

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Petitioner,

v.

MIRACOR MEDICAL SA,

Patent Owner.

IPR2025-00096
Patent 11,351,356

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

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Exhibit No.	Description
2001	Certification of Todd G. Vare
2002	Corrected Certification of Todd G. Vare
2003	Kenneth K. Liao et al., <i>End-Stage Congestive Heart Failure in the Adult Population: Ventricular Assist Devices</i> , Handbook of Cardiac Anatomy, Physiology, and Devices 725–732 (2015)
2004	Howard M. Loree II et al., <i>The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device</i> , 25 Artificial Organs 386–391 (2001)
2005	Greg W. Burgreen et al., <i>Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device</i> , 28 Artificial Organs 874–880 (2004)
2006	David J. Farrar et al., <i>Design Features, Developmental Status, and Experimental Results With the Heartmate III Centrifugal Left Ventricular Assist System With a Magnetically Levitated Rotor</i> , American Society of Artificial Internal Organs (ASAIO) Journal 310–315 (2007)
2007	Abbott, <i>A Father of HeartMate 3 Wants A Bigger Family</i> , 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., <i>Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System for Hemocompatibility</i> , 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, <i>The past, present and future of the device keeping alive Carew, thousands of HF patients</i> , 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	Reserved
2013	Donald Esmore et al., <i>VentrAssist Left Ventricular Assist Device: Clinical Trial Results and Clinical Development Plan Update</i> , 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., <i>A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings</i> , 23 Artificial Organs 780–784 (1999)
2020	Trevor Symalla et al., <i>Choosing the Appropriate Left Ventricular Assist Device for Your Patient</i> , 36 (Suppl 2) Indian Journal of Thoracic and Cardiovascular Surgery S256–S264.
2021	Milad Hosseinipour et al., <i>Rotary Mechanical Circulatory Support Systems</i> , 4 Journal of Rehabilitation and Assistive Technologies Engineering, 1–24 (2017)

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

CHALLENGED CLAIMS

Claim No.	Claim Language
[1PRE]	A method for assisting the blood circulation of a heart in a body, comprising:
[1A]	delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart
[1B]	while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart,
[1C]	wherein the magnetically driven rotor is axially aligned with the inflow tube
[1D]	and [the magnetically driven rotor] is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor,
[1E]	the magnetically driven rotor being rotatable about a central axis
[1F]	and [the magnetically driven rotor] being rigidly coupled to a first magnetic device
[1G]	that [first magnetic device] is located within the surrounding rotor housing
[1H]	[the first magnetic device is] at a position axially adjacent to the magnetically driven rotor,
[1I]	wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube
[1J]	and [the second magnetic device is] positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device

Claim No.	Claim Language
[1K]	while [the second magnetic device is] being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device,
[1L]	and a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor,
[1M]	wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and
[1N]	connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,
[1O]	the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.
[2]	The method of claim 1, wherein in response to the rotation of the magnetically driven rotor via the magneto coupling, guide surfaces of the magnetically driven rotor produce centrifugal flow components.
[3A]	The method of claim 2, wherein the surrounding rotor housing comprises at least one sealing wall between the first magnetic device and the second magnetic device,
[3B]	and the first magnetic device is positioned between the second magnetic device and the magnetically driven rotor.

Claim No.	Claim Language
[4]	The method of claim 3, wherein the first magnetic device rotates together with the magnetically driven rotor relative to the surrounding rotor housing.
[5]	The method of claim 1, wherein the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.
[6]	The method of claim 1, wherein both the magnetically driven rotor and first magnetic device are entirely spaced apart from the surrounding rotor housing by a gap during rotation of the magnetically driven rotor.
[7]	The method of claim 1, further comprising providing feedback signals to the external control unit from one or more sensors.
[10]	The method of claim 1, wherein the external control unit is configured to regulate operation of the second magnetic device based on a fixed control value.
[12]	The method of claim 1, wherein the second magnetic device is positioned closer to the blood outflow port than the second magnetic device is positioned relative to the suction end of the inflow tube.
[13]	The method of claim 1, wherein the heart assist pump device is a catheter device.

I. INTRODUCTION

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 11,351,356.

An Institution Decision dated May 19, 2025 (Paper 15), instituted trial to determine whether Petitioner has met its burden to show that challenged claims 1–7, 10, 12, and 13 of U.S. Patent No. 11,351,356 (Ex. 1001, herein “the ‘356 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 claim 1 requires, among other things, a magnetically driven rotor of a heart assist pump be rigidly coupled to a first magnetic device at a position axially adjacent to the magnetically driven rotor. As the Board recognized in its Institution Decision, neither Wampler nor Akamatsu teaches or suggests such a feature.

With regard to Ground 2, independent claim 1 requires, among other things, that a magnetically driven rotor be axially aligned with 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. 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 position the pump of Bourque-2001 at the apex of a 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 position at the apex of the heart at the time of the invention, a fact that a POSA would have readily appreciated.

Finally, with regard to Ground 4, independent claim 1 requires, among other things, delivering a heart assist pump device to the heart so that a suction end of an inflow tube is inserted into a ventricle of the heart. Petitioner admits that Schima

lacks any such teaching and contends that a POSA would have implanted 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 position at the apex of the heart 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 suitable for implantation the body, regardless of its position relative to the heart.

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 6 (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 such 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 flowing” over narrower constructions advanced by Petitioner. Paper 15 at 22–23. 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 “at a position axially adjacent” as reflecting the plain and ordinary meaning of the term consistent with the disclosure of the '356 patent. *Id.* at 25. 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 7–8. 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 '356 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, Grounds 1 and 2 would 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 '356 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 Flowing”

When advocating for their narrower construction, Petitioner takes the phrase “by the blood flowing” out of context from claim recitation [1M] and argues, because of an example in the specification and some examples in the art, that the term “by the blood flowing” requires the claimed medical device to have hydrodynamic bearings and that the term excludes devices having magnetic bearings. Pet. at 8–9. 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 element [1M] 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 flowing” means that the rotor is spaced apart from the housing and surrounded by flowing 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 maintain its position in the Institution Decision to give “by the blood flowing” its plain and ordinary meaning, which would encompass both a magnetic bearing and a hydrodynamic bearing.

D. “At A Position Axially Adjacent”

Patent Owner endorses the position adopted by the Board in the Institution Decision to give the term “at a position axially adjacent” its plain and ordinary meaning as “adjacent to one another as measured along a central axis.” Paper 15 at

23–26. 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 ‘356 patent or any extrinsic evidence. Paper 15 at 24. 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.*

As the Board noted, however, there is nothing in Ex. 1019 that so defines the term “at a position 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 25.

The Board should therefore maintain the claim construction adopted in the Institution Decision as its plain and ordinary meaning consistent with the '356 patent.

E. Throughout The Petition And Crosby Declaration, Petitioner Engages In Improper Claim Construction Based On 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 24–25.

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

A. Wampler Fails To Render Obvious Claims 1–7, 10, 12, And 13 (Ground 1)

The Petition fails to demonstrate that independent claim 1 of the '356 patent would have been obvious over Wampler² alone and therefore fails to prove any claim unpatentable under Ground 1.

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

Petitioner has not shown that Wampler teaches or suggests a method including delivering a heart assist pump device wherein a first magnetic device is at a position axially adjacent to a magnetically driven rotor to which it is rigidly coupled. The Institution Decision agrees with Patent Owner that the challenged claims are not obvious over Wampler:

Petitioner does not contend or show in the Petition that Wampler teaches a magnetically driven rotor coupled to

² Described at Leschinsky, ¶¶ 84–87.

a first magnetic device at a position adjacent to one another as measured along a central axis.

Paper 15 at 26.

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 26. 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 26–27.

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 element [1H] with the conclusory statement that any components "situated next to

each other on the same axis” would be axially adjacent. Pet. at 27. 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, ¶¶ 198–199. Such statements, however, ignore the plain and ordinary meaning of the claim terms that specify which axis is implicated. Leschinsky, ¶ 79.

Claim element [1E], for example, recites that the magnetically driven rotor is rotatable about a central axis, and element [1F] recites that the magnetically driven rotor is rigidly coupled to a first magnetic device. Accordingly, recitation in claim element [1H] that the first magnetic device is at a position axially adjacent to the magnetically driven rotor 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 [1L] by referencing the counterpart concept of radial adjacency. In particular, element [1L] recites that a blood outflow port is positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically

driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor. 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.*

In view of the recitations throughout claim 1 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 first magnetic device that is at a position axially adjacent to a magnetically driven rotor 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. Ground 1 Impermissibly Mixes Teachings From Distinct Embodiments Without A Supporting Rationale

Petitioner impermissibly selects features from distinct embodiments in Wampler without providing any analysis regarding *why* they would have been combined in the contended manner. 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 of FIGS. 1–8), though there is no discussion of why such teachings can be combined.

Instances of Petitioner's selective combining of features from distinct embodiments in Wampler without providing any supporting rationale are discussed below. Each of these unsupported modifications is improper.

a. Wampler Does Not Teach Or Suggest A Magnetically Driven Rotor Positioned Outside A Ventricle Of A Heart [1B]

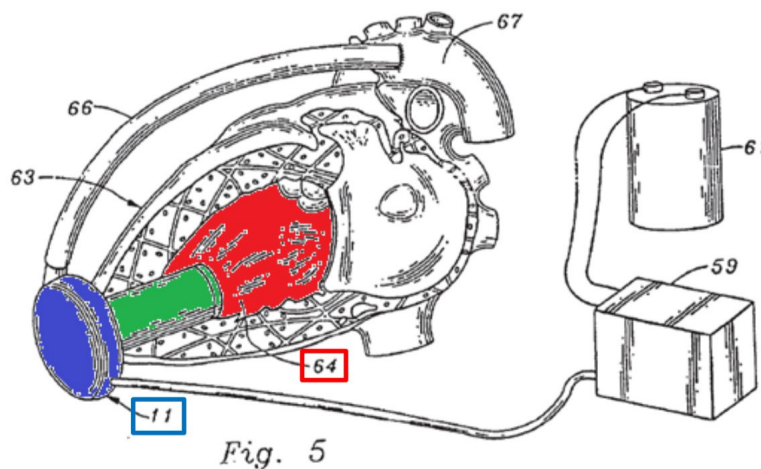
Petitioner has not shown that Wampler teaches or suggests a method including delivering a heart assist pump device to a heart so that a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart.

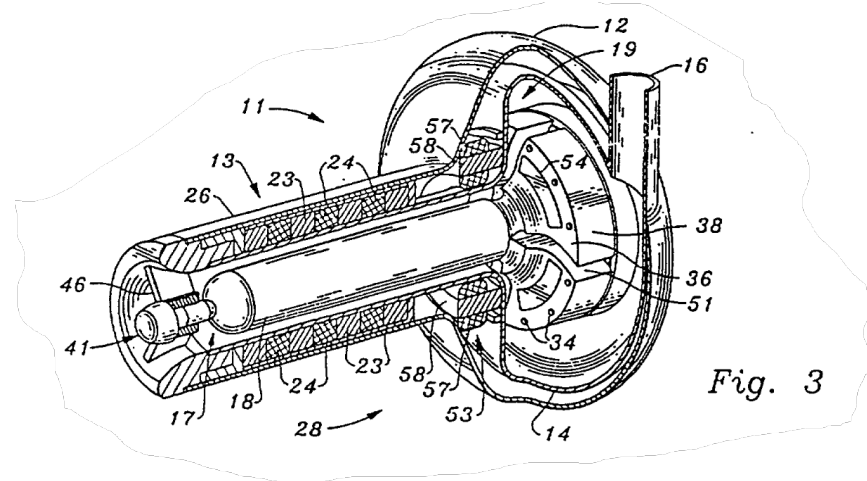
Petitioner points to Wampler's FIG. 5, which purports to show the "anatomical placement of the pump 11," including placement of the inlet tube 13 "into the apex of the left ventricle 64." Ex. 1008, ¶ [0075]; Pet. at 16.

Petitioner then switches to another embodiment of a pump and interprets the claimed rotor to be only the impeller 74 of the disclosed rotor 17 shown in FIG. 11 of Wampler. Crosby, ¶ 160. Wampler, however, includes no disclosure regarding the embodiment of FIG. 11 being implanted in the same manner as the embodiment of FIG. 5. Leschinsky, ¶ 101. There is, for example, no counterpart figure showing the embodiment of FIG. 11 implanted in a heart, nor is there text disclosure to this effect.

In addition, Petitioner selectively defines the rotor of Wampler in order to meet the [1B] recitation that the magnetically driven rotor is positioned outside the ventricle of the heart based on the illustrated positioning of the embodiment shown in FIG. 5. But Wampler defines its rotor 17 as including both the impeller 74 and a

support shaft or spindle 18. *See, e.g.*, Ex. 1008, ¶¶ [0051], [0074], and [0081], as well as FIGS. 3, 4, 11, 15, 17, and 19 (labeling the rotor 17 by pointing to a distal end portion of the rotor that is the shaft 18). FIG. 5 shows positioning of the pump 11 that would place the shaft 18 of the rotor (disposed inside the green inlet tube 13 in Petitioner's annotated FIG. 5 below) *within* the ventricle of the heart, contrary to the claim [1B] recitation. This is because the shaft 18 of the rotor 17 extends into the inlet tube 13, as shown in Petitioner's annotated FIG. 13, as well as FIG. 3 of Wampler that more particularly shows the embodiment of FIG. 5.





with that shown in FIGS. 11, 13, 15, 17, and 19, suggests a similar result would be reached if the later pump embodiments were positioned in the manner Petitioner contends. Leschinsky, ¶ 111.

b. Wampler Does Not Teach Or Suggest A Magneto Coupling Orienting A Magnetically Driven Rotor So That The Rotor Remains Entirely Spaced Apart From A Rotor Housing [1M]

Petitioner's discussion of this claim element highlights disclosure in Wampler 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; Crosby, ¶¶ 235–238; Ex. 1008, ¶¶ [0089]–[0092]. Petitioner focuses on these hydrodynamic bearings in the FIG. 11 *et seq.* embodiment to conclude that magneto coupling between magnetic pieces 88 of the impeller 74 and motor stators 90 and 94 drives rotation of the impeller 74 and, in response to that rotation, the hydrodynamic bearings maintain the impeller entirely spaced apart from the casing 14. Crosby, ¶ 239.

But, Petitioner relies on the embodiment of FIGS. 1–8 in Wampler to disclose various features where convenient, such as the implantation of the pump in a heart shown in FIG. 5. The embodiment of the pump shown in FIG. 5, however, includes thrust bearings 39 and 41 to maintain positioning of the rotor 17 relative to the housing 12. Ex. 1008, ¶¶ [0058]–[0062]. Given that the thrust

bearings 39, 41 involve contact with the rotor 17, however, this embodiment cannot satisfy the recitation of element [1M] that the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing. Leschinsky, ¶ 117.

Petitioner provides no explanation of why a POSA would, or even could, have substituted the various disclosed embodiments. This deficient analysis does not meet Petitioner's burden of proving claim 1 obvious.

c. Wampler Does Not Teach Or Suggest Connecting An External Control Unit To A Heart Assist Pump Device [1N]

For claim element [1N], Petitioner relies on the pump of FIG. 11 to allegedly teach the first and second magnetic devices, magneto coupling therebetween, and other elements of the claim. Indeed, Mr. Crosby has indicated he is relying only on the embodiment shown in FIG. 11. Ex. 2014 at 34–35. For element [1N], 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. 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.

d. Wampler Does Not Teach Or Suggest An External Control Unit Positioned Exterior To The Body While An Inflow Tube Is In A Heart [1O]

Here, as with element [1N], Petitioner relies on the pump of FIG. 11 to allegedly teach many elements of the claim, including the first and second magnetic devices, magneto coupling therebetween, etc. Indeed, Mr. Crosby has indicated he is relying only on the embodiment shown in FIG. 11. Ex. 2014 at 34–35. For element [1O], however, Petitioner cites to controller 59 and the implanted pump shown in FIG. 5 of Wampler, which shows components from the embodiment of FIGS. 1–8. Pet. at 40–41; 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, nor is the pump of FIG. 11 shown implanted in a heart. Leschinsky, ¶ 123. Neither Petitioner nor its expert provide argument or reasoning regarding how or why a POSA would have combined the two embodiments disclosed in Wampler.

B. Bourque-2001 And Wampler Fail To Render Obvious Claims 1–7, 10, 12, And 13 (Ground 2)

The Petition fails to demonstrate that independent claim 1 of the '356 patent would have been obvious over Bourque-2001³, alone or in view of Wampler, and

³ Described at Leschinsky, ¶¶ 88–91.

therefore fails to prove any claim unpatentable under Ground 2. Additionally, neither Bourque-2001 nor Wampler teaches the additional features of dependent claims 5 and 7.

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 Bourque teaches a rotor “axially aligned” with the inflow tube.

Paper 15 at 28, 32.

The method of claim 1 includes delivering a heart assist pump device to the heart by inserting a suction end of an inflow tube into a ventricle of the heart where the rotor is axially aligned with the inflow tube.

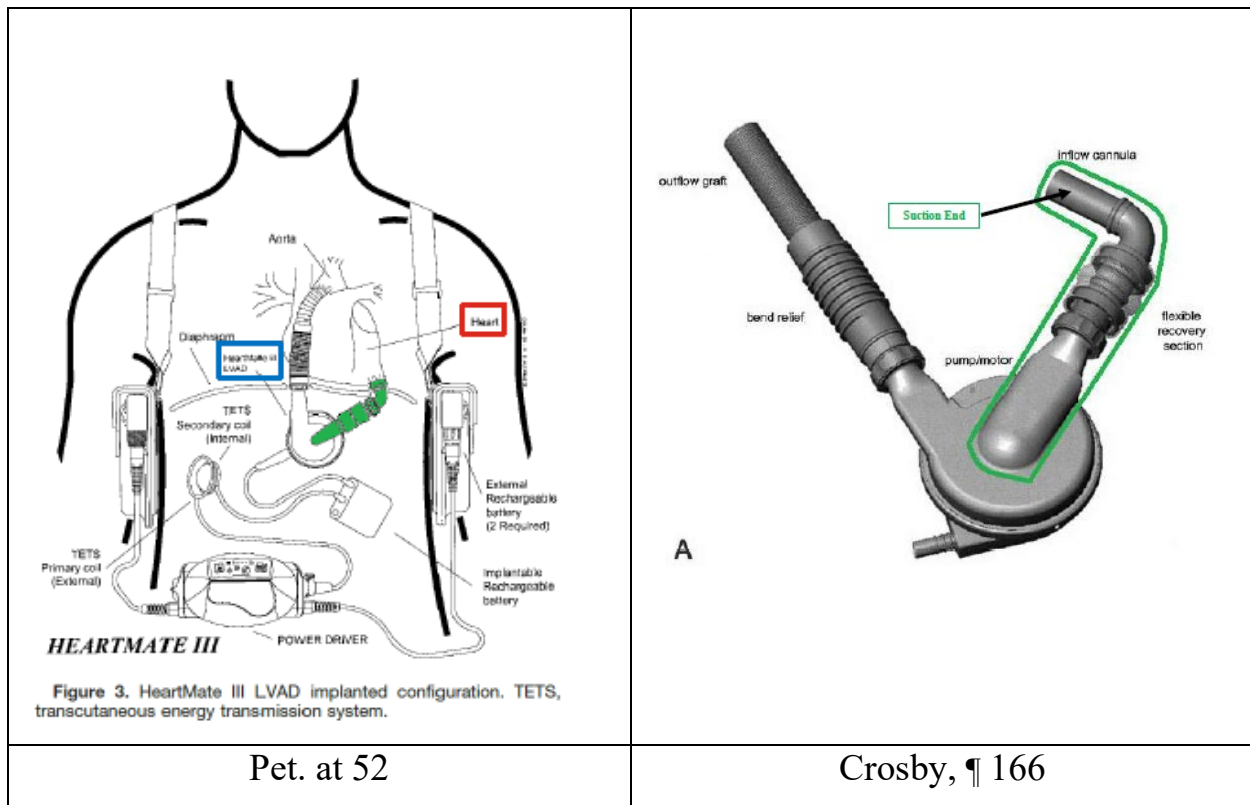
Claim 1 includes the following critical language:

[1A] delivering a heart assist pump device to the heart so that a *suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart ...*

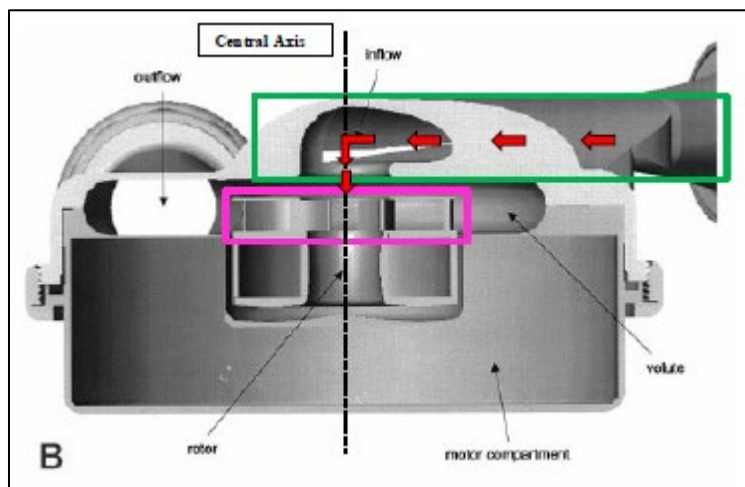
[1C] wherein the magnetically driven *rotor is axially aligned with the inflow tube...*

Ex. 1001 at 5:26–32. Bourque-2001 does not disclose this configuration, nor does it teach or suggest it, 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 50–52; Crosby, ¶¶ 163–166. 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 50–52; Crosby, ¶¶ 164–166), as illustrated below:



Petitioner uses annotated graphics in an attempt to make the facts seem different. Pet. at 54–55. Petitioner presents its graphic having red arrows representing that flow (the blood) in an attempt to show axial alignment:



Pet. at 55. 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, ¶ 131; *accord*, Paper 15 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, ¶¶ 130–134; *accord*, Paper 15 at 32.

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 15 at 34, 36. 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 credited, 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 15 at 35; Pet. at 86–87; Crosby, ¶¶ 472–475. In fact, at the time of these publications, *no* LVAD fit well at that position. Leschinsky, ¶ 150; Gallegos, ¶ 51. Wampler provides an artist's rendition of an aspirational implantation—but

the Wampler pump was never implanted. Leschinsky, ¶ 137; 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, ¶ 138; 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, ¶ 139; 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 (Crosby, ¶ 73)) 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

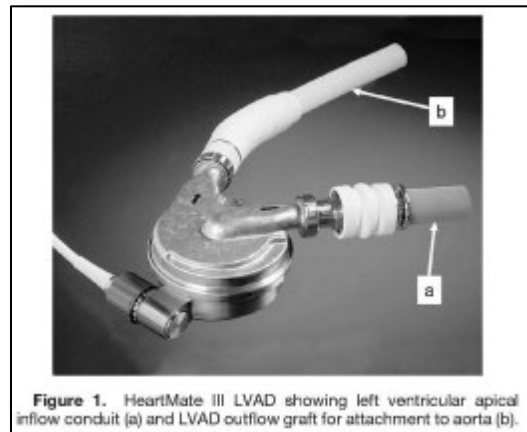
suggested that some freedom of movement between the native heart and pump ameliorates stresses imposed on the heart by an imperfectly placed pump, subdues unnecessary pump motion and potential tissue trauma caused by cardiac motion.”

Id. at 405; Leschinsky, ¶¶ 141–143; 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 its 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 '356 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 placement, spaced apart from the heart, by a flexible cannula to be the best fit. Leschinsky, ¶ 144; Gallegos, ¶ 56.

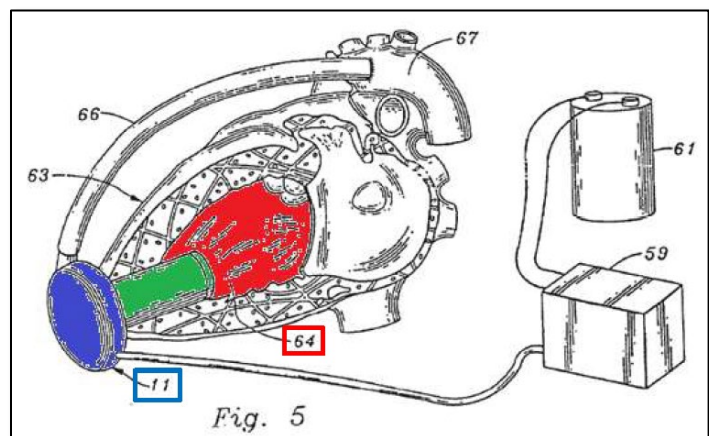
There is no doubt that Petitioner itself, through the Bourque-2001 reference and through other papers by Mr. Bourque and co-authors, taught POSAs that the best placement of an LVAD is in a preperitoneal pocket—the exact opposite of the motivation that they urge on the Board now.

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, ¶ 149; 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 56. Petitioner annotates Figure 5 of Wampler (Petitioner's annotation from page 56 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. Pet. at 84. 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, ¶¶ 147–149; Gallegos, ¶ 54.

- i. 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

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 87; Crosby, ¶¶ 473–476. The Institution Decision quoted this language from Petitioner. Paper 15 at 35. 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, ¶ 150; 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's 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, ¶ 151; 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, ¶ 151; 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, ¶ 153; 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, ¶ 152.

As of the priority date, none of the experts in this proceeding were aware of an LVAD being implanted at the apex of the heart. Leschinsky, ¶ 150; 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, ¶ 150; 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, ¶ 153; 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, ¶ 154; 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, ¶ 155; 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, ¶ 155; Gallegos, ¶ 66.

Similarly, weight is critical to the placement of an LVAD as well. The heart moves during a heartbeat. Leschinsky, ¶ 155; 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 Clinical Heartmate 3 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, ¶ 157–162; 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, ¶ 158; Gallegos, ¶ 59; Ex. 2010 at 5.

This new design was tested and described by Mr. Bourque in a 2016 ASAIO article. Leschinsky, ¶ 159; 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, ¶ 161; 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, ¶ 162; 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 15 at 36. 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, resulting in an "*axially aligned ... inflow tube*."

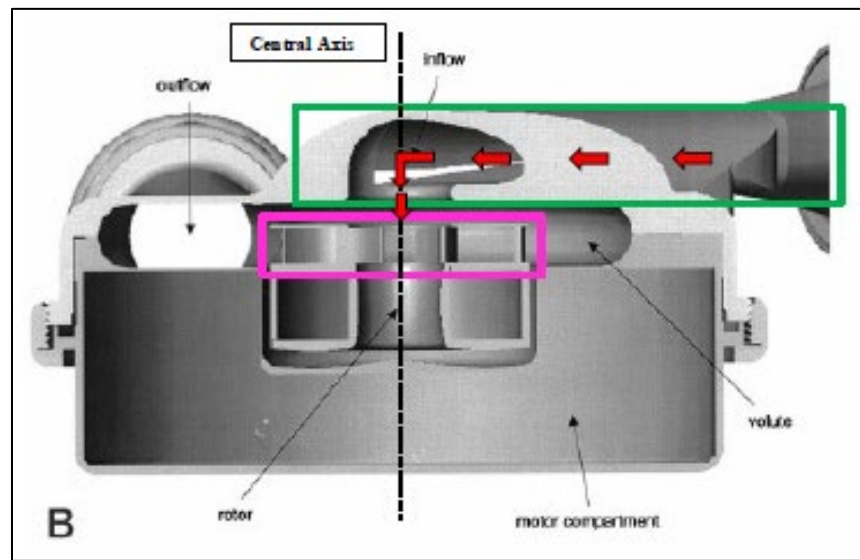
Pet. at 56 (citations omitted). The Petition goes on to describe a number of advantages that are said to flow from this placement at the apex of the left ventricle. *Id.* at 80–87. This is the motivation for which the Petition must supply sufficient evidence—but it does not.

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). For example, 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, ¶¶ 330, 326. Such a change would rotate the (green) inflow cannula 90 degrees to align with the central axis:



Id. at ¶ 326.

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, ¶ 136. 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 84–88; Crosby, ¶¶ 470–477. 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, ¶ 163; Gallegos, ¶ 68.

Petitioner also asserts that this combination would remove a flow restrictive elbow. Pet. at 83; Crosby, ¶¶ 462–465. 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, ¶ 164. This rationale is also tied by Petitioner to placement of the pump at the apex of the heart. Pet. at 81–82; Crosby, ¶ 464; Leschinsky, ¶ 164. 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 83–84; Crosby,

¶ 470. 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, ¶ 165. 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 (¶¶ 473–476). Pet. at 87 (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, ¶ 166; 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, ¶ 167. 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 ¶¶ 167–170. All of this would need to be redesigned to make the combination. *Id.*

3. No Combination Of Bourque-2001 And Wampler Teaches Or Suggests An External Control Unit Controlling A Second Magnetic Device In Response To Measurement Values Indicative Of Cardiac Output Of The Heart [Claim 5]

Petitioner contends that Bourque-2001 discloses an external controller that controls a second magnetic device in response to measurement values indicative of cardiac output of the heart. Pet. at 77; Crosby, ¶ 430. 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 controlled in response to any measured value indicative of *cardiac output* of the heart—especially where the pump is assisting, not replacing, the heart. Leschinsky, ¶ 172.

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, ¶ 173.

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

4. No Combination Of Bourque-2001 And Wampler Teaches Or Suggests Providing Feedback Signals To An External Control Unit From One Or More Sensors [Claim 7]

Petitioner contends that Bourque-2001 discloses use of an “ultrasonic flow probe” and “solid-state catheter-type pressure transducer” to provide feedback signals to an external control unit. Pet. at 78; Crosby, ¶¶ 439–440. Bourque-2001, however, does not disclose that measurements from these instruments were provided to the external control unit that controls operation of the pump. Bourque-2001 instead describes separately the use of “electronics” for “power and control of the LVAD” and “for data acquisition” that resided together on a shelf during its experiments. Ex. 1007 at 403. In addition, it discloses that “speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III,” while “all measurements were automatically processed and recorded using Labview.” *Id.* There is no indication that any feedback signal from a sensor was provided to an external control unit that was responsible for controlling the pump. Leschinsky, ¶ 174.

Wampler's purely prophetic Figure 5 provides even less guidance. Wampler hopes that its pump can be “interconnected” with “sensors on various organs.” Wampler never discloses a sensor, never explains how the output of such sensors are feedback, and never provides an algorithm by which such feedback can be integrated or applied by the external controller. Further, neither Wampler,

Bourque, nor the Petition explains a rationale that would motivate a POSA to hunt for undisclosed sensors for some purpose. Leschinsky, ¶ 175.

Accordingly, neither Wampler, Bourque, nor their combination teaches or suggests the elements of claim 7.

C. Akamatsu Fails To Render Obvious Claims 1–7, 10, 12, and 13 (Ground 3)

The Petition fails to demonstrate that independent claim 1 of the '356 patent would have been obvious over Akamatsu⁴ alone and therefore fails to prove any claim unpatentable under Ground 3.

1. Akamatsu Does Not Teach Or Suggest A Suction End Of An Inflow Tube Inserted Into A Ventricle Of The Heart [1A]

Akamatsu simply does not disclose claim element [1A], forcing Petitioner to fabricate teachings that are not present. First, Petitioner looks to the hypothetical human implantation embodiment and draws features onto a figure that are not present in the original figure or in the text describing that figure. Further, Petitioner mis-presents language from the *ex vivo* sheep embodiment in a failed effort to add disclosure to the hypothetical human embodiment. In the end, the hypothetical

⁴ Described at Leschinsky, ¶¶ 92–96.

human embodiment that Petitioner relies on provides no disclosure of this claim element, and the sheep studies provide no relief.

Petitioner essentially relies on the conceptual and aspirational drawing of Akamatsu's FIG. 1 to disclose claim element [1A] (as well as many others). Pet. at 90–91; Crosby, ¶ 486. In doing so, Petitioner marks up FIG. 1 to illustrate the heart (red), heart assist pump device (blue), and suction end of an inflow tube (green):

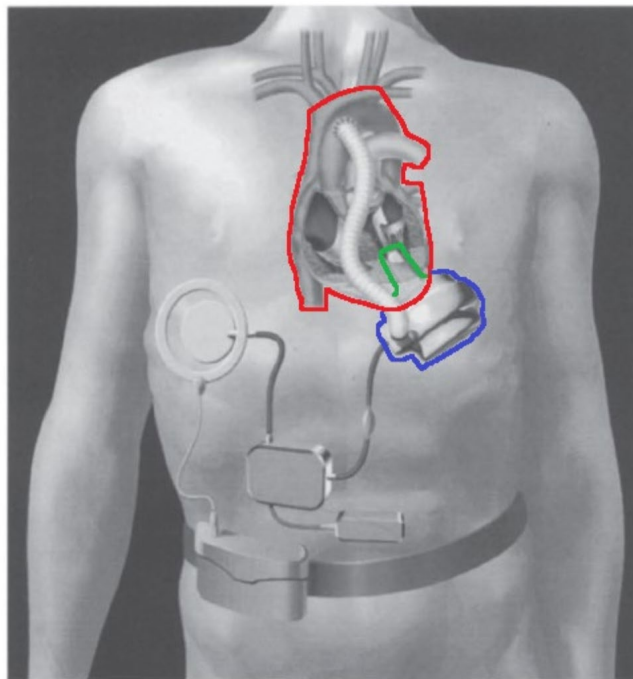


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Pet. at 91.

FIG. 1 of Akamatsu, however, does not actually show the configuration or positioning of the inlet port of Akamatsu's MSCP. Leschinsky, ¶¶ 176–177. It appears that Petitioner has essentially drawn its green line according to its desired

positioning of the inlet port, not positioning that has been actually disclosed in Akamatsu.

Petitioner's expert cites to the text of Akamatsu for further support of Petitioner's contention based on FIG. 1, noting that Akamatsu's disclosed "T-ILVAS also includes an 'inlet port' or 'inflow conduit,' which was 'inserted into the left ventricle through a cuff sutured to the left ventricular apex' during the *ex vivo* study performed on sheep." Crosby, ¶ 484 (citing Ex. 1006 at 4). This conclusion, however, ignores the implications of the text coming from description of the *ex vivo* study and incorrectly conflates "inlet port" with "inflow conduit." Leschinsky, ¶ 178.

Akamatsu discloses that its *ex vivo* study on sheep involved evaluation of the MSCP paracorporeally "for long-term durability and nonthrombogenicity in a chronic sheep left heart bypass model." Ex. 1006 at 4. This is in contrast to the "intrathoracic implantation of the MSCP" discussed following the *ex vivo* study. *See id.* at 5. Accordingly, the example to which Petitioner points for support is explicitly one that involved use of the MSCP *outside* the body (i.e., *ex vivo* or paracorporeally). Leschinsky, ¶¶ 179–180.

In this context, Akamatsu's mention of an "inflow conduit" as distinct from the "inlet port" of the MSCP shown in FIG. 2 makes sense because additional conduits would have been required to connect the prototype MSCP device

positioned outside the sheep body to the sheep heart in the *ex vivo* study. *Id.* at ¶ 181. Akamatsu discloses that “the blood-contacting surfaces of the pump and the inflow and outflow conduit were entirely modified with a heparin immobilization technique,” suggesting the *ex vivo* system included the pump (having an inlet port and outlet port), *as well as* inflow and outflow conduit to connect the exteriorly-positioned pump to the heart. *Id.* at ¶ 182; Ex. 1006 at 4. Akamatsu goes on to note that a “Dacron outflow graft...was sutured to the descending aorta and the inflow conduit was inserted into the left ventricle through a cuff sutured to the left ventricular apex,” again highlighting that components other than the pump “outlet port” and “inlet port” shown in FIG. 2 of Akamatsu were involved in the *ex vivo* study being described. *Id.*

Still further, Patent Owner now presents evidence showing conclusively that a POSA would not have placed the pump disclosed in Akamatsu as Petitioner contends because it would not have been possible to do so based on the size of the pump. Leschinsky, ¶ 184; Gallegos, ¶ 83. As a result, the intrathoracically implanted prototype pump was positioned in the chest cavity some distance from the heart and maintained use of connecting “inflow and outflow conduit” from the *ex vivo* study in order to connect the pump to the sheep heart. Leschinsky, ¶ 185. Indeed, the conceptual FIG. 1 does not show the diaphragm of the patient and, based on the size of the disclosed pump, a POSA would have implanted the pump

below the diaphragm in a preperitoneal or intraabdominal pocket. Leschinsky,

¶ 186; Gallegos, ¶ 84.

In particular, Akamatsu discloses that its pump weighed 400 grams and displaced 196 ml. Ex. 1006 at 4. This makes the disclosed pump approximately the size of the pump disclosed in Bourque-2001, which is to say more than twice the weight and volume of the HeartWare HVAD device that was the first to be positioned at the apex of the heart and inserted directly into the left ventricle of the heart. The table below summarizes the sizes of these devices:

Device	Weight (g)	Volume (ml)	Location
Bourque-2001 (HeartMate III prototype)	474	168	Pocket
Akamatsu	400	196	Pocket
HeartWare HVAD	145	50	Apex

Leschinsky, ¶ 187.

A POSA would have viewed the size of the pump disclosed in Akamatsu as prohibitive for implantation at the apex of the heart for the same reasons reviewed above with regard to Bourque-2001. Leschinsky, ¶ 188; Gallegos, ¶ 84. A POSA would therefore not have understood FIG. 1 of Akamatsu to provide the contended teaching due to the practical impossibility of implementation. *Id.* The reference

simply does not provide the teaching that Petitioner contends regarding a suction end of an inflow tube being inserted into a ventricle of the heart.

2. Akamatsu Does Not Teach Or Suggest A First Magnetic Device Axially Adjacent To A Magnetically Driven Rotor [1H]

Petitioner has not shown that Akamatsu teaches or suggests a method including delivering a heart assist pump device wherein a first magnetic device is at a position axially adjacent to a magnetically driven rotor to which it is rigidly coupled. The Institution Decision agrees with Patent Owner that the challenged claims are not obvious over Akamatsu:

Petitioner does not contend or show that Akamatsu teaches a magnetically driven rotor coupled to a first magnetic device at a position adjacent to one another as measured along a central axis.

Paper 15 at 38.

Petitioner essentially points to FIG. 2 of Akamatsu alone as support for teaching of claim element [1H], alleging with an annotated figure that the reference teaches a permanent magnet (purple) axially adjacent an impeller (pink) along a central axis (black). Pet. at 99; Crosby, ¶ 528.

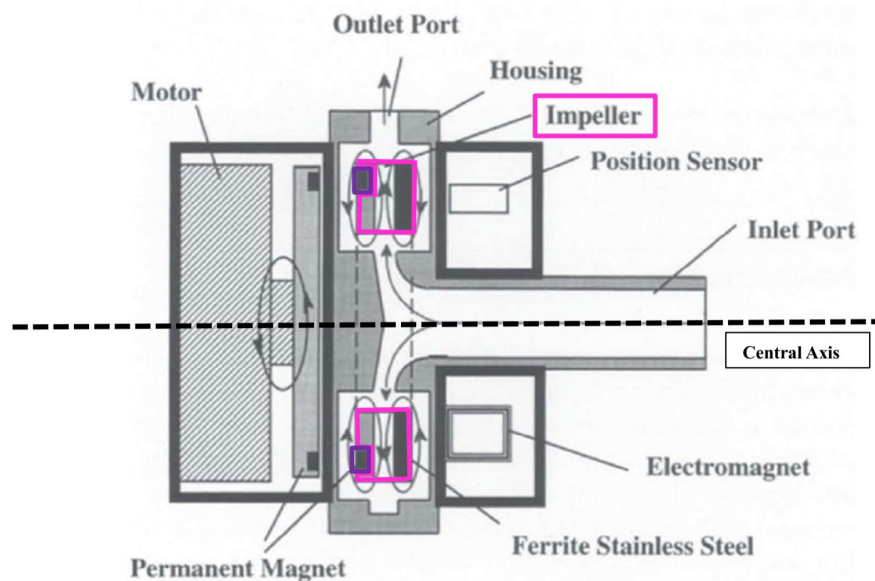


Fig. 2. Schematic cross section of the MSCP

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, ¶ 192. 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, ¶ 527 (citing Ex. 1006 at 4 and FIG. 2).

As discussed above in Section III.D, recitation in claim element [1H] that the first magnetic device is at a position axially adjacent to the magnetically driven rotor 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, ¶ 193. 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 first magnetic device that is at a position axially adjacent to a magnetically driven rotor 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.

3. Akamatsu Does Not Teach Or Suggest Connecting An External Control Unit To A Heart Assist Pump Device [1N]

For claim element [1N], 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 106;

Crosby, ¶¶ 568–572.

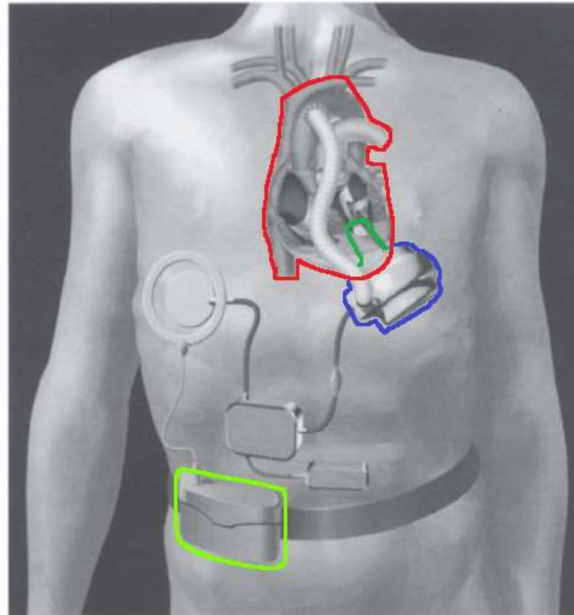


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

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, ¶ 197. 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 when describing Fig. 1, i.e., that it illustrates a "totally implantable" LVAD system, such a system would require that the

controller operating the pump be implanted, not external. Leschinsky, ¶ 197. 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.

Id. 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 ¶ 198. 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 107; Crosby, ¶¶ 568–570. 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, ¶ 200. 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 recitation of claim element [1N].

4. Akamatsu Does Not Teach Or Suggest An External Control Unit Positioned Exterior To A Body While An Inflow Tube Is In A Heart [1O]

In support of their position regarding claim element [1O], Petitioner points to their marked-up FIG. 1 from Akamatsu and suggests that it shows “a controller worn externally and positioned exterior to the body,” as well as “an inlet port that is ‘in the heart.’” Pet. at 108–109; Crosby, ¶ 576. But FIG. 1 is a conceptual illustration that does not specifically identify the components shown therein or illustrate their configuration in sufficient detail to determine whether the recitations

of claim 1 have been met. Leschinsky, ¶ 203. Despite Petitioner drawing a dark green line to denote positioning of the inlet port of Akamatsu's pump, the figure does not actually show the inlet port in this position. *Id.* at ¶ 204. Akamatsu therefore cannot teach or suggest claim element [1O].

D. Schima and Akamatsu Fail to Render Obvious Claims 1–7, 10, 12, and 13 (Ground 4)

The Petition fails to demonstrate that independent claim 1 of the '356 patent would have been obvious over Schima⁵, 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 claims 5 and 7.

1. No Combination Of Schima And Akamatsu Teaches Or Suggests A Suction End Of An Inflow Tube Inserted Into A Ventricle Of The Heart [1A]

Petitioner admits that Schima is silent regarding placement of its disclosed pump, and includes no disclosure regarding delivery of its disclosed pump such that a suction end of an inflow tube is inserted into a ventricle of the heart. Pet. at 115; Crosby, ¶¶ 630, 780. Schima, then, cannot be said to teach or suggest claim element [1A].

⁵ Described at Leschinsky, ¶¶ 97–99.

Petitioner relies upon Akamatsu to remedy this deficiency of Schima, suggesting that “it would have been obvious to implant Schima’s device in the configuration described by Akamatsu.” Pet. at 116. This contention has a number of problems.

First, the suggestion to simply implant a device not designed for operation in the human body fails as a gross oversimplification of the myriad issues that surround such an undertaking. Leschinsky, ¶¶ 205–207. Petitioner is not suggesting a combination of *certain elements* of Schima’s pump with the implantable device of Akamatsu, but instead contends that a POSA would have simply implanted “the Schima device in the configuration described by Akamatsu.” Pet. at 116. There is, however, no teaching or suggestion in Schima to suggest that its pump is configured for use in the body, even capable of being positioned at the heart in the manner claimed at all. Leschinsky, ¶ 208; Gallegos, ¶ 71; *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. Leschinsky, ¶ 210; Gallegos, ¶ 71. Even the illustrated connections of the inlet 13 and outlet 14 appear to be conventional barbed fittings configured for use with tubing and clamps to achieve

a seal, rather than structures configured to interface with the heart or other anatomical structures. Leschinsky, ¶ 212; Gallegos, ¶ 78.

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. Moving a device configured for use outside the body or in industrial settings to an implanted location within the body is a complicated endeavor that was not within the scope of disclosure in either Schima or Exhibit 1011, and would not have been obvious to a POSITA at the time of the invention. Leschinsky, ¶ 214; Gallegos, ¶ 72.

The idea that Schima discloses an extracorporeal pump not intended for implantation in the body is confirmed by reference to later work (Ex. 2022) by Heinrich Schima and several of the other inventors further describing the pump disclosed in Schima. In this 2009 paper, the authors describe the pump and various performance tests, noting that it performs “in the range of contemporary extracorporeal bearingless blood pumps.” Ex. 2022 at 256. The paper further describes that the Schima pump is likely to have “a production cost low enough to allow its use in disposable pump heads.” *Id.* at 257. This configuration of a disposable pump head that can be placed into a motor is similar to that disclosed in Ex. 1011 mentioned above. Leschinsky, ¶ 217; Gallegos, ¶¶ 75–77. A POSA at the

time of the invention would have understood what was later made more explicit in Ex. 2022, i.e., that the pump in Schima is an extracorporeal blood pump not intended for implantation in the body. Leschinsky, ¶ 218.

Moreover, Petitioner's reliance on Akamatsu as providing the required teaching to implant the device of Schima is incorrect. This is because, in proposing such a combination of the references, Petitioner inherits all of the deficiencies of Akamatsu described above under Ground 3, each of which is incorporated by reference here. *See supra*, § IV.C.

Regarding element [1A], for example, it is simply not clear from Akamatsu that the reference discloses delivering its pump so that a suction end of an inflow tube is inserted into a ventricle of the heart. *See id.* Petitioner essentially relies on the conceptual, low-resolution FIG. 1 of Akamatsu to suggest the claimed delivery of a heart assist pump recited in element [1A], but this configuration is not actually shown. Leschinsky, ¶ 220; Gallegos, ¶ 81. Instead, Petitioner marks up FIG. 1 to show a feature that is not clear in the original. *Id.* 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. *See, e.g., supra*, § IV.C.1; Ex. 1006 at 4; Leschinsky, ¶ 221. This suggests the inlet port of

Akamatsu's pump is not itself inserted into a ventricle of the heart. Leschinsky, ¶ 221.

Further, and as noted above, a POSA at the time of the invention would not have understood Akamatsu to provide a teaching of implanting its pump at the apex of the heart due to the size and weight of the disclosed pump. Leschinsky, ¶ 222; Gallegos, ¶ 84. Accordingly, implanting the pump of Schima (something that would not have been done by a POSA in the first place) in the manner of Akamatsu would have suggested to a POSA implantation at a position remote from the heart due to the size of the pump in Akamatsu. *Id.*

There is no disclosure in Schima that the size of its pump is significantly less than that of the Akamatsu pump. Leschinsky, ¶ 223; Gallegos, ¶ 85. Moreover, there is evidence to suggest Schima would also be too large to fit at the apex of the heart. *Id.* For example, Schima discloses a "diagonal pump" that utilized a conical rotor. Ex. 1005 at [0012]; Ex. 2022 at 251. Such a device generally has a larger axial height than a device with a flatter disc-shaped rotor, such as the pump in Akamatsu. Leschinsky, ¶ 223; Gallegos, ¶ 85. Accordingly, even if combining Schima and Akamatsu, a POSA would not have understood that implantation at the apex of the heart with an inlet tube disposed in the left ventricle of the heart was possible. Leschinsky, ¶ 224; Gallegos, ¶ 83.

Accordingly, Akamatsu fails to teach or suggest claim element [1A]. 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.

2. No Combination Of Schima And Akamatsu Teaches Or Suggests Connecting An External Control Unit To A Heart Assist Pump Device [1N]

Petitioner admits that Schima does not disclose connecting an external control unit to its pump. *See* Pet. at 136; Crosby, ¶ 719. Schima, then, cannot be said to teach or suggest claim element [1N].

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 136; Crosby, ¶ 720. 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.3.

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, ¶ 227. 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. *Id.*

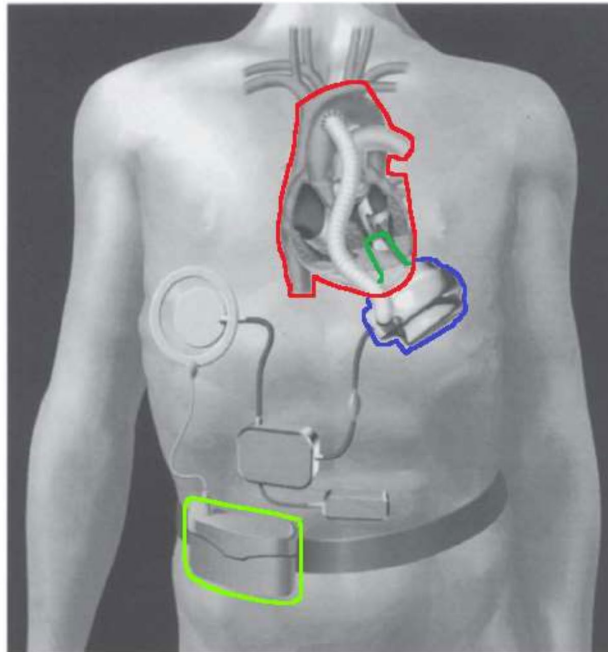


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

For all of the reasons detailed in § IV.C.3 above, Akamatsu fails to teach or suggest claim element [1N]. 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. No Combination Of Schima And Akamatsu Teaches Or Suggests An External Control Unit Positioned Exterior To A Body While An Inflow Tube Is In A Heart [1O]

Petitioner admits that Schima does not disclose claim element [1O]. Pet. at 138; Crosby, ¶ 722. In support of their position regarding claim element [1O], Petitioner refers to their earlier arguments with regard to claim elements [1A] and

[1N] that contend Akamatsu provides the missing teaching from Schima. Pet. at 138; Crosby, ¶¶ 723–724. 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.

As noted above, there are a number of issues with Petitioner's position. These include, for example, the fact that FIG. 1 is a low-resolution conceptual illustration that does not specifically identify the components shown therein or illustrate their configuration in sufficient detail to determine whether the recitations of claim 1 regarding placement of an inflow tube and controller have been met. Leschinsky, ¶ 213; Gallegos, ¶ 81. As a result, Petitioner has not carried its burden of proving that claim 1 is unpatentable under Ground 4.

4. Petitioner's Motivation To Combine Reasons All Fail

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 '356 patent—"reducing mechanical stress on the blood during pumping." Pet. at 147–148; Crosby, ¶¶ 781–782, 791. 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, ¶¶ 235–236; 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 148; Crosby, ¶¶ 783–785, 792–797. 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, ¶ 237. 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 148–149. This is true only when viewed with Petitioner's selective blinders. A POSA would have understood 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. Leschinsky, ¶ 238.

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 149. A POSA would not have had a reasonable expectation of success in attempting to deliver the extracorporeal pump of Schima to the heart. Leschinsky, ¶ 239. Furthermore, Akamatsu fails to teach or suggest delivering its pump to the heart as Petitioner contends. *Id.* Akamatsu's teachings are also deficient 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 239–240; Gallegos, ¶¶ 87–91.

5. No Combination Of Schima And Akamatsu Teaches Or Suggests An External Control Unit Controlling A Second Magnetic Device In Response To Measurement Values Indicative Of Cardiac Output Of The Heart [Claim 5]

Petitioner admits that Schima does not disclose any external control unit, so relies solely on Akamatsu to provide this teaching. Pet. at 143; Crosby, ¶ 750.

Petitioner contends that Akamatsu's disclosure of operating its pump at a "fixed

rotational speed” and separately measuring “aortic pressure and pump flow rate” teach the claim. Pet. at 47; Crosby, ¶¶ 750, 752–753. Disclosure of operating a pump at a fixed rotational speed while also taking measurements, however, does not teach or suggest that the measurements are provided to an external controller or that speed is set or adjusted by the external controller in response to the measurements. There is also no explanation as to how either aortic pressure (an inflow pressure) or a pump speed is indicative of cardiac output. Leschinsky, ¶ 242. Petitioner draws a connection that is not taught or suggested in the references themselves.

6. No Combination Of Schima And Akamatsu Teaches Or Suggests Providing Feedback Signals To An External Control Unit From One Or More Sensors [Claim 7]

Petitioner admits that Schima does not disclose any external control unit and relies on Akamatsu to provide this teaching. Pet. at 144; Crosby, ¶ 761. Petitioner contends that a POSA would understand Akamatsu's disclosure of “three position sensors to maintain the impeller free-floating at the center of the pump housing” as requiring providing feedback signals from the sensors to an external control unit. Pet. at 144; Crosby, ¶ 762. As noted above, however, Petitioner relies on an embodiment of a pump shown in Fig. 1 and described as a “totally implantable” LVAD that would require basic pump control by an *internal* control unit to allow a

user to remove the belt and attached component contended by Petitioner to be the external control unit. Leschinsky, ¶ 243. Accordingly, a POSA would not understand disclosure of using position sensors to maintain the impeller relative to the pump housing as requiring providing feedback signals to an external control unit.

V. CONCLUSION

For the reasons articulated above, the Board should find that the challenged claims of the '356 patent have not been shown to be unpatentable.

Respectfully submitted,

Date: September 30, 2025

/ Joshua P. Larsen /

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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 13,899 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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