

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Petitioner,

v.

MIRACOR MEDICAL SA,

Patent Owner.

IPR2025-00116
Patent 11,754,077

**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
2012	Chart of Petitioner's Correlation of Claim Elements

CHALLENGED CLAIMS

Claim No.	Claim Language
[1PRE]	A system for assisting the blood circulation of a heart, comprising:
[1A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart;
[1B]	a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle,
[1C]	the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor
[1D]	[the rotor] having guide surfaces to produce centrifugal flow components,
[1E]	the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor
[1F]	while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;
[1G]	a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device
[1H]	while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly,
[1I]	the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor;

Claim No.	Claim Language
[1J] ¹	a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly,
[1K] ²	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and
[1L] ³	an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,
[1M] ⁴	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

¹ This element was labeled [1K] in the Petition's Claim Index, as label [1J] was skipped.

² This element was labeled [1L] in the Petition's Claim Index, as label [1J] was skipped.

³ This element was labeled [1M] in the Petition's Claim Index, as label [1J] was skipped.

⁴ This element was omitted from the Petition's Claim Index.

Claim No.	Claim Language
[2]	The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.
[3]	The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.
[4]	The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.
[5]	The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.
[7]	The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[10]	The system of claim 1, wherein the heart assist pump device is a catheter device.
[16PRE]	A system for assisting blood circulation of a heart, the system comprising:
[16A]	a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;
[16B]	chamber walls at least partially defining a chamber to receive blood from the inflow tube;
[16C]	a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device

Claim No.	Claim Language
[16D]	that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor
[16E]	[the rotor] having guide surfaces to produce centrifugal flow components,
[16F]	the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation
[16G]	[the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;
[16H]	a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis
[16I]	and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,
[16J]	the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and
[16K]	a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,
[16L]	wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and

Claim No.	Claim Language
[16M]	an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output
[16N]	wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.
[17]	The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.
[18]	The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.
[19]	The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.
[20]	The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.
[21]	The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.
[22]	The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.
[23]	The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.

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Claim No.	Claim Language
[24]	The system of claim 16, wherein the first magnetic device comprises a permanent magnet.
[26]	The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.
[28]	The system of claim 16, wherein the heart assist pump device is a catheter device.

I. INTRODUCTION

Patent Owner Miracor Medical SA files this preliminary response to the Petition (“Pet.”) for *Inter Partes* Review of U.S. Patent 11,754,077 (“the ’077 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[] 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). 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 CONTRADICTIONARY 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 a gap sized for passage of the blood” 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 ’077 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 (Ex. 1008) and Bourque (Ex. 1007) 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 A Gap Sized For Passage Of The Blood”

Petitioner takes the phrase “by a gap sized for passage of the blood” out of context from claim recitations [1F], [1K], and [16L] and argues, because of an example in the specification and some examples in the art, that the term “by a gap sized for passage of the blood” 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 elements [1K] and [16L] that it is the magneto coupling that orients the rotor assembly to a position where it remains spaced apart from the surrounding housing or chamber walls such that blood flows between the rotor and the one or more walls. 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 meet the claim language.

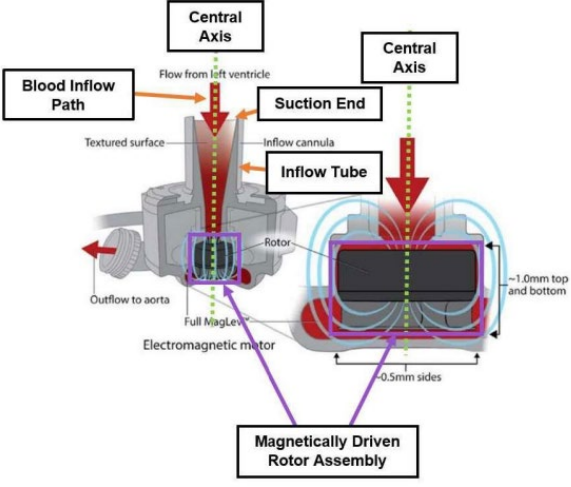
These contradictory positions cannot make out *prima facie* obviousness.

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 ten times⁵, 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:

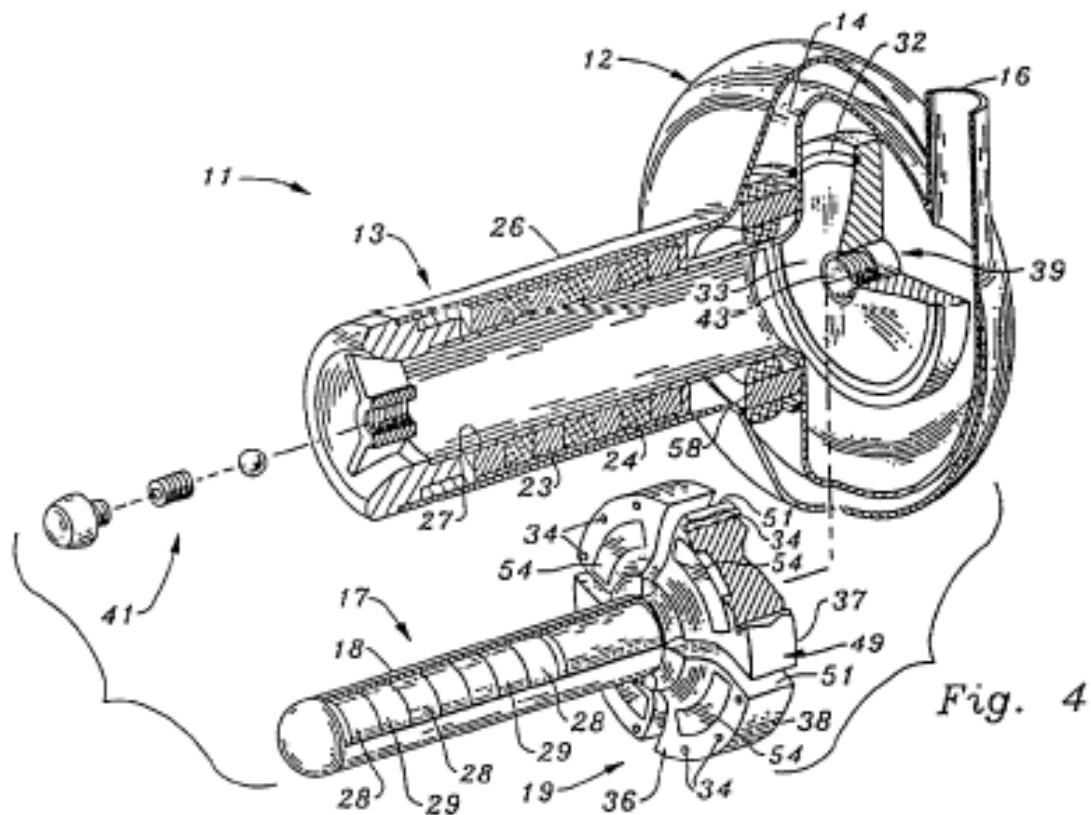
⁵ Exhibit 2011 details Petitioner’s and Crosby’s repeated references to the pleadings in the co-pending litigation as a statement of claim construction.

Crosby, ¶ 160	Ex. 1019 at 6
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 pp. 5–6 (Complaint, Ex. 12 [<i>sic</i>]). 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.	 The diagram illustrates a magnetically driven rotor assembly. It features a central axis with a suction end at the top and an outflow to the aorta at the bottom. A blood inflow path enters through an inflow cannula and an inflow tube. The rotor is positioned between the inflow tube and the outflow. The rotor is driven by an electromagnetic motor, which is part of a magnetically driven rotor assembly. The rotor has a textured surface and is surrounded by a full MagLev (magnetic levitation) system. Dimensions are indicated: ~1.0mm top and bottom, and ~0.5mm sides.

Mr. Crosby’s claim construction is not plain and ordinary meaning—it is advocacy dressed up as an alleged admission that was never made. Petitioner and Crosby merely take an arrow that happens to be drawn from the bottom in a notice pleading out of context. In fact, Patent Owner has taken no position on the claim construction of “magnetically driven rotor” in the parallel litigation.

Mr. Crosby’s claim construction of “rotor” is further directly opposed to Wampler’s own description of the Wampler rotor. Wampler states that a

“centrifugal pump impeller is attached to an impeller support shaft, or spindle, to form the pump rotor.” Ex. 1008, ¶ [0012]. That is, Wampler’s “rotor” includes more than just the impeller. Wampler shows this clearly in Figure 4 (below) in which the “rotor” is identified as element 17:



Ex. 1008.

The above example demonstrates how Petitioner’s and Crosby’s applications of the pleadings from the co-pending litigation as statements of claim construction result in no *prima facie* obviousness. Yet, they 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. *See* Ex. 2011.

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 16–52 (§ VIII.A) and 88–114 (§ 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 Grounds 1 and 3 without any obviousness analysis. Indeed, the Petition often includes nothing more about obviousness than conclusory statements and outline headings. *See, e.g.*, Pet. at 16, 88.

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 52–88 (§ VIII.B). Ground 4 asserts Schima and Akamatsu render the challenged claims obvious. Pet. at 115–145 (§ 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 combinations. 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 81–88, 144–145. The Crosby declaration is similarly unhelpful regarding Grounds 2 and 4, as it too fails to provide a sufficient rationale to support obviousness.

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)). Grounds 2 and 4 should fail for this reason.

C. Obviousness Grounds 1-4 Lack Particularity

“[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.’” *PeakLogic, Inc. v. Wave Neuroscience, Inc.*, IPR2022-01527, Paper 13 at 4–5 (PTAB May 18, 2023) (quoting 35 U.S.C. § 312(a)(3)). 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)). Further, in the event of a substantial failure to meet the particularity requirement, the Board can exercise its discretion

to deny an entire petition. *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 at 24. (PTAB Mar. 6, 2019) (informative).

Petitioner here fails to meet its burden of identifying “with particularity” the evidence that supports its asserted obviousness grounds. In Section V below, Patent Owner raises numerous instances of Petitioner’s lack of particularity and the resulting failure to identify teachings that disclose specific claim limitations. These failings are found throughout the various grounds for obviousness advanced in the Petition, and each constitutes an independent reason to deny institution.

Additionally, Grounds 1–4 are not sufficiently particular because, instead of explaining how the references allegedly disclose *each limitation of each challenged claim*, Petitioner only presents such information for about half of the claim elements (specifically, those of independent claim 1, dependent claims 2–5, 7, and 10, and, in some grounds, elements [16I] and/or [16J] of independent claim 16). For the other half of the claim elements, including most elements of independent claim 16 and all of dependent claims 17–24, 26, and 28, Petitioner merely cites to the Petition’s analysis of other non-identical claim language and to single paragraphs of the Crosby declaration that do the same. *See* Pet. at 45–52, 77–80, 111–114, 140–143. For example, in Ground 1, the entirety of the Petition’s analysis of claim element [16K] is “*See* [1J]. Ex.1003, ¶334.” *Id.* at 50.

Meanwhile, paragraph 334 of Crosby says only: “This element is invalid for the

same reasons discussed above in [1J], thus, I incorporate that discussion into my analysis here.”

Petitioner's attempted shortcut requires readers to identify differences between the two groups of claim limitations and to sort out for themselves how the references might apply to independent claim 16, as well as to each of dependent claims 17–24, 26, and 28. For example, while Petitioner correlates the elements of independent claim 16 to various elements of claims 1 and 2, *see, e.g., id.* at 45–51, there are significant differences between claim elements [16A]–[16N] and claim elements [1A]–[1E], [1G], [1H], [1J]–[1M], and [2]. Exhibit 2012 filed herewith shows a comparison of these limitations correlated by Petitioner. While there is some overlap, there are also numerous differences, many of which are highlighted in Exhibit 2012. Additionally, each of claims 18–24 recites structural elements that are not found in the independent claims, yet the Petition dedicates less than one page to all seven of these claims in each ground and cites only to earlier analyses of elements from independent claims 1 and 16. *See Pet.* at 51, 80, 114, 143. Patent Owner should not have to guess how the teachings of the references are intended to be applied to these differing limitations. Such an undertaking would be unduly burdensome for the Patent Owner and inefficient for the Board. On at least this basis, institution should be denied.

Moreover, Petitioner's "practice of citing the Declaration to support conclusory statements that are not otherwise supported in the Petition...amounts to incorporation by reference" in violation of 37 C.F.R. § 42.6(a)(3). *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 9–10 (PTAB Aug. 29, 2014) (informative) (declining to consider arguments from declaration not made in petition). For most elements of independent claim 16, as well as dependent claims 17–24, 26, and 28, Petitioner cites to single paragraph from Crosby that, in turn, incorporates numerous paragraphs discussing a different element of a different claim. *See, e.g.*, Pet. at 50 (for element [16K] in Ground 1, citing only "Ex.1003, ¶334"); Crosby, ¶ 334 (incorporating Crosby's own discussion of element [1J], found at ¶¶ 233–238 of the declaration). Collectively, these portions of Crosby (discussing claims 16–24, 26, and 28) cover 116 pages of his 502-page declaration, *id.* at pp. 170–203, 268–294, 370–398, 460–485, and incorporate roughly 261 other pages of the declaration, *id.* at pp. 98–170, 204–268, 311–370, 398–460. The Board has previously found reliance on substantially smaller amounts of declaration testimony, without sufficient explanation in the Petition, to violate Rule 42.6(a)(3). *Cisco*, IPR2014-00454, Paper 12 at 7–10 (involving tens of pages of declaration testimony).

In sum, the Petition has failed to meaningfully address many of the challenged claims in each of Grounds 1–4 or, at best, it has done so via prohibited

incorporation by reference of Crosby's declaration. Considering the Petition as a whole, the Board should exercise its discretion and decline to institute based on Petitioner's failure to comply with the particularity requirement of 35 U.S.C. § 312(a)(3). "[I]n the interests of efficient administration of the Office and integrity of the patent system and as a matter of procedural fairness to Patent Owner, the entire petition should be denied under 35 U.S.C. § 314(a)." *Adaptics*, Paper 20 at 24.

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 [p]etitioners...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 [p]etitioner having identified specifically the differences, we are unable to evaluate properly any rationale offered by [p]etitioner 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.

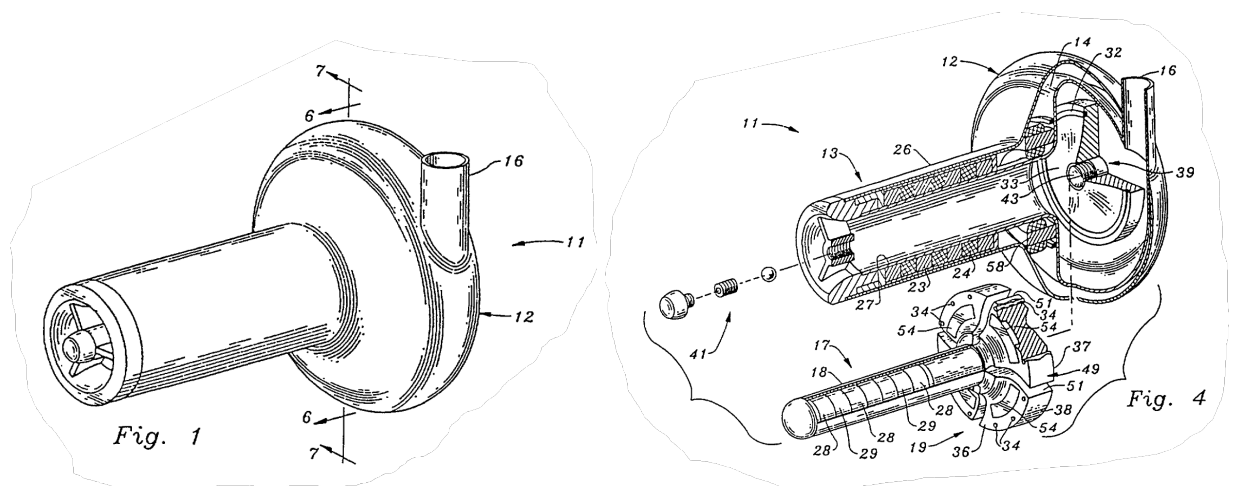
V. THE BOARD SHOULD NOT INSTITUTE *INTER PARTES* REVIEW BECAUSE THE PETITION FAILS TO ESTABLISH THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Wampler Fails to Render Obvious Any Challenged Claim (Ground 1)

The Petition fails to demonstrate that Wampler teaches or suggests multiple features recited in independent claims 1 and 16 of the '077 patent. Petitioner thus fails to show a reasonable likelihood that claim 1 or claim 16 is unpatentable under Ground 1. Because claims 2–5, 7, 10, 17–24, 26, and 28 depend from either claim 1 or claim 16 and recite additional features, Petitioner also necessarily fails to show a reasonable likelihood that these dependent claims are unpatentable under Ground 1.

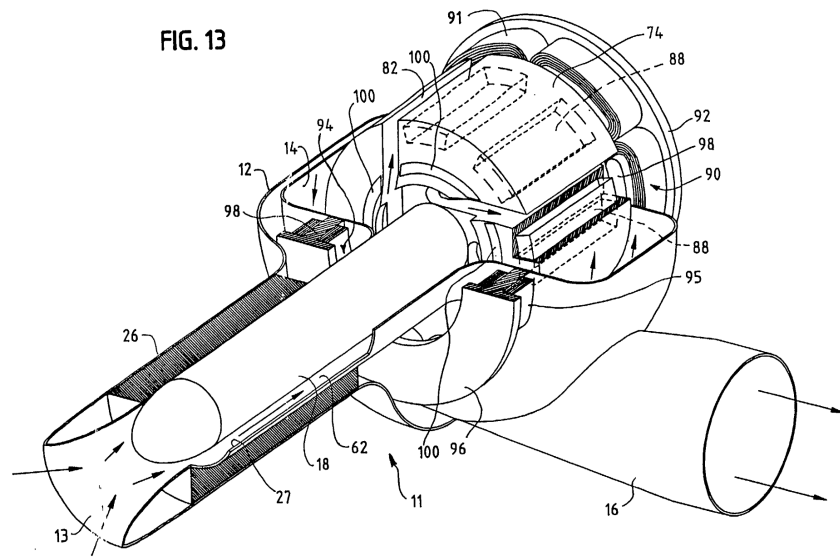
1. Wampler (Ex. 1008)

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.*

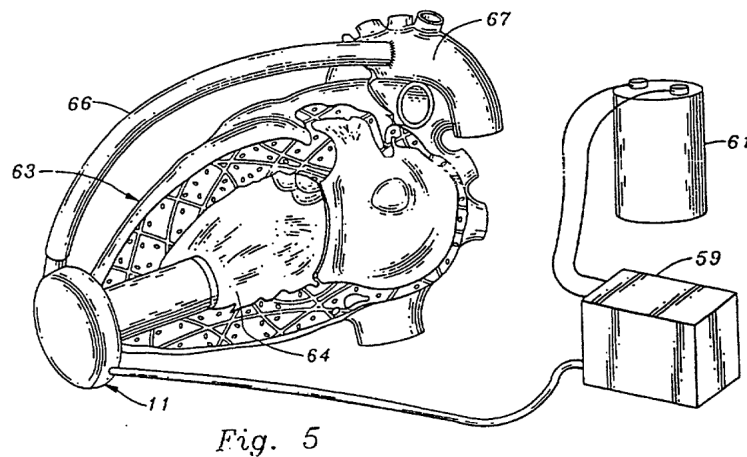


The rotor of Wampler is suspended within the pump housing using radial magnetic bearings that “maintain the support shaft and the impeller about a rotational axis.” *Id.*, ¶ [0013]. Further, the rotor is “axially restrained by a [sic] magnetic and hydrodynamic forces in combination with mechanical thrust 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 casts Ground 1 as obviousness over Wampler alone. However, 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 Rotor [1C], [16D]

Petitioner has not shown that Wampler teaches or suggests a system for assisting blood circulation of a heart including a magnetically driven rotor assembly with a first magnetic device that is axially adjacent to a rotor, as recited in independent claims 1 and 16 (elements [1C] and [16D]). Ground 1 fails on this basis alone.

Petitioner points to parallel litigation and contends that Patent Owner has taken a position that “a magnetic element sealed within a rotor is ‘rigidly coupled’

and ‘axially adjacent.’” Pet. at 20 n.6. 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 20–22.

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. *Id.* at 6–7. 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 its conclusion that Wampler teaches this claim element with reference to FIGS. 12 and 13 (among others) by its expert, along with conclusory statements regarding these figures showing supposed axial adjacency of magnet segments 88 and impeller 74. Crosby, ¶¶ 176–178. Such statements, however, ignore the plain and ordinary meaning of the claim terms that specify which axis is implicated.

Regarding claim 1, elements [1A], [1B], and [1E] all recite relation relative to a central axis. More specifically, elements [1A] and [1B] recite an inflow tube and a magnetically driven rotor assembly axially aligned with the inflow tube, while element [1E] recites that the magnetically driven rotor assembly is rotatable about a central axis. Accordingly, recitation in claim element [1C] that a first magnetic device of the magnetically driven rotor assembly is axially adjacent to a rotor would plainly mean that the two components are positioned adjacent to one another as measured along the recited central axis about which the magnetically driven rotor assembly 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.

Claim 16 also includes recitations that make clear the plain and ordinary meaning of the terms used. For example, claim 16 recites an inflow tube defining an inflow path along an inflow axis (element [16A]) and a magnetically driven rotor assembly axially aligned with the inflow axis (element [16C]). Further, element [16D] recites that a first magnetic device of the the magnetically driven rotor assembly is axially adjacent to a rotor. Still further, elements [16F] and [16G] recite that the rotor and first magnetic device of the magnetically driven rotor assembly are rotatable about an axis of rotation that is aligned with the inflow

axis. Accordingly, the claim makes clear that axial adjacency and alignment are with respect to the inflow axis.

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.

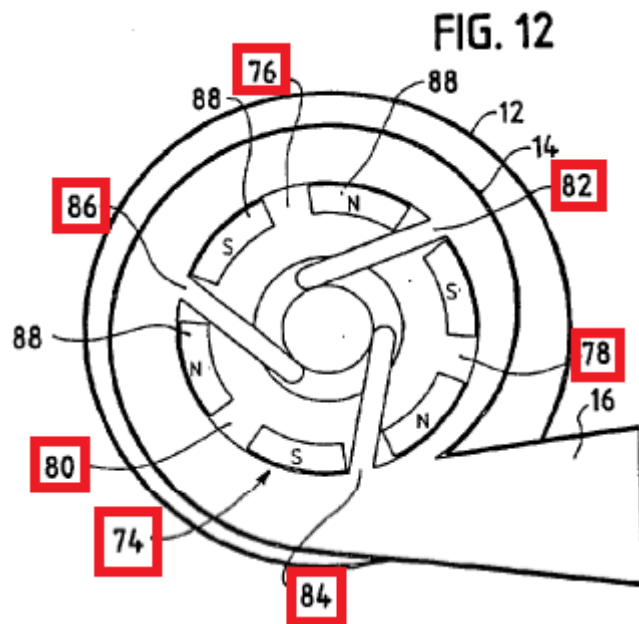
Accordingly, Wampler cannot teach or suggest a first magnetic device that is axially adjacent to a rotor based on the positioning of its magnet segments 88 and impeller 74 because these components are not adjacent to one another as measured along the central or inflow axis of the device. Instead, the magnet segments 88 and impeller 74 are aligned with, and overlap, one another as measured along the central or inflow 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. Wampler Does Not Teach Or Suggest A Second Magnetic Device Positioned Axially Closer To A First Magnetic Device Than To A Rotor [16J]

Petitioner has not shown that Wampler teaches or suggests a “system for assisting blood circulation of a heart” with “the second magnetic device positioned axially closer to the first magnetic device than to the rotor.” Ground 1 also fails on this basis for claim 16.

Before comparing the positions of the recited elements, it is important to understand what the three recited elements are. Petitioner first identifies

Wampler's impeller 74 as the
"magnetically driven rotor
assembly" that includes a rotor and
a first magnetic device. Pet. at 19–
22. As shown in Figure 12 of
Wampler (reproduced at right), the
impeller 74 includes three "blade
sectors" 76, 78, 80 that are



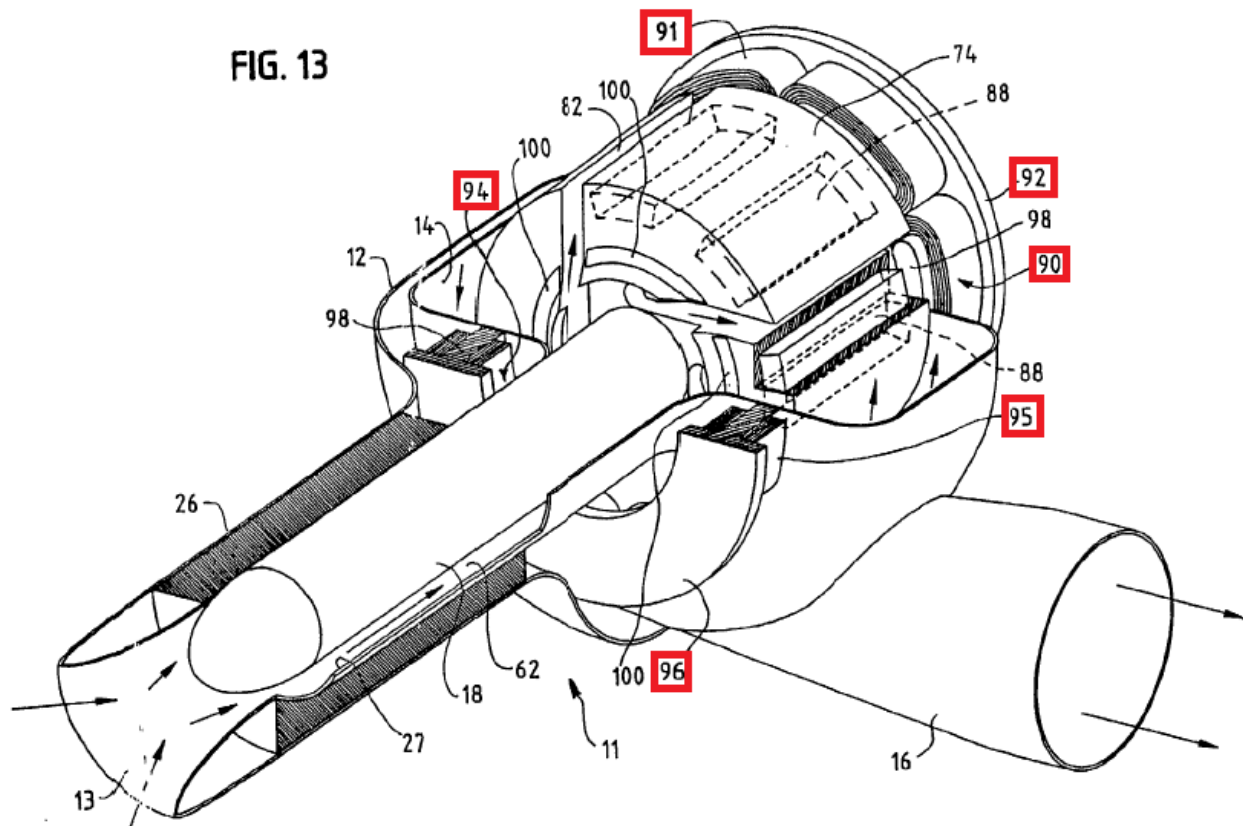
separated by slots 82, 84, 86. Ex. 1008, ¶ [0078]; *see also* Pet. at 22 (coloring the same figure to illustrate a “magnetically driven rotor assembly”). Wampler asserts that these thick blades with slots (providing the working surfaces for pumping blood) allow a small pump with a small number of blades that will potentially

damage the pumped blood less while still maintaining reasonable pump efficiency.

Ex. 1008, ¶ [0078].

Petitioner identifies the six motor rotor magnets 88, illustrated in Figure 12 above, as the claimed “first magnetic device.” Pet. at 20–22, 46–48.

Turning to the “second magnetic device,” Petitioner identifies two motor stators 90, 94 as the corresponding feature of Wampler. Pet. at 26–27. Figure 13 (shown below) illustrates that these two motor stators 90, 94 are located on opposite sides of the impeller 74. Ex. 1008, ¶¶ [0084]–[0085].



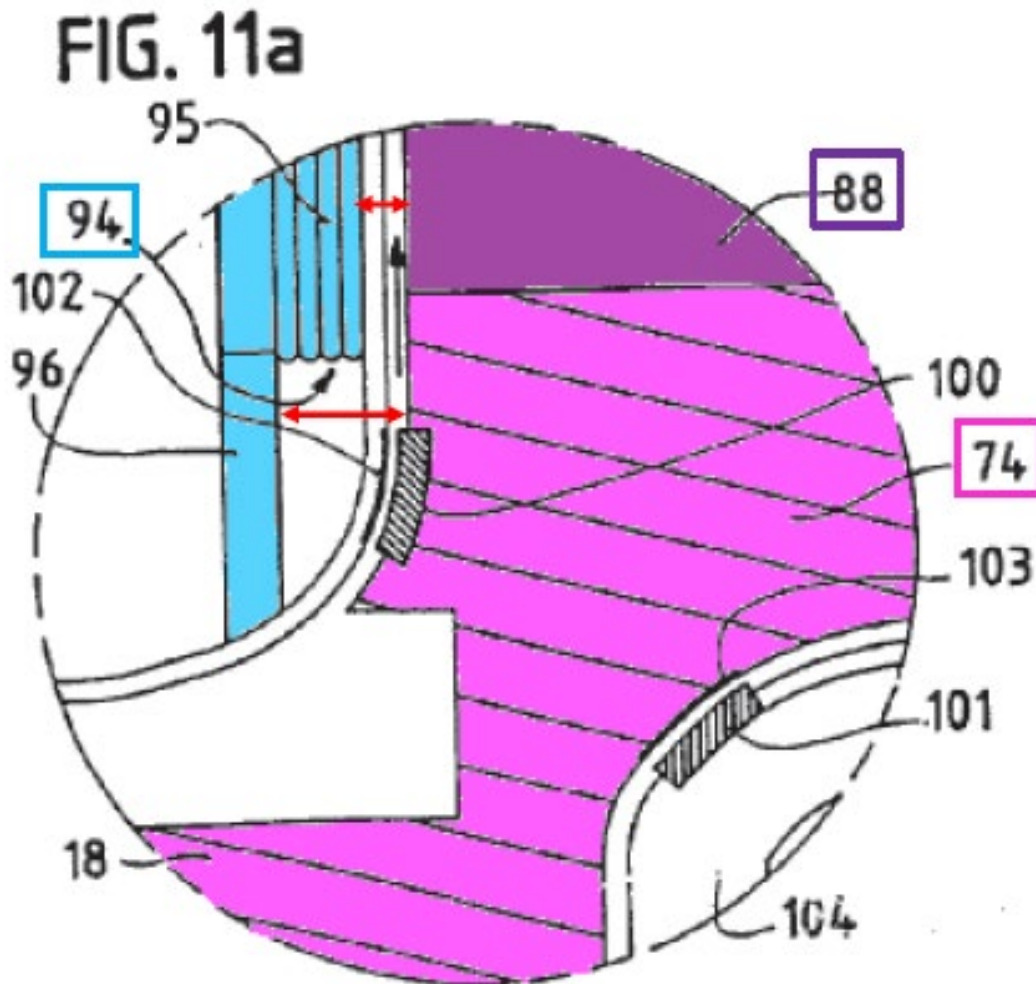
One motor stator 90 includes windings 91 and a back iron 92. The second motor stator 94 includes winding 95 and a back iron 96. The purpose of each back iron is to “complete a magnetic circuit.” *Id.*

Petitioner then simply states that the limitation “positioned axially closer to” is met based on FIG. 11. Pet. at 46–48.⁶ But it is clear from a casual review of Wampler, for example in Figure 13 above, that the “first magnetic device” (rotor magnets 88) are embedded within the “magnetically driven rotor” (impeller 74). Accordingly, the second magnetic device cannot be positioned axially closer to the first magnetic device than to the magnetically driven rotor. Wampler does not disclose this claim element.

Faced with these facts, Petitioner misdirects. Relying on its expert, Petitioner argues that the “back iron 96,” which completes a magnetic circuit, is farther from the magnetically driven rotor 74 than the stator coil 95, which provides the magnetic field that corresponds to the second magnetic device, is from the rotor magnet 88. Pet. at 48; Crosby, ¶ 328.⁶ Petitioner provides the following

⁶ Petitioner appears to have reversed and mislabeled claim elements [16I] and [16J] in the body of the Petition, as well as Crosby's declaration. Portions of the Petition and Crosby declaration addressing element [16J] are found under headings labeled [16I], and *vice versa*.

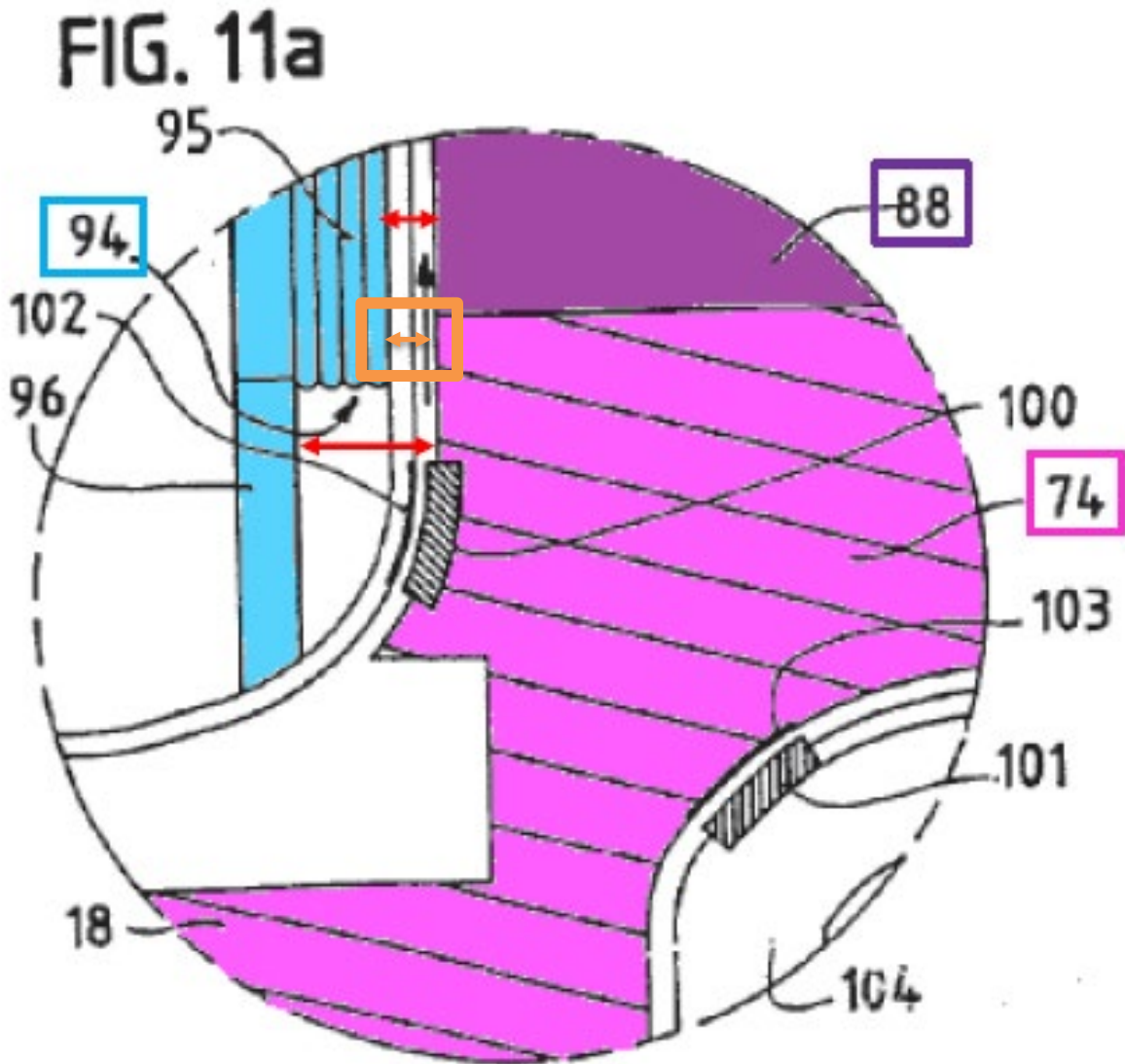
misleading Figure to illustrate its incorrect view that the second magnetic device is farther from the magnetically driven rotor than the from the first magnetic device:



Pet. at 48.

Petitioner defines the second magnetic device in two different ways in order to make its false comparison. Making the comparison correctly below by adding an orange arrow (highlighted within an orange box) to Petitioner's figure, there can be no doubt that the two elements—the magnetically driven rotor 74 and the first

magnetic device 88—are the exact same distance from the second magnetic device and the claim recitation is not met:



Being unable to show how Wampler teaches or suggests this claim element, Petitioner baldly asserts, in a footnote, that it was “an obvious design choice” because it is inconsequential. Pet. at 48, n.7. Notably, this assertion is inconsistent with the testimony of Petitioner’s own expert, who argues that a POSITA would

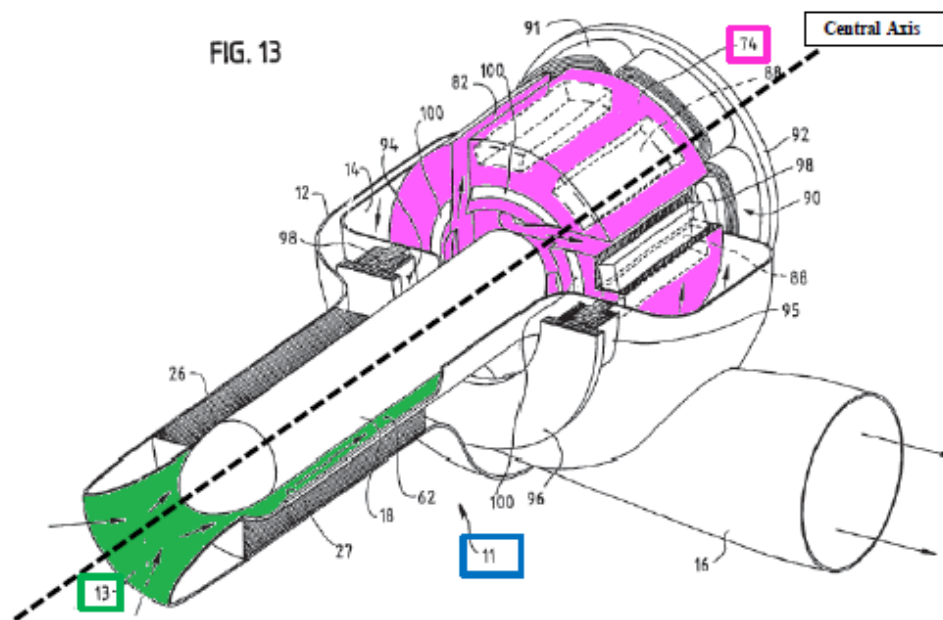
have been focused on adjusting the distance between the stator 94 and the magnets 88. Crosby, ¶ 328. Mr. Crosby's analysis, however, is addressed nowhere in the Petition and is also incomplete. Even if Crosby is right that the distance between the stator 94 and the magnets 88 matters, that still has no direct effect on the relative distance between the stator 94 and the impeller 74 (as compared to the stator 94 and the magnets 88). Neither Crosby nor Petitioner identifies any alleged motivation to change the axial distance between Wampler's stator 94 and impeller 74 or, more particularly, to make that distance greater than the axial distance between the stator 94 and magnets 88.

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

5. Wampler Does Not Teach Or Suggest A Magnetically Driven Rotor Spaced Apart From A Suction End Of An Inflow Tube [1B]

Petitioner has not demonstrated that Wampler teaches or suggests a system with “a magnetically driven rotor...spaced apart from [a] suction end [of an inflow tube] when the suction end of the inflow tube is inserted into the ventricle” of the heart. Ground 1 also fails on this basis for claim 1.

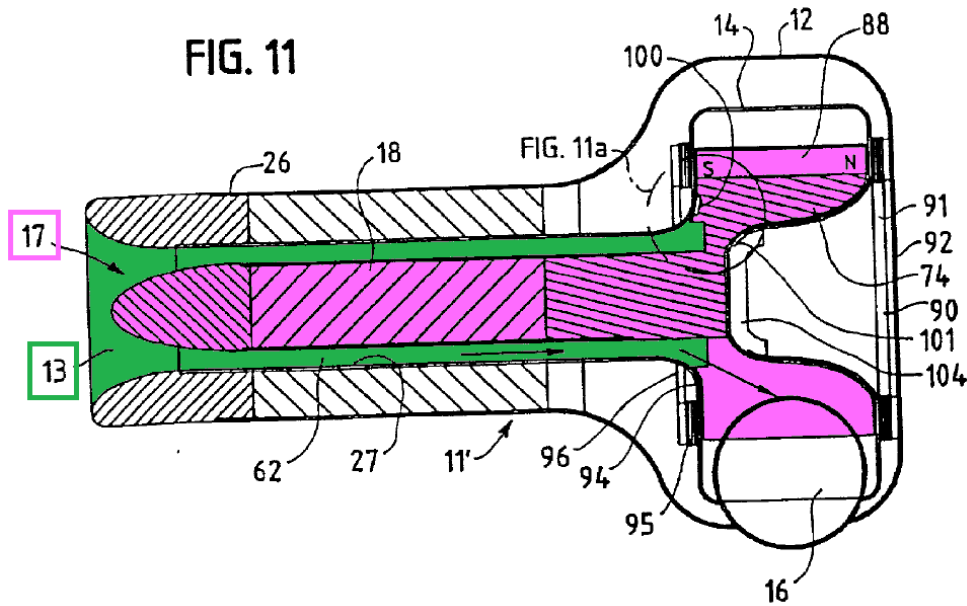
In effort to find element [1B] in Wampler, Petitioner selectively points to only one part of Wampler's rotor 17 (specifically, impeller 74) as corresponding to the claimed "magnetically driven rotor," while ignoring the other part of rotor 17 (namely, the shaft 18). Pet. at 18–19. By restrictively highlighting only the impeller 74 portion of the rotor 17 in their annotated FIG. 13 (reproduced below), Petitioner argues that this "rotor" is spaced apart from the suction end of inlet tube 13 (annotated green). *Id.*



This selective definition of "magnetically driven rotor," however, is at odds with the actual teachings of Wampler. In that reference, rotor 17 is consistently described as including both shaft 18 and impeller 19, 74. *See, e.g.*, Ex. 1008, ¶¶ [0051], [0074], and [0081]; *see also id.*, FIGS. 3, 4, 11, 15, 17, and 19 (labeling

rotor 17 by pointing to a distal end portion of shaft 18). Wampler explains that “[r]otation of the rotor 17, *including shaft 18 and impeller 19*, causes blood to flow through inlet tube 13 in the direction of arrows 62.” *Id.*, ¶ [0074] (emphasis added). Petitioner never identifies any basis for ignoring the rotating shaft 18 as part of the rotor 17, in contravention of Wampler’s teachings.

In fact, the suction end of the inlet tube 13 is ***not*** spaced apart from the complete rotor 17 of Wampler, as best seen in Wampler's FIG. 11 (annotated below by Patent Owner to highlight the inlet tube 13 in green and the rotor 17 in pink, i.e., the same color scheme used in the Petition):



As shown in the above drawing (as well as FIG. 13), Wampler's magnetically driven rotor 17 extends into the suction end of the inlet tube 13. These components are not "spaced apart" as recited in claim element [1B]. To suggest

otherwise can only be explained as an impermissible attempt at hindsight reconstruction of claim 1.

6. 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.”).

Examples of Petitioner's selective picking and choosing of features from distinct embodiments in Wampler without providing any supporting rationale for combining are discussed under the sub-headings below. Each of these unsupported modifications is improper, and Ground 1 also fails on this basis.

a. Wampler's First Embodiment Lacks At Least A Second Magnetic Device Positioned Axially Closer To A First Magnetic Device Than To A Rotor [16J] And A Magneto Coupling Orienting A Magnetically Driven Rotor Assembly So That The Rotor Assembly Remains Entirely Spaced Apart From The Housing / Walls [1K], [16L]

For claim elements [1A], [1L], and [1M] (as well as claim elements [16A], [16M], and [16N]), Petitioner relies on the pump embodiment shown in Wampler's FIGS. 1–8. Pet. at 16–17, 38–41, 45, 51. Petitioner must do so because only this first embodiment of Wampler is illustrated and described as being implanted in a

heart and including controller 59 and power supply 61 that “may be worn external by the user.” *See* Ex. 1008, ¶¶ [0070], [0075], FIG. 5.

For claim elements [1B]–[1K] (as well as claim elements [16B]–[16L]), however, Petitioner cites primarily (and sometimes exclusively) to features of the pump embodiment shown in Wampler's FIGS. 11–14. Pet. at 18–38, 45–50. For example, with respect to claim element [16J], Petitioner relies entirely on the later embodiment of Figures 11–14 of Wampler, as discussed above in Section V.A.4, (Neither those figures, nor any other portion of Wampler, teaches or suggests this claim element, but for the present purposes, it is sufficient to note that the cited figures all relate to this alternative embodiment of Wampler.)

Similarly, for claim element [1K], which requires that “the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood,” and the similar recitation of claim element [16L], the Petition again relies entirely on the pump embodiment of Figures 11–14 of Wampler. Petitioner's discussion of this claim element focuses on Wampler's disclosure of hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102, 103 that are carried by either the impeller or the casing, or an attachment to the casing. Pet. at 36–38, 50;

Crosby, ¶¶ 239–245, 337⁷; Ex. 1008, ¶¶ [0089]–[0092]. Petitioner asserts that, in response to rotation of the impeller 74, these “hydrodynamic bearing[s] ‘force[] the raised pad and the contact surface apart,’ such that the impeller 74 and magnetic pieces 88 remain entirely spaced apart from the casing 14.” Crosby, ¶ 246 (quoting from Ex. 1008, ¶ [0092]).

Of course, Petitioner cannot rely on Wampler's first embodiment (FIGS. 1–8) for claim elements [1K] and [16L] because that embodiment includes thrust bearings 39 and 41 to maintain positioning of the rotor 17 relative to the housing 12. Ex. 1008, ¶¶ [0058]–[0062], FIG. 7. Given that the thrust bearings 39, 41 involve *contact* with the rotor 17, this embodiment cannot satisfy the recitation of elements [1K] and [16L] that the magnetically driven rotor remains *entirely spaced apart* from the surrounding housing or walls during rotation of the rotor.

⁷ The Petition and Crosby are rife with errors that make them difficult to follow.

See, e.g., supra footnotes 1-4 and 6. In this instance, the Petition (p. 50) and Crosby (¶ 337) incorporate by reference their earlier analysis of element [1M], but that element bears no resemblance to element [16L]. This example highlights layers of incorrect practice and errors that contribute to the Petition's lack of particularity, as addressed in Section IV.C.

Although Petitioner has cherry-picked features from distinct embodiments of Wampler in an attempt to arrive at the claimed inventions, the Petition provides no explanation whatsoever about *how or why* a POSITA would have combined these different embodiments in the contended manner. This deficient analysis 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 or claim 16 obvious.

b. Wampler's Later Embodiment Lacks At Least An External Control Unit [1L], [1M], [16M], [16N]

Claims 1 and 16 each recite "an external control unit" configured to regulate or control operation of a second magnetic device to thereby magnetically drive the rotation of a magnetically driven rotor via a magneto coupling with a first magnetic device. Once again, Petitioner attempts to arrive at a system with these features by jumping between disclosed embodiments in Wampler without explaining how or why a POSITA would have been motivated to combine the embodiments in the manner contended.

As discussed above, Petitioner has relied on the pump embodiment of FIGS. 11–14 to allegedly teach the first and second magnetic devices, magneto coupling therebetween, and other elements of claims 1 and 16. *See generally* Pet. at 18–38, 45–50. For claim elements [1L], [1M], [16M], and [16N], however, Petitioner cites to controller 59 shown in FIG. 5 of Wampler, where the controller is used

with the pump embodiment of FIGS. 1–8. Pet. at 38–41, 51; Ex. 1008, ¶¶ [0070]–[0072].

There is, however, no disclosure in Wampler of the pump of FIGS. 11–14 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 these two embodiments as proposed. To the contrary, Petitioner simply assumes complete combinability and interchangeability between the various embodiments disclosed in Wampler without any reasoning for doing so. In fact, Wampler's first embodiment of Figures 1–8 has at least a different motor, different bearings, and different magnet arrangements compared to Wampler's later embodiment of Figures 11–14. But Petitioner merely cherry-picks features from these distinct embodiments in Wampler without any articulated rationale to support its contentions regarding obviousness.

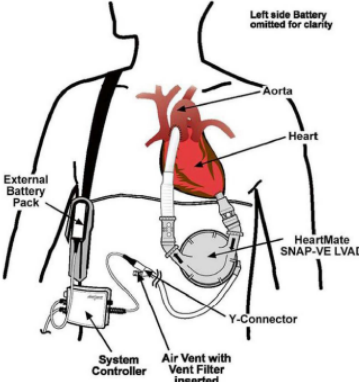
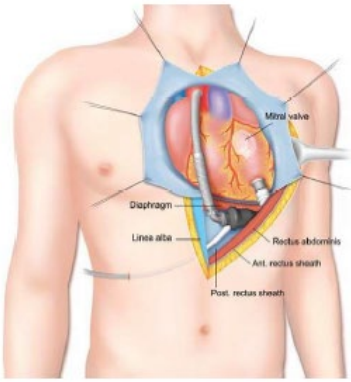
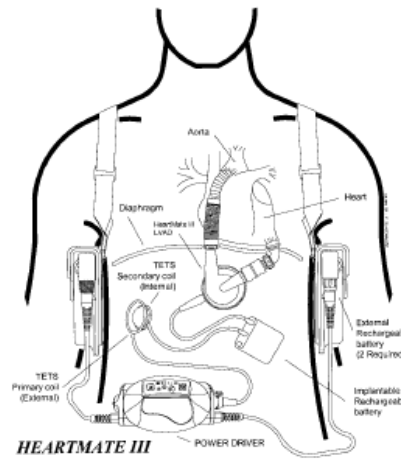
This complete lack of analysis and reasoning for combining different elements from distinct embodiments in Wampler leaves Patent Owner to guess at the obviousness analysis. It is not sufficient to meet Petitioner's burden to show a reasonable likelihood of success in proving unpatentability over Wampler.

B. Bourque And Wampler Fail To Render Obvious Any Challenged Claim (Ground 2)

The Petition fails to demonstrate that Bourque teaches or suggests multiple features recited in independent claims 1 and 16 of the '077 patent or that a POSITA would have found it obvious to modify Bourque based on Wampler. As a result, Petitioner fails to show a reasonable likelihood that claim 1 or claim 16 is unpatentable under Ground 2. Because claims 2–5, 7, 10, 17–24, 26, and 28 depend from either claim 1 or claim 16 and recite additional features, Petitioner also necessarily fails to show a reasonable likelihood that these dependent claims are unpatentable under Ground 2.

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
 Ex. 2003, FIG. 39.1 at 727.	 Ex. 1013, FIG. 3 at 25	 Ex. 1007, FIG. 3 at 403.

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:

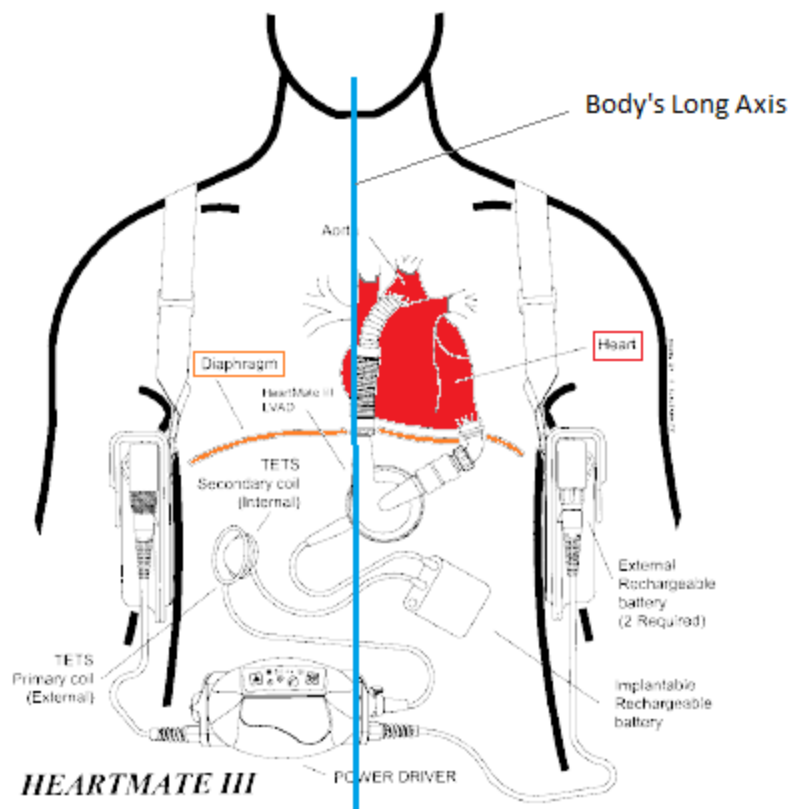


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

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. Claims 1 And 16 Require A Specific Configuration Between The Inflow Tube And The Rotor Assembly

The systems of independent claims 1 and 16 each comprise a heart assist pump device that includes a rotor assembly axially aligned with an inflow tube. Specifically, claim 1 includes the following critical language:

[1A] a heart assist pump device deliverable to the heart and comprising: *an inflow tube defining a blood inflow path...*

[1B] a magnetically driven *rotor assembly configured to be axially aligned with the inflow tube* and...

Ex. 1001, 4:31–33. Similarly, claim 16 includes the following critical language:

[16A] a heart assist pump device deliverable to the heart and comprising: *an inflow tube defining a blood inflow path along an inflow axis...*

[16C] a magnetically driven *rotor assembly configured to be axially aligned with the inflow axis...*

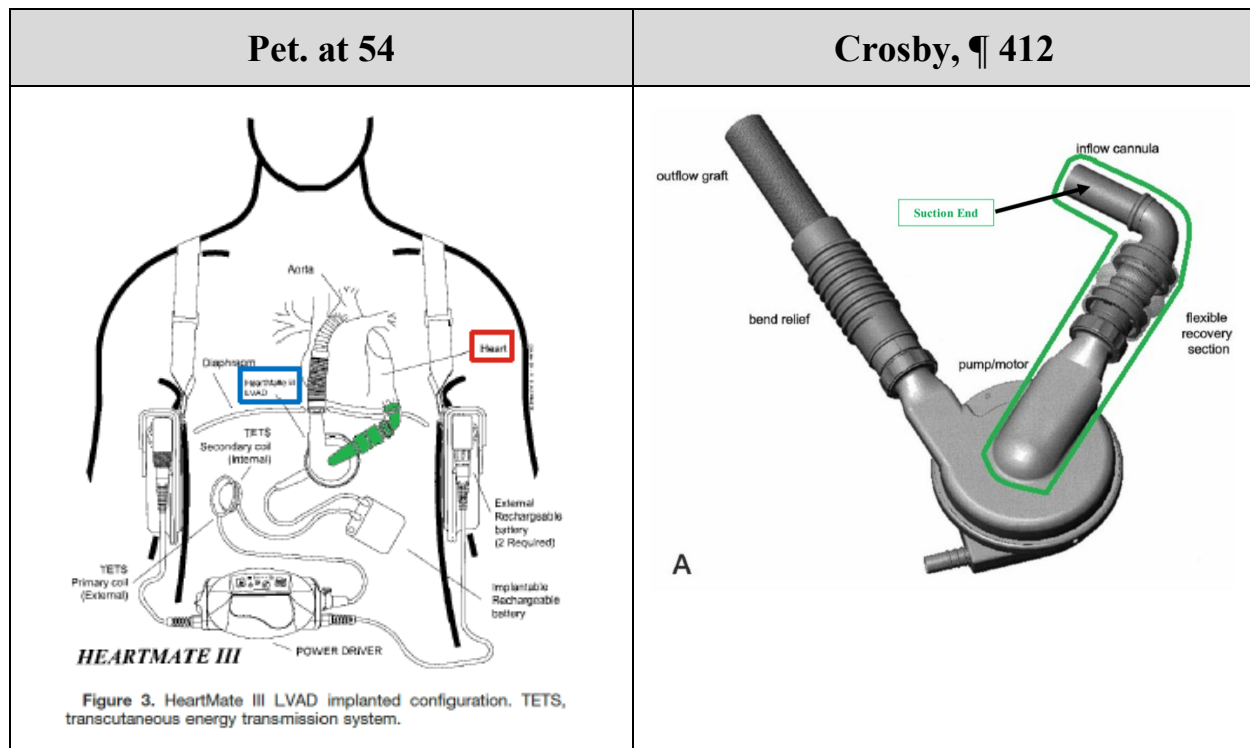
Id. at 5:55–58.

Bourque does not disclose these configurations, nor does it teach or suggest them, 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 argues, as it must, that the end of the “flexible recovery section” or “inflow cannula” is the “inflow tube” that is “insertable into a left ventricle” of a heart. Pet. at 52–54; Crosby, ¶¶ 411–412. 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 52–54; Crosby, ¶¶ 411–412):



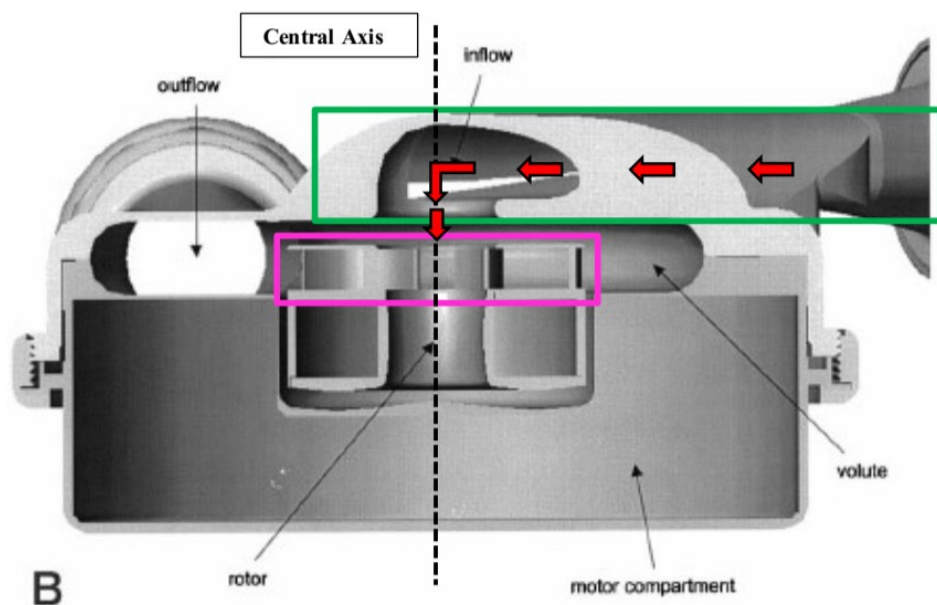
There is no doubt about the portion of the Bourque device that Petitioner alleges corresponds to the “inflow tube” and that it must extend all the way to the heart.

b. The Inflow Tube, Properly Identified, Is Not Axially Aligned With The Rotor Assembly As Recited

Having defined the inflow tube, it is clear that “the magnetically driven rotor assembly” is *not* “axially aligned” with the “inflow tube” (element [1B]) or an “inflow axis” (element [16C]) in Bourque. In fact, the rotor’s axis in Bourque is perpendicular to the inflow tube or inflow axis of the inflow tube. Bourque recognizes that this configuration, with the inflow tube extending perpendicular to

the rotor, “resulted in a sharp bend in the flow before it enters the impeller.” Ex. 1007 at 402.

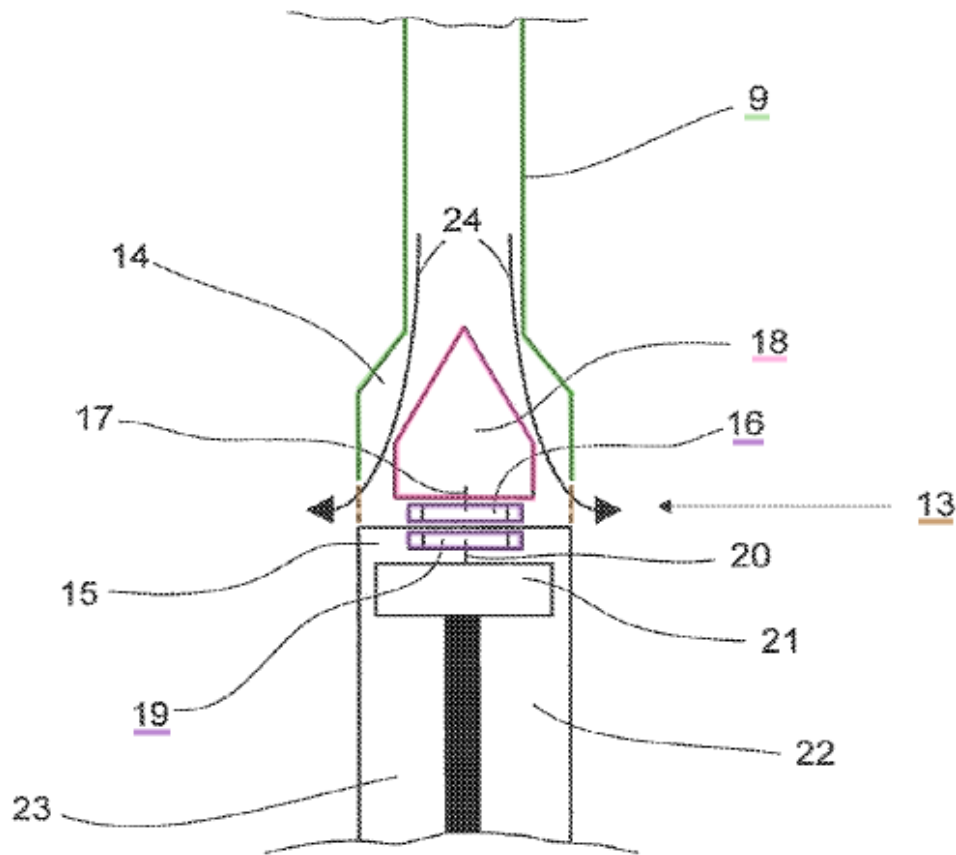
Petitioner uses annotated graphics in an attempt to make the facts seem different. Pet. at 55–57. Petitioner presents its graphic with added red arrows representing that flow (the blood) in an attempt to show axial alignment:



Id. at 55. There are numerous problems with this presentation.

First, the claims recite that the inflow tube or inflow axis of the inflow tube is aligned with the rotor assembly—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 extending perpendicular to the central axis of the rotor assembly. The claim language is not met. By way of comparison,

the '077 patent includes an inflow tube 9 defining a central or inflow axis that is aligned with a magnetically driven rotor 18:



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

Further, Petitioner's added red arrows are not correct. While the arrows appear to be designed to allege axial alignment with the blood 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:

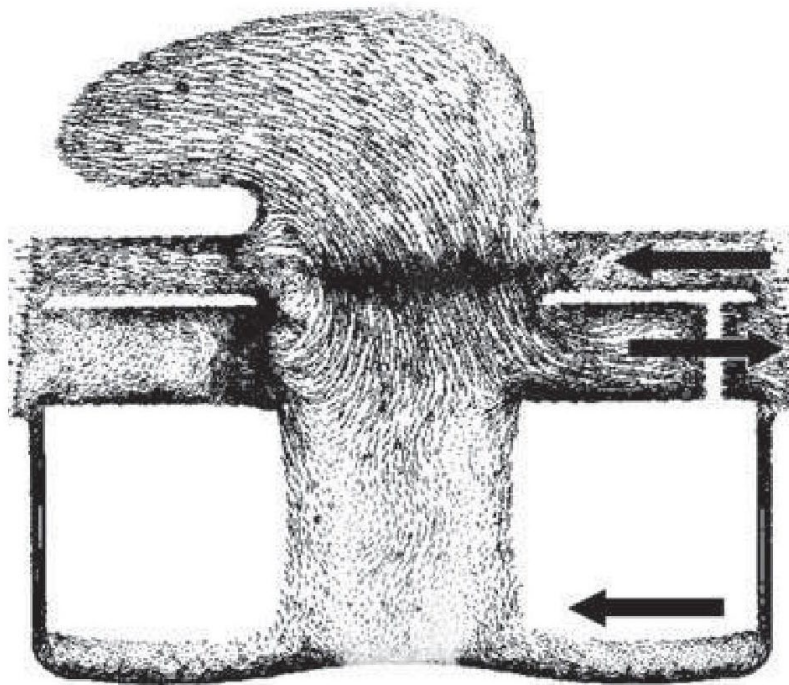


FIG. 6. Planar cut through middle of pump. Arrows indicate local flow directions.

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 the 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, ¶ 423) 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. The Petition never explains why Petitioner's own “clinical experience” should be ignored. In fact, the Petition includes no counter to these reasons for not making the combination because Petitioner never 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 '077 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.

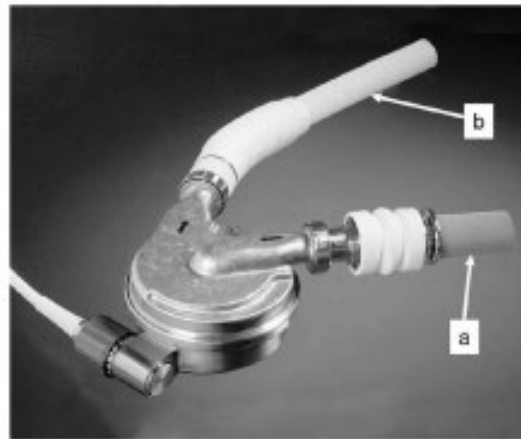


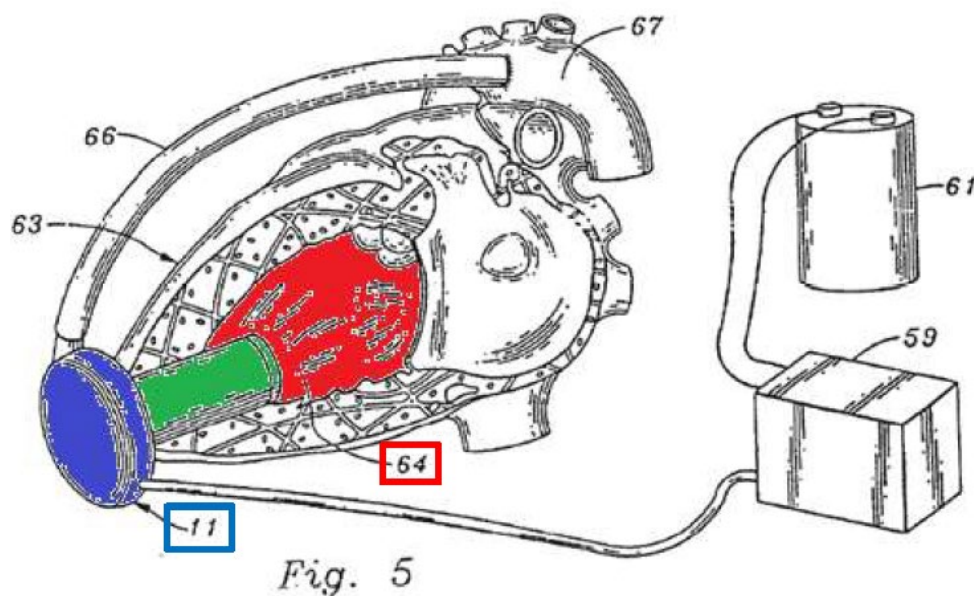
Figure 1. HeartMate III LVAD showing left ventricular apical inflow conduit (a) and LVAD outflow graft for attachment to aorta (b).

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 align with the “inflow axis” in view of Wampler. Pet. at 57. To show how Wampler fits one of its pump embodiments to the heart, Petitioner annotates Figure 5 of Wampler as follows:



Id. at 56.

Petitioner further argues that a key reason for making the combination is to provide the “good anatomical compatibility” that Wampler promises. *Id.* at 83. 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 Any Challenged Claim (Ground 3)

The Petition fails to demonstrate that Akamatsu teaches or suggests multiple features recited in independent claims 1 and 16 of the '077 patent. Petitioner thus fails to show a reasonable likelihood that claim 1 or claim 16 is unpatentable under Ground 3. Because claims 2–5, 7, 10, 17–24, 26, and 28 depend from either claim 1 or claim 16 and recite additional features, Petitioner also necessarily fails to show a reasonable likelihood that these dependent claims are unpatentable under Ground 3.

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.

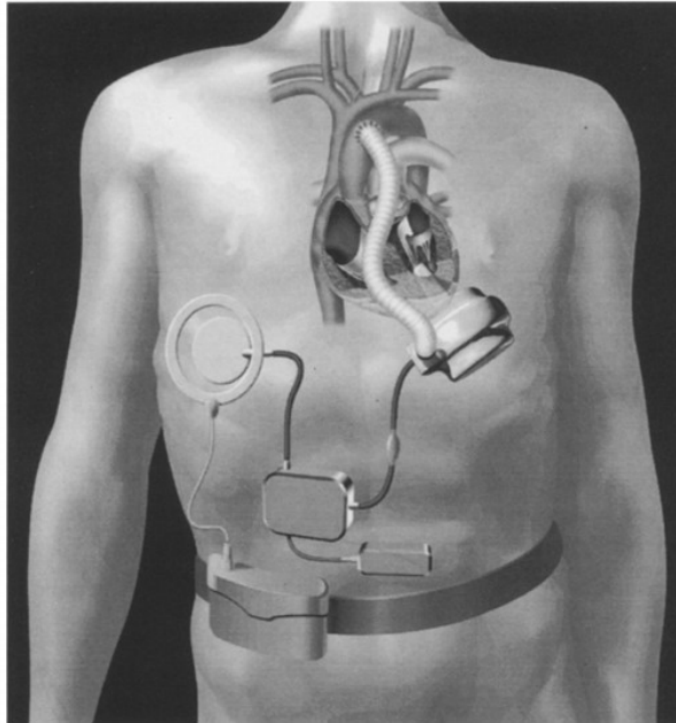


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

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.

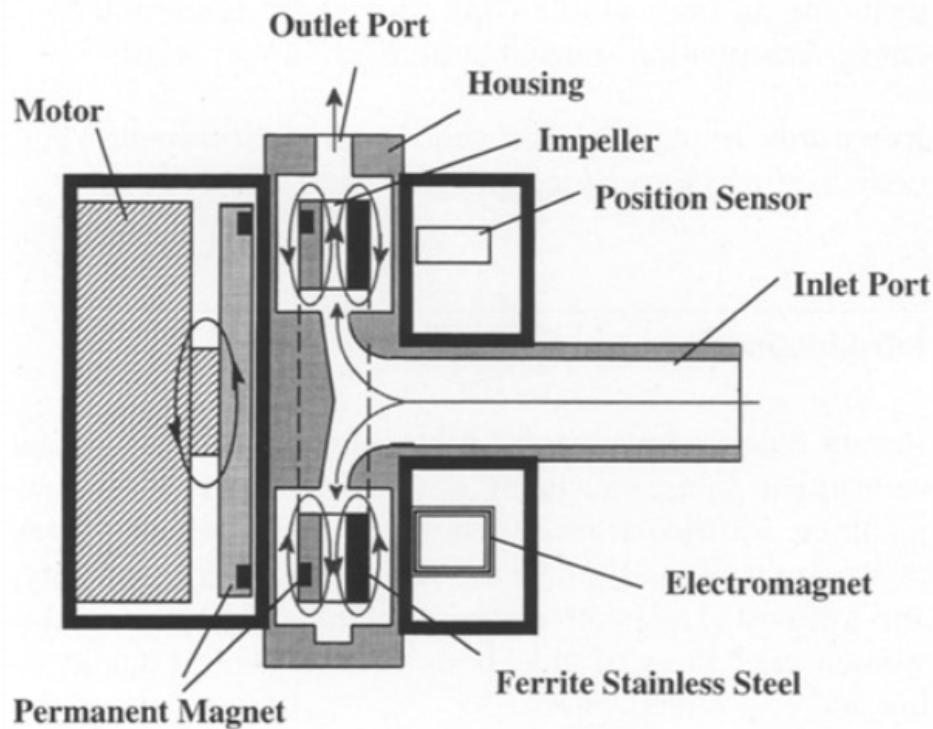


Fig. 2. Schematic cross section of the MSCP

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 casts Ground 3 as obviousness over Akamatsu alone. However, 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 First Magnetic Device Axially Adjacent To A Rotor [1C], [16D]

Petitioner has not shown that Akamatsu teaches or suggests a system for assisting blood circulation of a heart including a magnetically driven rotor assembly with a first magnetic device that is axially adjacent to a rotor, as recited in independent claims 1 and 16 (elements [1C] and [16D]). Ground 3 fails on this basis alone.

Petitioner essentially points to FIG. 2 of Akamatsu alone as support for teaching of elements [1C] and [16D], 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 93, 111; Crosby, ¶¶ 682, 802.

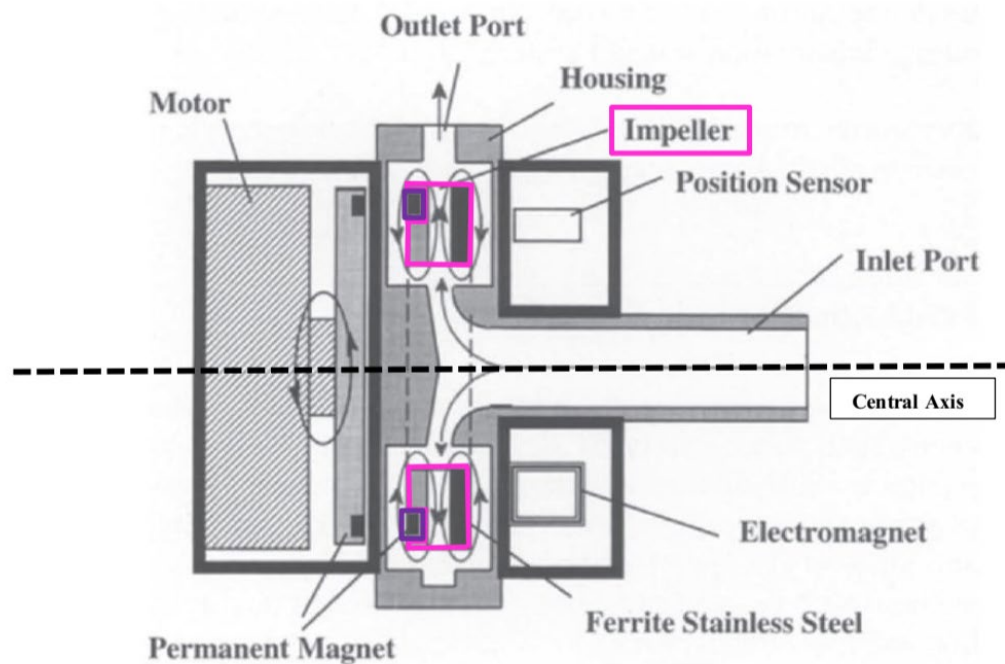


Fig. 2. Schematic cross section of the MSCP

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: "Akamatsu-1999 discloses '*the magnetically driven rotor assembly* ('impeller' and embedded 'permanent magnets')." Crosby, ¶ 683.

As discussed above in Section V.A.3, recitation in elements [1C] and [16D] that the first magnetic device is axially adjacent to a rotor would plainly mean that the two components are positioned adjacent to one another as measured along the

previously recited central axis or inflow axis about which the magnetically driven rotor assembly 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 or inflow 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 axially adjacent to a 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 or inflow axis based on the disclosed configuration. *See* Ex. 1006, FIG. 2.

4. Akamatsu Does Not Teach Or Suggest A Second Magnetic Device Positioned Axially Closer To A First Magnetic Device Than To A Rotor [16J]

Petitioner has not shown that Akamatsu teaches or suggests a “system for assisting blood circulation of a heart” with “the second magnetic device positioned

axially closer to the first magnetic device than to the rotor.” Ground 3 fails on this basis.

Before comparing the positions of the recited elements, it is important to understand what the three recited elements are. Petitioner first identifies the “impeller” as the “rotor.” Pet. at 93–94 (two figures shown below).

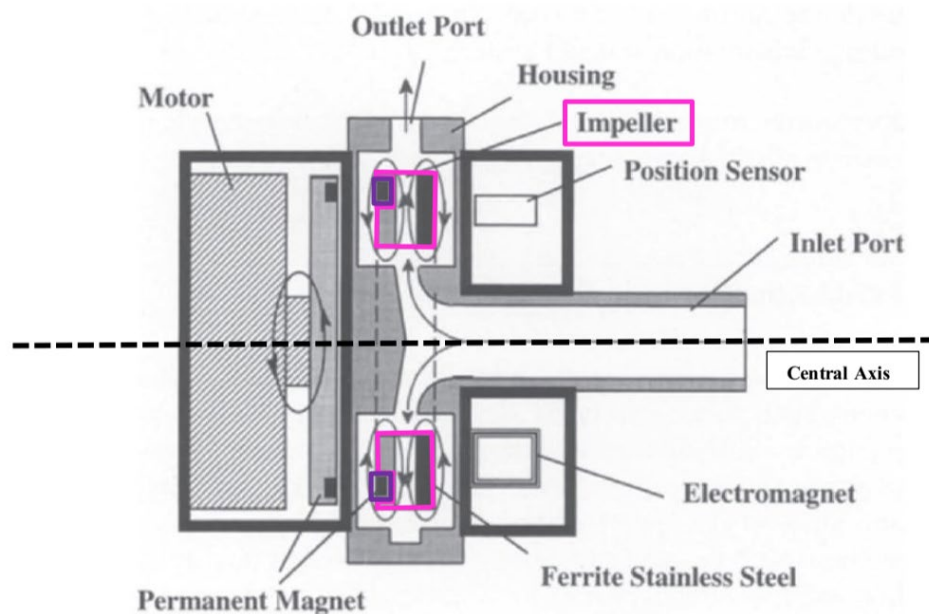
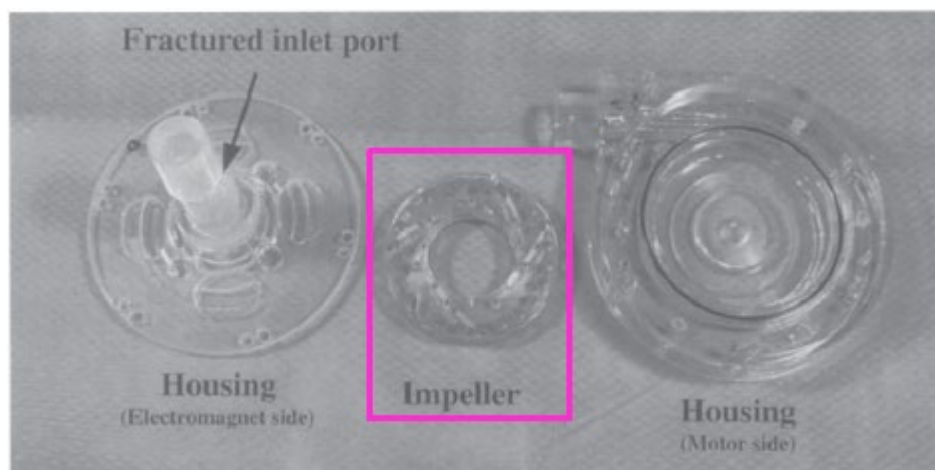


Fig. 2. Schematic cross section of the MSCP



Akamatsu provides essentially no information about the construction of this impeller.

According to Petitioner, the first magnetic device is met by the permanent magnet within the impeller. *Id.* (Petitioner posits that Crosby finds the permanent magnets in both FIGS. 2 and 5, but Crosby only addresses FIG. 2); Crosby, ¶¶ 682. The first magnetic device is said to be shown in the purple boxes added by Petitioner to FIG. 2:

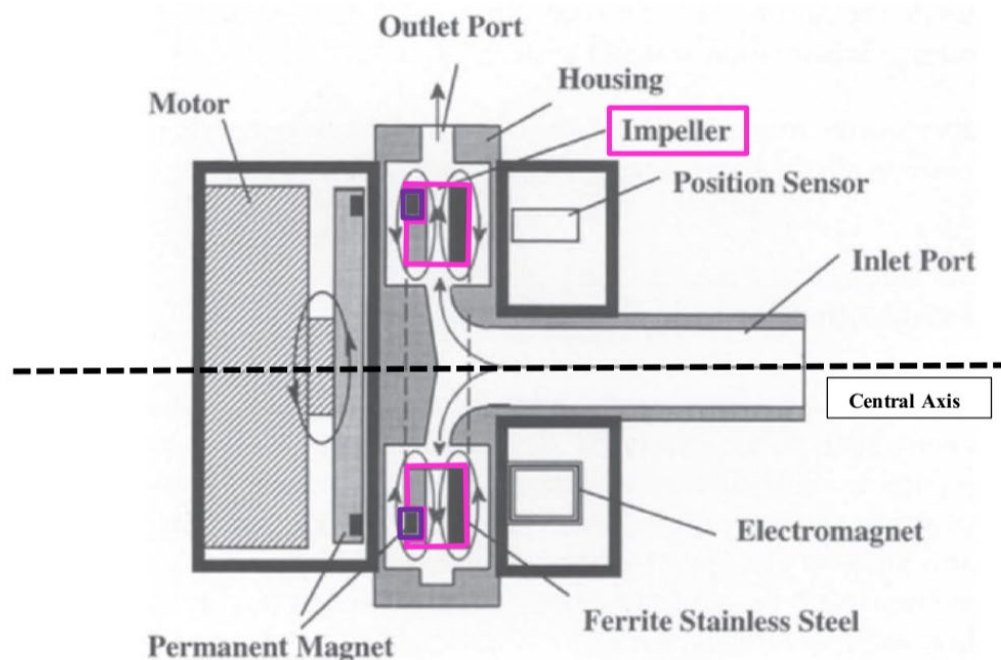


Fig. 2. Schematic cross section of the MSCP

Pet. at 93.

Further according to the Petitioner, permanent magnets found in the motor of Akamatsu, illustrated by Petitioner in blue on FIG. 2 below along with an axis, map to the second magnetic device.

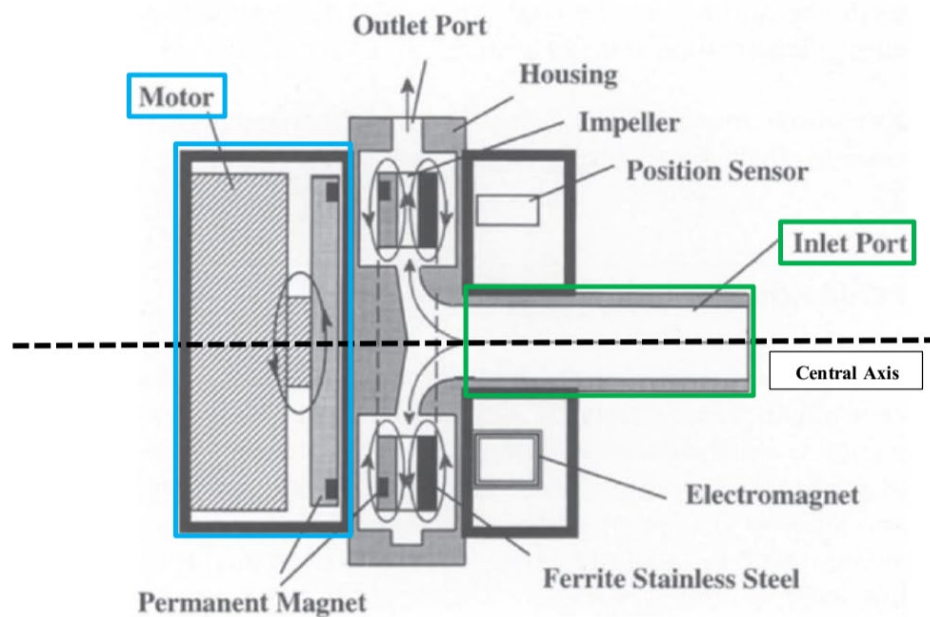


Fig. 2. Schematic cross section of the MSCP

Pet. at 98.

Turning to element [16J], Petitioner simply states that the “positioned axially closer to” claim limitation is met without actually providing any reason for saying so. Pet. at 112⁸. Petitioner cites to the Crosby declaration at paragraph 817, but this paragraph merely directs the reader to other sections addressing different claim language, i.e., element [1K] and claim [2].

Regardless of Petitioner’s flawed contentions, the only disclosure in Akamatsu on this topic is the schematic cross-sectional diagram of FIG. 2. Ex.

⁸ Similar errors as noted above in footnote 6 are present here, with Petitioner seemingly swapping elements [16J] and [16I].

1006 at 2. Not only does the permanent magnet appear at most to be flat with the left side of the impeller as illustrated (and thus exactly even in axial distance—here, in the X-axis), but close inspection of the schematic suggests that the permanent magnet may be inside the impeller, that is, covered by the dark-lined box that marks the outside of the impeller. Alas, the schematic cross-section of FIG. 2 is not clear, and neither Petitioner nor its expert provide any explanation or evidence beyond merely pointing to FIG. 2 and saying that element [16J] is met—when it plainly isn't. FIG. 2 itself, without annotation, shows that, at best, the first magnetic device and the magnetically driven rotor are at the same axial distance (same component in the X-direction) from the second magnetic device:

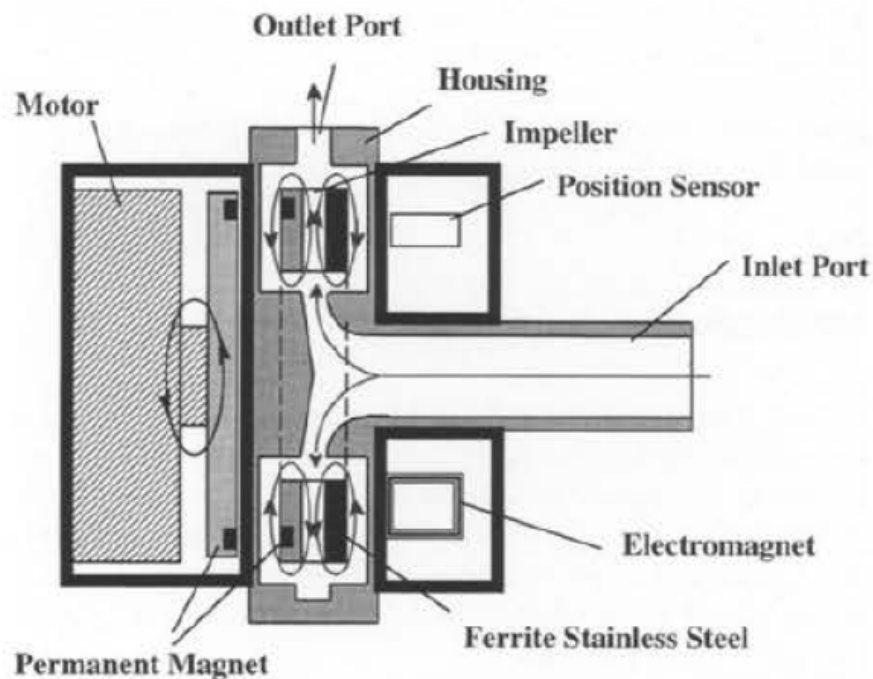


Fig. 2. Schematic cross section of the MSCP

Ex. 1006 at 2. There is no evidence of anything else.

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

5. Akamatsu Does Not Teach Or Suggest An External Control Unit Connectable To A Heart Assist Pump Device [1M], [16N]

Petitioner has not shown that Akamatsu teaches or suggests a system including a heart assist pump device that is insertable into a ventricle of a heart and an external control unit that “is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,” as recited in independent claim elements [1M] and [16N]. Ground 3 also fails on this basis.

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 105, 113; Crosby, ¶¶ 748, 829, 832 (these passages address elements [1L] and [16M] where the external controller is first recited).

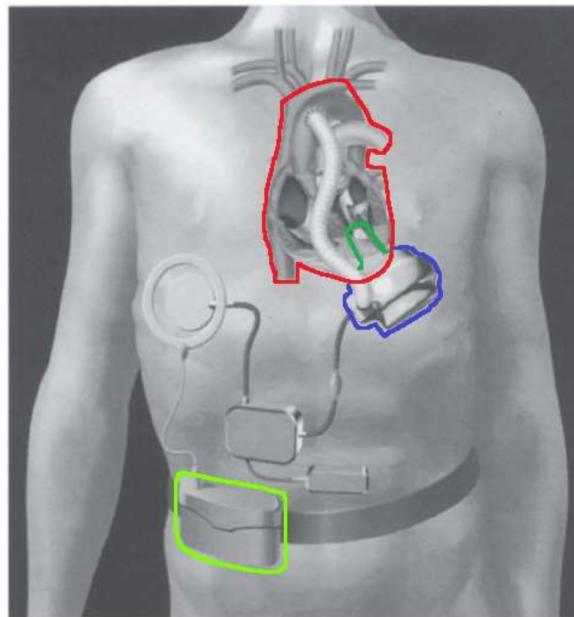


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

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. Petitioner should not be allowed 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.

Further, 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 elements [1M] and [16N].

D. Schima And Akamatsu Fail To Render Obvious Any Challenged Claim (Ground 4)

The Petition fails to demonstrate that Schima and Akamatsu, even in combination, teach or suggest multiple features recited in independent claims 1 and 16 of the '077 patent. Petitioner thus fails to show a reasonable likelihood that claim 1 or claim 16 is unpatentable under Ground 4. Because claims 2–5, 7, 10,

17–24, 26, and 28 depend from either claim 1 or claim 16 and recite additional features, Petitioner also necessarily fails to show a reasonable likelihood that these dependent claims are unpatentable under Ground 4.

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.”⁹ *Id.* at [0010]. The flow surfaces are disclosed as vanes formed on the rotor that 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 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].

1. No Combination Of Schima And Akamatsu Teaches Or Suggests A Heart Assist Pump Device Deliverable To The Heart And Insertable Into A Ventricle [1A], [16A]

Petitioner has not shown that any combination of Schima and Akamatsu teaches or suggests a system including a heart assist pump device deliverable to the

⁹ Petitioner argues that Patent Owner admits a similar Schima reference mentioned in the '077 patent discloses everything in the claims. Pet. at 14, n.2. In fact, the '077 patent specification cites 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, 2:29–30. This is far from Petitioner's contended admission by Patent Owner that all elements of the claims are disclosed.

heart with an inflow tube that is insertable into a ventricle of the heart, as recited in independent claim elements [1A] and [16A]. Ground 4 fails on this basis alone.

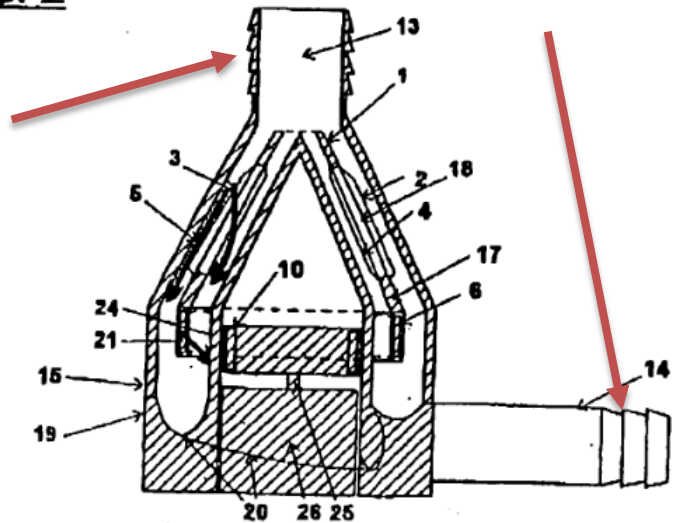
Petitioner essentially admits that Schima is silent regarding placement of its disclosed pump, and includes no disclosure regarding delivery of its disclosed pump to a heart. Pet. at 145 (“Shima focuses on pump design alone.”); *see also* Crosby at ¶¶ 896–903 (relying solely on other references mentioned in Schima for this alleged disclosure). Petitioner relies upon Akamatsu to remedy this deficiency of Schima, suggesting that “it would have been obvious to implant Schima’s device in the configuration described by Akamatsu.” Pet. at 116. But 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 Schima’s pump “so that its inlet tube 13 is ‘inserted into the left ventricle,’ as taught by Akamatsu.” *Id.* at 117. There is, however, no teaching 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 (highlighted with red arrows at right) configured for use

Fig.
Abb. 2



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.

Petitioner's expert, however, goes so far as to say that the pump in Schima is designed to be deliverable to the heart such that the barbed inlet 13, clearly designed to attach a tube, is inserted into a ventricle of the heart. Crosby, ¶ 904. The supposed support for this obviously wrong statement is that Schima wishes to improve on the prior art referenced in paragraphs [0004]–[0008] of Schima. Crosby, ¶¶ 898–904. But these paragraphs of Exhibit 1005 only describe the

control of a rotor to maintain gaps between the rotor and its surrounding housing—and Schima criticizes the rotor control of each reference and concludes that the “present invention therefore has the object of overcoming these disadvantages. Mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps are to be avoided.” Ex. 1005 at [0004]–[0009]. From these paragraphs, Crosby draws the *non sequitur* that Schima was setting out to design its barbed inflow tube connector to be placed in the ventricle of the heart. Crosby, ¶¶ 898–904. We don’t need Crosby to fabricate stories about the cited prior art, because Schima explicitly tells us what they were doing: they were trying to manage gaps around the rotor, not invent new designs for connecting to a heart.

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. It is simply not clear from

Akamatsu that the reference discloses delivering its pump to a heart such that an inflow tube is inserted into a ventricle of the heart, as Petitioner asserts. Petitioner relies on the conceptual, low-resolution FIG. 1 of Akamatsu to suggest the delivery of a heart assist pump recited, as in claim elements [1A] and [16A], but this configuration is not actually shown and does not support the insertion of an inlet tube into a ventricle of the heart as Petitioner argues in its proposed combination. Instead, Petitioner marks up FIG. 1 to show a feature that is not clear in the original. Pet. at 117. Further, Akamatsu discloses its “paracorporeally” positioned pump, as well as its “intrathoracically implanted” pump, in a manner that suggests the use of “inflow and outflow conduit” that would have extended between the “inlet port” and “outlet port” of the pump to the descending aorta and a cuff sutured to the ventricular apex, respectively. Ex. 1006 at 4. This suggests the inlet port of Akamatsu’s pump is not itself inserted into a ventricle of the heart, as Petitioner argues in its obviousness combination.

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 at least claim elements [1A] and [16A].

2. No Combination Of Schima And Akamatsu Teaches Or Suggests An External Control Unit Connectable To A Heart Assist Pump Device [1M], [16N]

Petitioner has not shown that any combination of Schima and Akamatsu teaches or suggests a system including a heart assist pump device that is insertable into a ventricle of a heart and an external control unit that “is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,” as recited in independent claim elements [1M] and [16N]. Ground 4 also fails on this basis.

Petitioner admits that Schima does not disclose an external control unit connected to its pump. *See* Pet. at 133; Crosby, ¶ 982 (both referencing element [1L] where an external controller is first recited). Schima, then, cannot be said to teach or suggest elements [1M] and [16N].

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 133–134; Crosby, ¶ 983–984. 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 filling in the gaps in Akamatsu's disclosure in a convenient manner that supports its 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.

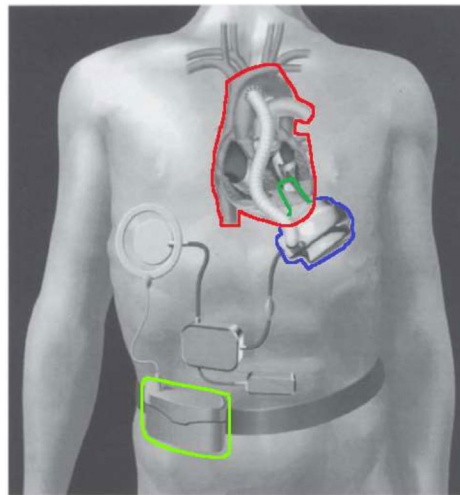


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

For all of the reasons detailed in Section V.C.5 above, Akamatsu fails to teach or suggest elements [1M] and [16N]. Given that Petitioner admits Schima does not teach or suggest these elements, no combination of these two references can do so either, so Ground 4 fails to show a reasonable likelihood that claim 1 or claim 16 is unpatentable.

VI. THE PETITION SIGNIFICANTLY EXCEEDS THE WORD LIMIT

The Petition's word-count certification indicates it is 89 words under the 14,000-word limit. *See* Pet. at 149. 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., “¶¶54–55” vs. “¶¶ 54–55”), statutes (e.g., “§102” vs. “§ 102”), and other sections of the document (e.g., “§VIII.A.1.i” vs. “§ VIII.A.1.i”). While such improper formatting only undercounts one word with each occurrence, these citations occur

so frequently that at least 1,036 words have been improperly undercounted, as shown below:

Improper Formatting	Omitted Words
No space after “Ex.” (e.g., “Ex.1001” vs. “Ex. 1001”)	655
No space between ¶ symbol and numeral	354
No space between § symbol and numeral or letter (correct in Table of Authorities and Certificates of Compliance and Service)	27
TOTAL	1,036

With proper formatting, the Petition's word count would be nearly 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, Certificate of Compliance, and Certificate of Service—which are 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. § 42.24.¹⁰

Furthermore, the Petition attempts an additional massive circumvention of the word limit by omitting an analysis for about half of the challenged claims, as discussed above in Section IV.C. In each of Grounds 1–4, Petitioner addresses claims 16–24, 26, and 28 by referencing non-identical elements of claims 1–5, 7,

¹⁰ 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).

and 10,¹¹ in most cases without any additional analysis. *See* Pet. at 45–52, 77–80, 111–114, 140–143. These sections of the Petition also cite to paragraphs for Crosby's analyses of claims 16–24, 26, and 28, which collectively span 116 pages of his 502-page declaration. *See id.*; Crosby at pp. 170–203, 268–294, 370–398, 460–485.¹² “This practice of citing the Declaration to support conclusory statements that are not otherwise supported in the Petition... amounts to incorporation by reference” in violation of 37 C.F.R. § 42.6(a)(3). *Cisco*, IPR2014-00454, Paper 12 at 9–10 (refusing consideration of such arguments). These tactics allow Petitioner to save a large number of words, but at the expense of identifying with particularity the evidence supporting its challenge to each claim. *See supra*, § IV.C.

This Petition is an opportunity for the Board to stop permitting these abusive practices, which 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

¹¹ Exhibit 2012 highlights differences in claim language between independent claims 1 and 16, for example, which are largely ignored by Petitioner.

¹² These 116 pages of Crosby, in turn, incorporate roughly 261 other pages of the declaration, specifically, paragraphs found on pages 98–170, 204–268, 311–370, and 398–460 thereof.

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.

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: March 12, 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 13,999 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 /

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*Lead Counsel for Patent Owner
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CERTIFICATE OF SERVICE

Under 37 C.F.R. § 42.6(e), the undersigned certifies that on this 12th day of March 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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