UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner

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

REPLY DECLARATION OF PETER CROSBY IN SUPPORT OF PETITIONER'S REPLY

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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 "*Rotary Pump Comprising a Hydraulically Mounted Motor*"
1006	Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, J Artif Organs 1999, Vol. 2, pp. 3-7
1007	Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor*, ASAIO Journal 2001
1008	U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled "*Sealless rotary blood pump*"
1009	Miracor's Supplemental Initial Response to Invalidity Contentions, dated September 20, 2014
1010	Frazier et al. *Total Heart Replacement with Dual Centrifugal Ventricual Assist Devices*, ASAIO Journal 2005
1011	Schob, *Centrifugal pump without bearings or seals*, World Pumps Vol. 2002, No. 430, pp. 34-37
1012	Rose et al, *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*, 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., *Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices,*

	The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842
1015	LaRose et al., *Heartware – A novel miniaturized passive maglev centrifugal VAD*, ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137
1016	Qian et al., *Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump*, Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38
1017	Akamatsu et al., *Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump*, 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., *Magnetos for automobilists, how made and how used*, 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. *Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor*, 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) of Supplemental Invalidity Contentions, dated September 20, 2024
1027	U.S. Pat. No. 5,324,177
1028	Allaire, et al., *Prototype Continuous Flow Ventricular Assist Device*, J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690

1029	Kung and Hart, *Design Considerations for Bearingless Rotary Pumps*, J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis
1032	Declaration of Saranya Raghavan in support of motion for Pro Hac Vice Admissions
1033	Leschinsky, et al., *The CorInnova Implantable Cardiac Assist System for Direct Cardiac Compression*, 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., *Animal Models for Cardiac Research*, 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 https://www.linkedin.com/in/kbourque/
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," *Artificial Organs* 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. *My Journey with the HeartWare Ventricular Assist Device- An Obituary*. *The VAD Journal*. 2022; 8(1):e2022813.
1050	Potapov et al., The MicroMed DeBakey VAD—Part I: The Pump and the Blood Flow, *JECT. 2003;35:274–283*

I, Peter Crosby, do hereby declare as follows:

I. INTRODUCTION

1. I am the same Peter Crosby who previously submitted a declaration ("First Declaration" or "First Decl.," Ex.1003) in this proceeding on behalf of Petitioner Abbott Laboratories ("Abbott" or "Petitioner") in support of its petition for inter partes review ("IPR") of U.S. Patent No. 11,351,356 ("'356 patent," Ex.1001). I understand that the Patent Trial and Appeal Board ("Board") instituted IPR of the '356 patent. Paper No. 15. I submit this declaration on behalf of Petitioner in support of Petitioner's Reply.

2. In particular, I respond to opinions expressed in the expert declaration of Boris Leschinsky ("Leschinsky Declaration" or "Leschinsky Decl.," Ex.2015) and to the expert declaration of Dr. Robert Gallegos ("Gallegos Declaration" or "Gallegos Decl.," Ex.2017), which were submitted in support of Patent Owner's ("Miracor" or "Patent Owner" or "PO") Response to the Petition.

3. In providing my opinions in this declaration, in addition to my experience, education, and training, and the materials identified in my First Declaration (Ex.1003), I have also considered the materials cited in the Leschinsky Declaration (Ex.2015) and the Gallegos Declaration (Ex.2017), as well as any other

materials cited herein. I also attended their cross-examinations and reviewed their testimony.

4. I confirm that my scope of work and compensation has not changed since I submitted my First Declaration in this proceeding. No part of my compensation is dependent upon my opinions given or the outcome of this proceeding.

5. Like my First Declaration, unless otherwise noted, all **emphasis** in any quoted material has been added. Claim terms are *italicized*. Exhibit titles are underlined.

II. SUMMARY OF OPINIONS

6. For the reasons stated in my First Declaration and in this declaration, I maintain that the challenged claims are anticipated and/or rendered obvious under all four grounds:

i. **Ground 1:** Wampler.

ii. **Ground 2:** Bourque in view of Wampler.

iii. **Ground 3:** Akamatsu.

iv. **Ground 4:** Schima in view of Akamatsu.

III. QUALIFICATIONS AND LEGAL STANDADS

7. A description of my experience, education, and training is provided in my First Declaration.

8. I continue to rely on the legal standards outlined in my First Declaration.

IV. LEVEL OF ORDINARY SKILL IN THE ART

9. It is my understanding that, for purposes of their Institution Decision, the Board adopted the definition of a skilled artisan proposed in my First Declaration: a POSA at the time of the invention "would have at least a bachelor's degree in engineering; knowledge and experience in human circulatory system anatomy and physiology; and at least five years' experience designing and developing implantable medical devices." Institution Decision at 18.

10. I understand that Mr. Leschinsky proposed that the definition of a POSA should be narrower—instead of having experience designing and developing "implantable *medical* devices," Mr. Leschinsky opines that a POSA would possess experience with "implantable *cardiac assist* devices in particular." Leschinsky Decl., ¶59.

11. As shown by my qualifications provided in my CV and as explained in my First Declaration, I met the qualifications of a POSA under either party's definition. Unlike Mr. Leschinsky, I have extensive experience designing and developing implantable centrifugal cardiac assist devices. As I testified during my cross-examination, for about five years, from "2005" to "2010," I "was actively

involved" in "designing and manufacturing" the VentrAssist cardiac assist device, which is a third-generation centrifugal LVAD, and I "work[ed] to improve" the device, and I led "all of the research and development and manufacturing" of the device. Ex.2014, 10:17-13:3.

12. Mr. Leschinsky does not appear to have any experience designing or developing third-generation LVADs. During his cross examination, he conceded he had not worked on any such devices as of the priority date and I am not aware that he has developed any such devices since the priority date:

> Q. So you you've never worked on the design or development of a third generation LVAD prior to 2007, correct?
>
> A. Magnetic suspension and then like spaced apart?
>
> Q. That's right.
>
> A. No, I have not.

Ex.1040, 159:16-22.

13. Earlier in my career, I also served as "head of [a] Biomedical Engineering Department" responsible for supporting "an Intra-Aortic Balloon Pump (IABP)," which Mr. Leschinsky agrees is "part of the subject matter of the '356 Patent" (Ex.1003 ¶15), and is an implantable cardiac assist device (Leschinsky Decl., ¶33). Further, during my time at Telectronics, I worked on developing

"implantable cardiac pacemakers and defibrillators." Ex.1004, 2-3. Given Mr. Leschinsky's opinion that any device that "assists the heart" is a ventricular assist device under his "functional definition," my experience at Telectronics also relates to an implantable cardiac assist device. Ex.1040, 29:6-18.

14. Combining my experience with the VentrAssist together with the experience from earlier in my career as head of Biomedical Engineering at Royal North Shore Hospital (RNSH) and Telectronics, I have "at least five years' experience designing and developing implantable cardiac assist devices." Leschinsky Decl., ¶59.

15. I also have "45 years of experience in the medical device industry," "15 years in product research and development, including participation in design, engineering, [and] manufacturing," and experience bringing "over a dozen [medical device] products from concept to market release, through research and development." Ex.1003 ¶¶ 8-11.

16. Mr. Leschinsky's definition of a POSA should be rejected for at least two reasons.

17. First, it fails to consider the educational level of active workers in the field" at the time of the invention. Kevin Bourque, author of Bourque (Ex.1007), had years of experience designing medical devices, but he would not be considered a

POSA under Mr. Leschinsky's definition because he lacked the years of experience with "implantable *cardiac assist* devices in particular." POR 3-4. Mr. Bourque joined Thermo Cardiosystems in March of 1997, only a few years before filing the Bourque reference. Ex.1043. Before that, he does not appear to have any experience with cardiac assist devices. Ex.1043.

18. Second, Mr. Leschinsky failed to explain why he requires 5 years' experience here, but in a similar context, only required 2 years' experience. In connection with a post-grant review (PGR) related to a heart assist device (Ex.1040 (48:7-12; 51:1-5)), and involving references from the named inventor (Ex.1034 (Leschinsky discussing three references by Werner Mohl (PGR Exs. 1006, 1016, and 1024)), Mr. Leschinsky opined that only two years' experience was necessary. Ex.1034, ¶36. He fails to adequately explain why he now requires a significantly different definition of a POSA here.

19. My opinions expressed here would not change regardless of which party's POSA definition is adopted. Further, I understand that Dr. Wieselthaler, an experienced surgeon who implants cardiac assist devices, agrees with my assessments. Ex.1041.

V. TERMINOLOGY

20. As I explained in my First Declaration, the terms Left Ventricular Assist System (LVAS) and Left Ventricular Assist Device (LVAD) are synonymous. An LVAD consists of several main elements: a) an inflow cannula (tube, or conduit) placed with its opening in the left ventricle of the heart; b) the pump itself; c) an outflow cannula from the pump to the circulatory system, typically to the aortic root; d) a system to provide power and control to the pump; and e) a power source (typically a body worn battery pack). An implantable LVAD is surgically placed inside a patient.

21. I understand that the Patent Owner's expert, Mr. Leschinsky, has opined that this definition is "overly limiting" because it "include[s] only blood pumps." Ex.2015, ¶ 33. Further, I understand that Mr. Leschinsky has opined that LVADs include configurations such as direct cardiac compression devices, aortic counterpulsation devices (e.g., intra-aortic balloon pumps), etc., as well as certain alternative LVAD configurations, such as an inflow cannula placed in the left atrium rather than the left ventricle. Ex.2015, ¶ 33. I disagree with this overly broad definition, which is inconsistent with how the term "LVAD" is used in the art.

22. A left ventricular assist device (LVAD) is a mechanical apparatus implanted in conjunction with the patient's own heart and vasculature to enhance cardiac output. Unlike a total artificial heart (TAH), which completely replaces the native ventricles and connects directly to the pulmonary artery and aorta after removal of the heart, an LVAD supplements heart function rather than substituting the organ entirely. *See* generally Ex. 1048.

23. LVADs are also distinct from percutaneous ventricular assist devices (pVADs). Some circulatory support systems are introduced percutaneously—meaning they are not permanently implanted—and are referred to as pVADs. One example, the Impella system, uses a catheter inserted into the femoral artery to deliver a small pump with the inlet in the left ventricle, from where it pumps blood to the ascending aorta. Many of the pVAD components remain external, making these devices suitable for temporary support ranging from about six hours to two weeks. *See* generally Ex. 1048.

24. LVADs are further differentiated from other mechanical circulatory support (MCS) modalities such as the intra-aortic balloon pump (IABP), direct cardiac compression devices, and extracorporeal membrane oxygenation (ECMO). *See* generally Ex. 1048.

25. The IABP typically involves a balloon situated in the descending thoracic aorta that inflates during diastole to boost coronary blood flow and deflates in systole to decrease afterload, thereby aiding cardiac output. These devices are generally placed percutaneously and synchronize with the cardiac rhythm using electrocardiogram or arterial pressure monitoring. *See* generally Ex. 1048.

26. Direct cardiac compression devices are mechanical systems engineered to physically compress the heart, thereby facilitating or restoring circulation during cardiac arrest or profound cardiac failure. These systems employ rhythmic external or internal compression to replicate the heart's pumping action and improve perfusion to critical organs. Their use is primarily reserved for acute care or surgical settings when standard resuscitation is inadequate.

27. Extracorporeal membrane oxygenation (ECMO) is a sophisticated life-support intervention that temporarily takes over the heart and lungs' functions in cases of severe cardiac or respiratory compromise. Blood is routed through an external circuit for oxygenation and carbon dioxide removal before being returned to the patient. ECMO is predominantly implemented in intensive care environments as transitional support for recovery, transplantation, or further therapeutic measures when conventional treatments fail. *See* generally Ex. 1048.

VI. OVERVIEW OF THE 356 PATENT

28. As I discussed in my First Declaration, I have read the patent (Ex.1001) and relevant portions of the prosecution history (Ex.1002), which I incorporate herein by reference.

29. I agree with Mr. Leschinsky's opinion that "[i]t is true that the '356 patent discloses one embodiment of its 'device to assist the performance of a heart' that is built around a catheter." Leschinsky Decl., ¶51; *see also* ¶54 ("the example embodiment disclosed in the '356 patent"). I also agree with Mr. Leschinsky's concession that "there's no other examples … in the '356 patent" besides the catheter embodiment. Ex.1040, 210:21-24.

30. Mr. Leschinsky opines that this lone embodiment "would not have been understood by a POSA as limiting the scope of the disclosure." Leschinsky, ¶51. But Mr. Leschinsky misses the point. The lone catheter embodiment *is* the disclosure. There is no other description besides the description of a catheter device.

31. Mr. Leschinsky disagrees with my opinion that "there was nothing novel disclosed in the '356 Patent's specification about the design of the rotor." Leschinsky, ¶56. He states that "[j]ust because a rotor design may include features from a prior work does not mean, for example, that there are no additional features

included, or that there are no new features." Leschinsky, ¶56. Tellingly, however, Mr. Leschinsky does not identify any additional or new features of a rotor.

32. All elements of the claims are found in the prior art, with each element simply performing the same function it had been known to perform and yielding no more than a POSA would expect from such an arrangement. For example, the claimed rotor, magnetic elements, inflow, outflow, controller, and pump housing, as well as the configuration of these elements, were are all disclosed in the prior art. And the claimed elements function just as they do as in the prior art.

VII. CLAIM CONSTRUCTION

A. "*Magneto Coupling*" and "*By The Blood Flowing*"

33. I understand from the institution Decision that the Board has adopted the broader of the two constructions for the terms "*magneto coupling*" and "*by the blood flowing*" that I discussed in my First Declaration. I maintain that the narrower constructions I proposed are the correct plain and ordinary meaning of these two claim terms. In particular, the plain and ordinary meaning of "*magneto coupling*" narrowly refers to a specific rotor drive-type, which requires a transfer of torque between two "rotating magnets," as disclosed in Grounds 3-4. Ex.1003, ¶¶68–83, 212. And the plain and ordinary meaning of "*by the blood flowing*"

narrowly refers to a specific bearing-type, which requires a hydrodynamic bearing, as disclosed in Grounds 1 and 4. Ex.1003, ¶¶90–94.

34. But my opinions remain the same under the broader construction adopted by the Board, because the broader construction of "*magneto coupling*" includes at least two different drive-types: the use of "rotating magnets" (i.e., Grounds 3 and 4); and the use of an "electromagnetic driver" (i.e., Grounds 1 and 2)." Ex.1003, ¶¶84–87, 212–13, 366–67, 538–39, 693–98. And the broader construction of "*by the blood flowing*" includes two bearing-types: "a magnetic bearing" (i.e., Grounds 1, 2, and 3); and a "hydrodynamic bearing" (i.e., Grounds 1 and 4). Ex.1003, ¶¶96–98, 233–34, 385–86, 561–62, 713–14 .

B. "*Axially adjacent*"

35. The dispute turns on whether the meaning of "*axially adjacent*" includes components that "overlap or occupy the same portion of an axis."

36. For infringement at the district court, Miracor has alleged that Abbott's HeartMate 3 has a magnet "in" a rotor, which is "*axially adjacent*" (Ex.1019; Ex.1036). But in this proceeding, Mr. Leschinsky opines that a magnet "embedded within" a rotor is not axially adjacent. Leschinsky Decl., ¶¶78, 113-114; 189-190. Those two interpretations of "*axially adjacent*" are irreconcilable.

1. PO's construction from its infringement contentions shows that "*axially adjacent*" may include overlap.

37. As I explained in my First Declaration, I relied on Ex.1019, PO's position from its Complaint filed in the Parallel Proceeding. I similarly rely on PO's position from its infringement contentions (Ex.1036), which show "*axially adjacent*" as including components that overlap or occupy the same portion of an axis. Mr. Leschinsky's construction of "*axially adjacent,*" which excludes components that "overlap[] or occupy[] the same portion of an axis" (Leschinsky Decl., ¶¶78, 82, 113-114; 189-190), contradicts Miracor's infringement contentions, because the components accused of infringement also overlap and occupy the same portion of an axis.

38. In construing "axially adjacent," Mr. Leschinsky conceded that he had not considered how Miracor has apparently construed this term in the district court litigation:

> Q. Did you review or consider Miracor's infringement contentions from the district court litigation in preparing your opinion for the IPRs?
>
> A. No.
>
> Q. Did you consider, for example, how Miracor understands certain claim terms in alleging infringement of the HeartMate [3] product in district court litigation in

> forming your opinion as to how those same terms should be interpreted in the IPRs?
>
> A. No.

Ex.1040, 98:6-17.

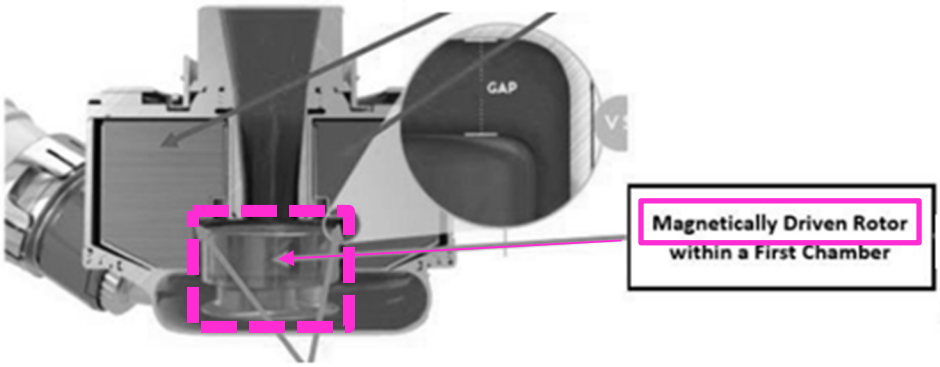
39. Mr. Leschinsky could not identify the components of the HeartMate 3 pump that Miracor alleges are first magnetic device and the rotor.

> Q. You're saying that if you were to try to identify the permanent magnet within the HeartMate [3] clinical pump [accused in the district court litigation] in this diagram, you would have to do that analysis sitting here today?
>
> A. I cannot do that sitting here today, but I can do that.
>
> Q. You haven't done that?
>
> A. I have not done it.

Ex.1040, 106:19-107:3.

40. If he had reviewed Miracor's infringement contentions, as I have, he would have realized that his construction of "*axially adjacent,*" which excludes components that "overlap[] or occupy[] the same portion of an axis" (Leschinsky Decl., ¶78, 82, 113-114; 189-190), is irreconcilable with Miracor's infringement contentions.

41. For infringement, Miracor alleges that the "**Rotor**" of Petitioner's HeartMate 3 is a *magnetically driven rotor*:

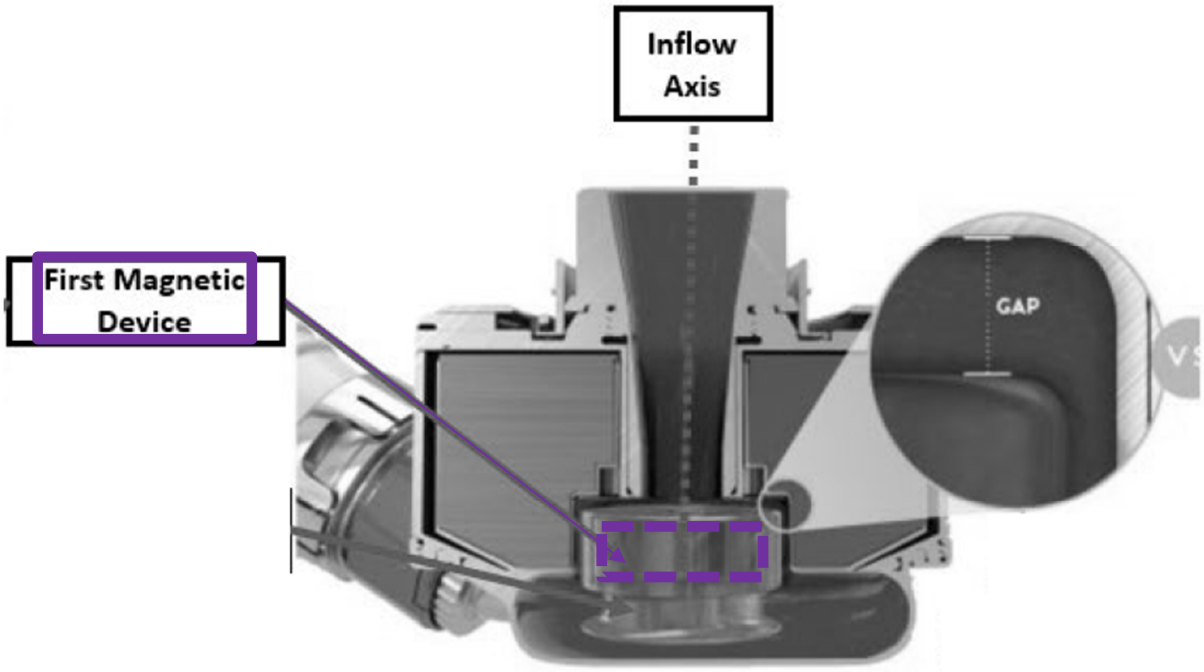


Ex.1036, 20 (annotated).[1] Miracor's identification above is consistent with Mr. Leschinsky's opinion that "everything that rotates is a rotor." Ex.1040, 70:7-9.[2]

42. Miracor also alleges that "a **permanent magnet** **in** the **Rotor**," of HeartMate 3 is a *first magnetic device*:

[1] For different claim elements, PO's infringement contentions point to different positions of the **Rotor** as satisfying a *magnetically driven rotor*.

[2] As discussed below regarding Wampler, I disagree that everything that rotates, such as a shaft, is necessarily a rotor.

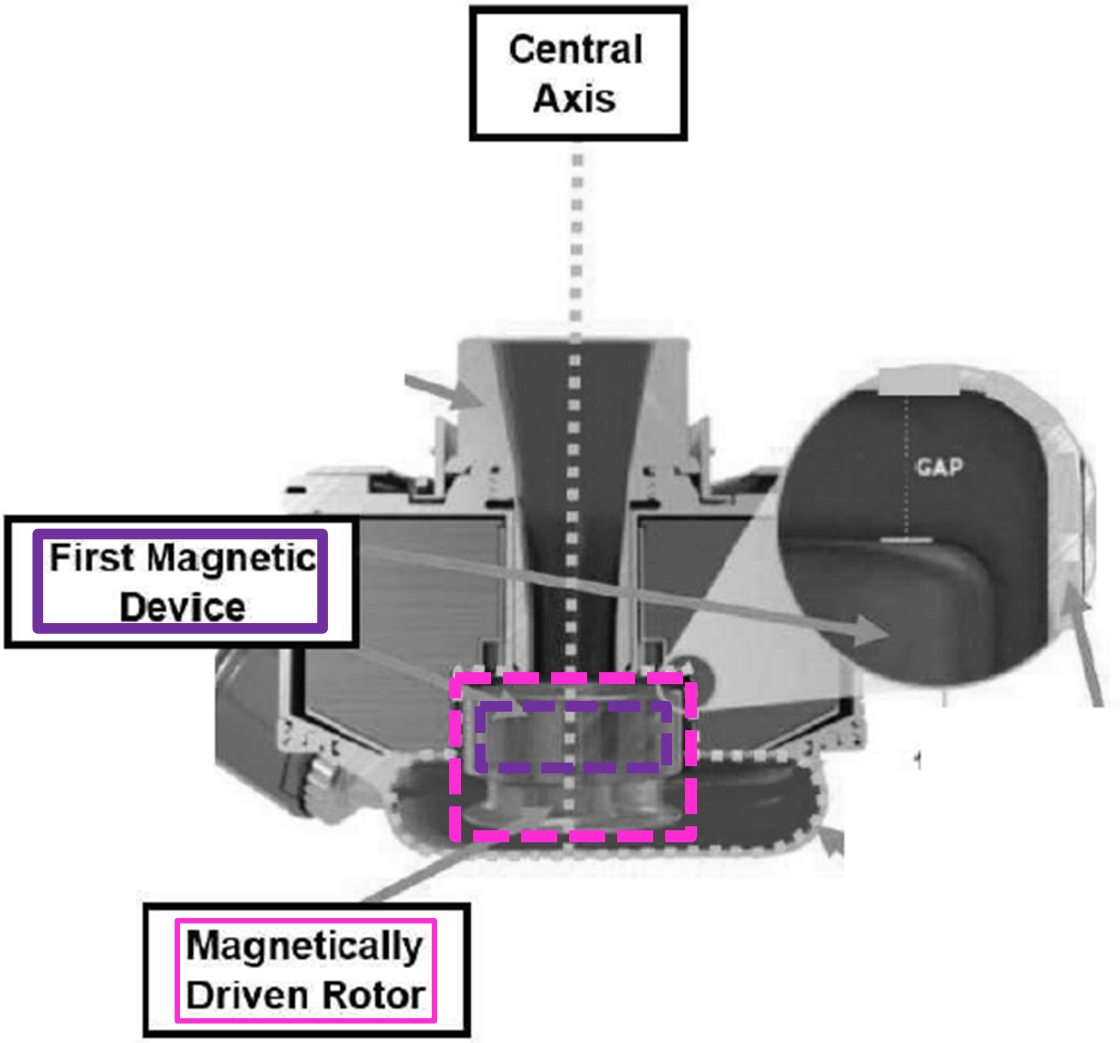


The Rotor is fully supported by magnetic levitation, obviating mechanical or fluid bearings and essentially eliminating Rotor mechanical wear as a reliability factor. Both drive (i.e. rotation) and levitation of the Rotor is accomplished using a single Stator comprising iron pole pieces, a back-iron, 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.1036, 5, 9 (annotated).

43. As depicted below, the HeartMate 3's "**Rotor**" and its "**permanent magnet in the Rotor**" are arranged in the exact position that Mr. Leschinsky opines is "distinct" from *axially adjacent*—the components are "aligned,"

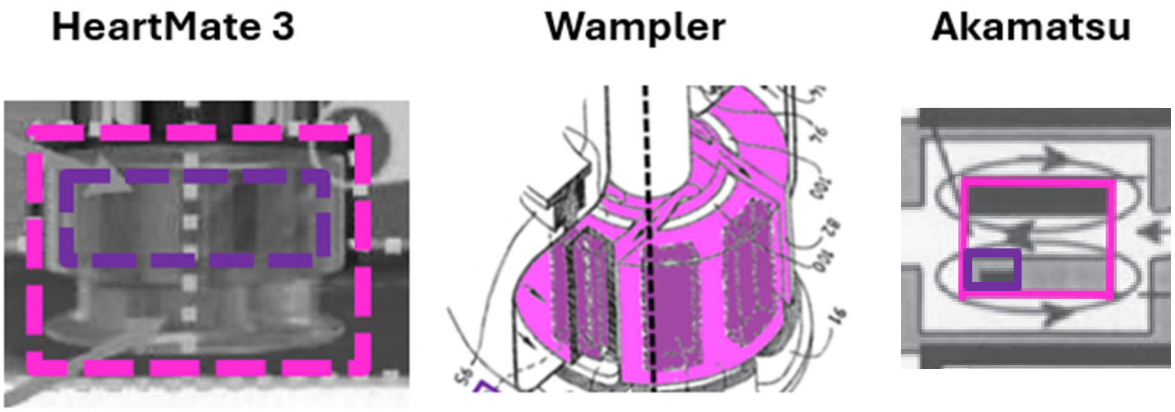
"overlap," and "occupy[] the same portion of an axis upon which they are positioned:"



Ex.1036, 5 (annotated).

44. The orientation of the rotor and the first magnetic device of the accused HeartMate 3 device closely resembles the orientation of the rotor and the

first magnetic device of Wampler and Akamatsu: the accused HeartMate 3's "**permanent magnet** [is] **in** the **Rotor**" (Ex.1036, 9); Wampler's **magnet segments** are "**embedded within"** the **impeller** blades" (Ex.2015, ¶¶113-114); and Akamatsu's "**permanent magnet** [is] **embedded in** the **impeller**" (Ex.2015, ¶¶189-190):



Ex.1036, 5 (annotated); Ex. 1008 Fig. 13 (annotated); Ex. 1006 Fig. 2 (annotated).

45. I apply PO's claim construction from its infringement contentions that "*axially adjacent*" includes components that "overlap or occupy the same portion of an axis."

46. If the rotor components of the accused HeartMate 3 are "*axially adjacent,*" then the Wampler and Akamatsu rotor components also must satisfy this limitation.

2. Even under Mr. Leschinksy's construction, both Wampler and Akamatsu are "*axially adjacent*"

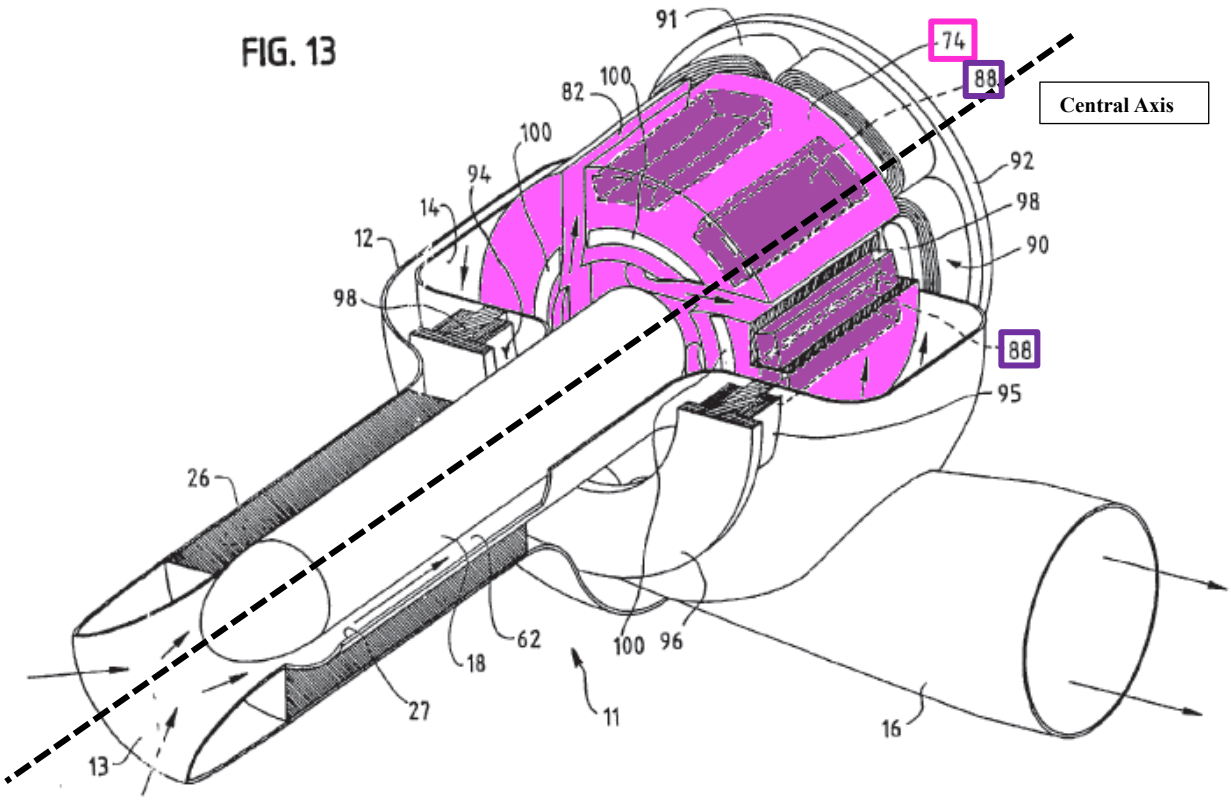
47. Mr. Leschinsky concedes that that "*axially adjacent*" components have "positioning" that is "next to one another, including perhaps touching or sharing a common side," when "measured along the axis about which the rotor spins." Ex.2015, Leschinsky Decl., ¶¶82–83.

48. Both Wampler and Akamatsu have a **first magnetic device** and **magnetically driven rotor** that are "touching or sharing a common side," when "measured along the axis." Ex.2015, Leschinsky Decl., ¶¶82–83.

49. Regarding Wampler, Mr. Leschinsky conceded that Wampler's **impeller 74** and its **magnetic pieces 88** are "parallel to the central axis of the rotor" (Ex.1040, 71:15-20)—i.e., these components are axially aligned with each other. Mr. Leschinsky also conceded that they are adjacent—"they are embedded, so they clearly are in contact with the rotor because they're inside it." Ex.1040, 75:9-19. And that they share a common side which are touching, because "all sides of the -- of the magnetic pieces are in contact with the internal volume of the rotor." Ex. 1040, 75:9-19.

50. Again, Mr. Leschinsky concedes that that "*axially adjacent*" components have "positioning" that is "next to one another, including perhaps

touching or sharing a common side," when "measured along the axis about which the rotor spins." Ex.2015, Leschinsky Decl., ¶¶82–83. Because Wampler's **magnetic pieces 88** and its **impeller 74** are both axially aligned and adjacent, and they are touching and share a common side, they are therefore *axially adjacent*, as shown:



Ex. 1008, Fig. 13.

51. Regarding Akamatsu, Mr. Leschinsky similarly conceded that Akamatsu's **impeller** and its **permanent magnet** are "axially aligned" and

adjacent (touching or sharing a common side)—meaning that they are "*axially adjacent*." Regarding "axially aligned," Mr. Leschinsky admitted that "the central axis of the impeller is the same as the central axis of the magnets, so in that sense they are axially aligned." Ex.1040, 77:18-24. Regarding adjacency, Mr. Leschinsky also conceded that "the permanent magnet is embedded in the impeller, so to that extent they're touching." Ex.1040, 78:5-11. And there can be no dispute that they share a common side. Ex.1040, 78:12-17.

52. Again, Mr. Leschinsky concedes that that "*axially adjacent*" components have "positioning" that is "next to one another, including perhaps touching or sharing a common side," when "measured along the axis about which the rotor spins." Ex.2015, Leschinsky Decl., ¶¶82–83. Because Akamatsu's **impeller** and its **permanent magnet** are both axially aligned and adjacent, and they are touching and share a common side, they are therefore *axially adjacent*, as shown:

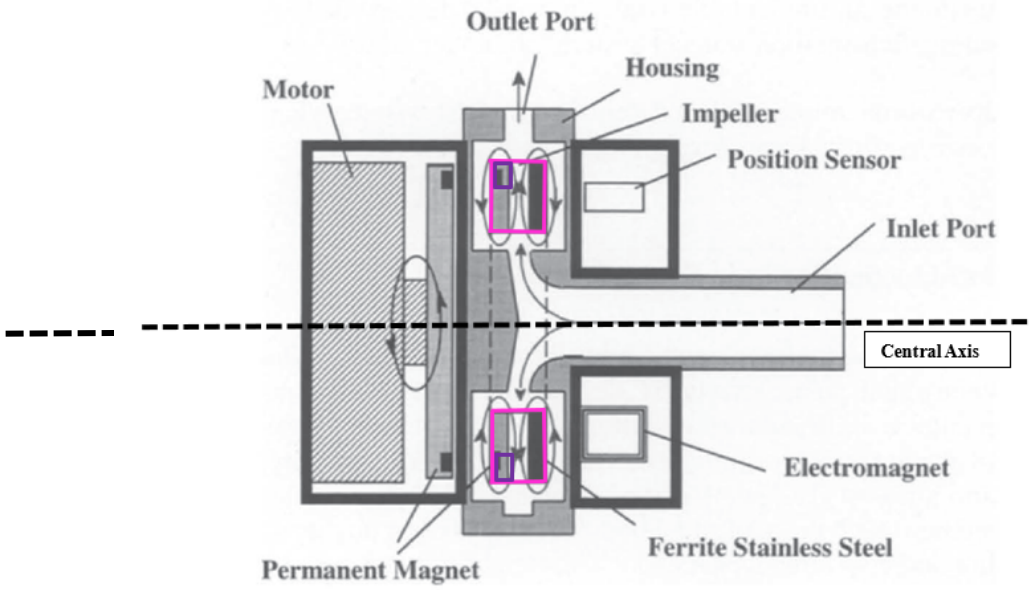


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

VIII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

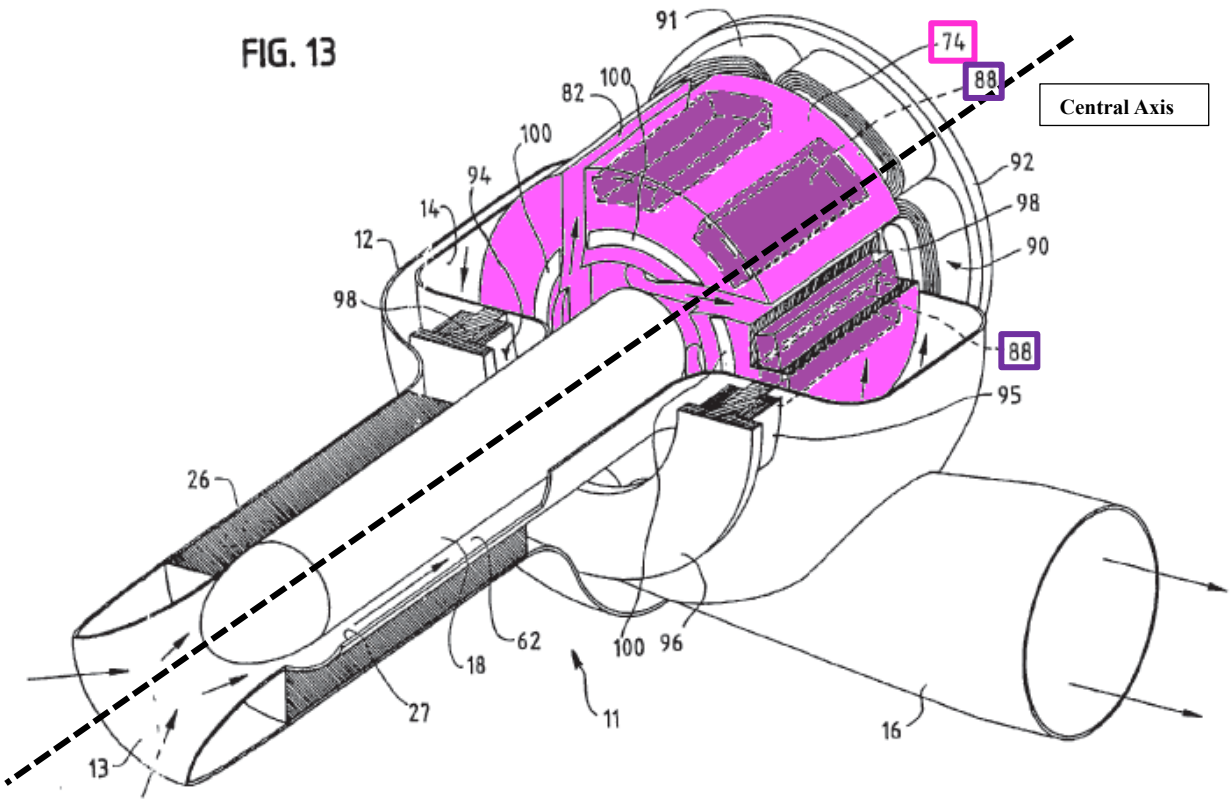
A. Ground 1: Wampler

1. [1H]: "axially adjacent"

53. As discussed above (*supra* VI.B), under PO's construction from the Parallel Proceeding, Wampler teaches or suggests this limitation because Wampler's magnet segments 88 and impeller 74 are aligned with, and overlap, one another as measured along the central axis. Ex.2015, ¶114.

54. Wampler also satisfies Mr. Leschinsky's construction. Mr. Leschinsky concedes that "*axially adjacent*" components have "positioning" that is "next to

one another, including perhaps touching or sharing a common side," when "measured along the axis." Leschinsky, ¶¶82–83. Mr. Leschinsky also concedes that Wampler's **magnet pieces 88** ("*a first magnetic device*") "are embedded within" its **impeller** ("*a magnetically driven rotor*"). Leschinsky Decl., ¶¶113-114. These components, therefore, are touching and share common sides when measured along an axis ("*axially adjacent*"):



Ex.1008, [0080]–[0081]; Ex.1003, ¶¶197–98.

55. During cross-examination, Mr. Leschinsky conceded that Wampler's **impeller 74** and its **magnetic pieces 88** are "parallel to the central axis of the rotor" (Ex.1040, 71:15-20)—i.e., these components are axially aligned with each other. Mr. Leschinsky also conceded that they are adjacent—"they are embedded, so they clearly are in contact with the rotor, because they're inside it." Ex.1040, 75:9-19. And that they share a common side which are touching, because "all sides of the -- of the magnetic pieces are in contact with the internal volume of the rotor." Ex.1040, 75:9-19. Again, Mr. Leschinsky concedes that "*axially adjacent*" components have "positioning" that is "next to one another, including perhaps touching or sharing a common side," when "measured along the axis about which the rotor spins." Leschinsky Decl., ¶¶82–83. Because Wampler's **magnetic pieces 88** and its **impeller 74** are both axially aligned and adjacent, and they are touching and share a common side, they are therefore *axially adjacent*. Ex. 1008, Fig. 13. Accordingly, Wampler teaches or suggests this limitation.

2. I relied on a single embodiment of Wampler, which developed into the HVAD.

56. Mr. Leschinsky opines that I "mixe[d] teachings from distinct embodiments in ways that" he does "not believe a POSA would have found obvious to do." Leschinsky Decl., ¶120. That is wrong. I did not combine any

embodiments. Instead, as explained in my First Declaration, I relied on Wampler's disclosure of a complete device depicted in FIGS. 11-14, which Mr. Leschinsky refers to as Wampler's "second embodiment." Leschinsky Decl., ¶120. I did not combine elements from FIGS. 1-8, which Mr. Leschinsky refers to as Wampler's "first embodiment." Leschinsky Decl., ¶87.

57. There was no need for a POSA to combine elements from the first and second embodiments, because Wampler explicitly teaches that the second embodiment blood pump shown in FIGS. 11-14 can be implanted as shown in FIG. 5. Wampler teaches that the "blood pump 11`" is "similar in many respects to blood pump 11 illustrated in FIGS. 1-8," and that features of the embodiment of FIGS. 11-14 "may be identical to those illustrated" for the embodiment of FIGS. 1-8. Wampler [0080]–[0082]; Ex.1003 ¶¶154, 174 n.16, 183. Wampler further teaches that "[v]arious elements from the FIGS. 1-8 embodiment can be used in the FIGS. 11-20 embodiments." Ex.1008, [0102]. As I previously explained, the primary difference is that the embodiment of FIGS. 1-8 uses "thrust bearings" whereas the embodiment of FIGS. 11-14 uses hydrodynamic bearings. Ex.1003, ¶235. Accordingly, I relied on descriptions of the identical and similar features of FIGS 1-8 in the instances that those descriptions applied equally to FIGS. 11-14.

58. Further, Mr. Leschinsky does not dispute that the second embodiment is an alternative to the embodiment shown in FIG. 5:

> Q. And just to be clear, you've opined that these are alternative embodiments, correct?
>
> A. That's what the report says, yes.
>
> Q. You are not disputing that the embodiment of Figures 1 through 8, which is partially illustrated in Figure 5, can be implanted in a heart, correct?
>
> …
>
> A. I am not disputing that it can be implanted in the heart, even at the apex of the heart. The way it's shown in Figure 5, right? No, I'm not disputing that. That's what it shows.

Ex.1040, 111:5-18.

59. Even if not expressly disclosed, a POSA would have found it obvious that the second embodiment depicted in FIGS. 11-14 could be implanted at the apex of the heart and configured with a controller as shown in Fig. 5, because that is the only implantation position and configuration that the Wampler reference contemplates. Ex.1008, [0074]–[0075].

60. Mr. Leschinsky opines that Wampler's second embodiment's "pump housing [is] larger and extend[s] further into the extracardiac space" than the first

embodiment, such that "a POSA would [] have appreciated that [] the pump of Fig. 11 in Wampler is not shown implanted [as in Fig. 5]." Leschinsky Decl., ¶104. I disagree. First, the '356 patent is completely silent about the size of the pump. Second, Wampler's first embodiment (pump 11) and second embodiment (pump 11`) are approximately equal in size and shape such that a POSA would understand they could be implanted in the same manner as shown in Fig. 5. The comparison below illustrates that the two are approximately equal in size and shape.

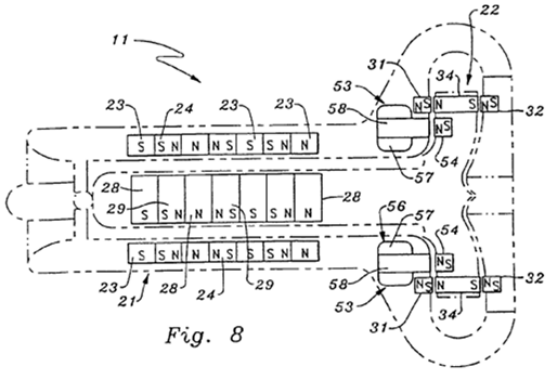
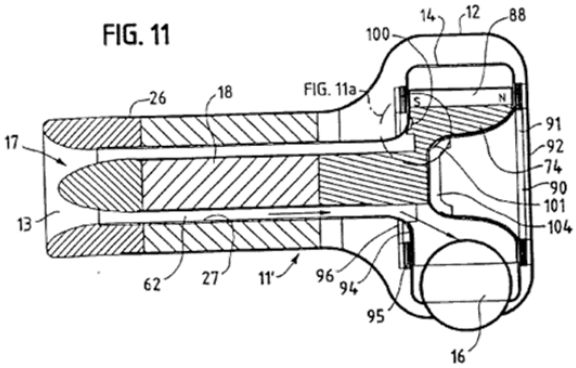


Fig. 8



Compare Ex. 1008, Fig. 8 (pump 11) *with* Fig. 11 (pump 11`).

61. Mr. Leschinsky also opines that "a POSA would have learned that the pump of Wampler was not actually implanted in a human as shown in Fig. 5 and

work toward this goal focused on the first embodiment of the pump shown in Fig. 5, not the second embodiment shown in Fig. 11." Leschinsky, ¶103. That is wrong. Wampler's second embodiment (pump 11`) was developed into the HeartWare HVAD, which was clinically implanted in many patients before the priority date. Ex.1044.

62. To support his opinion, Mr. Leschinsky opines that a POSA would have looked to "additional relevant publications" and cites an article co-authored by Wampler written in 1999. Leschinsky, ¶103 (citing Ex.2019). But that article concludes that "[a]nother prototype, suitable for implantation in animals for 2-4 weeks, is being fabricated to complete validation of the design." Ex.2019 at 4. By 2007, a POSA would have been aware that other prototypes had been developed based on Wampler.

63. By 2004, the same group that published Ex.2019 in 1999 published another article discussing another prototype—the HVAD. Ex.1015. Both prototypes discussed in Ex.2019 and Ex.1015 came out of the work being done by Richard Wampler. Ex.2019 is attributed to Kriton Medical, which later became HeartWare, as mentioned in the title of Ex.1015. A POSA working in this space would have been aware of this development—HeartWare's predecessor company, Kriton Medical, filed for bankruptcy in 2003, and the company's intellectual

property was sold to HeartWare. Moreover, both Ex.2019 and Ex.1015 were co-authored by V. Indravudh.

64. Dr. Gallegos agrees that the HVAD disclosed in 2004 developed from the disclosure in Wampler :

> Q. Yes. So to revisit that, do you agree that the HeartWare HVAD is a Wampler pump?
>
> …
>
> A. Yes, it's a pump that ultimately became known as HeartWare . . . .

Ex.1045, 103:25–104:4.

65. As explained in my opening declaration, HeartWare reported that the HVAD, which was a third-generation LVAD, had a "small size" that allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch, thus, [t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for intrapericardial pump placement and fast implantation" at the apex of the heart. Ex.1003, ¶476 (citing Ex.1015 and discussing Wampler and HVAD). Given that the design described in Ex.1015 is largely identical to the Wampler second embodiment and the fact that these were developed by the same group, a POSA would have

understood that the Wampler second embodiment of FIGS 11-14 had been developed into the HVAD.

66. As detailed below (*infra*¸¶¶103-104), a POSA would have also been aware that a clinical trial of the HVAD implanting the device at the apex of the heart in human patients had already begun in March 2006. Ex.1044.

67. During his cross examination, Mr. Leschinsky conceded that the Wampler pump could be implanted at the apex of the heart as shown in FIG. 5:

> Q. So in your view, the Wampler prototype and the HeartWare HVAD are examples of pumps that can be implanted at the apex of the heart of some patients?
>
> A. Of a good enough, large enough number of patients, yes.

Ex.1040, 96:12-17..

68. Accordingly, Mr. Leschinsky's opinion that "a POSA would have learned that the pump of Wampler was not actually implanted in a human as shown in Fig. 5" is factually incorrect.

i. *[1A]*

69. Wampler teaches or suggests "*delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart*." Ex.1003, ¶¶154-157.

70. Miracor's Patent Owner Response does not address element [1A] for Wampler. Thus, I understand that this element is not disputed. Mr. Leschinsky, however, opines that there is no disclosure of the Wampler second embodiment of FIGS. 11-14 being *inserted into a ventricle of the heart* as shown in FIG. 5. I disagree for the reasons stated above. *See supra* ¶¶56–63.

71. During cross-examination, Mr. Leschinsky conceded that the inflow tube that *is inserted into a ventricle of the heart* is similar for both the first and second Wampler embodiments:

> Q. Okay. I'm going to refer you to the second sentence of Paragraph 80 [of Wampler, Ex.1008] which says, "Referring to Figures 11, 11-A, 12, 13, and 14, the Blood Pump, 11 prime, shown therein is similar to many respects to blood pump 11 illustrated in Figures 1 through 8." Do you see that?
>
> A. Yes.
>
> Q. Did you consider that statement in forming your opinion that the two embodiments were disjoined?
>
> …
>
> A. Well, it says what it says, and I agree with what it says. It's similar. For example, the spindle is similar. We talked about this. And the shape of the pump, broadly

> speaking, at least in **the portion that goes into the ventricle is similar**, but there are differences. So there's nothing -- I mean, I don't see any contradiction here.
>
> Q. Okay. So you agree that there are similarities between the two embodiments?
>
> A. Yes, there are similarities.

Ex.1040, 132:8-133:8.

72. Mr. Leschinsky's concession that the portion that goes into the ventricle is similar between the first and second embodiments supports my opinion that a POSA would understand the second embodiment of FIGS. 11-14 would be configured as shown in FIG. 5.

ii. *[1B]*

73. Wampler teaches or suggests "*while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart*." Ex.1003, ¶¶158-166.

74. Mr. Leschinsky does not dispute that the impeller 74, which I identified as the claimed *magnetically driven rotor* would be *positioned outside the ventricle of the heart*:

> Q. At the bottom of Paragraph 101, you have two side-by-side figures from Wampler, namely Figure 5 and Figure 13. Do you see that?
>
> A. Yes.
>
> …
>
> Q. Okay. If the embodiment that's shown in Figure 13 were inserted into the apex of the heart as shown in Figure 5, would you agree that the impeller 74 would be positioned outside the ventricle of the heart?
>
> …
>
> A. 74 refers to impeller; is that correct?
>
> Q. Yes.
>
> A. I don't -- I need to look at this. But **the entire part that is pink, which is what you call the impeller, I suppose, would be outside the heart, that's correct**.

Ex.1040, 114:19-115:17.

75. But Mr. Leschinsky opines that I selectively defined Wampler's "impeller 74" as the claimed "*magnetically driven rotor*," and insists that the Wampler rotor also includes the spindle or shaft 18. Leschinsky Decl., ¶¶109-112.

76. Mr. Leschinsky, however, does not dispute that the impeller 74 is the element that functions as a rotor to pump blood:

> Q. Is there a specific aspect of the rotor that is imparting acceleration to the blood?
>
> A. Well, the rotor has basically two components, the impeller and the spindle. The spindle certainly applies acceleration to the blood because it rotates, and the blood that comes in does not rotate. So it makes a -- makes the blood into -- into -- you know, imparts some rotational movement on the blood just by drag.
>
> Clearly **the impeller itself is the one that imparts centrifugal force and forces the flow of blood to turn and then to go towards the outlet**.

Ex.1040, 119:20-120:10.

77. Mr. Leschinsky's opinion that "everything that rotates is a rotor" (Ex.1040, 70:7-9), including the spindle, also contradicts the '356 patent's specification, which contemplates that "a shaft" and "a rotor" are separate elements. Ex.1001, 4:50-53 ("a shaft 17 with a rotor 18"); Ex.1001, Fig. 2. My mapping of Wampler's impeller 74 as the claimed *magnetically driven rotor* is therefore consistent with how a POSA would understand the term and is also consistent with the specification.

iii. *[1M]*

78. Mr. Leschinsky does not contest that second embodiment of Wampler (FIGS. 11-14), which is the embodiment I relied upon, discloses this limitation. Leschinsky Decl., ¶118. Thus, as I explained in my First Declaration, Wampler discloses this limitation—*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*.

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

79. Limitation [1N] requires "connecting an external control unit to the heart assist pump device." Limitation [1O] requires that "the external control unit being positioned exterior to the body." For these limitations, Mr. Leschinsky opines that I "mixe[d] teachings from distinct embodiments," that "the only disclosure of an external controller in Wampler is with regard to Fig. 5 showing the first pump embodiment," and that "the second pump embodiment shown in Fig. 11 of Wampler, but this embodiment is not shown implanted in a heart or in use with an external controller." Leschinsky ¶¶120-125.

80. But as explained above, Wampler explicitly teaches that the second embodiment blood pump shown in FIGS. 11-14 can be implanted as shown in FIG.

5. *See supra* ¶¶56–57. Even if not explicitly disclosed, a POSA would have found it obvious, because the HVAD had already been clinically implanted in humans. *See supra* ¶¶61. Further, the HVAD included a "driveline," which would suggest to a POSA that it was connected to an external controller. Ex.1015.

81. Moreover, Mr. Leschinsky conceded that a POSA would understand that the Wampler second embodiment (FIGS. 11-14) could be connected to a controller and that the controller could be external:

> Q. Would a POSA understand that the embodiment of Figures 11 through 13 could be connected to a controller?
>
> A. **They could be**.
>
> …
>
> Q. But if you were to try to design a way to control the operation of the pump shown in Figures 11 through 13, a POSA would understand one way to do it would be to use an internal controller, correct?
>
> A. One way would be to use an internal controller. **One way is to use an external controller**. One way is to incorporate within the, you know, pump. You know, I -- it's a speculative answer here because there's nothing in the patent that describes that.

Ex.1040, 127:10-129:4.

82. Moreover, as Mr. Leschinsky conceded, a POSA would have understood that any pump would need to use a controller, and that the concept of having an external controller was well known as of the priority date:

> Q. But generally **the concept of having controllers be either internal or external was known in the art** prior to 2007, correct?
>
> A. Broadly speaking.
>
> …
>
> Q. I'm trying to understand how you're interpreting regulation -- regulating operation of the second magnetic device.
>
> A. **Any pump of that type would have a -- the main controller** that makes it work.

Ex.1040, 130:9-12, 198:16-23. And the only controller described in Wampler is "worn externally." Ex. 1008, [0070].

83. Thus, as I explained in my First Declaration, Wampler discloses these limitations.

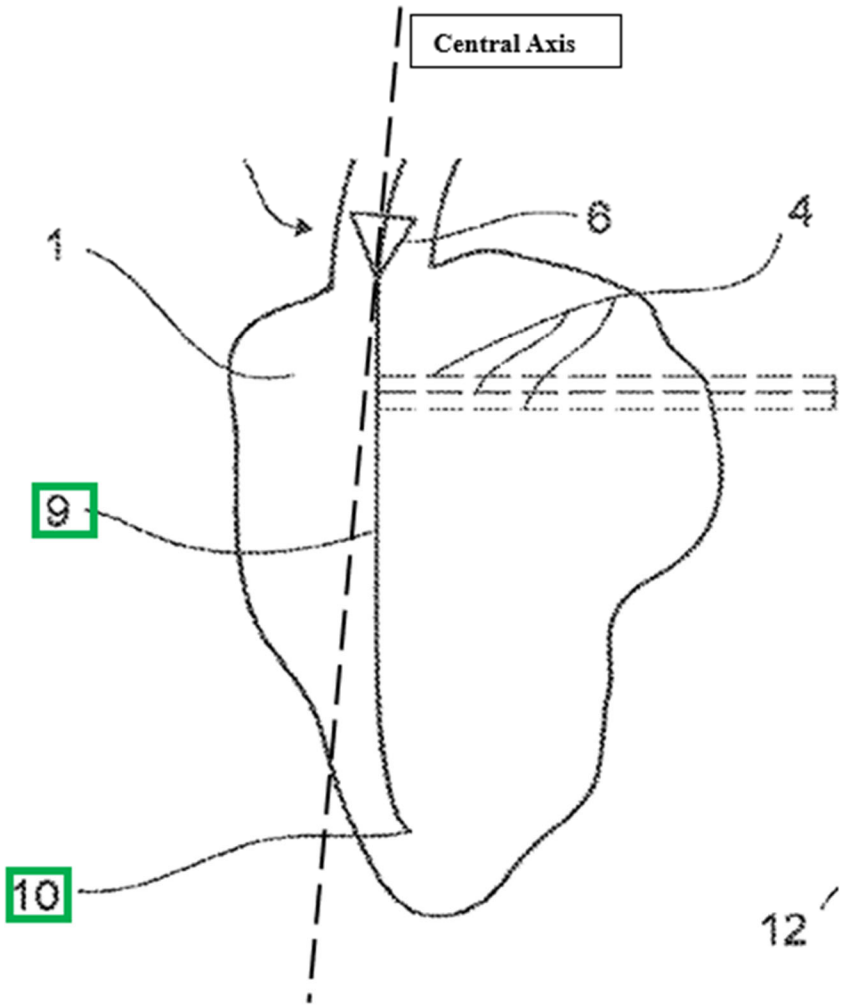
A. Ground 2: Obviousness of the Challenged Claims over Bourque in view of Wampler

1. Bourque alone renders obvious the Challenged Claims.

84. I understand that, in the Institution Decision, the Board agreed with Patent Owner that the challenged claims are not obvious over Bourque alone, in particular because the reference does not teach or suggest a rotor "axially aligned" with an inflow tube. But I disagree with this determination.

85. The claim merely requires that the "*rotor*" be "*axially aligned*" with the "*inflow tube.*" Ex.1001 at 5:26–32. Mr. Leschinsky insists this claim language requires that the entirety of the "structure that is the *inflow tube*" be aligned in a straight, unbent line along the rotor's axis. Leschinsky Decl., ¶¶127-131. But Mr. Leschinsky's requirement would exclude the specification's only disclosed embodiment. Ex.1001, Figs. 1-3.

86. Mr. Leschinsky states "the '356 patent includes an inflow tube 9 that is axially aligned with a magnetically driven rotor 18." Leschinsky Decl., ¶131. But in my opinion Mr. Leschinsky is misrepresenting the '356 patent. The specification's lone embodiment has an inflow "tube 9" and "suction end 10" that are angled and bent away from the a "rotor [6]'s" axis:



Ex.1001, Fig. 1 (annotated).

87. Mr. Leschinsky agrees that the lone embodiment of the '356 patent has an inflow tube that curves:

> Q. And element 9, as shown here, has some flexibility or curvature, correct?
>
> A. You're referring to position 10?

> Q. Yes.
>
> A. Well, **it's a little curved** from a straight line, yes.
>
> Q. So if we start at the portion of 9 that's closer to element 6 and we follow that line all the way down to where it's marked 10, you would agree that the central axis follows element 9, correct?
>
> A. I would agree.
>
> Q. So you would agree that the central axis of a tube is not necessarily a straight line?
>
> …
>
> A. It's mostly straight here. Again, it's a cartoon representation. I wouldn't necessarily make too many conclusions from -- from -- I mean, **it does show a little curve** . . . .

Ex.1040, 135:19-136:14.

88. Indeed, the catheter device of the ’356 patent has an inflow “tube 9” and “suction end 10” that curve away from the “rotor [6]’s” axis. Although the inflow tube and its suction end may curve or bend to enter chambers of the heart, it maintains a continuous, central axis running through its cylindrical shape. Even when the catheter’s tube and suction end are not perfectly straight—i.e., it curves—this central axis follows the path of the catheter’s curvature, ultimately

aligning with the axis of the rotor 6. In other words, regardless of the bends or curves, the inflow tube's axis remains colinear and in alignment with the rotor's axis at the point where they join. A POSA would reading the claim term "*axially aligned*" would understand that the '356 patent's lone embodiment illustrates that axial alignment does not require perfect straightness throughout the length of the inflow tube; instead, it means that the central axes of connected cylindrical components—the rotor and inflow tube—can remain colinear and functionally aligned, even if the inflow tube bends.

89. That logic applies equally to the Bourque device. The inflow tube of Bourque has a central axis, and although the Bourque inflow tube (and its axis) may bend at its elbow, its central axis remains axially aligned with the rotor, satisfying the requirement for "*axially aligned*" in the system.

90. Thus, whether the inflow tube of the Bourque device curves through its elbow is inconsequential here, because the "*rotor*" is still "*axially aligned*" with the "*inflow tube*." At any rate, Mr. Leschinsky does not dispute that a rotor axially aligned with an inflow tube is a characteristic feature of a centrifugal pump—by design, fluid enters the pump along its axis towards the rotor. Ex.1003, ¶328; Ex.1008, [0076].

2. Modifying Bourque as taught by Wampler would have been obvious.

91. In my First Declaration, I opined that a POSA would have been motivated to eliminate Bourque's elbow so that its inflow tube would also serve as the inflow cannula. Ex.1003, §X.B.9. Mr. Leschinsky and Dr. Gallegos argue 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. I disagree because there were multiple independent motivations to eliminate Bourque's elbow. Plus, the claims of the '356 patent do not specify whether the pump itself must be placed above or below the diaphragm, as Miracor's experts suggest. At any rate, a POSA would have reasonably expected that the Bourque/Wampler combination could fit either above or below the diaphragm.

v. PO fails to rebut multiple independent reasons to combine Bourque and Wampler.

92. My First Declaration explained that 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**:

1. Wampler expressly teaches that Bourque's "flow-restrictive elbow fitting" was unnecessary. Ex.1003, ¶464;
2. The combination would eliminate "components of its inflow assembly" that caused "clinical troubles." Ex.1003, ¶470;

3. The references are "directed toward the same field of endeavor" (Ex.1003, ¶466), are "reasonably pertinent to a problem described by the [challenged] Patent" (Ex.1003, ¶467), and would have involved merely "the arrangement of old elements" (Ex.1003, ¶468); and

4. Instead of below the diaphragm in a preperitioneal pocket, the combination could be implanted above the diaphragm at "the apex of the heart," which would lead to "reduced infection rates." Ex.1003, ¶¶471–72.

Mr. Leschinsky's and Dr. Gallegos's opinions focus on the fourth reason, contesting whether a POSA would be motivated to fit the Bourque/Wampler combination at the apex of the heart above the diaphragm. POR 27. But fitting the pump at the apex of the heart above the diaphragm is not required by the claims. Because they have not contested the other three motivations which I provided, I rely on my First Declaration for those explanations.

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

93. As I explained in my First Declaration, a POSA "would have had a reasonable expectation of success that the Bourque/Wampler combination" would work "because numerous other similar devices" "with similar designs" "us[ing] an inflow tube that is inserted into the left ventricle" were already in existence. Ex.1003, ¶476. In particular, I referenced Wampler, the HVAD, and the Akamatsu devices. Ex.1003, ¶476.

a. Placement below the diaphragm.

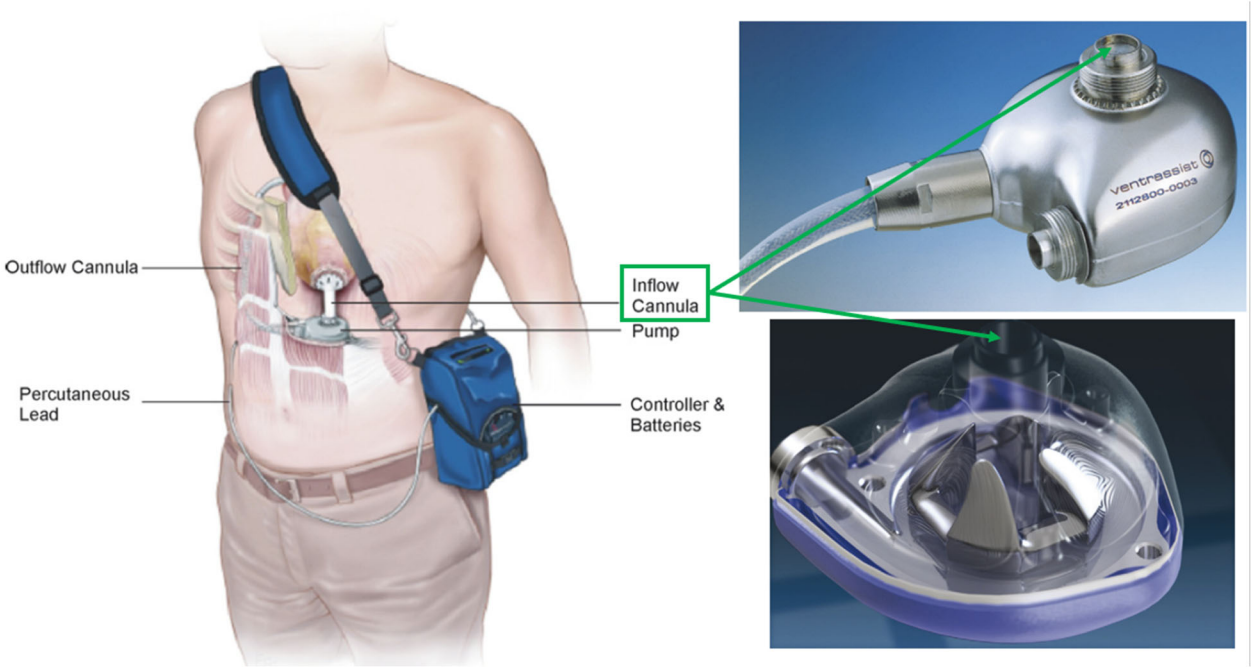
(1) The VentrAssist.

94. Mr. Leschinsky and Dr. Gallegos point to another device—the VentrAssist—to contest whether a POSA would have reasonably expected the Bourque/Wampler combination to work. Mr. Leschinsky and Dr. Gallegos both similarly argue that "VentrAssist was implanted in a preperitoneal pocket rather than at the apex of the heart" (Leschinsky Decl., ¶151) and that POSAs "would have been aware that a device the size of the VentrAssist could … [be placed] in a subdiaphragmatic pocket." Gallegos Decl., ¶57. While Mr. Leschinsky and Dr. Gallegos focus on the subdiaphragmatic placement of the VentrAssist pump, they ignore that the VentrAssist closely resembles the Bourque/Wampler combination and had an *axially aligned* inflow tube that was placed in a ventricle of the heart. Miracor's experts' comparison of these pumps, therefore, supports my opinions that a POSA would have been motivated with a reasonable expectation of success to make the Bourque/Wampler combination.

95. The VentrAssist was developed by my former company, Ventracor. Like the Wampler second embodiment (Figs. 11-14) (i.e., the HVAD), the Bourque pump, Akamatsu (i.e., the DuraHeart), and Schima, the VentrAssist is also a "a third-generation, implantable, centrifugal blood pump." Ex.2013, 2. And

also like those devices, the VentrAssist also uses *magneto coupling* (if broadly construed to include electromagnetic drive) to drive the impeller. Ex.2013, 2 ("The impeller blades spin when an electrical current is sequentially switched between three pairs of coils contained within the pump's titanium housing.").

96. The VentrAssist comprises an *axially-aligned* inflow tube—its inflow "cannula attached from the failing left ventricle delivers blood from the heart to the VentrAssist." Ex.2013, 2. Shown below (left) in white is its "inflow cannula," which aligns with the teaching of Wampler: "[t]he inlet tube [] serves as the inflow cannula and is placed into the apex of the left ventricle." Ex.1003, ¶464 (quoting Ex.1008, [0075]). Shown below (right) is the absence of an elbow in the inflow cannula, which also aligns with the teaching of Wampler: "[o]wing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1003, ¶464 (quoting Ex.1008, [0076]).



Ex.2013, Figs 1-3 (annotated).

97. Mr. Leschinsky and Dr. Gallegos concede that a POSA would have reasonably expected that the Bourque/Wampler combination could be implanted just like the VentrAssist. Mr. Leschinsky testified that "VentrAssist was implanted in a preperitoneal pocket rather than at the apex of the heart, just like the pump in Bourque, and just as a POSA would have expected". Leschinsky Decl., ¶151. Similarly, Dr. Gallegos testified that "[f]or a pump the size of that disclosed in Bourque, I believe a POSA would have appreciated that the preperitoneal or intrabdominal pockets were [] practical options for placement." Gallegos Decl., ¶47. The clinical use of the VentrAssist would have further supported a POSA's reasonable expectation that the Bourque/Wampler combination would work. The

VentrAssist had its "first human use in June 2003." Ex.2013, 2. By 2007, it was "approved for use in Europe ('CE Marked')" and "87 patients ha[d] been implanted with the VentrAssist." Ex.2013, abstract, 8.

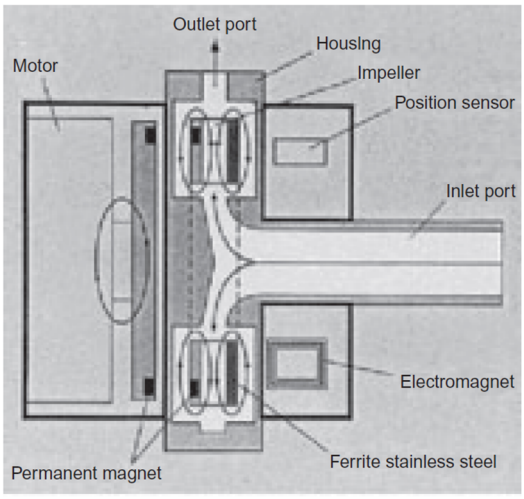
98. On another note, the VentrAssist and the pump disclosed in Schima share numerous features, such that a POSA would understand the Schima pump would be implantable and also would be able to be implanted in the configuration as taught by Akamatsu, as I explained in my First Declaration. For example, both the VentrAssist and Schima have: fittings for connections to an inflow and outflow; a conical impeller and conical housing to facilitate hydrodynamic suspension of the impeller; an axial inflow and radial outflow of the pump, allowing for a 90 degree redirection of the blood without a flow-restrictive elbow fitting; magneto coupling drive (applying Mr. Leschinsky's definition); and other similarities. *Compare* Ex.2013, Figs 1-3 *with* Ex.1005, Fig. 2,

(2) The DuraHeart (i.e., Akamatsu).

99. As discussed in my First Declaration, the Akamatsu pump—"the DuraHeart"—would have similarly provided a POSA with a reasonable expectation of success that the Bourque/Wampler combination would work. Ex.1003, ¶476; Ex.1046. "The technology developed by Akamatsu" was developed into the "DuraHeart VAD." Ex.1046, 325. The "schematic representation of the

maglev concept" of the DuraHeart (left; Ex.1046, FIG. 2(B)) is substantively identical to the schematic representation shown and described in Akamatsu (right; Ex.1006, Fig. 2):

B



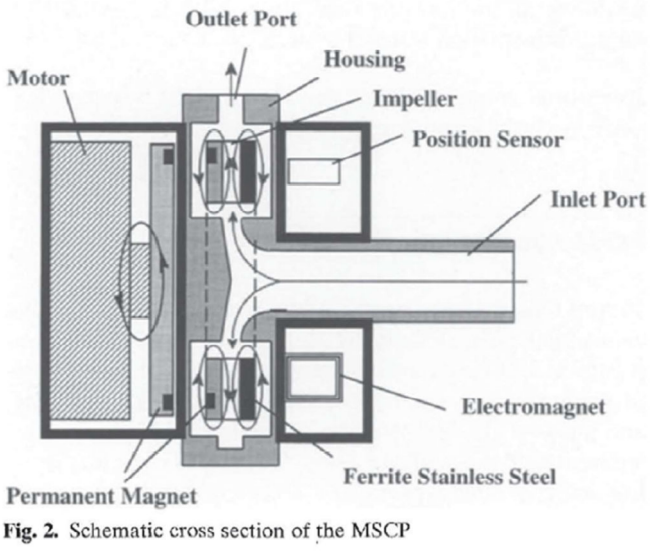


Fig. 2. Schematic cross section of the MSCP

Ex.1046, FIG. 2(B); Ex.1006, Fig. 2.

100. By 2006, the Akamatsu pump had been implanted in 20 patients. Ex.1046, 327. Neither Mr. Leschinsky nor Dr. Gallegos dispute that Akamatsu has an "*axially aligned*" inflow tube. And Mr. Leschinsky concedes that the Akamatsu pump was also "approximately the size of the pump disclosed in Bourque." Leschinsky Decl., ¶187. Given the similar size, that clinical trials had already begun for the Akamatsu DuraHeart device, and that it had an *axially aligned* inflow tube, a POSA would have reasonably expected the Bourque/Wampler combination could similarly fit.

b. Placement above the diaphragm at the apex.

101. By 2007, numerous LVADs had been clinically implanted at the apex of the heart and above the diaphragm. Thus, a POSA would have also expected the Bourque/Wampler combination could fit above the diaphragm at the apex of the heart.

(3) The HVAD (i.e., Wampler's second embodiment (FIGS. 11-14)).

102. Mr. Leschinsky and Dr. Gallegos insist that that implantation at the apex was "aspirational," although it was shown in Wampler. Mr. Leschinsky thought the HVAD was not "clinically implanted" "in a human" until "5 years after the priority date." Leschinsky Decl., ¶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 Decl., ¶163. Dr. Gallegos similarly believed that, "as of the priority date … [i]mplanting these devices at the apex of the heart … was impossible." Gallegos, ¶ 51. Both Mr. Leschinsky and Dr. Gallegos are wrong.

103. By 2006, HeartWare had further developed Wampler's second embodiment (FIGS. 11-14) into the HVAD and begun a clinical trial implanting the device in patients above the diaphragm at the apex of the heart:



Ex.1044.

104. As explained in my First Declaration, 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); **¶¶Error! Reference source not found.-Error! Reference source not found.** (analyzing the HVAD). By 2006, the company commenced a "CE mark clinical study" for "twenty patients" and anticipated sales for the device as early as 2007. Ex.1044; Ex.1041, ¶¶51-61.

(4) Akamatsu studies.

105. In addition to the HVAD, the Akamatsu sheep studies would have provided further assurance to a POSA. "[I]ntrathoracic implantation" of the Akamatsu pump above the diaphragm "demonstrated excellent anatomical fit in a

small [sheep] weighing 45 kg." Ex.1006, 4. Given that the Akamatsu pump was "approximately the size of the pump disclosed in Bourque" (Leschinsky Decl., ¶187), a POSA would expect a similar "anatomical fit" for the Bourque/Wampler combination when implanted intrathoracically, at least for many adults.

(5) Other LVADs.

106. A POSA would have been aware of several other LVADs that had been implanted at the apex of the heart as of the priority date, which would have given a POSA an expectation that the Bourque/Wampler combination could fit there too. For example, the "Jarvik 2000" was inserted into the apex of the left ventricle and small enough "to sit within the ventricle." Ex.2020, 6. Similarly, the MicroMed DeBakey LVAD "is implanted into a pericardial space above the diaphragm" and "connected with the apex of the left ventricle via a titanium inflow cannula and with the ascending aorta by a Dacron graft," as shown in Figure 2:

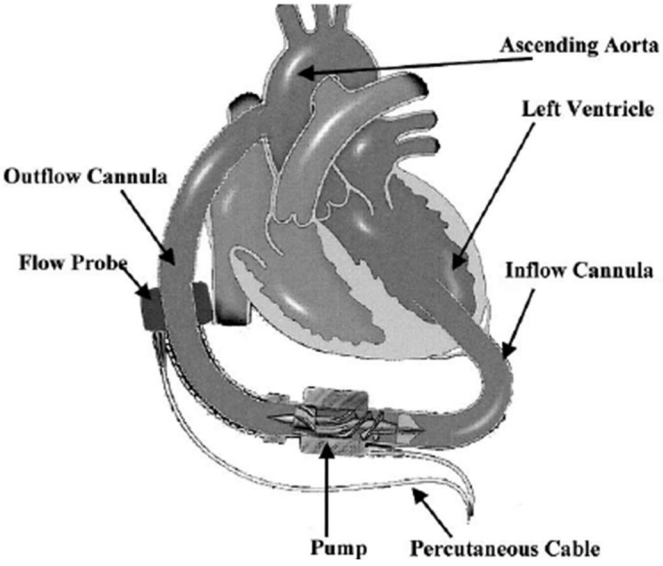


Figure 2. Implantation of the MicroMed DeBakey VAD. The titanium inflow cannula is connected to the apex of the left ventricle and the Dacron outflow cannula to the ascending aorta (published with permission of MicroMed Inc., Woodlands, TX).

Ex.1050, 276.

(6) Enhancements to make the Bourque/Wampler combination smaller.

107. There's no dispute that a POSA would have been motivated to minimize the size of a pump. Ex.2014, 80:1–9 ("I know from my 45 years of experience in this industry that there's a drive to make things smaller all the time."); Ex. 1040, 167:13-17 ("a POSA was generally motivated to make LVAD devices smaller"); Gallegos Decl., ¶62 ("a POSA would have known that any device implanted in the pericardial space should be of minimum possible size to avoid impinging on the heart or adjacent lungs"). But Mr. Leschinsky and Dr. Gallegos ignore that the Bourque/Wampler combination would have been made smaller than the size of the Bourque pump. For instance, Dr. Gallegos concedes

that the proposed modification—to eliminate the elbow—would have "made it smaller." Gallegos Decl., ¶60 (quoting Ex.2007). But instead of appreciating that the Bourque/Wampler combination would have been smaller, Mr. Leschinsky and Dr. Gallegos instead focus entirely on the size of the Bourque pump.

108. As I explained in my First Declaration, "a POSITA would have had a reasonable expectation of success that the Bourque/Wampler combination would fit well between the apex of the heart and the adjacent diaphragm" because of "enhancements to make the device smaller[], which would help its placement at the cardiac apex." Ex.1003, ¶476. Indeed, by 2006, the Bourque author recognized that the pump could be made "mini." Leschinsky Decl., ¶159; Ex. 2007 at 5–6. For example, Mr. Leschinsky concedes that "chip sizes reduced over time, so this allowed shrinking the device" from 2001 by the time of the 2007 priority date. Leschinsky Decl., ¶160. Mr. Leschinsky also concedes that "miniaturized electrical motors" for *magneto coupling* in an LVAD were already disclosed in patents before the priority date. Ex.1040, 64:5-9.

IX. CONCLUSION

109. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and

the like so made are punishable by fine or imprisonment, or both, under section 1101 of Title 18 of the United States Code.

Dated: Monday, December 22, 2025

Peter Crosby