

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

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

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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<i>Standard Oil Co. v. Am. Cyanamid Co.,</i> 774 F.2d 448 (Fed. Cir. 1985)	30

EXHIBIT LIST

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

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

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

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

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

	driven rotor assembly via a magneto coupling with the first magnetic device
[1H]	while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly,
[1I]	the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor;
[1K]	a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly
[1L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and
[1M]	an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,
[2]	The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.
[3]	The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.
[4]	The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.
[5]	The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive

	source configured to regulate the operation of the second magnetic device.
[7]	The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[10]	The system of claim 1, wherein the heart assist pump device is a catheter device.
[16PRE]	A system for assisting blood circulation of a heart, the system comprising:
[16A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[16B]	chamber walls at least partially defining a chamber to receive blood from the inflow tube;
[16C]	a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device
[16D]	that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor
[16E]	[the rotor] having guide surfaces to produce centrifugal flow components,
[16F]	the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation
[16G]	[the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;
[16H]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[16I]	and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,

[16J]	the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and
[16K]	a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,
[16L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and
[16M]	an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output
[16N]	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.
[17]	The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.
[18]	The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.
[19]	The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.
[20]	The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.

[21]	The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.
[22]	The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[23]	The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.
[24]	The system of claim 16, wherein the first magnetic device comprises a permanent magnet.
[26]	The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[28]	The system of claim 16, wherein the heart assist pump device is a catheter device.

I. INTRODUCTION

Patent Owner provided no basis to reconsider the Board’s institution analysis. The Challenged Claims 1-5, 7, 10, 16-24, 26, and 28 are unpatentable.

II. PERSON OF ORDINARY SKILL IN THE ART

The Institution Decision (“ID”) found Petitioner’s definition of a POSA “consistent with the ’077 patent and the asserted prior art.” ID, 10. PO contends it 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 experience that PO’s definition requires, and his opinions remain the same under either definition. Ex.1042, ¶¶11-19. Petitioner’s experts have both developed a third-generation LVAD—PO’s experts have not. Ex.1041, ¶11; Ex.1042, ¶11. 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. He also served as “head of [a] Biomedical Engineering Department” responsible for supporting “an Intra-Aortic Balloon Pump (IABP)” (Ex.1003, ¶15), which is an implantable cardiac assist device

(Ex.2015, ¶33). Crosby also has “45 years of experience in the medical device industry.” Ex.1003, ¶¶8-15.

PO impugns Crosby’s 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 opined in a similar case involving the named inventor that only 2 years’ experience was required. Ex.1042, ¶18.

III. Claim Construction

A. “*Magneto Coupling*” and “*By a Gap Sized For Passage Of The Blood*”

The Board need not construe these two terms and can instead “apply [PO’s] broader construction[s]” because they “encompass[]” Petitioner’s constructions. ID, 10-12. If construed, Petitioner maintains that 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*” and “*axially closer*”

The Board need not resolve these disputed terms 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 these claim terms. If the Board reaches Ground 1 (Wampler) and Ground 3 (Akamatsu), for purposes of this proceeding, Petitioner assumes PO’s positions from the Parallel Proceeding infringement contentions (Ex.1036) for both terms.

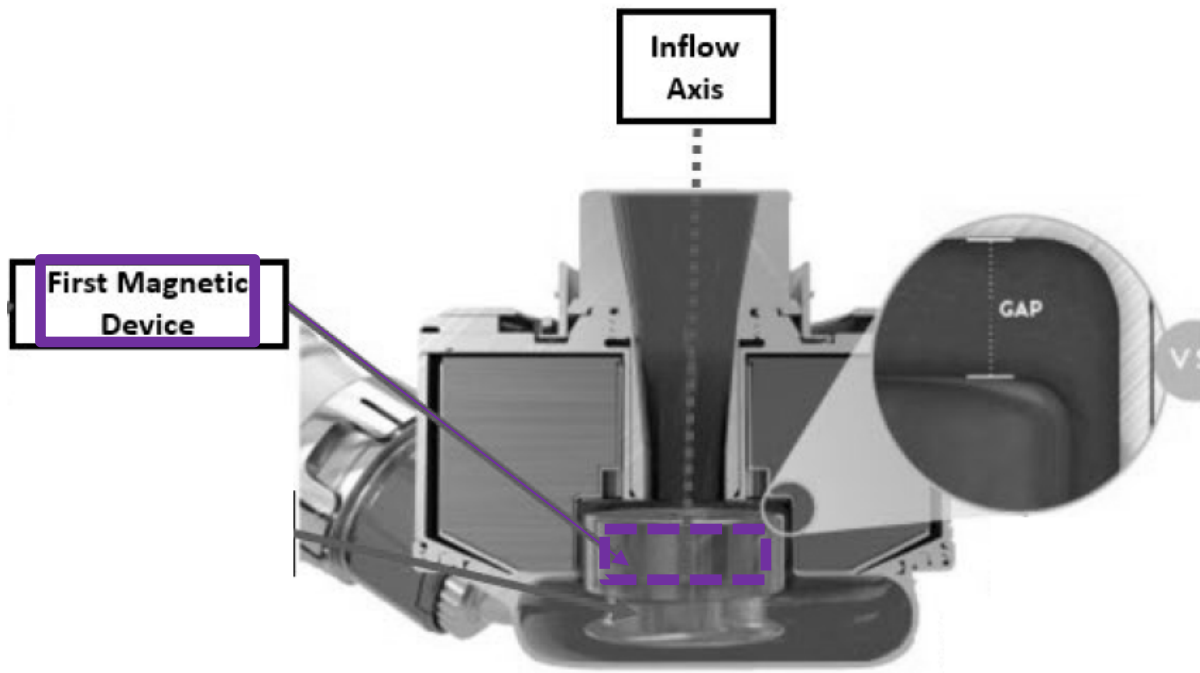
1. “*Axially adjacent*”

The dispute turns on whether the meaning of “*axially adjacent*” includes components that “overlap or occupy the same portion of an axis.” POR, 14-15, 51. Petitioner’s analysis of Wampler relied on PO’s position from its Complaint (“chart mapping”) filed in the Parallel Proceeding (Ex.1019). ID, 11-12. Petitioner assumed PO’s “interpretation” “that a magnetic element sealed **within** a rotor” is “*axially adjacent*.” ID, 11 (citing Pet. 20). The Board, however, “f[ound] nothing in [PO’s Complaint]” that defines “*axially adjacent*” to mean a magnetic element “**within** a rotor.” ID, 12.

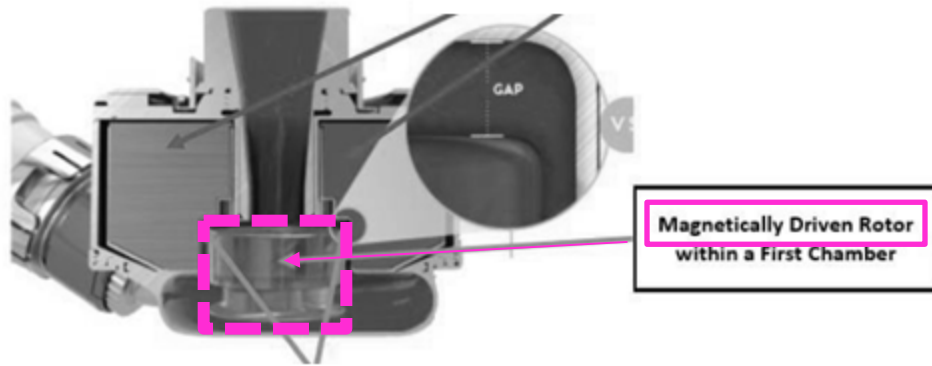
For purposes of this proceeding, Petitioner assumes PO’s infringement contentions position (Ex.1036), which show that “*axially adjacent*” includes

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.

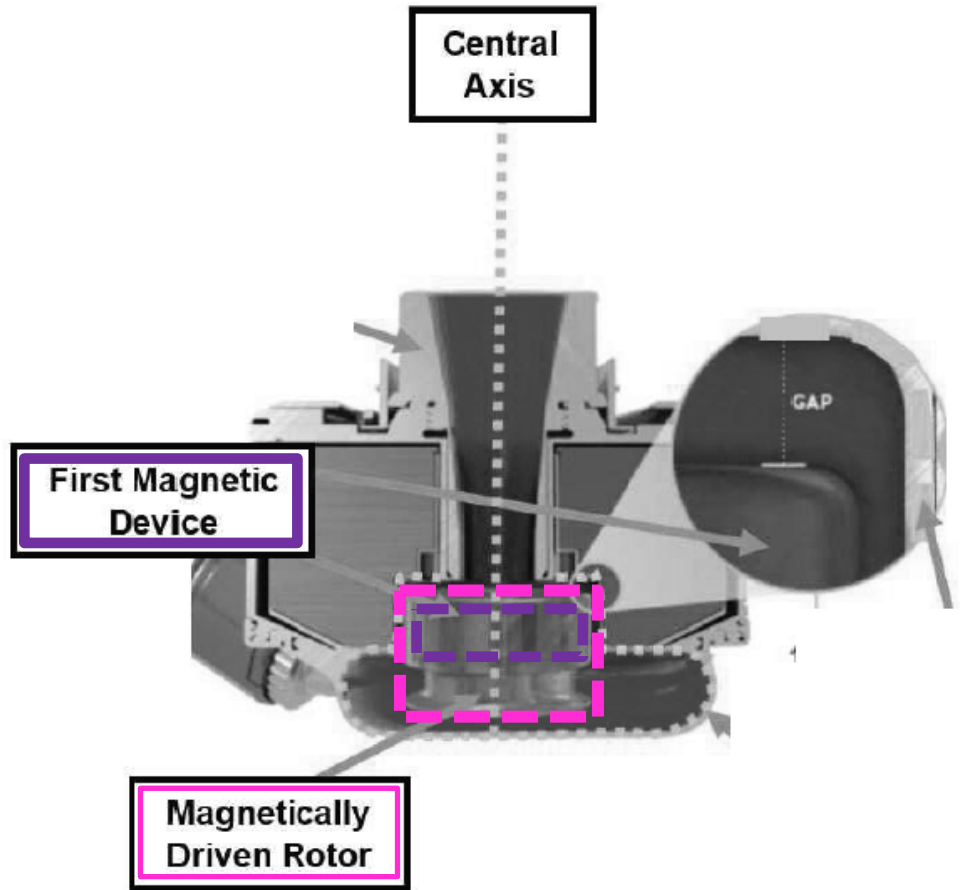


Ex.1042, ¶¶41-43 (discussing Ex.1036, 5, 8-9). PO also contends that the “**Rotor**” of Petitioner’s HeartMate 3 is a “*magnetically driven rotor*”:



Ex.1042, ¶¶41-43 (discussing Ex.1036).¹ As shown below, HeartMate 3’s “**Rotor**” and its “**permanent magnet in the **Rotor****” accused of infringement “are aligned with one another such that they overlap or occupy the same portion of an axis upon which they are positioned:”

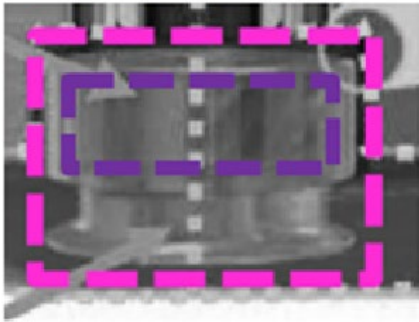
¹ For all six IPRs, Petitioner cites PO’s ’879 patent infringement contentions, which includes both “*axially closer*” and “*axially adjacent*” terms. For different limitations, PO’s infringement contentions point to different portions of the **Rotor** as satisfying a “*magnetically driven rotor.*”



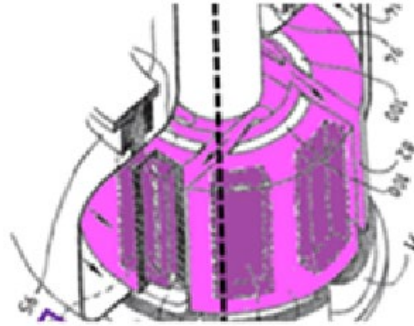
Ex.1042, ¶¶41-43 (discussing Ex.1036). Because PO’s infringement contentions allege that a “**permanent magnet in the Rotor**” is “*axially adjacent*,” PO undoubtedly interprets “*axially adjacent*” as including components that “overlap or occupy the same portion of an axis.” POR, 14-15, 52.

Wampler and Akamatsu satisfy PO’s infringement construction—the alignment of the accused device closely resembles the prior art: the accused HeartMate 3 has a “**permanent magnet in the Rotor**” Ex.1042, ¶¶44-45; Wampler has **magnet segments** “embedded within” the **impeller** blades (POR, 16); and Akamatsu has a “**permanent magnet embedded in the impeller**” (POR, 51):

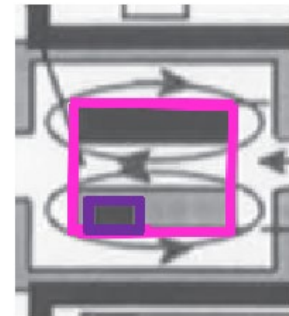
HeartMate 3



Wampler



Akamatsu



Ex.1042, ¶¶44-45. Thus, either *axially adjacent* includes parts that overlap or occupy the same portion of an axis (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 apparent 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, 52), 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*

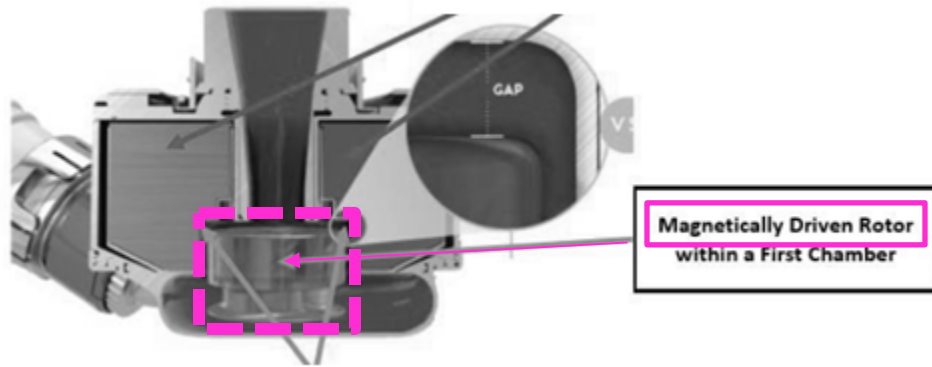
Techs. LLC v. Google LLC, 10 F.4th 1375, 1381 (Fed. Cir. 2021). The Board should not allow PO to argue that a magnet “in” a rotor is “*axially adjacent*” (Ex.1042, ¶49), but that a magnet “embedded in” a rotor is not. POR, 16, 51; *see also Revvo Technologies, Inc. v. Cerebrum Sensor Technologies, Inc.*, 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 Wampler and Akamatsu.

2. “*Axially closer*”

In a related IPR with an identical claim limitation, the Board invited “further development of the positions of the Parties” to resolve “whether only **a portion of** the second magnetic device need be ‘positioned *axially closer* to the first magnetic device than to the magnetically driven rotor’ to satisfy claim 1.” IPR2025-00112 (’357 IPR), Paper No. 13, at 25.

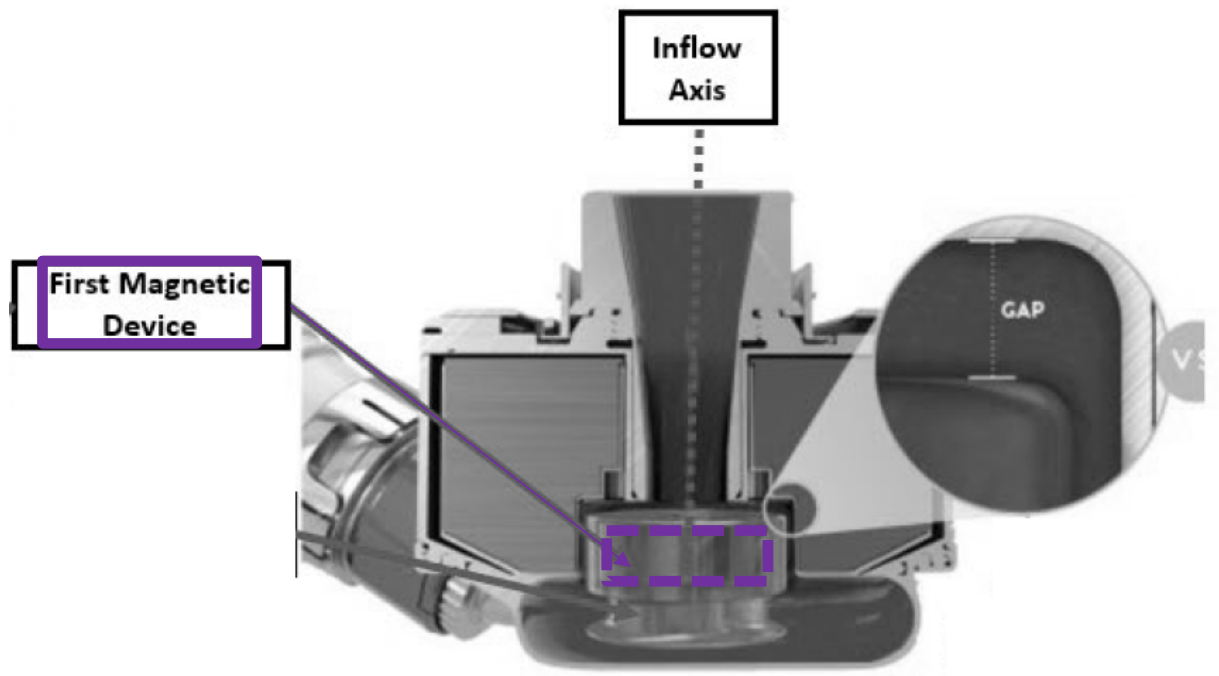
In the Parallel Proceeding, PO contends limitation [16J] is satisfied even if “*the second magnetic device [is] positioned axially closer to the first magnetic device than to [only **a portion of**] the magnetically driven rotor.*” Ex.1042, ¶¶58-61 (discussing Ex.1036). PO concedes “that it is possible to rely on a distance defined by only a portion of a component.” IPR2025-00112 (’357 IPR), Paper No. 20 at 9.

Particularly, PO measures the relevant distance from only a portion of *the magnetically driven rotor*. PO contends that the “**Rotor**” of Petitioner’s HeartMate 3 is a “*magnetically driven rotor*”:

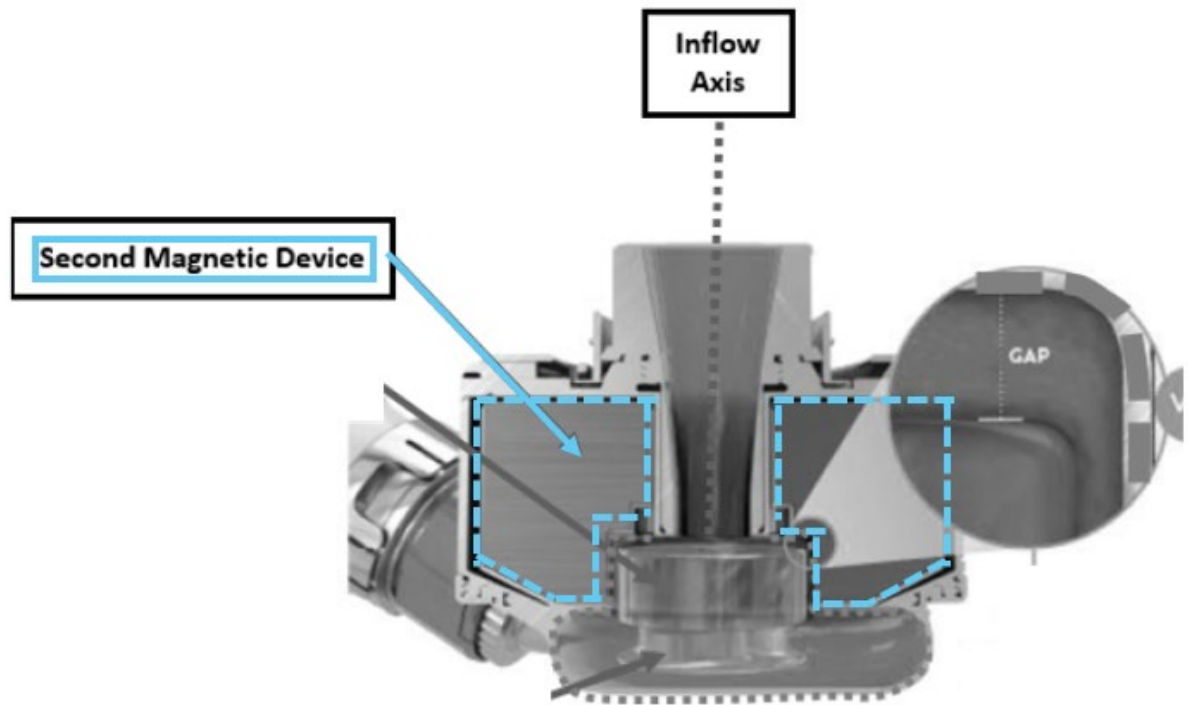


Ex.1042, ¶¶58-61, (discussing Ex.1036). PO alleges that “a **permanent magnet** in the **Rotor**,” of HeartMate 3 is a “*first magnetic device*”:

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.

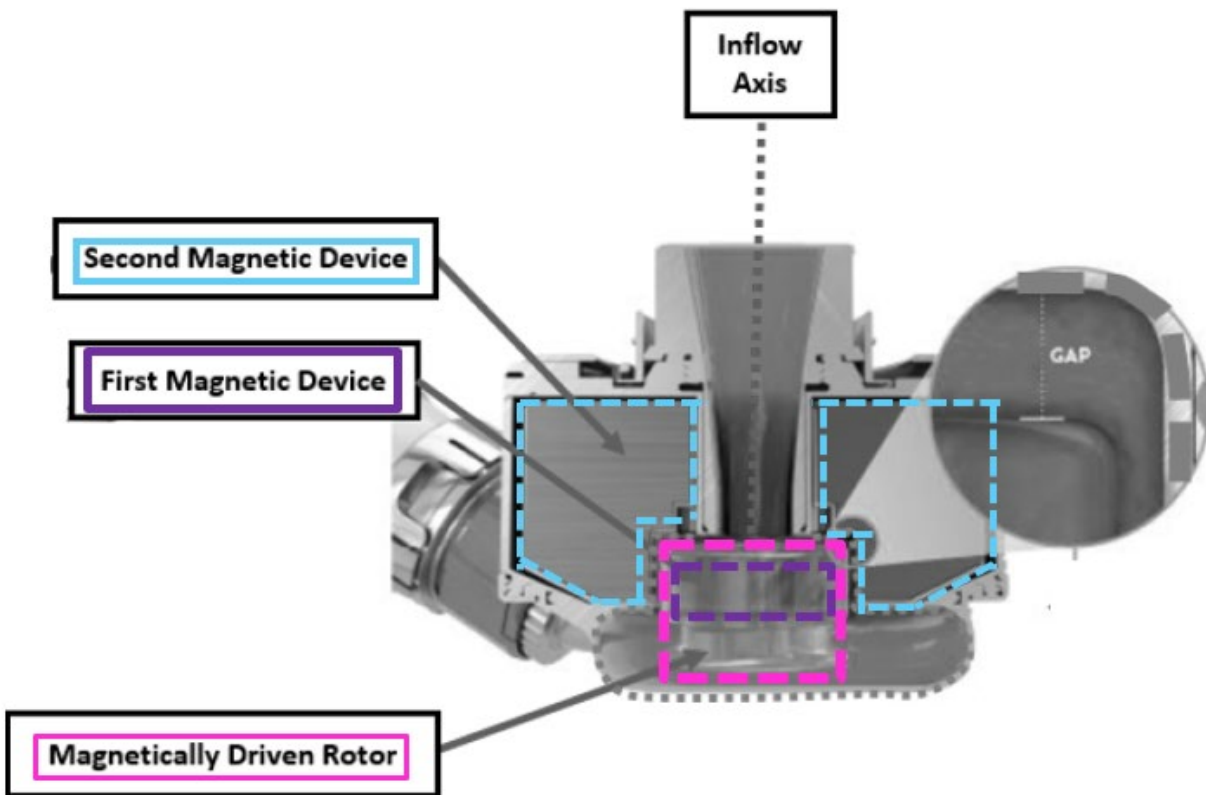


Ex.1042, ¶¶58-61 (discussing Ex.1036). And PO alleges that the “**Motor**” is a “*second magnetic device*”:



Ex.1042, ¶¶58-61 (discussing Ex.1036).

As shown below, the HeartMate 3's alleged **Rotor** surrounds the **permanent magnet**:



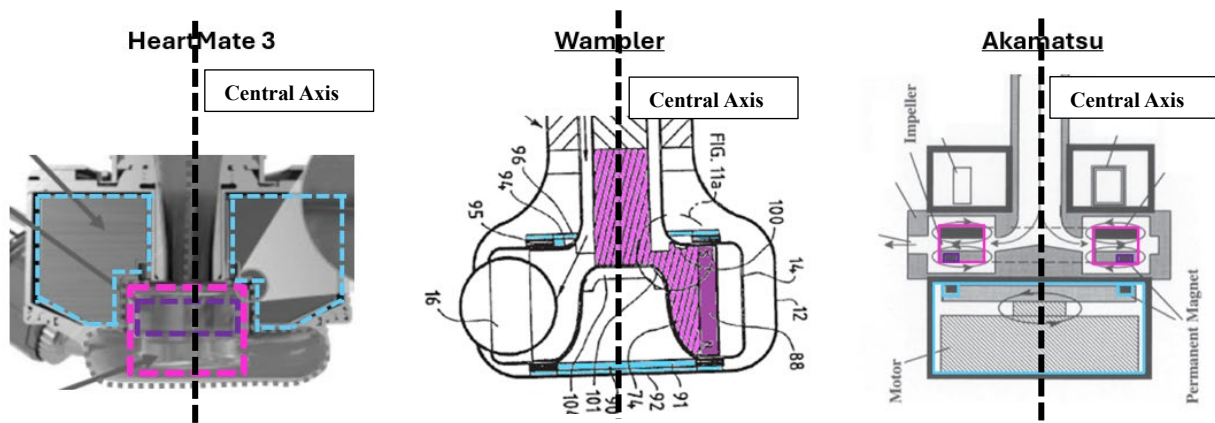
Ex.1042, ¶¶58-61 (discussing Ex.1036).

PO’s positions between the forums differ. For infringement, PO argues the “axially closer” limitation is satisfied, despite that HeartMate 3’s **Rotor** “surrounds” the **permanent magnet**. Ex.1042, ¶61. For invalidity, PO argues this precise arrangement—where a “[rotor] surrounds the rotor magnets”— “cannot be positioned axially closer.” POR, 17.

For infringement, because the HeartMate 3’s alleged **Rotor** surrounds the **permanent magnet**, PO undoubtedly measures “axially closer” from only a portion of the **Rotor**. Thus, PO’s infringement contentions show “*axially closer*” as

being satisfied where the “*the second magnetic device [is] positioned axially closer to the first magnetic device than to [only **a portion of**] the magnetically driven rotor.*” Petitioner assumes PO’s position in the Parallel Proceeding for purposes of this proceeding.

Applying PO’s apparent construction shown in its infringement contentions here, Wampler and Akamatsu both disclose the “*axially closer*” limitation. Indeed, the arrangement of the accused device closely resembles the prior art: the accused HeartMate 3 has a “**Motor**” and a “**permanent magnet in the **Rotor****” Ex.1042, ¶¶62-63; Wampler comprises “**motor stators**” (POR, 15) and “**magnets 88 embedded within the **impeller****” (POR, 17); and Akamatsu has a “**motor**” and a “**permanent magnet ... within the **impeller****” (POR, 50):



Ex.1042, ¶¶62-63. Thus, either *axially closer* includes arrangements where the *second magnetic device* and *first magnetic device* are *axially closer* than to **a portion of** the *magnetically driven rotor* (meaning Wampler and Akamatsu satisfy

this limitation); or *axially closer* requires “*all* of the ‘second magnetic device’ to be ‘positioned *axially closer* to the first magnetic device than to [*all* of] the magnetically driven rotor’” (meaning the accused product does not infringe). IPR2025-00112 (’357 IPR), Paper No. 13, at 25. Leschinsky conceded he had not considered, much less reconciled, this inconsistency. Ex.1040, 98:6-17; 106:19-107:3.

The Board should adopt PO’s apparent construction from its infringement contentions. *See Revvo Tech.*, Paper 20, 4. If the Board instead adopts PO’s narrowed construction that “*axially closer*” requires that the “minimum distance between components is ... axially closer” (POR, 9), such a construction would bar PO from contending that the accused HeartMate 3 infringes.

IV. THE CHALLENGED CLAIMS ARE UNPATENTABLE

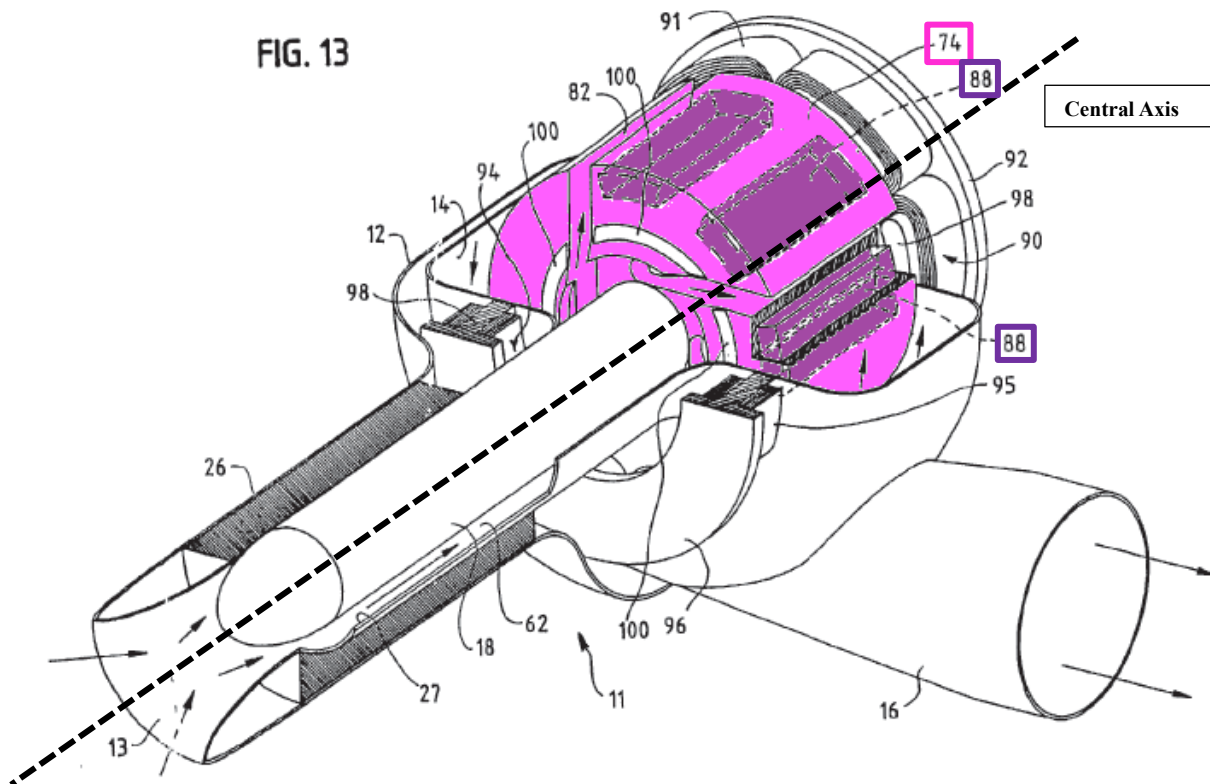
A. Ground 1: Wampler

1. [1C], [16D]: “axially adjacent”

Under PO’s Parallel Proceeding construction (*supra* §III.B.1), Wampler demonstrates 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 POR construction, Wampler also demonstrates 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** (“*first magnetic device*”) and its **impeller** (“*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):



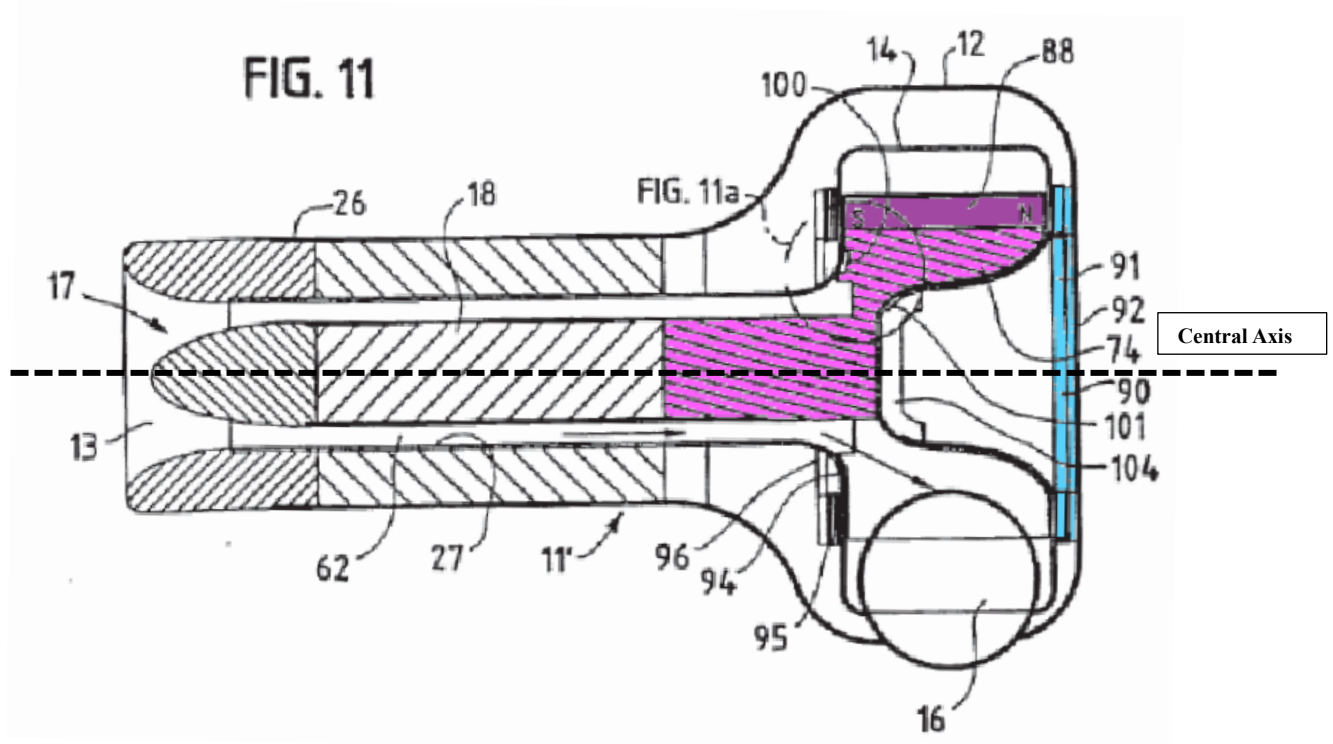
Ex.1042, ¶¶70-71 (discussing Ex.1008); Ex.1003, ¶¶172-174.

2. [16J]: “axially closer”

Under PO’s Parallel Proceeding construction (*supra* §III.B.2), Wampler demonstrates this limitation because the “**motor stators 90 and 94**” (*second magnetic device*) are “adjacent to” (Ex.1008, [0085]) i.e., *axially closer* to,

magnetic pieces 88 (first magnetic device) than to a portion of the “**impeller 74**” (“*magnetically driven rotor*”). Ex.1042, ¶¶72-74; Pet, 31-34. Indeed, the positioning of the Wampler components closely resembles that of the accused device: the accused HeartMate 3 has a “**Motor**” and a “**permanent magnet in the Rotor**” Ex.1042, ¶¶62-63; and Wampler has “**motor stators**” and “**magnets 88 embedded within the impeller**” (POR, 13).

Wampler also demonstrates this limitation under PO’s POR construction. The “minimum distance” (POR, 18) between “**motor stator 90**” and “**magnetic pieces 88**” is “*axially closer*” than the minimum distance to the “**impeller 74**,” which curves away from “**motor stator 90**:”



Ex.1042, ¶75 (discussing Ex.1008).

3. [1B]

PO argues that Petitioner “selectively points to only one part of” Wampler’s rotor 17, “impeller 74,” as the claimed “*magnetically driven rotor*,” and insists that it also “includes the [] shaft 18.” POR, 19-22. 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, ¶¶78-81. 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 *spaced apart from a suction end of an inflow tube* by its positioning 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, 3:54-56 (“a shaft 17 with a rotor 18”).

4. 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, 22-27. 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, ¶¶83-84; 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 “combine[d] 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). Petitioner is not “combining multiple embodiments from a single reference.” *Id.*

Like Wampler’s disclosure of an “alternative” blood pump with different bearings, Ex.1042, ¶¶83-84, 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, 192; Ex.1042, ¶83-84; *see also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir.

2016) (motivation to combine not required where prior art reference “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.” Ex.2015, ¶117 (“controller shown in Fig. 5 ... operating the first embodiment”). 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, ¶¶87-90.

i. [1K], [16L]

PO does not dispute that the Second Embodiment includes “hydrodynamic bearings [that] maintain the impeller entirely spaced apart from the casing 14,” which discloses that the rotor “*remains entirely spaced apart ... by the blood flowing.*” 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, the bearings (hydrodynamic vs. thrust) are presented as alternatives. PO’s “First Embodiment” argument should be disregarded. *Supra* §IV.A.2.

ii. [1L], [1M], [16M], [16N]

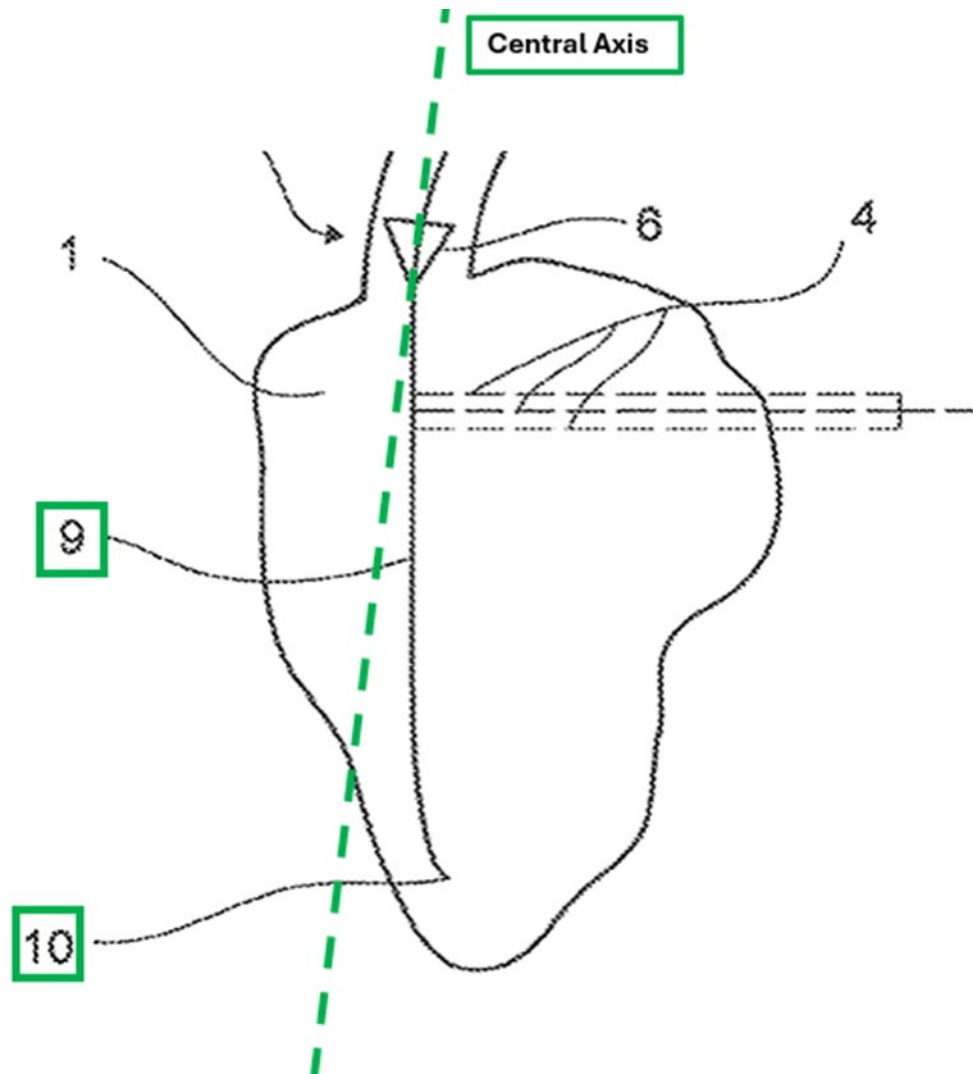
Again, PO is wrong that there is “no disclosure in Wampler of the [Second Embodiment] coupled to the controller 59 of FIG. 5” and that Petitioner had to explain “why a POSA would have combined [] two embodiments disclosed in Wampler.” POR, 26-27. As explained, the Second Embodiment is configured in the same manner as FIG. 5, including its connection to controller 59. *Supra* §IV.A.4. Moreover, Leschinsky conceded that “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, ¶¶87-90.

B. Ground 2: Bourque/Wampler

1. Bourque alone renders the Challenged Claims obvious.

PO insists that “*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, 28-30. But the claim merely requires that the “*rotor*” be “*axially aligned*” with the “*inflow tube*.” Ex.1001, 4:35-36. 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, ¶50 (“’077 patent discloses one embodiment”). Leschinsky agrees that 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.1040, 135:19-136:14 (“it’s a little curved”);

Ex.1042, ¶¶93-96. “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 '077 patent's inflow tube—both inflow tubes are “*axially aligned*” with their respective rotors. Ex.1042, ¶¶97-98. 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, ¶421; 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., 83. PO responds that “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, 32-33, 36-37. 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) (“claims’ actual limitations [] are not limited to [a specific] nerve.”).

Moreover, PO’s argument based on bodily incorporation has been considered improper countless times, including in the ID. ID, 22. “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).

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, 37; 32 (“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, ¶¶102-108. 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., 84;

2. The combination would “eliminate” “peripheral hardware” that caused “clinical troubles.” Pet., 85-86;
3. The references “are analogous” and the “combination would have been the arrangement of old elements.” Pet., 83-84; and
4. Instead of “in a preperitoneal pocket,” implanting at “the apex of the heart” would “reduce rates of infection.” Pet., 86-88.

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., 56, 82-84; Ex.1008, [0076]; Leschinsky, ¶¶126-127. 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, 31; Leschinsky, ¶¶12-127. The Wampler design, however, allows for “an axially aligned inlet tube.” Leschinsky, ¶160. This is reason enough to uphold the Bourque/Wampler combination. Ex.1041, ¶49.

PO fails to rebut the second reason—that the “peripheral hardware” of the Bourque pump, such as its “inflow...components” and “recovery section,” “account for most of the...clinical trouble.” Pet., 84-85. 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, 33-35. 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 “directed toward the same field,” third-generation centrifugal LVADs that employ magneto coupling, and “solve the same problem” as the ’077 patent to assist the heart. *Axonics*, 73 F.4th at 955; Pet., 83; Ex.1003, ¶¶645-647; 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, 33. But those “space constraints” are “not part of the [] claims.” *Axonics*, 73 F.4th at 957 (“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, 35. 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,

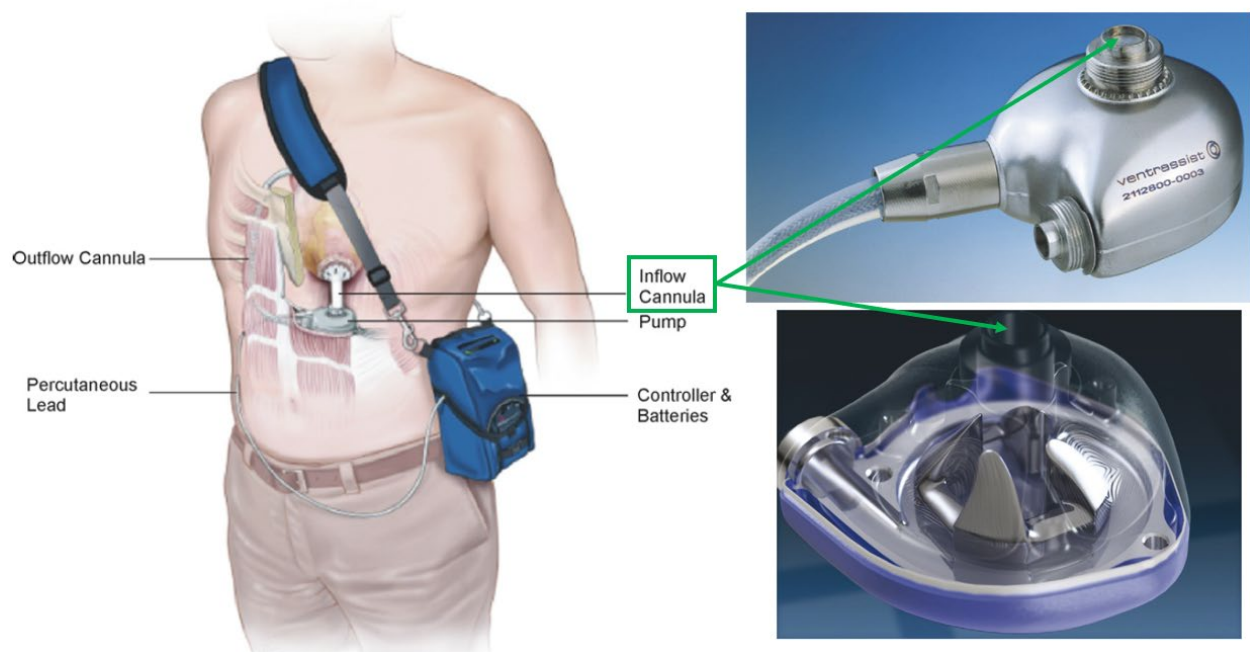
1197-98 (Fed. Cir. 2014) (original emphasis). And “[t]here is no question, based on the disclosures in the prior art, that [placement either above or below the diaphragm] presented a suitable option.” *Id.* at 1198. As explained in the Petition and detailed below, “several similar LVADs [] fit well” at these two positions. ID, 21; Pet., 87–88; Ex.1003, ¶¶651–653.

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., 83 (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); *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, 37-39. 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. 83), 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, ¶¶102-105. By 2007, “87 patients ha[d] been implanted with the VentrAssist.” Ex.2013, abstract.

Similarly, by 2006, the Akamatsu pump, i.e., the DuraHeart, had been implanted in 20 patients. Ex.1042, ¶¶107-108; 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, 64. 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, 101.

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, ¶¶109-114. PO insists “that the Bourque-2001 pump is too big to fit” at the apex of the heart (POR, 36), 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, 32, 56. 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; Ex.1042, ¶¶110-112.

As explained in the Petition, 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); ¶¶654-655 (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 (“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, ¶143, ¶92 ("HeartWare HVAD [] was clinically implanted ... years after ... the priority date of the '077 patent."). Thus, in his view, implantation at "the apex of the heart ... would have been practically impossible." Leschinsky, ¶156. 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" and "fit well ... at the apex of the heart." Pet., 88.

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 to a POSA 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, 64), a POSA would expect a similar “anatomical fit” for the Bourque /Wampler combination, at least for many adults. Ex.1041, ¶¶73-79; Ex.1042, ¶113.

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, ¶¶114); 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., 88); the Bourque pump from 2001 could have been made smaller by 2007 due to advances in electronics (Ex.1042, ¶¶115-116); 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, 42 (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, ¶116; ID, 23 (“relying on a later patent to show that it included ‘inventive activity’ ... is not an admission”).

3. [Claim 7] and [Claim 26]

Bourque discloses multiple “*feedback signals*” from “*one or more sensors*” being provided to an “*external control unit.*” 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, ¶¶529-531.

C. Ground 3: Akamatsu

1. [1C], [16D]: “axially adjacent”

Under PO’s construction from the Parallel Proceeding (*supra* §III.B.1), Akamatsu discloses 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 discloses 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, 52. 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*”):

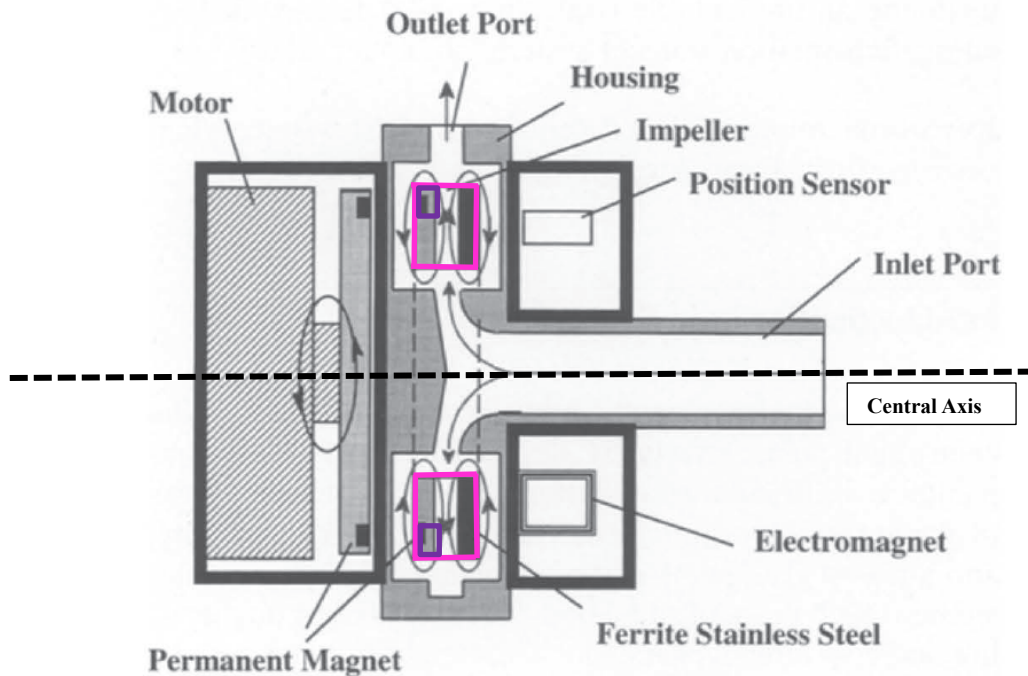
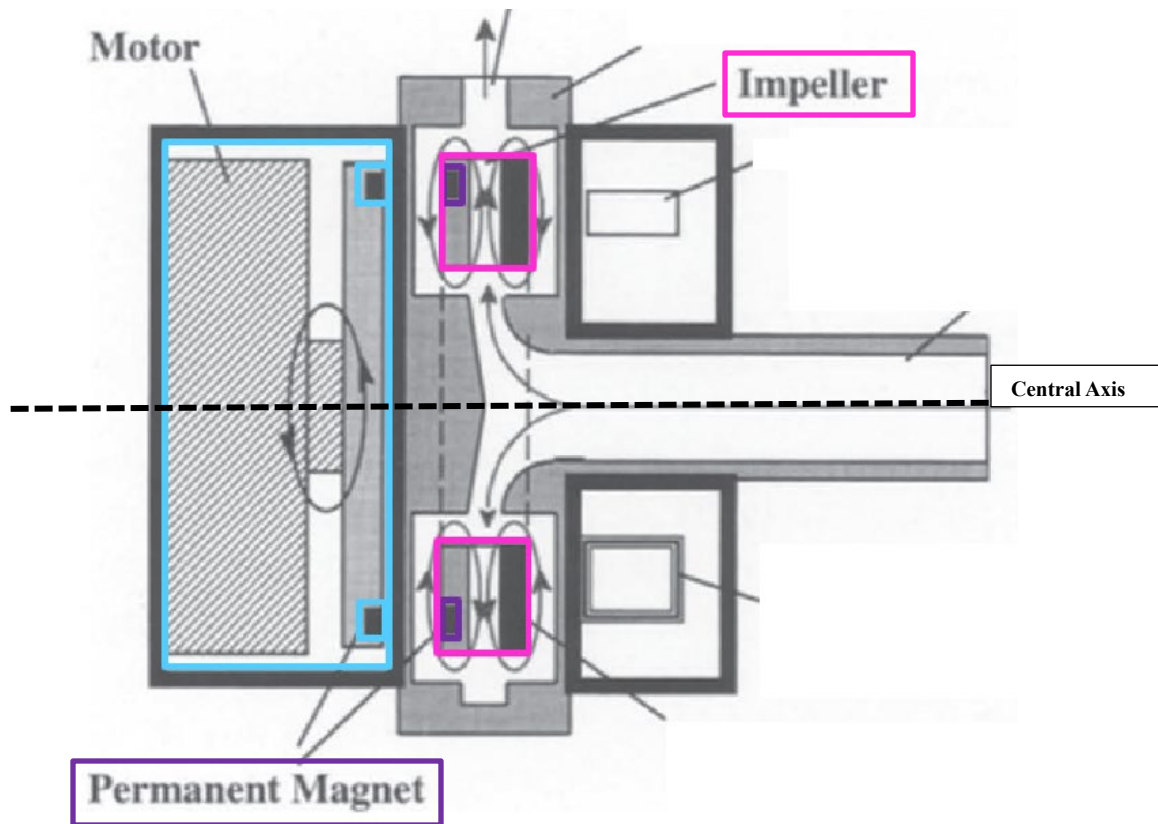


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2; Ex.1042, ¶¶51-52.

2. [16J]: “axially closer”

Under the PO’s construction from the Parallel Proceeding (*supra* §III.B.2), Akamatsu discloses this limitation because the **motor** (“*second magnetic device*”) is “positioned *axially closer*” to the “**permanent magnet** inside the **impeller**” (“*first magnetic device*”) than to a portion of the **impeller** (“*magnetically driven rotor*”):



Ex.1042, (¶¶67) (discussing Ex.1006). Indeed, the positioning of the Akamatsu components closely resembles that of the accused device: the accused HeartMate 3 has a “**Motor**” and a “**permanent magnet in the Rotor**” Ex.1042, (¶¶63-67); and Akamatsu has a “**motor**” and a “**permanent magnet inside the impeller**” (POR, 53).

3. [1M], [16N]

PO disputes that Akamatsu discloses “a controller (worn externally in Figure 1).” POR, 55. But Leschinsky conceded that “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,” i.e., via an electric wire through the skin,

demonstrates to a POSA that the that the controller was external, as Crosby explained. Ex.1003, ¶¶755-757.

D. Ground 4: Schima/Akamatsu

1. [1A], [16A]

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 elements [1A] and [16A]. POR, 59-64. 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, ¶¶897-903 (discussing Schima, [0004]-[0008]).

PO argues that the shape of the Schima pump suggests it is an extracorporeal device. POR, 61-62. But PO ignores that Schima’s pump, including its “fittings” and its shape, closely resemble the VentrAssist, an implantable LVAD. Ex.1042, ¶106.

Even if Schima’s pump is “extracorporeal,” PO’s argument that it cannot be combined “with the implantable device of Akamatsu” (POR, 59–64) 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); Ex.1040, 36:3-6; 21:14-22:10.

2. [1M], [16N]

PO argues that the proposed Schima/Akamatsu combination does not teach or suggest an external control unit that is “connectable to the heart assist pump device.” POR, 65. 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. And an “*inflow tube...insertable into a ventricle of the heart*” would have been obvious as discussed. *Supra* §IV.D.1.

3. [Claim 7] and [Claim 26]

PO does not dispute that Akamatsu teaches this claim. POR, 50-58. The Akamatsu pump “*deliver[s] feedback signals*” indicative of pump speed to the controller to “operate[.]” “the pump ... at a fixed rotational speed.” Ex.1003, ¶¶781, 1014-1015. (quoting Ex.1006, 4); *see also supra*, §IV.C.3.

V. CONCLUSION

The Challenged Claims are unpatentable.

Dated: December 22, 2025

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 5,510 words (as determined by the Microsoft Word word-processing system used to prepare the brief and including annotated figures), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on December 22, 2025,
I caused to be served a true and correct copy of the foregoing and any
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