

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
PRELIMINARY RESPONSE TO PETITION**

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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)

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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

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

Patent Owner Miracor Medical SA files this preliminary response to the Petition (“Pet.”) for *Inter Partes* Review of U.S. Patent 11,351,356 (“the ’356 patent”), setting forth the reasons a trial should **not** be instituted. 37 C.F.R. § 42.107.

The Board should deny institution because Petitioner does not carry its burden to show unpatentability of at least one of the challenged claims of the ’356 patent. Petitioner’s failures extend from its inappropriate and contradictory claim construction to its incomplete—or completely absent—obviousness analysis, despite all of its grounds being advanced under 35 U.S.C. § 103. Moreover, attempting to address Petitioner’s obviousness grounds—despite their lack of required particularity—shows that each of the grounds fails to teach or suggest several of the elements recited in the challenged claims.

II. PERSON OF ORDINARY SKILL IN THE ART

For purposes of this preliminary response, Patent Owner takes no position regarding the appropriate level of skill for a person of ordinary skill in the art (POSITA) because the reasons for non-institution addressed below do not turn on the level of ordinary skill used. Patent Owner reserves the right to address this issue in its merits response, should the Board decide to institute.

III. PETITIONER ENGAGES IN INAPPROPRIATE AND CONTRADICTORY CLAIM CONSTRUCTION

A. Petitioner Proposes Two Claim Constructions That Contradict Its Grounds of Unpatentability

Petitioner proposes narrowing claim constructions for the terms “magneto coupling” and “by the blood flowing” that Petitioner actually contradicts in its grounds of unpatentability. These narrowing positions—essentially Petitioner’s non-infringement positions in the co-pending litigation—would eliminate at least the Wampler and Bourque references from consideration. Petitioner’s claim construction proposals are not serious, and they result in Petitioner’s grounds being unclear.

B. “Magneto Coupling”

For the purpose of Petitioner’s argument, 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 construction. Both Wampler and Bourque use electromagnetic drivers—if the Board were to adopt Petitioner's proposed claim construction, Ground 1 and Ground 2 would necessarily fail. One might ask, why would Petitioner propose limiting constructions that would exclude its own grounds? The only answer is that Petitioner is merely advancing its district court non-infringement positions in this proceeding.

In fact, 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 claim construction.

The problem that remains, however, is that the Petition contradicts itself in a way that allows no *prima facie* obviousness position. Petitioner argues that “magneto coupling” must exclude electromagnetic drivers, and then points to electromagnetic drivers in Wampler and Bourque as forming one side of the

“magneto coupling” of the claims. As further explained below, the burden is on Petitioner to provide clear and particular grounds. This Petition fails that test.

C. “By the Blood Flowing”

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 reference applies magnetic bearings.

Petitioner's analysis 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. Put back in context, there is no reason in the plain meaning of the claim language that magnetic bearings should be excluded from the scope of the claim.

Again, Petitioner's analysis, while wrong, creates a situation that undercuts its own *prima facie* position. It cannot be the case that the claim excludes

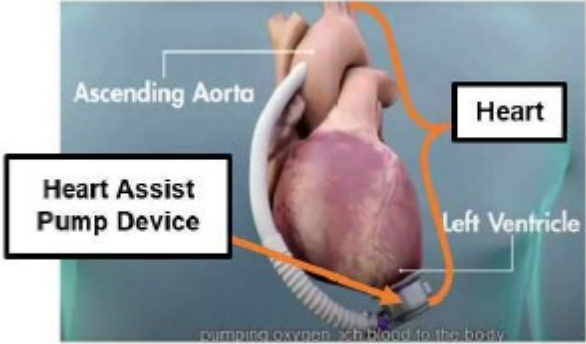
magnetic bearings, but the magnetic bearings of Bourque discloses the claim language. These contradictory positions cannot make out *prima facie* obviousness.

D. Throughout the Petition and the Crosby Declaration, Petitioner Engages in Improper Claim Construction Based on the Notice Pleadings from Co-Pending Litigation

Petitioner and its expert (Peter Crosby, whose declaration, Exhibit 1003, is referred to herein as “Crosby”) 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 times¹, 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.

For example, in discussing the Wampler reference, Mr. Crosby engages in the following claim construction:

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

Crosby, ¶ 160	Ex. 1019 at 4
<p>I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the “rotor” of the “HeartMate 3” to the “magnetically driven rotor” element recited in Claim 1. Ex. 1019, at [p.] 4 (Complaint, Ex. 7). For the purposes of my analysis, I map the limitation of a “magnetically driven rotor” to the “impeller 74” of the embodiment of the rotor 17 described in Figure 11 of Wampler-169 in the same way.</p>	 <p>The diagram shows a human heart with a heart assist pump device connected to it. The pump device is connected to the ascending aorta and the left ventricle. An orange line indicates the flow of blood from the pump device to the left ventricle. Labels include 'Ascending Aorta', 'Heart', 'Heart Assist Pump Device', and 'Left Ventricle'. A caption at the bottom reads 'pumping oxygen-rich blood to the body'.</p>

Mr. Crosby’s claim construction is not plain and ordinary meaning—it is advocacy dressed up as an alleged admission that was never made. Mr. Crosby and Petitioner engage in this erroneous process for nearly every claim element, rendering Petitioner’s analysis unreliable and ambiguous as to what exactly it is that the prior art is alleged to meet.

Worse, Petitioner takes opposed and contradictory positions on its “claim constructions.” For example, Mr. Crosby maps “magnetically driven rotor” to the “impeller” when he is attempting to argue that Wampler shows a magnetically

driven rotor that is outside the heart (only Wampler's impeller, not its whole rotor, is outside the heart). But later, Petitioner maps "magnetically driven rotor" differently to serve a different purpose. When attempting to argue that Wampler's rotor meets the requirement that a first magnetic device is axially adjacent to the magnetically driven rotor, the Petition points to the complaint and states:

In Parallel Litigation, PO asserts that a magnetic element sealed within a rotor is "*at a position axially adjacent to the magnetically driven rotor.*" Ex. 1019, 5–7.

Assuming that interpretation...

Pet. at 26 (emphasis in original). That is, the rotor is now not just the impeller that can be said to be outside the heart but, rather, is the entire rotating structure including the portion enclosing the magnet. This example demonstrates how Petitioner's repeated applications of the pleadings from the co-pending litigation as a statement of claim construction, particularly in ways that are improper and inconsistent, result in no *prima facie* obviousness.

IV. THE BOARD SHOULD NOT INSTITUTE *INTER PARTES* REVIEW ON INCOMPLETE OR AMBIGUOUS OBVIOUSNESS GROUNDS

It is well-settled that establishing a *prima facie* case of obviousness requires an explicit analysis of (1) the scope and content of the prior art, (2) differences between the prior art and the relevant claims, and (3) the level of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). That analysis must

include “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

A. Obviousness Grounds 1 and 3 Are Incomplete

The Petition fails to establish *prima facie* cases of obviousness, especially for Grounds 1 and 3 that are presented as single-reference obviousness challenges (Ground 1 based on Wampler alone and Ground 3 based on Akamatsu alone). Pet. at 16–50 (§ VIII.A) and 88–115 (§ VIII.C). First, the Petition fails to identify the differences between the prior art and the claims at issue. Second, the Petition fails to propose modifications to the respective primary references. Third, the Petition fails to assert rationales to support the obviousness conclusions. Instead of meeting these requirements of *Graham* and *KSR*, the Petition simply concludes the claims are obvious for Ground 1. Pet. at 41, 50. Ground 3 also lacks any analysis and does not even include conclusory statements beyond the outline headings. Pet. at 88, 109, and 115.

The Crosby declaration adds nothing to the Petition regarding Grounds 1 or 3. The testimony is often almost word-for-word identical to the petition and, like the Petition, acknowledges no deficiency in the references, proposes no modification to the references, and proffers no rationale to support an obviousness

contention with respect to any claim. *See Kinetic Techs. Inc. v. Skywords Solutions, Inc.*, IPR2014-00530, Paper 8 at 13 (PTAB Sept. 29, 2014) (“Merely repeating an argument from the Petition in the declaration of a proposed expert does not give that argument enhanced probative value. Accordingly, we give the cited evidence of [petitioner’s expert] Declaration no probative weight.”).

The Board cannot view Grounds 1 and 3 as anticipatory grounds because they are not presented as such; nor is it the Board’s role to fill the gaps in Petitioner’s reasoning and factual assertions. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (“[W]e find no support for the PTO’s position that the Board is free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR.”); *see also SAS Institute Inc. v. Iancu*, 138 S.Ct. 1348, 1355 (U.S. 2008) (“in an *inter partes* review the petitioner is master of its complaint”).

B. Obviousness Grounds 2 and 4 Are Incomplete

Ground 2 asserts Bourque and Wampler render the challenged claims obvious. Pet. at 50–88 (§ VIII.B). Ground 4 asserts Schima and Akamatsu render the challenged claims obvious. Pet. at 115–149 (§ VIII.D). While these grounds identify at least some deficiency of the primary reference and contend a secondary reference remedies the deficiency, they similarly present incomplete analysis of

why a POSITA would have been motivated to make the contended combination. In sections addressing motivation to combine the references of Grounds 2 and 4, Petitioner essentially includes a laundry list of obviousness buzzwords but does not actually provide a coherent rationale for the contended combination. Pet. At 80-88, 147-149.

The Crosby declaration is similarly unhelpful regarding Grounds 2 and 4. The testimony is often almost word-for-word identical to the petition and, like the petition, does not provide sufficient rationale to support its obviousness contentions.

Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *Magnum Oil Tools*, 829 F.3d at 1380. Because Petitioner has not offered any coherent reason why a POSITA would have made a combination with a requisite modification, Petitioner has not sufficiently shown that the challenged claims would have been obvious. *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.” (citing *In Touch*

Technologies, Inc. v. VGO Communications, Inc., 751 F.3d 1327, 1352 (Fed. Cir. 2014)) (emphasis in original)). Thus, Grounds 2 and 4 fail.

C. The Obviousness Grounds Lack Particularity

Petitioner's obviousness grounds fail to carry their burden to "show[] that there is a reasonable likelihood that the petitioner would prevail regarding at least 1 of the claims in the challenged petition." 35 U.S.C. § 314(a). "[A] petitioner must make its case-in-chief in the petition" and the petition must "identify 'with particularity' the 'evidence that supports the ground for the challenge to each claim.' 35 U.S.C. § 312(a)(3)." *PeakLogic, Inc. v. Wave Neuroscience, Inc.*, IPR2022-01527, Paper 13 at 4–5 (PTAB May 18, 2023). The Board has held that "with particularity" requires that the petition identify "the particular features of each reference in the modified device of [the] asserted ground." *IronRidge, Inc. v. Pregasus Solar, Inc.*, PGR2022-00024, Paper 9 at 40 (PTAB Aug. 10, 2022) (citing *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012)).

Petitioner here fails to meet their burden of identifying "with particularity" the evidence that supports their asserted grounds. In Section V below, Patent Owner raises numerous instances of Petitioner's lack of particularity and resulting failure to identify teachings that disclose the claim limitations. These failings are

found throughout the various grounds for obviousness advanced in the Petition, and the Board should therefore deny institution.

D. Incomplete Obviousness Grounds Should Not Be Tolerated

Obviousness grounds that do not meet the requirements noted above should not be relied upon to institute a trial. For example, the Board has routinely denied incomplete obviousness challenges that fail to identify the differences between the prior art and the claimed invention. *See Synopsys, Inc. v. Mentor Graphics Corp.*, IPR2012-00041, Paper 16 at 14, 16, 18 (PTAB Feb. 22, 2013) (not instituting review on obviousness grounds where “petition does not clearly point out the differences between the claimed invention and [the prior art reference]” and petitioner did not “explain why a person of ordinary skill in the art would have found the claimed subject matter obvious in spite of those differences”); *Google Inc. v. EveryMD.com LLC*, IPR2014-00347, Paper 9 at 21–25 (PTAB May 22, 2014) (denying institution where petition’s obviousness contentions “place the burden on us to sift through the information presented by Petitioners...and identify any differences between the claimed subject matter and the teachings” of the references”); *SAP America Inc. v. Clouding IP, LLC*, IPR2014-00299, Paper 8 at 18–19 (PTAB July 9, 2014) (“Without Petitioner having identified specifically the

differences, we are unable to evaluate properly any rationale offered by Petitioner for modifying [the primary reference] in view of [the secondary reference].”).

Instituting trial on the incomplete or ambiguous obviousness grounds in the Petition would be unfair and prejudicial to Patent Owner, as it cannot meaningfully respond to the challenge without knowing what modification of the primary reference is proposed or how that modification would be supported by an obviousness rationale. The grounds in a review trial should not be moving targets.

Grounds 1 and 3 especially—which contain no specific modification of the primary reference or identified supporting rationale—appear to be anticipation challenges masquerading as obviousness challenges. This would be confusing for the Board and Patent Owner, injecting uncertainty and complication into a trial that is supposed to be a focused, streamlined proceeding.

Because the presented grounds are *prima facie* deficient as obviousness challenges, the Board should deny institution of *inter partes* review.

V. THE BOARD SHOULD NOT INSTITUTE *INTER PARTES* REVIEW BECAUSE THE PETITION FAILS TO ESTABLISH THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

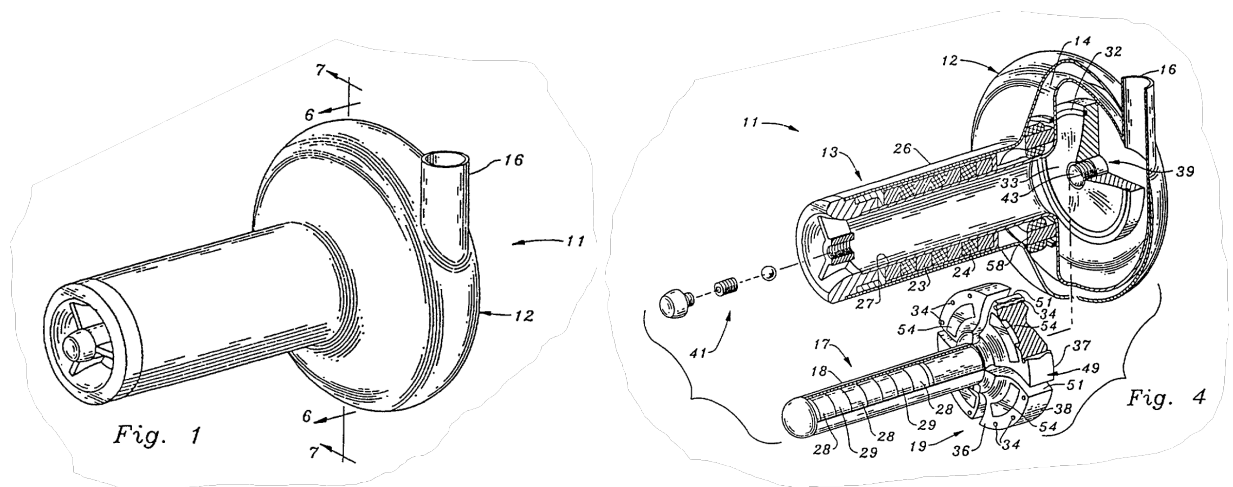
A. Wampler Fails to Render Obvious Claims 1–7, 10, 12, and 13 (Ground 1)

The Petition fails to demonstrate that Wampler teaches or suggests multiple features recited in claim 1 of the '356 patent. Petitioner thus fails to prove there is

a reasonable likelihood that claim 1 is unpatentable. Because claims 2–7, 10, 12, and 13 depend from claim 1 and recite additional features, Petitioner also necessarily fails to prove that there is a reasonable likelihood that these dependent claims are unpatentable.

1. Wampler (Ex. 1008)

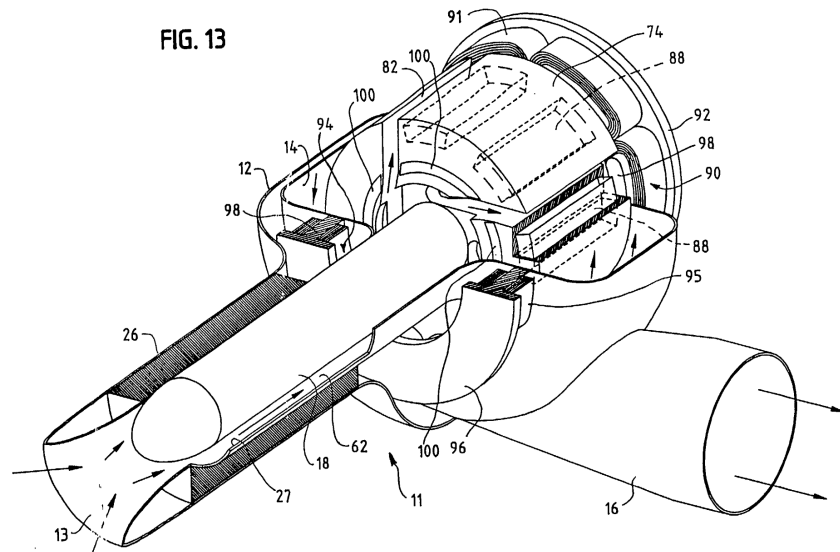
Wampler describes a “rotary blood pump [that] includes a housing and a pump rotor.” Ex. 1008, ¶ [0012]. The reference further describes that “a centrifugal pump impeller is attached to an impeller support shaft, or spindle, to form the pump rotor.” *Id.* The rotor is disposed within a pump housing that includes “an elongate inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller.” *Id.*



The rotor of Wampler is suspended within the pump housing using radial magnetic bearings that “maintain the support shaft and the impeller about a

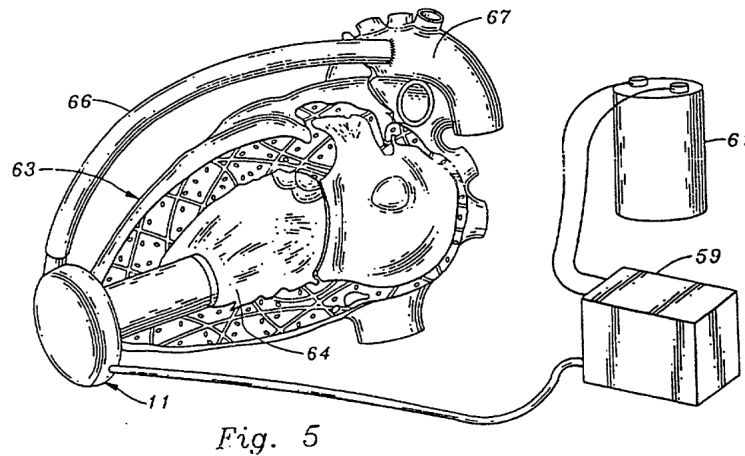
rotational axis.” *Id.*, ¶ [0013]. Further, the rotor is “axially restrained by a [*sic*] magnetic and hydrodynamic forces in combination with mechanical thrust bearings, or touchdowns.” *Id.*, ¶ [0014].

The rotor impeller has “sealed, hollow chambers...provided within the thick impeller blades” that “house magnets used in the pump drive system.” *Id.*, ¶¶ [0017] and [0018]. The rotor is rotated by “magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing.” *Id.*, ¶ [0018].



Wampler discloses several embodiments of blood pumps, including a first embodiment shown in FIGS. 1–8 and alternative embodiments shown in FIGS. 11–20. Notably, Wampler illustrates only the first embodiment implanted in a heart and including elements like a power supply and controller. *See, e.g., id.* at FIG. 5.

There is no illustration or disclosure of the alternative embodiments implanted in a heart or including ancillary components for driving the disclosed pumps.



2. Petitioner Fails to Provide an Obviousness Analysis for Wampler

As noted above in Section IV.A, Petitioner presents an obviousness ground for the '356 patent based on Wampler alone. In doing so, Petitioner (and its expert) identifies no deficiency in the teachings of Wampler with regard to the challenged claims, no modification to the teachings of Wampler required to address such a deficiency, and no rationale for why a POSITA at the time of the invention would have modified Wampler in the contended manner. Petitioner therefore fails to meet its burden to show “with particularity” how the challenged claims are unpatentable. Petitioner’s incomplete efforts to improperly advance an

anticipation rejection masquerading as an obviousness rejection should result in denial of institution.

3. 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. Ground 1 fails on this basis alone.

Petitioner begins its discussion by 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 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.

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.

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. 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.

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. 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.

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. In particular, 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. 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.

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.

4. Ground 1 Impermissibly Mixes Teachings from Distinct Embodiments without a Supporting Rationale

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

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

Four instances of Petitioner’s selective picking and combining of features from distinct embodiments in Wampler without providing any supporting rationale

for doing so are discussed under the sub-headings 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. Ground 1 also fails on this basis.

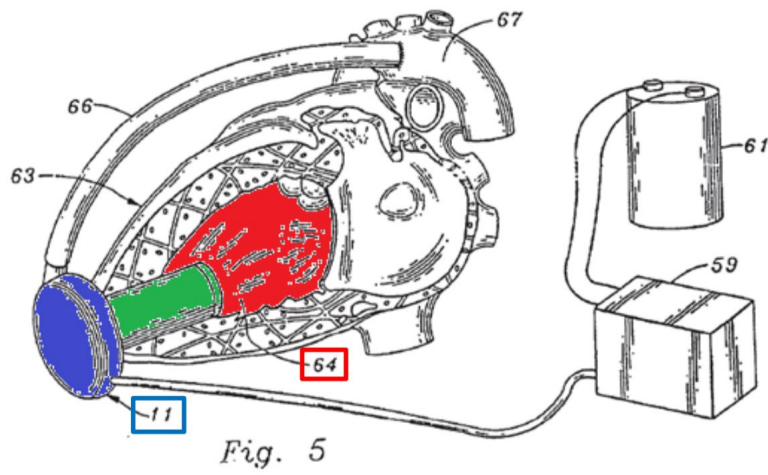
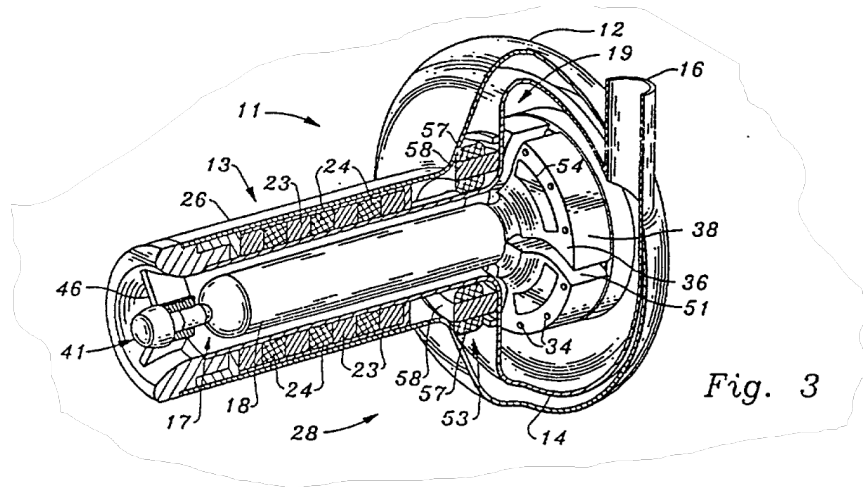
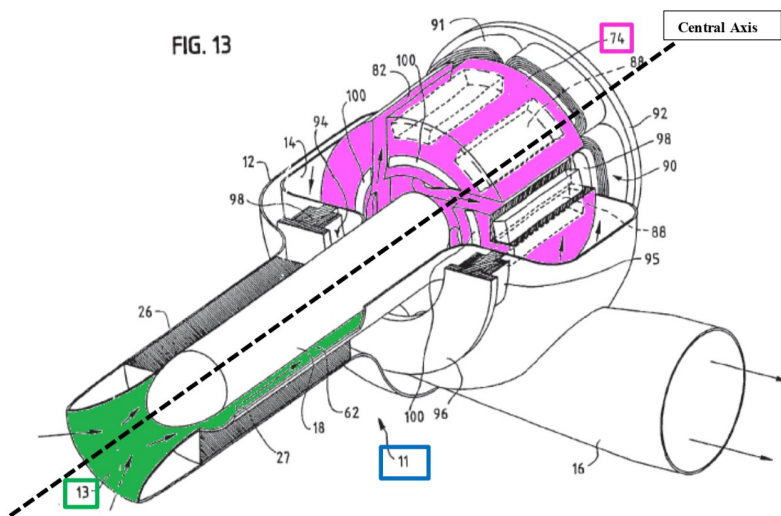
Petitioner contends that Wampler teaches the claim [1A] recitation (delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist device is inserted into the ventricle of the heart) by pointing to Wampler's FIG. 5, which purports to show the "anatomical 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.

To allege that Wampler teaches the claim [1B] recitation involving a magnetically driven rotor being positioned outside the ventricle of the heart, Petitioner 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. 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. This selective definition, however, is attempted hindsight reconstruction that is at odds with the teachings of the reference.

Wampler, for example, consistently 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). This is conveniently ignored by Petitioner because 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.



In view of this disclosure of the rotor 17 in Wampler, a POSITA would not have considered solely the impeller 74 as the rotor of Wampler. To suggest otherwise can only be explained as an impermissible attempt at hindsight reconstruction of the claim.

If the rotor 17 of Wampler includes the impeller 74 and shaft 18, the reference cannot teach or suggest a method that includes delivering a heart assist pump device to a heart so that a magnetically driven rotor of the device is positioned outside the ventricle of the heart. This is because, as FIG. 5 of Wampler shows, the inlet tube 13 of the pump 11 is “placed into the apex of the left ventricle” and the rotor 17, including its shaft 18, would extend through the inlet tube to a position adjacent to a distal end thereof, as shown in FIGS. 2, 3, 4, 7, and 8. *Id.*, ¶ [0075]. A similar configuration is shown in FIGS. 11, 13, 15, 17, and 19, suggesting that a similar result would be reached if the later pump embodiments were positioned in the manner Petitioner contends.

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 has not shown that Wampler teaches or suggests a method including delivering a heart assist pump device wherein a magneto coupling between first and second magnetic devices orients a magnetically driven rotor so

that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from a surrounding rotor housing by blood flowing from an inflow tube and to a blood outflow port. Ground 1 also fails on this basis.

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 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.

This analysis, however, also fails due to Petitioner's repeated selection of features from distinct embodiments in Wampler without any explanation about how or why a POSITA would have combined the different embodiments in the contended manner. For example, 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.

Petitioner therefore focuses on the embodiment of FIG. 11 instead to avoid the issue of thrust bearings, but provides no explanation of why a POSITA would have substituted the various disclosed embodiments. This deficient analysis leaves Patent Owner and the Board to connect the dots and does not meet Petitioner's burden of showing a reasonable likelihood of proving claim 1 obvious.

c. Wampler Does Not Teach or Suggest Connecting an External Control Unit to a Heart Assist Pump Device [1N]

Petitioner has not shown that Wampler teaches or suggests a method including connecting an external control unit to a heart assist pump device for regulating operation of a second magnetic device to thereby magnetically drive the rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device. Ground 1 also fails on this basis.

Petitioner's failure here again relates to the above-described tendency throughout the Petition to jump between disclosed embodiments in Wampler

without any explanation of how or why a POSITA would have been motivated to combine embodiments in the manner that the Petition contends.

In this instance, Petitioner has relied on the pump of FIG. 11 to allegedly teach the first and second magnetic devices, magneto coupling therebetween, and other elements of the claim. 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 POSITA would have combined the two embodiments disclosed in Wampler. To the contrary, Petitioner appears to simply assume complete combinability and interchangeability between the various embodiments disclosed in Wampler without any reasoning for doing so. Petitioner thereby proceeds to selectively pick elements from the different disclosed embodiments in Wampler without any articulated rationale to support its contentions regarding obviousness.

This complete lack of analysis and reasoning for combining different elements from distinct embodiments in Wampler leaves Patent Owner to guess at the obviousness analysis and is not sufficient to show a reasonable likelihood of success in proving unpatentability over 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]

Petitioner has not shown that Wampler teaches or suggests a method wherein an external control unit is positioned exterior to a body while an inflow tube of a heart assist pump device is in a heart. Ground 1 also fails on this basis.

Once again, Petitioner's failure here relates to its tendency throughout the Petition to jump between disclosed embodiments in Wampler without any explanation of how or why a POSITA would have been motivated to combine embodiments in the manner that the Petition contends.

Here, as with element [1N], Petitioner has relied 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. 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. Neither Petitioner nor their expert provide argument or reasoning regarding how or why a POSITA would have combined the two embodiments disclosed in Wampler. To the contrary, Petitioner appears to simply assume

complete combinability and interchangeability between the various embodiments disclosed in Wampler without any articulated rationale. Petitioner thereby proceeds to selectively pick elements from the different disclosed embodiments in Wampler without reasoning or rationale to support its contentions regarding the reference's teachings for any given claim element.

This complete lack of analysis and reasoning for combining different elements from distinct embodiments in Wampler leaves Patent Owner to connect the dots and is not a sufficient obviousness analysis to show a reasonable likelihood of success in proving the claims obvious over Wampler.

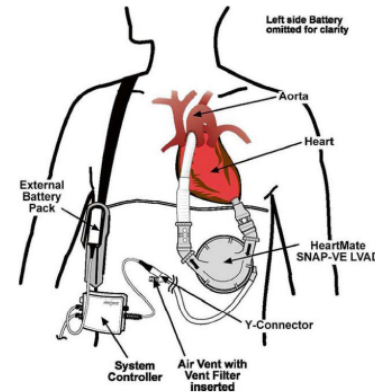
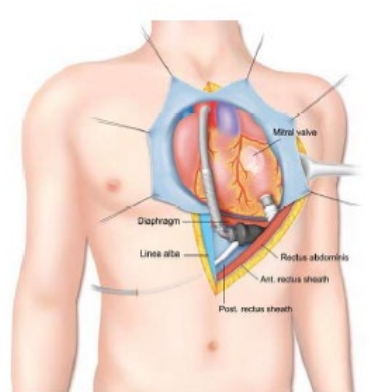
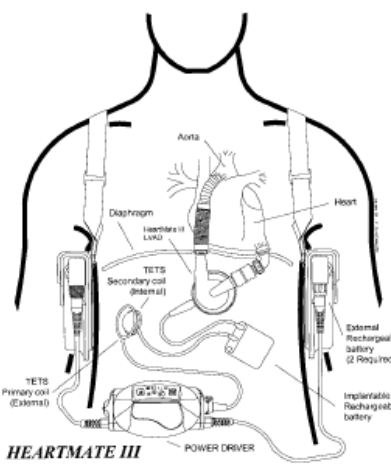
B. Bourque and Wampler Fail to Render Obvious Claims 1–7, 10, 12, and 13 (Ground 2)

The Petition fails to demonstrate that Bourque and Wampler, even in combination, teach or suggest multiple features recited in independent claim 1 of the '356 patent.

1. Bourque (Ex. 1007)

The HeartMate III pump shown in the 2001 Bourque reference relied on by Petitioner (Exhibit 1007, referred to herein as “Bourque”) was an early design concept for a centrifugal blood pump that could replace the prior HeartMate XVE (a flavor of the first HeartMate) and HeartMate II. Ex. 1007 at 401. These three pumps are implanted in similar ways. Each locates the pump in a pericardial or

abdominal pocket located below the heart. Ex. 1013 at 25 (“As with preperitoneal placement of the HeartMate XVE device, preperitoneal placement of the Heartmate II requires the dissection of a pocket.”) This location provides more room for a pump to be located, but creation of the pocket increases surgical risks.

HeartMate XVE	HeartMate II	HeartMate III
 <p>Ex. 2003, FIG. 39.1 at 727.</p>	 <p>Ex. 1013, FIG. 3 at 25</p>	 <p>Ex. 1007, FIG. 3 at 403.</p>

The flexible inflow cannula connects the pump at this remote location to the apex of the left ventricle. *See, e.g.*, Ex. 2004 at 387, with Bourque as second author, describing the same HeartMate III as having a “flexible cannula [that] is fitted upstream of the pump in-flow to improve anatomical fit, to decouple the pump from cardiac motion, and to provide a point for clamping and ligation for pump explant.”

Bourque describes the importance of this configuration this way:

To orient the pump in the least obtrusive position (i.e., in the human configuration, as in Figure 3), it was decided that the rotational axis of the pump's rotor should be perpendicular to the body's long axis. That resulted in a sharp bend in the flow before it enters the impeller. To minimize the losses in this transition, the flow is slightly accelerated through this elbow.

Ex. 1007 at 402. While the pump of Bourque was not implanted in humans (Bourque was an animal study), the planned layout illustrated in Figure 3 mimicked the placement of the HeartMate XVE and HeartMate II pumps in a peritoneal pocket because this is where the HeartMate III pump fits in the human configuration. Bourque's description of the configuration can be seen in the following annotated version of Figure 3 showing the body's long axis in blue, the heart in red, and the diaphragm in orange:

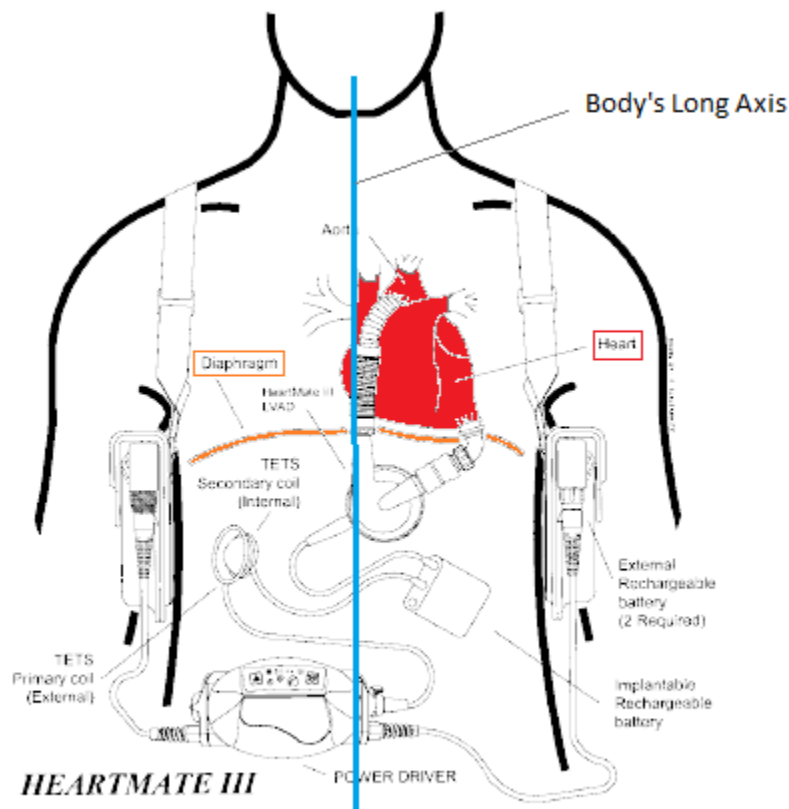


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

As illustrated, the rotational axis of the rotor (extending straight out of the page) is perpendicular to the body's long axis as Bourque describes. Because the pump is displaced from the heart, a flexible recovery section (Ex. 1007, FIG. 1A) extends in the plane of the page from the heart to the pump as explained above. The axis of the body is perpendicular to the axis of the rotor, which is perpendicular to the axis of the flexible recovery section.

2. Claim 1 Requires a Specific Relationship Between the Inflow Tube and the Rotor

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* and 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,

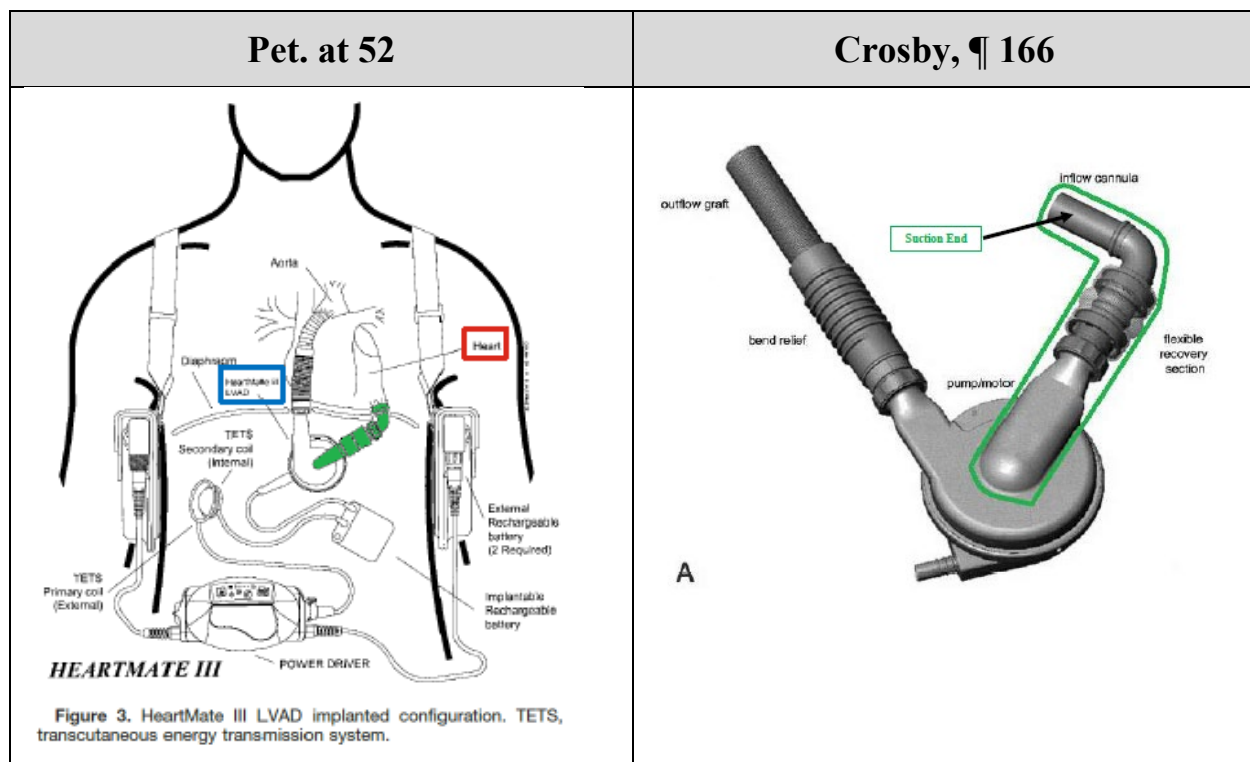
Ex. 1001 at 8. Bourque does not disclose this configuration, nor does it teach or suggest it, alone or combined with Wampler.

3. Bourque Fails to Teach or Suggest the Claimed Configuration

a. The Bourque Inflow Tube Connects the Pump to the Heart Across a Distance

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 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):

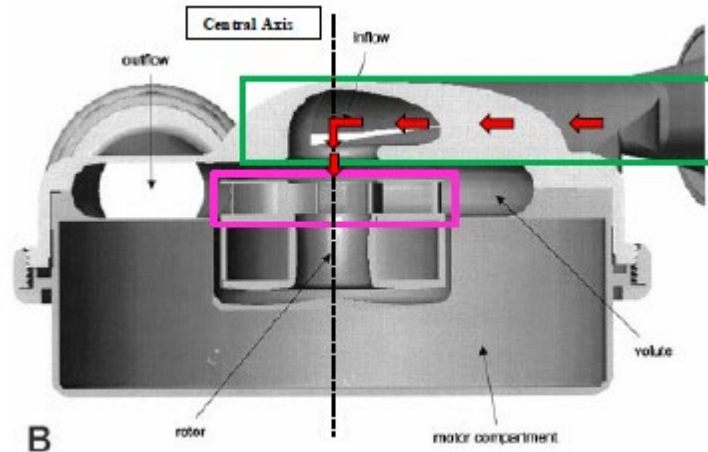


There is no doubt about the portion of the Bourque device that Petitioner alleges corresponds to the “inflow tube” and that it must extend all the way to the heart.

b. The Inflow Tube, Properly Identified, Is Not Axially Aligned with the Rotor as Recited

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

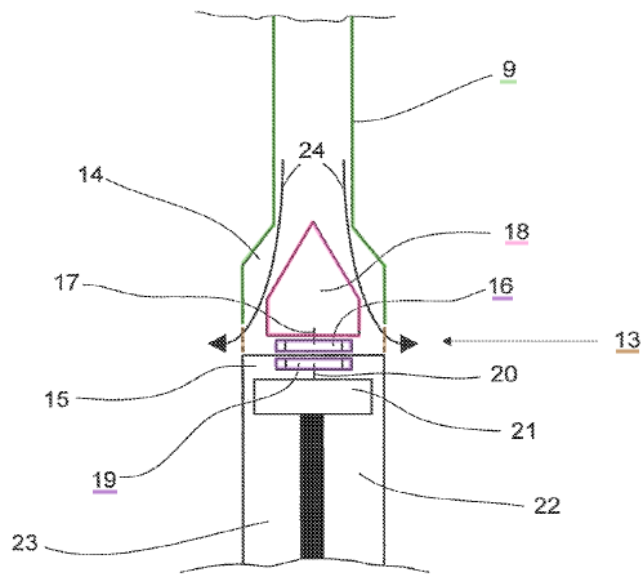
Petitioner uses annotated graphics in an attempt to make the facts seem different. Pet. at 54–55. Petitioner presents its graphic with added red arrows representing that flow (the blood) in an attempt to show axial alignment:



Id. 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. Instead, the inflow

tube (in green) is perpendicular to the central axis of the rotor. The claim language is not met. By way of comparison, the '356 patent includes an inflow tube 9 that is axially aligned with a magnetically driven rotor 18:



Ex. 1001, FIG. 2 (annotated with the colors used by Petitioner). Bourque includes an inflow tube that is not axially aligned with a magnetically driven rotor—they are perpendicular. At best, the Bourque inflow tube includes an opening in its sidewall in the region of the rotor—that is different than axial alignment.

Further, Petitioner's added red arrows are not correct. While the arrows appear to be designed to allege axial alignment with the flow, the blood does not make a 90 degree turn as illustrated by Petitioner. We know, because Petitioner published a computational fluid dynamics analysis of the HeartMate III pump (including Mr. Bourque as an author), showing that the flow is not so simple. Ex.

2005 at 874. That analysis shows first that the blood does not flow straight down along the central axis but curves into the pump at angles:

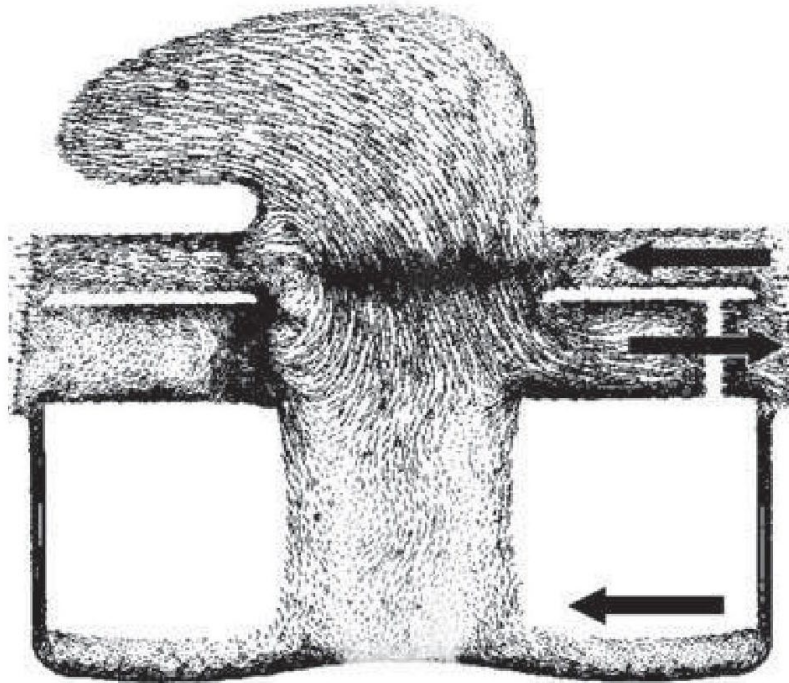


FIG. 6. Planar cut through middle of pump. Arrows indicate local flow directions.

Id. at 878.

Petitioner's computational fluid dynamics (CFD) analysis also "reveals a slight degree of swirling flow in the elbow. CFD analysis indicates that a small pocket of preswirl is induced from the impeller and migrates upward into the elbow." *Id.* Petitioner's pre-petition analysis is far more complex (and less axially aligned) than its Petition admits.

4. Wampler Cannot Be Combined with Bourque to Cure Its Deficiencies

Recognizing the problems with its position, Petitioner proposes to combine Bourque with Wampler and move the location of the HeartMate III pump within the patient's anatomy. In this attempt, however, Petitioner ignores both the teachings of Bourque and, more importantly, its own published experience showing why this combination will not work.

a. Petitioner's Combination Ignores Language in Bourque Warning Against Its Proposed New Arrangement

First, Bourque explains why the location of the HeartMate III pump as disclosed is important. Indeed, Bourque 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, ¶ 119) is the “least obtrusive position” in the “human configuration.” Ex. 1007 at 402. Bourque 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 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.

These reasons, stated expressly in Bourque, for keeping the HeartMate III pump where it is, instead of moving it as required by the proposed combination, are just 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 even acknowledges their existence.

In other publications, Petitioner and Mr. Bourque explain in greater detail why this peritoneal 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 simply ignores its own strong statements as to why its proposed combination should not be made.

In another paper 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 below. *Id.*

at 311. But even with 6 years of additional clinical experience 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 taught the preperitoneal placement, spaced apart from the heart, by a flexible cannula to be the best fit.

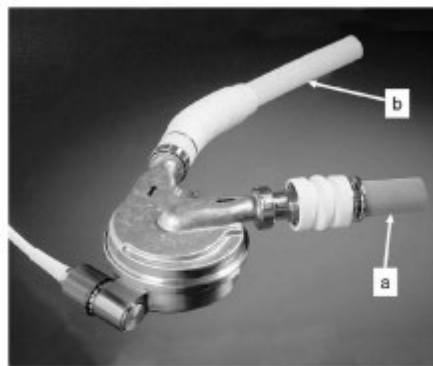


Figure 1. HeartMate III LVAD showing left ventricular apical inflow conduit (a) and LVAD outflow graft for attachment to aorta (b).

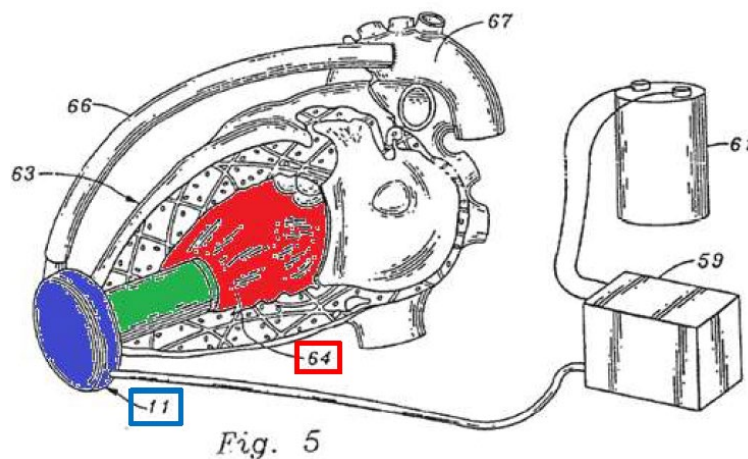
Id. at 311.

b. The Pump of Bourque Will Not Fit into Petitioner's Combination

A bigger problem for Petitioner's combination of Bourque with Wampler is that the Bourque pump is too big to fit—and we know that because Petitioner has essentially admitted it.

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 below) to show how Wampler fits one of its pump embodiments to the heart.



Petitioner further argues that a key reason for making the combination is to provide the “good anatomical compatibility” that Wampler promises. *Id.* at 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, ¶ [0076].

Bourque does not have such a compact disc. In fact, because of the size of its “motor compartment,” the Bourque HeartMate III pump will not fit well between the apex of the heart and the adjacent diaphragm. That is why Bourque

refers to its preperitoneal placement, away from the heart, as “the least obtrusive position...in the human configuration...” Ex. 1007 at 402.

Further, Petitioner 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 Wampler does.

Mr. Bourque noted the changes himself in an American Heart Association news article published in 2018: “Also potentially joining the field is HeartMate3. 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.” Ex. 2010 at 5.

This new design was tested and described by Mr. Bourque in a 2016 ASAIO article. 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, Mr. 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.

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. *Id.*; *see* Ex. 2009 (patent to the updated design with Mr. Bourque as the sole inventor).

There is no doubt that the HeartMate III pump described in Bourque is too big to work and fit as described by Petitioner in its combination of Bourque and Wampler—and there is no doubt because Petitioner repeatedly admitted it, and then engaged in inventive activity to redesign the pump to be small enough to work. An inventive redesign years later is not the mere “arrangement of old elements” that Petitioner argues. Pet. at 83.

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

Petitioner fails to demonstrate that Akamatsu teaches or suggests multiple features recited in claim 1 of the '356 patent. Petitioner, thus, fails to prove there is a reasonable likelihood that claim 1 is unpatentable. Because claims 2–7, 10, 12, and 13 depend from claim 1, Petitioner also necessarily fails to prove there is a reasonable likelihood that these dependent claims are unpatentable.

1. Akamatsu (Ex. 1006)

Akamatsu describes efforts of the “research group of Terumo, NTN, and the Setsunan University” to develop “an implantable left ventricular assist system (T-ILVAS) featuring a centrifugal blood pump with a magnetically suspended impeller (MSCP).” Ex. 1006 at 3. Akamatsu addresses efforts related to three prototype MSCPs: “the paracorporeal Model I, the implantable Model II (Fig. 3), and the modified Model II.” *Id.* at 4. Finally, there is disclosure of a “Model III system,” “for the next phase,” that includes “a prototype MSCP...and an implantable controller,” as well as “further developments...under way” regarding “a totally implantable LVAS, including a transcutaneous energy and information transfer system and internal/external batteries.” *Id.* at 7. Akamatsu includes a conceptual illustration of such a “totally implantable LVAS” in its FIG. 1, which is reproduced below.

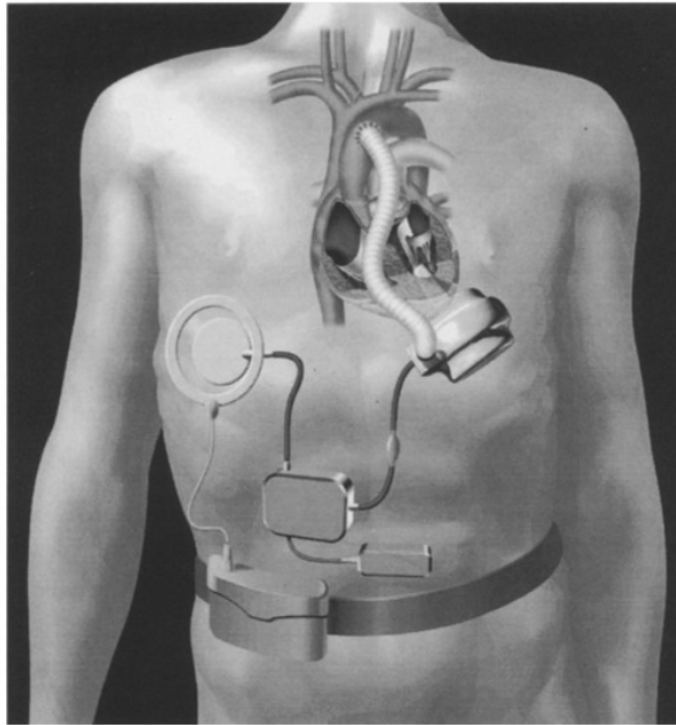


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Id. at 2.

Akamatsu describes “ex vivo” studies that evaluated the MSCP paracorporeally “for long-term durability and nonthrombogenicity in a chronic sheep left heart bypass model,” including valuation of Model I in one sheep and Model II in two sheep. *Id.* at 1. Akamatsu also describes “intrathoracic implantation of the MSCP” Model II and modified Model II prototypes in two sheep. *Id.* at 5. In the implantation cases, “the pump was percutaneously driven,” though no additional details are provided regarding what exactly this means. *Id.*

Regarding the prototype MSCPs, Akamatsu discloses that “the MSCP is composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor,” and refers to its FIG. 2 schematic. *Id.* at 4.

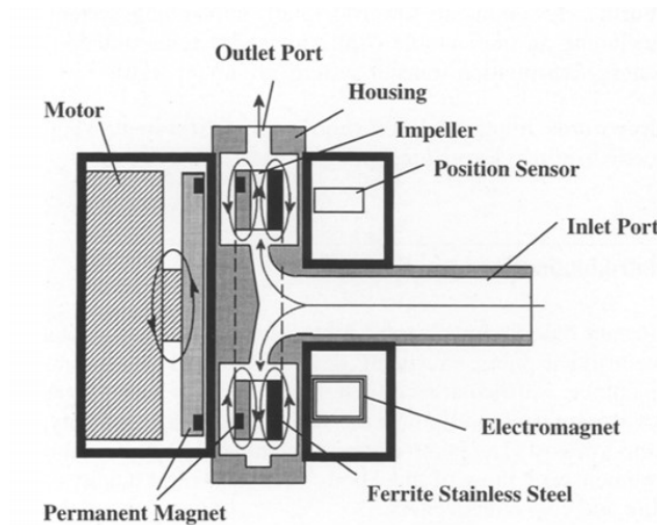


Fig. 2. Schematic cross section of the MSCP

Id. at 2.

Akamatsu notes that “the impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by...three electromagnets.” *Id.* at 4. Electric current of the electromagnets is “controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing.” *Id.*

2. Petitioner Fails to Provide an Obviousness Analysis for Akamatsu

As noted above in Section IV.A, Petitioner presents an obviousness ground for the '356 patent based on Akamatsu alone. In doing so, Petitioner (and its

expert) identifies no deficiency in the teachings of Akamatsu with regard to the challenged claims, no modification to the teachings of Akamatsu required to address such a deficiency, and no rationale for why a POSITA at the time of the invention would have modified Akamatsu in the contended manner. Petitioner therefore fails to meet its burden to show “with particularity” how the challenged claims are unpatentable. Petitioner’s incomplete efforts to improperly advance an anticipation rejection masquerading as an obviousness rejection should result in denial of institution.

3. Akamatsu Does Not Teach or Suggest a Suction End of an Inflow Tube Inserted into a Ventricle of the Heart [1A]

Petitioner has not shown that Akamatsu teaches or suggests a method including delivering a heart assist pump device to a heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart. Ground 3 fails on this basis alone.

Akamatsu simply does not disclose this claim element, 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 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 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):

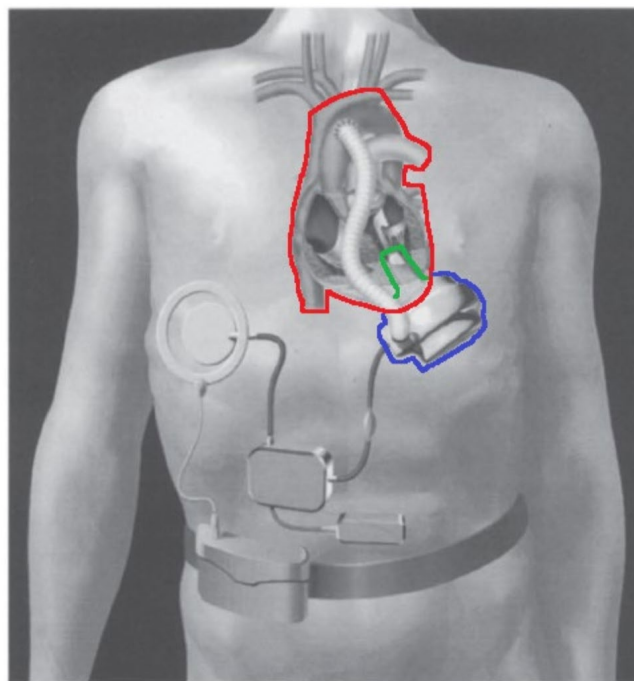


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Pet. at 91.

FIG. 1 of Akamatsu, however, is a low-resolution drawing that does not actually show the exact configuration or positioning of the inlet port of Akamatsu's MSCP. 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."

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).

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.

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 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.*

Further, Akamatsu does not include any disclosure regarding the positioning of its inlet port when discussing the study involving intrathoracic implantation of its prototype pump. Akamatsu simply notes that “the implantable Model II had a good anatomical fit in the chest cavity of a small sheep,” but nowhere does Akamatsu make clear that such positioning involved the insertion of the inlet port of the prototype pump into the left ventricle of the heart. *Id.* at 5. It is at least equally possible, and probably more likely given the pump dimensions and sheep size, that 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. Regardless, 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.

4. 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. Ground 3 also fails on this basis.

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.

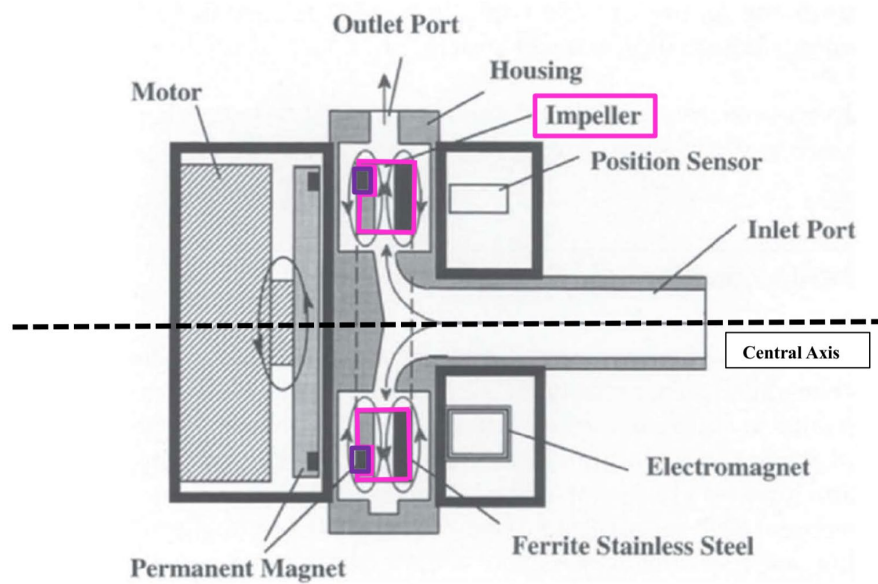


Fig. 2. Schematic cross section of the MSCP

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. 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 V.A.3, 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. 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.

The concept of “adjacent” components is clear from its plain and ordinary meaning. Adjacent components along an axis have positioning next to one another, perhaps touching or sharing a common side, when measured along the axis. 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.

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.

5. Akamatsu Does Not Teach or Suggest Connecting an External Control Unit to a Heart Assist Pump Device [1N]

Petitioner has not shown that Akamatsu teaches or suggests a method including connecting an external control unit to a heart assist pump device for regulating operation of a second magnetic device to thereby magnetically drive the

rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device. Ground 3 also fails on this basis.

Petitioner makes two confusing points in alleging that Akamatsu teaches this claim element: First, 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.

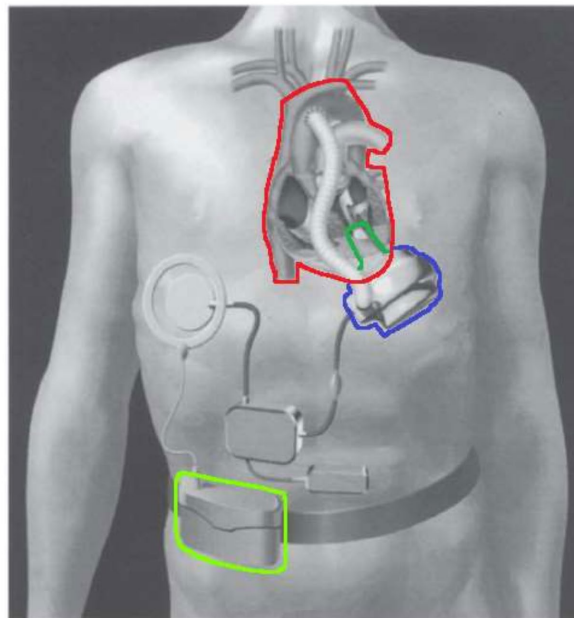


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

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. This is another reason not to allow Petitioner to

rely so heavily on this low-resolution conceptual illustration of a potential “future” system for an implantable Left Ventricle Assist System.

While it cannot be known for sure, looking at the image it seems equally—if not more—likely that the component highlighted in lime green is solely a power source, such as a battery. 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. The implanted disc is itself coupled to what appears to be an implanted controller disposed above the lime green highlighted component in FIG. 1. In support of this is Akamatsu's disclosure that its “next phase” involved “a prototype MSCP with...an implantable controller,” and that “further developments toward a totally implantable LVAS” include “a transcutaneous energy and information transfer system and internal/external batteries.” Ex. 1006 at 7.

Second, after incorrectly identifying what appears to be an external power source (coupled to an implanted controller) as the claimed external controller, Petitioner proceeds to suggest 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. 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.

Akamatsu simply lacks disclosure sufficient to teach or suggest the recitation of claim element [1N].

6. Akamatsu Does Not Teach or Suggest an External Control Unit Positioned Exterior to a Body while an Inflow Tube is in a Heart [1O]

Petitioner has not shown that Akamatsu teaches or suggests a method wherein an external control unit is positioned exterior to a body while an inflow tube of a heart assist pump device is in a heart. Ground 3 also fails on this basis.

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.

As discussed above in connection with claim elements [1A] and [1N], 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 have been met. Further, 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. 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 Schima and Akamatsu, even in combination, teach or suggest multiple features recited in independent claim 1 of the '356 patent. As a result, Petitioner fails to prove there is a reasonable likelihood that claim 1 is unpatentable. Because claims 2–7, 10, 12, and 13 depend from claim 1, Petitioner also necessarily fails to prove there is a reasonable likelihood that these claims are unpatentable.

1. Schima (Ex. 1005)

Schima purports to be directed to a “rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing.” Ex. 1005, ¶ [0001]. Schima's disclosed goal is to

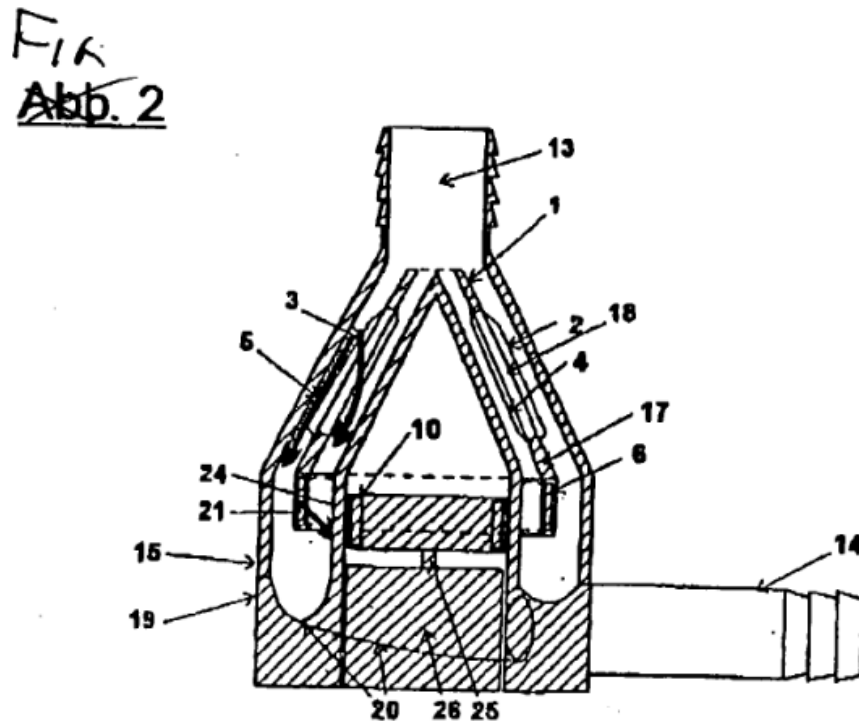
overcome disadvantages of prior devices by avoiding “mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps,” while favoring a “small” number of parts and “simple” construction. *Id.*, ¶ [0009].

Schima presents about a dozen different embodiments of rotary pumps, and describes that its “invention is characterized in that the rotor has flow-control surfaces for producing centrifugal flow components and flow components directed against the housing, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for contact-free journaling and stabilizing of the rotor in the housing.”² *Id.* at [0010]. The flow surfaces are disclosed as vanes formed on the rotor produce the various flow components. *Id.* at [0012].

Schima does not teach or suggest any practical implementation of its disclosed pump and instead discloses only details regarding the pump itself. In the

² Petitioner argues that Patent Owner admits a similar Schima reference mentioned in the '356 patent discloses everything in the claims. Pet. at 14, n.2. In fact, the '356 patent specification shows citation to the similar Schima publication with an indication that “rotor...design principles” found there may be helpful. *See* Ex. 1009 at 5, 7; Ex. 1001, 3:17–18. This is far from Petitioner's contended admission by Patent Owner that all elements of the claims are disclosed.

FIG. 2 embodiment relied upon by Petitioner, Schima discloses a pump with a rotor 1 driven by “an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25.” *Id.* at [0013].



2. 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 has not shown that any combination of Schima and Akamatsu teaches or suggests a method including 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. Ground 4 fails on this basis alone.

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].

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. Petitioner is not suggesting a *combination* of certain elements of Schima’s pump with the implantable device of Akamatsu, but instead contends that a POSITA would have simply implanted “the Schima device in the configuration described by Akamatsu.” *Id.* There is, however, no teaching or suggestion in Schima to suggest that its pump is configured for use in the body.

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. 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. There is simply no teaching or suggestion in Schima that it would have even been possible to implant its disclosed pump within the body.

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.

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*, § V.C.3.

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. Instead, Petitioner marks up FIG. 1 to show a feature that is not clear in the original. 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., id.*; Ex. 1006 at 4. This suggests the inlet port of Akamatsu’s pump is not itself inserted into a ventricle of the heart.

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

Accordingly, Petitioner’s obviousness contention fails to teach or suggest every element of claim 1 at least because Akamatsu fails to teach or suggest the portion of the claim that Petitioner admits is missing from Schima.

3. No Combination of Schima and Akamatsu Teaches or Suggests Connecting an External Control Unit to a Heart Assist Pump Device [1N]

Petitioner has not shown that any combination of Schima and Akamatsu teaches or suggests a method including connecting an external control unit to a heart assist pump device. Ground 4 also fails on this basis.

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*, § V.C.5.

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. Akamatsu is silent regarding what this component is, and it does not specifically identify any of the components pictured in FIG. 1. Instead, Petitioner is essentially filling in the gaps in Akamatsu's disclosure in a convenient manner that supports their contentions. Petitioner should not be allowed to so heavily rely

on a low-resolution conceptual illustration of a potential “future” system for an implantable Left Ventricle Assist System.

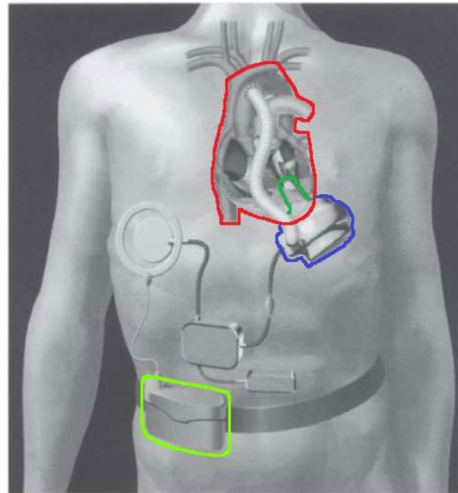


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

For all of the reasons detailed in § V.C.5 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 show a reasonable likelihood that claim 1 is unpatentable.

4. 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 has not shown that any combination of Schima and Akamatsu teaches or suggests a method wherein an external control unit is positioned exterior to a body while an inflow tube of a heart assist pump device is in a heart. Ground 4 also fails on this basis.

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*, §§ V.C.3-6.

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. As a result, Petitioner has not carried its burden of making out a *prima facie* case for obviousness and showing a reasonable likelihood that claim 1 is unpatentable in view of the references. Ground 4 should therefore fail.

VI. THE PETITION SIGNIFICANTLY EXCEEDS THE WORD LIMIT

The Petition's word-count certification indicates it is 19 words under the 14,000-word limit. *See* Pet. at 152. The Petition uses improper formatting, however, similar to what prompted a cautionary warning from the Board in *Axon*

Enterprise, Inc., v. Digital Ally, Inc., IPR2017-00375, Paper 9 at 2 n.2 (PTAB Jun. 6, 2017), as follows:

Petitioner, however, fails to use normal spacing in the Petition for numerous citations in order to reduce the word count. For example, Petitioner did not place spaces in many of its citations such as in “(Ex.1008, ¶22).” Pet. 3; *see also* The Blue Book, Twentieth Ed., Rule 3.3; *Pi-Net Int’l, Inc. v. JPMorgan Chase & Co.*, 600 F. App’x 774, 775 (Fed. Cir. 2015) (determining deletion of required spacing circumvents rule on word count). The Board expects the use of ordinary spacing in phrases and citations in submitted documents.

Like Axon’s petition, the current Petition regularly omits a space when citing to exhibits (e.g., “Ex.1001” vs. “Ex. 1001”), the expert’s declaration (e.g., “¶¶16–19” vs. “¶¶ 16–19”), and statutes (e.g., “§103” vs. “§ 103”). While such improper formatting only undercounts one word with each occurrence, these citations occur so frequently that at least 1,035 words have been improperly undercounted, as shown below:

Improper Formatting	Omitted Words
No space after “Ex.” (e.g., “Ex.1001” vs. “Ex. 1001”)	677
No space between ¶ symbol and numeral	328

No space between § symbol and numeral or letter (correct in Table of Authorities)	30
TOTAL	1035

With proper formatting, the Petition's word count would be more than 1,000 words over the limit. The result is an advantage to Petitioner and undue prejudice to Patent Owner.

The Office cautions against “deleting spacing...in order to circumvent the rules on word count” and warns that such formatting “may lead to a party's brief not being considered.” Consolidated Trial Practice Guide, Nov. 2019 Edition, at 40. Despite the severity of the warning, patent owners are often reluctant to point out such abuses in petitions for fear of being perceived as putting form over substance. The outcome is either a system tilted against patent owners or an “if-you-can't-beat-them-join-them” environment that degrades the process for everyone.

The Petition is signed by Scott Border, an experienced attorney listed by the Docket Navigator database as counsel in 148 *inter partes* reviews. Use of proper formatting in the Petition's Table of Authorities—which is excluded from the word count—in combination with incorrect formatting elsewhere in the Petition

indicates Mr. Border is aware of proper formatting and appears to have strategically used unorthodox formatting to circumvent 37 C.F.R. § 42.24.³

This Petition is an opportunity for the Board to stop permitting practices that are becoming pervasive. *Cf. Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1006 (Fed. Cir. 2016) (“The Board is not free to disregard its own regulations. Nor can it mandate compliance by only some parties.”). In these circumstances, an appropriate remedy would be denial of the Petition. Any lesser remedy would be inconsequential.

³ Additionally, Mr. Border has been counsel both in properly formatted petitions, *see, e.g., Microsoft Corp. v. B.E. Tech., LLC*, IPR2014-00040, Paper 1 (PTAB Oct. 9, 2013), and in numerous petitions that use improper formatting, *see, e.g., Microsoft Corp. v. Sterling Computers Corp.*, IPR2025-00270, Paper 1 (PTAB Jan. 17, 2025) (where Mr. Border is listed as lead counsel and similar tactics are utilized in sections of the petition subject to word count limits).

VII. CONCLUSION

For the reasons articulated above, the Board should deny institution. Patent Owner does not concede any issues not addressed or raised in this Preliminary Response.

Respectfully submitted,

Date: February 20, 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 PRELIMINARY RESPONSE
TO PETITION has 13,068 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.

/Joshua P. Larsen/

Joshua P. Larsen

Reg. No. 62,761

*Lead Counsel for Patent Owner
Miracor Medical SA*

CERTIFICATE OF SERVICE

Under 37 C.F.R. § 42.6(e), the undersigned certifies that on this 20th day of February 2025, I caused a true and correct copy of the foregoing PATENT OWNER MIRACOR MEDICAL SA'S PRELIMINARY RESPONSE TO PETITION, together with all exhibits filed therewith, to be served via e-mail on the following counsel of record for Petitioner:

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