 22, 2019 (now U.S. Pat. No. 11,123,540), which is a continuation of U.S. application Ser. No. 14/454,965 filed on Aug. 8, 2014 (now U.S. Pat. No. 10,251,984), which is a continuation of U.S. application Ser. No. 13/555,318 filed on Jul. 23, 2012 (now U.S. Pat. No. 8,801,590), which is a divisional of U.S. application Ser. No. 12/449,632 filed on Aug. 18, 2009 (now U.S. Pat. No. 8,255,050), which is the U.S. national phase of International Application PCT/IB2008/000421 filed on Feb. 27, 2008, which designated the U.S. and claims benefit of AT A 306/2007 filed Feb. 27, 2007.

**C. Lead and Back-Up Counsel and Service Information**

| Lead Counsel                                                                                                                                                                                                                         | Back-Up Counsel                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Scott M. Border<br/>(Reg. #77,744)<br/>Winston &amp; Strawn LLP<br/>1901 L Street, N.W.<br/>Washington, D.C. 20036<br/>Tel: (202) 282-5054<br/>Fax: (202) 282-5100<br/>sborder@winston.com</p>                                    | <p>Saranya Raghavan<br/>(<i>pro hac vice</i> to be submitted)<br/>WINSTON &amp; STRAWN LLP<br/>35 West Wacker Drive<br/>Chicago, Illinois 60601<br/>Telephone: (312) 558-5600<br/>Facsimile: (312) 558-5700<br/>sraghavan@winston.com</p>                           |
| Back-Up Counsel                                                                                                                                                                                                                      | Back-Up Counsel                                                                                                                                                                                                                                                     |
| <p>Charles B. Klein<br/>(<i>pro hac vice</i> to be submitted)<br/>WINSTON &amp; STRAWN LLP<br/>1901 L Street, N.W.<br/>Washington, D.C. 20036<br/>Telephone: (202) 282-5000<br/>Facsimile: (202) 282-5100<br/>cklein@winston.com</p> | <p>Nimalka R. Wickramasekera<br/>(<i>pro hac vice</i> to be submitted)<br/>WINSTON &amp; STRAWN LLP<br/>333 South Grand Avenue, 38th Floor<br/>Los Angeles, CA 90071<br/>Telephone: (213) 615-1700<br/>Facsimile: (213) 615-1750<br/>nwickramasekra@winston.com</p> |

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 517 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      | 1-4, 10-11, 14-15, 17,<br>21-22, 24, 26, 28-30,<br>32-<br>33, 35 | Wampler-169 (Ex.1008)                     |
| 2      | §103      |                                                                  | Bourque-2001 (Ex.1007) and<br>Wampler-169 |
| 3      | §103      |                                                                  | Akamatsu-1999 (Ex.1006)                   |
| 4      | §103      |                                                                  | Schima (Ex.1005) and<br>Akamatsu-1999     |

## V. THE 517 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 517 Patent

The 517 Patent concedes **the claimed pump design was known in the prior art:**

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

Ex.1001, 2:29-30.

## VI. CLAIM CONSTRUCTION

PO's apparent Parallel Litigation constructions differ from their plain and ordinary meanings. 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 517 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, ¶¶68-73 (analyzing Ex.1001, 2:60-62, 3:50-4:3, Fig.2). Contemporaneous art distinguished “*magneto coupling*” drives from another drive-type using stators—“[i]n both cases the torque is transmitted...onto the rotor by means of a rotating magnetic field. **In the magnetic coupling pump the rotating field is generated by rotating magnets**, in the [stator] pump, by electric stator windings.” Ex.1011, 1; Ex.1003, §VII.A.1 (analyzing “*magneto coupling*” described in Ex.1001, Ex.1011, Ex.1016, Ex.1022, Ex.1023, Ex.1024, Ex.1025). Thus, its plain meaning would be understood to be “a transfer of torque from one rotating permanent magnetic component to another rotating permanent magnetic component via a magnetic field.” Ex.1003, §VII.A.1.

PO conflates “*magneto coupling*” in Parallel Litigation with a stator drive using a **stationary electromagnet**, instead of a **rotating magnet**, to rotate the rotor magnet, and further alleges that a “stator” (a stationary element) achieves magneto coupling with a rotor. Ex.1019, 7-8; Ex.1003, ¶¶84-87.

### **B. By the Blood Flowing**

Pump rotors can be suspended in at least two different ways—using hydrodynamic or magnetic bearings. Ex.1003, ¶¶57-60. The 517 patent explains that its rotor suspension results from “[t]he rotor produc[ing] flow...directed against the housing” causing “non-contact...of the rotor in the housing.” Ex.1003, ¶92. 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.<sup>1</sup> A POSITA would have understood the phrase—“*spaced apart...by the blood*”—refers to a “hydrodynamic bearing.” Ex.1003,

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

§VII.A.2 (analyzing definition of hydrodynamic bearing described in Ex.1001, Ex.1005, Ex.1016).

PO's Parallel Litigation interpretation renders the claim language—*by the blood flowing*—meaningless by encompassing a magnetic bearing. Ex.1003, ¶95 (analyzing Ex.1019).

## VII. PRIOR ART

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

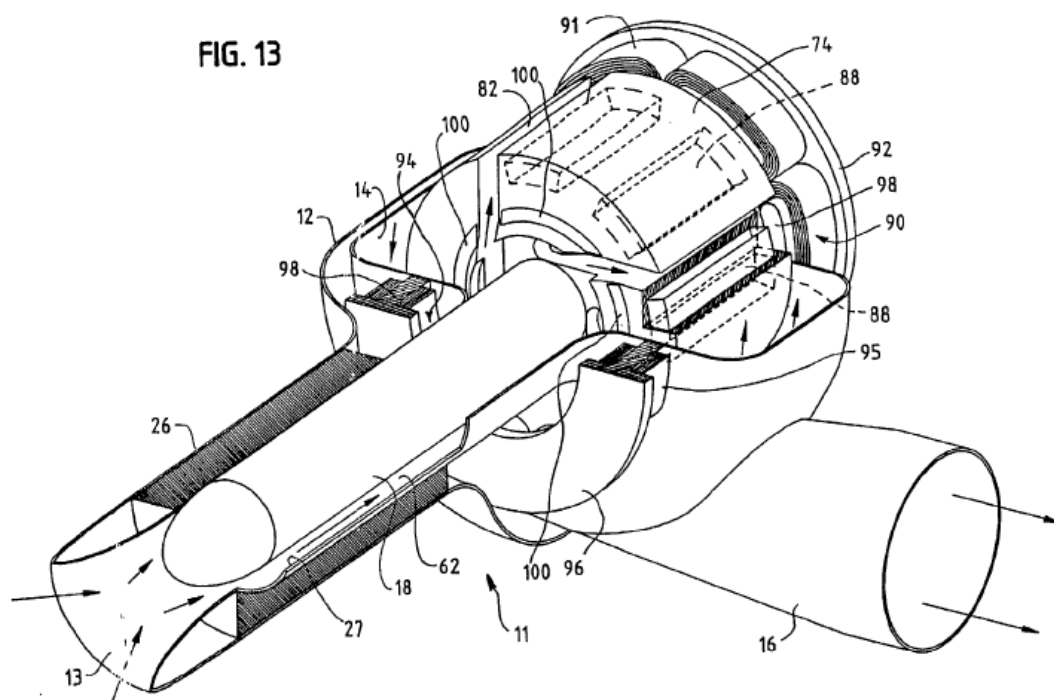
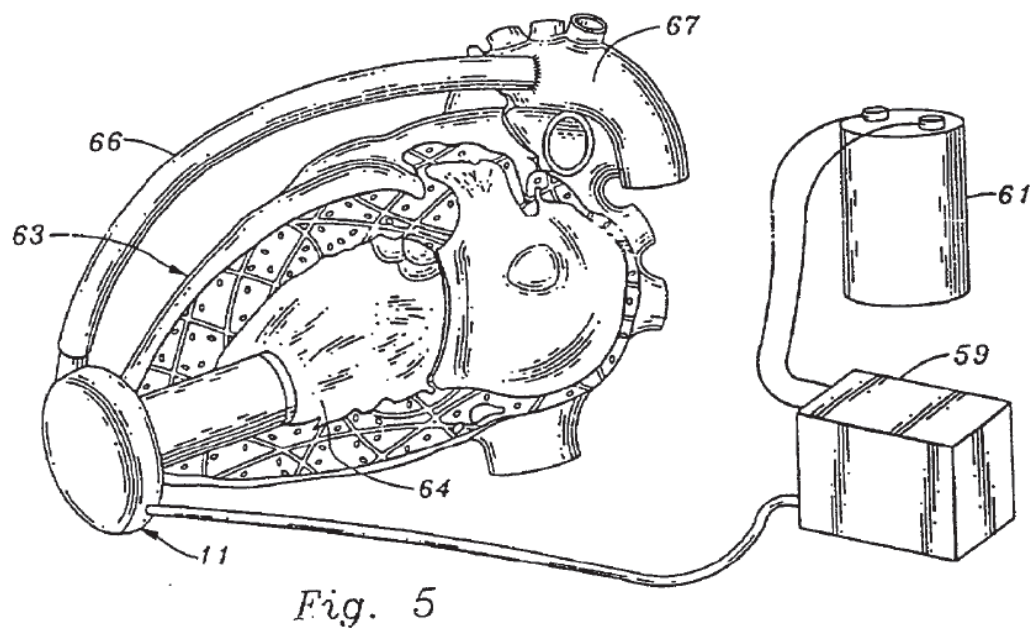
| LVADs        |              | Drive-type           |                     |
|--------------|--------------|----------------------|---------------------|
|              |              | Magneto coupling     | Electromagnetic     |
| Bearing-type | Hydrodynamic | <u>Schima</u>        | <u>Wampler-169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

Ex.1003, Ex.1003, ¶¶146-148.

### A. Wampler-169

U.S. Pub. No. 2002/0102169A1 (“Wampler-169”), published **August 1, 2002**, is prior art to the 517 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. 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 517 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 517 Patent at least under 35 U.S.C. §102(b).

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

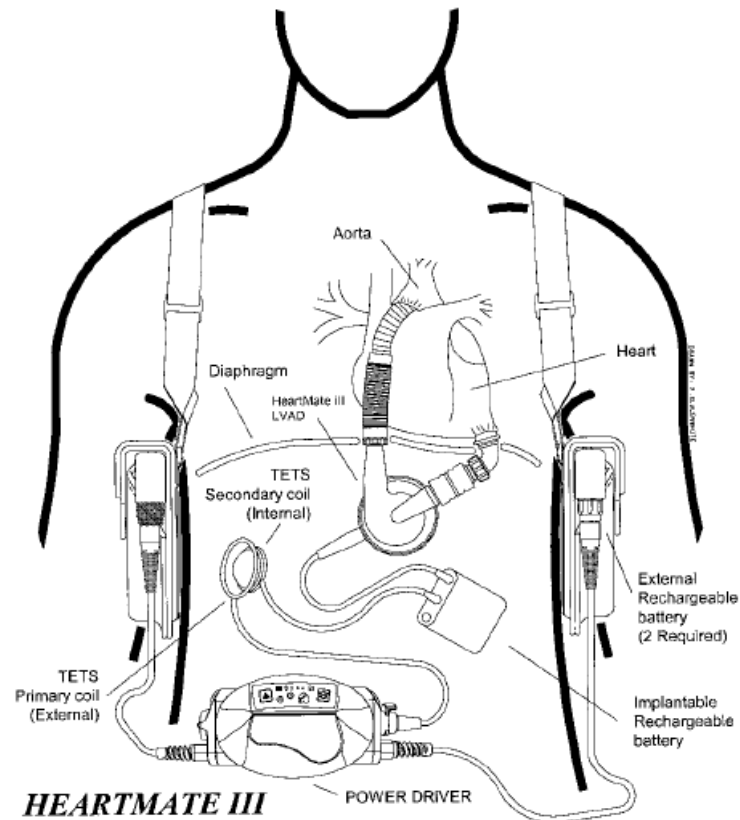


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

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. 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 517 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 517 Patent at least under 35 U.S.C. §102(b).

The Akamatsu-1999 pump is shown below:

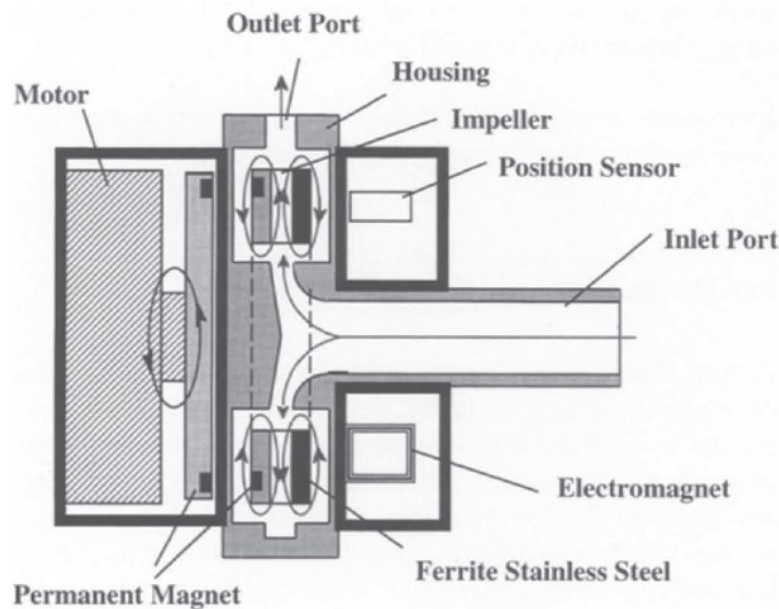


**Fig. 2.** Schematic cross section of the MSCP

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

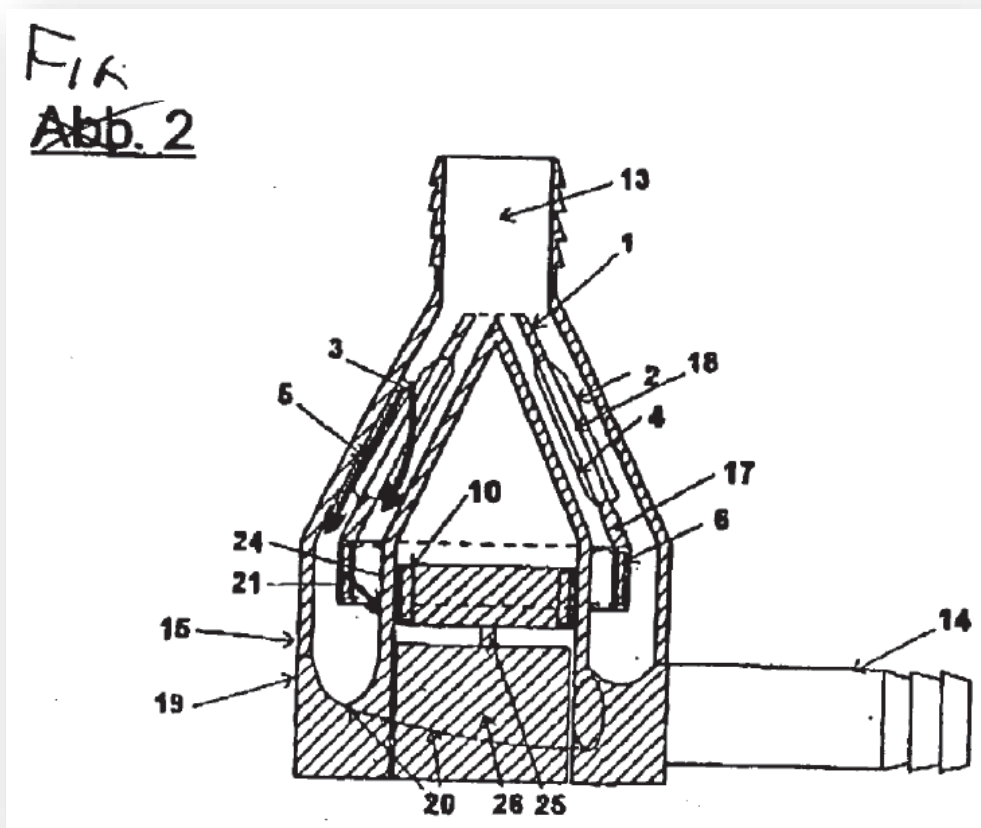
**D. Schima<sup>2</sup>**

U.S. Pub. No. 2003/0124007A1 (“Schima”), published **July 3, 2003**, is prior art to the 517 Patent at least under 35 U.S.C. §102(b).

The Schima pump is shown below:

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



Ex.1005, Fig. 2; Ex.1003, ¶¶137-145.

## VIII. CHALLENGED CLAIMS ARE UNPATENTABLE

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

#### 1. Claim 1

##### i. [1PRE]<sup>3</sup>

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

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

##### ii. [1A]

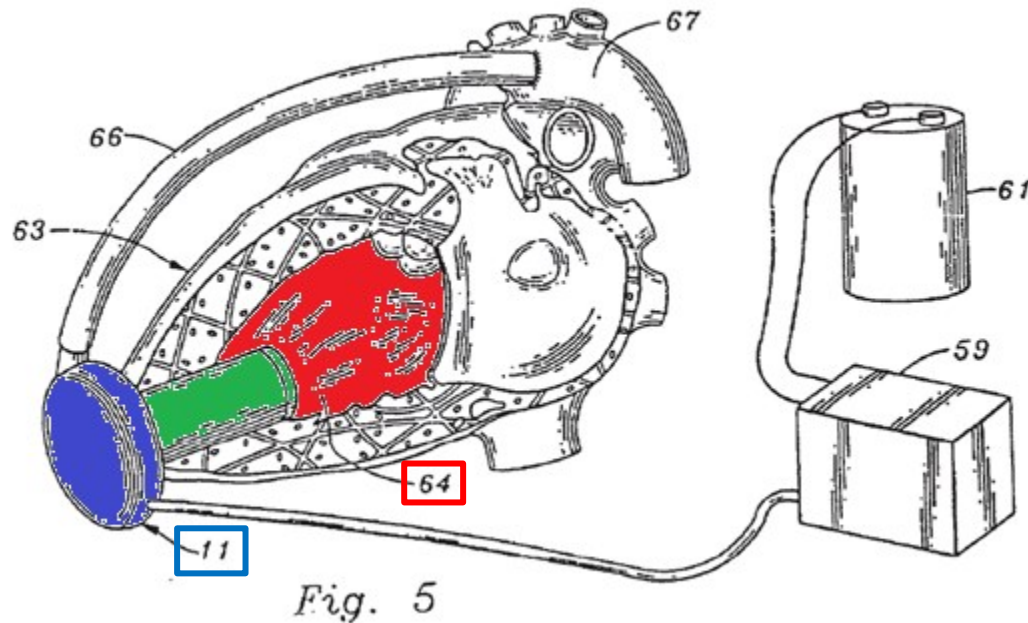
Wampler-169 discloses that “**pump 11**” (“*a heart assist pump device*”) is “implanted” so that “**inlet tube [13] serves as the inflow cannula** and is placed into the apex of the **left ventricle 64**” such that blood “flow[s] through **inlet tube 13** in the direction of arrows 62” (“*an inflow tube defining a blood inflow path and having*

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<sup>3</sup> The claims are included in the Claim Index, *infra* pp. ix-xii.

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

*a suction end insertable into a ventricle of the heart*”) while the remainder of the “compact and disc-shaped [pump] fit[s] well between the apex of the heart and the adjacent diaphragm” (*“deliverable to the heart”*) (Ex.1008, [0074]-[0076]), as shown:



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

Accordingly, Wampler-169 discloses “*a heart assist pump device* (“pump 11”) *deliverable to the heart and comprising: an inflow tube defining a blood*

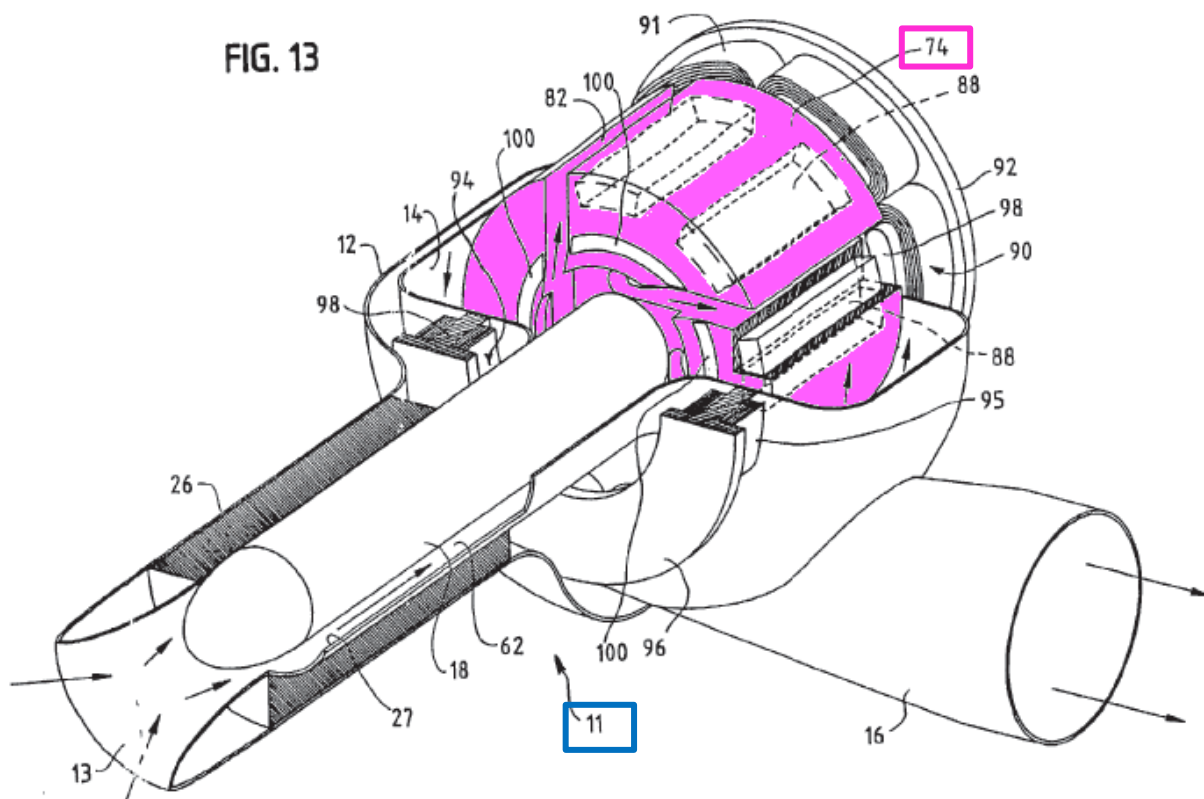
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<sup>5</sup> All figures annotated unless otherwise specified.

*inflow path and having a suction end* (“inlet tube 13”) insertable into *a ventricle of the heart* (“placed into the apex of the left ventricle 64”). Ex.1003, ¶157.

iii. *[1B]*

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

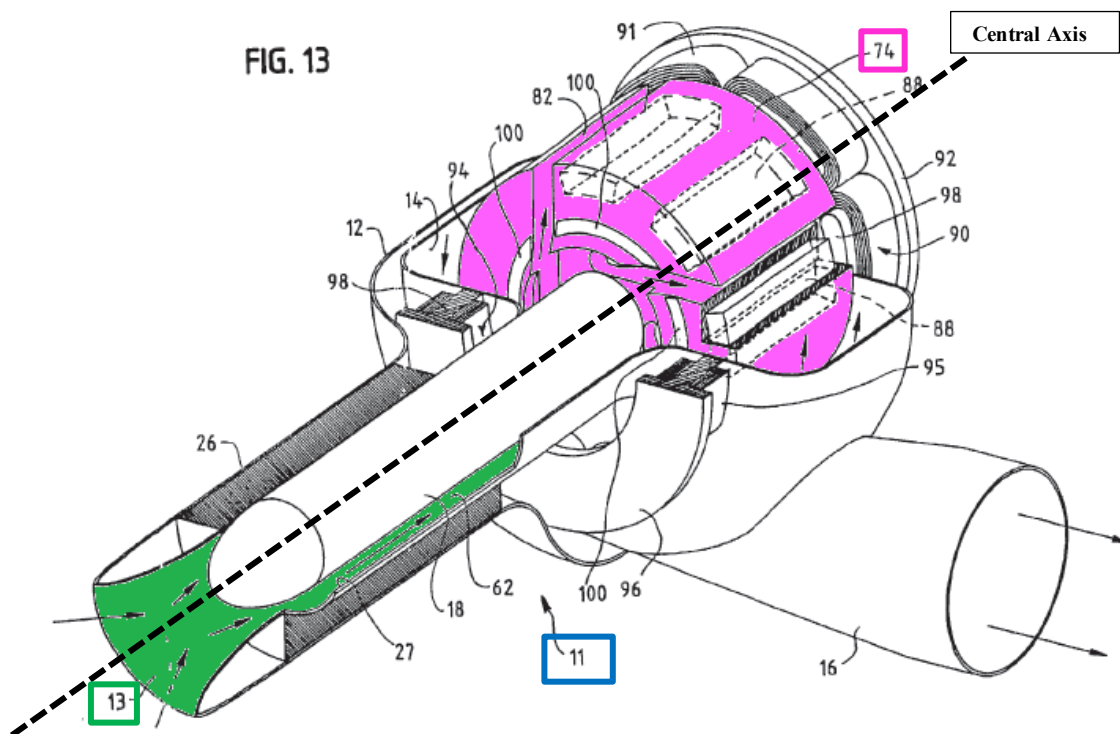


Ex.1008, Fig. 13; Ex.1003, ¶322; *see also id.*, ¶¶318, 321. As demonstrated in [1A], *supra*, inlet 13 “is placed into the apex” while the pump’s “disc-shaped” portion,

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including its **impeller**, fits between the heart and diaphragm (“*spaced apart from the suction end*”).

Wampler-169 discloses “axial inflow...of the blood” (“*axially aligned*”) <sup>6</sup> (Ex.1008, [0075]-[0076]; Ex.1003, ¶166) “to flow through **inlet tube 13** in the direction of the arrows” (Ex.1008, [0074]) towards “**impeller 74**,” which “rotat[es] about an longitudinal axis” (Ex.1008, [0081]), as shown:



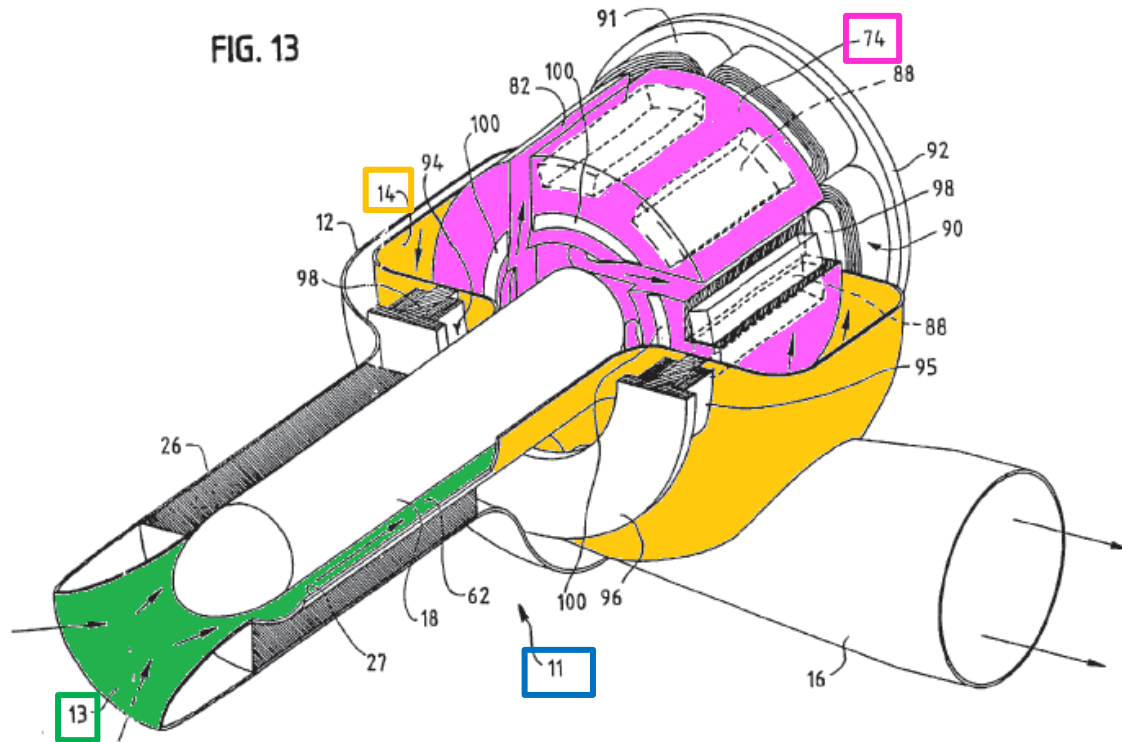
<sup>6</sup> “*Axially aligned*” components are configured to be colinear, or in the same line (or “axis” of rotation) in space. Ex.1003, ¶165.

Ex.1008, Fig. 13; *see also* [0082] (explaining that Fig. 13’s “longitudinal axis...may be identical to...FIGS. 1-8”). Ex.1003, ¶159.

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

iv. [1C]

Wampler-169 discloses the “*impeller 74*[’s]” “rotation” “within housing 12, within *casing 14*” (Ex.1008, [0081], Ex.1003, ¶170) (“*rotatable within a surrounding rotor housing*”) that “causes blood to flow through *inlet tube 13* in the direction of arrows” (“*to act upon blood flowing from the inflow tube toward the rotor*”) (Ex.1008, [0074], Ex.1003, ¶172), as shown:



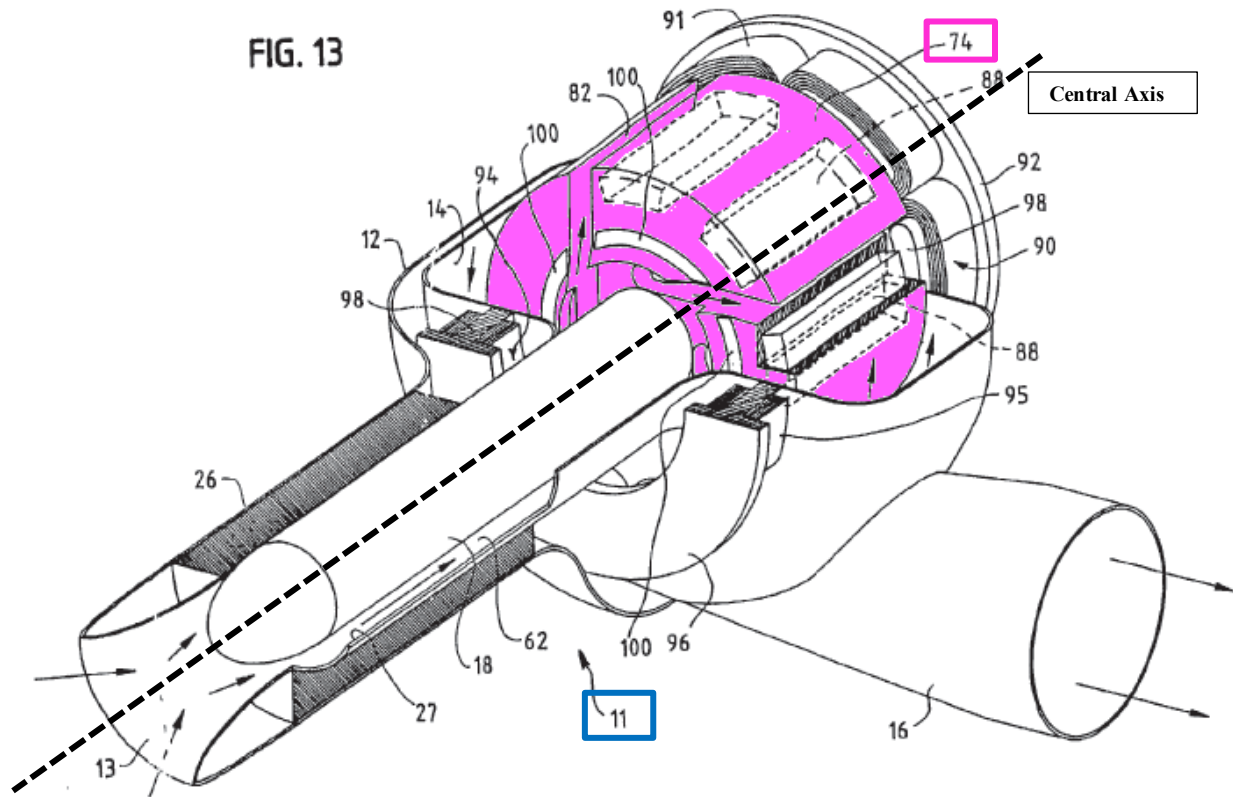
Ex.1008, Fig. 13. Ex.1003, ¶173.

Accordingly, Wampler-169 discloses that the magnetically driven rotor is “rotatable within *a surrounding rotor housing* (“casing 14”) to act upon blood flowing from the *inflow tube* (“inlet tube 13”) toward the *rotor* (“impeller 74”).”

Ex.1003, ¶174.

v. *[1D]*

As demonstrated in [1B], “drive is imparted to [rotate] the *impeller [74]*” (Ex.1008, [0018]) “about a rotational axis” (Ex.1008, [0013]; Ex.1003, ¶176), as shown:



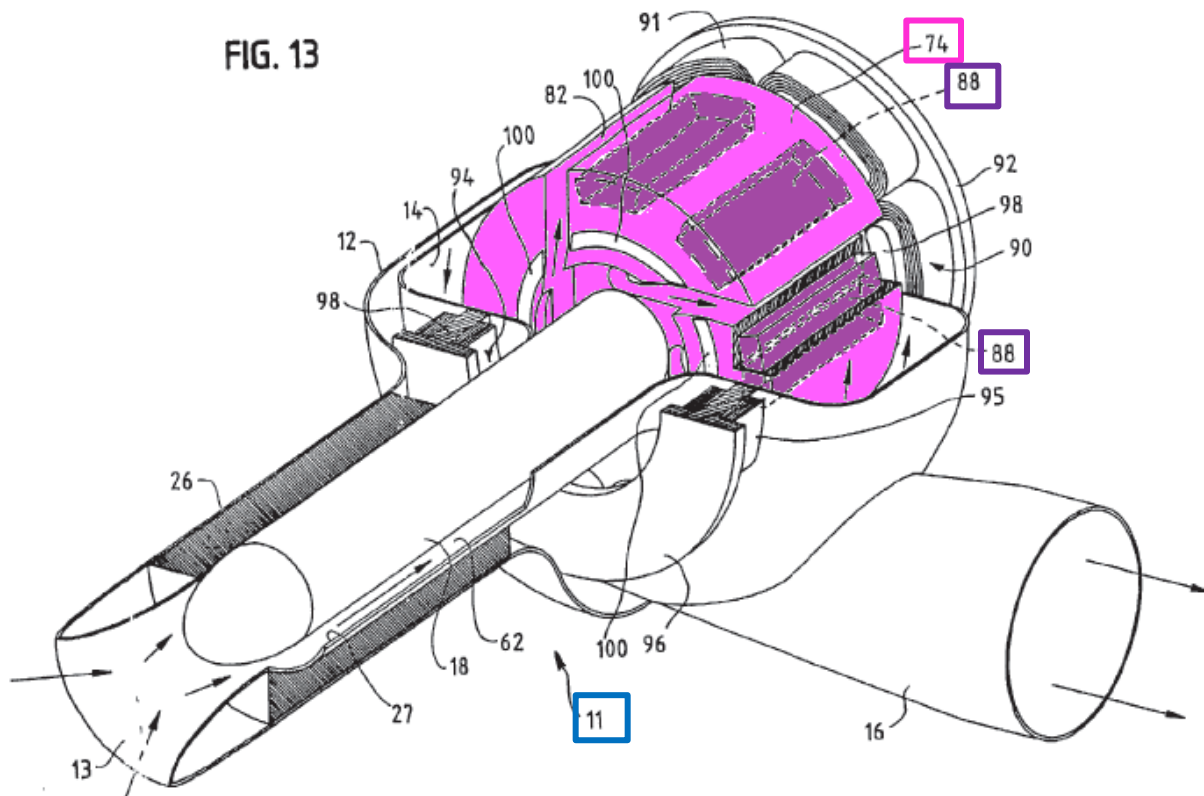
Ex.1008, Fig. 13; [0081]-[0082] (explaining that “axis” of Fig. 13 is identical to Figs. 1-8); *supra* [1B]-[1C]; Ex.1003, ¶177.

Accordingly, Wampler-169 discloses “*the magnetically driven rotor* (‘‘impeller 74’’) *being rotatable about a central axis.*” Ex.1003, ¶178.

vi. *[1E]*

Wampler-169 discloses that “drive is imparted to...**permanent magnetic segments**” (“*a first magnetic device*”) “imbedded within [the] **impeller [74]**”

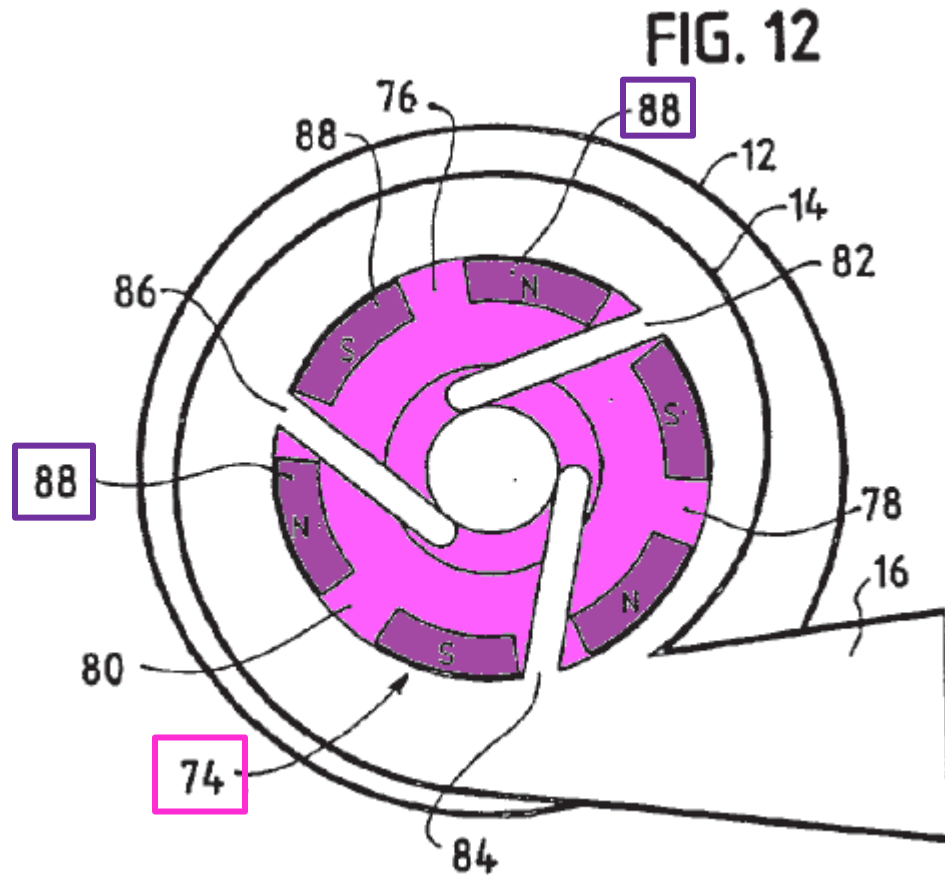
(“*rigidly coupled*”).<sup>7</sup> Ex.1008, [0018] *see also* [0070] (“magnetic segments...are encased in a jacket.”); Ex.1003, ¶180 (discussing that imbedded segments are *rigidly coupled*). Wampler-169 also refers to these “**segments**” as “**magnetic pieces 88**” (“*a first magnetic device*”), which “are inserted [*rigidly coupled*] in...the **impeller**” (Ex.1008, [0080]), as shown:



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

Ex.1008, Fig. 13. Ex.1003, ¶184; Ex.1003, ¶¶181-183 (analyzing interaction between “magnetic pieces 88” and “motor stators 90 and 94”).

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



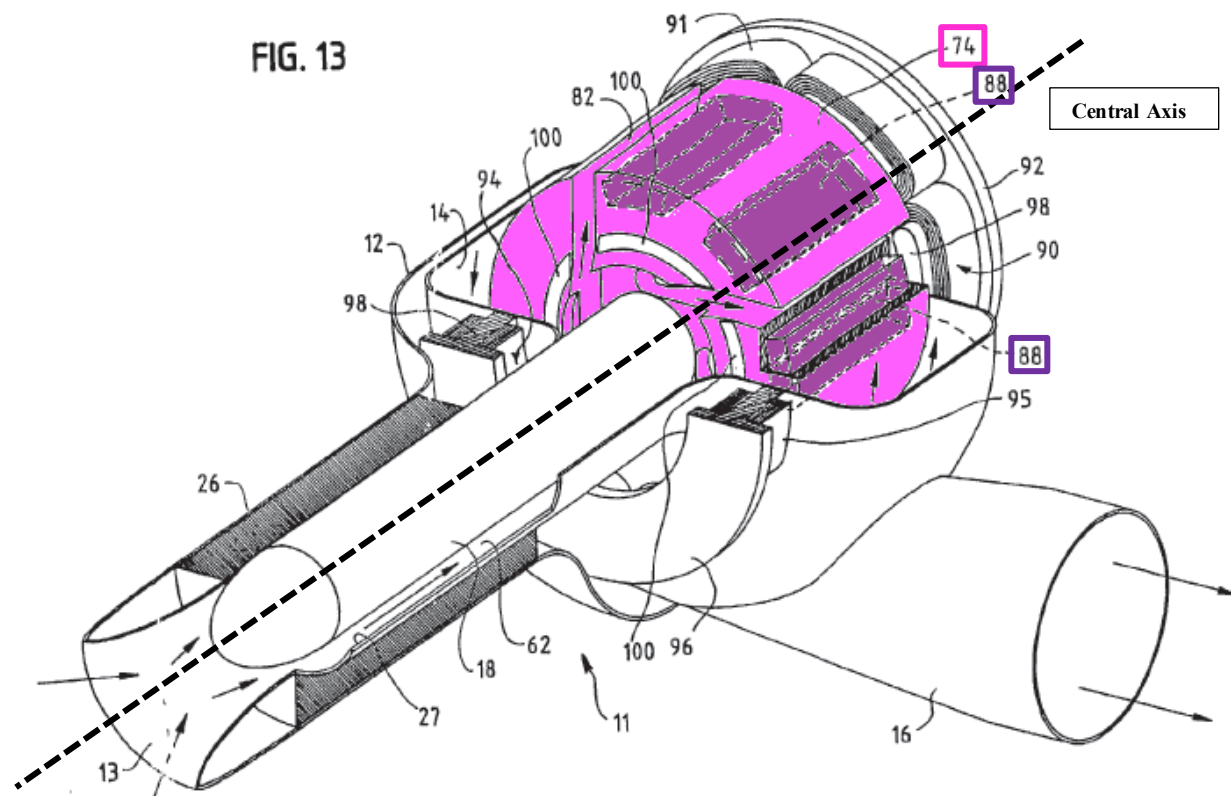
Ex.1008, Fig. 12; Ex.1003, ¶185.

Accordingly, Wampler-169 teaches or suggests the **magnetically driven rotor** (“impeller 74”) “being rigidly coupled to a **first magnetic device** (“magnetic pieces 88”).” Ex.1003, ¶186.

i. [1F]

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

Assuming that interpretation, as demonstrated in [1E], Wampler-169 discloses that the “**permanent magnetic segments** [are] imbedded within [‘*axially adjacent to*’] [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 in [‘*axially adjacent to*’]...the **impeller**” (Ex.1008, [0080]-[0081]; Ex.1003, ¶188), as shown:

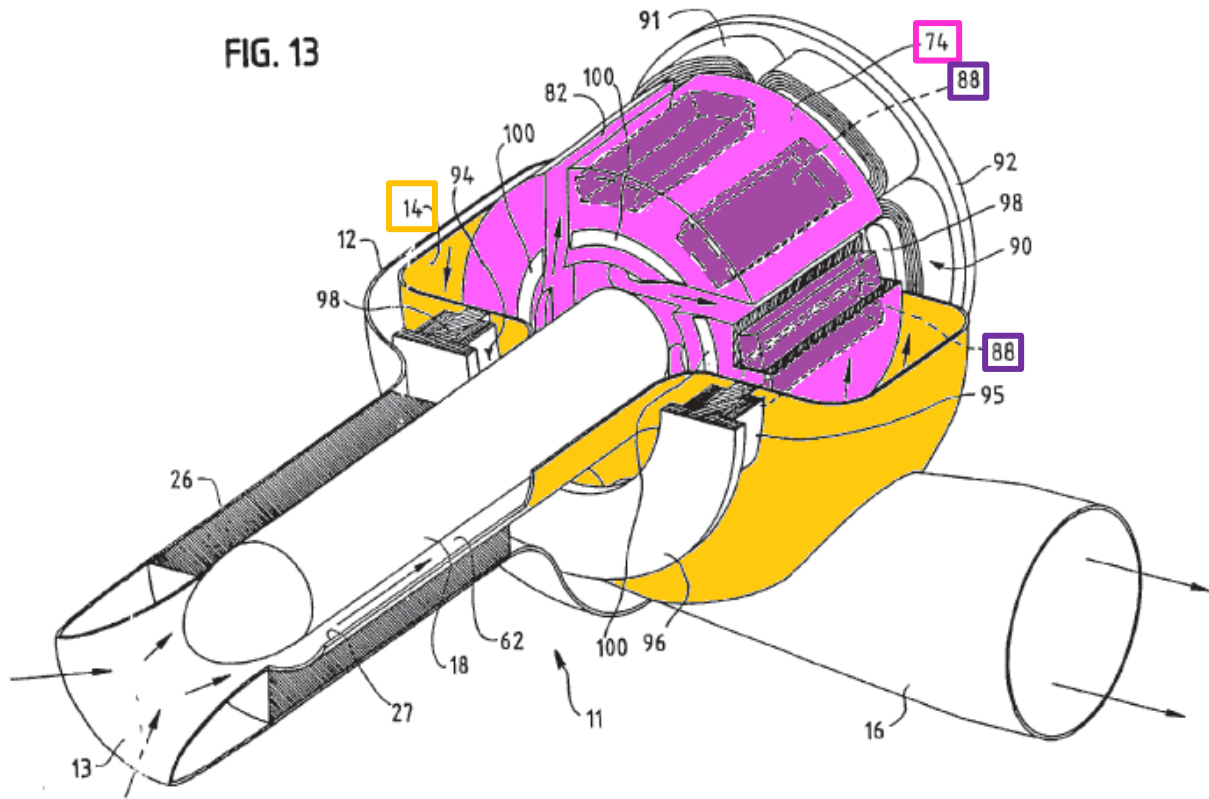


Ex.1008, Figs. 13; *supra* [1E]; Ex.1003, ¶189. Further, Mr. Crosby explains the “impeller” and “magnetic pieces” are *axially adjacent*—situated next to each other on the same axis. Ex.1003, ¶190.

Accordingly, Wampler-169 teaches or suggests that the **magnetically driven rotor** is “*axially adjacent to a first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶191.

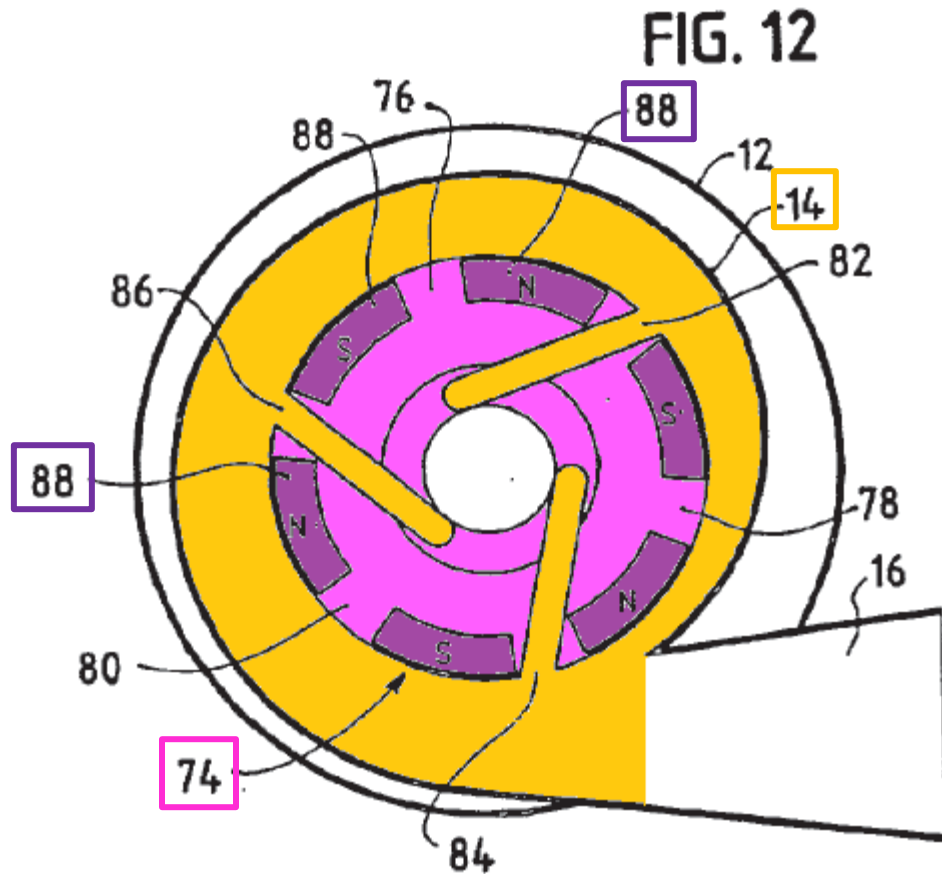
ii. *[1G]*

As demonstrated in [1C] and [1E], Wampler-169 discloses that **impeller 74**, having **magnetic pieces 88**, is “located within housing 12, within **casing 14**” (“*within the surrounding rotor housing*”) (Ex.1008, [0080]-[0081], Ex.1003, ¶193), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶196; *supra* [1C], [1E].

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



Ex.1008, Fig. 12; Ex.1003, ¶195.

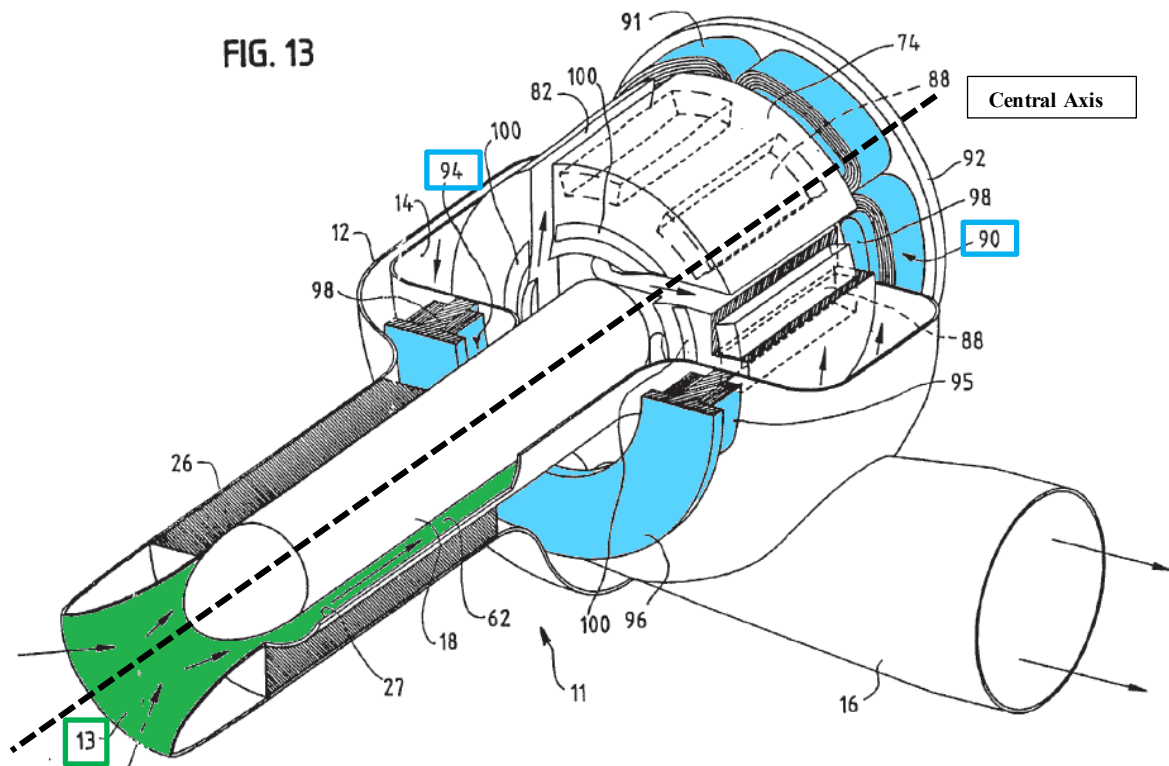
Accordingly, Wampler-169 discloses that the **first magnetic device** (“magnetic pieces 88”) “*is located within the surrounding rotor housing* (“casing 14”).” Ex.1003, ¶197.

### iii. [1H]

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 “**motor stators 90 and 94**” comprising elements “to complete a magnetic circuit” (Ex.1008, [0085];

Ex.1003 ¶200) (“*a second magnetic device*”) are “circular” (Ex.1008, [0018]) (“*axially aligned*”) and axially aligned with the “**inlet tube 13**” (“*inflow tube*”) (Ex.1008, [0080], ¶¶203-204), as shown:



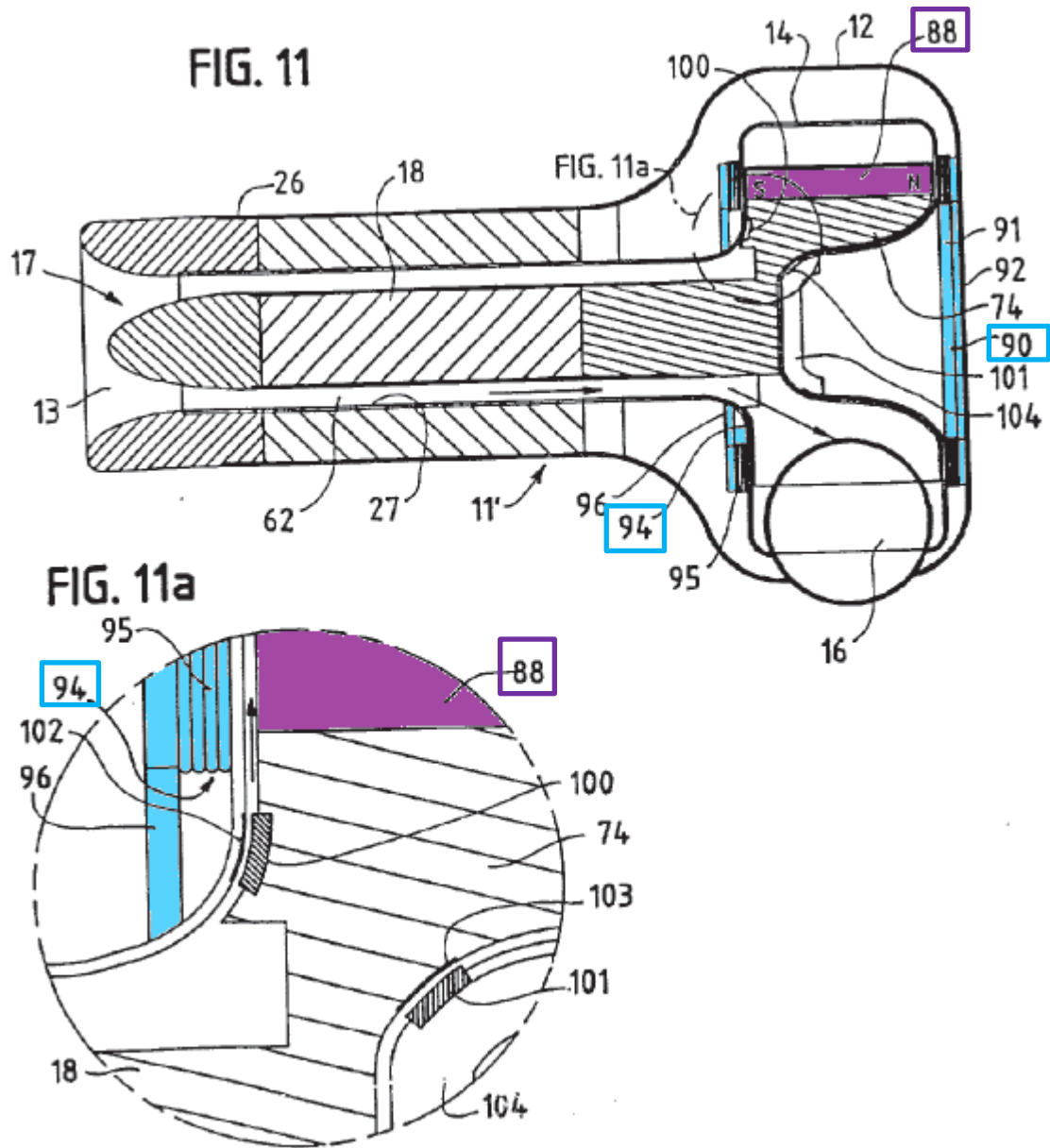
Ex.1008, Fig. 13, *see also* [0070]; Ex.1003, ¶206.

Accordingly, Wampler-169 discloses that “a *second magnetic device* (“motor stators 90 and 94”) *axially aligned with the inflow tube* (“inlet tube 13”).” Ex.1003, ¶207.

iv. *[1I]*

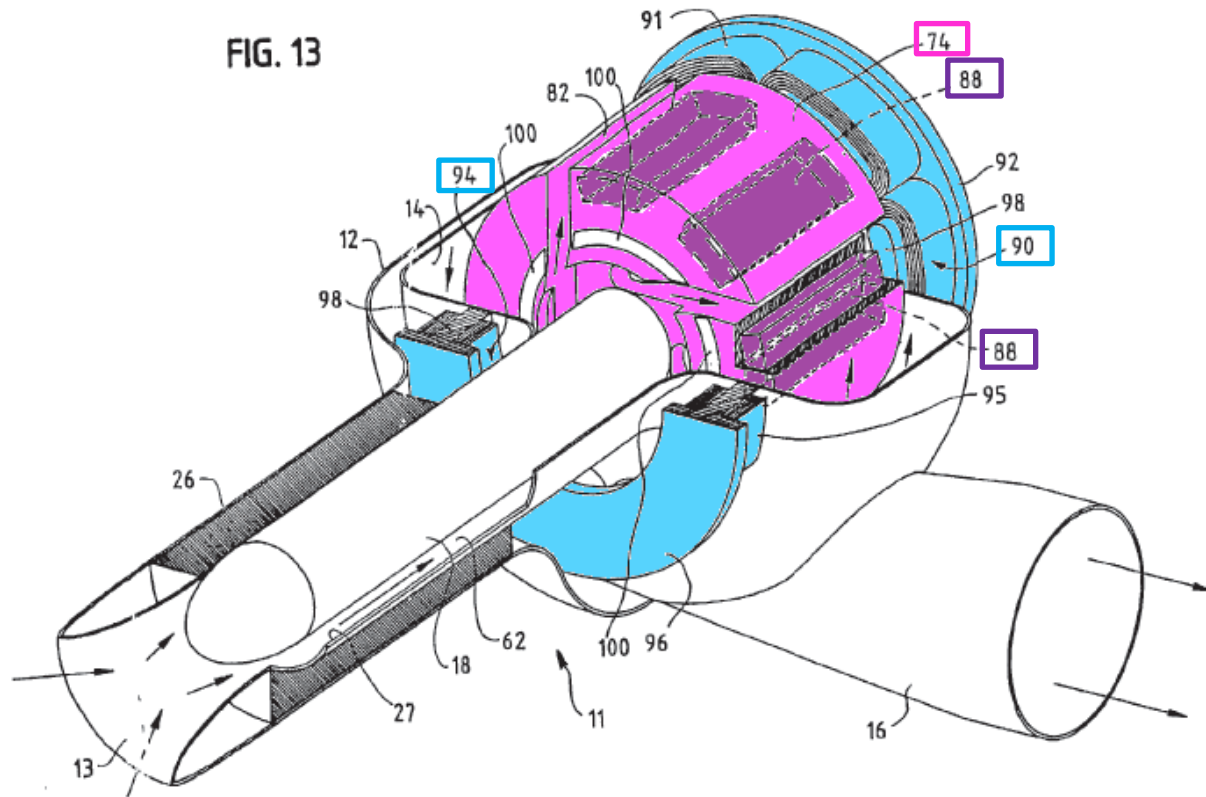
In Parallel Litigation, PO alleges that a “stator” satisfies this limitation.  
Ex.1019, 7-8.

Assuming that interpretation, Wampler-169 discloses that “drive is imparted to the **impeller** by magnetic interaction [*‘to magnetically drive...via a magneto coupling’*] between arcuate, **permanent magnetic segments [88]** imbedded within each **impeller** blade sector, and a **circular electromagnetic stator [90 and 94]** (*“positioned to magnetically drive rotation”*). Ex.1008, [0018]; Ex.1003, ¶¶211-212. Thus, the **stator** and its “windings[] are energized by the electrical output of [a] controller 59 to produce an electromagnetic field...[which] is effective to drive [*‘via a magneto coupling’*] **magnets [88]** and the [**impeller**], in rotary fashion.” Ex.1008, [0072]; Ex.1003, ¶211 (explaining this description of electromagnetic drive referencing Figures 1-8 applies to the embodiment of Figures 11-14).



Ex.1008, Figs 11-11a; Ex.1003, ¶213.

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



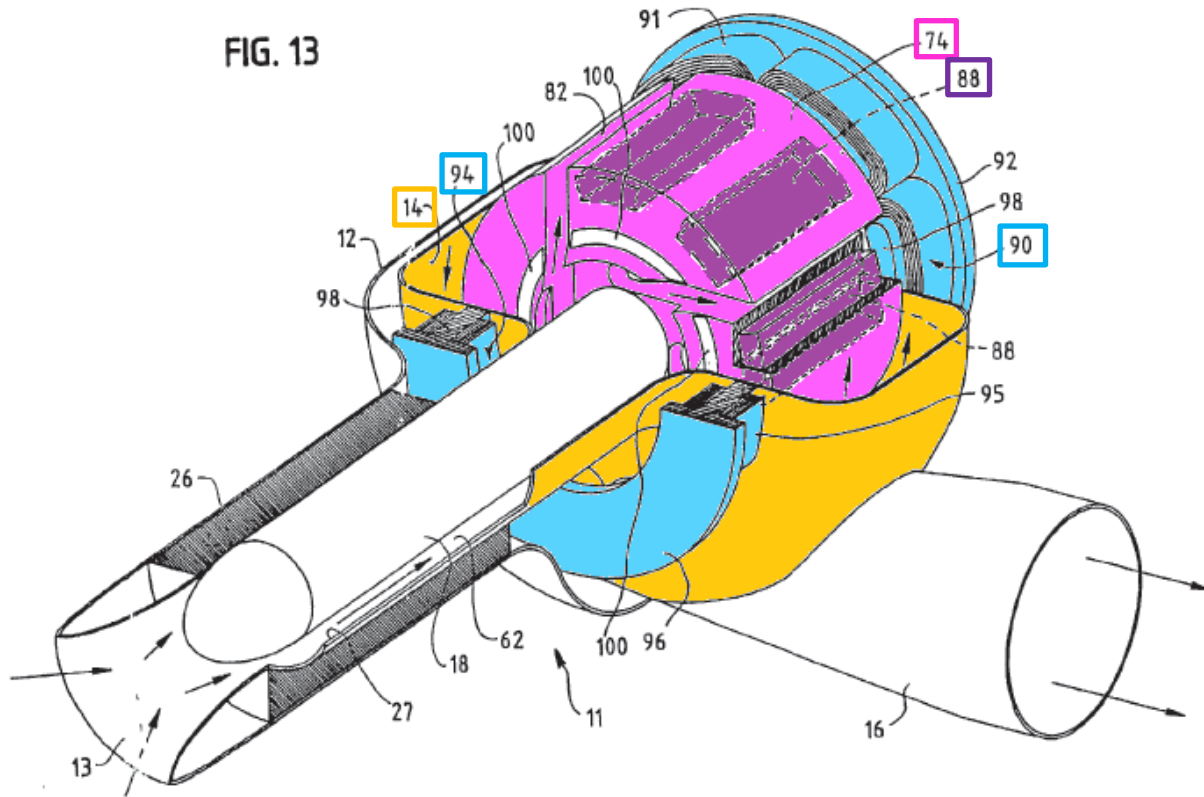
Ex.1008, Fig. 13; Ex.1003, ¶214.

Accordingly, Wampler-169 discloses that the *second magnetic device* (“motor stators 90 and 94”) is “*positioned to magnetically drive rotation of the magnetically driven rotor*” (“impeller 74”) *via a magneto coupling with the first magnetic device* (“magnetic pieces 88”).” Ex.1003, ¶215.

v. [1J]

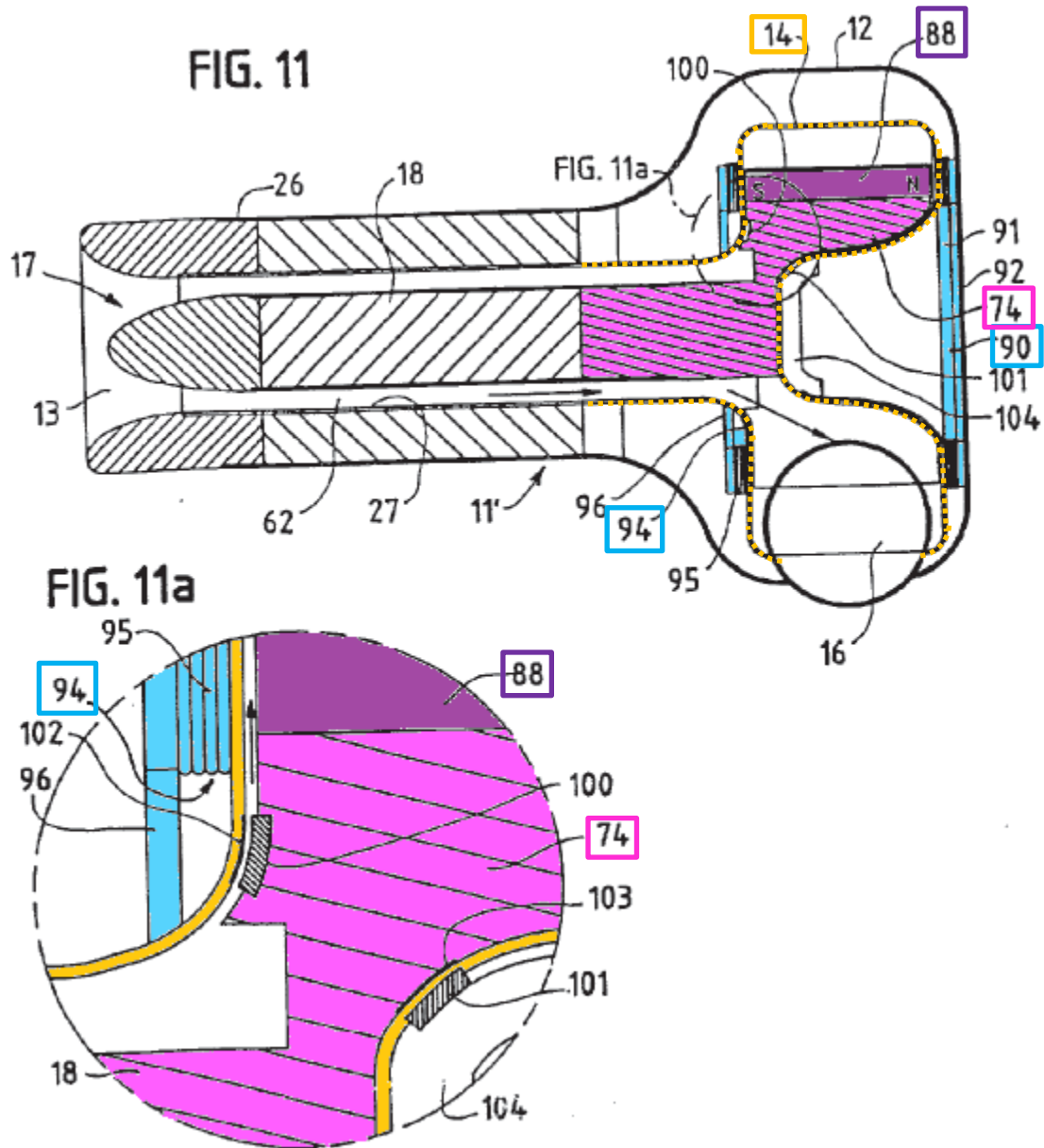
Wampler-169 discloses or at least renders obvious that the “*stator[s]*” are fixed between housing 12 and *casing 14*” (“*spaced apart*”) (Ex.1008, [0083]-[0084]; Ex.1003, ¶¶218-219) while the “*impeller*” and its “*magnetic pieces*” are

“enclos[ed]” within the **casing** (“sealed”) (Ex.1008, [0012], Ex.1003, ¶217), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶220. Wampler-169 discloses that blood enters “the interior of the casing 14” (“sealed...by at least one sealing wall”) and is “expelled from the casing” via a “discharge tube 16.” Ex.1008, [0074]; Ex.1003, ¶220. Mr. Crosby explains that it would have been obvious that “a thin-walled non-magnetic jacket be placed over these portions, to prevent contact between the magnets and the blood [‘sealed...by at least one sealing wall’].” Ex.1008, [0057]; Ex.1003, ¶220 (analyzing sealing to avoid “undesirable chemical reaction”).

Figures 11-11a illustrate the “**stator[s]**” fixed between housing 12 and **casing 14**” are *positioned axially spaced apart from the “impeller”* and its “**magnetic pieces 88**”:

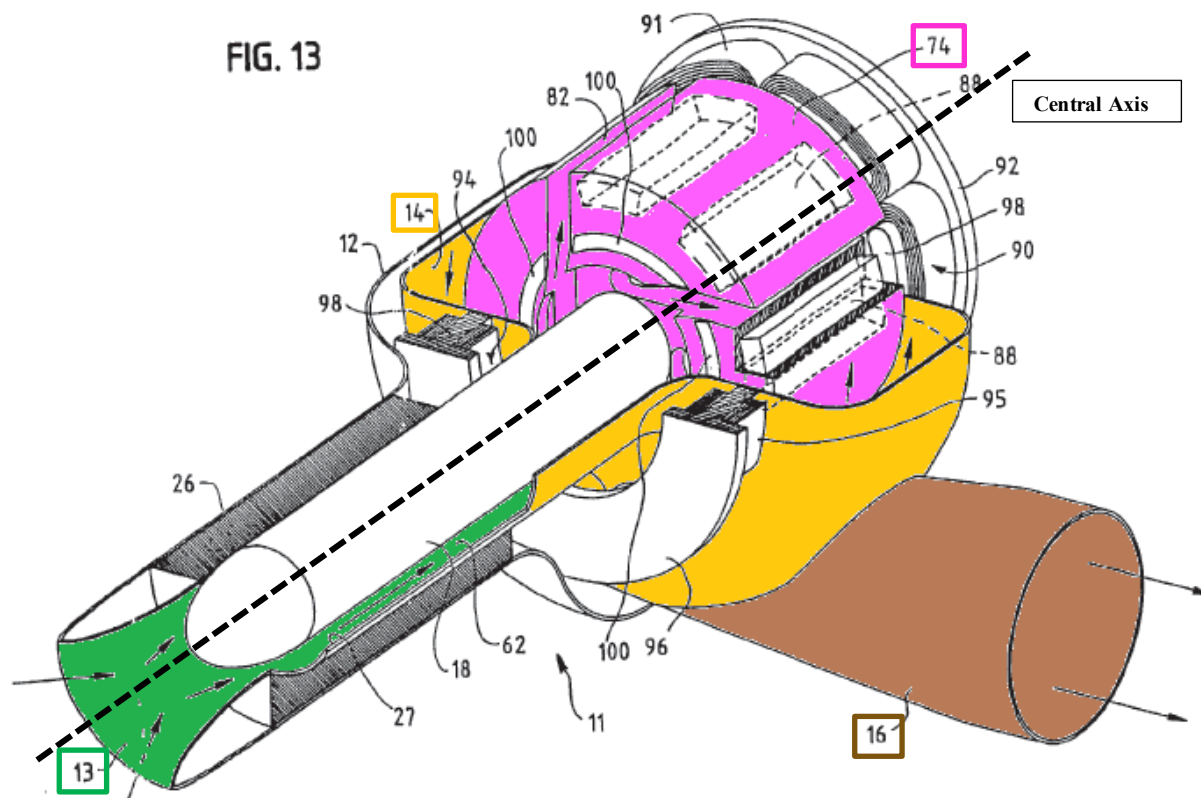


Ex.1008, Figs. 11-11a; Figs. 7-8b, [0070]; Ex.1003, ¶221.

Accordingly, Wampler-169 discloses that the *second magnetic device* (“motor stators 90 and 94”) is positioned according to [1H] “*while being spaced apart and sealed from both the magnetically driven rotor* (“impeller 74”) *and the first magnetic device* (“magnetic pieces 88”) *by at least one sealing wall* (“casing 14”), *the second magnetic device being positioned axially spaced apart from the magnetically driven rotor.*” Ex.1003, ¶222.

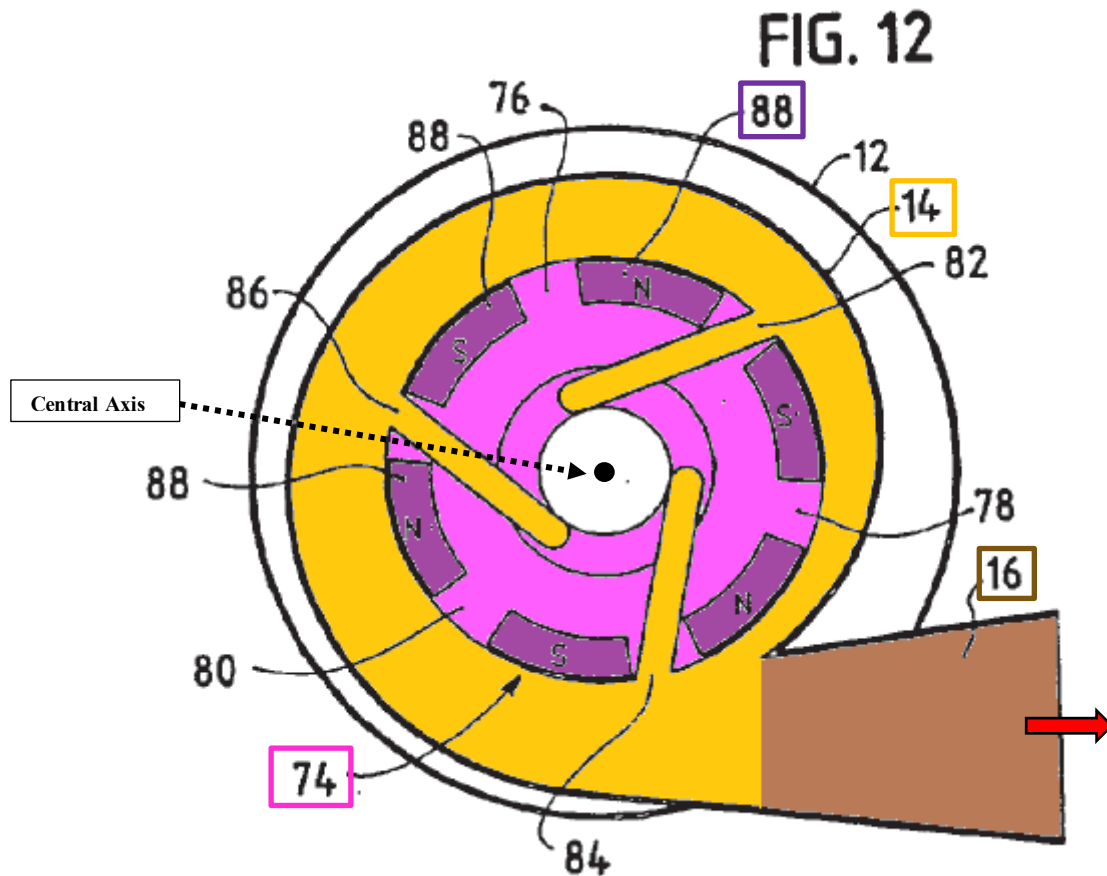
vi. [1K]

Wampler-169 discloses that “**discharge tube 16**” (“*a blood outflow port*”) has “a tangential orientation with respect to a radius of the casing” (“*positioned radially adjacent*”) allowing “radial outflow of the pump [in] a 90-degree redirection of the blood” (“*in a direction transverse to the central axis*”) (Ex.1008, [0074]-[0076], [0080]; Ex.1003, ¶224), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶226.

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



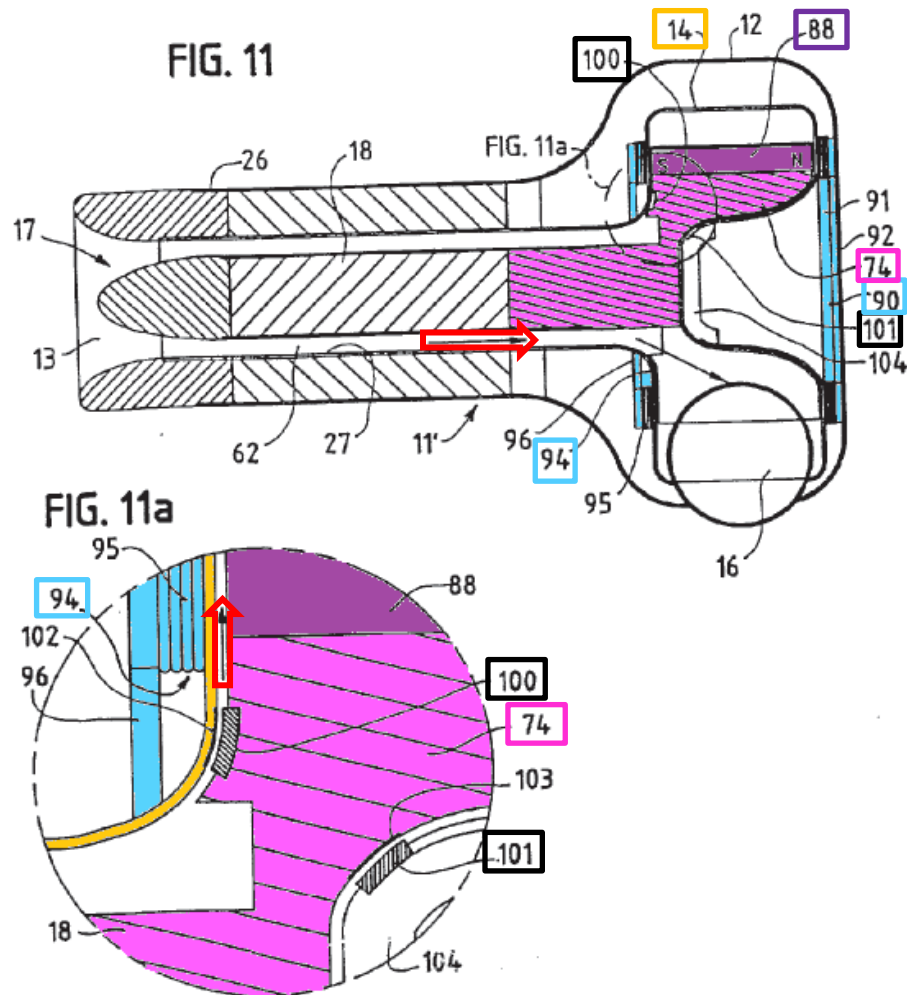
Ex.1008, Fig. 12; Ex.1003, ¶227.

Accordingly, Wampler-169 discloses “a **blood outflow port** (“discharge tube 16”) positioned radially adjacent the **magnetically driven rotor** (“impeller 74”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“casing 14”) in a direction transverse (“a 90-degree redirection”) to the **central axis** of the **magnetically driven rotor**.” Ex.1003, ¶228.

vii. [1L]

Wampler-169 discloses that “once rotation [of the **impeller**] begins” (“when the magnetically driven rotor is rotated”) “relative movement between the

[impeller] and...the hydrodynamic action of the fluid film [(‘*by the blood flowing*’; **red** arrows)] produces increased pressure within the bearing gap which forces the [impeller] and the [casing] apart” (“*remains adjacent to and spaced apart*”) (Ex.1008, [0092]; Ex.1003, ¶234), as shown:



Ex.1008, Figs. 11-11a; Ex.1003, ¶235.

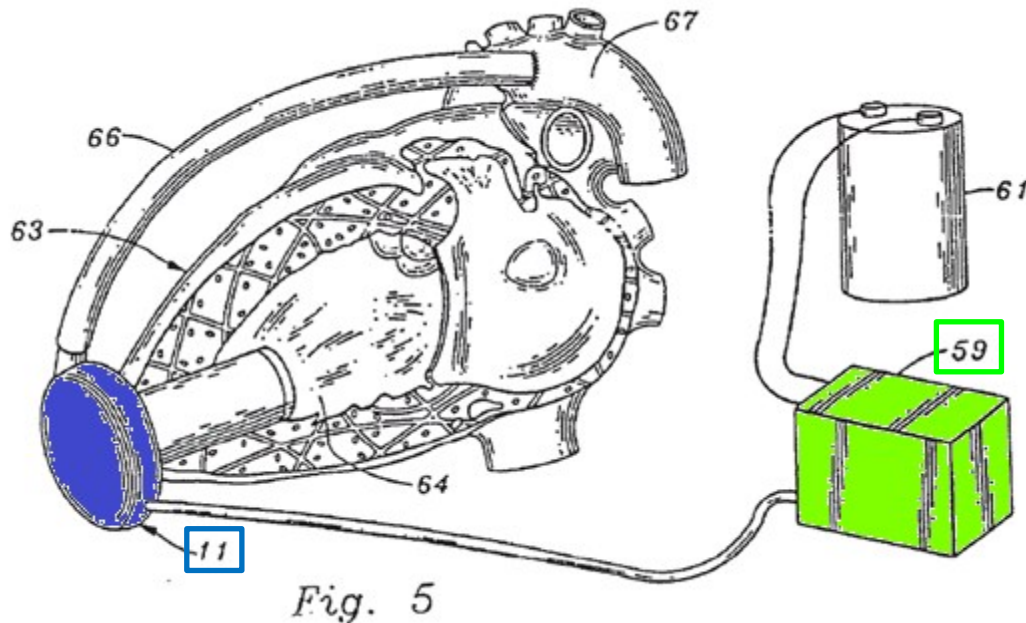
Said another way, Wampler-169 teaches that “hydrodynamic bearings are formed” “*when the magnetically driven rotor is rotated*”—“**once rotation**

**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, ¶236.

Accordingly, Wampler-169 discloses that “*wherein when the magnetically driven rotor is rotated* (“once rotation...begins”), *the magnetically driven rotor* (“impeller 74”) *remains adjacent to and spaced apart* (“force[d] apart”), *from the surrounding rotor housing* (“casing 14”) *by the blood flowing* (“fluid film”) *from the inflow tube* (“inlet tube 13”) *and to the blood outflow port* (“discharge tube 16”).” Ex.1003, ¶237.

#### viii. [1M]

Wampler-169 discloses that the motor stators “are energized by the electrical output of **controller 59**” (Ex.1008, [0072]), which “may be worn externally by the user” (Ex.1008, [0070]) (“*an external control unit*”), and which can be “manually adjusted or programmed to determine the running rate of pump” (Ex.1008, [0071]; Ex.1003, ¶240) (“*configured to regulate operation*”) by “produc[ing] an electromagnetic field...to drive...the rotor” (“*to thereby magnetically drive the rotation*”) (Ex.1008, [0072]; Ex.1003, ¶239), as shown:



Ex.1008, Fig. 5; Ex.1003, ¶242; *see also* ¶¶239-241 (analyzing how controller regulat[es] operation).

Accordingly, Wampler-169 teaches or suggests “an **external control unit** (“controller 59”) configured to regulate operation (“to determine the running rate of pump”) of the **second magnetic device** (“motor stators 90 and 94”), wherein the **external control unit** is connectable to the **heart assist pump device** (“pump 11”) for controlling the **second magnetic device** (“motor stators 90 and 94”) to thereby magnetically drive the rotation of the **magnetically driven rotor** (“impeller 74”) via the magneto coupling (as demonstrated in 1[H]) with the **first magnetic device** (“magnetic pieces 88”).” Ex.1003, ¶243.

## 2. Claims 2, 3, and 4

### i. [2]

Wampler-169 discloses that the “centrifugal pump **impeller**” “includes...blade sectors” (Ex.1008, [0012]-[0013]) (“*guide surfaces*”) so that “[r]otation of...**impeller** 19, causes blood to flow through inlet tube 13 in the direction of arrows 62” towards the “discharge tube” (“*produce centrifugal flow components*”). Ex.1008, [0074], Fig. 6 (showing arrows 62); Ex.1003, ¶¶247-248.

Accordingly, Wampler-169 discloses that “*wherein the magnetically driven rotor* (“impeller 74”) *comprises guide surfaces* (“blade sectors”) *to produce centrifugal flow components*” (“arrows 62”). Ex.1003, ¶250.

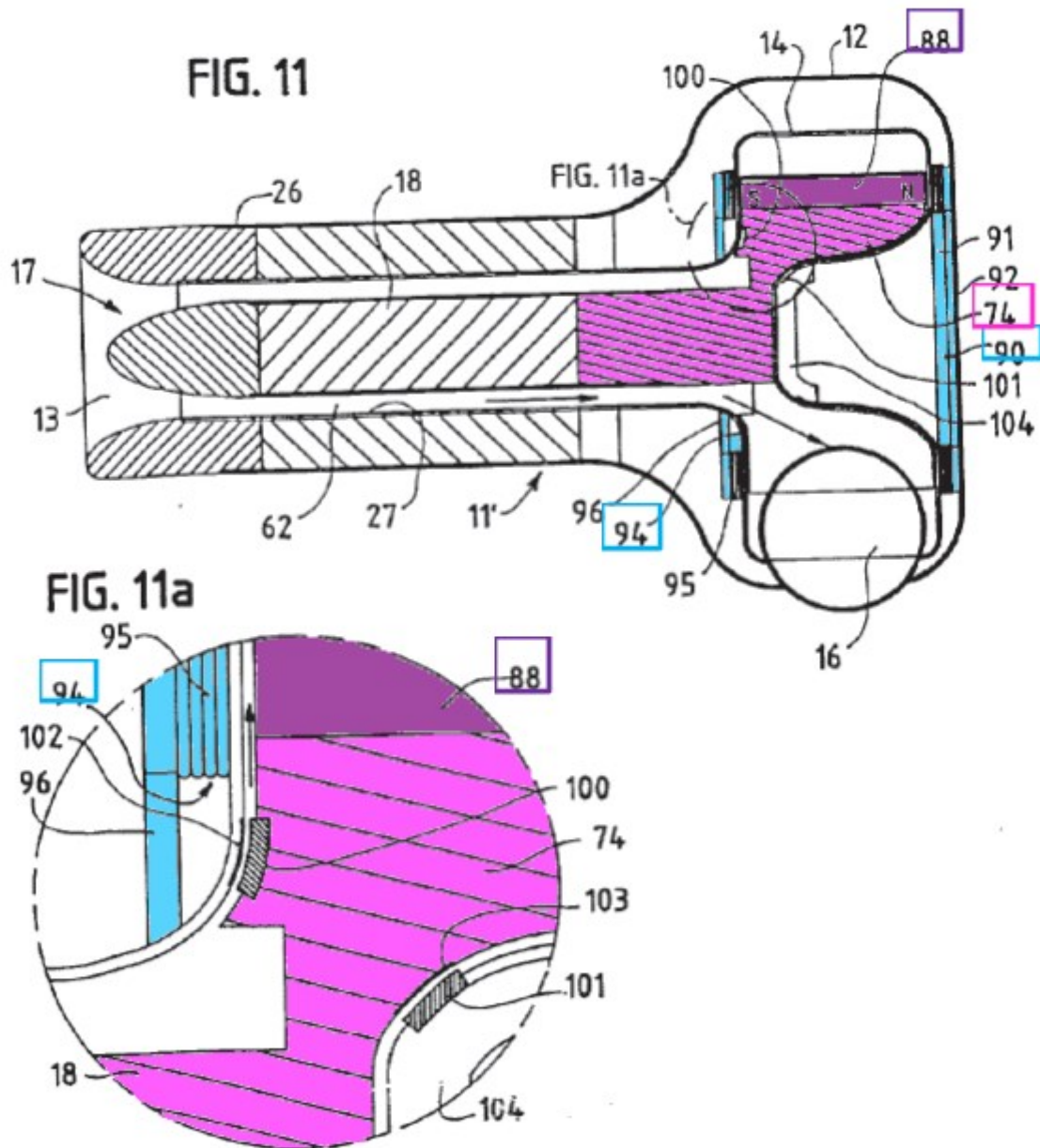
### ii. [3A]

For the reasons demonstrated in [1J] that the **stators** are “*spaced apart and sealed...by at least one sealing wall*” of **casing 14**” (Ex.1008, [0083]), Wampler-169 discloses or at least renders obvious that “*the surrounding rotor housing* (“casing 14”) *comprises the at least one sealing wall* (“casing 14”).” *Supra* [1J]; Ex.1003, ¶¶255, 257.

### iii. [3B]

In Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is positioned between the second magnetic device and the magnetically driven rotor. *See*, Ex.1019.

Assuming that interpretation, as demonstrated in [1E]-[1F] and [21G] (analyzing “*axially closer*”), the rotor has “imbedded” “**magnetic pieces 88**” (Ex.1008, [0018]; Ex.1003, ¶260) “*positioned between the “**impeller 74**” and “**motor stators 90 and 94**”* (Ex.1008, [0080]; Ex.1003, ¶261), as shown:



Ex.1008, Figs 11-11a; *supra* [1E]-[1F] (analyzing axially adjacent position); Ex.1001 ¶262.

Accordingly, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *is positioned between the second magnetic device* (“motor stators 90 and 94”) *and the magnetically driven rotor* (“impeller 74).” Ex.1003, ¶263.

#### iv. [4]

For the reasons demonstrated in [1E] that the “**impeller**” and “**magnetic pieces**” are *rigidly coupled*, Wampler-169 discloses that “*the first magnetic device* (“magnetic pieces 88”) *rotates together with the magnetically driven rotor* (“impeller 74”) *relative to the surrounding rotor housing* (“casing 14”). *Supra* [1E] (analyzing Ex.1008, [0018], [0080]). Ex.1003, ¶¶266-267.

### 3. Claims 10, 14, and 15

#### i. [10]

For the reasons demonstrated in [1I] and [1L] that “once rotation begins,” “*the blood flowing*” produces a “fluid film...within the bearing gap” (“*entirely spaced apart...by a gap during rotation*”) (Ex.1008, [0092]) that causes the “**impeller**” and its “**magnetic pieces**” to be “suspended within the **housing**” (Ex.1008, [0013]), Wampler-169 discloses that “*both the magnetically driven rotor* (“impeller 74”) *and first magnetic device* (“magnetic pieces 88”) *are entirely spaced apart from the*

*surrounding rotor housing* (“casing 14”) *by a gap during rotation of the magnetically driven rotor.*” Ex.1003, ¶¶273-274.

ii. [14]

As demonstrated in [1M], the “external” “**controller**” may be “manually adjusted or programmed to determine the running rate of pump.” Ex.1008, [0071], [0018] (“control unit allows...motor...to be programmed”); Ex.1003, ¶¶278-279.

Accordingly, Wampler-169 teaches or suggests that “*the external control unit* (“controller 59”) *is configured to regulate operation of the second magnetic device* (“motor stators 90 and 94”) *based on a control value.*” Ex.1003, ¶280.

iii. [15]

As demonstrated in [1M] and [14], the “external” “**controller**” can be “manually adjusted or programmed to determine the running rate of pump...[and] may be interconnected to sensors on various organs...[to] automatically...tailor operation of the pump to the user's physical activity and condition.” Ex.1008, [0071]; [0018] (“The control unit allows the speed...to be...determined by the user’s physical activity”); *supra* [M]; Ex.1003, ¶285.

Accordingly, Wampler-169 teaches or suggests that “*wherein the control value is indicative of a defined cardiac output* (“user's physical activity and condition”) *for control of the heart assist pump device* (“tailor operation of the pump”).” Ex.1003, ¶287.

#### 4. Claim 11

See [15] (analyzing “sensors” which *deliver feedback signals* of “the user's physical activity”). Ex.1003, ¶445.

#### 5. Claim 17

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Ex.1019, 4. Assuming that interpretation, because Wampler-169's pump comprises an “inflow cannula” (Ex.1008, [0075]) it “*is a catheter device*.” Ex.1003, ¶¶291-294.

Accordingly, Wampler-169 discloses that “*the heart assist pump device* (“pump 11”) *is a catheter device*.” Ex.1003, ¶295.

#### 6. Claim 21

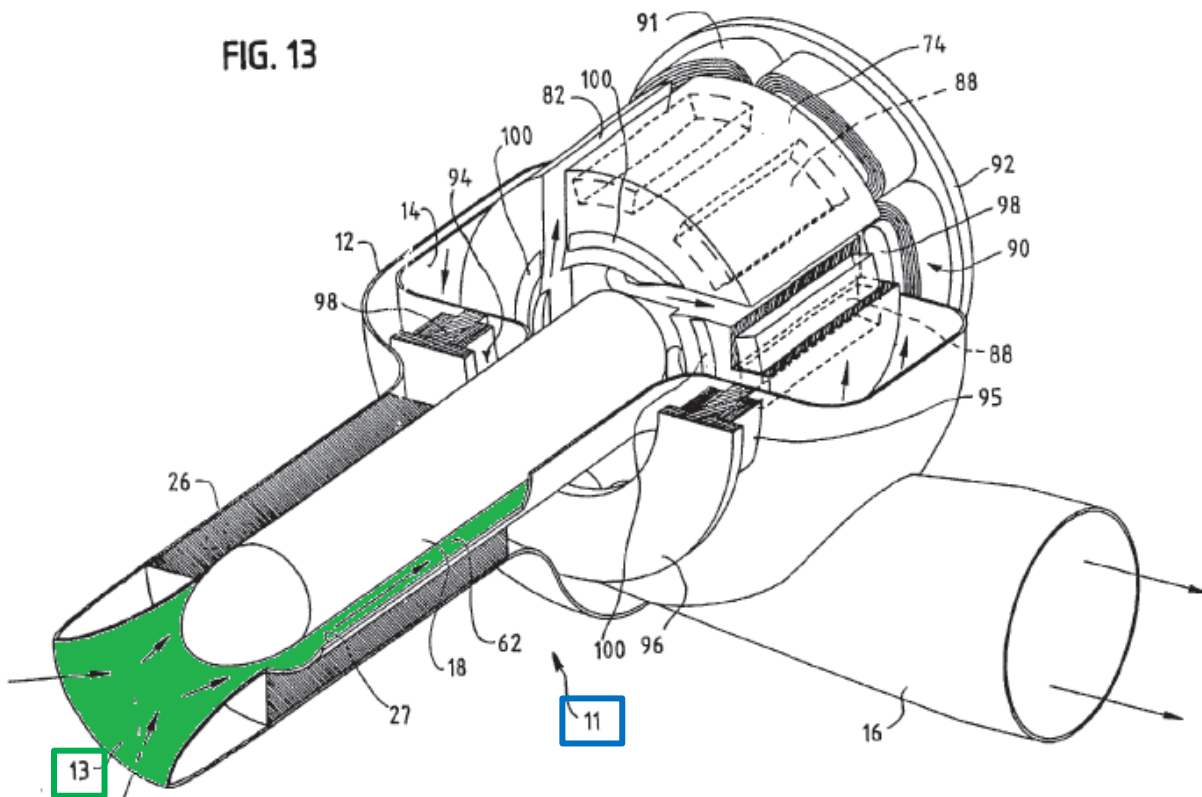
Claim 21 is rendered obvious for the same reasons as claim 1. Ex.1003, ¶296.

##### i. [21PRE]

See [1PRE]. Ex.1003, ¶297.

##### ii. [21A]

See [1A] (analyzing “*an inflow tube defining a blood inflow path*” (“inlet tube 13”) and “*insertable into a left ventricle*” (“placed into the apex of the left ventricle 64”)). Ex.1003, ¶301. The “inlet tube 13” defines a blood inflow path along an inflow axis (i.e., central axis), as shown:



Ex.1008, Fig. 13; Ex.1003, ¶305.

### iii. [21B]

See [1C] and [3A] (analyzing a “*surrounding rotor housing*” (“casing 14”) comprising “*at least one sealing wall*”). Ex.1003, ¶308. Wampler-169 discloses “*walls...defining a chamber*” of [21B] for the reasons it discloses a “*surrounding rotor housing compris[ing] at least one sealing wall*” of [3A]. *Supra* [3A]; Ex.1003, ¶310.

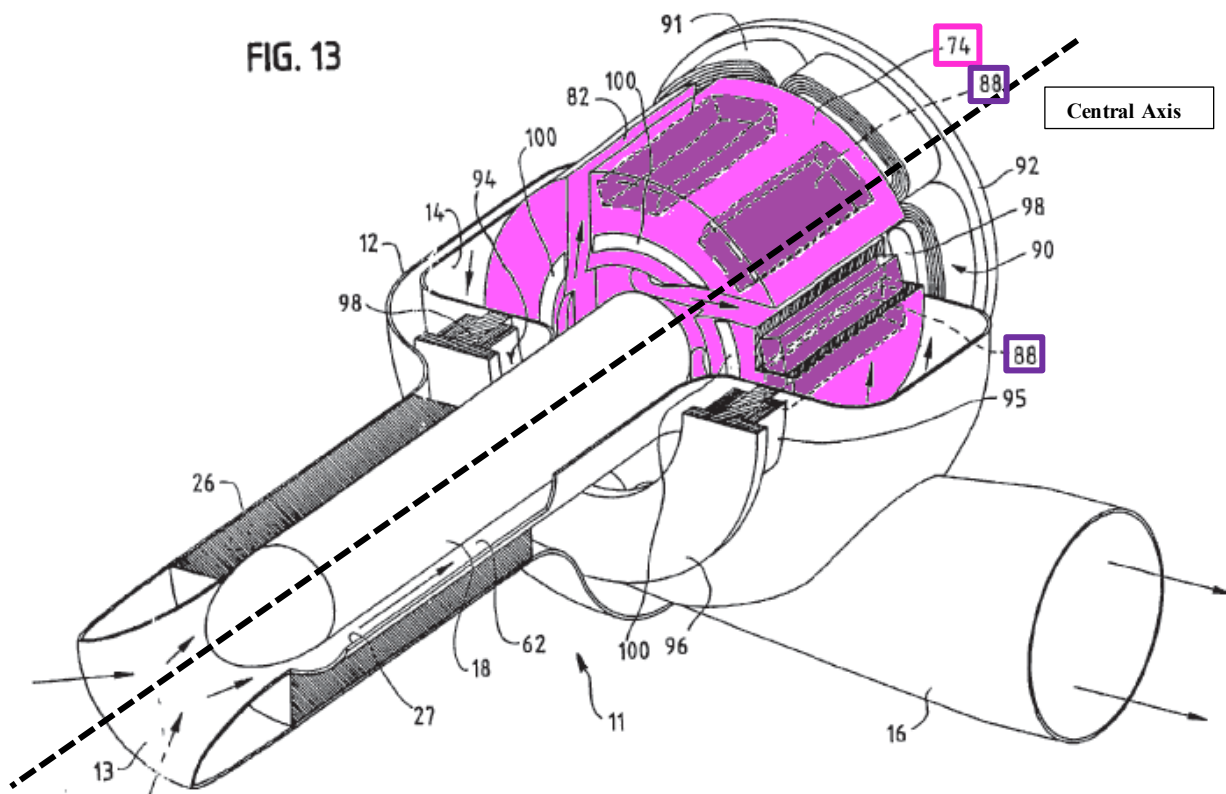
### iv. [21C]

See [1B] (analyzing “a *magnetically driven rotor*” (“impeller 74”) axially aligned with the *inflow tube* (“inlet tube 13”)) and [1E] (analyzing the *magnetically*

*driven rotor* (“impeller 74”) “being rigidly coupled to a *first magnetic device*” (“magnetic pieces 88”). Ex.1003, ¶316.

v. [21D]

See [1F], [21C]; Ex.1003, ¶332. Wampler-169 discloses that both its *magnetically driven rotor* (“impeller 74”) and *first magnetic device* (“magnetic pieces 88”) are “axially adjacent” to each other and both are “axially aligned with the inflow axis” (i.e., central axis), as shown:



Ex.1008, Figs. 13; *supra* [1F]; Ex.1003, ¶316

vi. [21E]

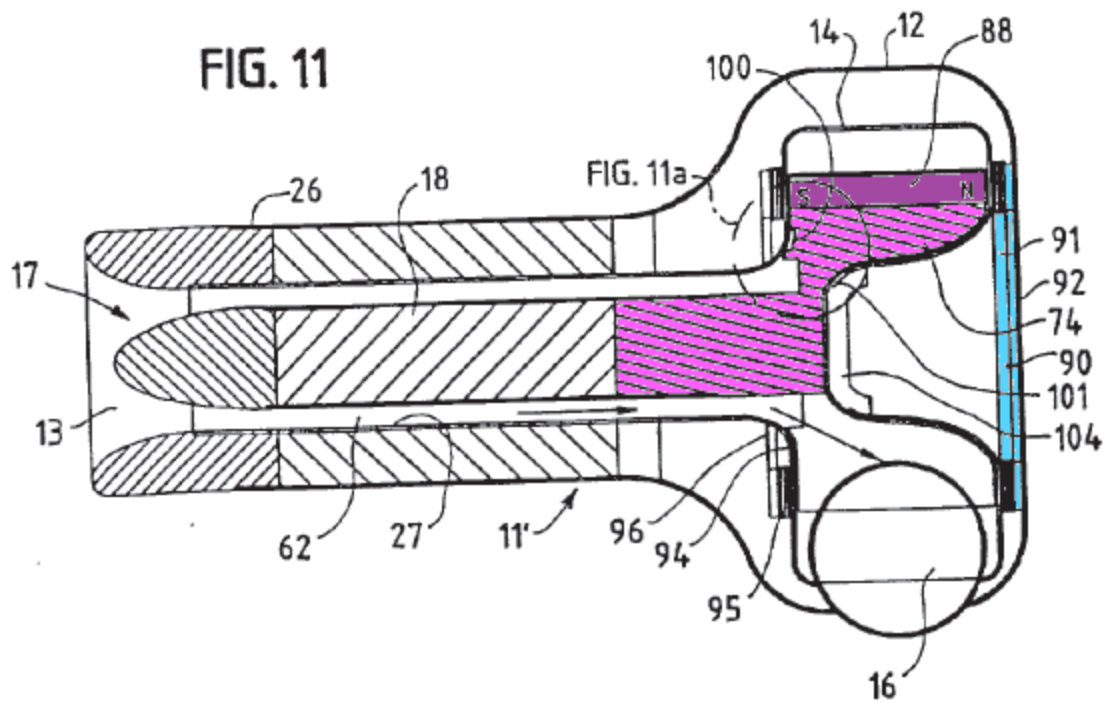
See [1C]-[1D]. Ex.1003, ¶339.

**vii. [21F]**

See [1H]-[1I]. Ex.1003, ¶346. Wampler-169 discloses a “*magnetic drive system comprising a second magnetic device*” of [21F] for the reasons it discloses a “*second magnetic device*” (“motor stators 90 and 94”) “*positioned to magnetically drive rotation*” of claim [1H]-[1I].

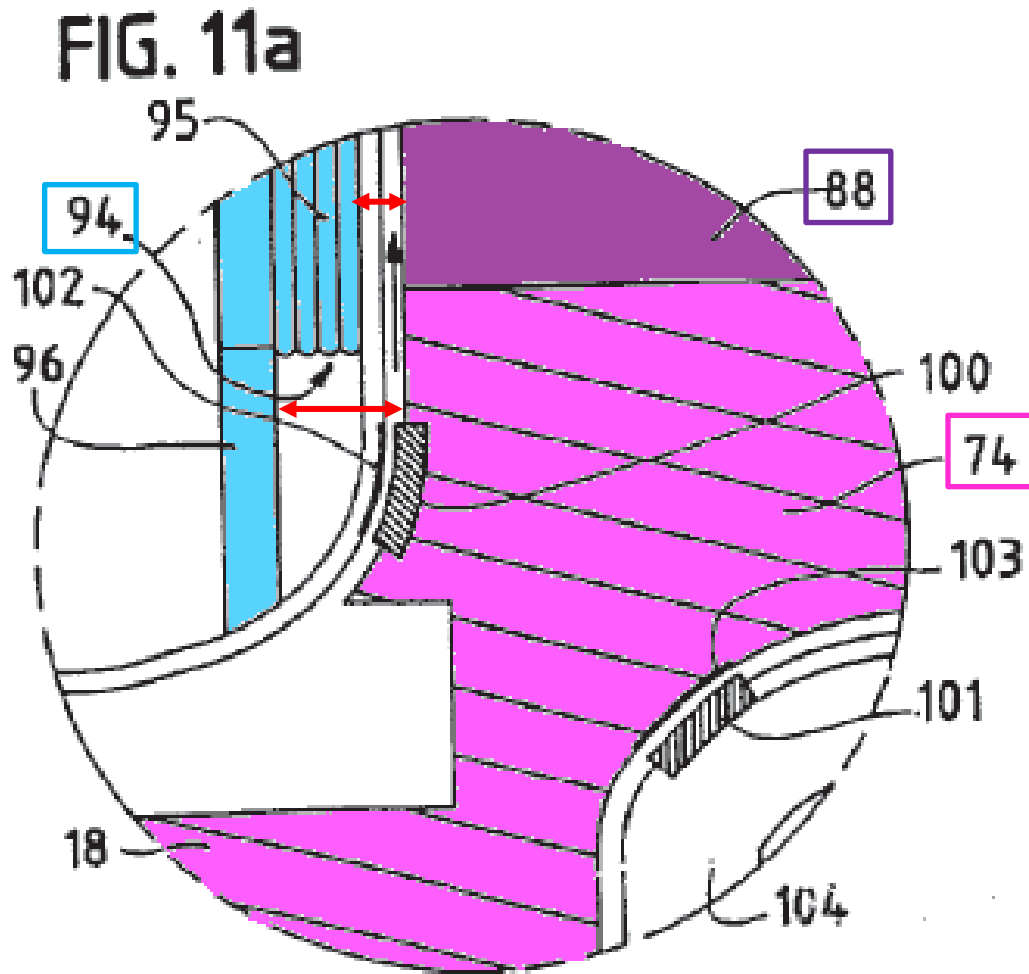
**viii. [21G]**

See [1J] and [3B]. Ex.1003, ¶357. Wampler-169 discloses or at least renders obvious that the *second magnetic device*” is “*positioned axially closer*” to the *first magnetic device* of [21G] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor* of [3B]. *Supra* [1J] and [3B]. Figure 11 illustrates 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, ¶362.

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, ¶362 (analyzing the “axially closer” to effectively generate torque).<sup>8</sup>

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<sup>8</sup> 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 517 Patent does not suggest that such

**ix. [21H]**

See [1I]. Ex.1003, ¶365.

**x. [21I]**

See [1K]. Ex.1003, ¶374.

**xi. [21J]**

See [1L]. Ex.1003, ¶381.

**xii. [21K]**

See [1M] and [15]. Ex.1003, ¶391.

**xiii. [21L]**

See [1M]. Ex.1003, ¶400.

**7. Claim 22**

See [2]. Ex.1003, ¶406.

**8. Claims 24, 26, and 32**

See [3] and [10] (analyzing “*entirely spaced apart...by a gap*”). Ex.1003, ¶¶413, 439. Wampler-169 discloses a “*gap configured to be occupied by the blood*” of [24] for the reasons it discloses that the *magnetically driven rotor* is *entirely*

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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).

*spaced apart... by a gap*” from the *surrounding rotor housing* of [10]. *Supra* [3] and [10].

## 9. Claims 28-29

*See* [1G] and [1J]. Ex.1003, ¶423. Wampler-169 discloses that “*one or more walls separates*” the *magnetically driven rotor* from the *magnetic drive system* of [29] for the reasons it discloses that the *second magnetic device* is “*sealed...by at least one sealing wall*” from the *magnetically driven rotor* of [1J]. *Supra* [1G] and [1J].

## 10. Claim 30

*See* [1E]. Ex.1003, ¶435.

## 11. Claim 33

*See* [11]. Ex.1003, ¶445.

## 12. Claim 35

*See* [17]. Ex.1003, ¶450.

Wampler-169 therefore renders obvious the Challenged Claims. Ex.1003, ¶¶ 149-455.

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

**1. Claim 1**

**i. [1PRE]**

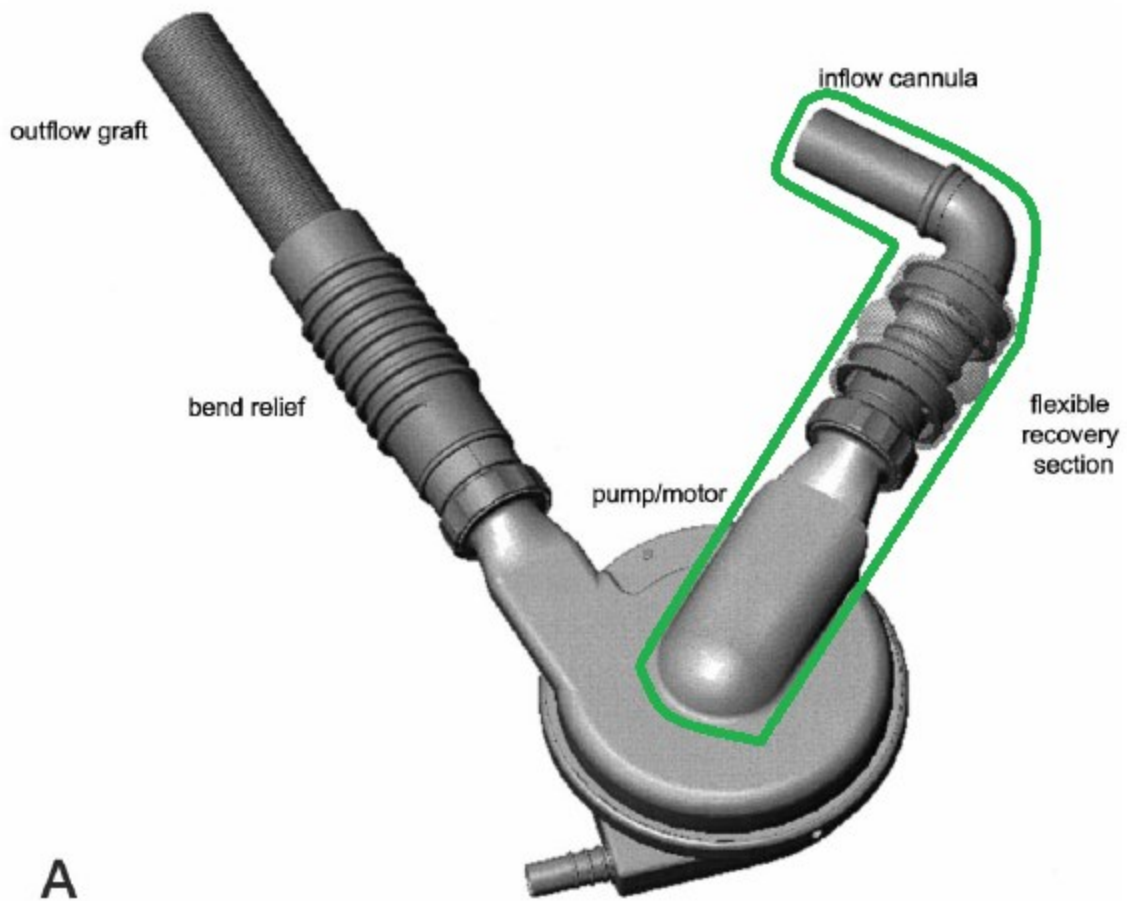
Bourque-2001 discloses the “HeartMate III”—“a centrifugal pump” that is a “long-term, compact left **ventricular** assist device (LVAD)” “to treat” “people...diagnosed with congestive heart failure” (“*a system for assisting the blood circulation of a heart in a body*”). Ex.1007, 401; Ex.1003, ¶457.

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

Accordingly, Bourque-2001 discloses “*a system for assisting the blood circulation of a **heart*** (“reliable device to treat CHF”).” Ex.1003, ¶458.

**ii. [1A]**

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



Ex.1007, Fig. 1A; Ex.1003, ¶464.

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

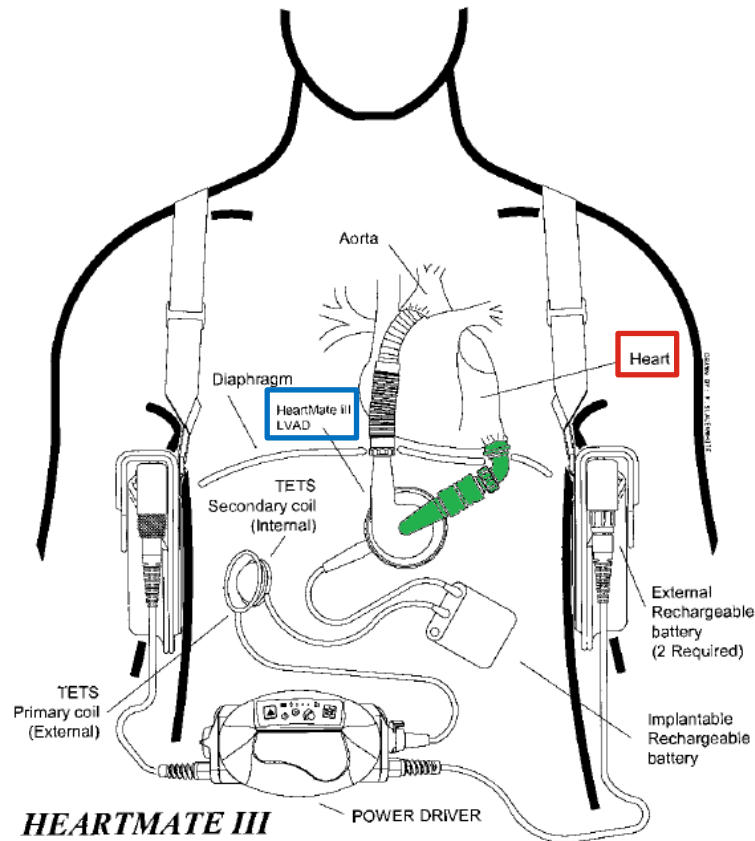


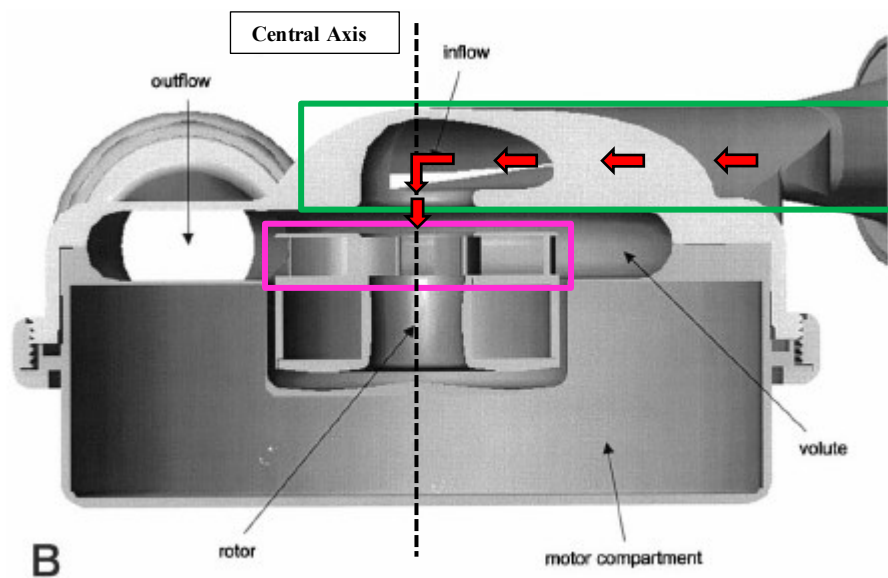
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. Ex.1003, ¶463.

Accordingly, Bourque-2001 discloses “*a heart assist pump device* (“HeartMate III LVAD”) deliverable to the *heart* and comprising: *an inflow tube defining a blood inflow path and having a suction end* (“an inflow subassembly that includes a left ventricular (LV) cannula”) insertable into *a ventricle of the heart* (“left ventricular apical cannulation”).” Ex.1003, ¶465.

iii. [1B]

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

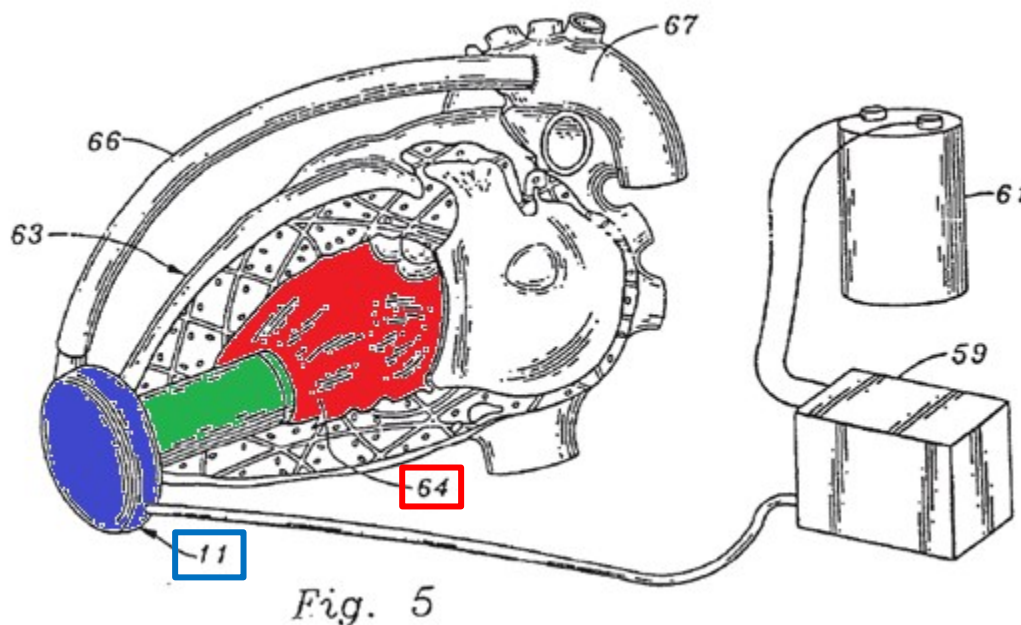


Ex.1007, Fig. 1B. Ex.1003, ¶470. Further, as demonstrated in [1A] and shown above in Fig. 1B, the **impeller** is “*spaced apart from the suction end*” of the **inflow subassembly**. Ex.1003, ¶476; *supra* [1A].

The 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, ¶471. Nevertheless, by virtue of Bourque-2001’s device being “a centrifugal pump,” its

“**impeller**” is axially aligned with the “**inflow subassembly**” as flow “leav[es] the inflow conduit to enter the impeller.” Ex.1007, 402. Indeed, axial inflow is characteristic of centrifugal pumps. Ex.1003, ¶472.

To the extent one asserts that Bourque-2001 does not disclose this limitation, as detailed below (*infra* §VIII.B.13), it would have been obvious to modify Bourque-2001’s “impeller” to “*be axially aligned with*” the “inflow subassembly” in view of Wampler-169. Bourque-2001 taught that the “elbow” of its “centrifugal pump” was **flow restrictive**. Ex.1007, 402. Wampler-169, however, appreciated that “[t]he centrifugal design of the pump allows...a 90 degree redirection of the blood [] **without the necessity of a flow-restrictive elbow fitting**” (Ex.1008, [0076], as shown:



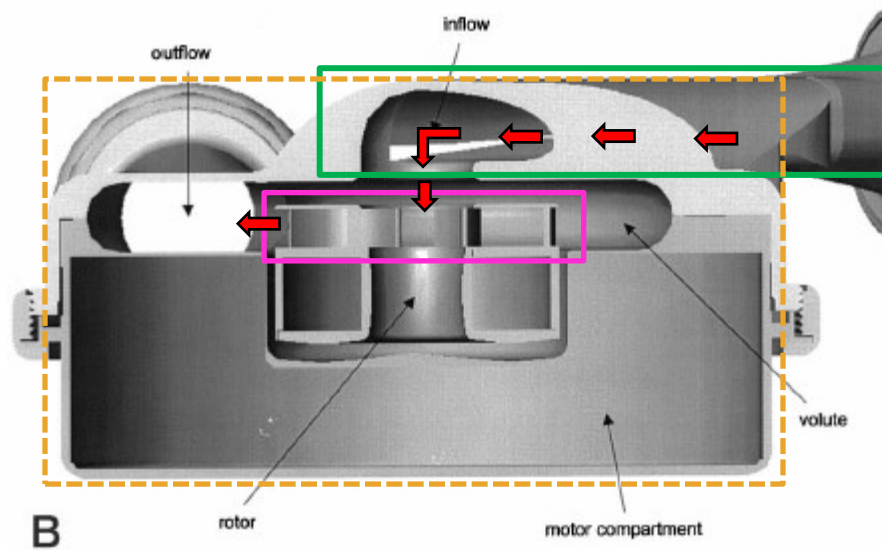
Ex.1008, Fig. 5. Ex.1003, ¶¶473-474.

Mr. Crosby explains (*infra* §VIII.B.13) that a POSITA would have been motivated with a reasonable expectation of success to modify the HeartMate III “inflow subassembly” to serve as the “inflow cannula...placed into the apex of the left ventricle” as taught by Wampler-169, resulting in an “*axially aligned...inflow tube*.” Ex.1007, 402; Ex.1008, [0076], Fig. 5; Ex.1003, ¶474.

Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest that “a *magnetically driven rotor* (“impeller”) *axially aligned with the inflow tube* (“an inflow subassembly”; “inlet tube 16 [that] serves as the inflow cannula”) *and being spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle*.” Ex.1003, ¶477.

#### iv. [1C]

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

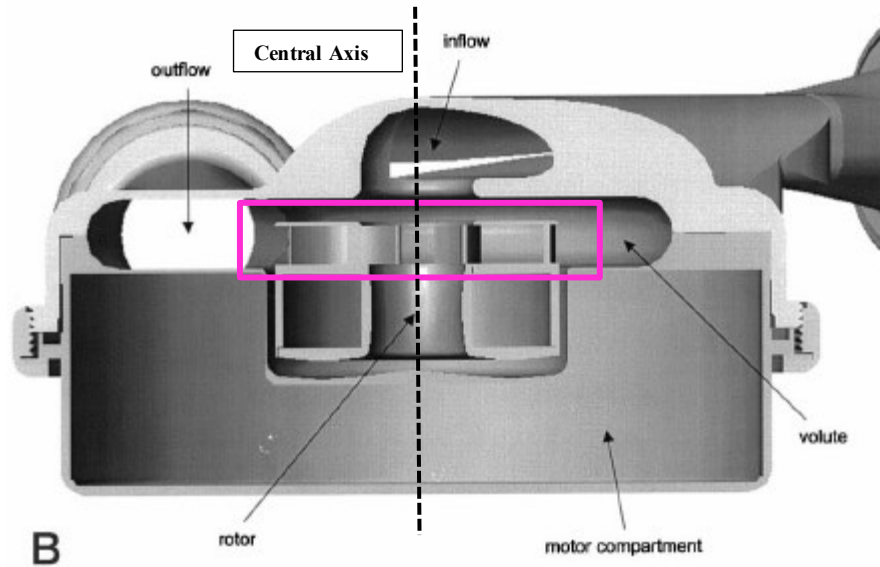


Ex.1007, Fig. 1B; *see also* Fig. 8 (showing flow measurements of impeller “act[ing] upon blood”). Ex.1003, ¶482.

Accordingly, Bourque-2001 discloses that the magnetically driven rotor “is rotatable within *a surrounding rotor housing* (“upper housing and lower housing”) to act upon blood flowing from the *inflow tube* (“an inflow subassembly”) toward the *rotor* (“impeller”).” Ex.1003, ¶483.

v. *[1D]*

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

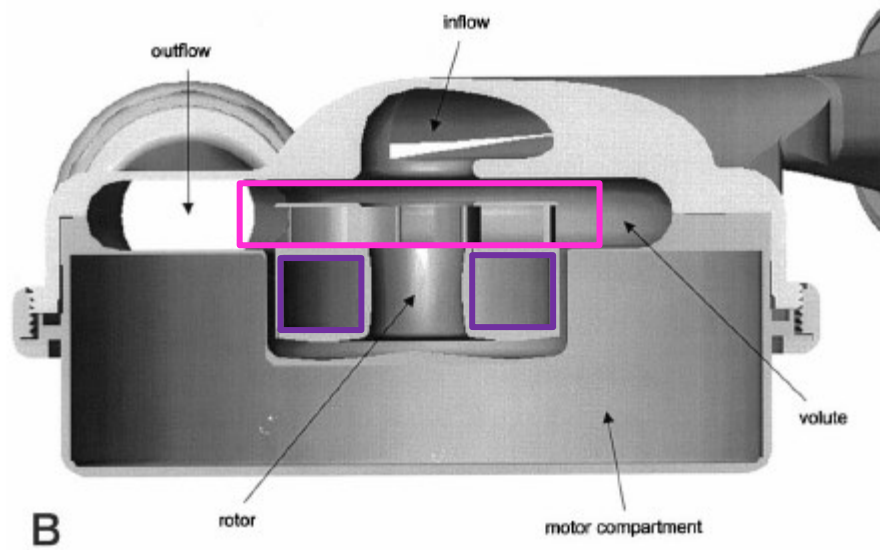


Ex.1007, Fig. 1B; *see also* 402 (“rotational axis [is] perpendicular to the body’s long axis”). Ex.1003, ¶485.

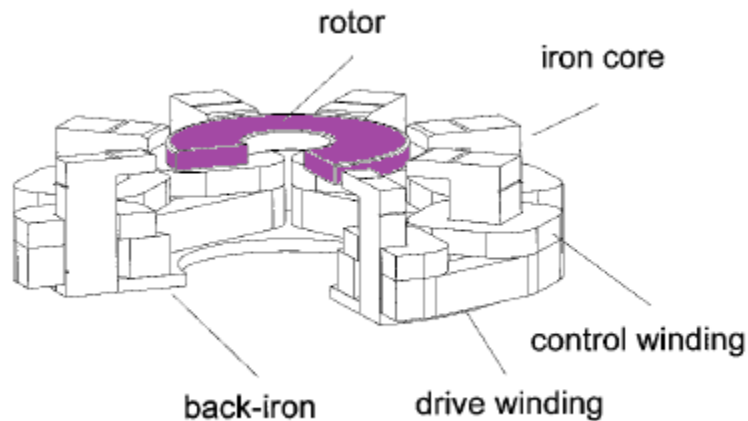
Accordingly, Bourque-2001 discloses “*the magnetically driven rotor* (“impeller”) *being rotatable about a central axis* (“rotational axis”).” Ex.1003, ¶487.

vi. *[1E]*

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



Ex.1007, Fig. 1B. Ex.1003, ¶492.



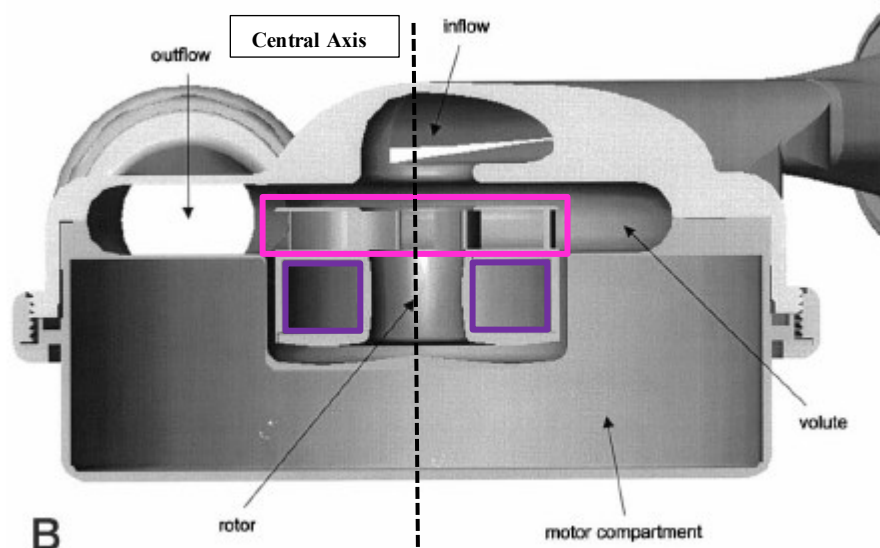
Ex.1007, Fig. 4, 402-403. Ex.1003, ¶491.

In Parallel Litigation, PO asserts that a similar arrangement of an impeller and magnetic elements satisfies this limitation. Ex.1019, 5-6.

Accordingly, Bourque-2001 discloses the *magnetically driven rotor* (“impeller”) “*being rigidly coupled to*” a *first magnetic device* (“passively magnetic elements”).” Ex.1003, ¶493.

vii. *[1F]*

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

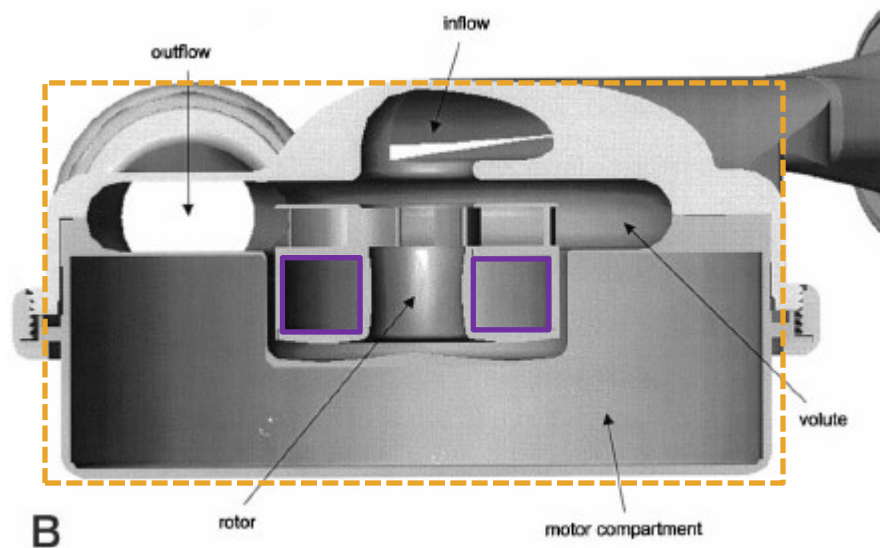


Ex.1007, Fig. 1B; Ex.1003, ¶495.

Accordingly, Bourque-2001 discloses that the *magnetically driven rotor* (“impeller”) is “*axially adjacent to a first magnetic device* (“passively magnetic elements”).” Ex.1003, ¶496.

## viii. [1G]

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

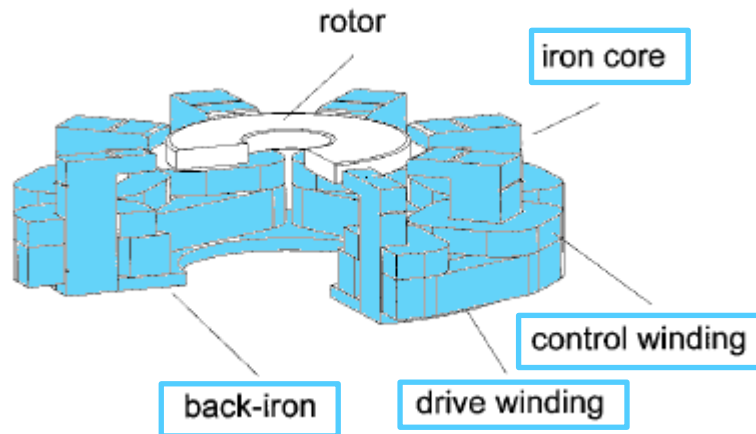


Ex.1007, Fig. 1B; *see also* 403 (discussing rotation “without contact between the rotor and housing”); *supra* [1C]; Ex.1003, ¶500.

Accordingly, Bourque-2001 discloses that the *first magnetic device* (“passively magnetic elements”) “*is located within the surrounding rotor housing* (“upper housing and lower housing”).” Ex.1003, ¶501.

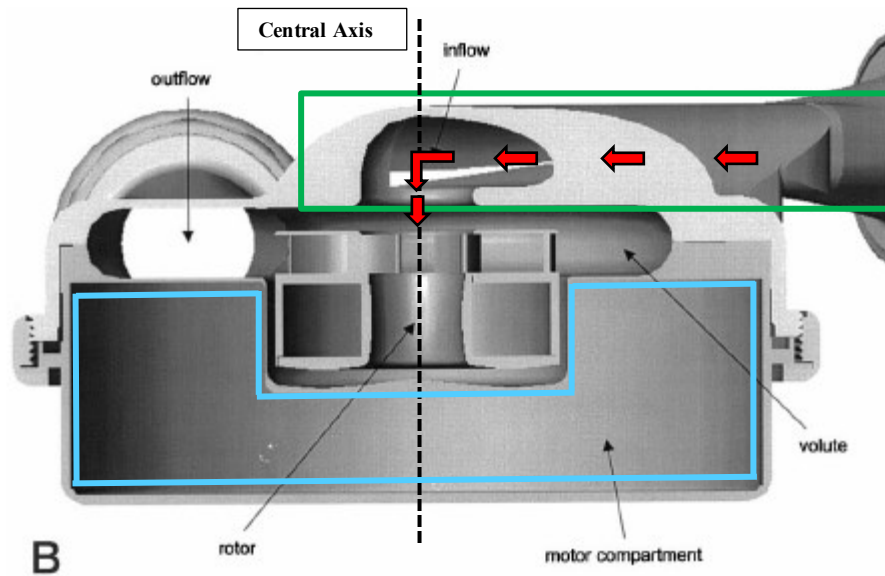
## ix. [1H]

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



Ex.1007, Fig. 4; Ex.1003, ¶504.

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



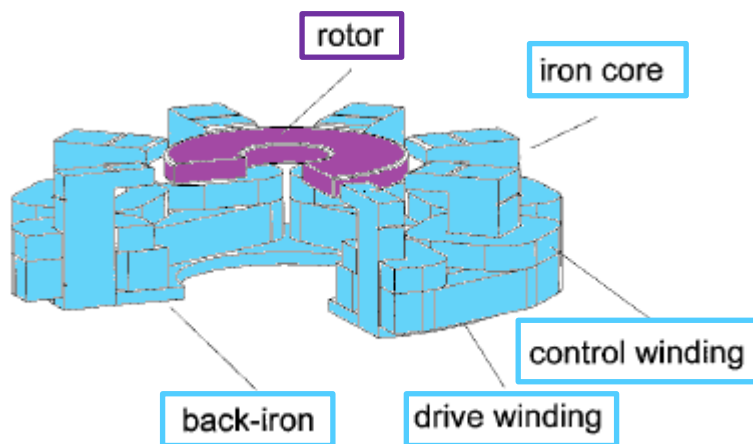
Ex.1007 at Fig. 1B, 401-403; Ex.1003, ¶506. As demonstrated in [1B], to the extent that Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 that the **motor** be *axially aligned with the inflow subassembly*. Ex.1003, ¶508.

Accordingly, Bourque-2001 or Bourque-2001/Wampler-169 teach or suggest that “a *second magnetic device* (“motor” with drive windings) *axially aligned with the inflow tube* (“an inflow subassembly” of Bourque-2001 or “inlet tube 13” of Wampler-169).” Ex.1003, ¶509.

**x. [II]**

In Parallel Litigation, PO alleges that a “stator” design satisfies this limitation. Ex.1019, 7-8.

Assuming that interpretation, as demonstrated in [1M], Bourque-2001 discloses a similar “stator” design—the “HeartMate III **motor** includes drive” (Ex.1007, 402-403), and as shown in Figure 4, “the motor’s ‘J’ core configuration (i.e., the stator laminations are J shaped)” (Ex.1007, 404) are *positioned to magnetically drive rotation of the rotor via a magneto coupling* with the “**passively magnetic elements**”:

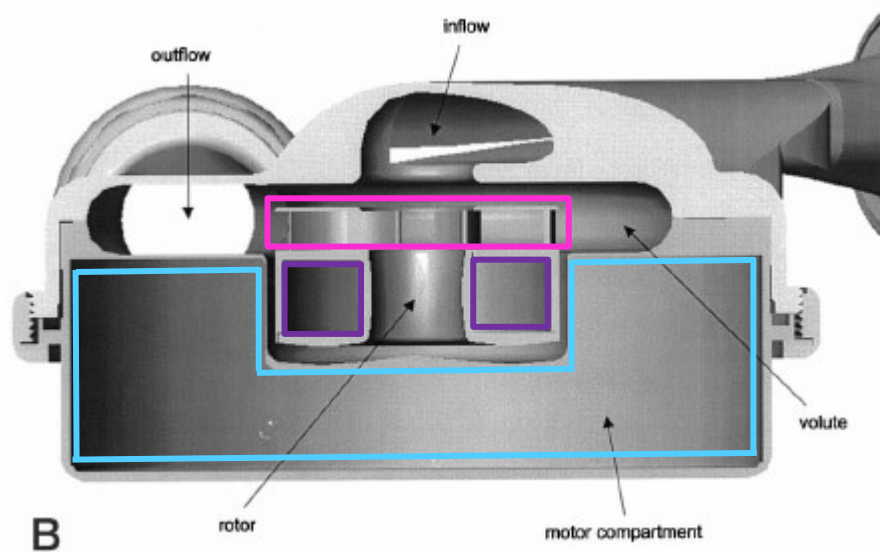


Ex.1007, Fig. 4, 402-404; Ex.1003, ¶512, *see also* ¶¶513-514 (discussing speed and flow rates).

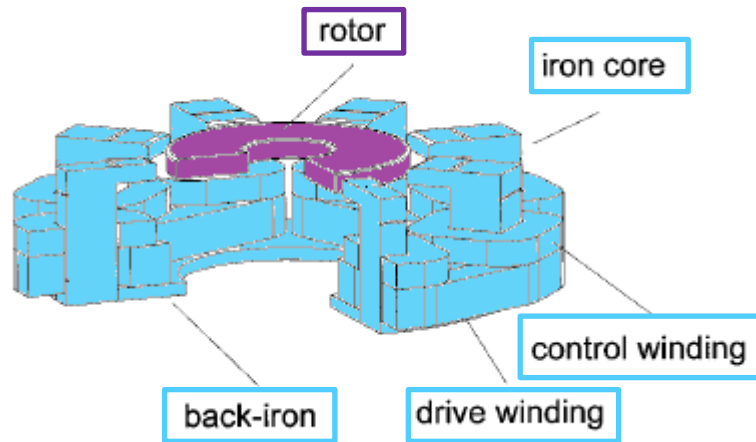
Accordingly, Bourque-2001 discloses that the **second magnetic device** (“motor” with drive windings) is “*positioned to magnetically drive rotation of the magnetically driven rotor* (“impeller”) *via a magneto coupling with the first magnetic device* (“passively magnetic elements”).” Ex.1003, ¶515.

## xi. [1J]

Bourque-2001 discloses that “[t]he rotor is...magnetically levitated” (“axially spaced apart”) to prevent “contact between the rotor and housing” “in which the motor is enclosed” (“sealed...by at least one sealing wall”) so that the motor is spaced apart and sealed from the rotor’s impeller and magnetic elements (Ex.1007, 402-403), as shown:



Ex.1007, Fig. 1B; Ex.1003, ¶520.



Ex.1007, Fig. 4; Ex.1003, ¶521.

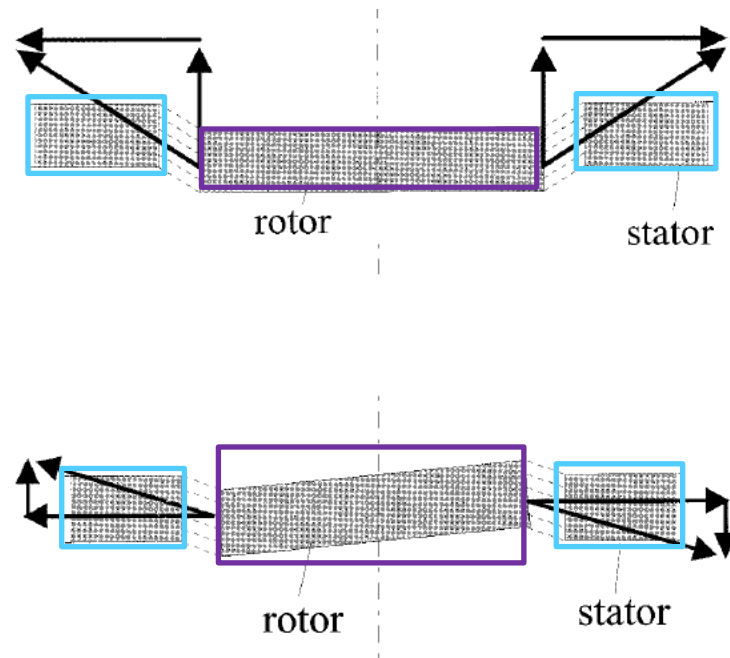


**Figure 5.** Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

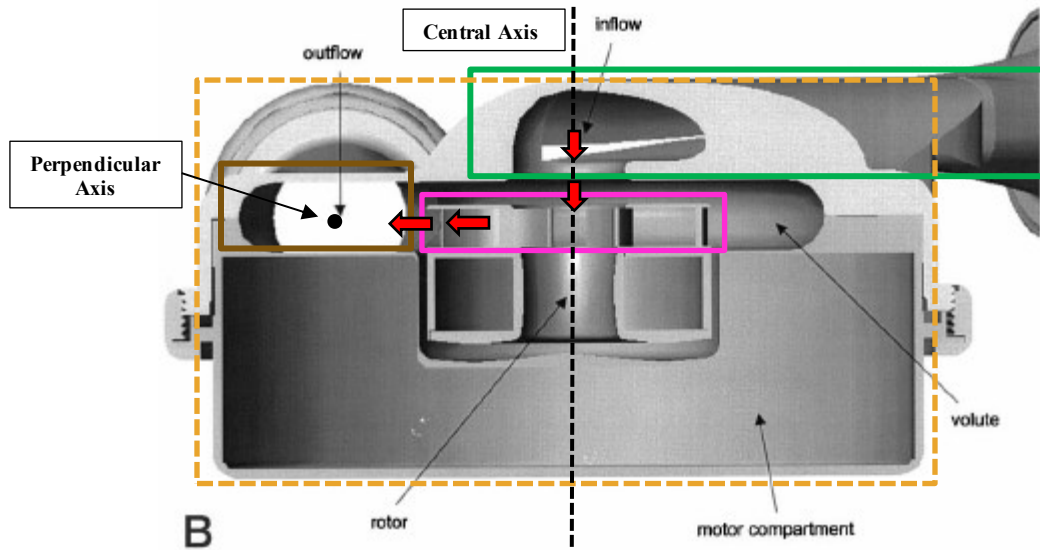
Ex.1007, Fig. 5, 401; Ex.1003, ¶521. Bourque-2001 discloses that “the pump components were designed to achieve the desired flow paths”—from the “inflow

section,” through the impeller, “toward the outflow” (“*sealed...by at least one sealing wall*”). Ex.1007, 402; Ex.1003, ¶520.

Accordingly, Bourque-2001 discloses the **second magnetic device** (“motor”) “*being spaced apart and sealed from both the magnetically driven rotor*” (“impeller”) and the **first magnetic device** (“passively magnetic elements”) *by at least one sealing wall* (“lower housing”), the **second magnetic device** *being positioned axially spaced apart from the magnetically driven rotor.*” Ex.1003, ¶522.

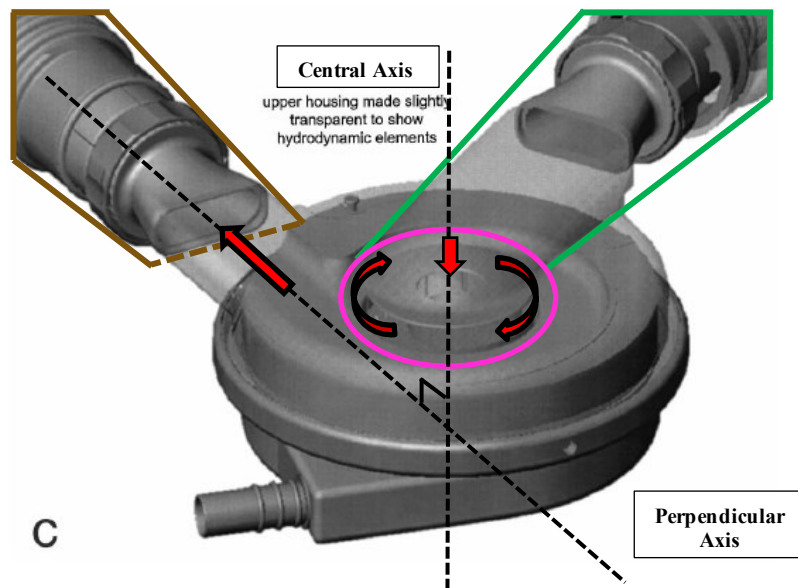
**xii. [1K]**

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



Ex.1007, Fig. 1B; Ex.1003, ¶526.

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



Ex.1007, Fig. 1C; Ex.1003, ¶527.

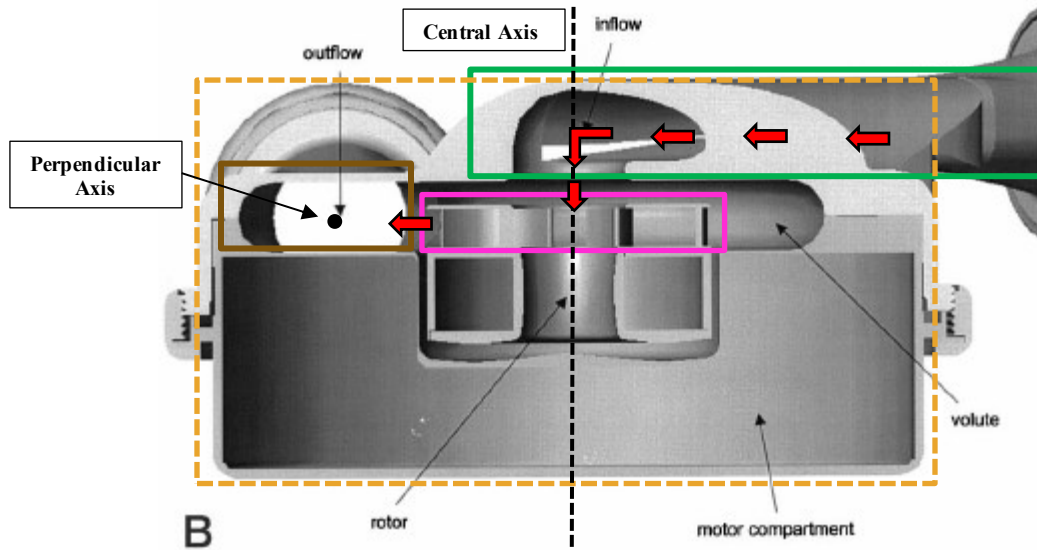
To the extent Bourque-2001 does not disclose this limitation, it would have been obvious in view of Wampler-169 for the same reasons discussed in [1B] that there would be “a 90-degree [*transverse to the central axis*] redirection of the blood.” Ex.1003, ¶473; *infra* §VIII.B.13; Ex.1008, [0076].

Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, teach or suggest that “a **blood outflow port** (“outflow channel”) *positioned radially adjacent the magnetically driven rotor* (“impeller”) *such that blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing* (“upper housing and lower housing”) *in a direction transverse to the central axis* (“an inflow subassembly”) *of the magnetically driven rotor.*” Ex.1003, ¶528.

### xiii. [1L]

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

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



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

Bourque-2001 further discloses that the HeartMate III’s “rotor is magnetically suspended, eliminating contact” (“*remains adjacent to and spaced apart from*”) with the housing. Ex.1007 at 401. Ex.1003, ¶531.

Accordingly, Bourque-2001 discloses “*wherein when the magnetically driven rotor (“impeller”) is rotated, the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing (“upper housing and lower housing”) by the blood flowing from the inflow tube (“an inflow subassembly”) and to the blood outflow port (“outflow channel”).*” Ex.1003, ¶535.

## xiv. [1M]

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

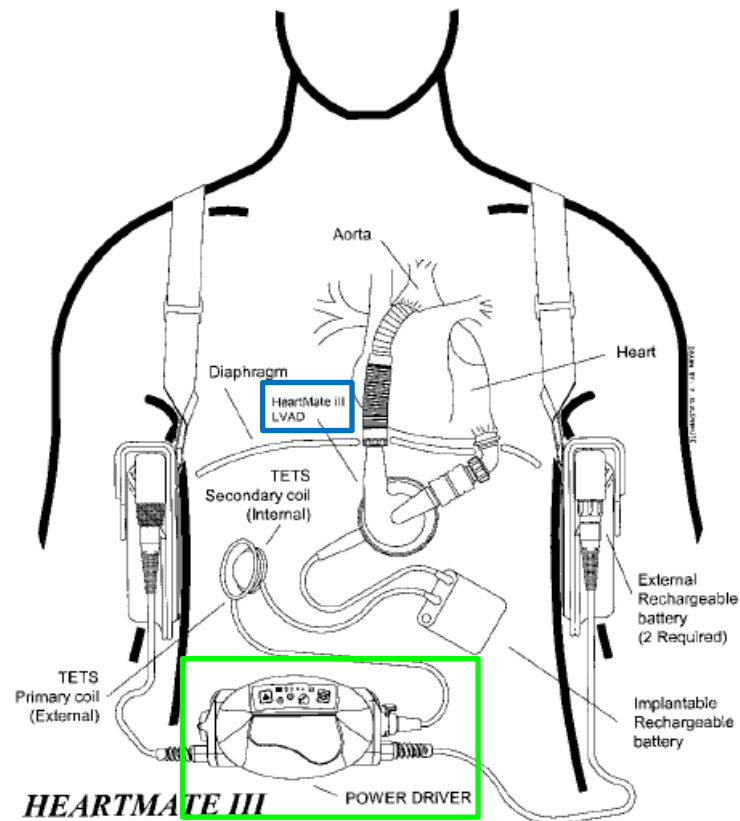


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶540.

Bourque-2001 further discloses that “[s]peed and motor parameters were set and controlled using software” (“*to regulate operation*”) and that the “motor drive

and control electronics” were *external*, because they had not been “incorporat[ed]...within the pump.” Ex.1007, 405; Ex.1003, ¶537.

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

Accordingly, Bourque-2001 discloses “an **external control unit** (“electronics for power and control”) *configured to regulate operation of the second magnetic device* (“motor”), wherein the **external control unit** is connectable (“electronic cable...exteriorized percutaneously”) to the **heart assist pump device** (“HeartMate III LVAD”) *for controlling the second magnetic device 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, ¶541.

Bourque-2001, or Bourque-2001/Wampler-169, therefore teach or suggest claim 1. Ex.1003, ¶¶456-541.

## 2. Claims 2, 3, and 4

### i. [2]

Bourque-2001 discloses that “blades of the impeller” (“*guide surfaces*”) “direct[] [the flow] toward the outflow” (“*produce centrifugal flow components*”). Ex.1007, 402. Further, by virtue of its “centrifugal” design, the impeller produces centrifugal flow components. Ex.1007, 401; Ex.1003, ¶545.

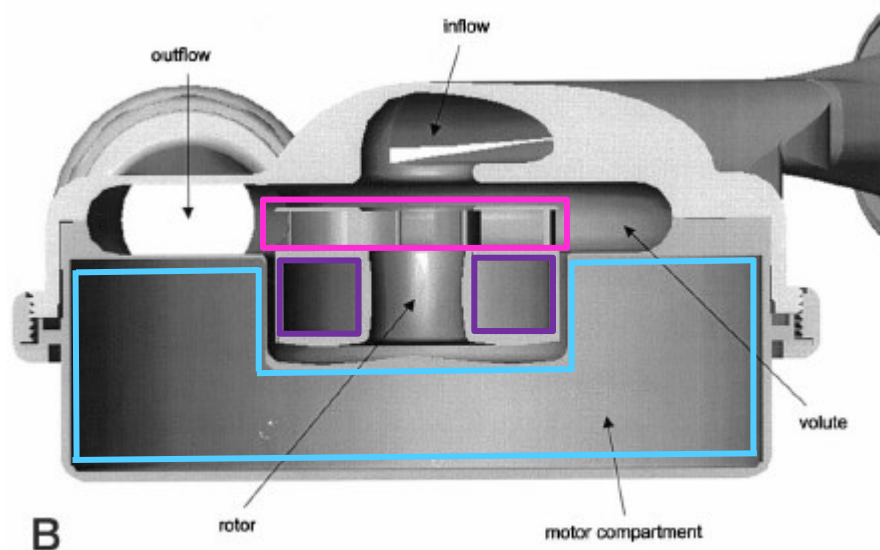
Accordingly, Bourque-2001 discloses that “*the magnetically driven rotor (“impeller”) comprises guide surfaces (“blades”) to produce centrifugal flow components.*” Ex.1003, ¶547.

ii. [3A]

As explained in [1J], “the motor is enclosed” by at least one sealing wall of the “housing” (Ex.1007, 401), thus, Bourque-2001 discloses that “*the surrounding rotor housing (“upper housing and lower housing”) comprises at least one sealing wall (“motor is enclosed”).*” Ex.1003, ¶¶549-552.

iii. [3B]

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



Ex.1007, Fig. 1B; *supra* [1H]-[1J]; Ex.1003, ¶555.

Accordingly, Bourque-2001 discloses that “*the first magnetic device* (“passively magnetic elements”) *is positioned between the second magnetic device* (“motor”) *and the magnetically driven rotor* (“impeller”).” Ex.1003, ¶¶554-555.

iv. [4]

As demonstrated in [1E], the rotor’s “impeller” and “magnetic elements” are “rigidly coupled,” thus, Bourque-2001 discloses that “*the first magnetic device* (“passively magnetic elements”) *rotates together with the magnetically driven rotor* (“impeller”) *relative to the surrounding rotor housing* (“upper housing and lower housing”).” Ex.1007, 401; *supra* [1E]. Ex.1003, ¶559.

3. Claims 10, 14, and 15

i. [10]

For the reasons demonstrated in [1J] and [1L] that “the levitation system’s...gaps [prevent] contact between the rotor and housing” (Ex.1007, 402), Bourque-2001 discloses that “*both the magnetically driven rotor* (“impeller”) *and first magnetic device* (“passively magnetic elements”) *are entirely spaced apart from the surrounding rotor housing* (“upper housing and lower housing”) *by a gap* (“gaps”) *during rotation of the magnetically driven rotor.*” Ex.1007, 401-402; *supra* [1J], [1L]; Ex.1003, ¶¶565-567.

ii. [14]

As demonstrated in [1M], the “**electronics for power and control** of the LVAD” allows for “[s]peed and motor parameters [to be] set and controlled” for example, to be “gradually adjusted to maintain volume flow rates” including at “desired maximum flow (10 L/min at 135 mm Hg)” and “prescribed to run at 3,500 rpm” (“*control value*”). Ex.1007, 403. Accordingly, Bourque-2001 discloses that “*the **external control unit** (“electronics for power and control”) is configured to regulate operation of the **second magnetic device** (“motor”) based on a control value.*” *Supra* [1M]; Ex.1003, ¶570.

iii. [15]

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit (e.g. output as measured in liters of blood per minute) are “*control value[s]...indicative of defined cardiac output.*” Ex.1019, 12. Assuming that interpretation, as demonstrated in [14], Bourque-2001 discloses that “*the control value* (“prescribed to run at 3,500 rpm”) *is indicative of a defined cardiac output* (desired maximum flow (10 L/min at 135 mm Hg)) *for control of the **heart assist pump device** (HeartMate III LVAD)*” Ex.1003, ¶¶577-578.

4. Claim 11

*See* [15]. Ex.1003, ¶722. Further, Bourque-2001 discloses that “measurements were made with an ultrasonic flow probe...[and] catheter-type

pressure transducers,” which Mr. Crosby explains are *sensors* that *deliver feedback signals* to the “electronics...for data acquisition.” Ex.1007 at 403; Ex.1003, ¶724. Thus, Bourque-2001 discloses “*one or more sensors that deliver feedback signals to the external control unit* (“electronics”).”

## 5. Claim 17

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Assuming that interpretation, because Bourque-2001’s LVAD comprises “a left ventricular (LV) cannula” (Ex.1007, 401), Bourque-2001 discloses that the “*heart assist pump device* (“HeartMate III LVAD”) *is a catheter device*.” Ex.1003, ¶586.

## 6. Claim 21

Claim 21 is rendered obvious for the same reasons as claim 1. Ex.1003, ¶588.

### i. [21PRE]

See [1PRE]. Ex.1003, ¶589.

### ii. [21A]

See [1A]-[1B] (analyzing an axially aligned “*inflow tube*” (“*an inflow axis*”)). Ex.1003, ¶¶462, 594.

iii. [21B]

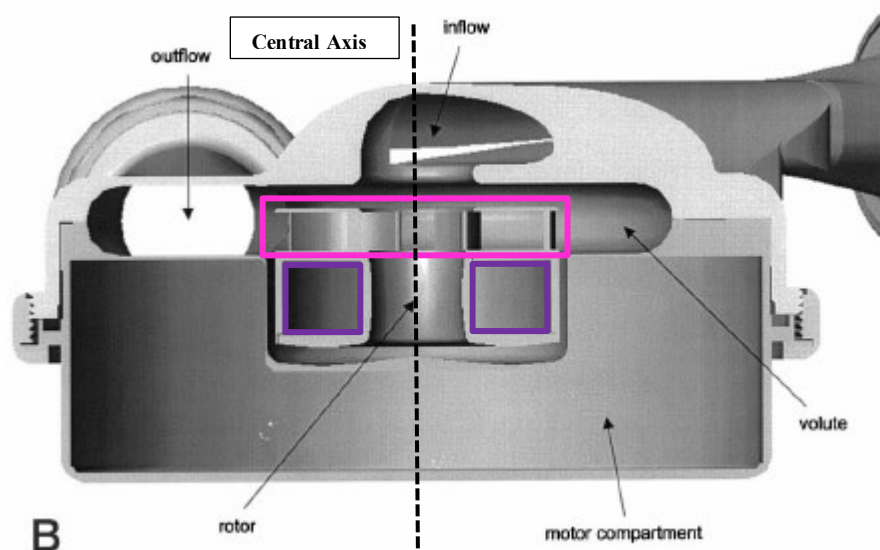
See [1C] and [3A]. Ex.1003, ¶601. Bourque-2001 discloses “walls...defining a *chamber*” of [21B] for the reasons it discloses a “*surrounding rotor housing compris[ing] at least one sealing wall*” of [3A]. *Supra* [3A].

iv. [21C]

See [1B] and [1E]. Ex.1003, ¶606.

v. [21D]

See [1F], [21C]. Ex.1003, ¶619. Bourque-2001 discloses or Bourque-2001/Wampler-169, teach or suggest (*see* [1B]) that both its *magnetically driven rotor* (“impeller”) and *first magnetic device* (“passively magnetic elements”) are “*axially adjacent*” and “*axially aligned with the inflow axis*” (i.e., central axis), as shown:



Ex.1007, Fig. 1B; *supra* [1F]; Ex.1003, ¶621.

**vi. [21E]**

See [1C]-[1D]. Ex.1003, ¶625.

**vii. [21F]**

See [1H]-[1I]. Ex.1003, ¶632. Bourque-2001 discloses a “*magnetic drive system comprising a second magnetic device*” of [21F] for the reasons it discloses a “*second magnetic device*” of claim [1H]-[1I].

**viii. [21G]**

See [1J] and [3B]. Ex.1003, ¶641. Bourque-2001 discloses that the *second magnetic device* is “*positioned axially closer*” to the *first magnetic device* of [21G] for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor* of [3B]. *Supra* [1J] and [3B].

**ix. [21H]**

See [1I]. Ex.1003, ¶648.

**x. [21I]**

See [1K]. Ex.1003, ¶655.

**xi. [21J]**

See [1L]. Ex.1003, ¶662.

**xii. [21K]**

See [1M], [15]. Ex.1003, ¶670.

**xiii. [21L]**

See [1M]. Ex.1003, ¶677.

**7. Claim 22**

See [2]. Ex.1003, ¶683.

**8. Claims 24, 26, and 32**

See [3] and [10] (analyzing “*entirely spaced apart...by a gap*”). Ex.1003, ¶¶689, 716. Bourque-2001 discloses a “*gap configured to be occupied by the blood*” of [24] for the reasons it discloses that the *magnetically driven rotor* is *entirely spaced apart... by a gap*” from the *surrounding rotor housing* of [10]. *Supra* [3] and [10].

**9. Claims 28-29**

See [1G] and [1J]. Ex.1003, ¶700. Bourque-2001 discloses that “*one or more walls separates*” the *magnetically driven rotor* from the *magnetic drive system* of [29] for the reasons it discloses that the *second magnetic device* is “*sealed...by at least one sealing wall*” from the *magnetically driven rotor* of [1J]. *Supra* [1G] and [1J].

**10. Claim 30**

See [1E]. Ex.1003, ¶712.

**11. Claim 33**

See [11]. Ex.1003, ¶722.

**12. Claim 35**

See [17]. Ex.1003, ¶729.

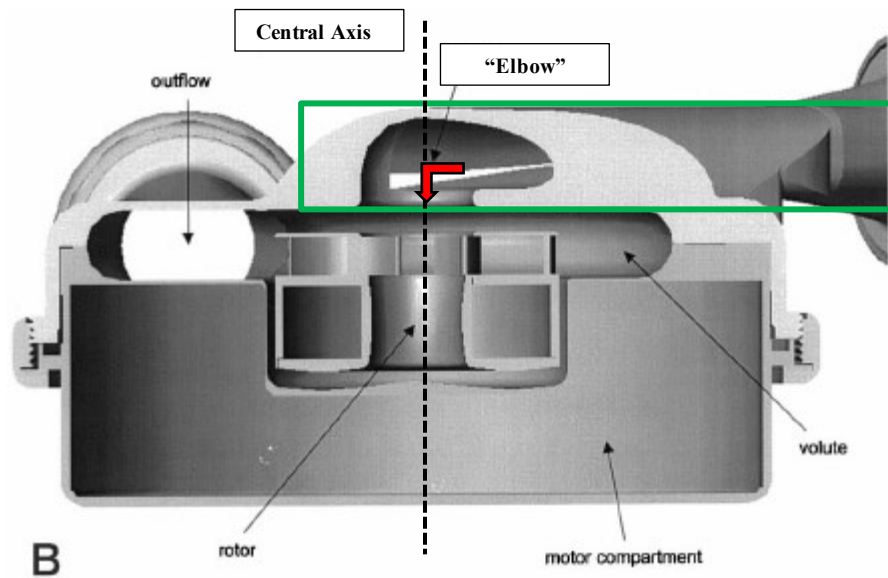
Bourque-2001 therefore renders obvious the Challenged Claims. Ex.1003, ¶¶456-734.

**13. Motivation to Combine Bourque-2001 with Wampler-169**

It would have been obvious to include Wampler-169's techniques related to its *axially aligned...inflow tube* in the Bourque-2001 HeartMate III for the reasons explained below. Ex.1003, ¶735.

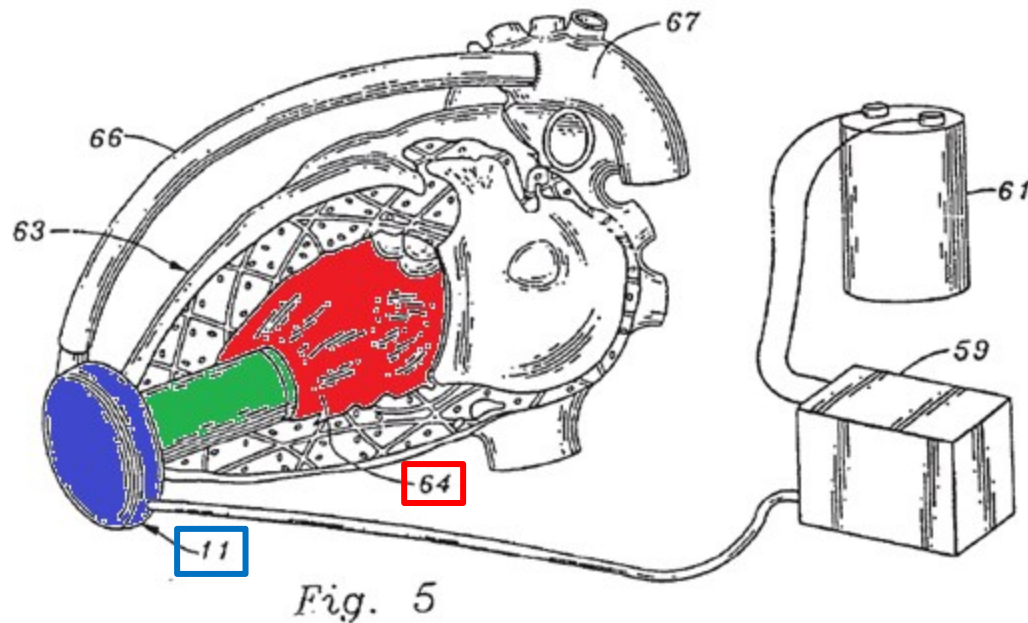
A POSITA would have recognized that, by virtue of the “centrifugal design,” both Bourque-2001's HeartMate III and Wampler-169's pump comprise “axial inflow and radial outflow” that result in “a 90 degree redirection of the blood.” Ex.1003, ¶736; Ex.1008, [0075]-[0076]; Ex.1007, 402.

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, ¶¶740-741 (discussing a different “elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans”).

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



Ex.1008, Fig. 5. Ex.1003, ¶741. With this design, “[g]ood anatomic compatibility is possible...fitting well between the apex of the heart and the adjacent diaphragm.” Ex.1008, [0076].

A POSITA would have been motivated to apply the teachings of Wampler-169 to Bourque-2001 to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex of the left ventricle as expressly taught by Wampler-169 for several reasons. Ex.1003, ¶747.

Bourque-2001 and Wampler-169 are analogous art to the 517 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; 2:52-62; Ex.1007, 401; Ex.1008, [0006], [0018]. Ex.1003, ¶743. Bourque-2001 and Wampler-169 are reasonably pertinent to a problem described by the 517 Patent:

reducing mechanical stress on the blood during pumping. Ex.1001, 2:20-24; Ex.1007, 401; Ex.1008, [0101]. Ex.1003, ¶744.

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, ¶745.

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, ¶¶746-747; 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, ¶747.

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, ¶¶741-747; 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, ¶747.

A POSITA would have further been motivated to reduce rates of infection by adhering to Wampler-169’s focus on “[g]ood anatomic compatibility” over Bourque-2001’s focus on “borrowing” from “presently available Heart-Mate systems” like the “HeartMate II.” Ex.1007, 403, 405. The HeartMate III’s “elbow” “resulted” from a design “deci[sion]” “[t]o orient the pump” below the “diaphragm” in a preperitoneal pocket position, as shown:

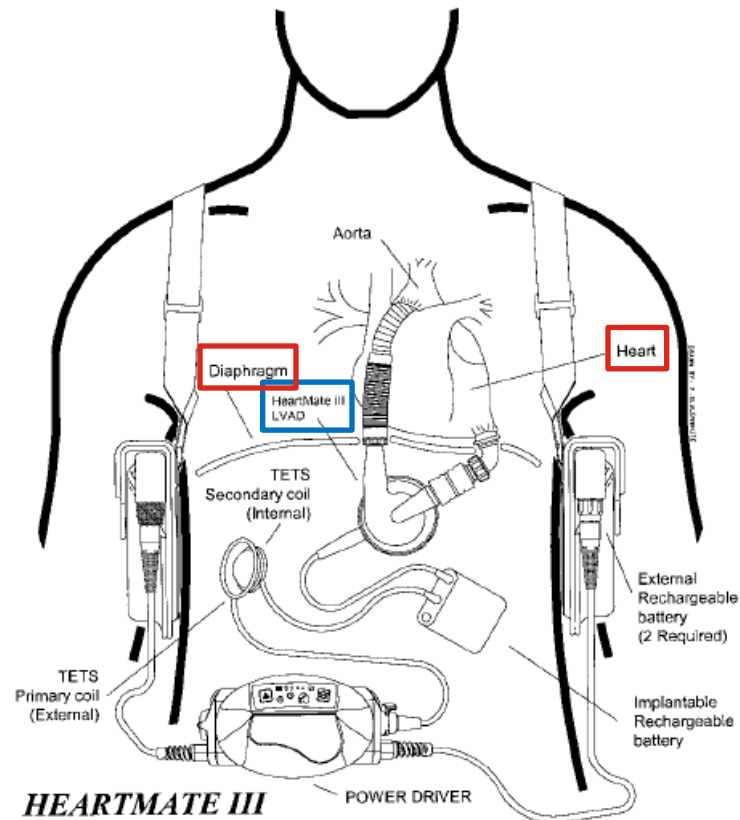


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3; Ex.1003, ¶748. 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, ¶749.

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:

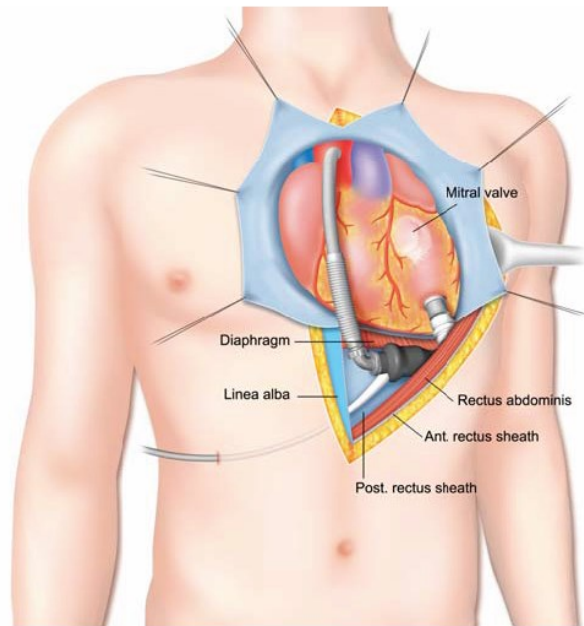


**Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).**

Ex.1013, 25; Ex.1003, ¶748 (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, ¶748. 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, ¶¶749-752.

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, ¶¶750-753 (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, ¶754. 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, ¶754.

Accordingly, it would have been obvious to modify Bourque-2001's pump to include Wampler's techniques to use an *axially aligned...inflow tube* to yield the Bourque-2001/Wampler-169 combination. Ex.1003, ¶755; *see also* ¶¶735-754.

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

**1. Claim 1**

**i. [IPRE]**

Akamatsu-1999 discloses a “left ventricular assist system (T-ILVAS),” which is a “**centrifugal pump**,” for “an implantable circulatory assist system” for the heart (**red**) (Ex.1006, 3), as illustrated in Figure 1:

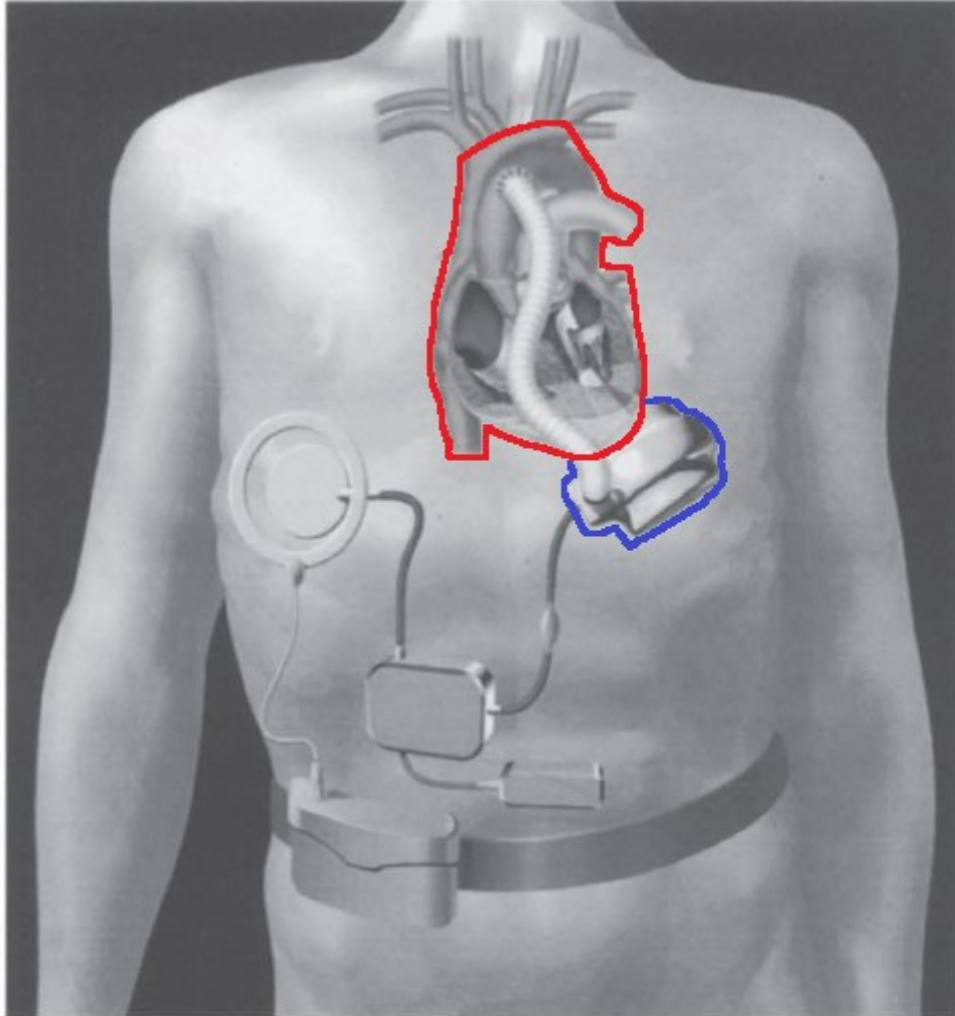


**Fig. 1.** Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶¶757-758.

Accordingly, Akamatsu-1999 discloses “a system for assisting the blood circulation of a *heart*.” Ex.1003, ¶758.

ii. [1A]

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

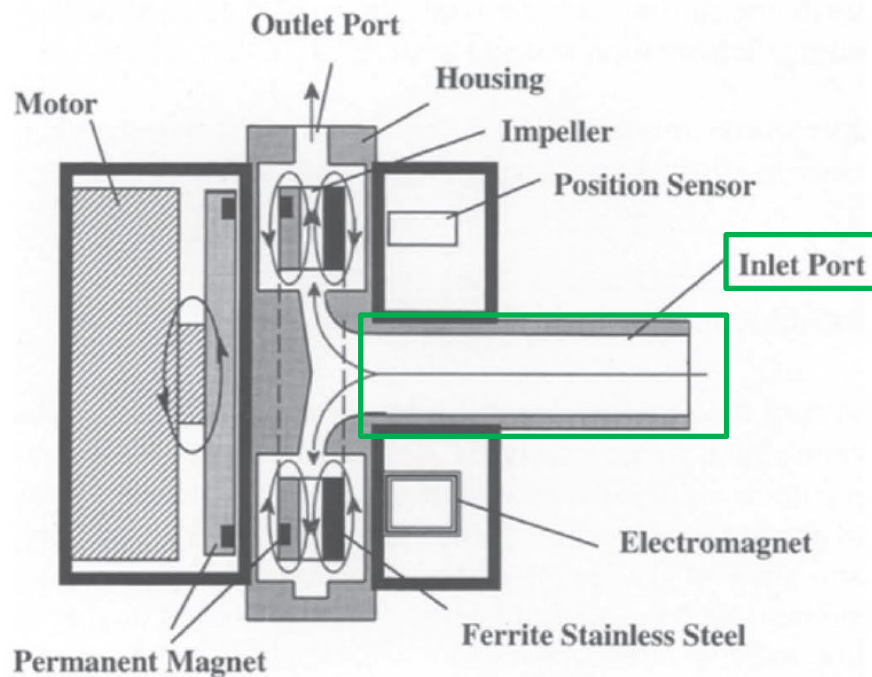


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶762.

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

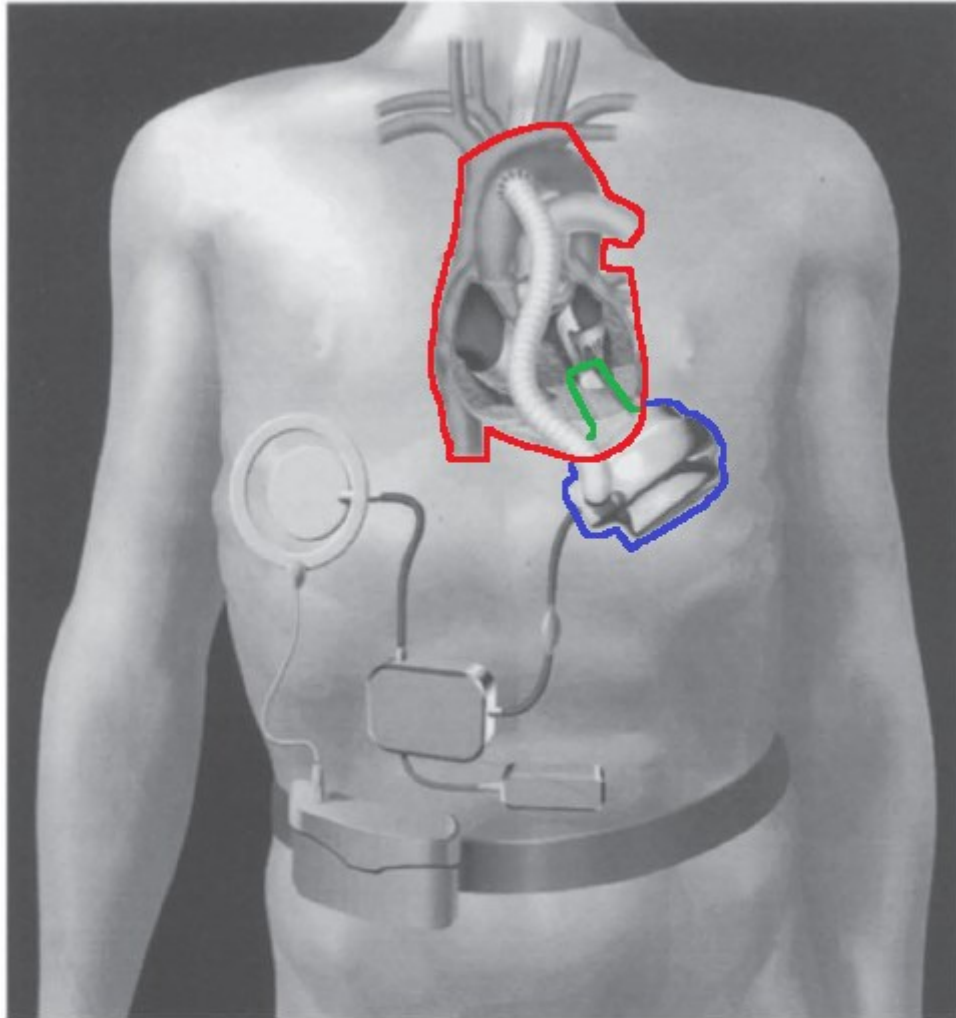


**Fig. 1.** Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶¶763-764.

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 and having a suction end* (“inlet port”) insertable into *a ventricle of the heart* (“inserted into the left ventricle”).” Ex.1003, ¶764.

iii. [1B]

Akamatsu-1999 discloses that its pump comprises an “**impeller** inside the pump” (“*spaced apart from the suction end*”) (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:

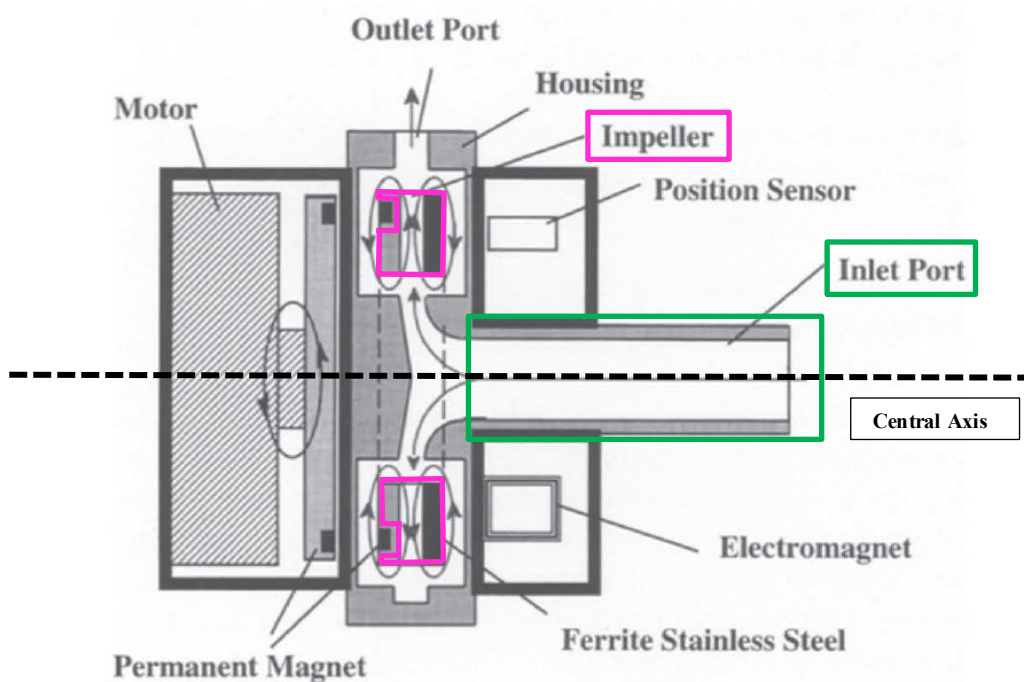


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2, Ex.1003, ¶771; Fig. 5 (photograph of “impeller”)

Accordingly, Akamatsu-1999 discloses “a **magnetically driven rotor** (“impeller”) *axially aligned with the inflow tube and being spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle.*” Ex.1003, ¶776.

## iv. [1C]

Akamatsu-1999 discloses that the pump's "**impeller** rotates" ("*being rotatable*") "at the center of the pump **housing**" ("*within a surrounding rotor housing*") to generate a "pump flow rate" ("*to act upon blood*"). Ex.1006, 4. Figure 2 illustrates that the "*blood [is] flowing from the*" "**inlet port**" "*toward the*" "**impeller**" (black arrows):

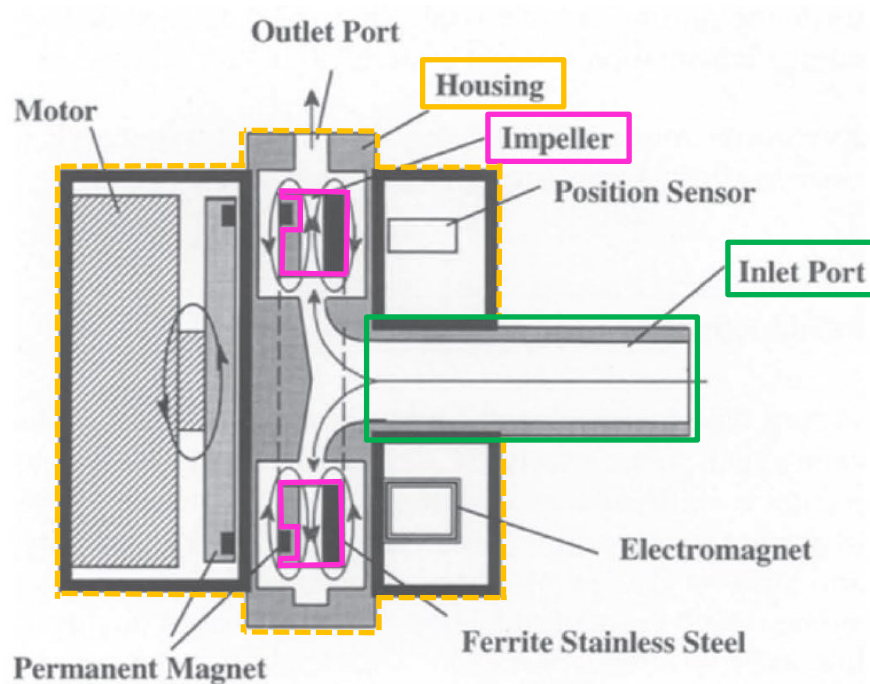


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶781.

Accordingly, Akamatsu-1999 discloses the **magnetically driven rotor** "*being rotatable within a surrounding rotor housing*" ("*housing*") *to act upon blood flowing from the inflow tube*" ("*inlet port*") *toward the rotor*" ("*impeller*")." Ex.1003, ¶783.

## v. [1D]

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

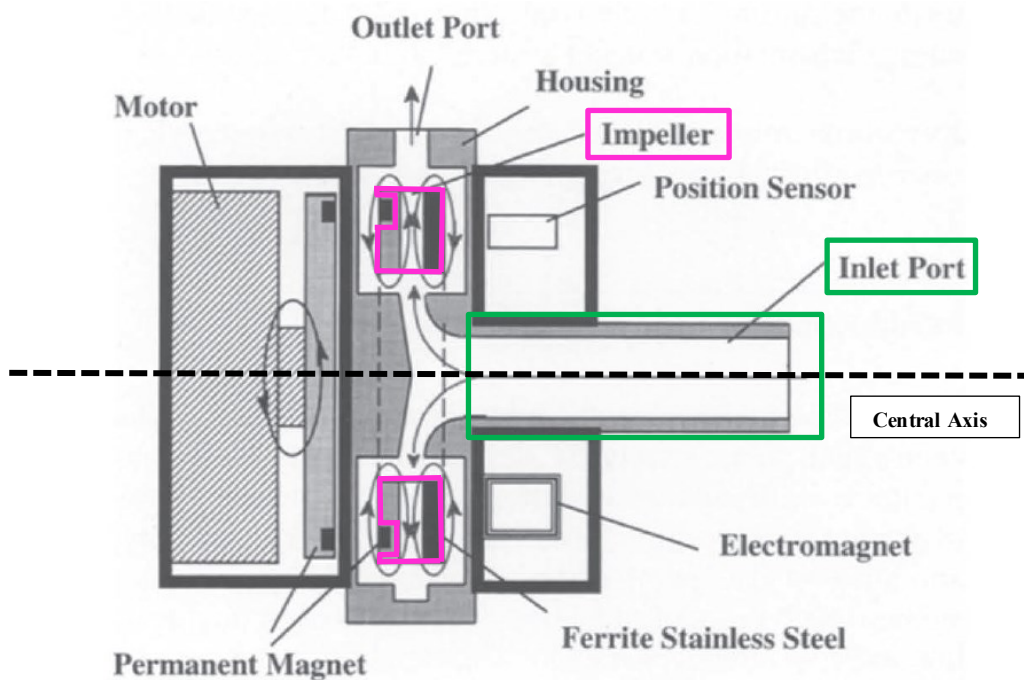


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶786-787.

Accordingly, Akamatsu-1999 discloses “the **magnetically driven rotor** (“impeller”) being rotatable about a central axis (“at the center”).” Ex.1003, ¶789.

## vi. [1E]

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

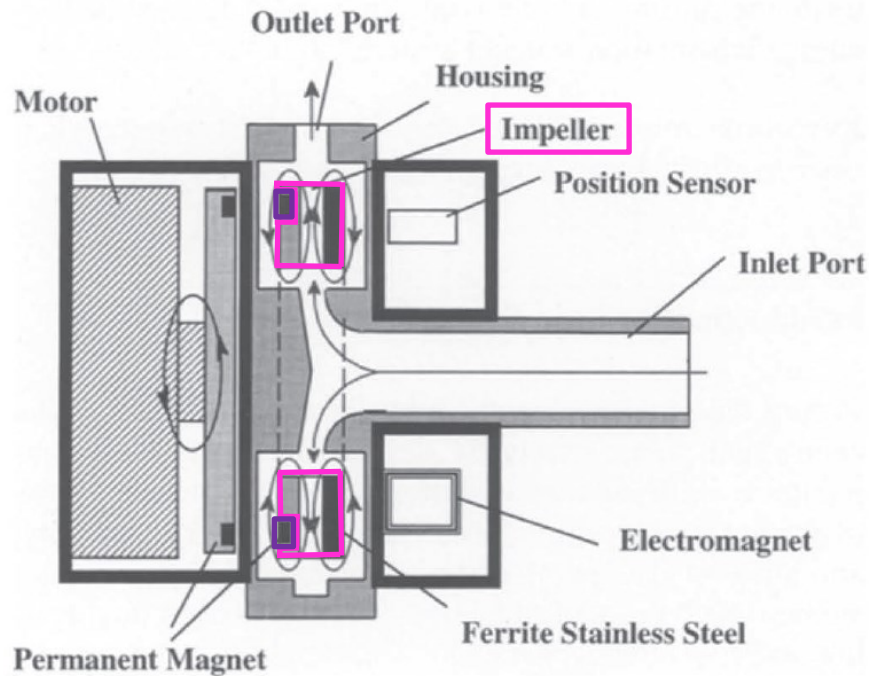


**Fig. 2.** Schematic cross section of the MSCP

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

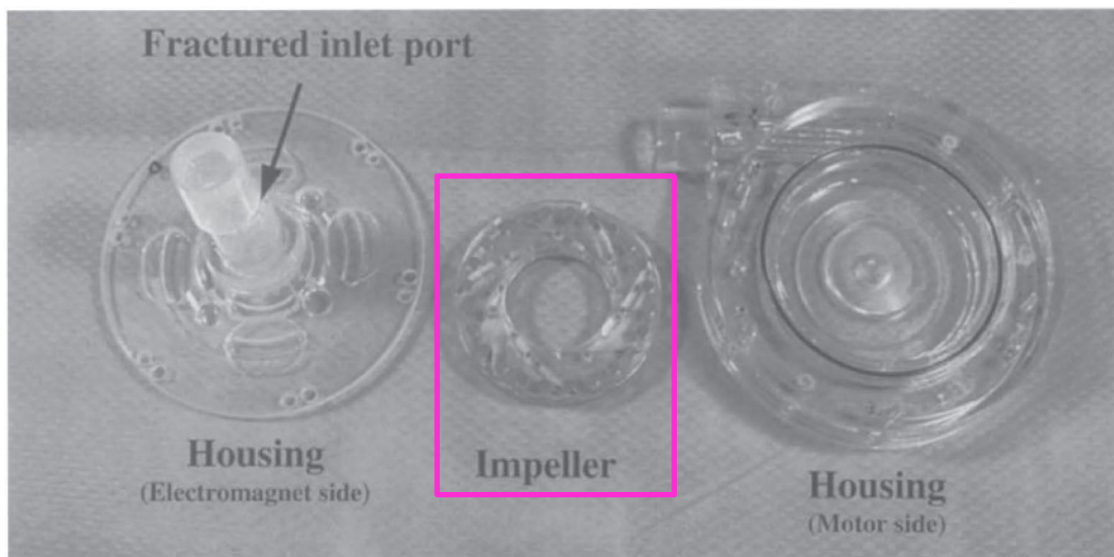


Fig. 5; Ex.1003, ¶¶791, 793.

Accordingly, Akamatsu-1999 teaches or suggests the **magnetically driven rotor** (“impeller”) “*being rigidly coupled to [a first magnetic device]* (impeller’s “permanent magnet”).” Ex.1003, ¶794.

vii. *[1F]*

Akamatsu-1999 discloses that the “**impeller**” is “*axially adjacent to*” the impeller’s “[p]ermanent [m]agnet” (Ex.1006, 3-4), as shown:

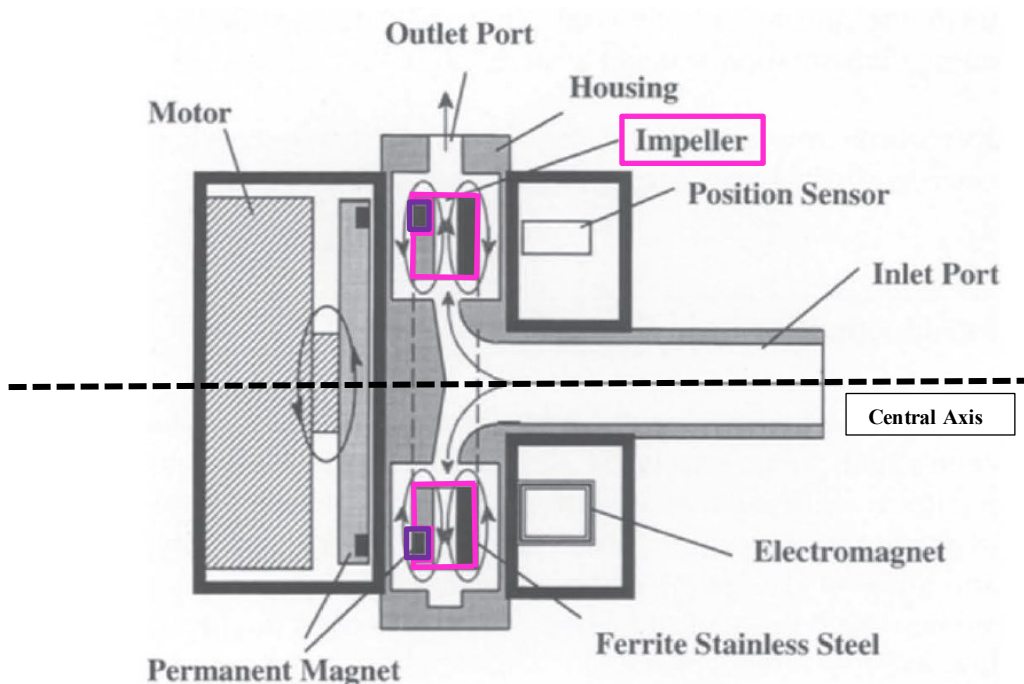


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Figure 5 (impeller photo); Ex.1003, ¶798.

Accordingly, Akamatsu-1999 teaches or suggests that the **magnetically driven rotor** is “*axially adjacent to a first magnetic device.*” Ex.1003, ¶799.

## viii. [1G]

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

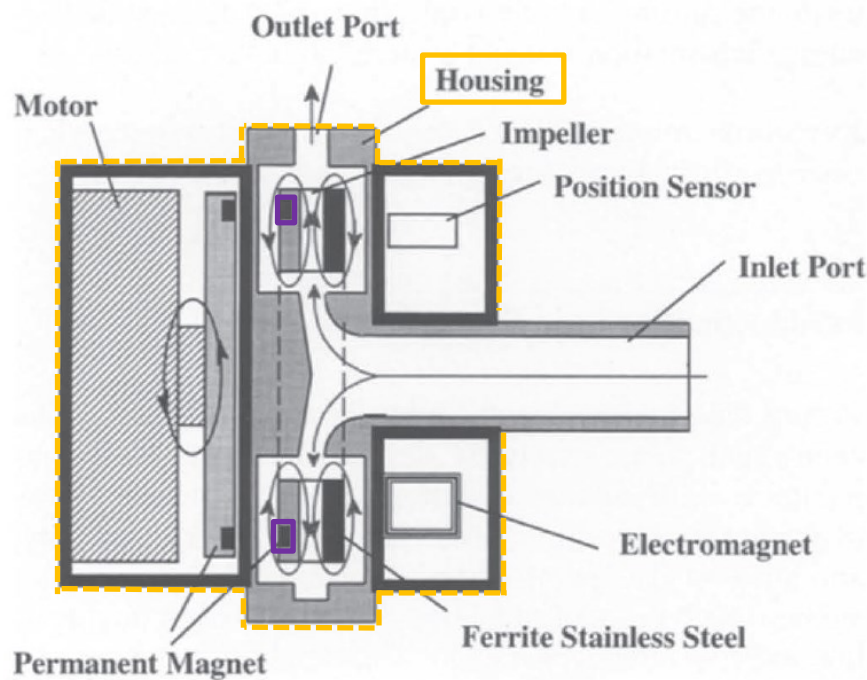


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶803.

Accordingly, Akamatsu-1999 discloses that the **first magnetic device** (impeller’s “permanent magnet”) “*is located within the surrounding rotor housing* (“housing”).” Ex.1003, ¶804.

## ix. [1H]

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

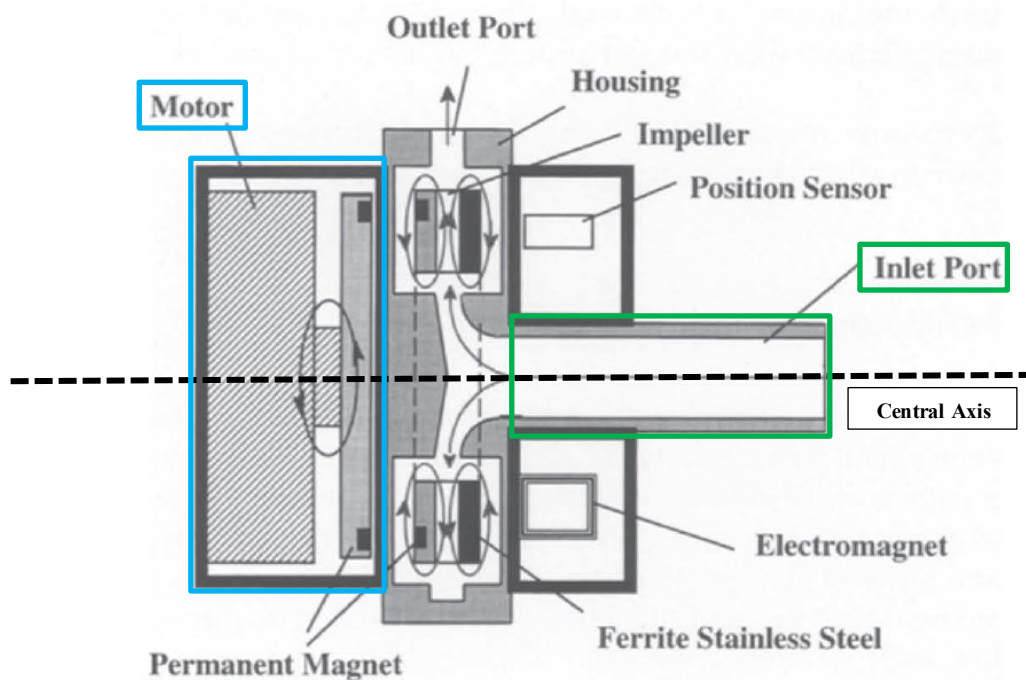


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶810.

Accordingly, Akamatsu-1999 discloses that “a *second magnetic device* (motor’s “permanent magnet”) axially aligned with the *inflow tube* (“inlet port”).”

Ex.1003, ¶811.

## x. [1I]

Akamatsu-1999 discloses that the “**impeller** rotates by a magnetic coupling”

(“via a magneto coupling”) “between the **impeller**’s **permanent magnet**] and the motor[’s **permanent magnet**],” thereby “providing contact-free rotation” (“positioned to magnetically drive rotation”), (Ex.1006, 3-4):

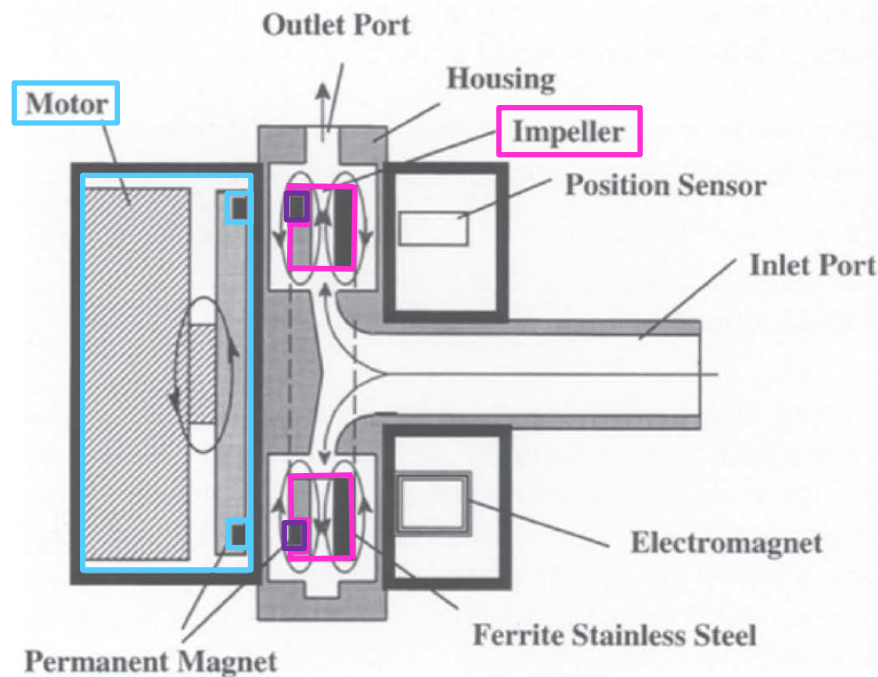


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶¶815, 817.

Accordingly, Akamatsu-1999 discloses that the **second magnetic device** (motor’s “permanent magnet”) is “positioned to magnetically drive rotation of the **magnetically driven rotor** (“impeller”) via a magneto coupling with the **first magnetic device** (impeller’s “permanent magnet”).” Ex.1003, ¶819.

**xi. [1J]**

Akamatsu-1999 discloses that the motor’s **permanent magnet** and the “suspended **impeller**...operate[] completely contact-free” (Ex.1006, 6) (“being

*positioned axially spaced apart*”) and the motor is “*sealed...by at least one sealing wall*” from both the **impeller** and its **permanent magnet**, as indicated by the solid black line surrounding the motor:

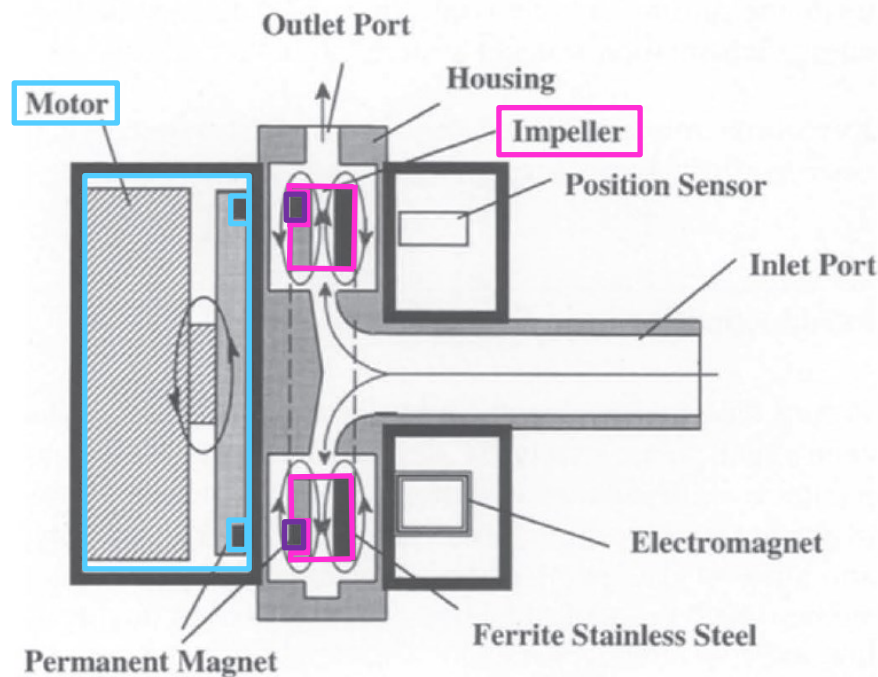


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2. Akamatsu-1999 also discloses sealing the device to prevent “leakage of blood into the...motor.” Ex.1006, 5; Ex.1003, ¶¶822-824.

Accordingly, Akamatsu-1999 discloses a **second magnetic device** (motor’s “permanent magnet”) “*while being spaced apart and sealed from both the magnetically driven rotor*” (“impeller”) and the **first magnetic device** (impeller’s “permanent magnet”) *by at least one sealing wall* (“housing”), the **second magnetic device** being positioned axially spaced apart from the **magnetically driven rotor**.” Ex.1003, ¶825.

## xii. [1K]

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

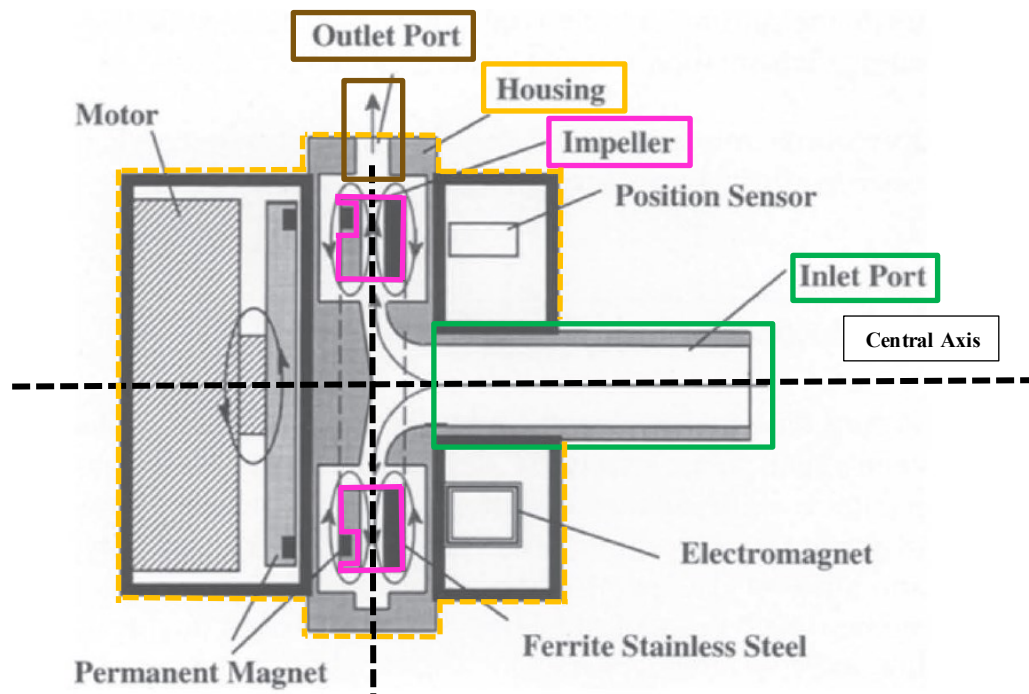


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶831.

Figure 3 illustrates the **outlet port** transverse to the **inlet port**:

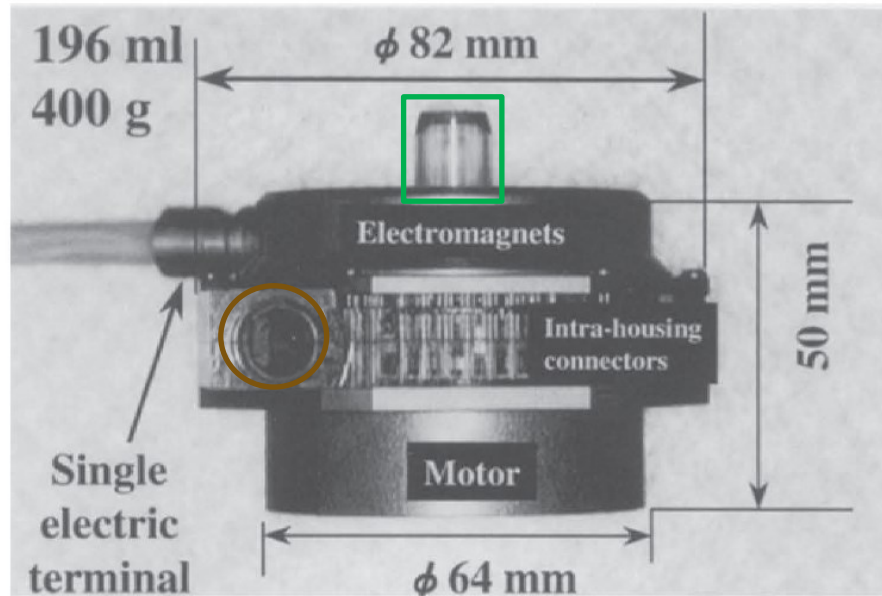


**Fig. 3.** Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3; Ex.1003, ¶¶832-833.

Accordingly, Akamatsu-1999 discloses that “a **blood outflow port** (“outlet port”) positioned radially adjacent the **magnetically driven rotor** (“impeller”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“housing”) in a direction transverse to the **central axis** of the **magnetically driven rotor**.” Ex.1003, ¶834.

### xiii. [1L]

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 [1I], Akamatsu-1999 discloses that the “**impeller** is suspended by a magnetic bearing” (Ex.1006, 3) and “rotates by a magnetic coupling,” thereby “providing contact-free rotation” (“remains adjacent to and spaced apart from the surrounding

rotor housing”), (Ex.1006, 4), which Figure 2 illustrates (black arrow) allows for the “blood flowing”:

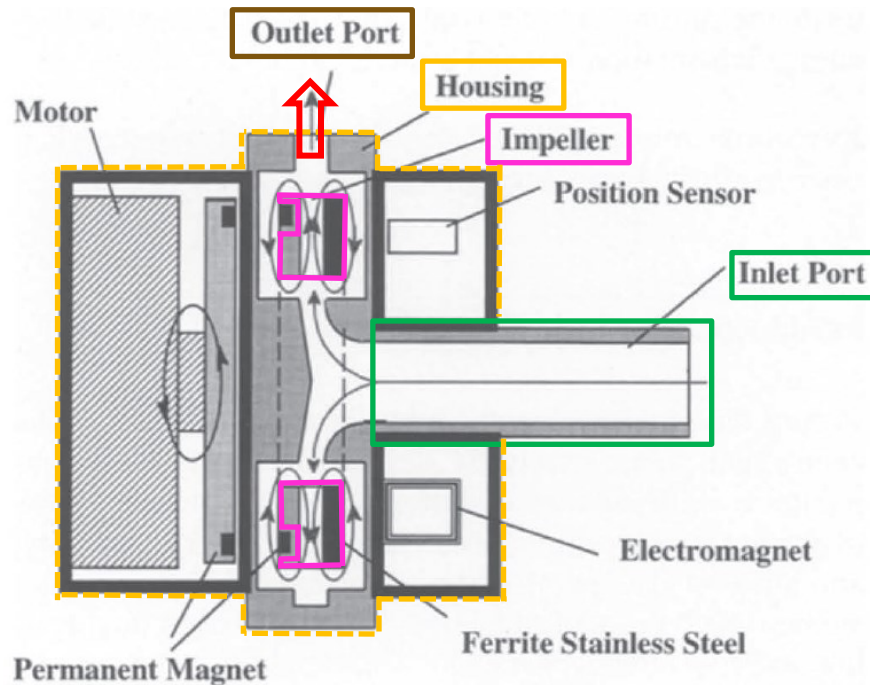


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶840. Indeed, the Akamatsu-1999 “magnetic suspension system” reported “excellent hydrodynamic performance with a low rate of hemolysis” (“spaced apart...by the blood flowing”). Ex.1006, 6.

Accordingly, Akamatsu-1999 discloses “wherein when the *magnetically driven rotor* (“impeller”) is rotated, the *magnetically driven rotor* remains adjacent to and spaced apart from the *surrounding rotor housing* (“housing”) by the blood flowing from the *inflow tube* (“inlet port”) and to the *blood outflow port* (“outlet port”).” Ex.1003, ¶841.

xiv. [1M]

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

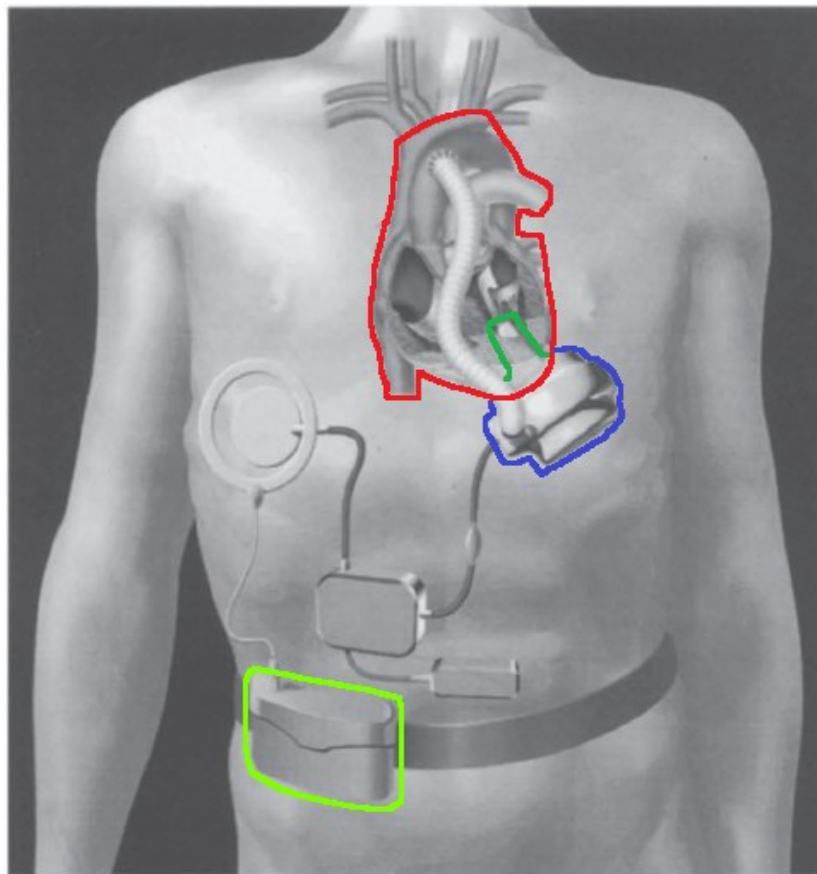


**Fig. 1.** Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1; Ex.1003, ¶846.

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

Ex.1006, 3. “The Model II pump,” however, which was the focus of the studies described in Akamatsu-1999, “was percutaneously driven” by “a single electric wire” with “intra-housing connectors” (“connectable to”) between the “motor” to a controller:

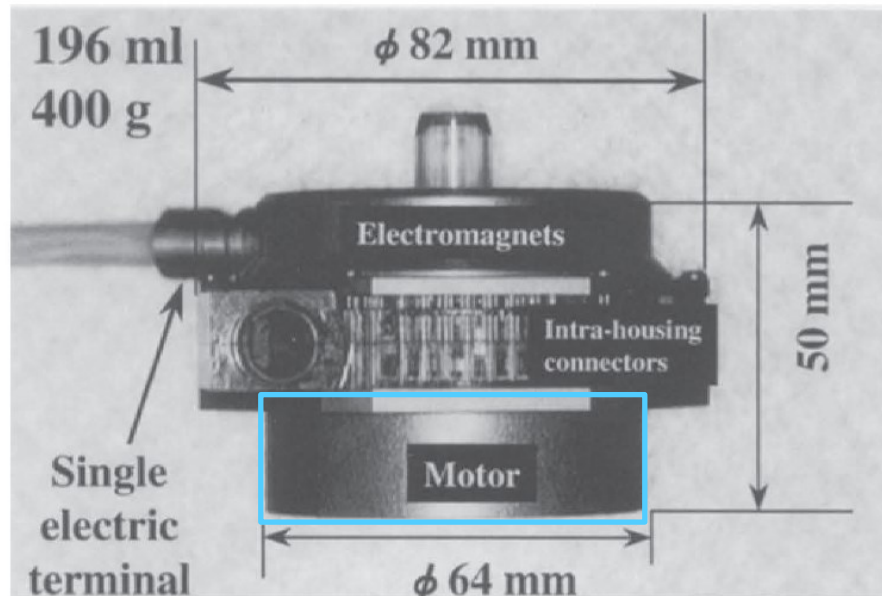


**Fig. 3.** Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3, 4-5; Ex.1003, ¶845.

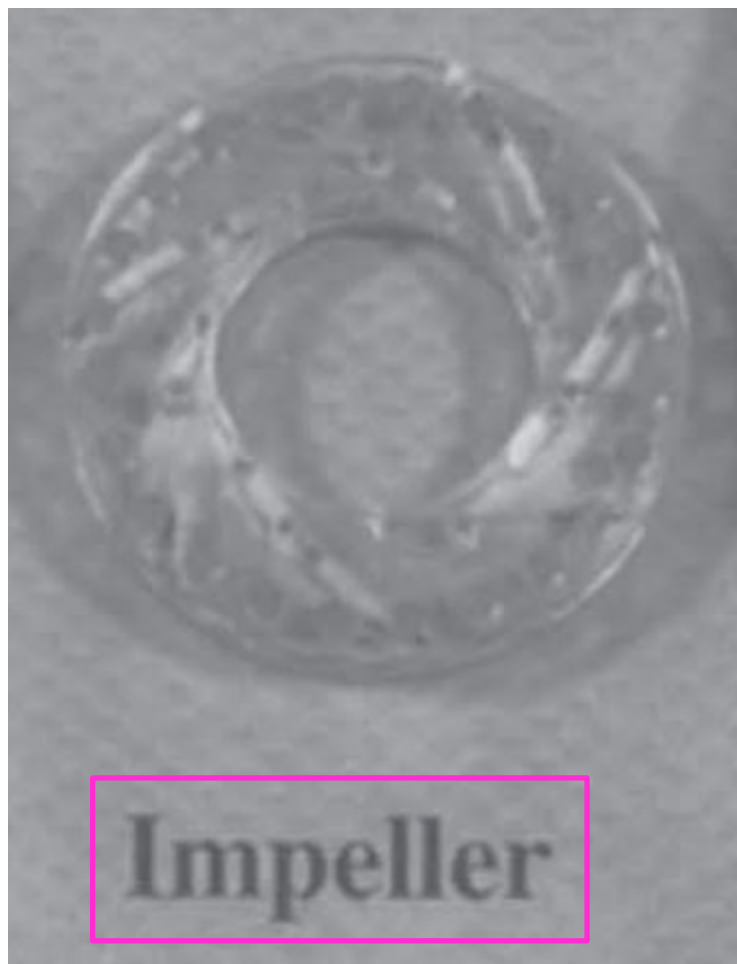
Accordingly, Akamatsu-1999 teaches or suggests “an **external control unit** (“controller”) configured to regulate operation of the **second magnetic device** (motor’s “permanent magnet”), wherein the **external control unit** is connectable to the **heart assist pump device** (“centrifugal pump”) for controlling the **second magnetic device** 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, ¶847.

**2. Claims 2, 3, and 4**

**i. [2]**

Akamatsu-1999 discloses in Figure 5 that its “**impeller**” has blades or edges, which Mr. Crosby explains are *guide surfaces* (Ex.1003, ¶¶850-851):



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, ¶852.

Accordingly, Akamatsu-1999 teaches or suggests “wherein the *magnetically driven rotor* (“impeller”) comprises guide surfaces to produce centrifugal flow components.” Ex.1003, ¶853.

ii. [3A]

As demonstrated in [1K], the “motor” is “sealed...by at least one sealing wall” of the housing, as shown by a solid black line (Ex.1006, 6):

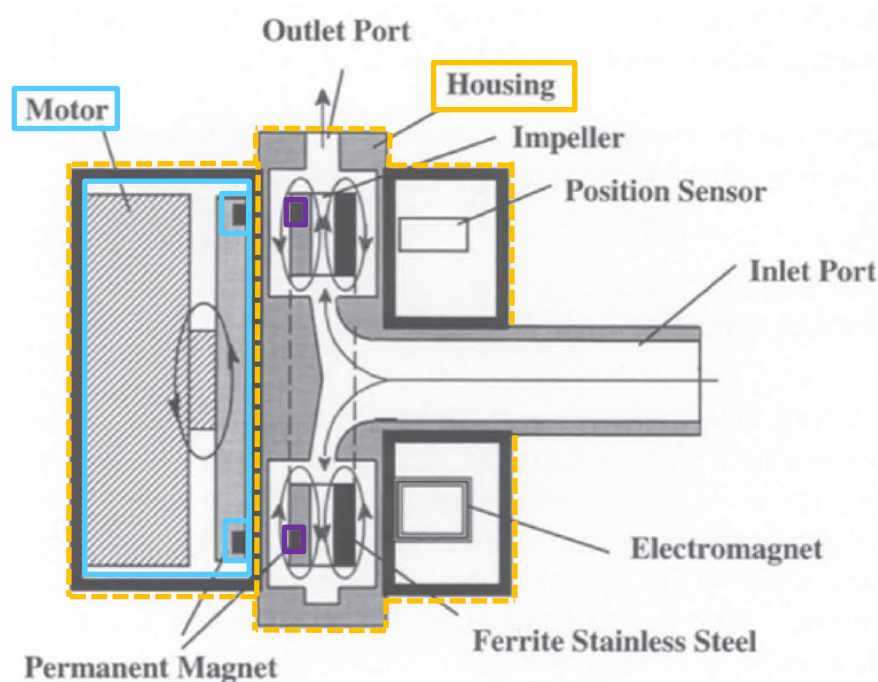


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶857.

Accordingly, Akamatsu-1999 discloses that “the *surrounding rotor housing* (“housing”) comprises at least one sealing wall.” Ex.1003, ¶858.

iii. *[3B]*

As demonstrated in [1I]-[1J], the impeller’s “permanent magnet” is positioned between the “impeller” and the motor’s “permanent magnet” (Ex.1006, 4):

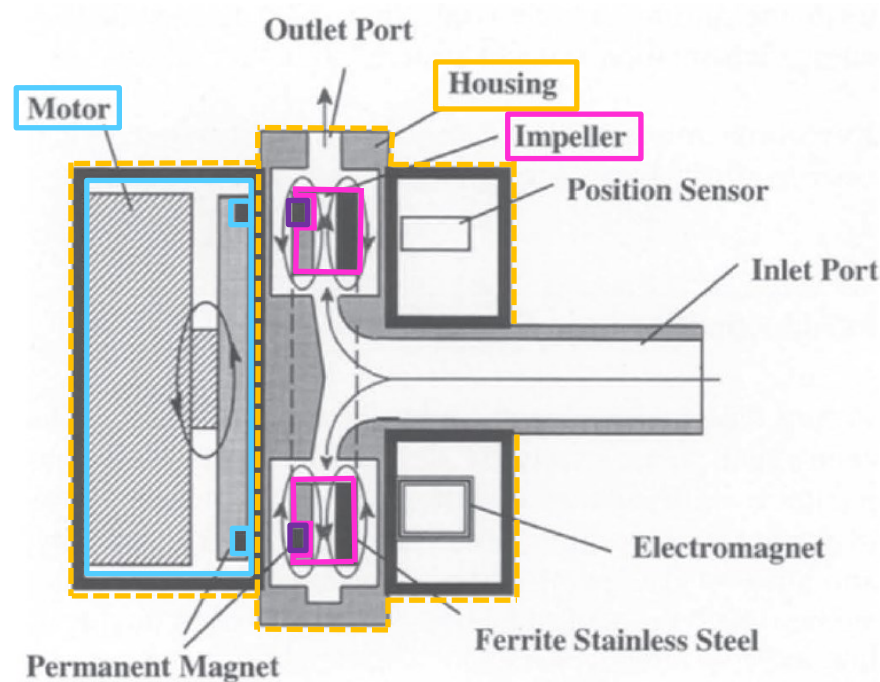


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1003, ¶861.

Accordingly, Akamatsu-1999 discloses that “the *first magnetic device* (“permanent magnet”) is positioned between the *second magnetic device* (motor’s “permanent magnet”) and the *magnetically driven rotor* (“impeller”).” Ex.1003, ¶862.

iv. [4]

As demonstrated in [1E], the “**impeller**” and its “**permanent magnet**” are “*rigidly coupled*,” Akamatsu-1999 discloses “*the first magnetic device* (“permanent magnet”) *rotates together with the magnetically driven rotor* (“impeller”) *relative to the surrounding rotor housing* (“housing”).” Ex.1003, ¶865.

3. Claims 10, 14, and 15

i. [10]

As demonstrated in [1J] and [1L], the motor’s **permanent magnet** and the “suspended **impeller**...operate[] completely contact-free” (“*entirely spaced apart...by a gap*”). Ex.1006, 6. Accordingly, Akamatsu-1999 discloses that “*both the magnetically driven rotor* (“impeller”) *and first magnetic device* (“permanent magnet”) *are entirely spaced apart from the surrounding rotor housing* (“housing”) *by a gap during rotation of the magnetically driven rotor*.” Ex.1003, ¶871.

ii. [14]

As demonstrated in [1N], Akamatsu-1999 discloses a “**controller**” to regulate the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” (“*a control value*”). Ex.1006, 3-4; Ex.1003, ¶876.

Accordingly, Akamatsu-1999 teaches or suggests that “*the external control unit* (“controller”) *is configured to regulate operation of the second magnetic device* (motor’s “permanent magnet”) *based on a control value*.” Ex.1003, ¶878.

**iii. [15]**

In Parallel Litigation, PO asserts that a fixed speed or lower speed limit are “*control value[s]...indicative of a defined cardiac output.*” Assuming that interpretation, Akamatsu-1999 discloses a “**controller**” to *control* the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” Ex.1006, 3-4; Ex.1003, ¶884.

Accordingly, Akamatsu-1999 teaches or suggests “*wherein the control value is indicative of a defined cardiac output (“operated at a fixed rotational speed”) for control of the heart assist pump device (“centrifugal pump”).*” Ex.1003, ¶885.

**4. Claim 11**

See [15]. Ex.1003, ¶1031. Further, Akamatsu-1999 discloses that “[t]he electric current of the electromagnet is controlled by using three position sensors [‘one or more sensors’].” Ex.1006, 3-4. Mr. Crosby explains that these “sensors” “*deliver feedback signals*” to the “**controller**,” thus, Akamatsu-1999 teaches or suggests “*one or more sensors that deliver feedback signals to the external control unit (“controller”).*” Ex.1003, ¶1033.

**5. Claim 17**

In Parallel Litigation, PO asserts that a pump device with an inflow cannula *is a catheter device*. Assuming that interpretation, because Akamatsu-1999’s

**centrifugal pump** comprises “an inlet port” “inserted into the left ventricle” (Ex.1006, 4), it “*is a catheter device.*” Ex.1003, ¶892.

## 6. Claim 21

Claim 21 is rendered obvious for the same reasons as claim 1. Ex.1003, ¶894.

### i. [21PRE]

See [1PRE]. Ex.1003, ¶895.

### ii. [21A]

See [1A]. Ex.1003, ¶899.

### iii. [21B]

See [1C] and [3A]. Ex.1003, ¶906. Akamatsu-1999 discloses “*walls...defining a chamber*” of [21B] for the reasons it discloses a “*surrounding rotor housing compris[ing] at least one sealing wall*” of [3A]. *Supra* [3A].

### iv. [21C]

See [1B] and [1E]. Ex.1003, ¶912.

### v. [21D]

See [1F], [21C]. Ex.1003, ¶924. Akamatsu-1999 discloses that both its *magnetically driven rotor* and *first magnetic device* are “*axially adjacent*” and “*axially aligned*”:

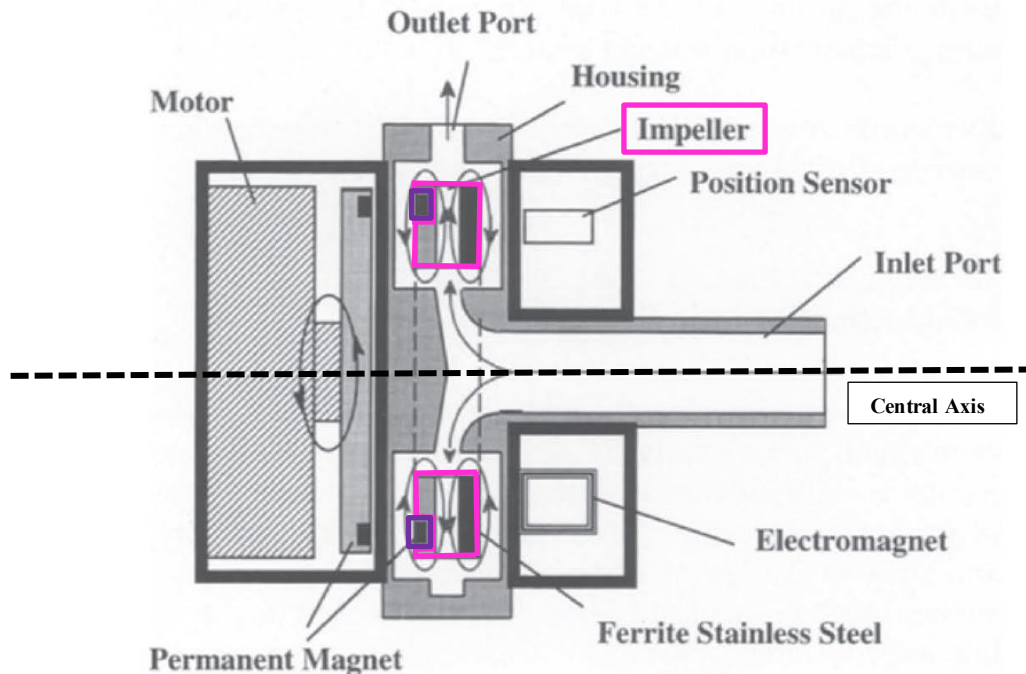


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; *see* [1F]; Ex.1003, ¶924.

**vi. [21E]**

*See* [1C]-[1D]. Ex.1003, ¶930.

**vii. [21F]**

*See* [1H]-[1I]. Ex.1003, ¶939. Akamatsu-1999 discloses a “*magnetic drive system comprising a second magnetic device*” of [21F] for the reasons it discloses a “*second magnetic device*” of claim [1H]-[1I].

**viii. [21G]**

*See* [1J] and [3B]. Ex.1003, ¶945. Akamatsu-1999 discloses that the *second magnetic device* is “*positioned axially closer*” to the *first magnetic device* of [21G]

for the same reasons as the *first magnetic device* “*is positioned between*” the *second magnetic device* and the *magnetically driven rotor* of [3B]. *Supra* [1J] and [3B].

**ix. [21H]**

*See* [1I]. Ex.1003, ¶952.

**x. [21I]**

*See* [1K]. Ex.1003, ¶961.

**xi. [21J]**

*See* [1L]. Ex.1003, ¶971.

**xii. [21K]**

*See* [1M] and [15]. Ex.1003, ¶979.

**xiii. [21L]**

*See* [1M]. Ex.1003, ¶987.

**7. Claim 22**

*See* [2]. Ex.1003, ¶993.

**8. Claims 24, 26, and 32**

*See* [3] and [10]. Ex.1003, ¶¶999, 1025. Akamatsu-1999 discloses a “*gap configured to be occupied by the blood*” of [24] for the reasons it discloses that the *magnetically driven rotor* is *entirely spaced apart... by a gap*” from the *surrounding rotor housing* of [10].

## 9. Claims 28-29

See [1G] and [1J]. Ex.1003, ¶1009. Akamatsu-1999 discloses that “one or more walls separates” the *magnetically driven rotor* from the *magnetic drive system* of [29] for the reasons it discloses that the *second magnetic device* is “sealed...by at least one sealing wall” from the *magnetically driven rotor* of [1J].

## 10. Claim 30

See [1E]. Ex.1003, ¶1021.

## 11. Claim 33

See [11]. Ex.1003, ¶1031.

## 12. Claim 35

See [17]. Ex.1003, ¶1036.

Akamatsu-1999 therefore renders obvious the Challenged Claims. Ex.1003, ¶¶756-1041.

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

### 1. Claim 1

#### i. [IPRE]

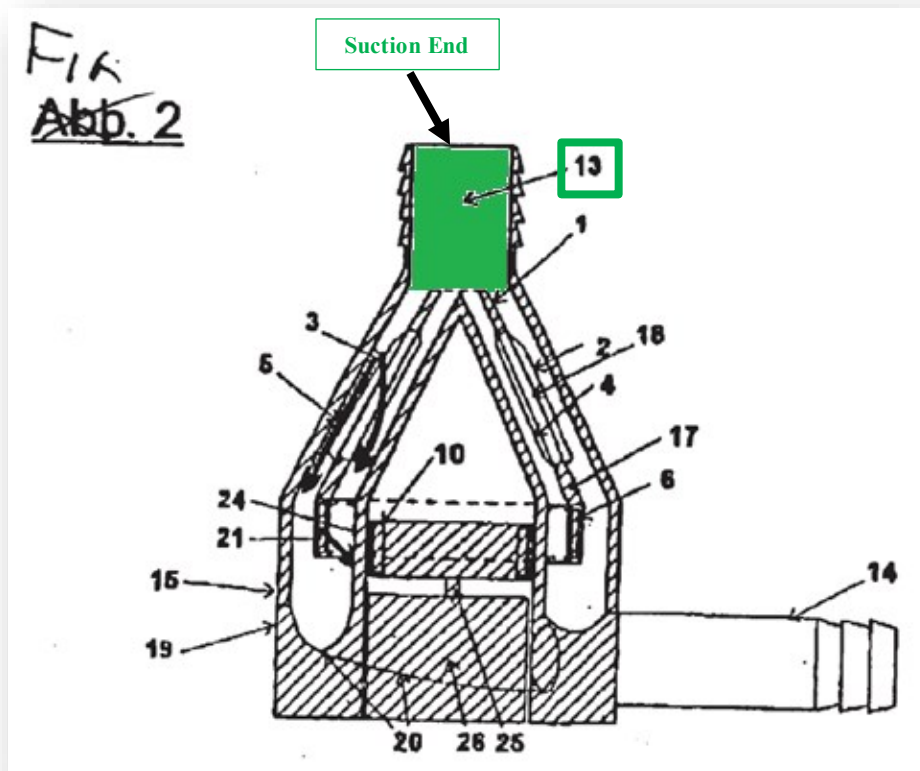
Schima discloses “a rotary pump for moving blood” (“*assisting the blood circulation*”). Ex.1005, [0001]; Ex.1003, ¶1043.

Mr. Crosby explains, *infra* §VIII.D.14, it would have been obvious that Schima's pump is "*for assisting...a heart.*" Ex.1003, ¶1044 (citing Ex.1005, [0004]-[0009]).

Accordingly, Schima teaches or suggests "*a system for assisting the blood circulation of a heart.*" Ex.1003, ¶1045.

ii. [1A]

Schima explains that its "pump" has "**inlet 13**" ("*an inflow tube defining a blood inflow path and having a suction end*") (Ex.1005, [0012]):



Ex.1005, Fig. 2; Ex.1003, ¶1048.

Mr. Crosby explains that Schima suggests that its pump is an LVAD designed to be “*deliverable to the heart*” so that inlet tube 13 is “*insertable into a ventricle of the heart.*” Ex.1003, ¶1049.

Further, Mr. Crosby explains (*infra* §VIII.D.14) that it would have been obvious to implant Schima’s device in the configuration described by Akamatsu-1999 (“*an inflow tube... insertable into a ventricle*”). Ex.1003, ¶1055. In the Schima/Akamatsu combination, Schima’s **pump** is “*deliverable to the heart*” so that its **inlet 13** is “inserted into the **left ventricle**,” as taught by Akamatsu-1999 (Ex.1006, 4) and illustrated:

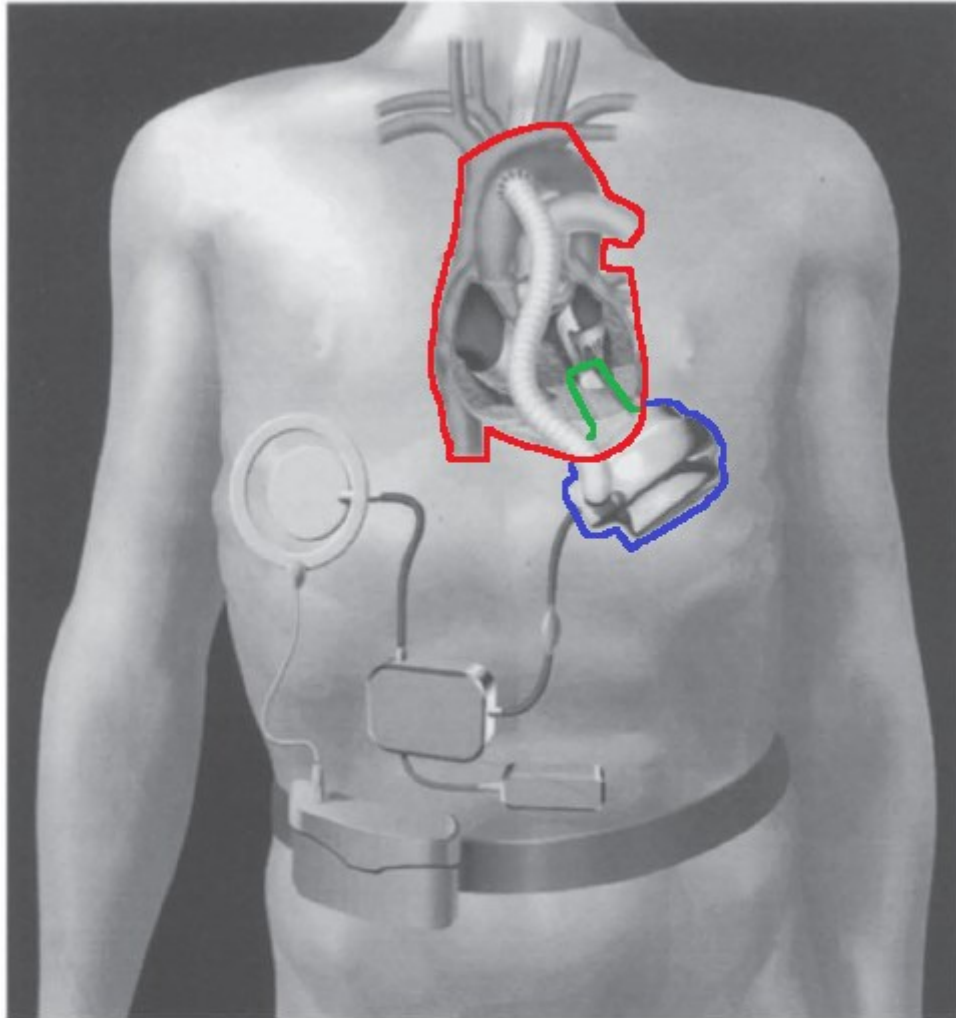


**Fig. 1.** Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

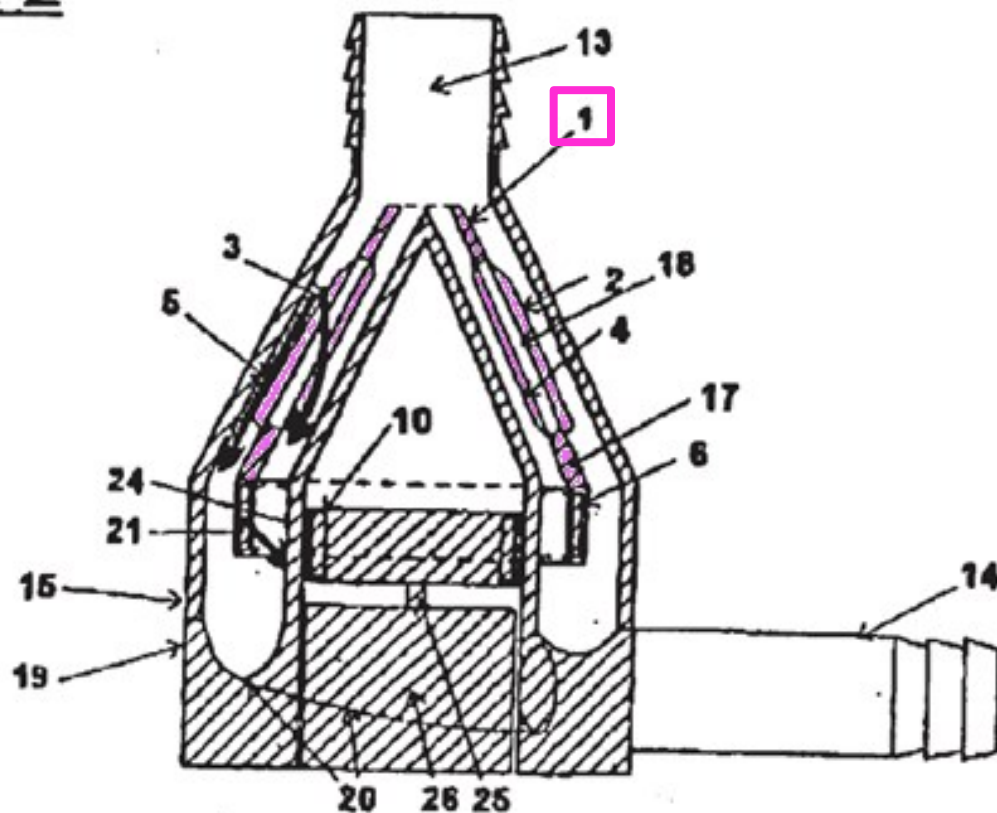
Ex.1006, Fig. 1; Ex.1003, ¶1058; *infra* §VIII.D.14.

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 and having a suction end* (“inlet 13”) insertable into *a ventricle of the heart*.” Ex.1003, ¶1060.

## iii. [1B]

Schima discloses that its “**pump**” includes “**rotor 1**” which “holds rotor magnets 6 that preferably transfer rotation energy” (“*magnetically driven rotor*”) (Ex.1005, [0012]; Ex.1003, ¶1062):

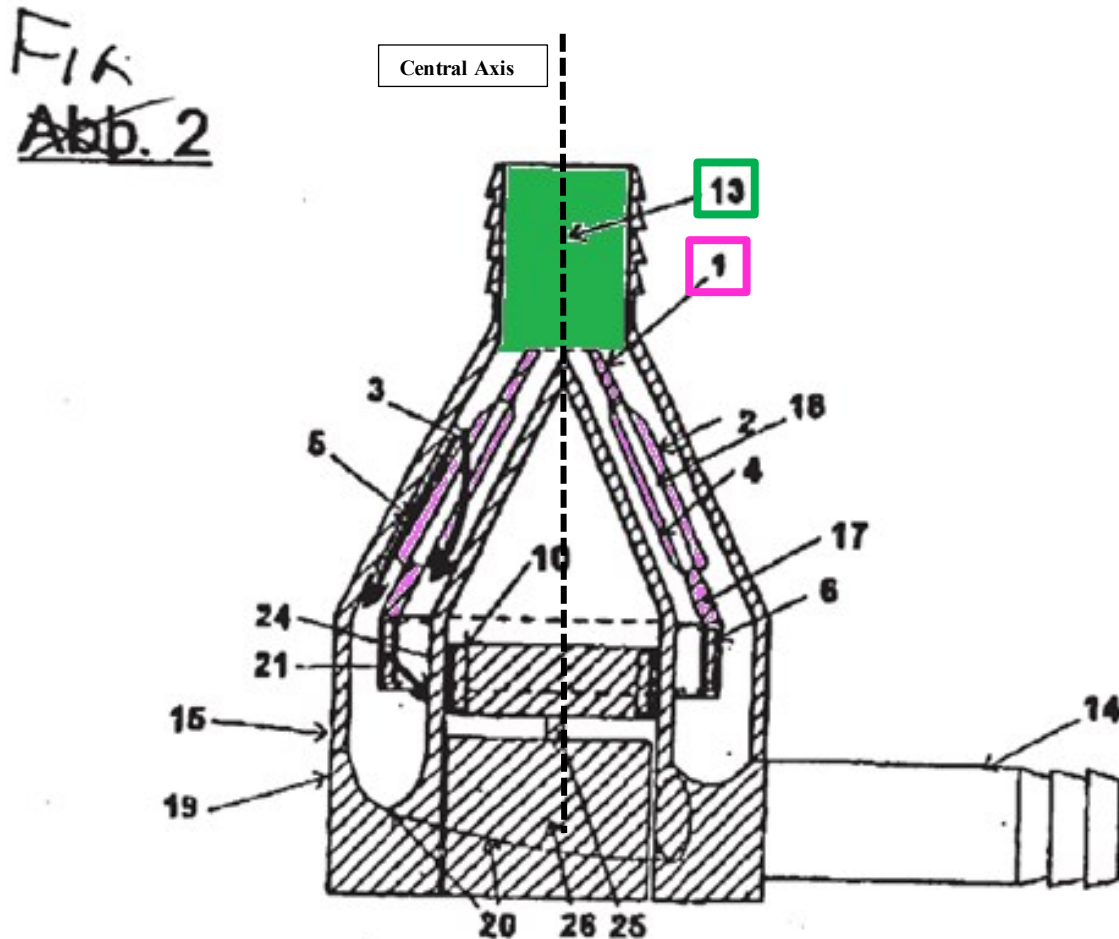
Fig.  
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶¶1062-1063.

Schima discloses that its **rotor** is “axially” *aligned* with **inlet 13** so that the inlet’s “flow [is] preferably axially against” “the pump housing” which “serves to

center the **rotor**” (Ex.1005, [0012]). As demonstrated in [1A], the **rotor** is also “*spaced apart from the suction end*” of inlet 13:



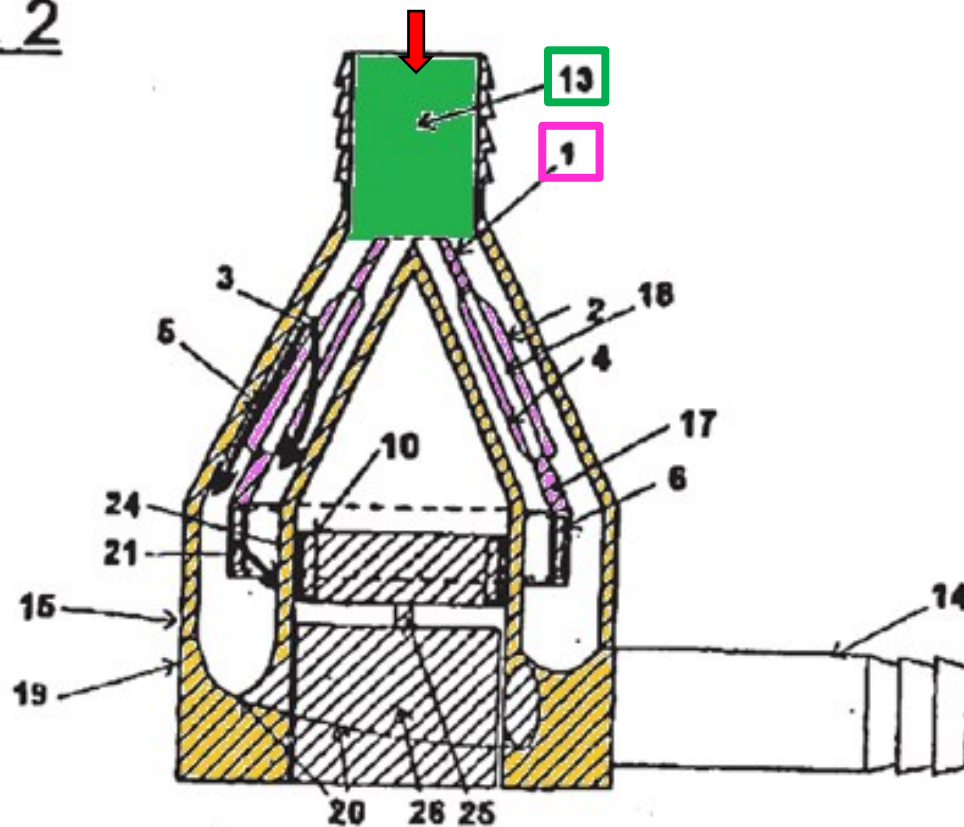
Ex.1005, Fig. 2; Ex.1003, ¶1068.

Accordingly, Schima teaches or suggests “a **magnetically driven rotor** (“rotor 1”) axially aligned with the **inflow tube** (“inlet 13”) and being spaced apart from the suction end when the suction end of the **inflow tube** is inserted into the **ventricle**.” Ex.1003, ¶1069.

## iv. [1C]

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

Fig.  
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶1073.

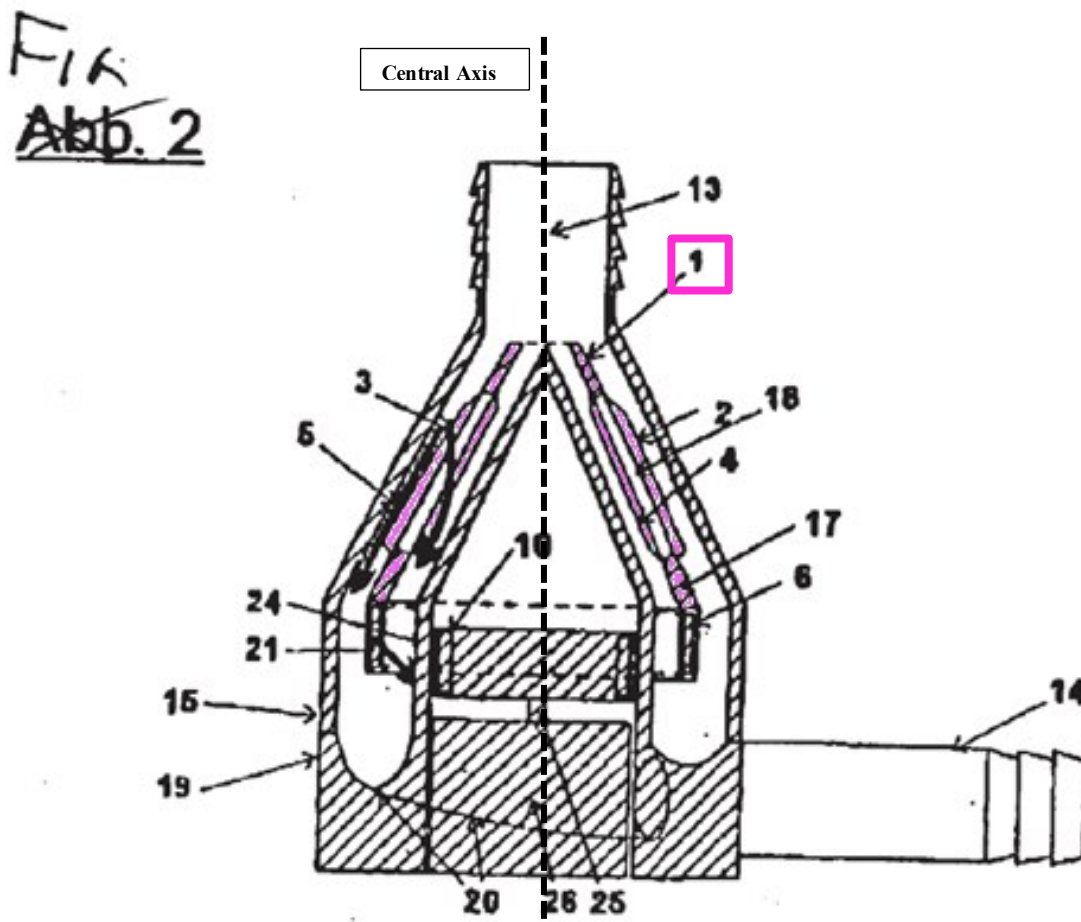
Accordingly, Schima teaches or suggests “the **magnetically driven rotor** being rotatable within **a surrounding rotor housing** (“pump housing 30”) to act

upon blood flowing from the **inflow tube** (“inlet 13”) toward the **rotor** (“rotor 1”).”

Ex.1003, ¶1074.

**v. [1D]**

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



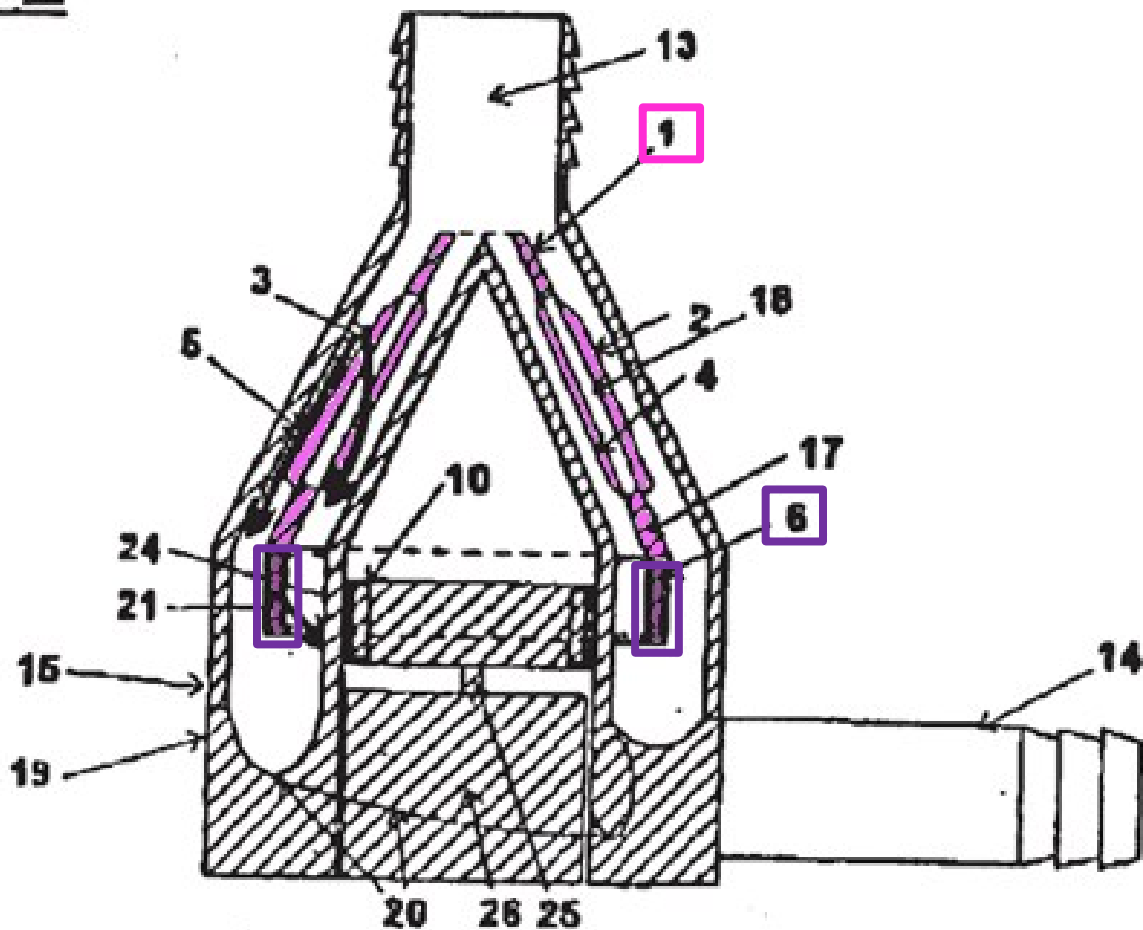
Ex.1005, Fig. 2; Ex.1003, ¶¶1076-1077. Further, because Schima is a “centrifugal blood pump[],” the rotor is by definition “*rotatable about a central axis.*” Ex.1003, ¶1079.

Accordingly, Schima teaches or suggests “*the magnetically driven rotor* (‘rotor 1’) *being rotatable about a central axis.*” Ex.1003, ¶1080.

vi. [1E]

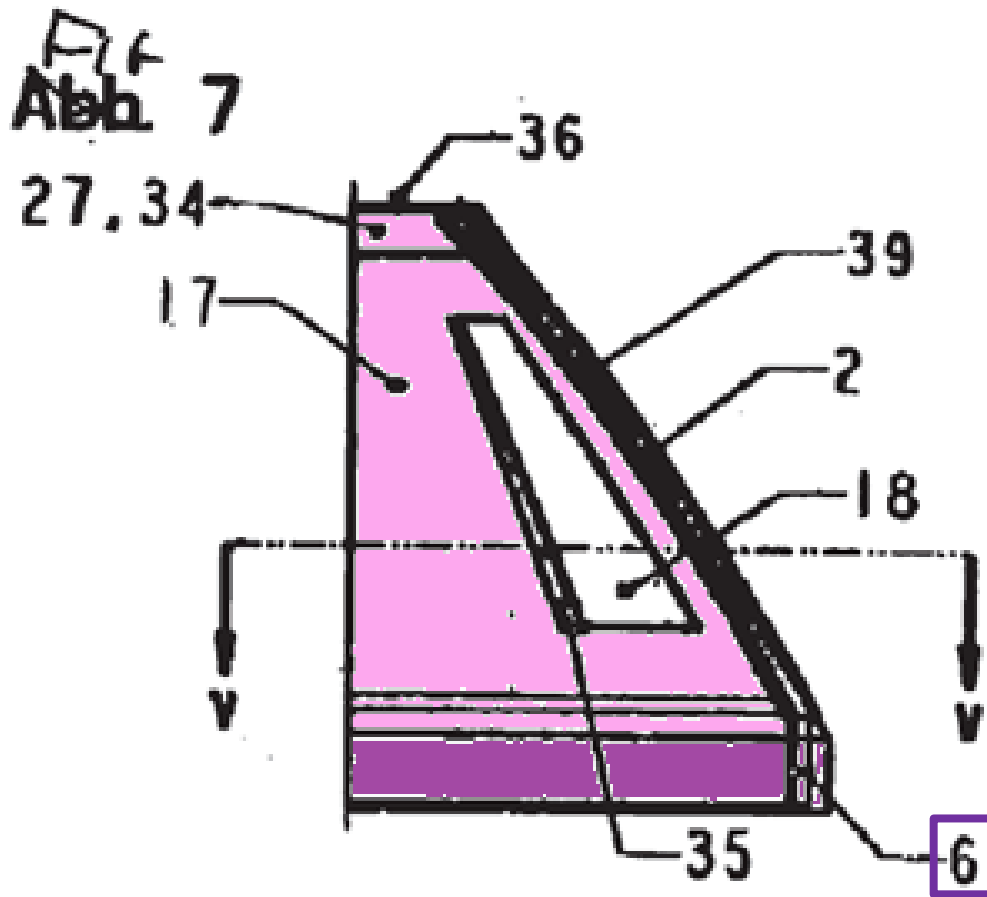
Schima discloses that “[t]he rotor holds [‘*being rigidly coupled to*’] rotor magnets 6 [‘*a first magnetic device*’].” Ex.1005, [0012]; Ex.1003, ¶1083. Figure 2 illustrates the rigid coupling between rotor magnets 6 and the rotor:

2



Ex.1005, Fig. 2; Ex.1003, ¶1084.

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



Ex.1005, [0012], Fig. 7; Ex.1003, ¶1085.

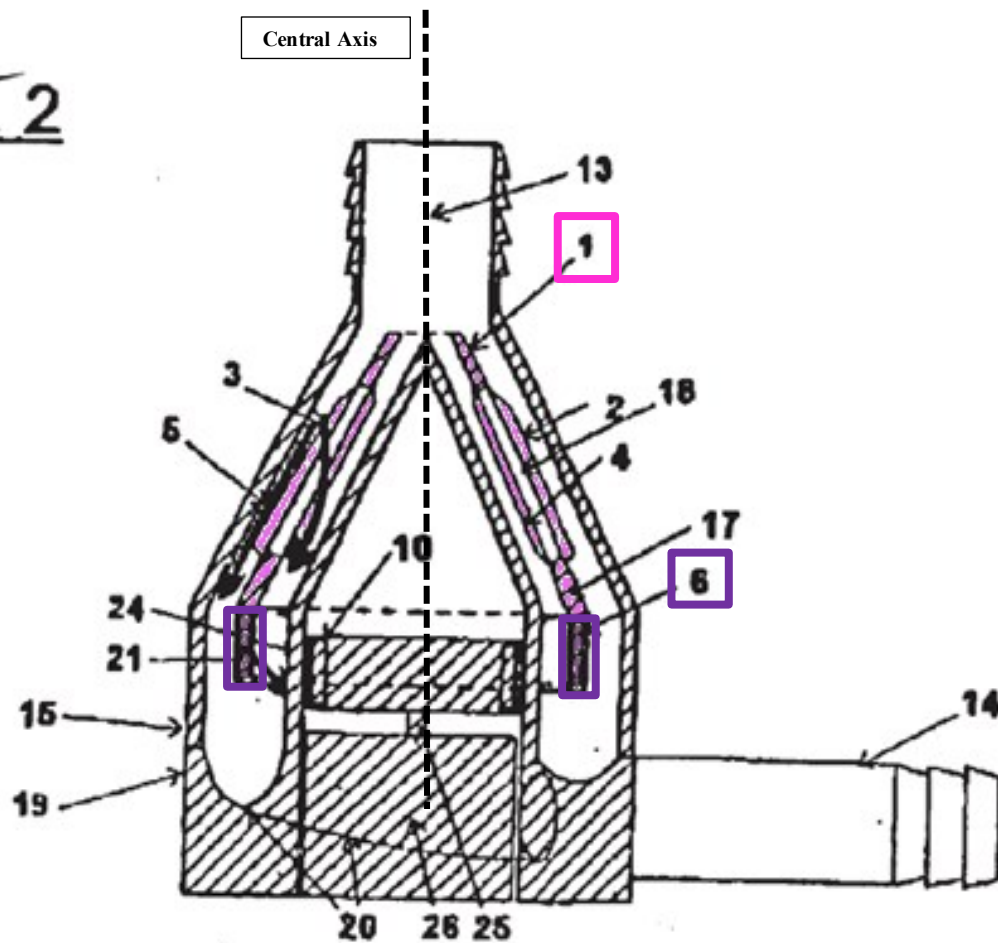
Accordingly, Schima teaches or suggests the *magnetically driven rotor* (“rotor 1”) “being rigidly coupled to” a *first magnetic device* (“rotor magnets 6”).”

Ex.1003, ¶1086.

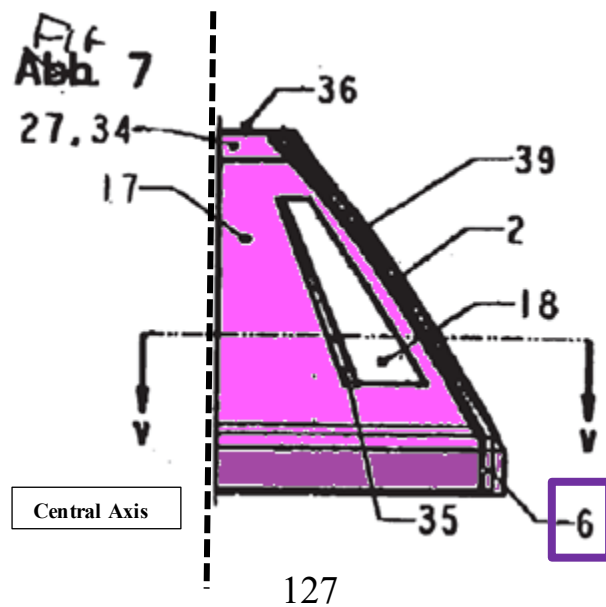
i. [1F]

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

Fig.  
Abb. 2



Ex.1005, Fig. 2; Ex.1003, ¶¶1088-1089.



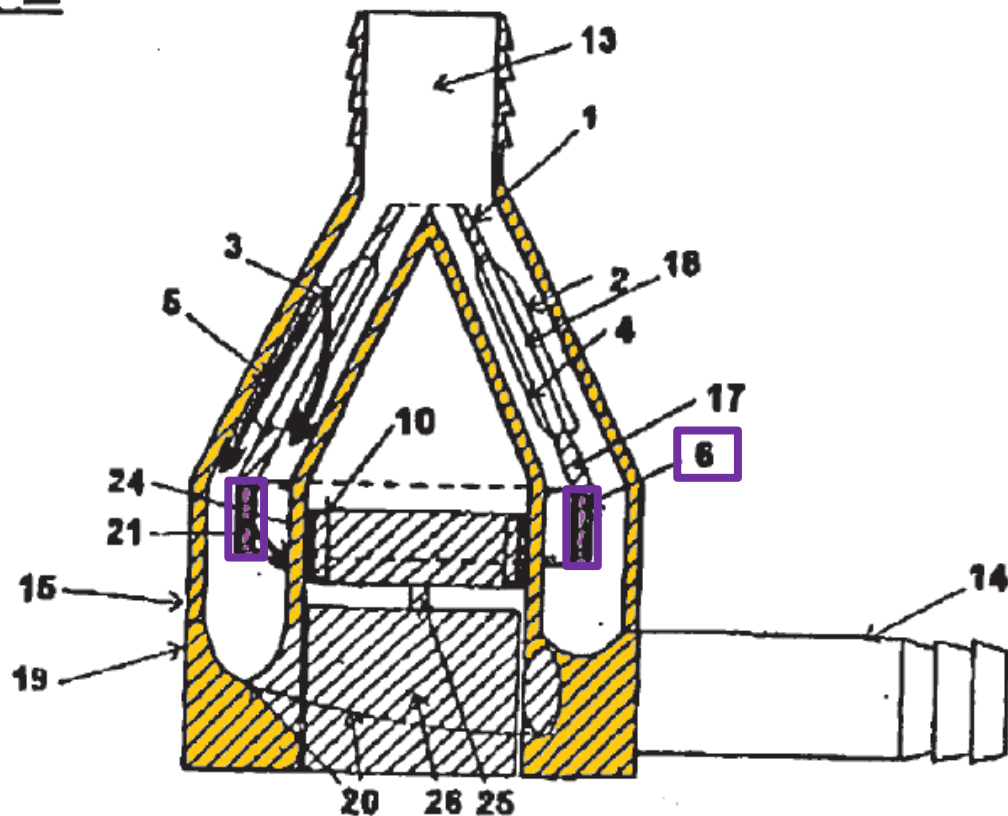
Ex.1005, Fig. 7; Ex.1003, ¶1090.

Accordingly, Schima teaches or suggests that the *magnetically driven rotor* (“rotor 1”) is “axially adjacent to a *first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶1091.

ii. [1G]

Schima discloses that “rotor magnets 6” “rotate[] in a *pump housing*” (“is located within the surrounding rotor housing”)” (Ex.1005, [0012]; Ex.1003, ¶1093):

Fig.  
Abb. 2

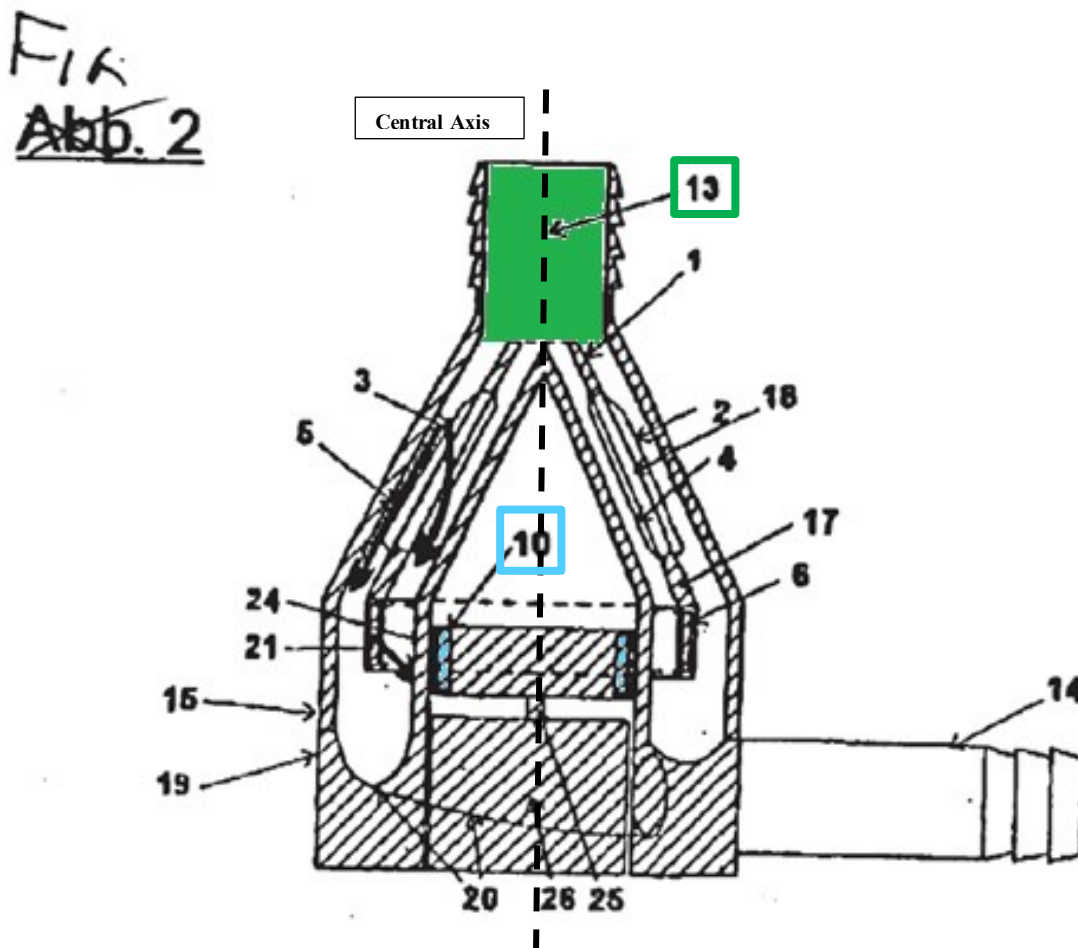


Ex.1005, Fig. 2; Ex.1003, ¶1096.

Accordingly, Schima teaches or suggests that the **first magnetic device** (“rotor magnets 6”) “*is located within the surrounding rotor housing* (“pump housing 30”).” Ex.1003, ¶1097.

iii. [1H]

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



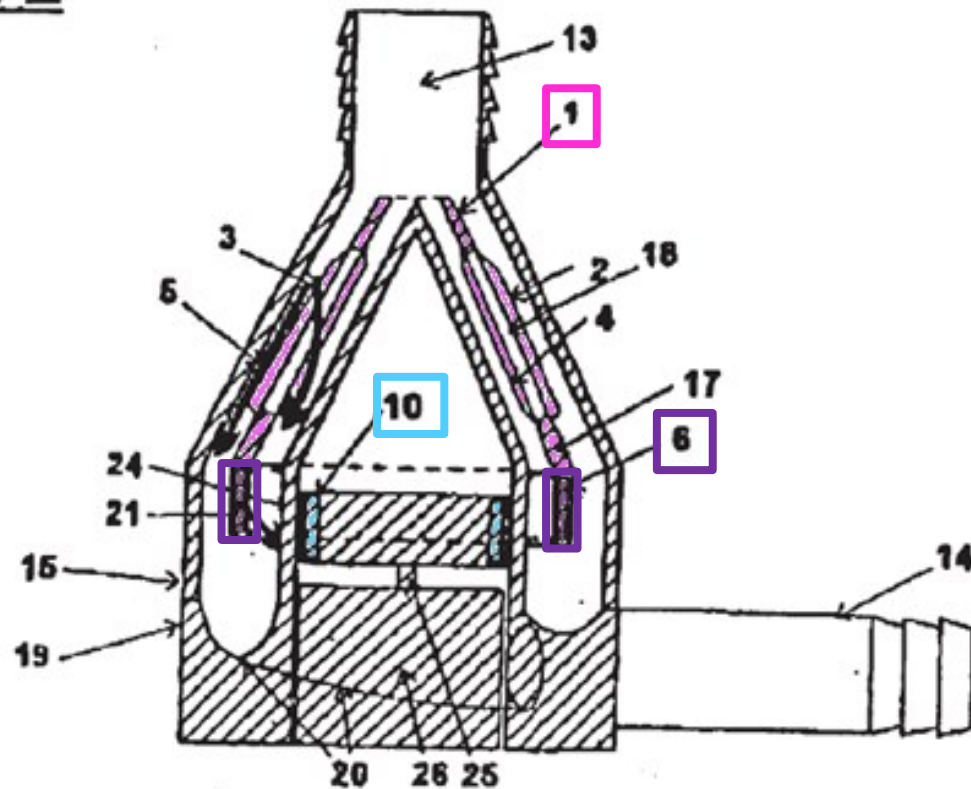
Ex.1005, Fig. 2; Ex.1003, ¶¶1099, 1102.

Accordingly, Schima teaches or suggests that “a *second magnetic device* (“magnets 10”) *axially aligned with the inflow tube* (“inlet 13”).” Ex.1003, ¶1103.

iv. [II]

Schima discloses that “**magnets 10**” are positioned to “ensure[] an axial component for the magnetic force” and “transfer rotation energy” (“*positioned to magnetically drive rotation...via a magneto coupling*”) to “**rotor magnets 6**” of the “**rotor**.” Ex.1005, [0012]-[0013]; *see also* claim 9 (claiming a “magnetic drive”). Schima further discloses that “[a]s shown in FIG. 2, the drive [*‘magnetically drive rotation’*] can...be an electric motor 26 which drives a rotating disk 24 with **magnets 10**:”

FIG.  
Abb. 2



Ex.1005, Fig. 2, [0013]; Ex.1003 ¶1108.

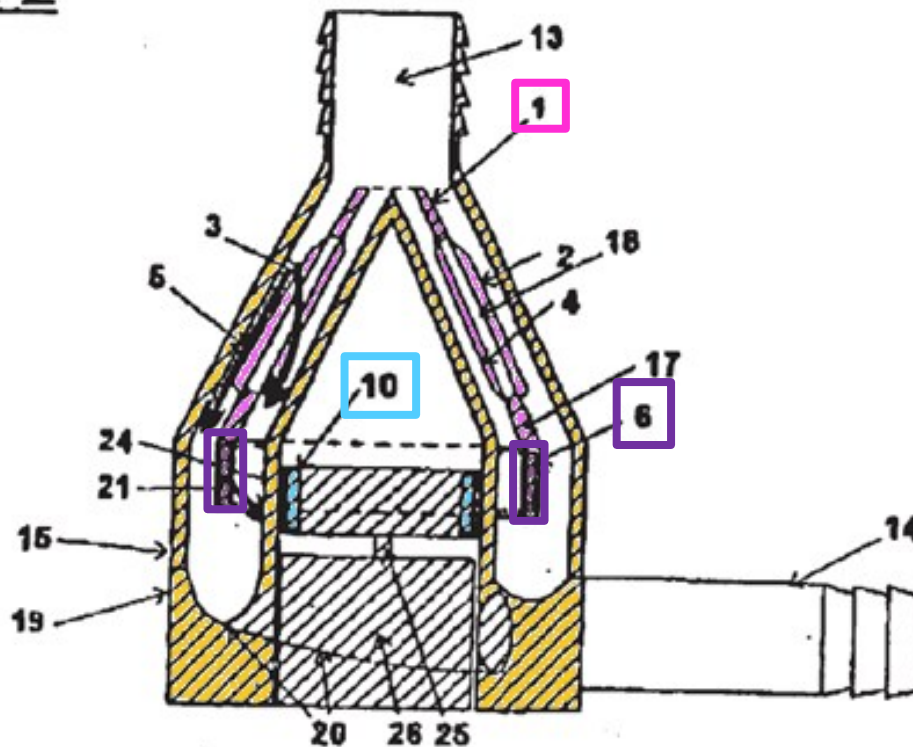
Schima also discloses “*magneto coupling*” under PO’s apparent construction. See §VI.A. Instead of using “a rotating disk 24 with magnets 10,” discussed above; “the drive can also” “work as shown in FIG. 1 with a **stator 12** [alternative ‘*second magnetic device*’]...creating a rotating magnetic field” that “causes the coupling force” (“*drive rotation...via a magneto coupling*”) “with **rotor magnets 6.**” Ex.1005, [0012]-[0013]. Ex.1003, ¶1110.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) is “*positioned to magnetically drive rotation of the magnetically driven rotor* (“rotor 1”) *via a magneto coupling* (“transfer rotation energy”) *with the first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶¶1111-1112.

v. [1J]

Schima discloses that the pump’s “drive” (*magnets 10* or *stator 12*) resides “inside the *housing* lower part 19” while the “*rotor* rotates in...a hollow conical upper part” of “*pump housing* 30.” Ex.1005, [0011]-[0012]; Ex.1003, ¶1114. Figure 2 illustrates that *magnets 10* are “*positioned axially spaced apart*” from the *rotor* and sealed by the “*housing walls*” (Ex.1005, [0023]) from both *rotor* and *rotor magnets 6*:

Fig.  
Abb. 2



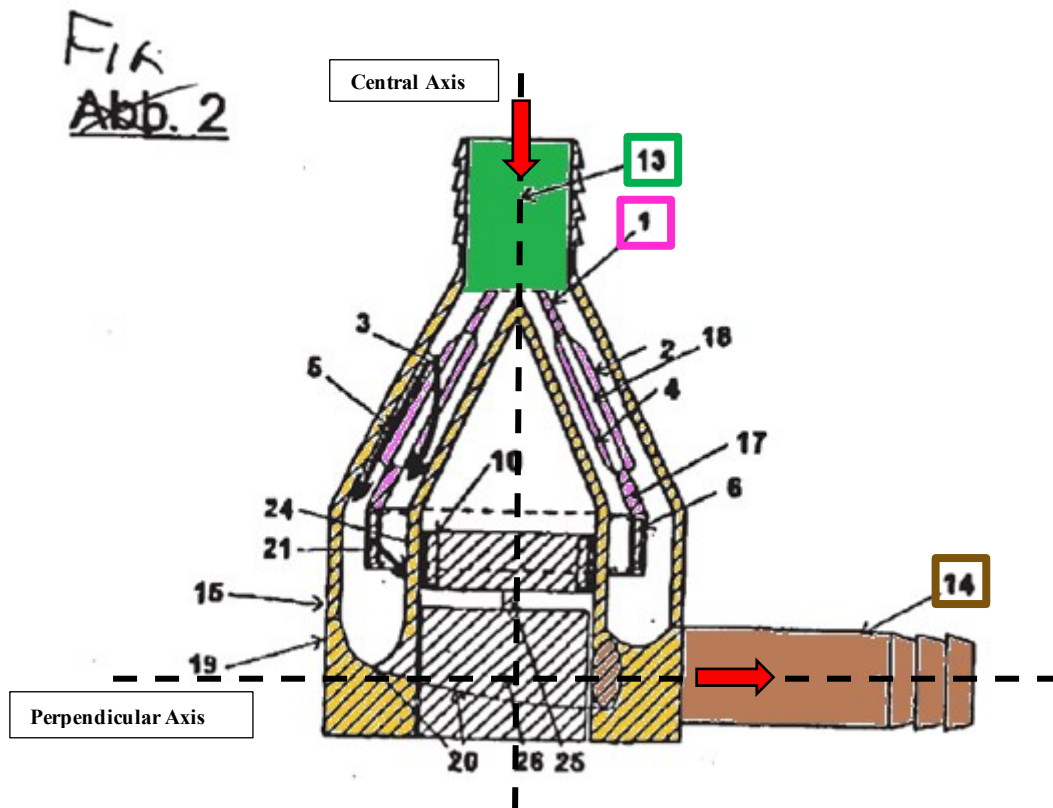
Ex.1005, Fig. 2; *see also* Fig. 1 (showing stator 12); Ex.1003, ¶1117.

Accordingly, Schima teaches or suggests a *second magnetic device* (“magnets 10” or “stator 12”) “being spaced apart and sealed from both the *magnetically driven rotor* (“rotor 1”) and the *first magnetic device* (“rotor magnets 6”) by at least one sealing wall (“housing 30 walls”), the *second magnetic device* being positioned axially spaced apart from the *magnetically driven rotor*.” Ex.1003, ¶1118.

vi. [1K]

Schima discloses “[a] spiral-shaped **outlet passage 20**...[to] **outlet 14**” (“a blood outflow port”). Ex.1005, [0012]. Given its “spiral-shape,” “**outlet 14**” is

“positioned radially adjacent the” **rotor**. Ex.1003, ¶1120. Figure 2 illustrates that “**outlet 14**” allows the “flow of the liquid” (“*blood driven*”) to exit the “**pump housing**” in a direction transverse to the central axis:

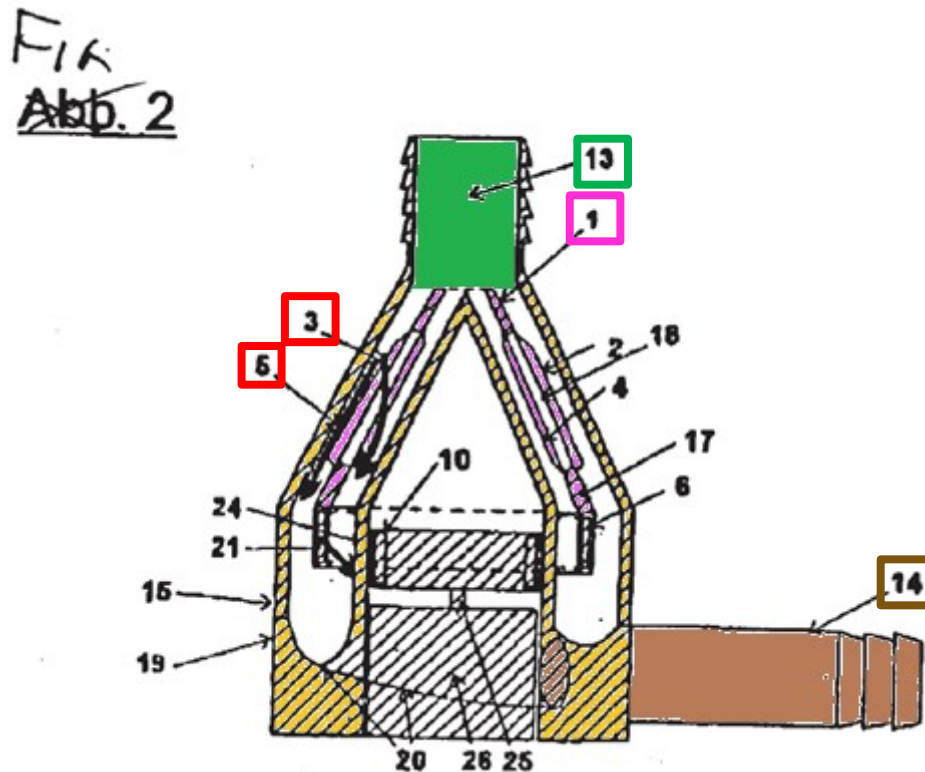


Ex.1005, Fig. 2; Ex.1003, ¶1122.

Accordingly, Schima teaches or suggests that “**blood outflow port** (“outlet 14”) positioned radially adjacent the **magnetically driven rotor** (“rotor 1”) such that blood driven by the **magnetically driven rotor** is configured to exit the **surrounding rotor housing** (“pump housing 30”) in a direction transverse to the **central axis** of the **magnetically driven rotor**.” Ex.1003, ¶1123.

## vii. [1L]

As demonstrated in [1I], Schima teaches or suggests that “rotation” of the rotor (“when the *magnetically driven rotor* is rotated”) “produce[s] centrifugal flow components” (“by the blood flowing”) “for contact-free journaling and stabilizing of the rotor in the housing” (“spaced apart from the...housing”). Ex.1005, [0010], [0012]-[0013]; Ex.1003, ¶1127. Figure 2 illustrates the “centering of the...rotor ...by the flow components [red] directed against the housing” (“by the blood flowing”):



Ex.1005, Fig. 2; Ex.1003, ¶1129.

Accordingly, Schima teaches or suggests that “*wherein when the magnetically driven rotor* (“rotor 1”) *is rotated, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing* (“pump housing 30”) *by the blood flowing* (“centrifugal flow components 3 and 5”)” *from the inflow tube* (“inlet 13”) *and to the blood outflow port* (“outlet 14”).” Ex.1003, ¶1130.

viii. [1M]

Schima does expressly disclose this element, however having “*an external control unit...connectable*” to Schima’s pump “*to regulate operation of the second magnetic device*” would have been obvious in view of Akamatsu-1999. Ex.1003, ¶1131.

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

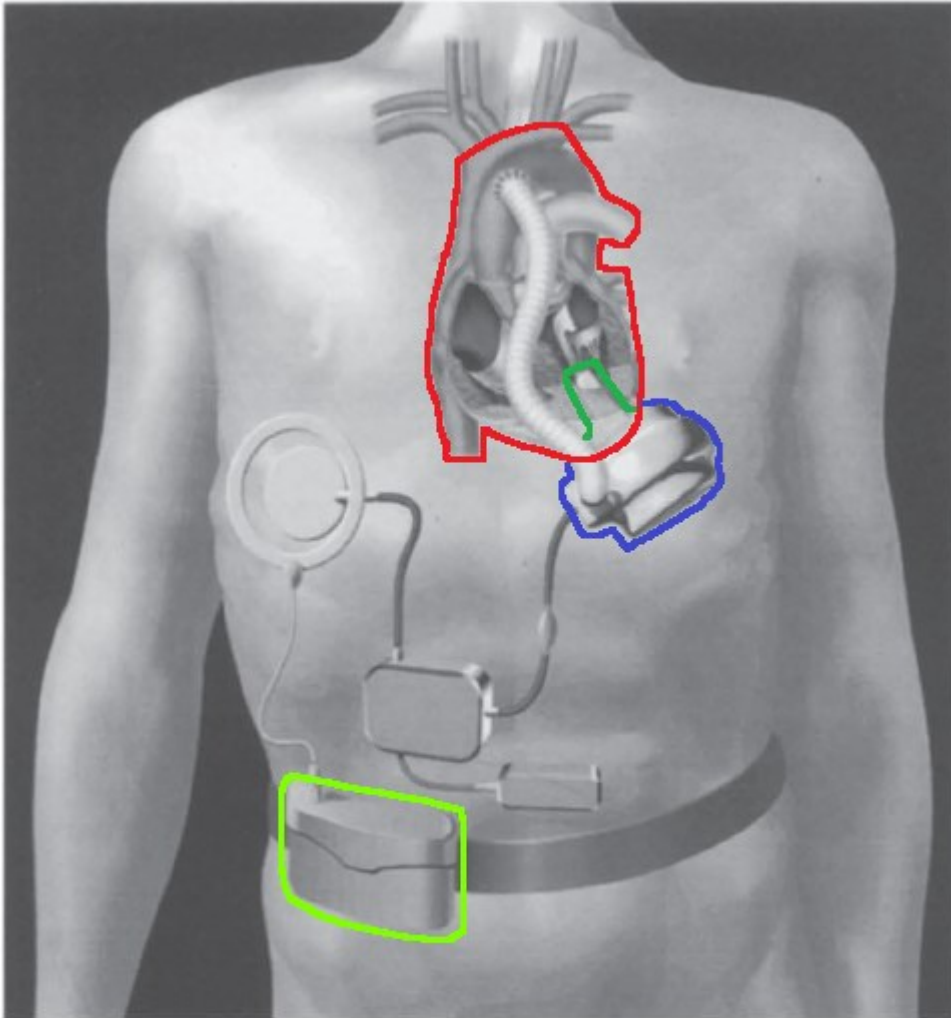


**Fig. 1.** Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

*Supra* §VIII.C.1.xiv; Ex.1006, 3-4; Ex.1003, ¶1132.

As detailed below (*infra* §VIII.D.14), Akamatsu-1999’s “controller” would be “connectable to” Schima’s pump and “configured to regulate operation” of Schima’s “electric motor 26 which drives...magnets 10” (or “stator 12”) (“*the second magnetic device*”).”

Accordingly, Schima/Akamatsu-1999 renders obvious “an *external control unit* configured to regulate operation of the *second magnetic device*, wherein the *external control unit* (“controller”) is connectable to the *heart assist pump device* (“pump”) for controlling the *second magnetic device* (“magnets 10” or “stator 12”) to thereby magnetically drive the rotation of the *magnetically driven rotor* (“rotor 1”) via the magneto coupling with the *first magnetic device* (“rotor magnets 6”).” Ex.1003, ¶1133.

## 2. Claims 2, 3, and 4

### i. [2]

Schima discloses that “[t]he *rotor* 1 has as flow surfaces 2 and 4 vanes” (“*guide surfaces*”) “that produce centrifugal flow components.” Ex.1005, [0012], [0010], Claim 1; Ex.1003, ¶1136.

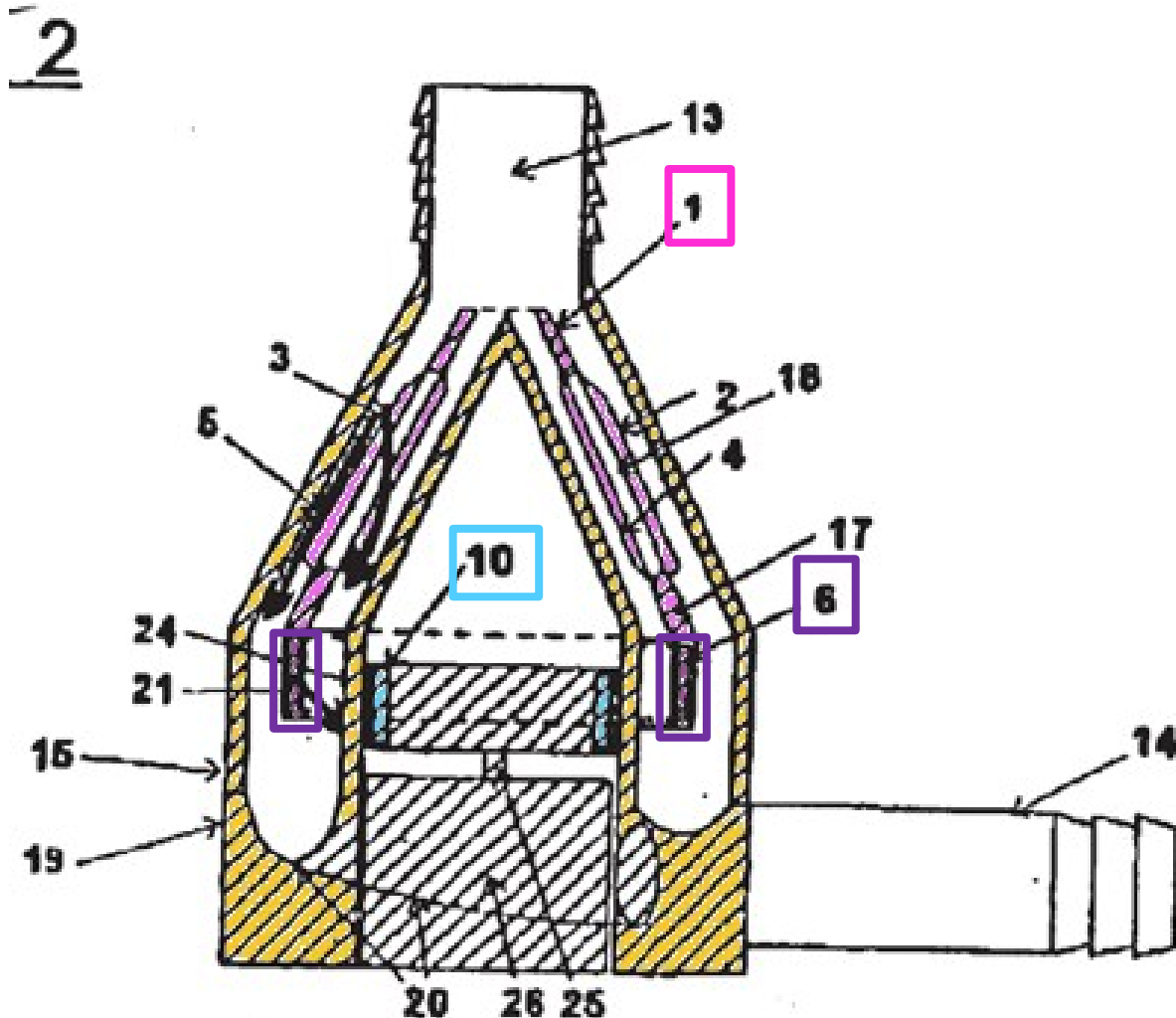
Accordingly, Schima teaches or suggests that “wherein the *magnetically driven rotor* (“rotor 1”) comprises *guide surfaces* (“vanes”) to produce centrifugal flow components (“centrifugal flow components”).” Ex.1003, ¶1140.

### ii. [3A]

As demonstrated in [1J], Schima discloses that the “housing” comprises “housing walls” (Ex.1005, [0023]), thus, Schima teaches or suggests that “the *surrounding rotor housing* (“pump housing 30”) comprises at least one sealing wall (“housing walls”).” Ex.1003, ¶1145.

## iii. [3B]

As demonstrated in [1I]-[1J], Schima discloses **rotor magnets 6** at the base of the **rotor**—“*positioned between*” the **rotor** and the *second magnetic device*:



Ex.1005, Fig. 2; Fig. 1 (“stator 12”); Ex.1003, ¶1148.

Accordingly, Schima teaches or suggests that “*the first magnetic device* (“rotor magnets 6”) *is positioned between the second magnetic device* (“magnets 10”; “stator 12”) *and the magnetically driven rotor* (“rotor 1”).” Ex.1003, ¶1149.

## iv. [4]

For the reasons discussed in [1E], that the “**rotor**” and “**rotor magnets**” are “*rigidly coupled*,” Schima teaches or suggests that “*the first magnetic device* (“rotor magnets 6”) *rotates together with the magnetically driven rotor* (“rotor 1”) *relative to the surrounding rotor housing* (“pump housing 30”).” Ex.1003, ¶1152.

## 3. Claim 10

As demonstrated in [1L], Schima discloses “contact-free” (“*by a gap*”) “journaling and stabilizing of the **rotor** in the **housing**.” Ex.1005, [0010]; Ex.1003, ¶1157.

Accordingly, Schima/Akamatsu-1999 renders obvious that “*both the magnetically driven rotor* (“rotor 1”) *and first magnetic device* (“rotor magnets 6”) *are entirely spaced apart from the surrounding rotor housing* (“pump housing 30”) *by a gap* (“contact-free journaling”) *during rotation of the magnetically driven rotor*.” Ex.1003, ¶1158.

## 4. Claims 14 and 15

As explained in [1M], it would have been obvious to combine Schima’s pump with Akamatsu-1999’s **external control unit**,...to regulat[e] operation of the **second magnetic device**. As demonstrated in Ground 3, Akamatsu-1999 discloses a “**controller**” to regulate the “**motor**” so that “[t]he pump was operated at a fixed rotational speed” (“*a control value*”). Ex.1006, 3-4; Ex.1003, ¶¶1161-1162.

Accordingly, Schima/Akamatsu-1999 renders obvious that “*the external control unit* (“controller”) *is configured to regulate operation of the second magnetic device* (“magnets 10”; “stator 12”) *based on a control value.*” Ex.1003, ¶1163.

For the same reasons, Schima/Akamatsu-1999 renders obvious “*wherein the control value is indicative of a defined cardiac output* (“a fixed rotational speed”) *for control of the heart assist pump device.*” Ex.1003, ¶1166-1169.

## 5. Claim 11

See [15]. Ex.1003, ¶1321. Further, as demonstrated in [1M] and Ground 3, Akamatsu-1999 discloses a “**controller**” using “position sensors” (“*one or more sensors*”) that “*provid[e] feedback signals*” to the “**controller**.” Ex.1006, 3-4; *supra* Ground 3, claim 33; Ex.1003, ¶1324.

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

## 6. Claim 17

In Parallel Litigation, PO asserts that a pump device with an inflow cannula “*is a catheter device.*” Assuming that interpretation, as explained in [1A], because Schima’s pump comprises an “inlet port,” it “*is a catheter device.*” Ex.1003, ¶¶1177-1178.

## 7. Claim 21

Claim 21 is rendered obvious for the same reasons as claim 1. Ex.1003, ¶1179.

### i. [21PRE]

See [1PRE]. Ex.1003, ¶1180.

### ii. [21A]

See [1A]. Ex.1003, ¶1185.

### iii. [21B]

See [1C] and [3A]. Ex.1003, ¶1201. Schima discloses “walls...defining a *chamber*” of [21B] for the reasons it discloses a “*surrounding rotor housing compris[ing] at least one sealing wall*” of [3A]. *Supra* [3A].

### iv. [21C]

See [1B] and [1E]. Ex.1003, ¶1206.

### v. [21D]

See [1F], [21C]. Ex.1003, ¶1217.

### vi. [21E]

See [1C]-[1D]. Ex.1003, ¶1224.

### vii. [21F]

See [1H]-[1I]. Ex.1003, ¶1232. Schima discloses a “*magnetic drive system comprising a second magnetic device*” of [21F] for the reasons it discloses a “*second magnetic device*” of claim [1H]-[1I].

**viii. [21G]**

See [1J] and [3B]. Ex.1003, ¶1239. Schima discloses that the *second magnetic device* is “positioned axially closer” to the *first magnetic device* of [21G] for the same reasons as [3B]. *Supra* [1J] and [3B].

**ix. [21H]**

See [1I]. Ex.1003, ¶1246.

**x. [21I]**

See [1K]. Ex.1003, ¶1256.

**xi. [21J]**

See [1L]. Ex.1003, ¶1263.

**xii. [21K]**

See [1M] and [15]. Ex.1003, ¶1271.

**xiii. [21L]**

See [1M]. Ex.1003, ¶1278.

**8. Claim 22**

See [2]. Ex.1003, ¶1283.

**9. Claims 24, 26, and 32**

See [3] and [10]. Ex.1003, ¶¶1290, 1316. Schima discloses a “gap configured to be occupied by the blood” of [24] for the reasons it discloses that the *magnetically driven rotor* is *entirely spaced apart... by a gap*” from the *surrounding rotor housing* of [10]. *Supra* [3] and [10].

**10. Claims 28-29**

See [1G] and [1J]; Ex.1003, ¶1300. Schima discloses that “*one or more walls separates*” the *magnetically driven rotor* from the *magnetic drive system* of [29] for the reasons it discloses that the *second magnetic device* is “*sealed...by at least one sealing wall*” from the *magnetically driven rotor* of [1J]. *Supra* [1G] and [1J].

**11. Claim 30**

See [1E]. Ex.1003, ¶1312.

**12. Claim 33**

See [11]. Ex.1003, ¶1321.

**13. Claim 35**

See [17]. Ex.1003, ¶1328.

Schima in view of Akamatsu-1999 therefore renders obvious the Challenged Claims. Ex.1003, ¶¶1042-1333.

**14. 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.14.

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.14.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.14.a.

Akamatsu-1999 and Schima are analogous art to the 517 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; 2:52-62; Ex.1006, 3; Ex.1008, [0001]. Ex.1003, ¶¶1336, 1346. *Second*, Akamatsu-1999 and Schima are reasonably pertinent to a problem described by the 517 Patent: reducing mechanical stress on the blood during pumping. Ex.1001, 2:20-24; Ex.1006, 8; Ex.1005, [0002], [0009]. Ex.1003, ¶¶1337, 1346.

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, ¶¶1338-1340 (discussing implantation), 1347-1352 (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, ¶1342. Schima is silent as to pump implantation and control. Ex.1003, ¶1344. 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, ¶1353.

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, ¶¶1353-1354; 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, ¶1343; 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 517 Patent as Wampler-169, Bourque-2001 (or Bourque-2001/Wampler-169), Akamatsu-1999,

Schima<sup>9</sup> (or Schima/Akamatsu-1999), were not cited or considered by the Examiner during prosecution of the 517 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 statistics<sup>10</sup> on median time-to-trial for civil actions in NDIL was 53.7 months. Trial can be expected in approximately July 2028, about two years after a FWD.

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

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

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<sup>9</sup> A German-language version of Schima was cited in an IDS by the applicant during prosecution of the 517 Patent but was not relied on by the Examiner.

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

**Other Considerations:** Factor 6 **weighs against** discretionary denial. The merits of this petition are particularly compelling—the prior art is robust in this field, and each primary reference has strikingly similar disclosures to that of the 517 Patent, is directed at the same problem, and proposes the same solutions as the 517 Patent using nearly identical architecture.

## **X. CONCLUSION**

The Challenged Claims of the 517 Patent are unpatentable for the reasons demonstrated above.

Dated: November 26, 2024

Respectfully Submitted,

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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 13,958 words (as determined by the Microsoft Word word-processing system used to prepare the brief and including annotated figures), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

Dated: November 26, 2024

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on November 26, 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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