UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Petitioner,

v.

MIRACOR MEDICAL SA,

Patent Owner.

IPR2025-00114
Patent 11,572,879

PATENT OWNER MIRACOR MEDICAL SA'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW

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TABLE OF AUTHORITIES

Cases

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LIST OF EXHIBITS

Exhibit No.	Description
2001	Certification of Todd G. Vare
2002	Corrected Certification of Todd G. Vare
2003	Kenneth K. Liao et al., *End-Stage Congestive Heart Failure in the Adult Population: Ventricular Assist Devices*, Handbook of Cardiac Anatomy, Physiology, and Devices 725–732 (2015)
2004	Howard M. Loree II et al., *The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device*, 25 Artificial Organs 386–391 (2001)
2005	Greg W. Burgreen et al., *Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device*, 28 Artificial Organs 874–880 (2004)
2006	David J. Farrar et al., *Design Features, Developmental Status, and Experimental Results With the Heartmate III Centrifugal Left Ventricular Assist System With a Magnetically Levitated Rotor*, American Society of Artificial Internal Organs (ASAIO) Journal 310–315 (2007)
2007	Abbott, *A Father of HeartMate 3 Wants A Bigger Family*, available at https://www.abbott.com/corpnewsroom/products-and-innovation/a-father-of-heartmate-3-wants-a-bigger-family.html (December 16, 2021)
2008	Kevin Bourque et al., *Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System for Hemocompatibility*, American Society of Artificial Internal Organs (ASAIO) Journal 375–383 (2016)
2009	U.S. Patent No. 10,500,321 to Bourque (issued December 10, 2019)

Exhibit No.	Description
2010	American Heart Association News, *The past, present and future of the device keeping alive Carew, thousands of HF patients*, available at https://www.heart.org/en/news/2018/06/13/the-past-present-and-future-of-the-device-keeping-alive-carew-thousands-of-hf-patients (June 13, 2018)
2011	Chart of Petitioner's Reliance on Pleadings from Parallel Litigation for Claim Construction
2012	Chart of Petitioner's Correlation of Claim Recitations
2013	Donald Esmore et al., *VentrAssist Left Ventricular Assist Device: Clinical Trial Results and Clinical Development Plan Update*, 32 European Journal of Cardio-Thoracic Surgery 735–744 (2007)
2014	Transcript of Deposition of Peter Crosby (September 4, 2025)
2015	Declaration of Boris Leschinsky
2016	Curriculum Vitae of Boris Leschinsky
2017	Declaration of Dr. Robert Gallegos
2018	Curriculum Vitae of Dr. Robert Gallegos
2019	Richard Wampler et al., *A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings*, 23 Artificial Organs 780–784 (1999)
2020	Trever Symalla et al., *Choosing the Appropriate Left Ventricular Assist Device for Your Patient*, 36 (Suppl 2) Indian Journal of Thoracic and Cardiovascular Surgery S256–S264.
2021	Milad Hosseinipour et al., *Rotary Mechanical Circulatory Support Systems*, 4 Journal of Rehabilitation and Assistive Technologies Engineering, 1–24 (2017)

Exhibit No.	Description
2022	Martin Stoiber et al., *A Passive Magnetically and Hydrodynamically Suspended Rotary Blood Pump*, 33 Artificial Organs 250–257 (2009)

CHALLENGED CLAIMS

Claim No.	Claim Language
[1PRE]	A system for assisting blood circulation of a heart, the system comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path aligned with a central axis;
[1B]	a magnetically driven rotor aligned with the central axis and
[1C]	that is rotatable about the central axis within a surrounding rotor housing to drive blood flowing from the inflow tube toward the magnetically driven rotor,
[1D]	the magnetically driven rotor being rigidly coupled and axially adjacent to a first magnetic device within the surrounding rotor housing;
[1E]	a second magnetic device axially aligned with the central axis
[1F]	and positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device
[1G]	while both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap sized for passage of the blood during rotation of the magnetically driven rotor; and
[1H]	a blood outflow port positioned radially adjacent the magnetically driven rotor such that the blood driven by the magnetically driven rotor exits the surrounding rotor housing in a direction substantially perpendicular to the central axis,
[1I]	wherein the magneto coupling orients the magnetically driven rotor so that the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and

Claim No.	Claim Language
[1J]	an external control unit configured to regulate operation of the second magnetic device, the external control unit being positionable exterior to a body when the heart assist pump device is delivered to the heart, wherein the external control unit is connectable to the heart assist pump device for operating the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.
[2]	The system of claim 1, wherein the magnetically driven rotor comprises: a guide surface to produce centrifugal flow components.
[4]	The system of claim 1, wherein the heart assist pump device further comprises a sealing wall positioned between the second magnetic device and the magnetically driven rotor.
[5]	The system of claim 4, wherein the sealing wall at least partially defines the gap sized for passage of the blood.
[7]	The system of claim 1, wherein the first magnetic device is positioned within a first chamber, the second magnetic device is positioned within a second chamber, and the first chamber is sealed from the second chamber
[8]	The system of claim 7, wherein the heart assist pump device further comprises a wall separating the first chamber from the second chamber.
[11PRE]	A system for assisting blood circulation of a heart, the system comprising:
[11A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[11B]	one or more walls at least partially defining a chamber to receive blood from the inflow tube;

Claim No.	Claim Language
[11C]	a magnetically driven rotor axially aligned with the inflow axis
[11D]	and [the magnetically driven rotor] being rigidly coupled and axially adjacent to a first magnetic device that is axially aligned with the inflow axis,
[11E]	the magnetically driven rotor and first magnetic device being rotatable about an axis of rotation aligned with the inflow axis to drive the blood flowing from the inflow tube;
[11F]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[11G]	and [the second magnetic device is] spaced apart from the magnetically driven rotor such that a wall of the one or more walls defining the chamber is positioned between the magnetically driven rotor and the second magnetic device,
[11H]	the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor so as to magnetically drive rotation of the magnetically driven rotor relative to the one or more walls via a magneto coupling with the first magnetic device; and
[11I]	a blood outflow port positioned such that the blood driven by the magnetically driven rotor exits the chamber in a direction substantially perpendicular to the inflow axis
[11J]	wherein the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor; and
[11K]	an external control unit configured to control operation of the second magnetic device based on a fixed value to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device.

Claim No.	Claim Language
[12]	The system of claim 11, wherein the magnetically driven rotor includes a guide surface to produce centrifugal flow components.
[14]	The system of claim 11, wherein the one or more walls and the magnetically driven rotor define a gap separating the magnetically driven rotor from the one or more walls, the gap configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor.
[15]	The system of claim 14, wherein the gap surrounds the magnetically driven rotor.
[16]	The system of claim 14, wherein at least part of the gap extends along a first axis substantially perpendicular to the inflow axis.
[18]	The system of claim 11, wherein the chamber is a first chamber within which the magnetically driven rotor is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[19]	The system of claim 18, wherein the wall of the one or more walls separates the first chamber from the second chamber.
[20]	The system of claim 11, wherein the external control unit is configured to regulate operation of the second magnetic device based on a defined cardiac output.

I. INTRODUCTION

Pursuant to 35 U.S.C. § 316(a)(8) and 37 C.F.R. § 42.120, Patent Owner Miracor Medical SA files this response to the Petition ("Pet.") for *Inter Partes* Review of U.S. Patent 11,572,879.

An Institution Decision dated June 10, 2025 (Paper 13), instituted trial to determine whether Petitioner has met its burden to show that challenged claims 1, 2, 4, 5, 7, 8, 11, 12, 14–16, and 18–20 of U.S. Patent No. 11,572,879 (Ex. 1001, herein "the '879 patent") are unpatentable on the following four Grounds:

1. Obviousness of all challenged claims over Wampler (Ex. 1008)
2. Obviousness of all challenged claims over Bourque-2001 (Ex. 1007) and Wampler (Ex. 1008)
3. Obviousness of all challenged claims over Akamatsu (Ex. 1006)
4. Obviousness of all challenged claims over Schima (Ex. 1005) and Akamatsu (Ex. 1006)

As explained herein and in the accompanying declarations of Boris Leschinsky (Ex. 2015, referred to herein as "Leschinsky") and Dr. Robert Gallegos (Ex. 2017, referred to herein as "Gallegos"), the Petition fails to show by a preponderance of evidence that the challenged claims are unpatentable.

With regard to Grounds 1 and 3, independent claims 1 and 11 require, among other things, a magnetically driven rotor of a heart assist pump be rigidly coupled and axially adjacent to a first magnetic device. As the Board recognized in its Institution Decision, neither Wampler nor Akamatsu teaches or suggests such a feature.

With regard to Ground 2, independent claims 1 and 11 require, among other things, that a magnetically driven rotor be axially aligned with an inflow axis defined by an inflow tube of a heart assist pump. As the Board recognized in its Institution Decision, Bourque-2001 does not teach or suggest such a feature, meaning it cannot render the challenged claims obvious alone. To remedy this and other deficiencies of Bourque-2001 related to its positioning relative to a heart, Petitioner combines Bourque-2001 with Wampler to modify the inflow tube of Bourque-2001 and deliver the pump of Bourque-2001 to the heart, as disclosed in Wampler. This combination, however, would not have been made a person of ordinary skill in the art ("POSA") at the time of the invention, as attested to by Mr. Leschinsky and Dr. Gallegos. In particular, the size of the pump in Bourque-2001 would have been impossible to deliver to the heart in the disclosed manner at the time of the invention, a fact that a POSA would have readily appreciated.

Finally, with regard to Ground 4, independent claims 1 and 11 require, among other things, a heart assist pump deliverable to the heart. Petitioner admits

that Schima lacks any such teaching and contends that a POSA would have delivered the pump of Schima in the manner of Akamatsu. This combination, however, would not have been made a POSA at the time of the invention, as attested to by Mr. Leschinsky and Dr. Gallegos. In particular, Akamatsu cannot be relied upon for the contended teaching because the size of the pump in Akamatsu would have been impossible to deliver to the heart in the contended manner at the time of the invention (like the pump in Bourque-2001) and because a POSA would have appreciated that the pump in Schima is not deliverable to the heart in the contended manner due to its configuration for extracorporeal use.

II. PERSON OF ORDINARY SKILL IN THE ART

Petitioner and its expert (Peter Crosby, whose declaration, Exhibit 1003, is referred to herein as "Crosby") have asserted that a POSA would be a person with "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." Pet. at 7 (citing Crosby, ¶ 18). While Patent Owner did not take a position on the level of skill in the art prior to institution, Patent Owner contends that a POSA would have a level of skill more particularly tailored to the field of implantable cardiac assist devices. That is, a POSA would possess 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 cardiac assist devices in particular.

Mr. Leschinsky testifies that this more specifically-directed level of skill in the art reflects the complicated and critical nature of cardiac assist devices. Leschinsky, ¶ 59. The field is high risk due to the level of complication involved in device development and the critical, life-supporting nature of the heart and associated circulatory system. *Id.* Dr. Gallegos, an experienced surgeon who implants cardiac assist devices, agrees with Mr. Leschinsky's assessment. Gallegos, ¶ 34.

To this point, Mr. Leschinsky notes that certain contentions from Petitioner and its expert, Mr. Crosby, fly in the face of what a POSA at the time of the invention would have understood was possible or advisable. Leschinsky, ¶ 60. Mr. Crosby's experience with continuous flow cardiac assist devices is more limited than that of Mr. Leschinsky and Dr. Gallegos—Mr. Crosby's only specific experience was serving as an executive at a company developing an implantable continuous flow cardiac assist device over 15 years ago. *Id.*; Ex. 1004. This lack of specific engineering experience designing and developing an implantable cardiac assist device, in contrast to Mr. Leschinsky, as well as lack of experience actually

implanting such devices, in contrast to Dr. Gallegos, may explain certain of Mr. Crosby's contentions that Patent Owner's experts find clearly incorrect.

III. CLAIM CONSTRUCTION

A. Patent Owner Agrees With Claim Constructions Adopted By The Board In The Institution Decision

In the Institution Decision, the Board adopted broader constructions of "magneto coupling" and "by the blood" over narrower constructions advanced by Petitioner. Paper 13 at 26–28. Patent Owner agrees with this decision and believes the adopted broader constructions for these terms are correct.

In addition, the Board adopted Patent Owner's proposed construction for the term "axially adjacent" as reflecting the plain and ordinary meaning of the term consistent with the disclosure of the '879 patent. *Id.* at 29–30. Patent Owner agrees with this decision as well.

B. "Magneto Coupling"

For the purpose of Petitioner's argument regarding its narrower construction, there are two types of magnetic couplings. The first type of magnetic coupling involves one permanent magnet driving movement of another permanent magnet. Pet. at 8–9. A second type of magnetic coupling involves an electromagnet (a stator) driving movement of a permanent magnet. Petitioner argues that "magneto coupling" as used in the '879 patent should be limited to the first type (two

permanent magnets) and that it must exclude the second type (electromagnetic driver), based on examples in the literature referring to a two-permanent-magnet system as magnetically coupled. *Id*.

But Petitioner does not believe its own proposed narrower construction. Both Wampler and Bourque-2001 use electromagnetic drivers—if the Board were to adopt Petitioner's proposed claim construction, Ground 1 and Ground 2 would necessarily fail.

Mr. Leschinsky testifies that the term "magneto coupling," which is a translation from the original German "MagnetKupplung" that simply means "magnetic coupling," would have been understood by a POSA as simply a way to couple the rotor to a drive element while sealing the two from one another and avoiding use of a direct mechanical coupling. Leschinsky, ¶ 67. There is no indication in the specification of the '879 patent that its disclosure of dual rotating magnets is anything other than a non-limiting example of a magnetic coupling. *Id.* at ¶ 66. Both rotating magnets and static magnetic drives were generally known at the time of the invention. *Id.* at ¶ 65. Schima, for example, shows both types of magnetic drives as interchangeable ways to drive the rotor. *Id.* at ¶ 68; Ex. 1005, Figs. 1–4 and [0012]–[0016].

Petitioner provides no recognizable basis for limiting the plain meaning of magnetic coupling to one type of magnet and excluding another type of magnet.

See Johnson Worldwide Associates, Inc., v. Zebco Corp., 175 F.3d 985, 989–992 (Fed. Cir. 1999) (claim terms are given full effect of their ordinary and customary meaning unless otherwise compelled, including giving full meaning to general descriptive terms without adding modifiers to broad terms).

The Board should not adopt this narrower claim construction. Instead, the Board should maintain its position in the Institution Decision to give "magneto coupling" its plain and ordinary meaning, which would encompass a magnetic coupling through both rotating magnets and the use of a rotating magnetic field developed from an electromagnetic driver.

C. "By The Blood"

When advocating for their narrower construction, Petitioner takes the phrase "by the blood" out of context from claim recitations [1I] and [11J] and argues, because of an example in the specification and some examples in the art, that the term "by the blood" requires the claimed medical device to have hydrodynamic bearings and that the term excludes devices having magnetic bearings. Pet. at 9–10. Again, this proposed claim construction would render Ground 2 null because the Bourque-2001 reference applies magnetic bearings.

Petitioner's analysis for this narrower construction leaves out entirely the recitation in claim elements [1I] and [11J] that it is the magneto coupling that

orients the rotor to this position where the blood flows between the rotor and the housing—that is, oriented so that there is a space between the rotor and housing that is filled by blood. Mr. Leschinsky testifies that a POSA would have understood that the magnetic coupling orients the magnetically driven rotor to be spaced apart from the surrounding rotor housing, i.e., dictates the position of the rotor in space. Leschinsky, ¶ 74. There is no reason that magnetic bearings should be excluded from the scope of the claim.

Put back in context, "by the blood" means that the rotor is spaced apart from the housing and surrounded by blood, regardless of whether that positioning is achieved via magnetic or hydrodynamic bearings. *Id.* at ¶ 76. This broader construction, which the Board adopted in its Institution Decision, is consistent with the plain meaning of the claim language.

The Board should not adopt Petitioner's narrower claim construction. Instead, the Board should maintain its position in the Institution Decision to give "by the blood" its plain and ordinary meaning, which would encompass both a magnetic bearing and a hydrodynamic bearing.

D. "Axially Adjacent"

Patent Owner endorses the position adopted by the Board in the Institution Decision to give the term "axially adjacent" its plain and ordinary meaning as

"adjacent to one another as measured along a central axis." Paper 13 at 29–30. Mr. Leschinsky testifies that this definition is consistent with what a POSA would have understood at the time of the invention. Leschinsky, ¶ 77.

As noted by the Board in the Institution Decision, Petitioner has not argued for a different plain and ordinary meaning of "axially adjacent" and does not identify any support a different construction from the specification of the '879 patent or any extrinsic evidence. Paper 13 at 28. The only support identified by Petitioner when asserting that a magnetic element sealed within a rotor is at a position axially adjacent thereto is Exhibit 1019 (a claim chart included as part of a complaint in the co-pending district court case). *Id.* at 28–29.

As the Board noted, however, there is nothing in Ex. 1019 that so defines the term "axially adjacent." *Id.* Just the opposite, Ex. 1019 at 5–7 contains no mention of "a magnetic element sealed within a rotor" or a contention that such a configuration would represent an "axially adjacent" orientation of such components. Instead, Patent Owner illustrates a Petitioner product and labels components identified as the claimed magnetically driven rotor and first magnetic device that are adjacent to one another as measured along a central axis. This is in accordance with the plain and ordinary meaning of the claim terms and does not suggest that any component "sealed within" another component would categorically be axially adjacent thereto.

In addition and as the Board noted, Patent Owner's proposed construction of this term is consistent with Petitioner's own construction in alleging unpatentability of the challenged claims based on the asserted combination of Bourque-2001 and Wampler. *Id.* at 29–30.

The Board should therefore maintain the claim construction adopted in the Institution Decision as its plain and ordinary meaning consistent with the '879 patent.

E. Throughout The Petition And The Crosby Declaration, Petitioner Engages In Improper Claim Construction Based On The Notice Pleadings From Co-Pending Litigation

As noted above, Petitioner and its expert repeatedly point to the complaint in the co-pending district court case and adopt correspondences alleged in a claim chart there (Ex. 1019) as "claim constructions." This analysis, repeated more than a dozen times,[1] ignores the plain and ordinary meaning of the claim terms and applies advocacy to twist their meaning in a way that benefits Petitioner's arguments.

[1] Exhibit 2011 details Petitioner's repeated reference to the pleadings in the co-pending litigation as a statement of claim construction.

In its Institution Decision, the Board rejected this kind of analysis at least with regard to the term "at a position axially adjacent," and Patent Owner urges that it be similarly rejected where otherwise utilized. *Id.* at 28–29.

IV. THE PETITION FAILS TO ESTABLISH THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Wampler Fails To Render Obvious Claims 1, 2, 4, 5, 7, 8, 11, 12, 14–16, And 18–20 (Ground 1)

The Petition fails to demonstrate that independent claims 1 and 11 of the '879 patent would have been obvious over Wampler[2] alone and therefore fails to prove any claim unpatentable under Ground 1.

1. Wampler Does Not Teach Or Suggest A Magnetically Driven Rotor Being Axially Adjacent To A First Magnetic Device [1D], [11D]

Petitioner has not shown that Wampler teaches or suggests a system for assisting blood circulation of a heart including a magnetically driven rotor rigidly coupled and axially adjacent to a first magnetic device, as recited in independent claim elements [1D] and [11D]. The Institution Decision agrees with Patent Owner that the challenged claims are not obvious over Wampler:

[2] Described at Leschinsky, ¶¶ 84–87.

> Petitioner does not contend or show in the Petition that Wampler teaches a magnetically driven rotor adjacent to a first magnetic device as measured along a central axis.

Paper 13 at 30.

Petitioner's case rests on pointing to parallel litigation and contending that Patent Owner has taken a position that "a magnetic element sealed within a rotor is 'at a position axially adjacent to the magnetically driven rotor.'" Pet. at 24. Support for this contention is supposedly found in Exhibit 1019 at 5–7. *Id.* Petitioner adopts this interpretation to conclude that Wampler's disclosure of permanent magnet segments that are imbedded within the impeller represent components that are axially adjacent to one another. *Id.* at 24–26.

Patent Owner notes that Exhibit 1019 at 5–7 contains no mention of "a magnetic element sealed within a rotor" or a contention that such a configuration would represent an "axially adjacent" orientation of such components. Instead, Patent Owner illustrates a Petitioner product and identifies the claimed magnetically driven rotor and first magnetic device that are adjacent to one another along a central axis. This is in accordance with the plain and ordinary meaning of the claim terms and does not suggest that any component "sealed within" another component would categorically be axially adjacent thereto. Leschinsky, ¶ 78.

Petitioner further supports their conclusion that Wampler teaches claim elements [1D] and [11D] with the conclusory statement that any components "situated next to each other on the same axis" would be axially adjacent. Pet. at 24. Petitioner supports this statement with reference to FIGS. 12 and 13 by its expert, along with conclusory statements regarding these figures showing axial adjacency of magnet segments 88 and impeller 74. Crosby, ¶¶ 183. Such statements, however, ignore the plain and ordinary meaning of the claim terms that specify which axis is implicated. Leschinsky, ¶ 79.

Claim element [1C], for example, recites that the magnetically driven rotor is rotatable about a central axis, and element [1D] recites that the magnetically driven rotor is rigidly coupled to a first magnetic device. Accordingly, the additional recitation in claim element [1D] that the magnetically driven rotor is axially adjacent to the first magnetic device would plainly mean that the two components are positioned adjacent to one another as measured along the previously recited central axis about which the magnetically driven rotor can rotate. Leschinsky, ¶ 80. Such an arrangement would therefore suggest that these two components are disposed next to—and not in the same position as—one another, as measured along the central axis about which the rotor can rotate. *Id*.

The claim further demonstrates the plain meaning of axial adjacency in element [1H] by referencing the counterpart concept of radial adjacency. In

particular, element [1H] recites that a blood outflow port is positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor exits the surrounding rotor housing in a direction substantially perpendicular to the central axis. Accordingly, the claim makes clear an understanding that "radial adjacency" involves positioning along a radial direction extending outward from the central axis of the magnetically driven rotor in a manner that is perpendicular to the central axis of the magnetically driven rotor. *Id.* at ¶ 81. This also clarifies that "axial adjacency" involves positioning in a direction extending along the central axis of the magnetically driven rotor that is parallel to, or coextensive with, the central axis of the magnetically driven rotor. *Id*.

Similar recitations are found in independent claim 11, for example, [11E] and [11D] that define similar relationships relative to an inflow axis defined by an inflow tube of the pump.

In view of the recitations throughout claims 1 and 11, and the plain and ordinary meaning of the terms used, Petitioner's contention that it can choose any axis to meet the recitation of "axially adjacent" is incorrect.

Further, the concept of "adjacent" components is clear from its plain and ordinary meaning. Adjacent components along an axis have positioning that is next to one another, perhaps touching or sharing a common side, when measured along the axis. *Id.* at ¶ 82. This is distinct from components that are aligned with one

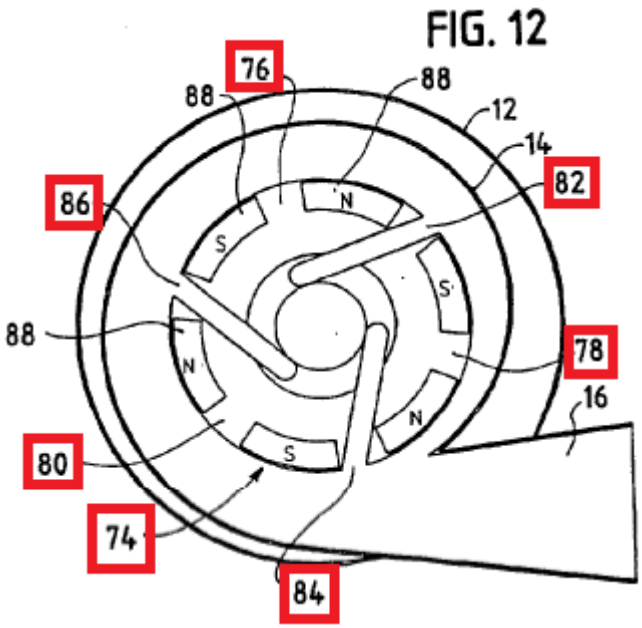
another such that they overlap or occupy the same portion of an axis upon which they are positioned. *Id*.

Accordingly, Wampler cannot teach or suggest a magnetically driven rotor that is axially adjacent to a first magnetic device based on the positioning of its magnet segments 88 and impeller 74 because these components are not adjacent to one another as measured along the central axis of the device. Instead, the magnet segments 88 and impeller 74 are aligned with, and overlap, one another as measured along the central axis based on the disclosed configuration where the magnet segments are housed within the impeller blades. *See* Ex. 1008, ¶ [0018] and FIGS. 3, 4, 7, 9, 11, 13, 15, 17, and 19.

2. Wampler Does Not Teach Or Suggest A Second Magnetic Device Positioned Axially Closer To A First Magnetic Device Than To A Magnetically Driven Rotor [11H]

Petitioner has not shown that Wampler teaches or suggests a "system for assisting the blood circulation of a heart" with "the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor."

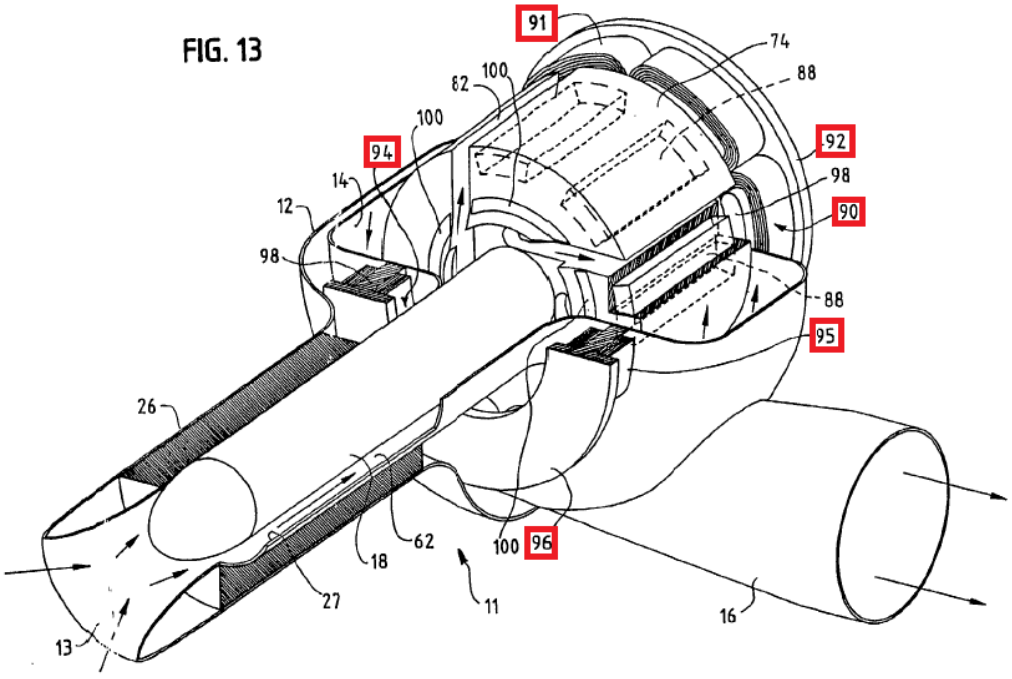
Before comparing the positions of the recited elements, it is important to understand what the three recited elements are. Petitioner first identifies Wampler's impeller 74 as the "magnetically driven rotor." Pet. at 21. As shown in Figure 12 of Wampler (shown to the right), the impeller 74 includes three "blade sectors" 76, 78, 80 that are separated by slots 82, 84, 86. Ex. 1008, ¶ [0078]; *see also* Pet. at 24 (coloring the same figure to illustrate a "magnetically driven rotor"). Wampler asserts that these thick blades with slots (providing the working surfaces for pumping blood) allow a small pump with a small number of blades that will potentially damage the pumped blood less, while maintaining reasonable pump efficiency. Ex. 1008, ¶ [0078].



Petitioner identifies the six motor rotor magnets 88, illustrated in Figure 12 above, as the claimed "first magnetic device." Pet. at 21–23, 31.

Turning to the "second magnetic device," Petitioner identifies two motor stators 90, 94 as the corresponding feature in Wampler. Pet. at 33. Figure 13 (shown below) illustrates that these two motor stators 90, 94 are located on

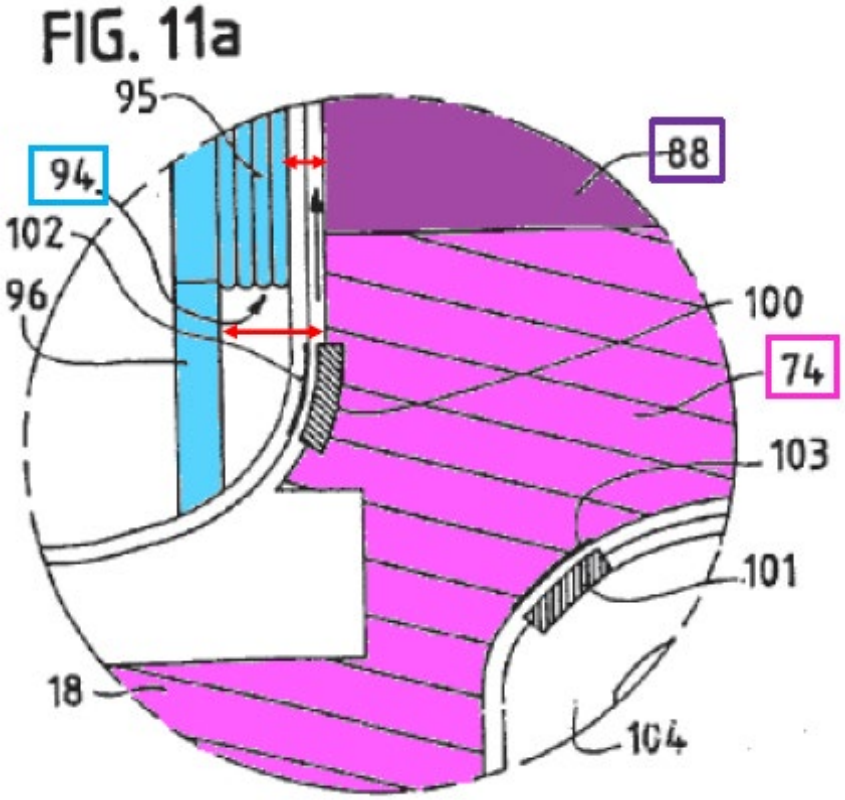
opposite sides of the impeller 74. Ex. 1008, ¶¶ [0084]–[0085]. One motor stator 90 includes windings 91 and a back iron 92. The second motor stator 94 includes winding 95 and a back iron 96. The purpose of each back iron is to "complete a magnetic circuit." *Id*.



Petitioner then simply states that the "positioned axially closer to" claim limitation is met without any reason for saying so. Pet. at 31–32. But it is clear from a casual review of Wampler, for example in Figure 13 above, that the "first magnetic device" (rotor magnets 88) are embedded within the "magnetically driven rotor" (impeller 74). Leschinsky, ¶ 105. Accordingly, the second magnetic device cannot be positioned axially closer to the first magnetic device than to the magnetically driven rotor at least because the impeller 74 (rotor) *surrounds* the

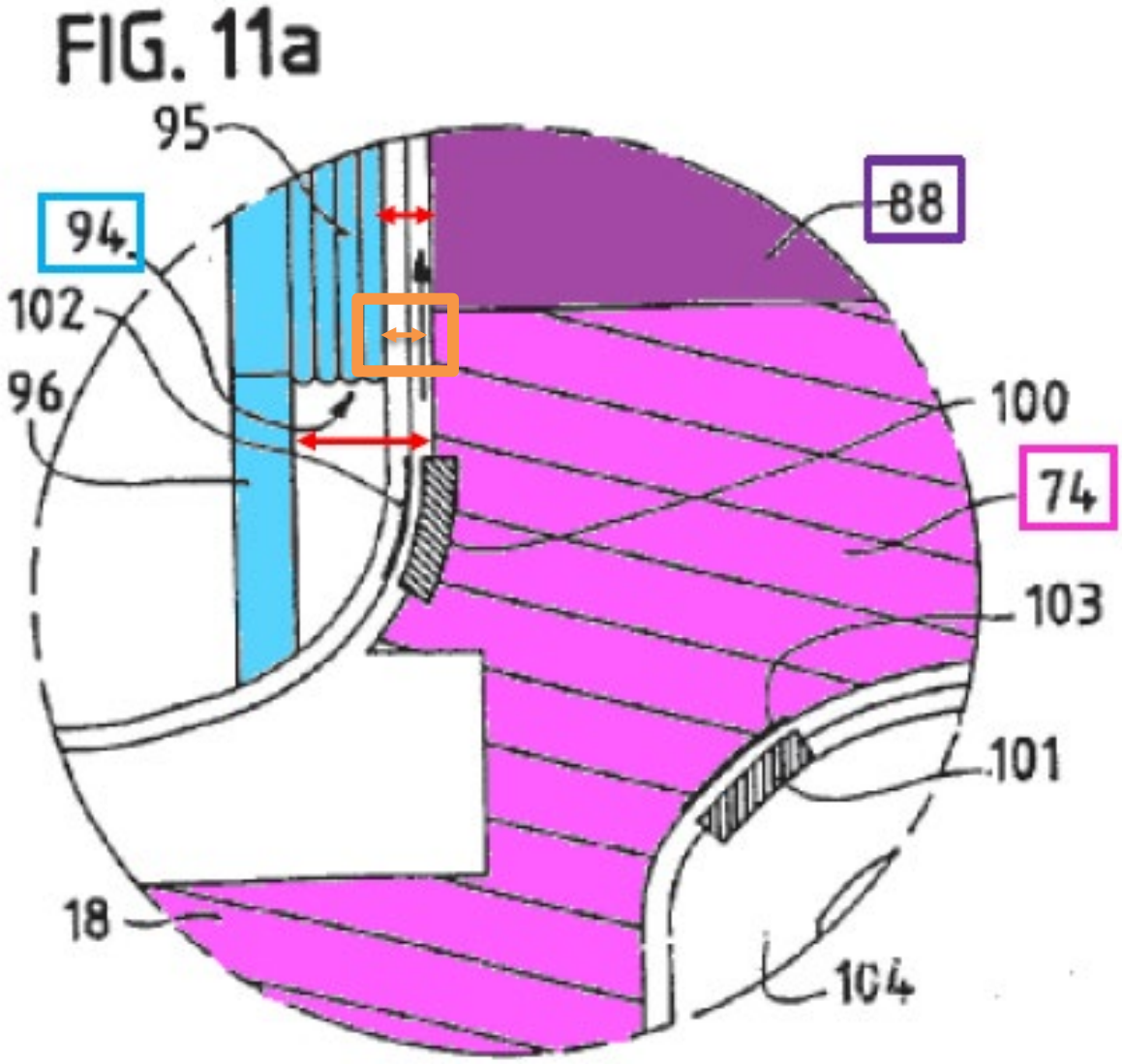
rotor magnets 88 (first magnetic device). *Id.* Wampler does not teach or suggest this claim element.

Faced with these facts, Petitioner misdirects. Relying on its expert, Petitioner argues that the "back iron 96," which completes a magnetic circuit, is farther from the magnetically driven rotor 74 than the stator coil 95, which provides the magnetic field that corresponds to the second magnetic device, is from the rotor magnet 88. Pet. at 32–34. Petitioner provides the following misleading Figure with two red arrows denoting measurement distances to illustrate its incorrect view that the second magnetic device is farther from the magnetically driven rotor than from the first magnetic device:



Pet. at 32.

Petitioner defines the second magnetic device in two different ways in order to make its false comparison—without any rationale for doing so other than to force its unpatentability position. To make the comparison correctly where different portions of the second magnetic device are at different distances relative to the magnetically driven rotor, a minimum distance should be utilized. Leschinsky, ¶ 107. This is done in the image below, where an orange arrow (highlighted within an orange box) is added to Petitioner's figure and shows that the second magnetic device is the exact same distance from the magnetically driven rotor and the first magnetic device. There can be no doubt that this claim recitation is not met. *Id.* at ¶ 108.



Unable to show how Wampler teaches or suggests this claim element, Petitioner baldly asserts, in a footnote, that it was "an obvious design choice" because it is inconsequential. Pet. at 33, n.8. Notably, this assertion is inconsistent with the testimony of Petitioner's own expert, who argues that a POSITA would have been focused on adjusting the distance between the stator 94 and the magnets 88. Crosby, ¶ 216. Mr. Crosby's analysis, however, is addressed nowhere in the

Petition and is also incomplete. Even if Petitioner is right that the distance between the stator 94 and the magnet 88 matters—that still has no effect on the relative distance between the stator 94 and the magnet 88 as opposed to the stator 94 and the impeller 74. Leschinsky, ¶ 109.

Petitioner further argues that, in parallel litigation, Patent Owner identifies that the stator provides a magneto coupling with the first magnetic device. Pet. at 33. Again, though, this has nothing to do with the relative distance between the stator and the impeller. Petitioner grasps at straws because there is no teaching or suggestion, and a POSA would find none, for element [11H] in Wampler.

Accordingly, Wampler cannot teach or suggest a second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor. *See* Ex. 1008, ¶ [0078], [0084]–[0085] and FIGS. 11, 12, and 13.

3. Ground 1 Impermissibly Mixes Teachings From Distinct Embodiments Without A Supporting Rationale

Petitioner also impermissibly selects features from distinct embodiments in Wampler without providing any analysis regarding *why* they would have been combined in the contended manner. Unless supported by the obviousness analysis required under Section 103, such mixing and matching of distinct embodiments within a single disclosure has been deemed inappropriate by the Board and the Federal Circuit.

For example, in *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, the Board found that the petition "fail[ed] to provide a sufficient rationale to combine teachings of [the cited reference's] different embodiments. Petitioner simply fails to explain sufficiently *why* one skilled in the art would have found it obvious to combine those teachings." IPR2017-01204, Paper 9 at 11 (PTAB Oct. 23, 2017) (emphasis in original). The petition's failure to provide such an explanation left the Board "unpersuaded that the features of [the cited reference's] various embodiments are interchangeable or that one skilled in the art would have combined those features in the manner proposed." *Id.* The obviousness grounds presented here are likewise deficient because they "fail to present any evidence regarding the factual considerations underlying the obviousness inquiry, including whether a skilled artisan would have been motivated" to combine distinct embodiments taught in a single reference. *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1403 (Fed. Cir. 2022); *see also In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) ("Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.").

Further, Petitioner's expert has admitted that Wampler discloses multiple distinct embodiments of a pump. Ex. 2014 at 34–35. ***Petitioner's expert also contends that he relies only on one of these embodiments, i.e., the embodiment***

shown in FIGS. 11 et seq. *Id*. But this is clearly not the case because Petitioner and its expert rely on teachings from other figures (e.g., FIG. 5) showing a different embodiment (i.e., the embodiment shown in FIGS. 1–8), though there is no discussion of why such teachings can be combined.

Examples of Petitioner's selective picking and choosing of features from distinct embodiments in Wampler without providing any supporting rationale for combining are discussed under the sub-headings below. Each of these unsupported modifications is improper.

a. Wampler's First Embodiment Lacks At Least A Second Magnetic Device Positioned Axially Closer To A First Magnetic Device Than To A Magnetically Driven Rotor [11H] And A Magneto Coupling That Orients A Magnetically Driven Rotor So That The Rotor Remains Spaced Apart From The Housing / Walls [1I], [11J]

For claim elements [11A] and [11K] (as well as claim elements [1A] and [1J], Petitioner relies on the pump embodiment shown in Wampler's FIGS. 1–8. Pet. at 16–18, 39–40, 47. Petitioner must do so because only this first embodiment of Wampler is illustrated and described as being delivered to the heart and including controller 59 and power supply 61 that "may be worn external by the user." Ex. 1008 at [0070], [0075], FIG. 5.

For claim elements [11B]–[11J] (as well as claim elements [1B]–[1I]), however, Petitioner cites primarily (and sometimes exclusively) to features of the

pump embodiment shown in Wampler's FIGS. 11–14. Pet. at 18–39. For example, with respect to claim element [11H], Petitioner relies entirely on the later embodiment of Figures 11–14 of Wampler, as discussed above in Section IV.A.2 (neither those figures, nor any other portion of Wampler, teaches or suggests this claim element but, for the present purposes, it is sufficient to note that the cited figures relate to an alternative embodiment of Wampler.). Still further and as noted above, Petitioner's expert has admitted that Wampler discloses multiple distinct embodiments of a pump, but they are relying only on one of these embodiments, i.e., the embodiment shown in FIG. 11. Ex. 2014 at 34–35.

For claim element [11J], which requires that "the magneto coupling orients the magnetically driven rotor so that both the magnetically driven rotor and the first magnetic device remain spaced apart from the one or more walls by the blood in response to rotation of the magnetically driven rotor," and the similar recitation of claim element [1I], the Petition again relies entirely on the pump embodiment of Figures 11–14 of Wampler. Petitioner's discussion of this claim element focuses on Wampler's disclosure of hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102, 103 that are carried by either the impeller or the casing, or an attachment to the casing. Pet. at 37–39, 47; Crosby, ¶¶ 238–241; Ex. 1008, ¶¶ [0089]–[0092]. Petitioner asserts that, in response to rotation of the impeller 74, these "hydrodynamic bearing[s] 'forces the raised pad and the contact

surface apart,' such that the impeller 74 remains entirely spaced apart from the casing 14." Crosby, ¶ 240 (quoting from Ex. 1008, ¶ [0092]).

Of course, Petitioner cannot rely on Wampler's first embodiment (FIGS. 1–8) for claim elements [1I] and [11J] because that embodiment includes thrust bearings 39 and 41 to maintain positioning of the rotor 17 relative to the housing 12. Ex. 1008 at [0058]–[0062], FIG. 7; Leschinsky, ¶ 113. Given that the thrust bearings 39, 41 involve *contact* with the rotor 17, this embodiment cannot satisfy the recitation of elements [1I] and [11J] that the magnetically driven rotor remains *spaced apart* from the surrounding rotor housing in response to rotation of the rotor. Leschinsky, ¶ 113.

Although Petitioner has cherry-picked features from distinct embodiments of Wampler in an attempt to arrive at the claimed invention, the Petition provides no explanation whatsoever about *how or why* a POSITA would have combined these different embodiments in the contended manner. This deficient analysis fails to show that the challenged claims are obvious over Wampler.

b. Wampler's Later Embodiment Lacks At Least An External Control Unit [1j], [11k]

Claims 1 and 11 each recite "an external control unit" configured to regulate or control operation of a second magnetic device to thereby magnetically drive the rotation of a magnetically driven rotor via a magneto coupling with a first magnetic

device. Once again, Petitioner attempts to arrive at a system with these features by jumping between disclosed embodiments in Wampler without explaining how or why a POSITA would have been motivated to combine the embodiments in the manner contended.

In this instance, Petitioner has relied on the pump of FIG. 11 to allegedly teach the first and second magnetic devices, magneto coupling therebetween, and other elements of claims 1 and 11. *See generally* Pet. at 18–39, 47. Indeed, Mr. Crosby has indicated he is relying only on the embodiment shown in FIG. 11. Ex. 2014 at 34–35. For elements [1J] and [11K], however, Petitioner cites to controller 59 shown in FIG. 5 of Wampler, which shows the controller in use with the pump embodiment of FIGS. 1–8. Pet. at 39–40; Ex. 1008, ¶¶ [0070]–[0072].

There is, however, no disclosure in Wampler of the pump of FIG. 11 coupled to the controller 59 of FIG. 5. Leschinsky, ¶ 115. Nor is there any argument or reasoning provided by Petitioner or its expert regarding how or why a POSA would have combined the two embodiments disclosed in Wampler. To the contrary, Petitioner appears to assume complete combinability and interchangeability between the various embodiments disclosed in Wampler without any reasoning for doing so, despite having recognized the distinction between the embodiments. Ex. 2014 at 34–35, 37. In fact, Wampler's first embodiment of Figures 1–8 has at least a different motor, different bearings, and different magnet

arrangements compared to Wampler's later embodiment of Figures 11–14. But Petitioner merely cherry-picks features from these distinct embodiments in Wampler without any articulated rationale to support its contentions regarding obviousness. A POSA would not have operated under this assumption. Leschinsky, ¶¶ 116–117. This deficient analysis fails to show that the challenged claims are obvious over Wampler.

B. Bourque-2001 And Wampler Fail To Render Obvious Claims 1, 2, 4, 5, 7, 8, 11, 12, 14–16, And 18–20 (Ground 2)

The Petition fails to demonstrate that independent claims 1 and 11 of the '879 patent would have been obvious over Bourque-2001[3], alone or in view of Wampler, and therefore fails to prove any claim unpatentable under Ground 2. Additionally, neither Bourque-2001 nor Wampler teaches the additional features of dependent claim 20.

1. Bourque-2001 Does Not, Itself, Render Claim 1 Obvious

The Institution Decision agrees with Patent Owner that the challenged claims are not obvious over Bourque-2001 alone:

> [O]n the current record we agree with Patent Owner that Petitioner does not sufficiently show in the Petition that

[3] Described at Leschinsky, ¶¶ 88–91.

> Bourque teaches a rotor "axially aligned" or "aligned" with the inflow tube or a central axis of the inflow tube.

Paper 13 at 33.

The systems of independent claims 1 and 11 each comprise a heart assist pump device that includes a rotor axially aligned with a central axis or an inflow axis extending along an inflow tube. Specifically, claim 1 includes the following critical language:

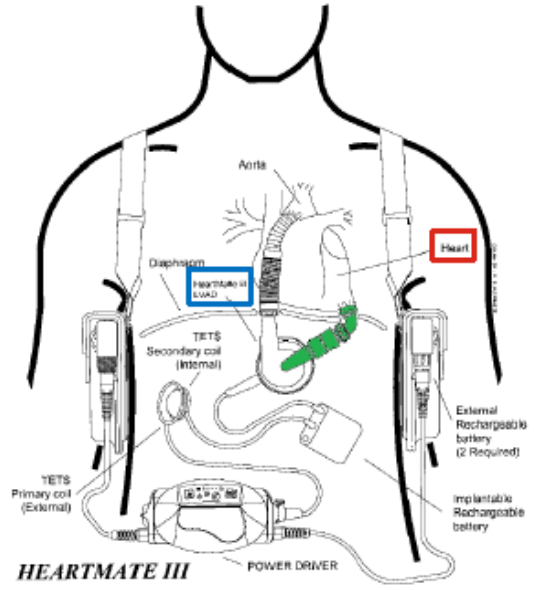
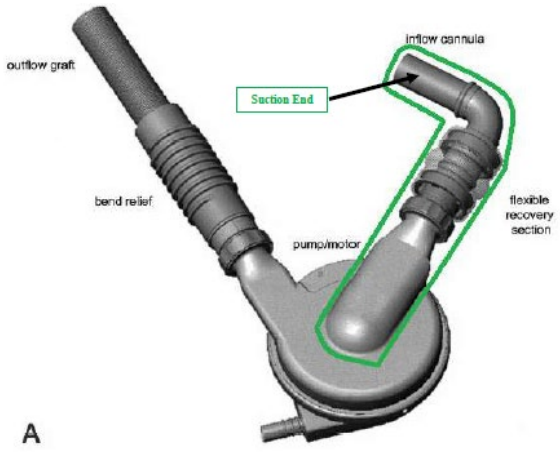
> [1A] a heart assist pump device deliverable to the heart and comprising: ***an inflow tube defining a blood inflow path aligned with a central axis***;
>
> [1B] a magnetically driven ***rotor aligned with the central axis*** and…

Ex. 1001, 5:23–26. Similarly, claim 11 includes the following critical language:

> [11A] a heart assist pump device deliverable to the heart and comprising: ***an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle***;
>
> …
>
> [11C] a magnetically driven ***rotor axially aligned with the inflow axis*** and…

Id. at 6:24–31. Bourque does not disclose these configurations, nor does it teach or suggest them, alone or combined with Wampler.

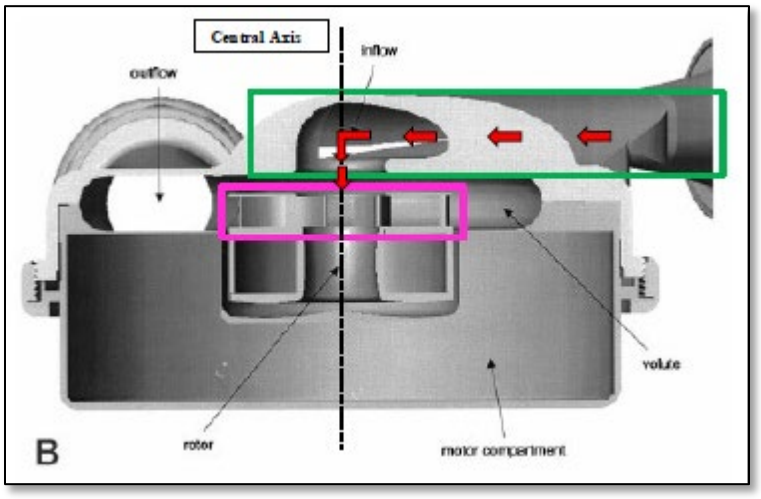
Petitioner, as it must, argues that the end of the "flexible recovery section" or "inflow cannula" is the "suction end" of an "inflow tube" that is "inserted into a ventricle of the heart." Pet. at 49–51; Crosby, ¶¶ 292–294. Accordingly, the entirety of the structure that connects the flow of blood from the heart to the pump in Bourque-2001 must correspond to the "inflow tube" of the claims. In addition to asserting it directly, Petitioner visualizes this correspondence by coloring the structure corresponding to the "inflow tube" in green (e.g., Pet. at 50–51; Crosby, ¶¶ 292–293), as illustrated below:

 **Figure 3.** HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.	
Pet. at 51	Crosby, ¶ 293

There is no doubt about the portion of the Bourque-2001 device that Petitioner alleges corresponds to the "inflow tube" and that it must extend all the way to the heart.

Having defined the inflow tube, it is clear that "the magnetically driven rotor" is ***not*** "axially aligned with the inflow tube." In fact, the rotor's axis in Bourque-2001 is perpendicular to the inflow tube. Bourque-2001 recognizes that this configuration, with the inflow tube perpendicular to the rotor, "resulted in a sharp bend in the flow before it enters the impeller." Ex. 1007 at 402.

Petitioner uses annotated graphics in an attempt to make the facts seem different. Pet. at 51–54. Petitioner presents its graphic having red arrows representing that flow (the blood) in an attempt to show axial alignment:



Id. at 52. There are numerous problems with this presentation.

First, the claim recites that the inflow tube and the rotor are axially aligned—not the flow. When Petitioner represents that the blood flows along the rotor axis, that does not show that the claim language is met. Leschinsky, ¶ 124; *accord* Paper 13 at 32.

Further, Petitioner's red arrows are not correct. While the arrows appear to be designed to show axial alignment with the flow, the blood does not make a 90 degree turn as illustrated by Petitioner—rather, the flow is much more complex than the Petition suggests. Leschinsky, ¶¶ 125–127; *accord*, Paper 13 at 37.

2. Wampler Cannot Be Combined With Bourque-2001 To Cure Its Deficiencies

Recognizing the problems with its position, Petitioner proposes to combine Bourque-2001 with Wampler and move the location of the prototype HeartMate III pump within the patient's anatomy. In its attempt, however, Petitioner ignores the teachings of Bourque-2001 and, more importantly, ignores its own published experience showing why this combination will not work. The Institution Decision considered this combination, referring to Patent Owner's reasons against the combination as "attorney arguments" and concluding that the combination would teach the claims "on the current record." Paper 13 at 42. Patent Owner has now presented, in the trial phase of this proceeding, multiple expert declarations and

published evidence that conclusively shows that a POSA would not have made this combination and that it would not teach the claims.

In particular, Petitioner argues, and the Institution Decision credits, that the asserted combination of Bourque-2001 and Wampler "would 'fit[] well between the apex of the heart and the adjacent diaphragm' due to the pump's development as a compact device and the existence of several similar LVADs that fit well at that position." Paper 13 at 40; Pet. at 82; Crosby, ¶¶ 426–429. In fact, at the time of these publications, ***no*** LVAD fit well at that position. Leschinsky, ¶ 130; Gallegos, ¶ 51. Wampler provides an artist's rendition of an aspirational implantation—but, in fact, the Wampler pump was never implanted. Leschinsky, ¶ 130; Gallegos, ¶ 44; Ex. 2014 at 45; Ex. 2019 at 783. Further, Bourque-2001 explains that its pump should not be implanted "at that position" and Wampler warns that pumps of the Bourque-2001 design are "large and heavy when compared to other rotary pump concepts" and further that they are complex and unreliable. Leschinsky, ¶ 131; Ex. 2019 at 780. The proposed combination, "to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler 169 to axially align the LV cannula with the impeller of the rotor" will not work for the purpose of the combination—to fit at the apex of the heart above the diaphragm—because the Bourque-2001 pump is too "large and heavy." Leschinsky, ¶ 132; Gallegos, ¶ 45.

a. Bourque-2001 Itself Warns Against The Proposed New Arrangement

First, Bourque-2001 explains why the location of the prototype HeartMate III pump as disclosed is important. Indeed, Bourque-2001 explains that the disclosed location (in a preperitoneal pocket, as opposed to fitting between the apex of the heart and the diaphragm as proposed in the combination) is the "least obtrusive position" in the "human configuration." Ex. 1007 at 402. Bourque-2001 creates "the sharp bend in the flow before it enters the impeller" because this is the way to fit the HeartMate III pump in this "least obtrusive position." Bourque-2001 goes on to state that "clinical experience has suggested that some freedom of movement between the native heart and pump ameliorates stresses imposed on the heart by an imperfectly placed pump, subdues unnecessary pump motion and potential tissue trauma caused by cardiac motion." *Id*. at 405; Leschinsky, ¶¶ 134–136; Gallegos, ¶ 55; Ex. 2014 at 63–64.

These reasons, stated expressly in Bourque-2001, for keeping the HeartMate III pump where it is instead of moving it as required by the proposed combination are ignored by Petitioner. Petitioner never explains why Petitioner's own "clinical experience" should be ignored. In fact, the Petition includes no counter to these reasons for not making the combination because Petitioner never acknowledges the existence of these reasons for not making the combination.

In other publications, Petitioner and Mr. Bourque explain in greater detail why this preperitoneal placement of the original HeartMate III design is important. Another 2001 publication by Petitioner (which includes Mr. Bourque as an author) asserts that HeartMate III includes a "flexible cannula [that] is fitted upstream of the pump inflow to improve anatomical fit, to decouple the pump from cardiac motion, and to provide a point for clamping and ligation for pump explant." Ex. 2004 at 387. Again, Petitioner ignores its own strong statements as to why its proposed combination should not be made.

Moreover, in a paper that was accepted for publication one month before the '879 patent's priority date, Petitioner discussed the relationship between the HeartMate III pump and a patient's heart (it was still the case that no human implantation of the HeartMate III pump had been described). Ex. 2006 at 310 (including Mr. Bourque as the second named author). There, Petitioner even redesigned the inflow cannula into a "left ventricular apical inflow conduit (a)" as shown in the figure to the right. *Id*. at 311. But even with 6 years and a redesigned inflow, the "pump is attached to the heart and circulatory system by a flexible inflow cannula inserted into the left ventricular apex." *Id*. Petitioner still viewed the preperitoneal

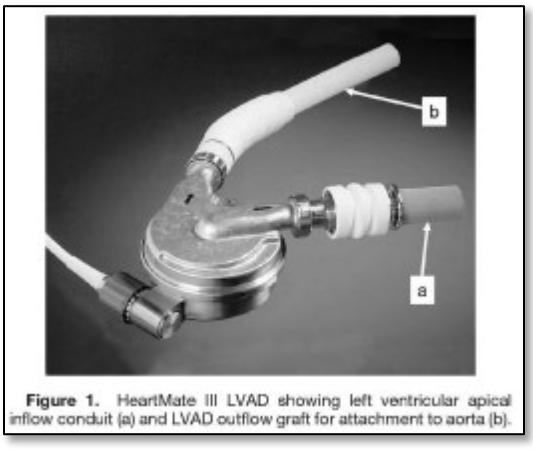


Figure 1. HeartMate III LVAD showing left ventricular apical inflow conduit (a) and LVAD outflow graft for attachment to aorta (b).

placement, spaced apart from the heart, by a flexible cannula to be the best fit. Leschinsky, ¶ 137; Gallegos, ¶ 56.

There is no doubt that Petitioner itself, through the Bourque-2001 reference and through other papers by Mr. Bourque and co-authors, taught POSAs that the best placement of an LVAD is in a preperitoneal pocket—the exact opposite of the motivation that they urge on the Board now.

b. The Pump Of Bourque-2001 Will Not Fit Into Petitioner's Combination

A bigger problem for Petitioner's combination of Bourque-2001 with Wampler is that the Bourque-2001 pump is too big to fit into the proposed combination. Leschinsky, ¶ 142; Gallegos, ¶ 69.

Petitioner argues that its expert explains how "a POSITA would have been motivated with a reasonable expectation of success to modify the HeartMate III 'inflow subassembly' to serve as the 'inflow cannula…placed into the apex of the left ventricle' as taught by Wampler-169, resulting in an '*axially aligned…inflow tube*.'" Pet. at

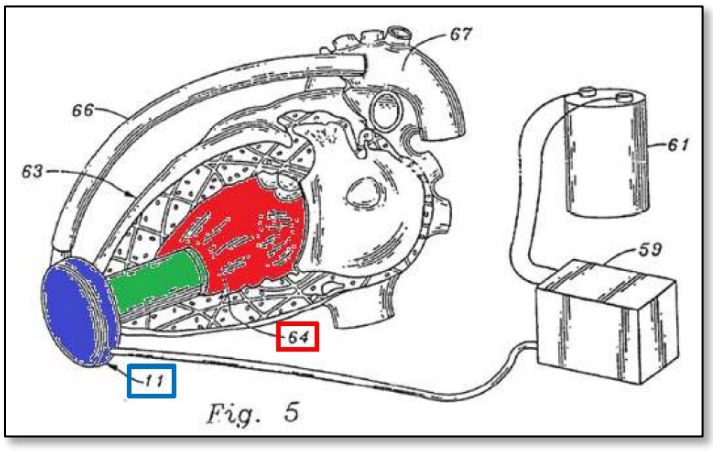


Fig. 5

52. Petitioner annotates Figure 5 of Wampler (Petitioner's annotation shown to the right) to show how Wampler fits one of its pump embodiments to the heart.

Petitioner further argues that a key reason for making the combination is to provide the "good anatomical compatibility" that Wampler promises. *Id.* at 77. But Wampler conditions this compatibility, providing that "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex. 1008 at [0076].

Bourque-2001 does not have such a compact disc. In fact, because of the size of its "motor compartment," the Bourque-2001 HeartMate III pump will not fit well between the apex of the heart and the adjacent diaphragm. Leschinsky, ¶¶ 140–142; Gallegos, ¶ 54.

i. <u>The State Of The Art At The Priority Date Was That There Were No Clinical LVADS Placed At The Apex Of The Heart As Petitioner's Motivation Requires</u>

Petitioner trumpets "the existence of several similar LVADs that fit well at that position [between the apex of the heart and the adjacent diaphragm]." Pet. at 82; Crosby, ¶¶ 426–429. The Institution Decision quoted this language from Petitioner. Paper 13 at 40. In fact, as of the priority date, none of the experts for either party was aware of LVADs being implanted at that position—the first pump

to be implanted at that position in a human was the HeartWare HVAD pump. Leschinsky, ¶ 143; Gallegos, ¶¶ 51–52; Ex. 2014 at 44, 52. The HeartWare HVAD, which was "smaller and can fit inside the pericardial space…received FDA approval for implantation as bridge to heart transplantation in 2012." Ex. 2003 at 728. Indeed, Patent Owner Expert Dr. Gallegos implanted this LVAD in the pericardial space after its FDA approval, which was several years after the priority date. Gallegos, ¶ 52.

In fact, Petitioner's expert Mr. Crosby was CEO of a company, Ventracor, that produced a centrifugal LVAD, VentrAssist, that was implanted in humans between 2003 and 2009. Ex. 2013 at 736; Ex. 2014 at 9–12. Despite being significantly smaller than the prototype HeartMate III LVAD from Bourque-2001, VentrAssist was placed in a preperitoneal pocket below the diaphragm. Leschinsky, ¶ 144; Ex. 2013 at 736; Ex. 2014 at 29–31. This is as a POSA would have expected for a pump of its size at the priority date. Leschinsky, ¶ 144; Gallegos, ¶ 57. In contrast to the proposed Wampler LVAD and the actual HeartWare LVAD, the HeartMate III prototype of Bourque-2001 is massive (three times the weight of HeartWare) and will not successfully meet the requirements of the supposed motivation to combine. Leschinsky, ¶ 146; Gallegos, ¶ 54.

The sizes, weights, implantation status, and dates for a variety of LVADs are collected in the table below:

Device	Weight	Volume	Location	Implanted in Humans?	Year of Publication or Approval
HeartMate II	281	63	Pocket	Yes	2000
Wampler	195	28	Apex	No	1998
Bourque-2001 (HeartMate III prototype)	474	168	Pocket	No	2001
HeartMate 3 (clinical)	200	80	Apex	Yes	2015
VentrAssist	298		Pocket	Yes	2003
HeartWare HVAD	145	50	Apex	Yes	2012

Leschinsky, ¶ 145.

As of the priority date, no one was implanting LVADs at the apex of the heart. Leschinsky, ¶ 143; Gallegos, ¶¶ 51–52; Ex. 2014 at 44, 52. Wampler proposed an LVAD that could be small enough to fit to the apex of the heart—but it was 10 years after Wampler's publication and 5 years after the priority date of the challenged patent that an LVAD was made small enough to fit there. Leschinsky, ¶ 143; Gallegos, ¶ 52; Ex. 2014 at 52.

A POSA at the priority date would not have believed that the prototype HeartMate III pump of Bourque-2001 could have been successfully placed at the

apex of the heart, as required by the stated motivation to combine, and would not have been so motivated. Leschinsky, ¶ 146; Gallegos, ¶ 53.

ii. Size Is Critical To The Proposed Motivation And Petitioner Ignores It

There is a very limited amount of space between the apex of the heart and the diaphragm. Leschinsky, ¶ 147; Gallegos, ¶ 62. A pump that is too large will occupy space that would otherwise be used by the heart, and possibly the lungs. *Id.* The heart continues to beat, even after an LVAD is implanted. Leschinsky, ¶ 148; Gallegos, ¶ 64. If the pump disrupts the movement of the heart, physiologic function will be impaired, especially on the right side of the heart which must still pump blood. Leschinsky, ¶ 148; Gallegos, ¶ 66.

Similarly, weight is critical to the placement of an LVAD as well. The heart moves during a heartbeat. Leschinsky, ¶ 148; Gallegos, ¶ 63. Typically, in a standing patient, the apex of the heart lifts and turns during a heartbeat. *Id.* When fixed to the apex of the heart, a heavy LVAD will impact movement of the heart while beating, again, impairing its physiological function. *Id.*

In his deposition, Petitioner's expert did not know and did not consider the relative size and weight of the different pumps he was describing and combining at the apex of the heart. Ex. 2014 at 78, 92, 108. He tried to explain that problem away by stating, without support, that by the priority date, a POSA would know

that size did not matter because the heart of an LVAD patient did not beat. Ex. 2014 at 61–65; Gallegos, ¶ 64.

But, Dr. Gallegos, who implanted both the HeartMate II (in a preperitoneal pocket below the diaphragm) and the HeartWare (in the pericardial space at the apex of the heart and above the diaphragm) LVADS, disagrees. Gallegos, ¶ 64. In his experience, the hearts of his patients continued to beat after implantation. *Id*. Further, this continued beating is important, especially for the right side of the heart. *Id.* at ¶¶ 64–66. When the pump is too big, it impacts the heart's ability to beat with dire consequences for the patient. *Id.* at ¶ 68. A POSA would not attempt to implant the HeartMate III from Bourque-2001, which is much larger than any of the other pumps discussed, because it would impair the remaining function of the patient's heart. *Id.* at ¶ 69.

iii. Petitioner's Own Experience With Heartmate III Shows That Significant Design Work Over Many Years Was Required To Ultimately Place The Heartmate III Pump At The Apex Of The Heart

Petitioner, through its employee Mr. Bourque, has admitted that significant, patentable, engineering changes needed to be made in order to reduce the size of HeartMate III so that it would fit in the way that the motivation to combine requires. Leschinsky, ¶¶ 150–155; Gallegos, ¶¶ 58–61.

Mr. Bourque noted the changes himself in an American Heart Association news article published in 2018: "Also potentially joining the field is HeartMate 3. A precursor to that was almost ready in 2006 when the company went back to the drawing board, creating a smaller, simpler version, said Kevin Bourque, a vice president of research and design for engineering at St. Jude Medical who has been working on this concept since the start." Leschinsky, ¶ 151; Gallegos, ¶ 59; Ex. 2010 at 5.

This new design was tested and described by Mr. Bourque in a 2016 ASAIO article. Leschinsky, ¶ 152; Gallegos, ¶ 59; Ex. 2008 at 375 *et seq*. In a 2021 interview, Mr. Bourque noted that "in 2006, we said, 'Let's stop, let's do exactly this (the original, larger HeartMate 3 design) but let's make it the clinical HeartMate 3 now, a mini one of those." Ex. 2007 at 5–6. Describing how Petitioner made the HeartMate 3 smaller, Bourque explained:

> "Couple of key things. One, by flipping the rotor upside down, we're able to gain a little bit of real estate. Second, the electronics themselves. Chips are smaller so we shrunk for that," Bourque said. "But then, ***when we got this small, we said wait a minute, now we don't need to implant it down here (in the abdomen), we can go right in the chest***. And that took away this whole business about creating a pocket for the pump and then requiring a conduit between the heart and the pump. We just put this

> (the inflow cannula, if you're scoring at home) right in the heart. So that made it smaller as well."

Id. at 7 (emphasis added).

Still further, Petitioner patented the design changes made to the HeartMate III pump to make it small enough, as Mr. Bourque admits, to mount it "right in the heart" instead of in the abdomen. Leschinsky, ¶ 154; Gallegos, ¶ 61; Ex. 2009. The Ex. 2009 patent illustrates Mr. Bourque's description of "flipping the rotor upside down." *Id*. When flipped upside down, the blood must pass through the stator to reach the rotor. *Id*. Figure 2 of the patent shows the rotor flipped upside down with the blood flowing through the stator to reach it. *Id*. This is described in the abstract of the patent, the summary of the invention, the detailed description, and in claim 1. Ex. 2009. Petitioner has patented the design that made the HeartMate III small enough to implant at the apex of the heart—these changes were not routine. Leschinsky, ¶ 155; Gallegos, ¶ 61.

Based on the asserted motivation, a POSA would not have expected to be able to change the inflow section of Bourque-2001 based on Wampler and have it fit to the apex of the heart without a complete redesign of the pump because the pump was too big to fit.

c. Patent Owner Is Not Requiring "Bodily Incorporation"—Instead There Is A Failure Of Evidence For The Stated Motivation To Combine

The Institution Decision refers to "Patent Owner's bodily incorporation argument." Paper 13 at 41–42. It isn't clear whether the Institution is referring to incorporation of LVADs into a patient's body or the legal notion that an obviousness combination does not necessarily require "bodily incorporation" of one reference into another. Regardless, the motivation to combine is stated clearly in the Petition and adopted in the Institution Decision—the Petition must provide sufficient evidence that a person of ordinary skill would be so motivated to make the combination. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." (emphasis in original)).

The Petition asserts that:

> A POSITA would have been motivated with a reasonable expectation of success to modify the HeartMate III "inflow subassembly" to serve as the "inflow cannula…placed into the apex of the left ventricle" as taught by Wampler-169

Pet. at 53 (citations omitted). The Petition goes on to describe a number of advantages that are said to flow from this placement at the apex of the left

ventricle. *Id.* at 75–83. This is the motivation for which the Petition must supply sufficient evidence—but it does not.

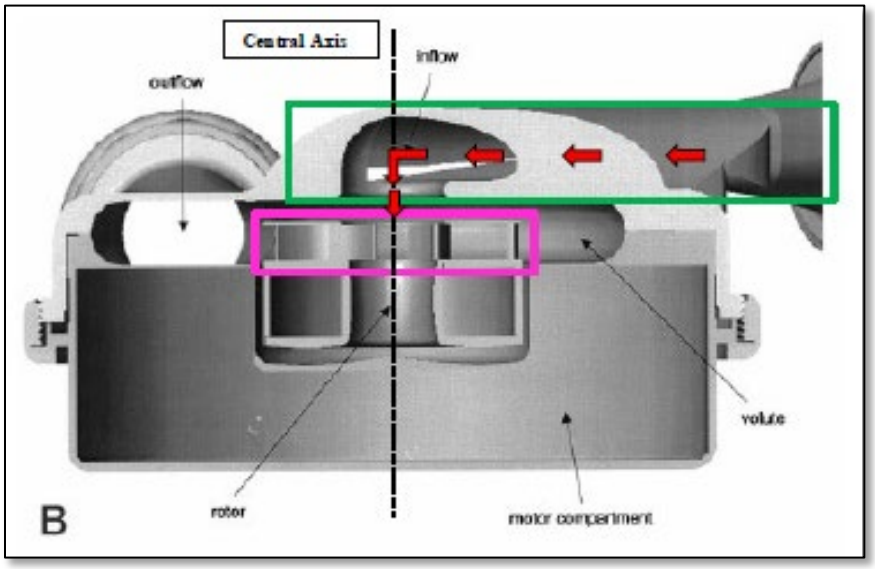
As explained above, there is no doubt that the HeartMate III pump described in Bourque-2001 is too big to work and fit as described by Petitioner. In analogous situations, claims have been found not obvious. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd*., 821 F.3d 1359, 1367–68 (Fed. Cir. 2016); *see also*, *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc*., 141 F.4th 1367, 1381–82 (Fed. Cir. 2025).

In *Intelligent Bio-Systems*, petitioner's motivation to combine depended upon the ability to meet a "quantitative deblocking requirement." *Intelligent Bio-Systems*, 821 F.3d at 1868. The Board found that the Petition did not credibly explain how, under suitable conditions, the references would meet the quantitative deblocking requirement. *Id*. Even though the claims did not require quantitative deblocking, the shortcoming in the evidence was "central to a finding of no motivation to combine." *Id*.

Petitioner's expert describes the proposed combination here this way:

> [I]t would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the impeller of the rotor …

Crosby, ¶ 316. Such a change would rotate the (green) inflow cannula 90 degrees to align with the central axis:



Id. at ¶ 312.

The motivation to make this change is so that the pump can be implanted directly "'into the apex of the left ventricle' as taught by Wampler-169." Crosby, ¶ 331; Paper 15 at 34–35. As explained above, a POSA would know that the HeartMate III pump is too large to be implanted in that way. Leschinsky, ¶ 129. Substantial evidence supports that this motivation fails in the same way as in *Intelligent Bio-Systems*. *Id*. Further, there is no evidence that the HeartMate III pump would fit as Petitioner's expert never considered its size. Ex. 2014 at 78, 92, 108.

d. Petitioner's Motivation To Combine Reasons All Fail

Petitioner proposes a number of reasons for making this modification to Bourque: most expressly involve moving the pump to the apex of the left ventricle, some implicitly require moving the pump to the apex of the left ventricle, and the remainder are false.

First, Petitioner argues that a POSA would be motivated expressly to move the Bourque pump from its preferred placement to the apex of the heart. Pet. at 76–80; Crosby, ¶¶ 416–425. As explained in detail above, a POSA would understand that moving the location of the Bourque-2001 pump as described would not work and would devastate the remaining functionality of the patient's heart. Leschinsky, ¶ 151; Gallegos, ¶ 68.

Petitioner also asserts that this combination would remove a flow restrictive elbow. Pet. at 76–78; Crosby, ¶¶ 416–423. It is not so clear that a POSA would have been motivated to remove this elbow for its own sake—Petitioner's own modeling of the flow through the elbow found benefits, including a washing flow that washed areas that might otherwise have had stagnation and the potential for thrombus formation. Ex. 2005 at 878; Leschinsky, ¶ 152. This rationale is also tied by Petitioner to placement of the pump at the apex of the heart. Pet. at 76–77; Crosby, ¶ 417; Leschinsky, ¶ 152. A POSA would not have made this change for

all the same reasons that a POSA would not have moved the Bourque-2001 pump to the apex of the heart.

Petitioner also argues that the proposed combination will allow the pump inlet to also serve as the inflow cannula as Wampler shows, thereby permitting removal of clinically troublesome inflow components. Pet. at 78–79; Crosby, ¶ 423. This rationale, however, requires that the pump be placed at the apex of the heart—this is what allows the inlet to also serve as the inflow cannula. Leschinsky, ¶ 158. As explained above, a POSA would not do this because the Bourque-2001 pump is too large. *Id*.

Finally, Petitioner argues that modifying the HeartMate III with "an inflow cannula apical tube, which is inserted into the apex of the left ventricle like the Wampler-169 technique is not complex and is well known in the art"—citing to the Poirier patent (Ex. 1018) and the Crosby Declaration (¶¶ 426–429). Pet. at 82 (internal quotations omitted). This is false. The Poirier patent says no more than that the inflow and outflow cannulas from the HeartMate II can also be used with HeartMate III type pumps—which is exactly the configuration used in Bourque-2001. Leschinsky, ¶ 159; Ex. 2014 at 74–76 (agreeing that the portions of Poirier cited by Petitioner refer to the HeartMate II type cannulas).

Contrary to Petitioner's explanations, there is no evidence that substituting Wampler's inlet in the HeartMate III would be "not complex"—and it certainly

was not known. Leschinsky, ¶ 160. Further, Wampler has a unique inlet in which the rotor has a spindle that extends into the outlet to provide radial magnetic bearings as well as a forward thrust bearing. *Id.* at ¶¶ 160–164. All of this would need to be redesigned to make the combination. *Id*.

3. No Combination Of Bourque-2001 And Wampler Teaches Or Suggests The External Control Unit Being Configured To Regulate Operation Of The Second Magnetic Device Based On A Defined Cardiac Output [Claim 20]

Petitioner contends that Bourque-2001 discloses an external controller configured to regulate operation of a second magnetic device based on a defined cardiac output. Pet. at 75; Crosby, ¶ 410. Bourque-2001 instead discloses its pump being "prescribed to run at 3,500 rpm perioperatively, then gradually adjusted to maintain volume flow rates 5 ± 1 L/min throughout the study." Ex. 1007 at 403. That is, Bourque-2001 indicates prescribing rpm rates for the pump adjusted based on ***pump*** output flow rates. There is no indication that the pump was regulated based on a ***defined cardiac output***—especially where the pump is assisting, not replacing, the heart. Leschinsky, ¶ 165.

Wampler's purely prophetic Figure 5 provides even less guidance. Wampler hopes to adjust the operation of the pump based on a patient's physical activity, but Wampler (1) never explains how this goal might be achieved and (2) never ties any of its goals to cardiac output. Leschinsky, ¶ 166.

Accordingly, neither Wampler nor Bourque-2001, nor their combination, teaches or suggests claim 5.

C. Akamatsu Fails To Render Obvious Claims 1, 2, 4, 5, 7, 8, 11, 12, 14–16, And 18–20 (Ground 3)

The Petition fails to demonstrate that independent claims 1 and 11 of the '879 patent would have been obvious over Akamatsu[4] alone and therefore fails to prove any claim unpatentable under Ground 3.

1. Akamatsu Does Not Teach Or Suggest A Magnetically Driven Rotor Being Axially Adjacent To A First Magnetic Device [1D], [11D]

Petitioner has not shown that Akamatsu teaches or suggests a system for assisting blood circulation of a heart that includes a magnetically driven rotor being rigidly coupled and axially adjacent to a first magnetic device, as recited in independent claim elements [1D] and [11D]. The Institution Decision agrees with Patent Owner that the challenged claims are not obvious over Akamatsu. Paper 13 at 43.

Petitioner essentially points to FIG. 2 of Akamatsu alone as support for teaching of claim element [1F], alleging with an annotated figure that the reference

[4] Described at Leschinsky, ¶¶ 92–96.

teaches a permanent magnet (purple) axially adjacent an impeller (pink) along a central axis (black). Pet. at 89–91; Crosby, ¶ 463.

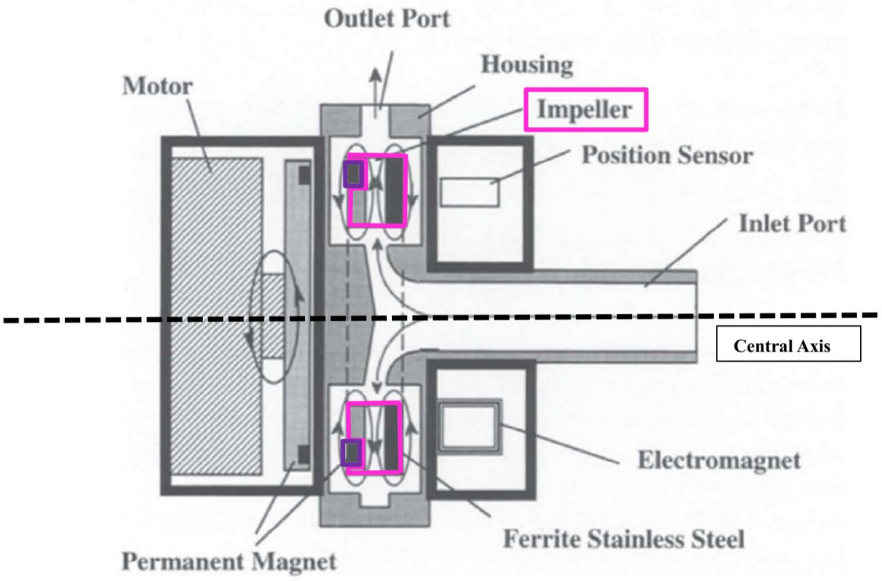


Fig. 2. Schematic cross section of the MSCP

Petitioner's marked up figure, however, highlights that the permanent magnet appears to be embedded within the impeller in an arrangement that axially aligns the two components rather than places them into an axially adjacent relation. Leschinsky, ¶ 170. Indeed, Petitioner's expert describes Akamatsu's teaching in exactly this way: "the permanent magnet embedded in the motor plate and the permanent magnet embedded in the impeller." Crosby, ¶ 466 (citing Ex. 1006 at 4 and FIG. 2).

As discussed above in Section III.D, recitation in claim element [1D] and [11D] that the magnetically driven rotor is axially adjacent the first magnetic device would plainly mean that the two components are positioned adjacent to one

another as measured along the previously recited central axis about which the magnetically driven rotor can rotate. Leschinsky, ¶ 171. Such an arrangement therefore indicates these two components are disposed next to—and not in the same position as—one another, as measured along the central axis about which the rotor can rotate. *Id*.

The concept of "adjacent" components is clear from its plain and ordinary meaning. *Id.* at ¶ 82. Adjacent components along an axis have positioning next to one another, perhaps touching or sharing a common side, when measured along the axis. *Id*. This is distinct from components that are aligned with one another such that they overlap or occupy the same portion of an axis upon which they are positioned. *Id.*

Accordingly, Akamatsu cannot teach or suggest a magnetically driven rotor that is axially adjacent to a first magnetic device based on the positioning of its permanent magnets and impeller because these components are not adjacent to one another as measured along the central axis of the device. Instead, the permanent magnets and impeller are aligned with, and overlap, one another as measured along the central axis based on the disclosed configuration. *See* Ex. 1006, FIG. 2.

2. Akamatsu Does Not Teach Or Suggest A Second Magnetic Device Positioned Axially Closer To The First Magnetic Device Than To The Magnetically Driven Rotor [11H]

Petitioner has not shown that Akamatsu teaches or suggests a "system for assisting the blood circulation of a heart" with "the second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor." Ground 3 fails on this basis.

Petitioner contends that the annotated figure shown below illustrates a second magnetic device (motor in blue) that is positioned axially closer to a first mangetic device (permanent magnet in purple) than to a magnetically driven rotor (impeller in pink). Pet. at 95; Crosby, ¶ 493.

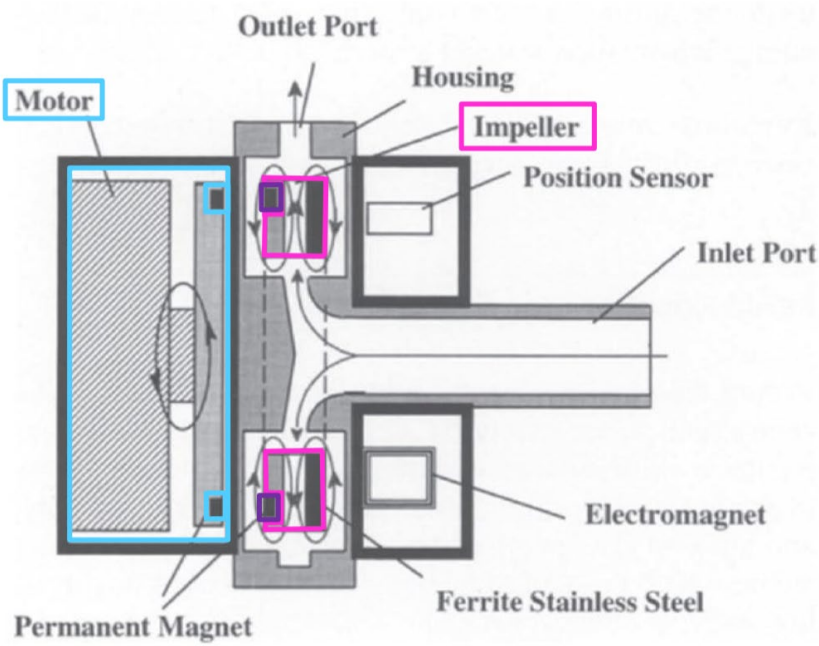


Fig. 2. Schematic cross section of the MSCP

Petitioner provides no further analysis than this brief description of the annotated figure. Leschinsky, ¶ 173. Further, Akamatsu provides essentially no information about the construction of its impeller. *Id.*

Petitioner's figure, with the impeller (magnetically driven rotor) annotated in pink and the permanent magnets in the impeller (the first magnetic device) annotated in purple, makes it seem as though the purple boxes extend to the left more than the pink boxes—implying that the first magnetic device is axially closer to the second magnetic device than the magnetically driven rotor—but that isn't the case. Leschinsky, ¶ 174.

The only disclosure in Akamatsu on this topic is the schematic cross-sectional diagram of FIG. 2. Ex. 1006 at 2. Not only does the permanent magnet appear at most to be flat with the left side of the impeller as illustrated (and thus exactly even in axial distance from the second magnetic device as the rotor—here, along the X-axis), but close inspection of the schematic suggests that the permanent magnet may be inside the impeller, that is, covered by the dark-lined box that marks the outside of the impeller. Leschinsky, ¶ 175. Alas, there is no way to know, because the schematic cross-section of FIG. 2 is not clear, and neither Petitioner nor its expert provide any explanation or evidence beyond merely pointing to FIG. 2 and saying that element [11H] is met—when it plainly isn't.

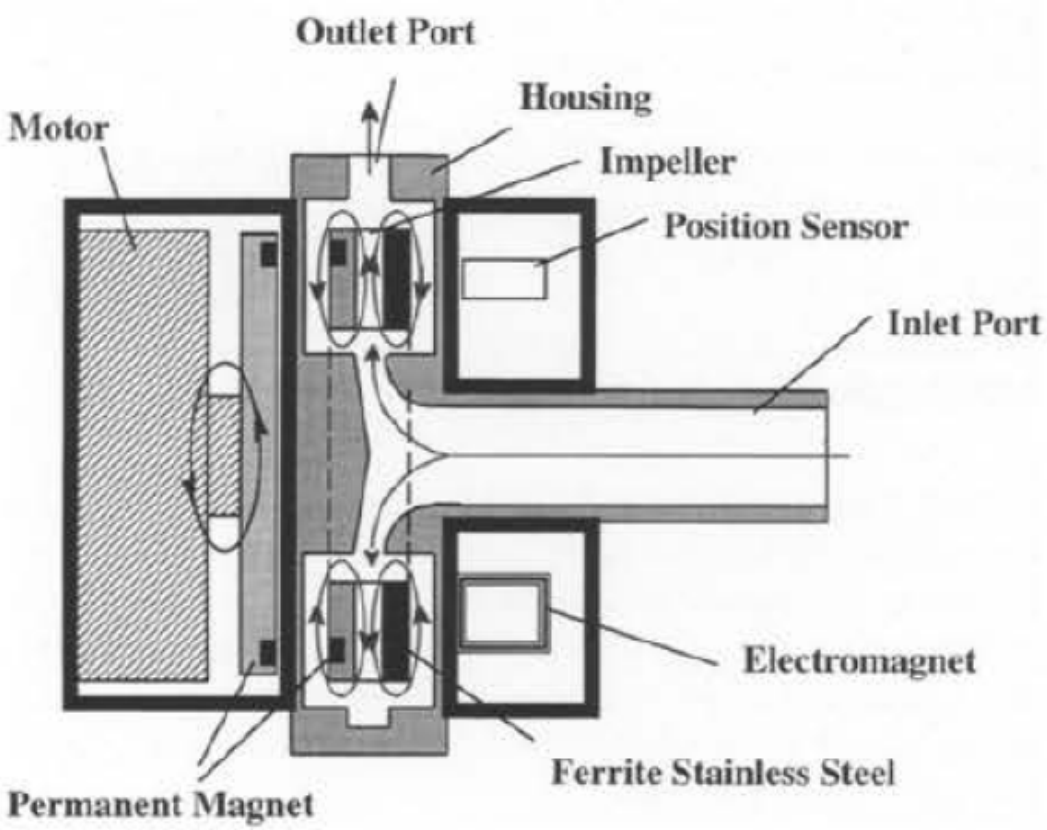


Fig. 2. Schematic cross section of the MSCP

FIG. 2 itself, without annotation, shows that, at best, the first magnetic device and the magnetically driven rotor are at the same axial distance (same distance in the x-direction) from the second magnetic device. Ex. 1006 at 2. There is no evidence of anything else. Leschinsky, ¶ 175.

Accordingly, Akamatsu cannot teach or suggest a second magnetic device positioned axially closer to the first magnetic device than to the magnetically driven rotor. *See* Ex. 1006 at 2.

3. Akamatsu Does Not Teach Or Suggest An External Control Unit Configured To Operate A Second Magnetic Device [1J], [11K]

Claim elements [1J] and [11K] require a system including an external control unit configured to regulate or control operation of a second magnetic device to thereby magnetically drive the rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device. Petitioner has not shown that Akamatsu teaches or suggests a system including the claimed external control unit.

Petitioner contends that Akamatsu "teaches or suggests a controller (worn externally in Figure 1)" and provides a marked-up version of FIG. 1 highlighting the alleged controller in lime green. Pet. at 99–101; Crosby, ¶¶ 513–518.

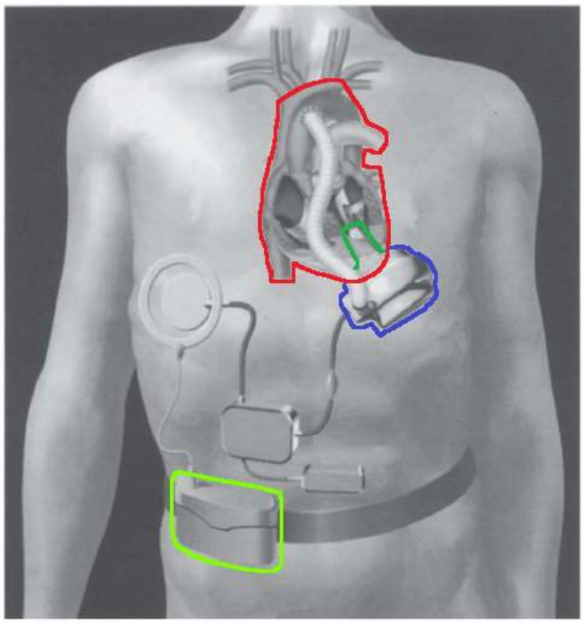


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

There is no basis, however, for this contention that the lime green highlighted component in Akamatsu's FIG. 1 is a controller. Akamatsu is silent regarding what this component is, and it does not specifically identify any of the components pictured in FIG. 1. Leschinsky, ¶ 179. Petitioner relies heavily on this low-resolution conceptual and aspirational illustration of a potential "future" system for a "totally implantable left ventricular assist system," but it is not clear what this figure shows. *Id.*; Ex. 1006 at 3.

Taking Akamatsu at its word for the paltry disclosure included regarding Fig. 1, it illustrates a "totally implantable" LVAD system, such a system would require that the controller operating the pump be implanted, not external. Ex. 1006 at 3; Leschinsky, ¶ 179. In such a system, a patient would need to be able to, for example, remove the illustrated belt and the lime green highlighted component coupled thereto, in order to do things like bathe. Leschinsky, ¶ 179. If the component outlined in lime green were the external controller, as contended by Petitioner, the pump would no longer run if the belt were removed. *Id.*

In the context of this "totally implantable" system, it is also possible that the component highlighted in lime green is a power source, such as a battery. *Id.* at ¶ 180. For example, the lime green highlighted component is coupled to a wire extending to a ring positioned over what appears to be an implanted disc, which appears likely to be a transcutaneous energy transfer (TET) system used to transfer

electrical power from outside the body to inside the body. *Id.* The implanted disc is itself coupled to what appears to be an *implanted* controller disposed above the lime green highlighted component in FIG. 1. *Id*. Akamatsu's disclosure of a future "prototype MSCP with…an implantable controller," and "a totally implantable LVAS" that includes "a transcutaneous energy and information transfer system and internal/external batteries" aligns with this view of Fig. 1. *Id.*; Ex. 1006 at 7.

Confusingly, after incorrectly identifying what appears to be an external power source (coupled to an implanted controller) as the claimed external controller in Fig. 1, Petitioner suggests that disclosure of the "next phase" Model III pump with an implantable controller is evidence that earlier disclosure of the "percutaneously driven" Model II pump involved use of an external controller. Pet. at 100; Crosby, ¶ 665. This, however, is another conclusory leap from Petitioner without backing from Akamatsu.

For example, the existence of a "percutaneously driven" pump in Akamatsu is not evidence that a controller for the pump was external to the body. Leschinsky, ¶ 182. To the contrary, a pump utilizing an at least partially implanted controller could still have been "percutaneously driven" by power cables extending from the controller to an external power source. *Id*.

Akamatsu simply lacks disclosure sufficient to teach or suggest the recitations of claim elements [1J] and [11K].

D. Schima And Akamatsu Fail To Render Obvious Claims 1, 2, 4, 5, 7, 8, 11, 12, 14–16, And 18–20 (Ground 4)

The Petition fails to demonstrate that independent claims 1 and 11 of the '879 patent would have been obvious over Schima[5], alone or in view of Akamatsu, and therefore fails to prove any claim unpatentable under Ground 4. Additionally, neither Schima nor Akamatsu teaches the additional features of dependent claim 20.

1. No Combination Of Schima And Akamatsu Teaches Or Suggests A Heart Assist Pump Device Deliverable To The Heart [1A], [11A]

Petitioner has not shown that any combination of Schima and Akamatsu teaches or suggests a system including a heart assist pump device deliverable to the heart so that an inflow tube defines a blood inflow path, as recited in independent claim elements [1A] and [11A].

Petitioner essentially admits that Schima is silent regarding its disclosed pump being deliverable to the heart. Pet. at 108–110 ("Shima focuses on pump design alone," at 135); *see also* Crosby, ¶¶ 552–559 (relying solely on other references mentioned in Schima for this alleged disclosure). Petitioner relies upon Akamatsu to remedy this deficiency of Schima, suggesting that it would have been

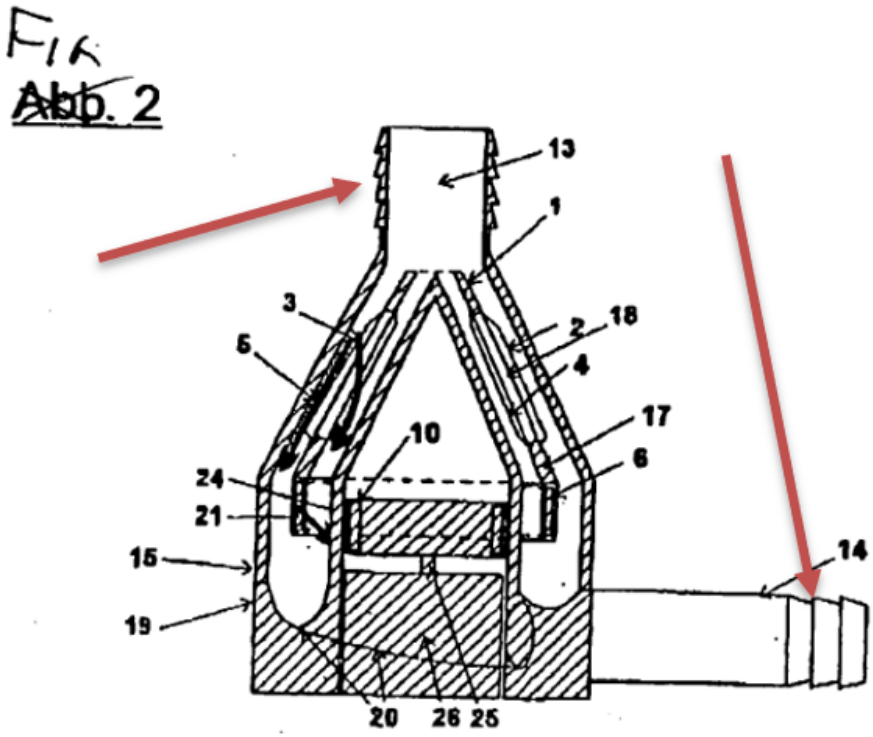
[5] Described at Leschinsky, ¶¶ 97–99.

obvious to a POSITA to implant Schima's device in the configuration described by Akamatsu. Pet. at 133; Crosby, ¶ 562. But this contention has a number of problems.

First, the suggestion to deliver a device to the heart that is not specifically designed for operation in the human body fails as a gross oversimplification of the myriad issues that surround such an undertaking. Leschinsky, ¶ 186. Petitioner is not suggesting a *combination* of certain elements of Schima's pump with the implantable device of Akamatsu, but instead contends that a POSITA would have simply implanted "Schima's device in the configuration described by Akamatsu." Pet. at 134; Leschinsky, ¶ 188. There is, however, no teaching or suggestion in Schima to suggest that its pump is configured for use in the body, or even capable of being delivered to the heart in the manner claimed at all. Leschinsky, ¶ 187; *see also supra* at § IV.B.2.c (failure of evidence for motivation to combine defeats combination).

For example, Schima discloses that its pump is suitable for use in "moving blood and other shear-sensitive liquids," which teaches away from a device specifically configured for implantation in the body. Given the highly specialized nature of implantable medical devices, and especially implantable cardiac assist devices, a suggestion that a pump is suitable for other uses would have been a

strong indicator to a POSA that delivery of this device into the body to the heart is not contemplated. Leschinsky, ¶ 189; Gallegos, ¶ 71.



Another example is the illustrated connections of the inlet 13 and outlet 14 that appear to be conventional barbed fittings (highlighted with red arrows above). Leschinsky, ¶ 191. Such fittings would have been understood by a POSA as being configured for use with tubing and clamps to achieve a seal, rather than structures configured to interface with the heart or other anatomical structures. *Id.*; Gallegos, ¶ 78. Indeed, a POSA would have understood that such fittings would not be capable of delivery to the heart, e.g., insertion into the heart through a hole formed therein, as such a connection would be rudimentary, unreliable, and potentially

traumatic to the heart. A POSA simply would not have thought it possible to do. *Id.*

The Petition, however, goes so far as to say that the barbed inlet 13—clearly designed to attach a tube—is instead designed to be inserted into a ventricle of the heart to define a blood inflow path. Crosby, ¶ 553. The supposed support for this obviously wrong statement is that Schima wishes to improve on the prior art referenced in [0004]–[0008] of Schima. Crosby, ¶¶ 553–559. But these paragraphs of Exhibit 1005 only describe the control of a rotor to maintain gaps between the rotor and its surrounding housing—and Schima criticizes the rotor control of each reference and concludes that the "present invention therefore has the object of overcoming these disadvantages. Mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps are to be avoided." Ex. 1005 at [0004]–[0009]. From these paragraphs, Crosby draws the *non sequitur* that Schima was setting out to design its barbed inflow tube connector to be placed in the ventricle of the heart. Crosby, ¶¶ 553–559. We don't need Crosby to fabricate stories about the prior art because Schima explicitly tells us what they were doing: they were trying to manage gaps around the rotor, not invent new designs for connecting to a heart.

Another example of why a POSA would not have considered the pump of Schima as deliverable to the heart is the inclusion of relatively sharp, 90-degree

edges found on external-facing surfaces of the Schima pump. Leschinsky, ¶ 192; Gallegos, ¶ 79. These edges are not found on devices that are deliverable to the heart in the contended manner due to their potential to cause trauma to surrounding tissue. *Id.*

By way of comparison, Exhibit 1011 cited by Petitioner is another reference directed to a multi-fluid-application pump design like Schima, and it acknowledges contemplated use only extracorporeally or in industrial settings outside the medical field. *See* Ex. 1011 at 3–4 and FIGS. 4–5. The Schima pump also appears similar to other known extracorporeal devices that would similarly not have been viewed by a POSA as deliverable to the heart. Leschinsky, ¶¶ 194–195; Gallegos, ¶¶ 72–74. Indeed, later work by Schima stated more explicitly the nature of its pump as an extracorporeal pump similar to those described above that would not have been deliverable to the heart in the contended manner. Leschinsky, ¶ 196; Gallegos, ¶¶ 75–77; Ex. 2022 at 256–257.

Delivering a device to the heart in the manner Petitioner contends when the device is configured for use outside the body or in industrial settings is a complicated endeavor that was not within the scope of disclosure in either Schima, Exhibit 1011, or any of the other cited references. Further, a POSA at the time of the invention would not have considered an extracorporeal pump to be deliverable to the heart in the manner contended. Leschinsky, ¶ 193; Gallegos, ¶ 80.

Mr. Leschinsky and Dr. Gallegos testify to what plainly makes more sense than Petitioner's strained contentions—that the pump of Schima was not deliverable to the heart the manner Crosby suggests. Leschinsky, ¶ 197; Gallegos, ¶ 80.

Moreover, Petitioner's reliance on Akamatsu as providing the required teaching to deliver the device of Schima to the heart is incorrect. It is simply not clear from Akamatsu that the reference discloses delivering its pump to the heart in the manner contended by Petitioner. *See* Pet. at 85–86.

Petitioner relies on the conceptual, aspirational, and low-resolution FIG. 1 of Akamatsu to suggest that the pump disclosed therein is deliverable to the heart, *id.*, but this configuration is not actually shown and does not support the contention that the pump of Akamatsu was deliverable to the heart in the manner Petitioner argues in its proposed combination. Instead, Petitioner marks up FIG. 1 and makes unsupported assertions about what it discloses. *Id*. at 110. Further, Akamatsu discloses its "paracorporeally" positioned pump, as well as its "intrathoracically implanted" pump, in a manner that suggests the use of "inflow and outflow conduit" that would have extended between the "inlet port" and "outlet port" of the pump to the descending aorta and a cuff sutured to the ventricular apex, respectively. Ex. 1006 at 4. This suggests the inlet port of Akamatsu's pump is not

deliverable to the heart in the manner Petitioner contends, i.e., delivered to the apex and inserted into a ventricle of the heart. Leschinsky, ¶ 200; Gallegos, ¶ 80.

Even if one assumes, *arguendo*, that it would have been obvious (and possible!) to simply "implant Schima's device in the configuration described by Akamatsu," doing so would not have resulted in a configuration that includes every element recited in the claims. This is because both references fail to teach or suggest claim elements [1A] and [11A].

2. No Combination Of Schima And Akamatsu Teaches Or Suggests An External Control Unit Configured To Operate Or Control A Second Magnetic Device [1J], [11K]

Petitioner has not shown that any combination of Schima and Akamatsu teaches or suggests a system including an external control unit configured to regulate or control operation of a second magnetic device to thereby magnetically drive the rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device.

Petitioner admits that Schima does not disclose an external control unit for its pump. Pet. at 124; Crosby, ¶ 623. Schima, then, cannot be said to teach or suggest claim elements [1J] and [11K].

Petitioner attempts to fill this gap by relying on Akamatsu and incorporating by reference their arguments regarding this claim element in connection with

Ground 3. Pet. at 124–125; Crosby, ¶ 624. In making such a combination, however, Petitioner inherits all of the deficiencies of Akamatsu described above with regard to Ground 3, each of which is incorporated by reference here. *See supra*, § IV.C.

For example, Petitioner again alleges that the lime green component shown in Akamatsu's FIG. 1 is an external controller. There is no basis, however, for this contention. Leschinsky, ¶ 210; Gallegos, ¶ 89. Akamatsu is silent regarding what this component is specifically, as it is for all other components in FIG. 1. Contrary to Petitioner's contentions, the only disclosure there is of this figure, describing it as a "totally implantable" LVAD, suggests there is an *implanted* controller instead. Leschinsky, ¶ 206; Gallegos, ¶ 90.

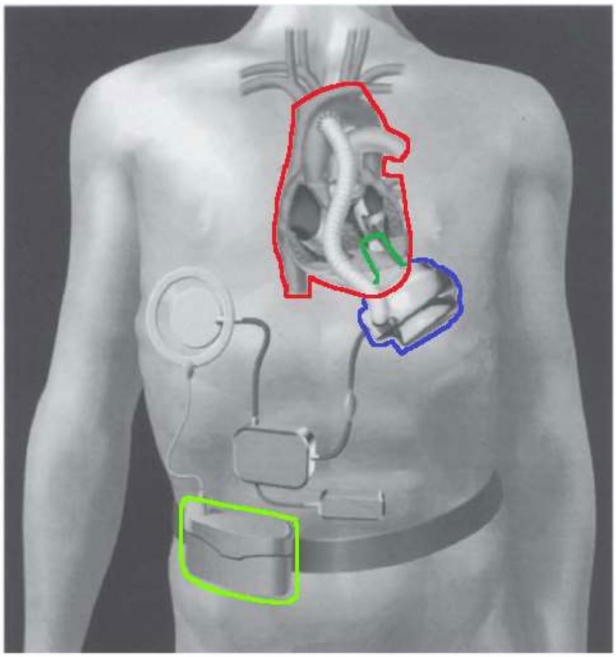


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

For all of the reasons detailed in § IV.C.3 above, Akamatsu fails to teach or suggest claim elements [1J] and [11K]. Given that Petitioner admits Schima does not teach or suggest this claim element, no combination of these two references can teach or suggest it, so Ground 4 fails to prove that claim 1 is unpatentable.

3. Petitioner's Motivation To Combine Reasons All Fail

Petitioner proposes a number of reasons for making this combination of Schima and Akamatsu, many of which abstract the pumps of Schima and Akamatsu to an extent that facilitates their combination but ignores important distinctions that would have stopped a POSA from making the contended combination, and the remainder are false.

For example, Petitioner contends that Schima and Akamatsu are analogous art directed to the same field of endeavor—"to assist with the performance of a heart with…a rotary pump and driven via magneto coupling,"—as well as addressing a pertinent problem described by the '879 patent—"reducing mechanical stress on the blood during pumping." Pet. at 134; Crosby, ¶¶ 657–658, 666. The identified field of endeavor and pertinent problem are taken at too high a level of abstraction, however, because they allow false equivalence to be drawn between the implantable pump of Akamatsu and the extracorporeal pump of Schima. Leschinsky, ¶¶ 210–211; Gallegos, ¶ 86. While both references may be

directed to assisting performance of a heart, a POSA would have immediately appreciated that the pump of Schima cannot be delivered to the heart in the manner disclosed in Akamatsu. *Id.*

Petitioner further contends that combining Schima and Akamatsu would be nothing more than an arrangement of old elements and yielding no more than would be expected of such an arrangement. Pet. at 134; Crosby, ¶¶ 659–660. Again, Petitioner overlooks the important point that a POSA would not have made the contended combination—whether the elements were old or not—based on characteristics of the references Petitioner ignores. Leschinsky, ¶ 212. For example, a POSA would not have considered the extracorporeal pump of Schima deliverable to the heart in the manner contended by Akamatsu. *Id.* And Akamatsu fails to provide the teaching Petitioner contends based on the size of the disclosed pump in Akamatsu that could not be delivered to the apex of the heart. *Id.*

Petitioner contends that the teachings of the two references are complementary. Pet. at 135. This is true only when viewed with Petitioner's selective blinders that a POSA would not have had. Including the context that a POSA would have understood, including the inability of Akamatsu to teach or suggest delivering its pump to the heart as Petitioner contends and the unsuitable nature of Schima for delivery to the heart in the manner Petitioner contends, the teachings are far less complementary. Leschinsky, ¶ 213.

Petitioner further contends that a POSA would have a reasonable expectation of success that Schima's pump could be controlled and implanted according to Akamatsu's teachings. Pet. at 135. This is false. A POSA would not have had a reasonable expectation of success in attempting to deliver the extracorporeal pump of Schima to the heart. Leschinsky, ¶ 214. Furthermore, Akamatsu fails to teach or suggest delivering its pump to the heart as Petitioner contends. *Id.* Akamatsu also has deficient teachings with regard to an external controller and, even if that were not an issue, a POSA would not have thought that a controller configured to use with Akamatsu's pump would be suitable for use with the Schima pump. *Id.* Pump-controller pairings for LVADs are specifically tailored and a POSA would not swap out one side of the pairing with any reasonable expectation of success. *Id.* at 197–198; Gallegos, ¶¶ 87–91.

4. No Combination Of Schima And Akamatsu Teaches Or Suggests The External Control Unit Being Configured To Regulate Or Control Operation Of The Second Magnetic Device Based On A Defined Cardiac Output [Claim 20]

Petitioner admits that Schima does not disclose any external control unit, so relies solely on Akamatsu to provide this teaching. Paper 1 at 124; Ex. 1003 ¶ 623.[6] Petitioner contends that Akamatsu's disclosure of operating its pump at a

[6] Petitioner's actual treatment of claim 20 is found at p. 133, but it merely points the reader to multiple other places in the Petition.

"fixed rotational speed" teaches the claim. Pet. at 126; Crosby, ¶ 626. Disclosure of operating a pump at a fixed rotational speed, however, does not teach or suggest regulating or controlling operation based on a defined cardiac output. For example, there is no explanation as to how a pump speed is related to a defined cardiac output. Leschinsky, ¶ 217. Petitioner draws a connection that is not taught or suggested in the references themselves.

V. CONCLUSION

For the reasons articulated above, the Board should find that the challenged claims of the '879 patent have not been shown to be unpatentable.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Under 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing PATENT OWNER MIRACOR MEDICAL SA'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW has 13,856 words, which is less than the 14,000 word limit, as determined by the word count feature of the word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

Under 37 C.F.R. § 42.6(e), the undersigned certifies that on this 30th day of September 2025, I caused a true and correct copy of the foregoing PATENT OWNER MIRACOR MEDICAL SA'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW, together with all exhibits filed therewith, to be served via e-mail on the following counsel of record for Petitioner:

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