

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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ABBOTT LABORATORIES,  
Petitioner,

v.

MIRACOR MEDICAL SA,  
Patent Owner.

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

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**PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

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**EXHIBIT LIST**

| No.  | Exhibit Description                                                                                                                                                                                                                                                             |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1001 | U.S. Patent No. 11,351,356                                                                                                                                                                                                                                                      |
| 1002 | U.S. Patent No. 11,351,356 File History                                                                                                                                                                                                                                         |
| 1003 | Declaration of Peter Crosby                                                                                                                                                                                                                                                     |
| 1004 | CV of Peter Crosby                                                                                                                                                                                                                                                              |
| 1005 | U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled “ <i>Rotary Pump Comprising a Hydraulically Mounted Motor</i> ”                                                                                                                                         |
| 1006 | Akamatsu et al., <i>Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump</i> , J Artif Organs 1999, Vol. 2, pp. 3-7                                                                                        |
| 1007 | Bourque et al., <i>HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor</i> , ASAIO Journal 2001                                                                                                                                               |
| 1008 | U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled “ <i>Sealless rotary blood pump</i> ”                                                                                                                                                                   |
| 1009 | Miracor’s Supplemental Initial Response to Invalidity Contentions, dated September 20, 2024                                                                                                                                                                                     |
| 1010 | Frazier et al. <i>Total Heart Replacement with Dual Centrifugal Ventricular Assist Devices</i> , ASAIO Journal 2005                                                                                                                                                             |
| 1011 | Schob, <i>Centrifugal pump without bearings or seals</i> , World Pumps Vol. 2002, No. 430, pp. 34-37                                                                                                                                                                            |
| 1012 | Rose et al, <i>Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure</i> , N Engl J Med. 2001 Nov 15, Vol. 345, No. 20, pp. 1435-43 |
| 1013 | HeartMate® II LVAS: Patient Management Guidelines, December 14, 2006                                                                                                                                                                                                            |
| 1014 | Schulman et al., <i>Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices</i> , The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842                                               |

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| 1015 | LaRose et al., <i>Heartware – A novel miniaturized passive maglev centrifugal VAD</i> , ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137                                                                                                                                                       |
| 1016 | Qian et al., <i>Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump</i> , Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38                                                                                |
| 1017 | Akamatsu et al., <i>Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump</i> , Artificial Organs 1997, Vol. 21, No. 7, pp. 645-638                                                                                                                                         |
| 1018 | U.S. Patent No. 6,050,975                                                                                                                                                                                                                                                                    |
| 1019 | Exhibit 7 of Complaint, dated November 27, 2023                                                                                                                                                                                                                                              |
| 1020 | Bottone et al., <i>Magnetos for automobilists, how made and how used</i> , Crosby Lockwood and Son, Ch. 1 (1907) (accessed at <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. Pat. 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                                                                                                                                                                                                                                                             |

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| 1031 | Order to Temporarily Stay Case Deadlines, No. 1:23-CV-16257 (N.D. Ill. Feb. 13, 2025)                                                                           |
| 1032 | Declaration of Saranya Raghavan in support of motion for Pro Hac Vice Admissions                                                                                |
| 1033 | Leschinsky, et al., <i>The CorInnova Implantable Cardiac Assist System for Direct Cardiac Compression</i> , Rev. Cardiovasc. Med. 2022; 23(6): 211              |
| 1034 | Abiomed, Inc., v. WhiteSwell Medical Ltd., PGR2021-00107, Ex. 2006, Declaration of Boris Leschinsky                                                             |
| 1035 | U.S. Patent No. 10,926,069                                                                                                                                      |
| 1036 | Miracor’s Supplemental Infringement Contentions, Ex. D - Claim Chart for U.S. Patent No. 11,572,879, dated May 28, 2024                                         |
| 1037 | [Reserved]                                                                                                                                                      |
| 1038 | Duplicate of Ex. 1015, introduced during cross-examination of Dr. Gallegos                                                                                      |
| 1039 | Gallegos, et al., <i>Animal Models for Cardiac Research</i> , In: Iaizzo, P.A. (eds) Handbook of Cardiac Anatomy, Physiology, and Devices. Humana Press (2005). |
| 1040 | Transcript of Cross-Examination of Boris Leschinsky (December 10, 2025)                                                                                         |
| 1041 | First Declaration of Dr. Wieselthaler                                                                                                                           |
| 1042 | Second Declaration of Peter Crosby                                                                                                                              |
| 1043 | LinkedIn profile of Kevin Bourque                                                                                                                               |
| 1044 | HeartWare Announcement: First Human Implant of HeartWare’s HVAD, March 2006                                                                                     |
| 1045 | Transcript of Cross-Examination of Dr. Robert Gallegos (December 15, 2025)                                                                                      |
| 1046 | Hoshi, et al., “Third-generation Blood Pumps With Mechanical Noncontact Magnetic Bearings,” <i>Artificial Organs</i> 30(5):324–338 (2006)                       |
| 1047 | CV of Dr. Georg Wieselthaler                                                                                                                                    |

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| 1048 | FEP Medical Policy Manual, Total Artificial Hearts and Implantable Ventricular Assist Devices (January 2024)                       |
| 1049 | Wieselthaler G. <i>My Journey with the HeartWare Ventricular Assist Device- An Obituary. The VAD Journal.</i> 2022; 8(1):e2022813. |
| 1050 | Potapov et al., The MicroMed DeBakey VAD—Part I: The Pump and the Blood Flow, <i>JECT.</i> 2003;35:274–283                         |

### **CLAIM INDEX**

| <b>Element</b> | <b>Claim language</b>                                                                                                                                                                                   |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [1PRE]         | A method for assisting the blood circulation of a heart in a body, comprising:                                                                                                                          |
| [1A]           | delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart                                    |
| [1B]           | while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart                                                                                      |
| [1C]           | wherein the magnetically driven rotor is axially aligned with the inflow tube,                                                                                                                          |
| [1D]           | and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor |
| [1E]           | the magnetically driven rotor being rotatable about a central axis                                                                                                                                      |
| [1F]           | and [the magnetically driven rotor] being rigidly coupled to a first magnetic device                                                                                                                    |
| [1G]           | that [the first magnetic device] is located within the surrounding rotor housing                                                                                                                        |
| [1H]           | [the first magnetic device is] at a position axially adjacent to the magnetically driven rotor                                                                                                          |
| [1I]           | wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube                                                                                    |

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

|      |                                                                                                                                                                                                                     |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [5]  | The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.                                           |
| [6]  | The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor. |
| [7]  | The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.                                                                                         |
| [10] | The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.                                                          |
| [12] | The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube.              |
| [13] | The method of claim 1, wherein the heart assist pump device is a catheter device.                                                                                                                                   |

## **I. INTRODUCTION**

Patent Owner provided no basis to reconsider the Board’s institution analysis. Claims 1-7, 10, and 12-13 of the 356 Patent are unpatentable.

## **II. PERSON OF ORDINARY SKILL IN THE ART**

The Board’s Institution Decision (“ID”) found that Petitioner’s definition of a POSA “reflect[s] the appropriate level of skill.” ID 18-19. PO contends the definition should be narrower—instead of experience designing “implantable *medical* devices,” PO argues that a POSA would possess experience with “implantable *cardiac assist* devices in particular.” POR, 3-4.

That distinction is inconsequential, because Crosby possesses the engineering experience that PO’s definition requires, and his opinions remain the same under either definition. Ex.1042, ¶¶11-15, 19. Petitioner’s experts have both developed a third-generation LVAD, while PO’s experts have not. Ex.1041, ¶11; Ex.1042, ¶¶11, 95. From “2005” to “2010,” Crosby “was actively involved” in “designing and manufacturing” the VentrAssist cardiac assist device, “work[ed] to improve” the device, and led “all of the research and development and manufacturing” of the device. Ex.2014, 10:17-13:3. Earlier in his career, Crosby served as “head of [a] Biomedical Engineering Department” responsible for supporting “an Intra-Aortic Balloon Pump (IABP),” which is also “part of the subject matter of the ’356 Patent” (Ex.1003, ¶15), and is an implantable cardiac

assist device (Ex.2015 (“Leschinsky”), ¶33). Crosby also has “45 years of experience in the medical device industry,” “15 years in product research and development,” and experience bringing “over a dozen [medical device] products” through development. Ex.1003, ¶¶8-15.

Despite Crosby’s qualifications, PO impugns his expertise for “lack[ing] experience actually implanting” cardiac assist devices. POR, 4-5. But PO’s expert, Leschinsky, also lacks that experience. Ex.1040, 11:14-15; 23:10-12. Regardless, Dr. Wieselthaler, a surgeon who implants cardiac assist devices, agrees with Crosby. Ex.1041, ¶45.

If the Board decides to resolve this dispute, PO’s narrow definition should be rejected for two reasons. First, it fails to consider the “educational level of active workers in the field” at the time of the invention. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). For example, PO’s definition would exclude the author of Bourque (Ex.1007). Ex.1042, ¶17. Second, Leschinsky previously opined in a similar case that only 2 years’ experience was required. Ex.1042, ¶17.

### **III. Claim Construction**

#### **A. “*Magneto Coupling*” and “*By The Blood Flowing*”**

The Board need not construe these two terms and can instead “apply [PO’s] broader construction[s]” because they “encompass[.]” Petitioner’s constructions.

ID, 21-23. If the Board decides to construe these terms, the plain meaning of “*magneto coupling*” refers to a transfer of torque between two “rotating magnets.” Ex.1003, ¶¶68-87. Further, “*by the blood flowing*” refers to a hydrodynamic bearing. Ex.1003, ¶¶88-98.

**B. “*Axially Adjacent*”**

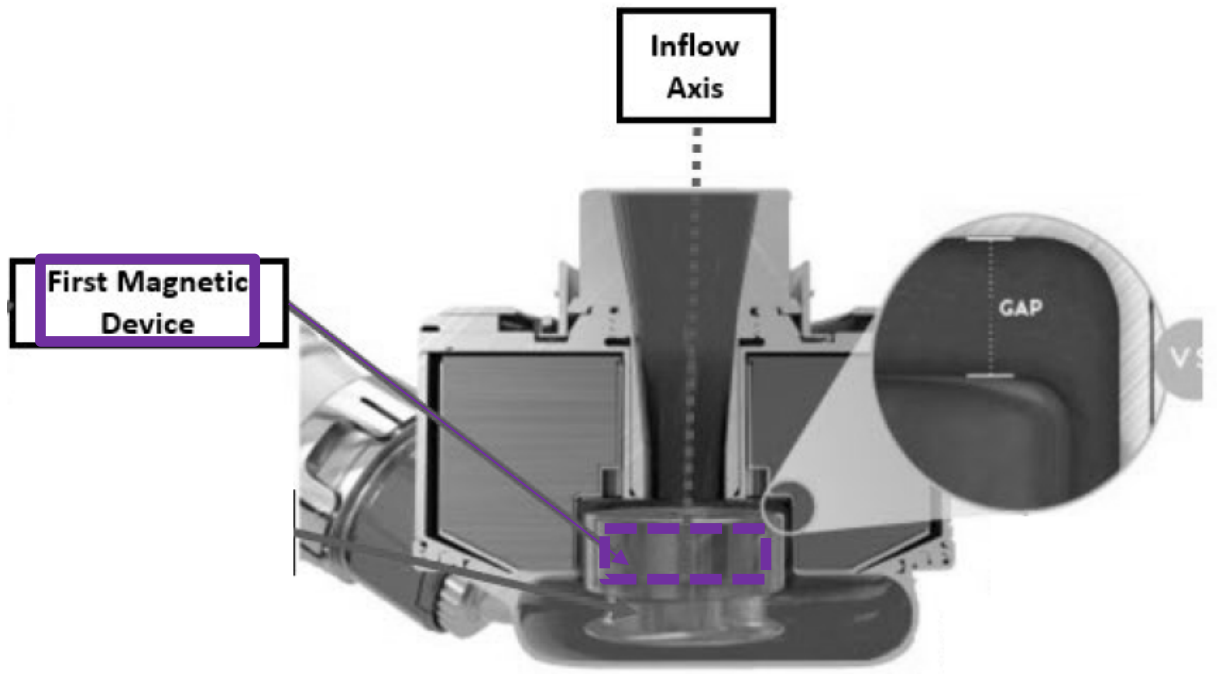
The dispute turns on whether “*axially adjacent*” includes components that “overlap or occupy the same portion of an axis.” POR, 14-15, 51. The Board, however, does not need to resolve this dispute if it finds the Challenged Claims unpatentable based on Ground 2 (Bourque) or Ground 4 (Schima), because PO does not contest that those grounds satisfy this claim term. For Ground 1 (Wampler) and Ground 3 (Akamatsu), if the Board reaches this dispute, Petitioner assumes PO’s position from the Parallel Proceeding for purposes of this proceeding that “*axially adjacent*” includes components that overlap or occupy the same portion of an axis. Ex.1042, ¶¶41-43.

In analyzing Wampler, Petitioner relied on PO’s position from its “Complaint filed in the Parallel Proceeding.” (Ex.1019). ID, 24. In particular, Petitioner assumed PO’s “interpretation” “that a magnetic element sealed within a rotor” is “*axially adjacent*.” ID, 24 (citing Pet. 26). The Board, however, “[f]ound] nothing in [PO’s Complaint] that defines” “*axially adjacent*” to mean a magnetic element “within a rotor.” ID, 24. The Board also found that, for other grounds,

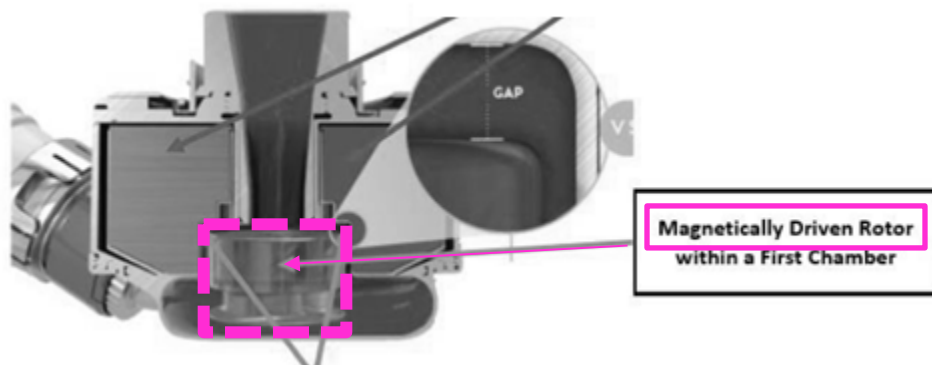
“Petitioner does not state that it is assuming Patent Owner’s alleged position.” ID, 24.

For purposes of this proceeding, Petitioner assumes PO’s position from its infringement contentions (Ex.1036) that “*axially adjacent*” includes components that overlap or occupy the same portion of an axis. PO contends that “a **permanent magnet in the Rotor**” of Petitioner’s HeartMate 3 product accused of infringement is a “*first magnetic device*”:

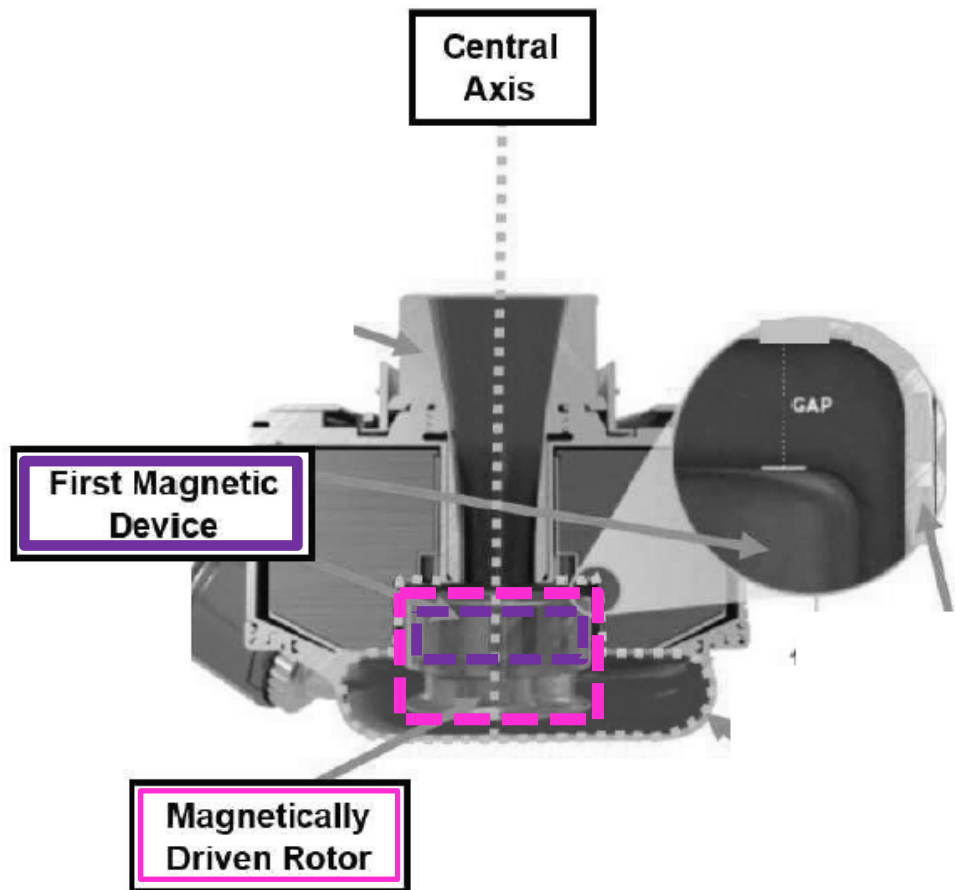
The Rotor is fully supported by magnetic levitation, obviating mechanical or fluid bearings and essentially eliminating Rotor mechanical wear as a reliability factor. Both drive (i.e. rotation) and levitation of the Rotor is accomplished using a single Stator comprising iron pole pieces, a back-iron, copper coils, and position sensors. By measuring the position of **a permanent magnet in the Rotor** and appropriately controlling the current in the drive and levitation coils, the radial position and rotational speed of the Rotor is actively controlled. Because of the permanent magnet’s attraction to the iron pole pieces, the rotor passively resists excursion in the axial direction, whether such excursion is translation or tilting.



Ex.1042, ¶¶41-43 (discussing Ex.1036, 5, 8-9). PO also contends that the “**Rotor**” is a “*magnetically driven rotor*”:



Ex.1042, ¶¶41-43 (discussing Ex.1036).<sup>1</sup> Shown below, HeartMate 3’s “**Rotor**” and its “**permanent magnet in the **Rotor****” accused of infringement “overlap or occupy the same portion of an axis:”

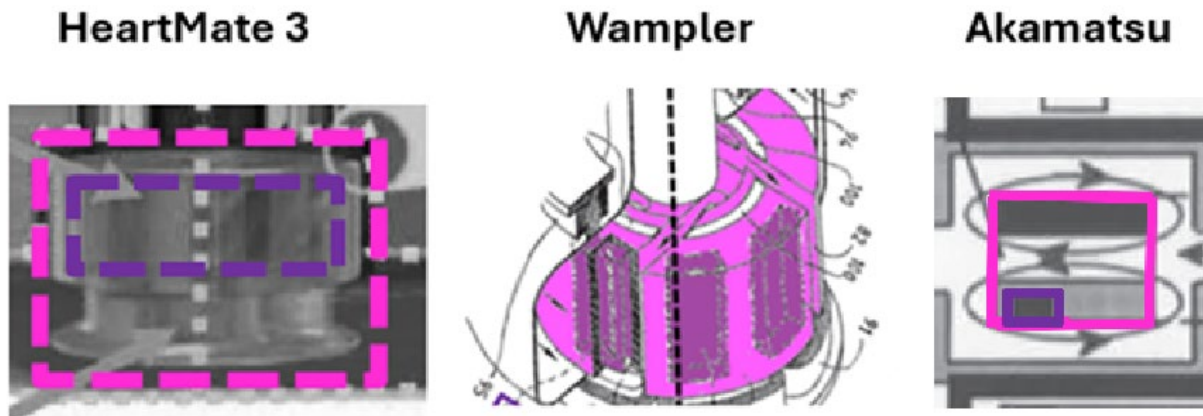


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<sup>1</sup> For all six IPRs, Petitioner cites PO’s ’879 patent infringement contentions, which includes both “*axially closer*” and “*axially adjacent*” terms. For different limitations, PO’s infringement contentions point to different portions of the **Rotor** as satisfying a “*magnetically driven rotor*.”

Ex.1042, ¶¶41-43 (discussing Ex.1036). Because PO’s infringement contentions allege that a “**permanent magnet in the **Rotor****” is “*axially adjacent*,” PO undoubtedly interprets “*axially adjacent*” as including components that “overlap or occupy the same portion of an axis.” POR, 14-15, 51.

The prior art (Wampler and Akamatsu) satisfies PO’s position from its infringement contentions. Indeed, the alignment of the accused device closely resembles the prior art: the accused HeartMate 3 has a “**permanent magnet in the **Rotor****” Ex.1042, ¶49; Wampler has “**magnet segments housed within the **impeller** blades**” (POR, 14-15); and Akamatsu has a “**permanent magnet embedded in the **impeller****” (POR, 51):



Ex.1042, ¶44. Thus, either *axially adjacent* includes parts that overlap (meaning Wampler and Akamatsu satisfy this limitation), or *axially adjacent* excludes such overlapping parts (meaning the accused product does not infringe). Leschinsky

conceded he had not considered, much less reconciled, this inconsistency. Ex.1040, 98:6-17; 106:19-107:3.

If the Board resolves this dispute, it should adopt PO's construction from its infringement contentions that "*axially adjacent*" includes components that "overlap or occupy the same portion of an axis." If the Board instead adopts PO's narrowed construction from its POR that "*axially adjacent*" is "distinct from components that ... overlap or occupy the same portion of an axis" (POR, 14-15, 51), such a construction would bar PO from contending that the accused HeartMate 3 infringes.

"[E]fforts to twist claims, 'like a nose of wax,' in 'one way to avoid [invalidity] and another to find infringement'" should be "rejected." *Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021). The Board should not allow PO to argue that a magnet "in" a rotor is "*axially adjacent*" (Ex.1042, ¶¶41-43), but that a magnet "embedded in" a rotor is not. POR, 14-15, 51. The Director has emphasized that "[t]he Board's claim construction rules are designed to ensure that the Board correctly construes claim terms and to minimize inconsistency in claim construction between forums." *Revvo Technologies, Inc. v. Cerebrum Sensor Technologies, Inc.*, IPR2025-00632, Paper 20, 4 (Squires Nov. 3, 2025) (precedential). "[PO]'s infringement contentions ... support[] Petitioner's assertion" that if the rotor components of the accused HeartMate 3 are *axially*

*adjacent*, then so too are the Wampler and Akamatsu rotor components. *Under Armour, Inc. v. Athalonz LLC*, IPR2024-00636, Paper 39 (PTAB, Sept. 11, 2025).

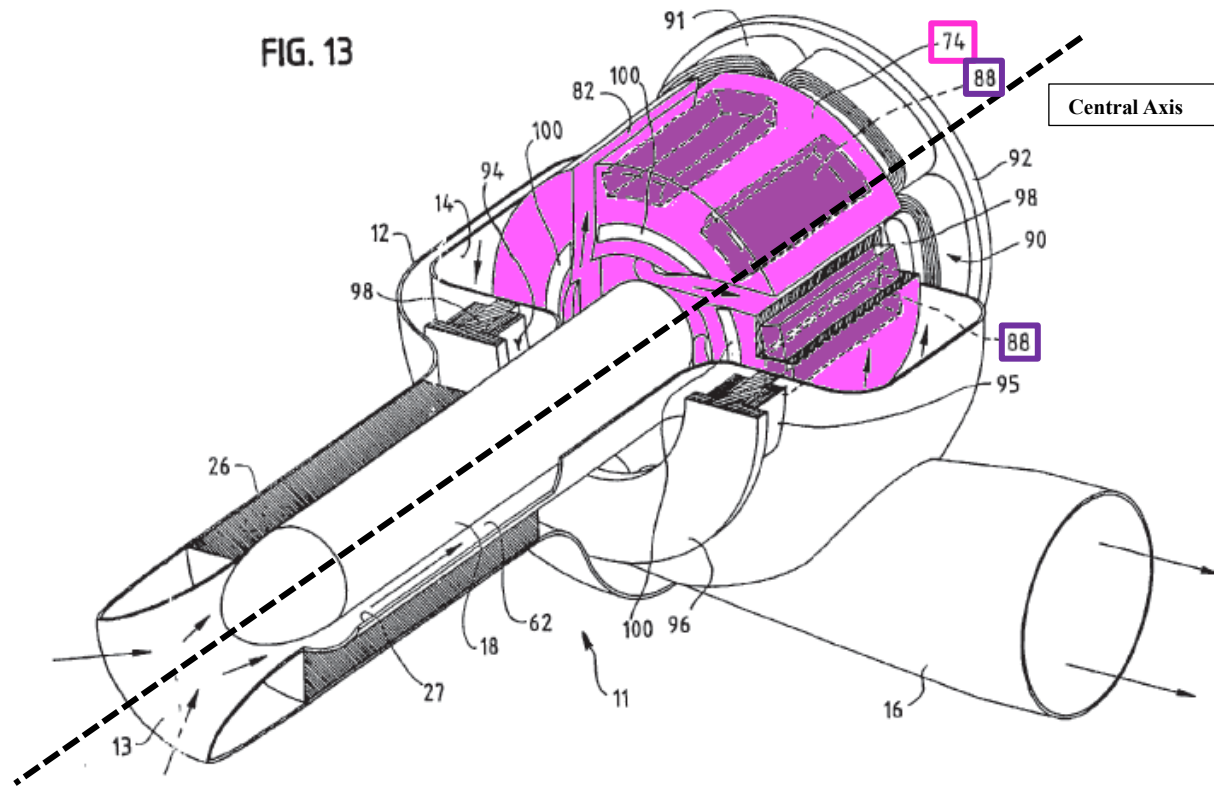
#### IV. THE CHALLENGED CLAIMS ARE UNPATENTABLE

##### A. Ground 1: Wampler

##### 1. [1H]:

Under PO's construction from the Parallel Proceeding (*supra* §III.B), Wampler teaches or suggests this limitation because PO concedes that its "magnet segments 88 and impeller 74 are aligned with, and overlap, one another as measured along the central axis." POR, 15.

Under PO's construction from the POR, Wampler also teaches or suggests this limitation. PO concedes that "*axially adjacent*" components "have positioning that is next to one another, perhaps touching or sharing a common side, when measured along the axis." POR, 14. Leschinsky admitted that Wampler's **magnet segments 88** ("*a first magnetic device*") and its **impeller** ("*a magnetically driven rotor*") are axially aligned (Ex.1040, 71:15-20 ("*parallel*")), touching (Ex.1040, 75:9-13 ("*in contact*")), and share common "sides" (Ex.1040, 75:14-19) when measured along an axis ("*axially adjacent*");



Ex.1042, ¶¶53-55 (discussing Ex.1008); Ex.1003, ¶197.

## 2. Petitioner relies on a single embodiment.

PO does not dispute that Wampler discloses all remaining limitations of the Challenged Claims. Instead, PO argues that “Petitioner impermissibly selects features from distinct embodiments in Wampler.” POR, 15-22. But that is incorrect—Petitioners rely only on the embodiment of FIGS. 11-14 (the “Second Embodiment”), which is an “alternative” blood pump to FIGS. 1-8 (the “First Embodiment”). Ex.1042, ¶¶56-60; Ex.1040, 111:5-18.

PO’s cited case is inapposite. In *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, IPR2017-01204, Paper 9 (PTAB Oct. 23, 2017), the petitioner combined

“different embodiments” and “treat[ed] various features” from fundamentally different pumps—a “reverse flow pump” and an “axial flow pump”—as “interchangeable with one another.” *Id.* at 9-11. But *Abiomed* is “distinguishable.” *Philip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00921, Paper 32 at 34, n.14 (PTAB June 30, 2022). Here, “combining multiple embodiments from a single reference is not what Petitioner is doing.” *Id.*

Like Wampler’s disclosure of an “alternative” blood pump with different bearings, Ex.1042, ¶¶56-60, the reference in *Philip Morris* disclosed a smoking device with “alternative” heating elements. *Id.* at 25-26. “No proof of motivation is required” when a reference “expressly teaches” that features of one embodiment are “identical to” features of another embodiment. *Id.* at 26-27, 34. Wampler makes it “readily apparent” that “it was not necessary to describe the features [of the Second Embodiment] that were previously described” for the First Embodiment. *Id.* at 28; Ex.1008, [0080]–[0082], [0102]; Ex.1003, ¶¶106, 154, 174; Ex.1042, ¶57; *see also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir. 2016) (motivation to combine not required where prior art “explicitly contemplates the combination of the disclosed functionalities.”).

Critically, PO does not dispute that Wampler’s First Embodiment is “implanted in a heart” and connected to a “controller.” Leschinsky, ¶122 (“the controller shown in Fig. 5 ... operating the first embodiment”); *see also id.*, ¶124.

PO's argument that Wampler's Second Embodiment does not disclose these same limitations is a misreading of Wampler. A POSA would have understood the Second Embodiment depicts an alternative blood pump configured as shown in FIG. 5. Ex.1042, ¶¶61-68.<sup>2</sup>

**i. [1B]**

PO concedes that Wampler's FIG. 5 shows the “anatomical placement of the pump” at “the apex of the left ventricle” (“*positioned outside the ventricle of the heart*”). POR, 17. But PO insists that Wampler “includes no disclosure” showing that the Second Embodiment can be “implanted in the same manner as the embodiment of FIG. 5,” or even whether it could be “implanted in a heart.” POR, 17.

Wampler, however, expressly teaches that the Second Embodiment can be implanted as shown in FIG. 5. Ex.1042, ¶57, ¶71. For example, Wampler explains that “the blood pump 11' [(the Second Embodiment)] is similar in many respects to blood pump 11 [(the First Embodiment)],” such as the “housing ..., casing, ...

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<sup>2</sup> “Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness.” *Bos. Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009).

discharge tube, ... and orientation ... for effectively channeling the blood.”

Ex.1008, [0080] (cleaned up). Additionally, Leschinsky conceded both embodiments comprise the same “inlet tube 13,” which is “the portion that goes into the ventricle.” Ex.1040, 132:8-133:8; Ex.1008, [0080]. Indeed, both embodiments use “the same names and reference numerals to identify features that are common.” *See Philip Morris*, IPR2020-00921, Paper 32 at 27. Moreover, by 2007, a POSA would have known that Wampler’s Second Embodiment had already been developed into the HVAD and clinically used in patients (as in FIG. 5).

Ex.1041, ¶¶51-61, ¶¶75-76; Ex.1042, ¶¶61-68.

PO also argues that “Petitioner selectively defines” Wampler’s “impeller 74” as the claimed “*magnetically driven rotor*,” and insists that it also “includes the [] shaft 18.” POR, 17–19. But Wampler describes that its “impeller” is the “*magnetically driven*” element, not its rotor or shaft. Ex.1008, [0018] (“Torque drive is imparted to the impeller by magnetic interaction”); Ex.1042, ¶¶74-77.

Leschinsky concedes that Wampler’s impeller—not the shaft—is responsible for pumping the blood (Ex.1040, 119:20-120:10) and that it is *positioned outside the ventricle of the heart*, Ex.1040, 114:19-115:17. PO’s argument that the rotor must include the shaft also contradicts its own patent specification, which contemplates that “a shaft” and “a rotor” are separate elements. Ex.1001, 4:50-53 (“a shaft 17 with a rotor 18”).

**ii. [1M]**

PO does not dispute that the Second Embodiment includes “hydrodynamic bearings [that] maintain the impeller entirely spaced apart from the casing 14,” which discloses this claim element. POR, 20-21. Instead, PO incorrectly argues that “Petitioner relies on the [First Embodiment],” which “includes thrust bearings” that “involve contact with the rotor,” and that Petitioner fails to explain why a POSA would “have substituted the various disclosed embodiments.” POR, 20–21. But as explained above, the bearings (hydrodynamic vs. thrust) are presented as alternatives. PO’s “First Embodiment” argument should be disregarded. *Supra* §IV.A.2.

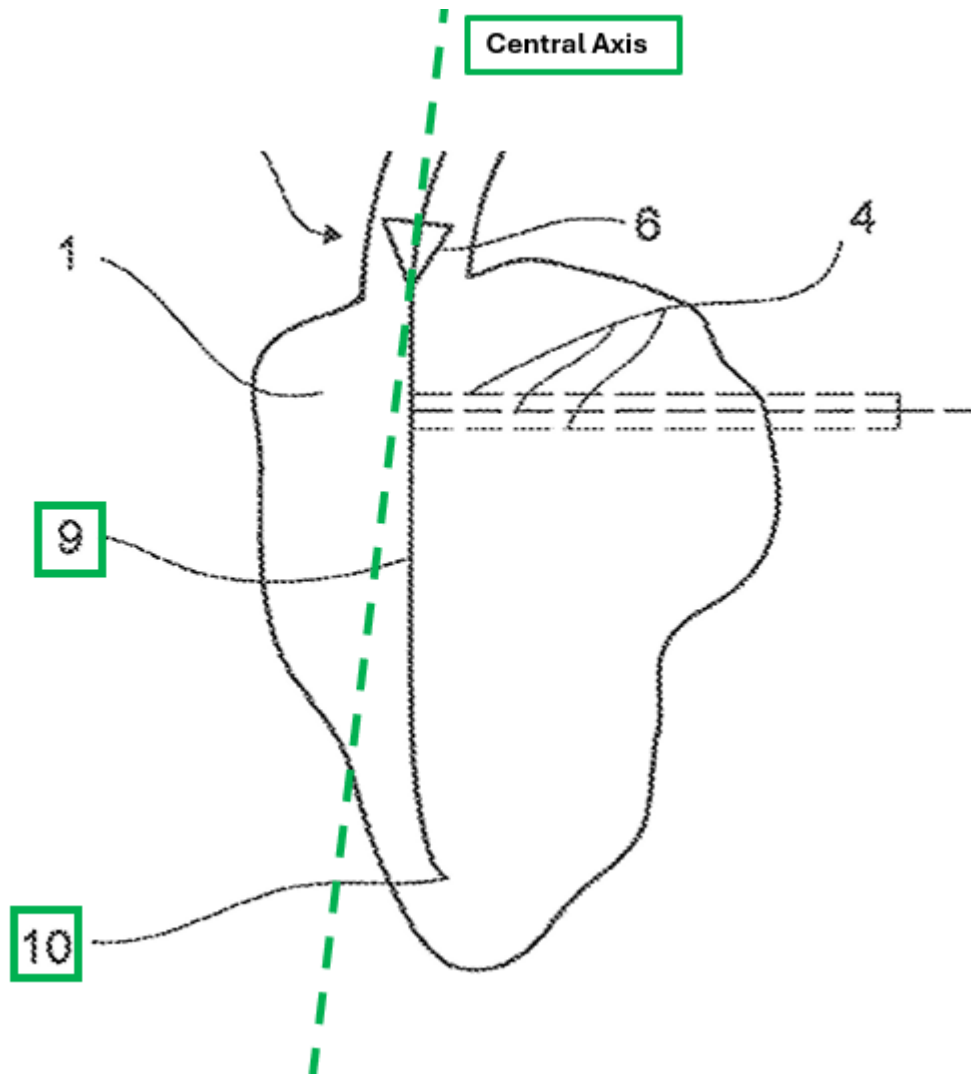
**iii. [1N] and [1O]**

Again, PO is wrong that there is “no disclosure in Wampler of the [Second Embodiment] coupled to the controller 59 of FIG. 5” and that Petitioner had to explain “why a POSA would have combined [] two embodiments disclosed in Wampler.” POR, 21-22. The Second Embodiment is configured in the same manner as FIG. 5, including its connection to controller 59. *Supra* §IV.A.2. Moreover, Leschinsky conceded “any pump of that type would have a . . . controller” (Ex.1040, 198:16-23), and Wampler describes a controller “worn externally.” Ex. 1008, [0070]; Ex.1042, ¶¶79-82.

**B. Ground 2: Bourque/Wampler**

**1. Bourque alone renders the Challenged Claims obvious.**

PO insists “*axially aligned*” requires “the entirety of the structure” of the “*inflow tube*,” including its “*suction end*,” be aligned in a straight, unbent line along the rotor’s axis. POR, 23-25. But the claim merely requires the “*rotor*” be “*axially aligned*” with the “*inflow tube*.” Ex.1001, 5:26–32. PO’s interpretation would exclude the specification’s “only disclosed embodiment,” which is “incorrect ... absent probative evidence on the contrary.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014); Leschinsky, ¶51 (“the ’356 patent discloses one embodiment”). Leschinsky agrees that the specification’s lone embodiment has an inflow “tube 9” and “suction end 10” that curve away from the “rotor [6]’s” axis:



Ex.1001, Fig. 1 (annotated); Ex.1042, ¶¶85-88 Ex.1040, 135:19-136:14 (“it’s a little curved”). “No [] evidence exists in this case” to require the entire inflow tube be “*axially aligned*,” which “would exclude the [Ex.1001] embodiment.” *GE Lighting*, 750 F.3d at 1311.

Logically, the elbow of the Bourque inflow tube is no different than the curve in the ’356 patent’s inflow tube—both inflow tubes are “*axially aligned*” with their respective rotors. Ex.1042, ¶¶89-90. PO also does not dispute that a rotor

axially aligned with an inflow tube is a characteristic feature of a centrifugal pump like Bourque—by design, fluid enters the pump along its axis towards the rotor. Ex.1003, ¶328; Ex.1041, ¶47; Ex.1008, [0076].

**2. A POSA was motivated to modify Bourque as taught by Wampler.**

A POSA would have been motivated “to eliminate [Bourque]’s elbow so that its inflow tube would also serve as the inflow cannula.” Pet., 82. PO responds “a POSA would not have made this combination,” because the Bourque pump is “too big” “to fit at the apex of the heart above the diaphragm.” POR, 26-27, 30-31. But PO applies “a legally incorrect framing of the motivation-to-combine question” because those “space constraints”—whether the pump is placed above or below the diaphragm—are “not part of the [] claims.” *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023).

Moreover, PO’s bodily incorporation argument has been considered improper countless times, including in the ID. ID, 36 (“Patent Owner’s bodily incorporation argument...is not convincing”). “The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *In re Keller*, 642

F.2d 413, 425 (C.C.P.A. 1981)); *see also Pulse Elecs., Inc. v. U.D. Elec. Corp.*, 860 F. App'x 735, 739 (Fed. Cir. 2021) (rejecting PO's "too large to fit" argument).

Compounding these errors, PO incorrectly argues that, "as of the priority date," "there were no clinical LVADs placed at the apex of the heart." POR, 31; 26 ("at the time ..., ***no*** LVAD fit well at that position."). As of 2006, one year before the priority date, a clinical trial had already begun implanting the HVAD—i.e., the Wampler Second Embodiment—at the apex of the heart above the diaphragm. Ex.1041, ¶¶53-61, ¶¶75-76; Ex.1045, 103:25-104:6; Ex.2014, 44:3-45:23. Other similar devices with axially aligned inflows—like Akamatsu and VentrAssist—had also begun clinical trials by 2006. Ex.1041, ¶¶62-68; Ex.1042, ¶¶94-100. Accordingly, the motivations and expectations of success to eliminate the Bourque elbow cannot be disputed.

**i. PO fails to rebut multiple, independent motivations to combine Bourque and Wampler.**

A POSA would have been motivated "to eliminate [Bourque]'s elbow so that its inflow tube would also serve as the inflow cannula" "**for several reasons**" (Pet., 82):

1. Wampler teaches that Bourque's "flow restrictive" "elbow was unnecessary." Pet., 83;
2. The combination would "eliminate" "peripheral hardware" that caused "clinical troubles." Pet., 83-84;

3. The references “are analogous” and the “combination would have been the arrangement of old elements.” Pet., 82-83; and
4. Instead of “in a preperitoneal pocket,” the combination could be implanted above the diaphragm at “the apex of the heart,” which would “reduce rates of infection.” Pet., 84-86.

PO concedes the first reason: the Bourque/Wampler combination allows for “redirection of the blood” “without the necessity” of the “flow-restrictive elbow fitting” used in Bourque. Pet., 55-56, 81-83; Ex.1008, [0076]; Leschinsky, ¶¶133–134. Leschinsky admits that the Bourque elbow is flow-restrictive, because the blood “does not flow straight down” into the pump, but instead “curves into the pump at angles” and “swirl[s] in the elbow.” POR, 25; Leschinsky, ¶¶133–134. The Wampler design, however, allows for “an axially aligned inlet tube.” Leschinsky, ¶167. This is reason enough to uphold the Bourque/Wampler combination. Ex.1041, ¶49.

PO fails to rebut the second reason—that the “peripheral hardware,” such as Bourque’s “inflow...components” and “recovery section,” “account for most of the...clinical trouble.” Pet., 83-84. Nor does PO dispute that Wampler taught how to eliminate these components that caused clinical troubles—by using the inlet to also “serve[] as the inflow cannula.” Pet., 83-84. PO argues that there were “strong statements” and “reasons ... for keeping” the peripheral hardware. POR, 28-29.

But a POSA “may be motivated to combine particular features of different references, *e.g.*, to secure some benefits at the expense of others, even when bodily incorporation would be impossible or inadvisable.” *Axonics*, 73 F.4th at 957.

The third reason is undisputed—Bourque and Wampler are “from the same field,” third-generation centrifugal LVADs that employ magneto coupling, and “solve the same problem” as the ’356 patent to assist the heart. *Axonics*, 73 F.4th at 955; Pet., 82-83; Ex.1003, ¶¶466-468; Ex.1040, 163:16-164:1.

PO’s argument focuses entirely on the fourth reason, and its assertions are incorrect. PO contests whether a POSA would be motivated to fit the Bourque/Wampler combination “at the apex of the heart above the diaphragm.” POR, 27. But those “space constraints” are “not part of the [] claims.” *Axonics*, 73 F.4th at 957 (“the Board committed a fundamental legal error in confining the motivation inquiry to ... [a specific anatomy] to which the [] patents are not limited.”).

Moreover, PO frames its arguments as a binary choice—that “the *best* placement of an LVAD is in a preperitoneal pocket—the exact opposite of the [apex position]” proposed in the Petition. POR, 29. But the law “does not require the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away.” *Par Pharm., Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1197-98 (Fed. Cir. 2014) (original emphasis). And “[t]here is no question, based on

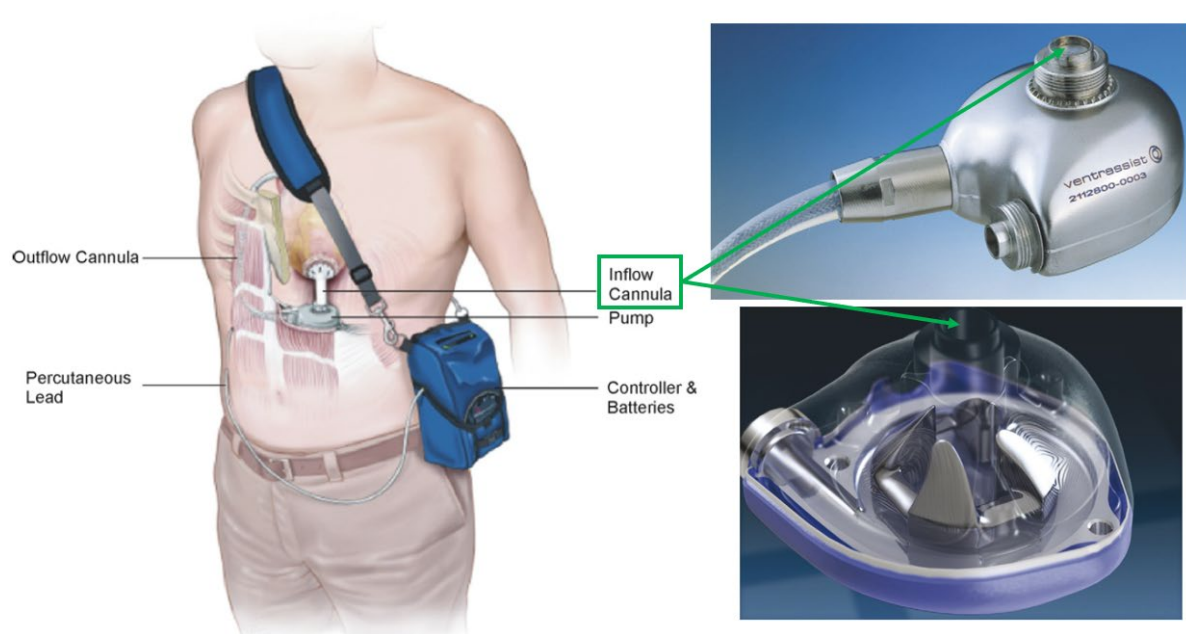
the disclosures in the prior art, that [placement either above or below the diaphragm] presented a suitable option.” *Id.* at 1198. As explained in the Petition and detailed below, “several similar LVADs [] fit well” at these two positions. ID, 35; Pet., 86–87; Ex.1003, ¶¶472–475. Indeed, PO ignores that the proposed combination does not require placement at the apex above the diaphragm—the combination “allows a considerable amount of flexibility during implantation.” Pet., 81 (quoting Ex.1008, [0076]). And because the “patent sets forth no human clinical or laboratory data showing” that its pump may be placed at the apex, it would be “clearly err[oneous] [to] find[] any difference between the claimed invention and the [prior art] on this point.” *Merck & Co. v. Teva Pharm.*, 395 F.3d 1364, 1374 (Fed. Cir. 2005) (reversing judgment of nonobviousness); *see also Alcon Research, Ltd. V. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (rejecting “argu[ment] that [the prior art] would not give a skilled artisan an expectation” of clinical safety, because “neither does the [] patent.”).

**ii. A POSA would have reasonably expected the Bourque/Wampler combination could fit either below or above the diaphragm.**

PO also argues that “a POSA would have expected” that “a pump of [Bourque]’s size at the priority date” would have been “placed in a preperitoneal pocket below the diaphragm,” similar to the placement of the “VentrAssist, that was implanted in humans between 2003 and 2009.” POR, 32-33. But that argument

supports Petitioner, because the VentrAssist closely resembles the

Bourque/Wampler combination:



Ex.2013, Figs 1-3 (annotated). Like the Bourque/Wampler combination, which “eliminate[s] [Bourque]’s elbow so that its inflow tube would also serve as the inflow cannula” (Pet. 82), the VentrAssist’s *axially aligned* “inflow cannula” (left, shown in white) is inserted into “the ventricular apex” of the heart, and connects to the pump without any elbow (right). Ex.1042, ¶¶94-97. By 2007, “87 patients ha[d] been implanted with the VentrAssist.” Ex.2013, abstract.

Similarly, by 2006, the Akamatsu pump (the DuraHeart), had been implanted in 20 patients. Ex.1042, ¶¶99-100; Ex.1046, 4. PO does not dispute that Akamatsu has an “*axially aligned*” inflow tube. And PO concedes that the Akamatsu pump was also “approximately the size of the pump disclosed in Bourque-2001.” POR,

49. Given that clinical trials had already begun for the VentrAssist and Akamatsu devices and that both devices had *axially aligned* inflow tubes, a POSA would have expected the Bourque/Wampler combination could similarly fit below the diaphragm. Ex.1041, ¶¶74-79; Ex.1042, ¶93.

A POSA would have also expected the Bourque/Wampler combination could fit above the diaphragm at the apex of the heart in light of the HVAD and the Akamatsu sheep studies. Ex.1041, ¶¶75-77; Ex.1042, ¶¶101-106. PO insists “that the Bourque-2001 pump is too big to fit” at the apex of the heart (POR, 30), and that implantation at the apex (as shown in FIG. 5 of Akamatsu) was “aspirational,” because it was not until “5 years after the priority date ... that an LVAD was made small enough to fit there.” POR, 26, 32-33. But PO and its experts are incorrect.

By 2006, HeartWare had developed Wampler’s Second Embodiment into the HVAD and begun a clinical trial implanting the device in patients above the diaphragm at the apex of the heart:



Ex.1044, 1 (“implantable in the pericardial space”); Ex.1041, ¶¶57-61, ¶¶75-76; Ex.1042, ¶¶102-104.

Petitioner explained the “HVAD” was already in “existence.” Pet., 87–88 (citing Ex.1015, HVAD). The HVAD’s “small size”—due to its “short integrated inflow cannula and an axial height less than one inch ... coupled with the perpendicular relationship of outflow to the inflow”—allowed for an “optimized fit” “between the apex of the heart and the adjacent diaphragm.” Ex.1003 ¶52 (discussing Ex.1015); ¶¶473-476 (analyzing the HVAD). By 2006, HeartWare commenced a “CE mark clinical study” for “twenty patients” and anticipated sales for the device to begin in 2007. Ex.1044, 1-2; Ex.2003, 5 (“the HeartWare pump is smaller and can fit inside the pericardial space”); Ex.2020, 3 (the HVAD “showed excellent survival”).

Because PO's experts incorrectly believed the HVAD to be "impossible," the Board "must disregard the testimony" since it "is plainly inconsistent with the record." *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378 (Fed. Cir. 2017). Leschinsky thought the HVAD was not implanted "in a human" until "5 years after the priority date." Leschinsky, ¶150, ¶96 ("the HeartWare HVAD [] was clinically implanted ... years after ... the priority date of the '356 patent."). Thus, in his view, implantation at "the apex of the heart ... would have been practically impossible." Leschinsky, ¶163. Dr. Gallegos's opinions are similarly flawed, and premised on his incorrect belief that, "as of the priority date [*he*] was not aware of any LVADs that were positioned at the apex of the heart" and that "[i]mplanting these devices at the apex of the heart ... was impossible." Gallegos, ¶51. But whether PO's experts knew of the HVAD "is irrelevant to the inquiry," because a POSA "is presumed to be aware of all the pertinent prior art." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). PO cannot dispute that the HVAD was pertinent art in "existence" that "fit well ... at the apex of the heart." Pet., 87.

In addition to the HVAD, which was small enough to fit into "pediatric patients" (Ex.2020, 7), the Akamatsu sheep studies would have provided assurance that larger pumps would fit at the apex too. "Intrathoracic implantation" of the Akamatsu pump above the diaphragm "demonstrated excellent anatomical fit in a

small [sheep] weighing 45 kg.” Ex.1006, 4. Dr. Gallegos described sheep studies as the “gold standard” for some cardiac preclinical studies because the “cardiovascular physiological parameters of sheep approximate those of humans” and “the anatomy of the adult ... is similar to humans.” Ex.1039, 7, 13 (discussing VAD “flow pumps ... implanted into [] sheep”). Given that the Akamatsu pump was “approximately the size of the pump disclosed in Bourque-2001” (POR, 49), a POSA would expect a similar “anatomical fit” for the Bourque/Wampler combination, at least for many adults. Ex.1041, ¶¶73-79; Ex.1042, ¶105.

PO also ignores that several other LVADs had been implanted at the apex of the heart by 2006 (Ex.1041, ¶¶75-76, 79; Ex.1042, ¶106); the Bourque/Wampler combination aimed to provide a compact device” that would enable it to “fit[] well between the apex of the heart and the adjacent diaphragm” (Pet., 87); the Bourque pump from 2001 could have been made smaller by 2007 due to advances in electronics (Ex.1042, ¶¶107-108); and a “miniaturized electrical motor” for magneto coupling was already disclosed in the art. Ex.1040, 64:5-9.

Finally, a POSA would have understood that Bourque’s placement at the preperitoneal pocket position was a relic—the Bourque pump “borrow[ed]” the “peripheral hardware” from older “HeartMate systems” which were placed there. Ex.1007, 5. But by “2006,”—before the priority date—Mr. Bourque had already opted to “take away this whole business about creating a [preperitoneal] pocket for

the pump” and instead “just put [the inflow cannula] in the [apex of the] heart.” POR, 36 (citing Ex.2007) (cleaned up). Bourque’s 2006 redesign for placement at the apex, which closely resembles the Bourque/Wampler combination, supports that a POSA in 2007 would have reasonably expected the proposed combination could work. Ex.1041, ¶¶80-83; Ex.1042, ¶108; ID, 37 (“relying on a later patent to show that it included ‘inventive activity’ ... is not an admission”).

### 3. [Claim 5]

Bourque discloses that “[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III.” Ex.1007, 3. These parameters are “*measurement values indicative of cardiac output,*” because the speed of the pump is a direct proxy indicative of cardiac output because it corresponds to blood outflow. Ex.1003, ¶¶429-430. Indeed, Bourque discloses that these parameters can be “adjusted to maintain volume flow rates.” Ex.1007, 3.

### 4. [Claim 7]

Bourque discloses multiple “*feedback signals ... from one or more sensors*” being provided to an “*external controller.*” These feedback signals include “flow measurements,” “pressure measurements,” and the monitoring of “[s]peed and motor parameters,” all of which would have been provided to Bourque’s “electronics for power and control.” Ex. 1003, ¶439-441.

**C. Ground 3: Akamatsu**

**1. [1A]**

PO argues that Akamatsu does not teach or suggest that “*a suction end of an inflow tube ... is inserted into a ventricle of the heart.*” POR, 45. But the Akamatsu device is a “left ventricular assist system, and by 2006, it had already been implanted in 20 patients. Ex.1046, 4. A POSA would have understood the suction end was “inserted into the left ventricle through a cuff sutured to the left ventricular apex,” just as it has been done during the ex vivo study performed on sheep. Ex.1003, ¶484. In those studies, the “intrathoracic implantation” of the Akamatsu pump above the diaphragm “demonstrated excellent anatomical fit in a small [sheep] weighing 45 kg.” Ex.1006, 4.

PO insists that “Akamatsu’s FIG. 1,” showing the device delivered to a ventricle of the heart, is merely a “conceptual and aspirational drawing.” POR, 46. Further, PO argues that “[a] POSA would have viewed the size of the pump disclosed in Akamatsu as prohibitive for implantation at the apex of the heart.” POR, 49. But Leschinsky admitted that “the inlet tube [] placed in the apex ... doesn’t mean that the pump is there.” Ex.1040, 139:16-140:5. So the Akamatsu device could be below the diaphragm, which would address PO’s concerns, but nevertheless have *a suction end ... inserted into a ventricle of the heart*, much like the VentrAssist. Ex.1042, ¶¶94-96.

## 2. [1H]:

Under PO's construction from the Parallel Proceeding (*supra* §III.B), Akamatsu teaches or suggests this limitation because PO concedes that its “permanent magnets and impeller are aligned with, and overlap, one another as measured along the central axis.” POR, 52.

Under PO's construction from the POR, Akamatsu also teaches or suggests this limitation. PO concedes that “*axially adjacent*” components “have positioning that is next to one another, perhaps touching or sharing a common side, when measured along the axis.” POR, 14. Leschinsky admitted (Ex.1040, 77:18-78:17) that Akamatsu's “**permanent magnet**” and its “**impeller**” are axially aligned, touching, and share common sides when measured along an axis (“*axially adjacent*”):

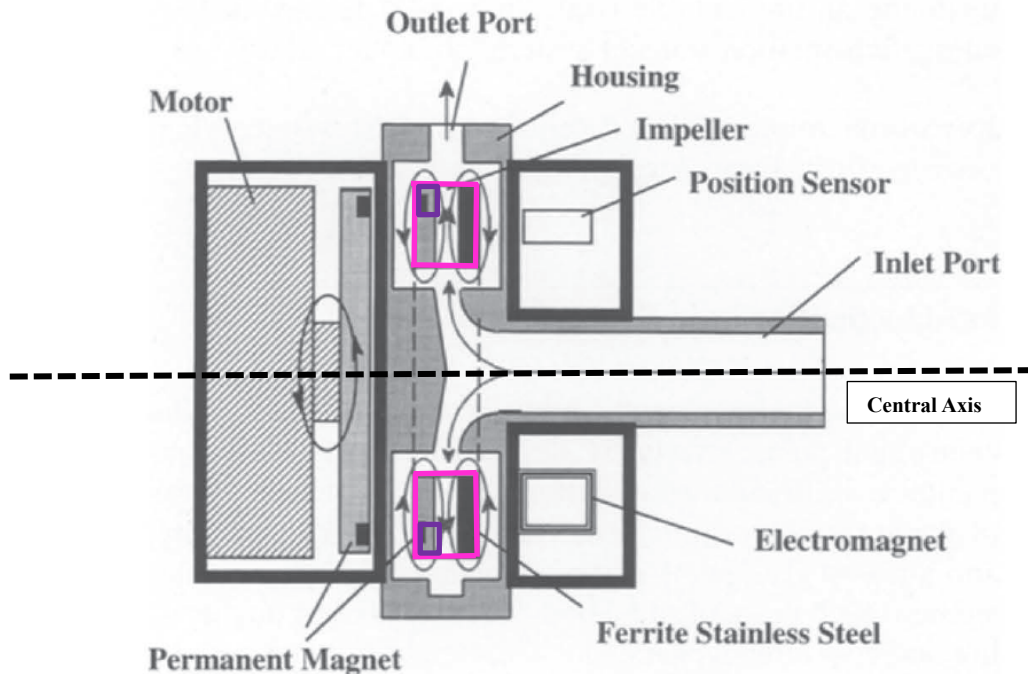


**Fig. 2.** Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1042, ¶39.

### 3. [1N]

PO disputes that Akamatsu “teaches or suggests a controller (worn externally in Figure 1).” POR, 52. But Leschinsky conceded that “the concept of having controllers be either internal or external was known in the art prior to 2007.” Ex.1040, 130:9-12. And the fact “[t]he pump was percutaneously driven,” demonstrates to a POSA that the that the controller was external. Ex.1003, ¶568.

### 4. [1O]

Akamatsu teaches or suggests this claim element for the same reasons as discussed above regarding [1A] and [1N].

**D. Ground 4: Schima/Akamatsu**

**1. [1A]**

PO insists that because “Schima is silent regarding placement of its disclosed pump,” it must be an “extracorporeal” pump and therefore “cannot [] teach or suggest claim element [1A].” POR, 56-58. But Leschinsky admitted that “Schima discloses various uses, including that ... it may be used as an LVAD.” Ex.1040, 207:2-9. Indeed, Schima “suggests” that its pump is an implantable LVAD (Pet., 116), because the specification repeatedly focuses on “overcoming” issues with prior art implantable LVADs. Ex.1003, ¶¶635-641 (discussing Schima, [0004]-[0008]).

PO argues that the shape of the Schima pump suggests it is an extracorporeal device. POR, 57-58. But PO ignores that Schima’s pump, including its “fittings” and its shape, closely resemble the VentrAssist, which was clinically implanted in patients before the priority date. Ex.1042, ¶98.

Even if Schima’s pump is “extracorporeal,” PO’s argument that it cannot be combined “with the implantable device of Akamatsu” amounts to a “a legally insufficient bodily incorporation argument.” *iRobot Corp. v. SharkNinja Operating LLC*, No. 2023-1398, 2024 WL 3687981, at \*5 (Fed. Cir. Aug. 7, 2024) (rejecting patentee’s argument that “the devices [had] significant differences in size, weight, configuration, and operation”). That argument also contradicts PO’s own experts’

testimony—Leschinsky opined that prior art pumps could operate either as “an extracorporeal device or it could [be] an implantable device.” Ex.1040, 36:3-6; 21:14-22:10.

## **2. [1N]-[10]**

PO argues that the proposed Schima/Akamatsu combination does not teach or suggest “connecting an external control unit to [the] pump.” POR, 61. But Leschinsky conceded that “any pump” would use a controller, and that a controller would be “internal or external.” Ex.1040, 130:9-12; 198:16-23. Moreover, Akamatsu teaches the use of an external controller. *Supra* §IV.C.3-4. And an “inflow tube [positioned] in the heart” would have been obvious as discussed. *Supra* §IV.D.1.

## **3. [Claim 5] and [Claim 7]**

PO does not dispute that Akamatsu teaches these claims. POR, 45-56. The speed of the pump is a direct proxy “*indicative of cardiac output*” because it corresponds to blood outflow. Ex.1003, ¶¶429-430, 750-752. And the Akamatsu pump “*provid[es] feedback signals*” indicative of pump speed to the controller to “operate[]” “the pump ... at a fixed rotational speed.” Ex.1003, ¶¶750-752, 760-763. (quoting Ex.1006, 4); *see also supra*, §IV.C.4.

## **V. CONCLUSION**

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

Dated: December 22, 2025

Respectfully Submitted,

/Scott M. Border/

Scott M. Border

Reg. No. 77,744

Winston & Strawn LLC

1901 L Street, N.W.

Washington, D.C. 20036

T: 202-282-5054

[sborder@winston.com](mailto:sborder@winston.com)

## **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 5,455 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: December 22, 2025

Respectfully Submitted,

/Scott M. Border/  
Scott M. Border  
Reg. No. 77,744  
Winston & Strawn LLC  
1901 L Street, N.W.  
Washington, D.C. 20036  
T: 202-282-5054  
[sborder@winston.com](mailto:sborder@winston.com)

## **CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on December 22, 2025,  
I caused to be served a true and correct copy of the foregoing and any  
accompanying exhibits be served via e-mail on the following counsel of record for  
Patent Owner:

Joshua P. Larsen  
**BARNES & THORNBURG LLP**  
E-mail: [joshua.larsen@btlaw.com](mailto:joshua.larsen@btlaw.com)

Ronald E. Cahill  
**BARNES & THORNBURG LLP**  
E-mail: [ronald.cahill@btlaw.com](mailto:ronald.cahill@btlaw.com)

Mark A. Hagedorn  
**BARNES & THORNBURG LLP**  
E-mail: [mark.hagedorn@btlaw.com](mailto:mark.hagedorn@btlaw.com)

Todd G. Vare  
**BARNES & THORNBURG LLP**  
[Todd.Vare@btlaw.com](mailto:Todd.Vare@btlaw.com)

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