

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00096
Patent 11,351,356 B2

Before ANNETTE R. REIMERS, JAMES A. TARTAL, and
JOHN D. HAMANN, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Denying Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64(c)

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Abbott Laboratories (“Petitioner”) bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Miracor Medical SA (“Patent Owner”). See 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4, 6, 7, 10, 12, and 13 of U.S. Patent No. 11,351,356 B2 (Ex. 1001, “the ’356 patent”) are unpatentable, but has not shown that claim 5 is unpatentable. We also deny Patent Owner’s Motion to Exclude Evidence (Paper 34).

I. INTRODUCTION

A. Summary of Procedural History

Petitioner¹ filed its Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–7, 10, 12, and 13 (the Challenged Claims) of the ’356 patent. Paper 1 (“Pet.”). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 15 (“Institution Decision” or “Inst. Dec.”). Patent Owner² filed a Response. Paper 22 (“PO Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 26 (“Pet. Reply”). Patent Owner filed a Sur-reply in support of the Patent Owner

¹ Petitioner identifies Thoratec LLC as another real party-in-interest. Pet. 3.

² Patent Owner identifies no additional real parties-in-interest. Paper 4, 2.

Response. Paper 33 (“PO Sur-reply”). Following oral argument, we entered a transcript of the hearing in the record.³ Paper 56 (“Tr.”).

Patent Owner also filed a Motion to Exclude Evidence. Paper 34 (“Motion” or “Mot.”). Petitioner filed a Response in opposition to the Motion (Paper 35, “Mot. Resp.”), and Patent Owner filed a Reply in support of the Motion (Paper 40, “Mot. Reply”).

B. Related Proceedings

Petitioner and Patent Owner identify as a related proceeding *Miracor Medical SA v. Abbott Laboratories and Thoratec LLC*, No. 1:23-cv-16257 (N.D. Ill.) (the “Parallel Proceeding”). Pet. 4; Paper 4, 2. Additionally, Petitioner filed petitions in IPR2025-00112, IPR2025-00113, IPR2025-00114, IPR2025-00115, and IPR2025-00116 challenging claims of other patents owned by Patent Owner related to the ’356 patent.

II. BACKGROUND

A. The ’356 Patent

The ’356 patent relates to medical care for normalizing and stabilizing cardiac function after a heart failure. Ex. 1001, 1:27–31. The ’356 patent explains that assisting heart performance using an external pump to remove blood from vessels and return it to a heart chamber via a ventricle catheter was known. *Id.* at 1:65–2:4. The ’356 patent describes a device that dispenses with the external blood pump and, instead, uses a heart ventricle catheter having, at its distal end, a fluid-driven rotary pump for improving blood circulation at a particular location. *Id.* at 2:23–42. The pump includes

³ Prior to the oral argument, Patent Owner filed an objection to Petitioner’s slide 38 (appearing in Exhibit 1054) as presenting new argument based on new evidence. Paper 54. We do not rely on slide 38 and find Patent Owner’s objection moot.

a “drive wheel . . . formed as a hydraulically or pneumatically operated paddle wheel, with the driving fluid being supplied to the paddle wheel via a lumen of the catheter and being carried off via a further lumen of the catheter.” *Id.* at 2:56–62. The drive wheel is magnetically coupled to a rotor, which rotates about an axis that is aligned with the longitudinal axis of the catheter. *Id.* at 2:63–3:4.

Figure 1 of the '356 patent is reproduced below.

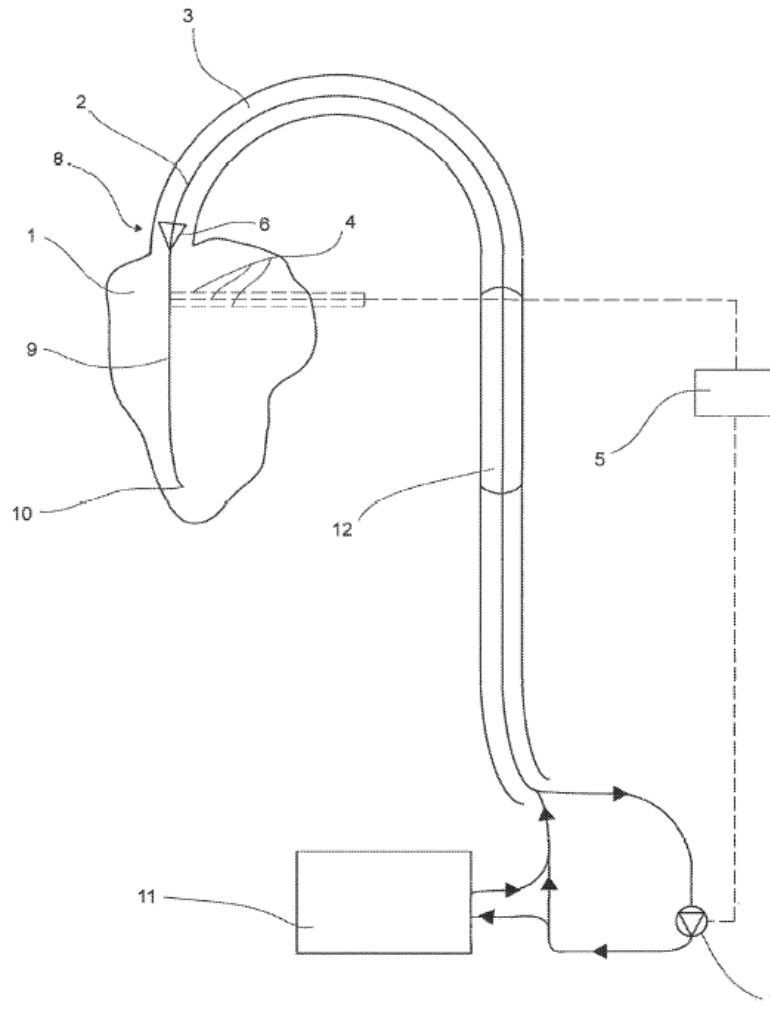


Fig.1

Figure 1 is a schematic drawing that illustrates a pump and drive arrangement according to an embodiment of the invention, including

ventricle catheter 2 inserted into heart 1 via aortic arch 3. *Id.* at 3:64–4:4, 4:8–12. Distal end 8 of catheter 2 includes rotor 6 and sensors 4 that pass signals to control arrangement 5. *Id.* at 4:13–18, 4:24–27. Catheter 2 also includes several lumina that supply fluid circulated by fluid pump 7, which regulates the fluid flow as a function of signals from control arrangement 5. *Id.* at 4:19–24. The fluid acts as a medium for driving rotor 6 to pump blood and assist circulation. *Id.*

Figure 2 of the '356 patent is reproduced below.

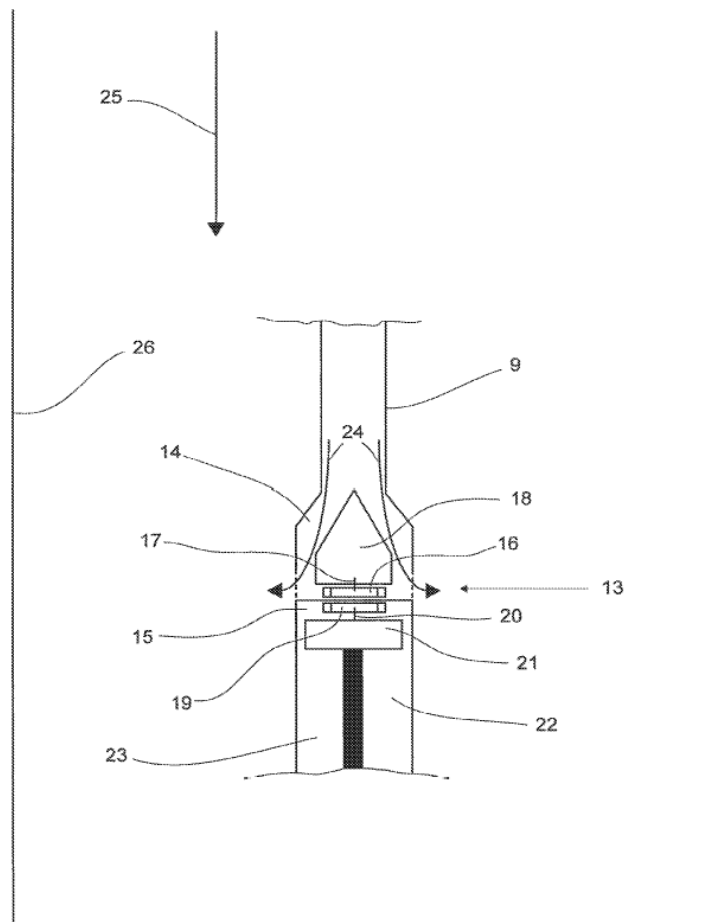


Fig. 2

Figure 2 of the '356 patent illustrates the distal end of catheter 2 inserted in vessel 26. *Id.* at 4:47–48, 4:61–67. End side 13 has pocket-shaped chambers 14 and 15. *Id.* at 4:48–50. In chamber 14, bar magnet 16 connects

to rotor 18 via shaft 17, and, in chamber 15, bar magnet 19 connects to drive wheel 21 via shaft 20. *Id.* at 4:50–53. Drive wheel 21 is formed as a paddle wheel that is acted upon by fluid supplied by pump 7 (shown in Figure 1) via lumen 22 and returned via lumen 23. *Id.* at 4:53–56. Fluid pressure supplied via lumen 22 rotates drive wheel 21, which rotates bar magnet 19 via shaft 20. *Id.* at 4:56–61. The rotation of bar magnet 19 causes bar magnet 16 to also rotate, which drives rotor 18 to form flow 24 in tube 9 to assist natural blood flow 25 in vessel 26. *Id.* at 4:61–67.

B. Illustrative Claim

Petitioner challenges claims 1–7, 10, 12, and 13 of the '356 patent. Pet. 1. Claim 1, the sole independent claim, is illustrative of the claimed subject matter and is reproduced below, with bracketed labels annotated by Petitioner:

1. [1PRE] A method for assisting the blood circulation of a heart in a body, comprising:
 - [1A] delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart [1B] while a magnetically driven rotor of the heart assist pump device is positioned outside the ventricle of the heart [1C] wherein the magnetically driven rotor is axially aligned with the inflow tube [1D] and is rotatable within a surrounding rotor housing of the heart assist pump device to act upon blood flowing from the inflow tube toward the magnetically driven rotor, [1E] the magnetically driven rotor being rotatable about a central axis [1F] and being rigidly coupled to a first magnetic device [1G] that is located within the surrounding rotor housing [1H] at a position axially adjacent to the magnetically driven rotor, [1I] wherein the heart assist pump device further includes: a second magnetic device axially aligned with the inflow tube [1J] and positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with

the first magnetic device [1K] while being spaced apart and sealed from both the magnetically driven rotor and the first magnetic device, [1L] and a blood outflow port positioned radially adjacent the magnetically driven rotor such that blood driven by the magnetically driven rotor is configured to exit the surrounding rotor housing in a direction substantially perpendicular from the inflow tube and the central axis of the magnetically driven rotor, [1M] wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port; and

[1N] connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device, [1O] the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart.

Ex. 1001, 5:24–6:6; Certificate of Correction; Pet. ix–x.

C. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds (Pet. 6):

Claims Challenged	35 U.S.C. §⁴	Reference(s)/Basis
1–7, 10, 12, 13	103(a)	Wampler ⁵
1–7, 10, 12, 13	103(a)	Bourque, ⁶ Wampler
1–7, 10, 12, 13	103(a)	Akamatsu ⁷
1–7, 10, 12, 13	103(a)	Schima, ⁸ Akamatsu

Petitioner relies on the Declaration of Peter Crosby (Ex. 1003), dated November 5, 2024, the Reply Declaration of Peter Crosby (Ex. 1042), dated December 22, 2025, and the Declaration of Dr. Georg Wieselthaler (Ex. 1041), dated December 22, 2025, as support for its contentions. The record includes a transcript of the deposition of Peter Crosby (Ex. 2014), dated September 4, 2025, a transcript of the second deposition of Peter Crosby (Ex. 2027), dated January 8, 2026, and a transcript of the deposition

⁴ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. We apply the pre-AIA version of § 103 here because the ’356 patent reflects a priority date earlier than the effective date of the AIA. *See* Ex. 1001, codes (22), (60).

⁵ U.S. Patent Application Publication No. 2002/0102169 A1, published Aug. 1, 2002 (Ex. 1008, “Wampler”).

⁶ Bourque et al., HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor, *ASAIO J.* 401–405 (2001) (Ex. 1007, “Bourque”).

⁷ Akamatsu et al., Development of Terumo Implantable Left Ventricular Assist System (T-ILVAS) with a Magnetically Suspended Centrifugal Pump, *J. Artif. Organs* 2:3–7 (1999) (Ex. 1006, “Akamatsu”).

⁸ U.S. Patent Application Publication No. 2003/0124007 A1, issued July 3, 2003 (Ex. 1005, “Schima”).

of Dr. Georg Wieselthaler (Ex. 2028), dated January 15, 2026. Petitioner also provides a declaration from Sylvia D. Hall-Ellis, PhD., concerning the authenticity and public availability of Bourque and Akamatsu. Ex. 1030.

Patent Owner relies on the Declaration of Boris Leschinsky (Ex. 2015), dated September 30, 2025, and the Declaration of Dr. Robert Gallegos (Ex. 2017), dated September 30, 2025. The record includes a transcript of the deposition of Boris Leschinsky (Ex. 1040), dated December 10, 2025, and a transcript of the deposition of Dr. Robert Gallegos (Ex. 1045), dated December 15, 2025.

III. ANALYSIS

A. Legal Standards for Obviousness

Petitioner contends under four grounds that the Challenged Claims are unpatentable based on obviousness. Pet. 6. 35 U.S.C. § 103(a) sets forth as follows:

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418

(2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). “Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted). “[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner contends a person of ordinary skill in the art at the time of the invention “would have at least a bachelor’s degree in engineering; knowledge and experience in human circulatory system anatomy and physiology; and at least five years’ experience designing and developing implantable medical devices.” Pet. 6 (citing Ex. 1003 ¶ 18).

Patent Owner asserts that a person of ordinary skill in the art would have possessed “at least a bachelor’s degree in engineering, knowledge and experience in human circulatory system anatomy and physiology, and at least five years’ experience designing and developing implantable cardiac

assist devices in particular.” PO Resp. 3–4. Patent Owner argues that its proposed level of skill, in contrast to Petitioner’s proposal, “reflects the complicated and critical nature of cardiac assist devices” in a field that is “high risk due to the level of complication involved in device development and the critical, life-supporting nature of the heart and associated circulatory system.” *Id.* at 4 (citing Ex. 2015 ¶ 59; Ex. 2017 ¶ 34).

During oral argument Petitioner addressed Patent Owner’s proposed level of ordinary skill, arguing that Patent Owner’s more narrow definition fails to consider the educational level of active workers in the field, and specifically the experience of the author of one of the asserted references, and that it was inconsistent with the position taken by Mr. Leschinsky in other cases. Tr. 105:14–107:17; *see also* Pet. Reply 1–2 (stating that the distinction in Patent Owner’s proposed level of skill is “inconsequential” and that “Mr. Crosby possesses the engineering experience that [Patent Owner’s] definition requires, and his opinions remain the same under either definition” (citing Ex. 1042 ¶¶ 11–15, 19)). Patent Owner acknowledges that it does “not seek to exclude anyone” based on Patent Owner’s proposed level of skill, states that “the difference between our definition as to theirs is we say implantable cardiac assist devices, and they say implantable medical devices,” and maintains that its proposed level of skill does not exclude the author of the asserted reference and reflects “that the subject matter is specifically technical” and “drives how that person would see the requirements for building this heart assist pump device.” Tr. 116:3–117:12. Patent Owner states that “[a]natomy has to matter,” but there is no evidence to suggest that a person with five years of experience in implantable medical devices would not have been aware of or understood the relevant anatomy as

compared to a person with five years of experience in implantable cardiac assist devices. *See id.* at 114:2–115:2.

We find that the '356 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of skill reflected in these references and in the '356 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner, which we adopt. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). We further find that our determinations in this Decision would be the same if we were to instead adopt the level of skill proposed by Patent Owner. In short, for purposes of resolving any issue in dispute in this proceeding, the evidence does not suggest that a person of ordinary skill in the art with five years of experience in implantable cardiac assist devices would have understood the disclosures and teachings at issue here in a materially different manner than a person with five years of experience in implantable medical devices.

C. Summary of Asserted Prior Art References

1. Summary of Wampler

Wampler, titled “Sealless Rotary Blood Pump,” relates “to continuous flow pumps of rotary design, suitable for permanent implantation in humans for use as chronic ventricular assist devices.” Ex. 1008, code (54), ¶ 2. Wampler explains that left ventricular assist devices (LVADs) using rotary pumps to provide continuous flow are “smaller, simpler, and less expensive” than prior art designs that used pumps to provide cyclic or pulsating blood flow. *Id.* ¶ 4. According to Wampler, the prior art did not disclose “a durable rotary blood pump” due to the “unique problems with the rotary pump’s driveshaft seal.” *Id.* ¶ 5. To address this issue, Wampler discloses

an improved rotary blood pump that eliminates the need for a driveshaft seal.
Id. ¶ 6.

Figure 3 of Wampler, reproduced below, is a partial cross-sectional view of a first embodiment of a sealless rotary blood pump. *Id.* ¶ 50.

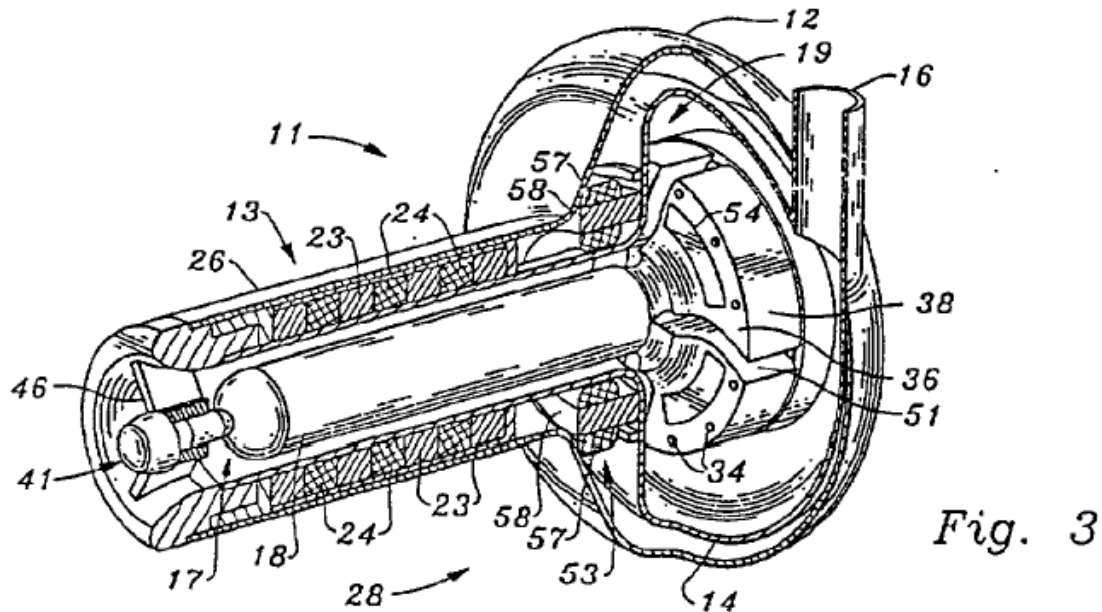


Figure 3 depicts pump 11 including housing 12 with elongated inlet tube 13 and discharge tube 16. *Id.* ¶ 50. Casing 14 encloses rotor 17, which includes spindle 18 and attached impeller 19. *Id.* ¶ 51. Forward magnetic bearing 21 and rearward magnetic bearing 22 “levitate rotor 17 and maintain it in proper radial alignment with respect to its longitudinal axis.” *Id.* ¶ 52; *see also id.* ¶ 54 (explaining that “magnetic polarizations and repulsive forces produced by the magnets and the pole pieces of forward magnetic bearing 21 are such that magnetic levitation of support shaft 18 results”). Motor 53 includes arcuate magnetic segments 54 imbedded in upper face portion 36 of impeller 19. *Id.* ¶ 70. Magnetic segments 54 have alternating polarity orientations and are directed toward motor stator 56 mounted on the outer surface of impeller casing 14. *Id.* Motor stator 56 includes pole

piece 58 and windings 57, which are energized to generate an electromagnetic field that drives magnets 54 to rotate impeller 19 of rotor 17. *Id.* ¶¶ 70, 72. According to Wampler, “[m]otor 53, with windings 57 and pole piece 58, together with magnets 54, function not only to transmit torque but also provide a restoring radial magnetic force that acts as a radial bearing.” *Id.* ¶ 73.

Figure 13 of Wampler, reproduced below, illustrates a second embodiment of a rotary blood pump. *Id.* ¶¶ 34, 37.

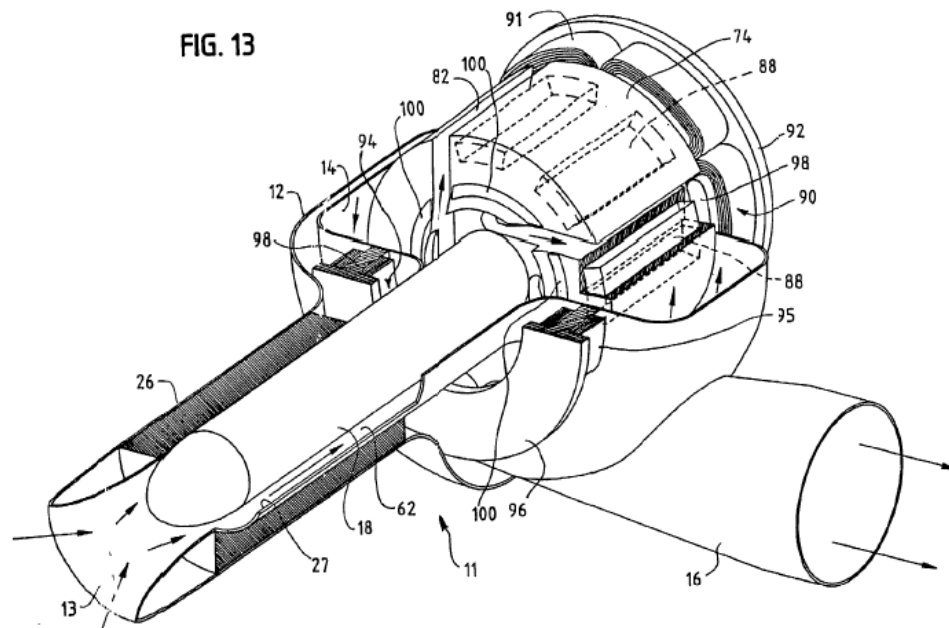


Figure 13 shows a second embodiment of pump 11 that includes first motor stator 90 comprising windings 91 and back iron 92 located at the rear side of impeller 74, between housing 12 and casing 14. *Id.* ¶ 83. Second motor stator 94 comprises windings 95 and back iron 96 fixed to casing 14 on the forward side of impeller 74. *Id.* ¶ 84. Motor stators 90 and 94 are positioned on opposite sides of casing 14 so that each is adjacent to the pole faces of rotor magnets 88. *Id.* ¶ 85.

Wampler explains that one of several advantages to the arrangement described in the second embodiment is that “hydrodynamic bearings can be

located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device.” *Id.* ¶ 89. The hydrodynamic bearings may take the form of raised pads 100 symmetrically located about impeller 74 that are spaced from a contact surface by a gap. *Id.* ¶¶ 89, 92. According to Wampler, once impeller rotation begins, the relative movement between the raised pads and the contact surfaces produces increased pressure within the gaps that forces the raised pads and contact surfaces apart to aid in axial and/or radial support. *Id.* ¶¶ 92–93.

2. Summary of Bourque

Bourque is titled “HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor” and relates to a “long-term, compact left ventricular assist device (LVAD) . . . featuring a centrifugal pump with a magnetically levitated rotor.” Ex. 1007, 1.⁹ Bourque explains that second generation LVAD research focused on continuous flow pumps over positive displacement pumps because continuous flow pumps have fewer mechanical parts, are smaller, and have lower cost. *Id.* According to Bourque, the HeartMate III further improves upon second generation LVADs because the pump has no mechanical bearings. *Id.* Instead, “[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.” *Id.*

⁹ We refer to the page numbers added by Petitioner at the lower right corner of Exhibit 1007.

Figure 1B of Bourque, reproduced below, is a cross-sectional view of a model representing a HeartMate III pump. *Id.* at 2.

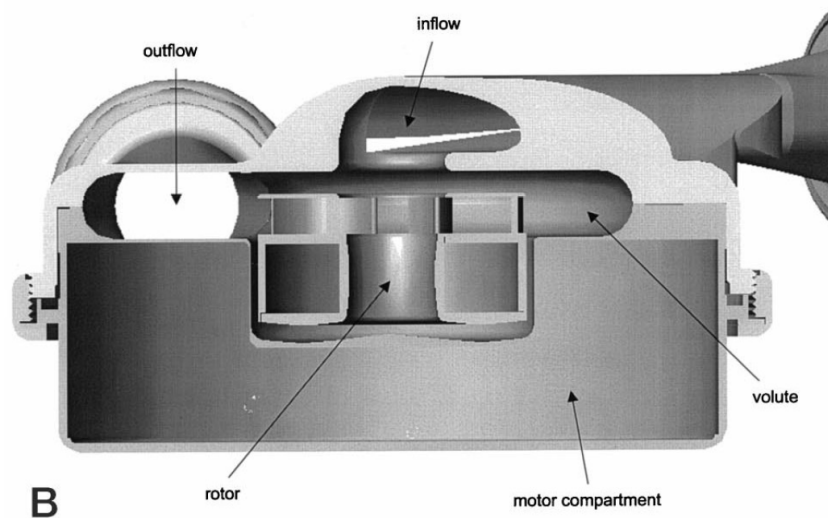


Figure 1B depicts a HeartMate III pump including an upper housing and a lower housing clamped together by a screw ring. *Id.* at 1–2. The upper housing includes an inflow channel, an outflow channel, and an upper half of a volute. *Id.* The lower housing includes a lower half of the volute and a cavity for a rotor, which encloses a motor. *Id.* The rotor includes an impeller and passive magnetic elements. *Id.*

Figure 4 of Bourque, reproduced below, is a cross-sectional diagram of the HeartMate III motor. *Id.* at 2.

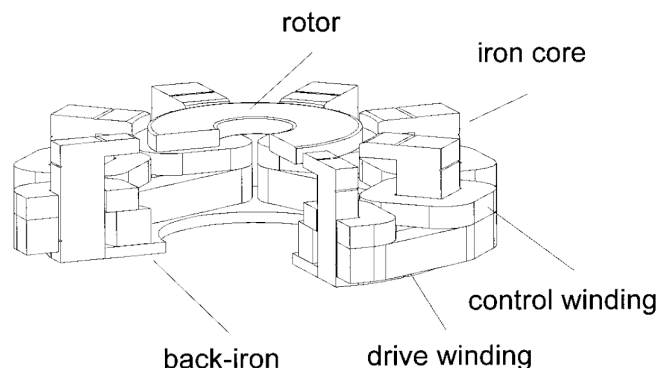


Figure 4 depicts a single magnetic structure including a back-iron, a drive winding, an iron core, and a control winding. *Id.* at 3. The magnetic

structure drives the rotor and controls rotor levitation. *Id.* at 2. Bourque explains that “[t]he rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom . . . and actively magnetically levitated in the remaining degrees of freedom.” *Id.* at 2–3; *see also id.* at 2 (explaining that “the magnetic suspension (passive in the axial direction, actively controlled in the radial direction) . . . describes the levitation system’s capacity to counteract imposed deviations of rotor position”).

3. *Summary of Akamatsu*

Akamatsu, titled “Development of Terumo Implantable Left Ventricular Assist System (T-ILVAS) with a Magnetically Suspended Centrifugal Pump [(MSCP)],” relates to a “study describ[ing] recent progress in the development of the T-ILVAS, focusing on ex vivo and in vivo evaluations of the prototype MSCP.” Ex. 1006, 1.¹⁰ Akamatsu explains that “the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear,” making it “expected to be one of the most durable blood pumps.” *Id.*

¹⁰ We refer to the page numbers added by Petitioner at the lower right corner of Exhibit 1006.

Figure 2 of Akamatsu, reproduced below, is a schematic cross-sectional view of a MSCP. *Id.* at 2.

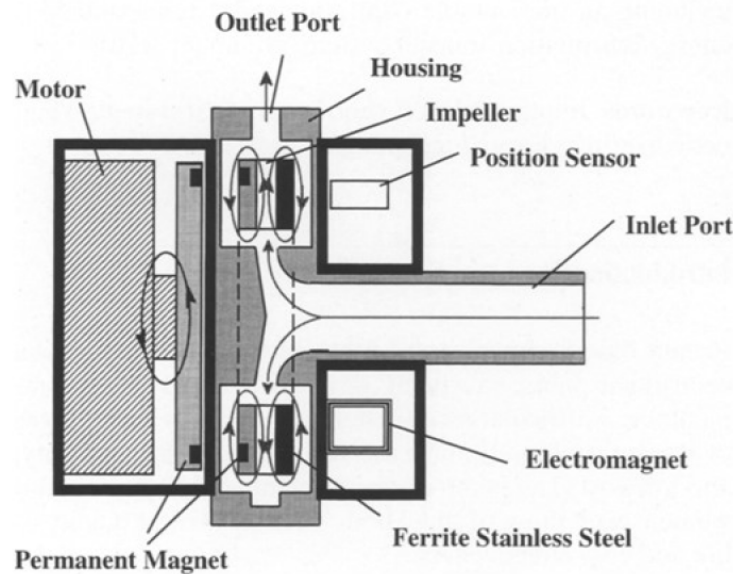


Figure 2 depicts a MSCP with its main components including a housing with an inlet port and an outlet port, an impeller suspended by a magnetic bearing, and a DC brushless motor. *Id.* The magnetic bearing comprises electromagnets and position sensors that are used to control the electric current in the electromagnets in order to suspend and “maintain the impeller free-floating at the center of the pump housing.” *Id.* The motor rotates the impeller via a magnetic coupling. *Id.* The impeller is suspended in the housing by the magnetic bearing, which comprises three electromagnets. *Id.*

4. Summary of Schima

Schima is titled “Rotary Pump Comprising a Hydraulically Mounted Rotor” and “relates 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, code (54), ¶ 1. Schima explains that an object of the disclosed invention is to provide a pump with a small number of parts and a simple construction that avoids mechanical

depositions, dead-water zones, zones of reduced flow velocity, and small gaps. *Id.* ¶ 9

Figure 1 of Schima, reproduced below, is a cross-sectional view of a pump according to one embodiment. *Id.* ¶ 11.

Fig.
Abb. 1

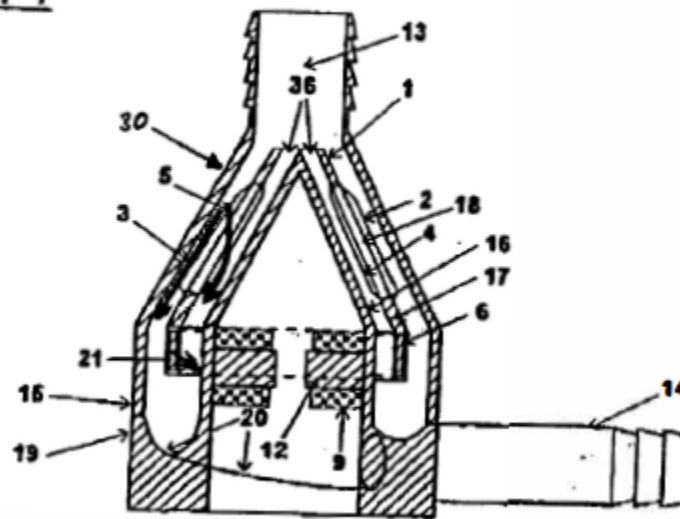


Figure 1 depicts hollow conical rotor 1 having vanes 2 and 4 that produce flow components 3 and 5, and rotor magnets 6. *Id.* ¶ 12. Rotor 1 rotates in housing 30, which comprises hollow conical upper part 15 with inlet 13, and lower part 19 with conical middle part 16 and outlet 14. *Id.* Rotor 1 also includes inlet opening 36 that distributes incoming liquid between the rotor and middle part 16. *Id.* Flow components 5 are directed axially against the conical surface of middle part 16 to effect centering of rotor 1. *Id.* Housing lower part 19 also includes stator 12 with coils 9 for generating a rotating magnetic field. *Id.* Rotor magnets 6 and stator 12 work together and are axially offset so that coupling force 21 is “effective at an angle and provide[s] an axial component for additional stabilizing of the rotor 1.” *Id.*

Figure 2 of Schima, reproduced below, is a cross-sectional view of a second pump embodiment with a different drive arrangement. *Id.* ¶ 13.

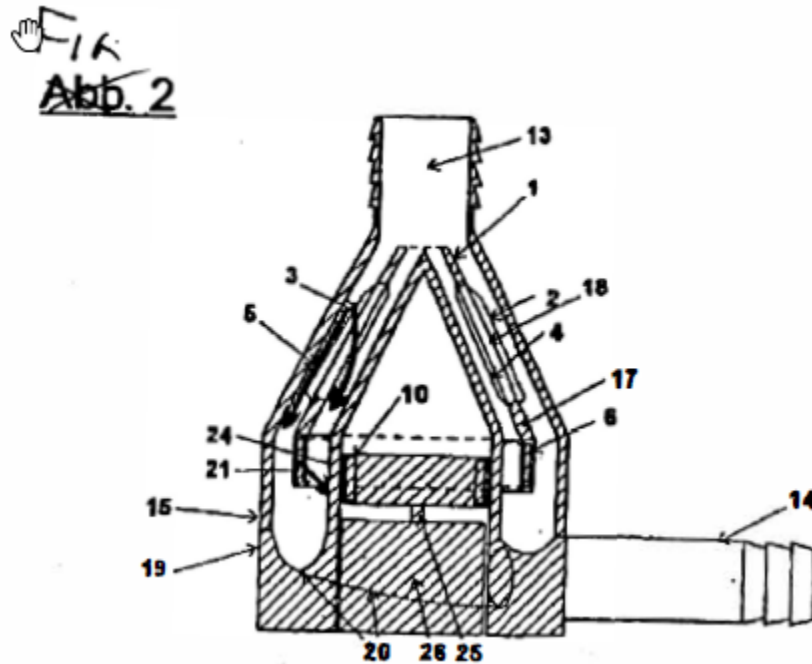


Figure 2 depicts electric motor 26 driving rotating disk 24 with magnets 10 via shaft 25. *Id.* According to Schima, “[t]his embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the magnetic force 21.” *Id.*

D. Claim Construction

In this proceeding we construe claims using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing

claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–1317.

Under the heading “Claim Construction,” Petitioner addresses two claim terms in the Petition: “magneto coupling” and “by the blood flowing.” Pet. 7–9. Additional claim terms that are at issue are “at a position axially adjacent” and “axially aligned.” We address each of these terms in turn below.

1. “*magneto coupling*”

Claim 1 recites, in relevant part, “a second magnetic device . . . positioned to magnetically drive rotation of the magnetically driven rotor via a magneto coupling with the first magnetic device.” Ex. 1001, 5:24–6:6. Petitioner argues that “magneto coupling” means “a transfer of torque from one rotating permanent magnetic component to another rotating permanent magnetic component via a magnetic field.” Pet. 8 (citing Ex. 1003 ¶¶ 68–87). According to Petitioner, this construction is consistent with the ’356 patent, which describes “a coupling between two rotating ‘bar magnets’—a drive wheel rotates one bar magnet which causes another bar magnet (connected to a rotor) to rotate.” *Id.* (citing Ex. 1003 ¶¶ 54–55 (analyzing Ex. 1001, 2:32–56, 4:47–67, Fig. 2)).

Patent Owner argues that “magneto coupling” should be afforded “its plain and ordinary meaning, which would encompass a magnetic coupling through both rotating magnets and the use of a rotating magnetic

field developed from an electromagnetic driver.”¹¹ PO Resp. 7. Patent Owner directs us to the testimony of Mr. Leschinsky, who explains that a person of ordinary skill in the art “would have understood the ’356 patent to use ‘magneto coupling’ to generally describe a way to couple the rotor to the drive component and transfer torque via a magnetic field to enable sealing the rotor from the drive component and avoiding a direct mechanical coupling to the drive component of the pump.” Ex. 2015 ¶ 66. According to Patent Owner, “Petitioner provides no recognizable basis for limiting the plain meaning of magnetic coupling to one type of magnet and excluding another type of magnet.” PO Resp. 6 (citing *Johnson Worldwide Associates, Inc., v. Zebco Corp.*, 175 F.3d 985, 989–992 (Fed. Cir. 1999)).

We agree with Patent Owner that Petitioner does not provide a sufficient basis for limiting the plain meaning of “magneto coupling.” That the ’356 patent describes embodiments using bar magnets does not serve to require the use of permanent magnets for the recited “magneto coupling.” *See Sisvel Int’l S.A. v. Sierra Wireless, Inc.*, 81 F.4th 1231, 1236 (Fed. Cir. 2023) (quoting *Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”)). Moreover, the claim language here is not so limited.

¹¹ Patent Owner notes that Petitioner’s grounds of unpatentability based on Wampler and Bourque depend on the disclosure only of electromagnetic drives in each reference, implying that “Petitioner does not believe its own proposed narrower construction.” PO Resp. 6; *see also* Pet. 8 (Petitioner alleging that in the Parallel Proceeding Patent Owner “conflates ‘magneto coupling’ . . . with a stator drive using a stationary electromagnet, instead of a rotating magnet, to rotate the rotor magnet,” and asserting that as the basis for Petitioner’s reliance on Wampler and Bourque as teaching a “magneto coupling” in this proceeding (citing Ex. 1019, 12; Ex. 1003 ¶¶ 84–87)).

Nor do we find persuasive Petitioner's argument that prior art distinguished "magneto coupling" drives from drives using stators. Pet. 7–8 (citing Ex. 1011, 1 (explaining that the rotating field is generated by rotating magnets in a magnetic coupling pump and by electric stator windings in a stator pump)). Petitioner does not explain how this cited reference evidences that one of ordinary skill in the art would have understood "magneto coupling" requires rotating permanent magnets. At most, this reference teaches an example device that provides "magneto coupling." See Ex. 1011, 1. In sum, we agree with Patent Owner that "magneto coupling," consistent with our Institution Decision, encompasses generating a rotating field either by rotating magnets or by an electromagnet / stator. See Inst. Dec. 22.

2. *"by the blood flowing"*

Claim 1 recites, in relevant part, "the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port." Ex. 1001, 5:54–57. Petitioner does not offer an express construction of "by the blood flowing," but instead contends "that type of suspension" produces a "fluid film" and was referred to in the art as a "hydrodynamic bearing," in contrast to a "magnetic bearing," which uses "magnetic polarizations and repulsive forces." Pet. 8–9 (citing Ex. 1008 ¶¶ 54, 89–92). Petitioner adds in support that the '356 patent "explains that its rotor suspension results from '[t]he rotor produc[ing] flow . . . directed against the housing' causing 'non-contact...of the rotor in the housing.'" *Id.* at 8 (citing Ex. 1003 ¶ 92). Thus, Petitioner argues the claim term encompasses only a hydrodynamic bearing.

Patent Owner argues that “in context, ‘by the blood flowing’ means that the rotor is spaced apart from the housing and surrounded by flowing blood, regardless of whether that positioning is achieved via magnetic or hydrodynamic bearings.” PO Resp 8 (citing Ex. 2015 ¶ 76). More specifically, Patent Owner argues claim 1 requires that “it is the magneto coupling that orients the rotor to this position where the blood flows between the rotor and the housing—that is, oriented so that there is a space between the rotor and housing that is filled by blood.”¹² *Id.* at 7–8 (citing claim 1’s limitation of “wherein the magneto coupling orients the magnetically driven rotor so that, in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port”).

We agree with Patent Owner that Petitioner fails to show a sufficient basis for narrowing the meaning of “by the blood flowing,” and, consistent with our Institution Decision, we conclude that “by the blood flowing” encompasses both a hydrodynamic bearing and a magnetic bearing. *See* Inst. Dec. 23. Simply put, Petitioner does not show a basis in the intrinsic record to limit the claim term to a specific embodiment. *See Sisvel Int’l*, 81 F.4th at 1236. Moreover, the language of claim 1 that Patent Owner cites contradicts Petitioner’s limiting of the claim term to only a hydrodynamic

¹² Patent Owner notes that Petitioner’s ground of unpatentability based only on Bourque depends on the disclosure only of a magnetic bearing. PO Resp. 7; *see also* Pet. 9 (Petitioner alleging that in the Parallel Proceeding Patent Owner purportedly interprets the “by the blood flowing” as “encompassing a magnetic bearing,” and asserting that as the basis for Petitioner’s reliance on Bourque as teaching “by the blood flowing” in this proceeding) (citing Ex. 1003 ¶ 95; Ex. 1019, 12).

bearing. Nor does Petitioner’s reliance on the cited art serve to contradict the clear claim language. In sum, we conclude that “by the blood flowing,” encompasses both a hydrodynamic bearing and a magnetic bearing.

3. “*at a position axially adjacent*”

Claim 1 recites, in relevant part, “a magnetically driven rotor of the heart assist pump . . . being rigidly coupled to a first magnetic device . . . at a position axially adjacent to the magnetically driven rotor.” Ex. 1001, 5:26–39. Although Petitioner does not directly address “axially adjacent” in the Claim Construction portion of the Petition (*see* Pet. 7–9), in its analysis of alleged obviousness over Wampler, Petitioner states that it assumes the “interpretation” of “axially adjacent” that Petitioner alleges Patent Owner asserts in the Parallel Proceeding, specifically, “that a magnetic element sealed within a rotor is ‘at a position axially adjacent to the magnetically driven rotor.’” Pet. 26 (citing Ex. 1019, 5–7); *see also id.* at 98–99 (making a similar argument in regard to Akamatsu’s magnet within a rotor housing). Petitioner also states that “Mr. Crosby explains the ‘impeller’ and ‘magnetic pieces’ are axially adjacent—situated next to each other on the same axis.” Pet. 27 (citing Ex. 1003 ¶¶ 199, 355). Mr. Crosby, however, offers no explanation and instead states in a conclusory manner that Wampler’s impeller 74 has “embedded magnetic pieces 88 where the impeller 74 and magnetic pieces 88 are axially adjacent along the central axis.” Ex. 1003 ¶ 199 (citing Ex. 1008, Fig. 13). In regard to Bourque, Mr. Crosby states without explanation that Bourque’s “impeller” and “passively magnetic element” are “‘axially adjacent’ along the central axis.” *Id.* ¶ 355 (citing Ex. 1007, Fig. 1B). In its analysis of alleged obviousness over Bourque and Wampler, rather than rely on Wampler’s alleged “magnetic element sealed within a rotor” to meet the “axially adjacent” limitation, Petitioner instead

refers (without further explanation) to a figure in Bourque that Petitioner alleges shows a “magnetically driven rotor” adjacent to a “first magnetic device,” as measured along a central axis. Pet. 61–62 (citing Ex. 1003 ¶ 355–356). Similarly, in its analysis of alleged obviousness over Schima and Akamatsu, Petitioner refers (without further explanation) to a figure in Schima that Petitioner alleges shows “‘a continuous magnetic ring’ at the base of (‘axially adjacent to’) the rotor.” Pet. 127–128 (citing Ex. 1003 ¶ 684; Ex. 1005, Figs. 2, 7).

Thus, Petitioner applies different meanings to the term “axially adjacent” to different grounds in the Petition: the first being “a magnetic element sealed within a rotor” and the second implicitly being two components adjacent one another as measured along a central axis. As to the first applied meaning, Petitioner’s unsupported, conclusory assertion that a magnetic element sealed in a rotor is “at a position axially adjacent” to the rotor sheds no light on the meaning of “axially adjacent.” Petitioner does not argue that this is the plain and ordinary meaning of “axially adjacent,” much less identify any support for this construction either from the Specification of the ’356 patent or from any persuasive extrinsic evidence. We further find unsupported Petitioner’s allegation that Patent Owner “asserts that magnetic element sealed within a rotor is ‘at a position axially adjacent to the magnetically driven rotor.’” See Pet. 26 (citing Ex. 1019, 5–7).

Petitioner cites to Exhibit 1019, identified by Petitioner as Exhibit 7 to a complaint filed in the Parallel Proceeding, which refers to “a first magnetic device that is located within the surrounding rotor housing at a position axially adjacent to the magnetically driven rotor.” Pet. viii; Ex. 1019, 6. Exhibit 1019, however, depicts a device with parts labeled “First Magnetic Device” and “Magnetically Driven Rotor” along a “Central Axis.”

Ex. 1019, 7. In this regard, Patent Owner states that Exhibit 1019 “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,” and that “[i]nstead, Patent Owner illustrates a Petitioner product and identifies the claimed magnetically driven rotor and first magnetic device that are adjacent to one another along a central axis,” which 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.” PO Resp. 12 (citing Ex. 2015 ¶ 78). We find nothing in Exhibit 1019 that defines “at a position axially adjacent” to mean “a magnetic element sealed within a rotor,” as Petitioner alleges in the Petition.

Patent Owner argues in its Response that “at a position axially adjacent” should be given its plain and ordinary meaning of “adjacent to one another as measured along a central axis.” PO Resp. 8; *see also* Ex. 2015 ¶¶ 77–83 (Mr. Leschinsky addressing the claim term “at a position axially adjacent” and explaining that a person of ordinary skill would have understood it to mean that the “magnetic device and the rotor are ‘adjacent’ to one another, i.e., disposed next to one another, as measured along the central axis about which the rotor spins”). Patent Owner’s construction is also supported by Petitioner’s expert, Mr. Crosby, who agrees that “adjacent to one another as measured along a central axis,” could be “one meaning,” along with “many other meanings.” Ex. 2014, 19:13–20:11.

In further support of Patent Owner, Mr. Leschinsky states that a person of ordinary skill “would not have understood components embedded or sealed within one another to be ‘at a position axially adjacent’ to one another,” because “embedding components” implicates “a relationship of

axial overlap rather than adjacency” and “adjacency along an axis” means that two components are positioned next to one another when measured along the axis,” which is “distinct from positioning that involves components overlapping or occupying the same portion of an axis upon which they are positioned.” Ex. 2015 ¶¶ 78, 82. Mr. Leschinsky’s testimony in this regard is *undisputed* by Petitioner, and we note that Petitioner bears the burden of showing how the claim is to be construed. *See* 37 C.F.R. § 42.104(b)(3).

In its Reply, Petitioner doubles-down on its assertion that we “should adopt [Patent Owner’s] construction from its infringement contentions,” and that Patent Owner “undoubtedly interprets ‘*axially adjacent*’ as including components that ‘overlap or occupy the same portion of an axis.’” Pet. Reply 7–8. That, however, is not how we construe claims under *Philips*. Moreover, on the substance of Petitioner’s Reply allegations, we find, once again, Petitioner’s contentions of what Patent Owner purportedly asserts in the Parallel Proceeding to be unsupported. In its Reply, Petitioner does not further address Exhibit 1019 (the only cited support in the Petition for its argument about positions taken by Patent Owner in the Parallel Proceeding), and turns instead to Exhibit 1036, stating: “[f]or purposes of this proceeding, Petitioner assumes [Patent Owner’s] position from its infringement contentions (Ex. 1036) that ‘axially adjacent’ includes components that overlap or occupy the same portion of an axis.” *Id.* at 4. In the Petition, Petitioner does not identify or address components as being axially adjacent because they “overlap or occupy the same portion of an axis” in any context, and did not discuss any alleged infringement contentions as being relevant to claim construction. *See generally* Pet.

Petitioner's Reply makes one thing clear: Petitioner has offered no independent evidence in support of any construction of "axially adjacent" and instead mistakenly "assumes [Patent Owner's] position from its infringement contentions (Ex. 1036) that 'axially adjacent' includes "components that overlap or occupy the same portion of an axis." Pet. Reply 3–9. We reject Petitioner's assertion that a claim term may be defined based solely on an alleged infringement contention of Patent Owner in district court. *See id.* at 8. As to the merits of Petitioner's argument based on alleged infringement contentions, Petitioner's assertions concerning Exhibit 1036 appear to be based on what Patent Owner identifies as an erroneous arrow in a single figure pertaining to a filing in the Parallel Proceeding. *See* PO Sur-reply 5–6 (stating that "Petitioner, however, points to one erroneously placed arrow on one half of the figure on page 20 of the Exhibit [1036] (while not recognizing the 16 correct figures in that document alone) and announces that Patent Owner has taken a position on axially adjacent in the co-pending litigation that is different than the position it takes here"); Tr. 57:14–60:2. In short, even if we were to rely on infringement contentions in the Parallel Proceeding for claim construction, we find no persuasive support for Petitioner's argument that "axially adjacent" includes components that overlap or occupy the same portion of an axis based on purported infringement contentions in the Parallel Proceeding.

Mr. Crosby also does not support Petitioner's suggestion that we construe "*axially adjacent*" to include components that overlap or occupy the same portion of an axis. Mr. Crosby's testimony simply mirrors Petitioner's arguments and states that he relies "on [Patent Owner's] position from its infringement contentions (Ex. 1036), which show 'axially adjacent' as including components that overlap or occupy the same portion of an

axis.” Ex. 1042 ¶ 37; *see also id.* ¶ 46 (Mr. Crosby stating that “I apply [Patent Owner’s] claim construction from its infringement contentions that “*axially adjacent*” includes components that “overlap or occupy the same portion of an axis”). We find Mr. Crosby’s testimony in this regard unreliable for the same reasons, that is, because it is not sufficiently supported by the infringement contentions upon which it purports to rely.

In sum, on this record we find no support for Petitioner’s assertions that “a magnetic element sealed within a rotor is ‘at a position axially adjacent to the magnetically driven rotor’” and that “axially adjacent” includes components that “overlap or occupy the same portion of an axis”). *See* Pet. 26; Pet. Reply 4. We find Patent Owner’s definition of “axially adjacent” reflects its plain and ordinary meaning, and is consistent with the disclosure of the ’356 patent (which illustrates only a “magnetically driven rotor” positioned next to a “first magnetic device” as measured along a central axis).¹³ *See* Ex. 1001, Fig. 2. In sum, consistent with our Institution Decision, we conclude that the plain and ordinary meaning of “at a position axially adjacent” is “at a position adjacent to one another as measured along a central axis.” *See* Inst. Dec. 25.

4. “*axially aligned*”

Claim 1 recites, in relevant part, “the magnetically driven rotor is axially aligned with the inflow tube.” Ex. 1001, 5:26–39. Petitioner does not directly address “axially aligned” in the Claim Construction portion of

¹³ It is also consistent with the construction Petitioner applies in, for example, its contentions based on Bourque. *See* Pet. 61–62 (relying on Bourque’s teaching of a rotor and magnetic device adjacent to one another as measured along a central axis with regard to the “axially adjacent limitation” and not on Wampler’s magnets embedded in the impeller at the same location along a central axis).

the Petition. *See* Pet. 7–9. In support of Petitioner’s allegations of obviousness over Wampler, Mr. Crosby states that “[f]or components to be ‘axially aligned’ as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or ‘axis’) in space”). Ex. 1003 ¶ 168; *see also* Pet. 19 (citing Ex. 1003 ¶ 168). Turning to the Specification, it states only that “[t]he device is designed in a structurally particularly simple manner such that the axis of rotation of the rotor is in alignment with the longitudinal axis of the catheter or is parallel thereto.” Ex. 1001, 3:1–4. As seen in Figures 1 and 2 of the ’356 patent, reproduced above, the center axis of catheter 2, with inflow tube 9, and rotor 18 are aligned along the same central axis of the structures, however, the entirety of the central axis of catheter 2 is not a perfectly straight line.

Mr. Crosby, in describing the disclosure of the ’356 patent in his Reply Declaration, further explains as follows:

Although the inflow tube and its suction end may curve or bend to enter chambers of the heart, it maintains a continuous, central axis running through its cylindrical shape. Even when the catheter’s tube and suction end are not perfectly straight—i.e., it curves—this central axis follows the path of the catheter’s curvature, ultimately aligning with the axis of the rotor 6. In other words, regardless of the bends or curves, the inflow tube’s axis remains colinear and in alignment with the rotor’s axis at the point where they join. A [person of ordinary skill in the art] would reading the claim term “*axially aligned*” would understand that the ’356 patent’s lone embodiment illustrates that axial alignment does not require perfect straightness throughout the length of the inflow tube; instead, it means that the central axes of connected cylindrical components—the rotor and inflow tube—can remain colinear and functionally aligned, even if the inflow tube bends.

Ex. 1042 ¶ 88. While we credit much of Mr. Crosby’s testimony in this regard, we find that elsewhere he mischaracterizes the testimony of

Mr. Leschinsky. *Id.* ¶ 85. In particular, Mr. Crosby inaccurately asserts that “Mr. Leschinsky insists this claim language [i.e., ‘axially aligned’] requires that the entirety of the ‘structure that is the *inflow tube*’ be aligned in a straight, unbent line along the rotor’s axis.” *Id.* (citing Ex. 2015 ¶¶ 127–131). We fail to see where in Mr. Leschinsky’s cited testimony he stated or implied that “axially aligned” requires a “straight, unbent line.”

In a similar vein, we disagree with Petitioner’s argument during the oral hearing that the dispute “boiled down to . . . whether it’s enough for just a portion of the inflow assembly to be axially aligned with the rotor to meet the claim limitation.” Tr. 9:4:8. Nowhere in the Petition did Petitioner argue that the limitation in claim 1 requiring “the magnetically driven rotor is axially aligned with the inflow tube” only requires that the rotor be “axially aligned” with a “portion” of the inflow tube. Nor is that argument consistent with Mr. Crosby’s testimony of what “axially aligned” means. The claim language is unambiguous. The claim makes no reference to the axis of “a portion” of the inflow tube, and there is no evidence to suggest that the relevant axis of the inflow tube varies depending upon what “portion” of the inflow tube is relied upon.

We apply the plain and ordinary meaning of “axially aligned,” and, consistent with the intrinsic evidence, conclude that “axially aligned” requires that the central axis of two components be in alignment, but does not require a perfectly straight axis for the entire length of both components.

E. Alleged Obviousness over Wampler

Petitioner contends that the subject matter of claims 1–7, 10, 12, and 13 of the ’356 patent would have been obvious over Wampler. Pet. 16–50; Pet. Reply 9–15. Petitioner relies on the testimony of Mr. Crosby in support of its contentions. Ex. 1003 ¶¶ 149–306; Ex. 1042 ¶¶ 53–83. In

opposition, Patent Owner argues, among other things, that Petitioner fails to show how Wampler teaches “a magnetically driven rotor . . . coupled to a first magnetic device . . . *at a position axially adjacent* to the magnetically driven rotor,” as required by claim 1. PO Resp. 11–15; PO Sur-reply 8–9. Patent Owner relies on the testimony of Mr. Leschinsky as support for its arguments. Ex. 2015 ¶¶ 100–125.

As explained above (*supra* Section III.D.3), we find “at a position axially adjacent” to mean at a position “adjacent to one another as measured along a central axis,” and that Petitioner fails to show that “axially adjacent” components encompasses components that are just embedded or sealed within one another or components that overlap or occupy the same portion of an axis. The entirety of Petitioner’s arguments rests on Petitioner’s assertion that in the Parallel Proceeding, Patent Owner “asserts that a magnetic element sealed within a rotor is ‘*at a position axially adjacent to the magnetically driven rotor.*’” *Id.* at 26 (citing Ex. 1019, 5–7). According to Petitioner, “[a]ssuming that interpretation . . . [Wampler] discloses that the ‘permanent magnetic segments [are] imbedded [*“at a position axially adjacent”*] within [the] impeller.’” *Id.* at 26–27 (citing Ex. 1008 ¶¶ 70, 80).

We addressed and rejected this “assumed” claim construction for the reasons discussed above. *See supra* Section III.D.3. Accordingly, because Petitioner’s contentions are premised on an unsupported claim construction that we reject, Petitioner fails to show how Wampler teaches or suggests “a magnetically driven rotor . . . coupled to a first magnetic device . . . *at a position axially adjacent* to the magnetically driven rotor,” as required by claim 1, as well as by claims 2–7, 10, 12, and 13, which depend from claim 1. In its Reply, Petitioner suggests that “[u]nder [Patent Owner’s] construction from the [Patent Owner Response], Wampler also teaches or

suggests this limitation,” because Patent Owner “concedes that ‘*axially adjacent*’ components ‘have positioning that is next to one another, perhaps touching or sharing a common side, when measured along the axis.’” Pet. Reply 9 (citing PO Resp. 14). Petitioner mischaracterizes Patent Owner’s arguments and ignores Patent Owner’s showing that “axially adjacent” components are “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.” PO Resp. 14 (citing Ex. 2015 ¶ 82). Because the undisputed meaning of “axially adjacent” does not encompass components such as Wampler’s that are embedded or sealed within one another, or overlap or occupy the same portion of an axis, Petitioner fails to show how Wampler teaches “a magnetically driven rotor . . . coupled to a first magnetic device . . . *at a position axially adjacent* to the magnetically driven rotor,” as required by claim 1. For the preceding reasons, Petitioner fails to show by a preponderance of the evidence that the subject matter of any of the Challenged Claims would have been obvious over Wampler.

F. Alleged Obviousness over Bourque and Wampler

Petitioner contends that the subject matter of claims 1–7, 10, 12, and 13 of the ’356 patent would have been obvious over the combination of Bourque and Wampler. Pet. 50–88; Pet. Reply 15–27. Petitioner relies on the testimony of Mr. Crosby and Dr. Wieselthaler in support of its contentions. Ex. 1003 ¶¶ 307–478; Ex. 1041 ¶¶ 29–83; Ex. 1042 ¶¶ 84–108. More particularly, Petitioner contends that Bourque teaches each limitation recited in independent claim 1. Pet. 50–75. Additionally, for each of limitations [1C], [1I], [1L], and [1O], Petitioner further contends that, “to the extent” it might be argued that Bourque fails to disclose the limitation, each of these limitations would have been obvious in view of Wampler. Pet. 55,

64, 69, 74. Petitioner also addresses the motivation to combine Bourque and Wampler and asserts a reasonable expectation of success. Pet. 80–88.

In opposition, Patent Owner primarily argues that Bourque fails to disclose limitations [1A] and [1C], and that Petitioner fails to provide a sufficient rationale for the asserted combination of Bourque with Wampler. PO Resp. 22–42. Patent Owner also contends certain limitations of dependent claims 5 and 7 are not taught by either Bourque or Wampler. *Id.* at 43–45. Patent Owner does not dispute that Bourque teaches limitation [1H] (i.e., a rotor coupled to a first magnetic device at a position axially adjacent to the rotor). Patent Owner relies on the testimony of Mr. Leschinsky (Ex. 2015 ¶¶ 126–175) and the testimony of Dr. Gallegos (Ex. 2017 ¶¶ 36–39, 41–69) as support for its arguments.

1. Independent Claim 1

We focus our discussion below on the disputed limitations of claim 1. Claim 1 (limitations [1A]–[1C]) recites, in relevant part, inserting “a suction end of an inflow tube” into a ventricle of the heart and positioning a “magnetically driven rotor” outside the ventricle of the heart, where “the magnetically driven rotor is axially aligned with the inflow tube.” Petitioner first argues that Bourque, alone, teaches a rotor “axially aligned” with the inflow tube, and, second, that Bourque, in combination with Wampler, also teaches this limitation. Pet. 50–56. In opposition, Patent Owner argues that Bourque, alone, does not teach this limitation. *Id.* at 23–24. Patent Owner does not dispute that the limitation is taught by Wampler in combination with Bourque, and instead argues Wampler cannot be combined with Bourque. PO Resp. 26–42.

a) *Whether Bourque Teaches [1C] “the magnetically driven rotor is axially aligned with the inflow tube”*

As to Petitioner’s argument based on Bourque, alone, we agree with Patent Owner that Petitioner does not sufficiently show that Bourque teaches a rotor “axially aligned” with the inflow tube. Petitioner contends that Figure 3 of Bourque teaches “delivering a heart assist pump device (“HeartMate III LVAD”) to the heart so that a suction end of an inflow tube (“an inflow subassembly that includes a left ventricular (LV) cannula”) of the heart assist pump device is inserted into a ventricle of the heart (“left ventricular apical cannulation”).” Pet. 52 (citing Ex. 1003 ¶¶ 314, 316).

Petitioner’s annotated version of Figure 3 of Bourque is reproduced below.

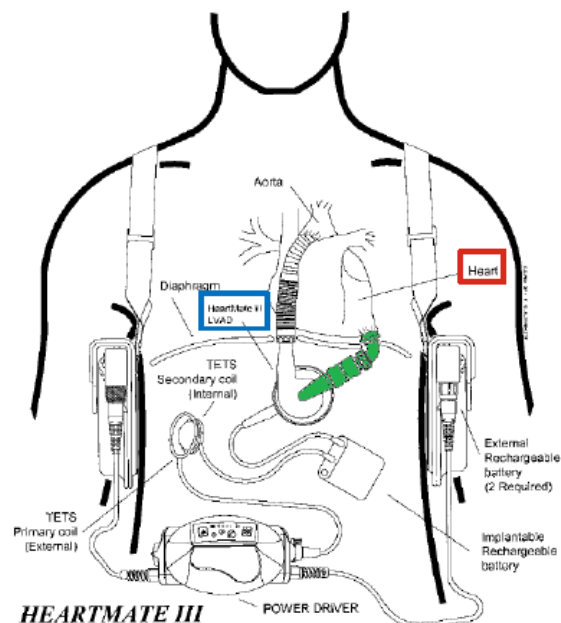
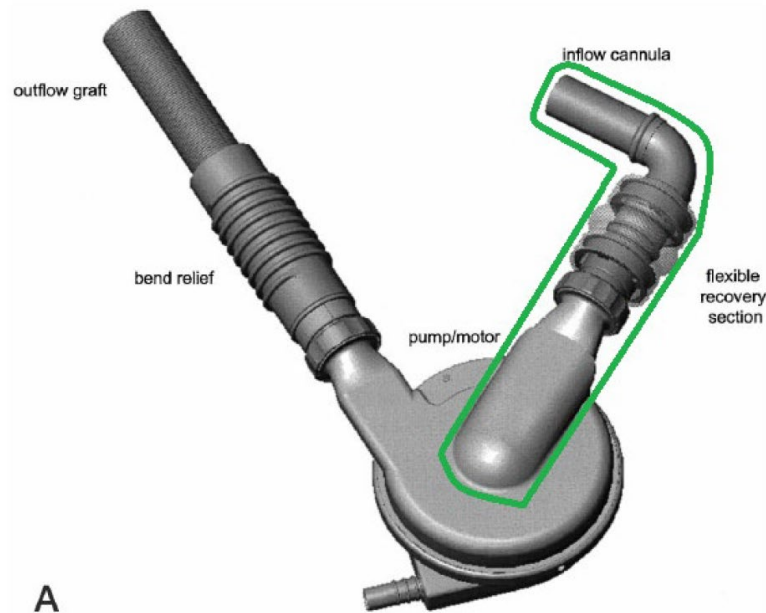


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Pet. 52; Ex. 1007, Fig. 3. The annotated version of Figure 3 of Bourque shows a human chest region with internal features identified as the “Heart” (labeled in a red outline) and an implanted heart assist pump device (labeled “HeartMateIII LVAD” in a blue outline). Petitioner identifies an element

colored green in Figure 3 as “an inflow subassembly that includes a left ventricular (LV) cannula,” which Petitioner asserts corresponds to the “suction end of an inflow tube,” as required by claim 1 of the ’356 patent. *Id.* We note that the suction end of the inflow subassembly in Figure 3 of Bourque is not actually illustrated, but instead is shown as having entered the heart.

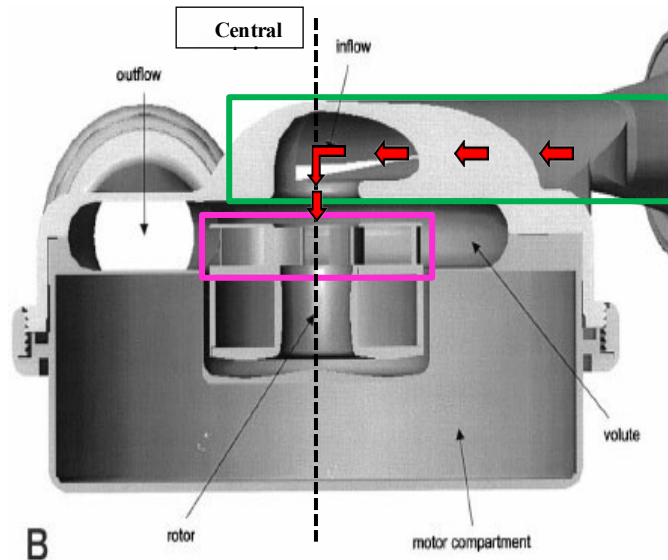
Petitioner also provides an annotated version of Figure 1A of Bourque, reproduced below.



Pet. 51. Figure 1A of Bourque shows, in relevant part, a “pump/motor” connected to an “inflow cannula” via a “flexible recovery section.”

Ex. 1007, Fig. 1A. Portions of the pump/motor, the flexible recovery section and the inflow cannula are surrounded by a green outline, as annotated by Petitioner, which presumably corresponds to green text in the Petition reading “inflow cannula.” Pet. 51. In Figure 1A, the “inflow cannula” and “flexible recovery section” form a right angle prior to the connection with the “pump/motor.”

Petitioner provides an annotated version of Figure 1B of Bourque, reproduced below, to purportedly show how Bourque’s “impeller” (corresponding to the recited “rotor”) is allegedly axially aligned with the “inflow subassembly” (corresponding to the recited “inflow tube”).



Pet. 53; Ex. 1007, Fig. 1B. Petitioner’s annotated version of Figure 1B, above, shows Bourque’s inflow assembly (in a green outline) perpendicular to Bourque’s impeller (in a pink outline). Petitioner annotated red arrows allegedly showing fluid flowing from right to left through the inflow assembly, where upon it makes an abrupt 90 degree turn into the impeller. Petitioner argues as follows:

This inflow subassembly further comprises an “elbow” that “result[s] in a sharp bend in the flow before it enters the impeller.” Ex.1007, 402. Ex.1003, ¶327. Nevertheless, by virtue of [Bourque’s] device being “a centrifugal pump,” its “impeller” is axially aligned with the “inflow subassembly” as flow “leav[es] the inflow conduit to enter the impeller.” Ex.1007, 402. Indeed, axial inflow is characteristic of centrifugal pumps. Ex.1003, ¶328.

Pet. 55 (emphasis omitted). Petitioner identifies the entire inflow subassembly of Bourque as corresponding to the recited “inflow tube.”

To show the required axial alignment, Petitioner appears to rely on an unidentified portion of Bourque’s inflow subassembly, after the 90-degree bend, where Petitioner alleges “flow ‘leav[es] the inflow conduit to enter the impeller.’” *Id.*

Patent Owner argues Petitioner fails to show how Bourque teaches the recited “axially aligned” configuration for multiple reasons. PO Resp. 23–25. First, Patent Owner argues, and we agree, that Petitioner improperly conflates axial alignment of the inflow tube and rotor, which are structural elements, with the flow of fluid (shown by Petitioner as red arrows in its annotated version of Bourque Figure 1B reproduced above). *See* PO Resp. 25 (stating that “the claim recites that the inflow tube and the rotor are axially aligned—not the flow”). To the extent blood flow is somehow indicative of axially alignment, we further agree with Patent Owner that Petitioner’s annotation of fluid flow with red arrows showing a 90 degree turn in Figure 1B of Bourque does not reflect reality. As Patent Owner explains, it is known that “the blood does not make a 90 degree turn as illustrated by Petitioner—rather, the flow is much more complex.” *Id.* (citing Ex. 2015 ¶¶ 130–134). Petitioner implicitly argues that regardless of the structure, the “axis” for purposes of determining “axially aligned” is necessarily coextensive with the centerline of flow (i.e., the centerline of the tube through which blood flows) regardless of whether the inflow tube is straight, bends (as in the embodiment of the ’356 patent), or includes a 90-degree elbow (as in Bourque). We are not persuaded for two reasons: there is no evidentiary support for such an assertion and it would effectively read the limitation “axially aligned” out of the claim as any structure with a fluid flow path from an inflow tube to a rotor would be “axially aligned.”

Petitioner, who bears the burden, fails to show any sufficient basis a person

of ordinary skill in the art would have understood the requirements of claim 1 in such a manner. Again, the claim language requires the structure of the inflow tube to be “axially aligned” with the structure of the rotor, not merely the flow through the structure.

Likewise, we find no sufficient support for Mr. Crosby’s assertion that “an axially aligned inflow tube is a characteristic feature of a centrifugal pump,” merely because “fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference.” Ex. 1003 ¶ 328. Mr. Crosby’s focus is again on the fluid flow, not the structure of the inflow tube, and he cites no support. Petitioner asserted during the hearing that “a centrifugal pump by definition has an inflow tube that is axially aligned with a rotor.” Tr. 10:16–18. As support, Petitioner identified a disclosure in Wampler, which states “[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation,” and that “[o]wing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting.” Tr. 16:8–17; Ex. 1008 ¶ 76. Contrary to Petitioner’s assertion, Wampler does not support the notion that “a centrifugal pump by definition has an inflow tube that is axially aligned with a rotor,” but instead addresses the “inflow” and “outflow” of the blood.

Relatedly, Petitioner argued during the oral argument that Bourque teaches the required axial alignment because the claim only requires “a portion of the inflow subassembly to be axially aligned with the rotor to meet the claim language.” Tr. 9:4–10. As explained above, the claim language is unambiguous: “the magnetically driven rotor is axially aligned with the inflow tube.” *See supra* Section III.D.4. Petitioner’s argument is inconsistent with its own expert’s testimony, who explained that “axial

alignment does not require perfect straightness,” not that the claim language only required “a portion” of the inflow tube to be axially aligned.”

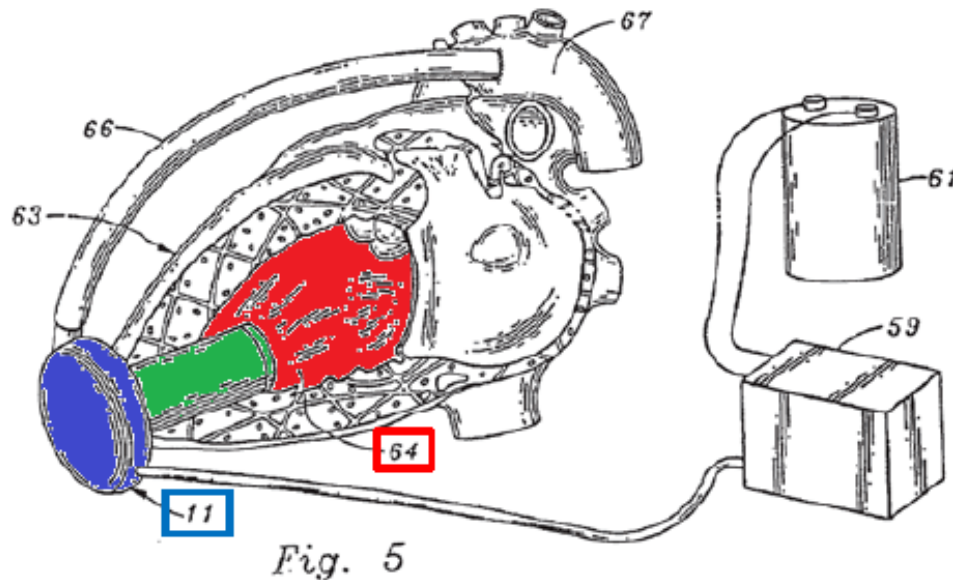
Accordingly, Petitioner’s assertion that Bourque teaches axially alignment, as required by claim 1, because some portion of the inflow tube of Bourque is axially aligned fails.

Even if we were to agree that Bourque need only teach a portion of the inflow tube is axially aligned, Petitioner fails to show any such disclosure in Bourque. As seen in Petitioner’s annotated version of Figure 1B, the inflow tube appears as a horizontal cylinder that terminates in a 90-degree bend (shown in a green box) coupled to a “volute.” *See* Pet. 54–55; Ex. 1007, Fig. 1B. Petitioner fails to clearly identify any “portion” of the inflow tube that is “axially aligned” with the rotor, but instead implies that because there is a 90-degree bend there must be some portion, however small, that is axially aligned. We find such reasoning insufficiently supported, not persuasive, and inconsistent with Bourque’s express disclosure that “the rotational axis of the pump’s rotor” is “perpendicular to the body’s long axis,” resulting “in a sharp bend in the flow before it enters the impeller.” Ex. 1007, 2. Petitioner fails to show how Bourque, alone teaches a rotor “axially aligned” with the inflow tube.

b) Whether Wampler Teaches [1C] “the magnetically driven rotor is axially aligned with the inflow tube”

As an alternative to relying on Bourque, alone, Petitioner also proposes “to modify [Bourque’s] ‘impeller’ to be ‘axially aligned with’ the ‘inflow subassembly’ in view of [Wampler]”. Pet. 55.

Petitioner provides an annotated version of Figure 5 of Wampler, reproduced below.



Pet. 56; Ex. 1008, Fig. 5.¹⁴ Petitioner’s annotated Figure 5 of Wampler illustrates inlet tube 13 (colored green) extending from the apex of the left ventricle 64 of the heart (colored red) into pump 11 (colored blue), with the rotor of the pump along the same axis as the inlet tube. *See id.* at 16–17. Patent Owner does not dispute Petitioner’s contention that the inlet tube and rotor taught by Wampler are axially aligned. *See generally* PO Resp. Patent Owner does not otherwise dispute that the asserted combination of Bourque and Wampler teaches or suggests each of the limitations of claim 1.

¹⁴ We note that under Petitioner’s obviousness ground based only on Wampler, Petitioner relies on a different embodiment disclosed in Figure 13 of Wampler. *See* Pet. 19–20. With regard to obviousness over only Wampler, the Parties dispute whether Petitioner is improperly relying on different embodiments. *See* PO Resp. 15–22; Pet. Reply 10–12. With regard to obviousness over Bourque and Wampler, there is no dispute that the only cited evidenced relied upon by Petitioner in regard to the “axially aligned” limitation is the embodiment shown in Figure 5 of Wampler. *See* Pet. 56.

Accordingly, we find Petitioner has shown by a preponderance of the evidence that the asserted combination of Bourque and Wampler teaches or suggests each of the limitations of claim 1. We address below the sufficiency of Petitioner's rationale for the asserted combination. *See infra* Section III.F.5.

2. *Dependent Claim 5*

Claim 5 depends from claim 1. Claim 1 requires “connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device.” Corresponding to this limitation, Petitioner shows, and Patent Owner does not dispute, that Bourque teaches connecting external “electronics for power and control of the LVAD,” and that “[s]peed and motor parameters were set and controlled using software.” Pet. 72 (quoting Ex. 1007, 405). Claim 5 further requires that “the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.” Ex. 1001, 6:19–21. Petitioner contends this is disclosed by Bourque.¹⁵ Pet. 77 (citing Ex. 1003 ¶ 430; Ex. 1007, 403, Fig. 3).

First, Petitioner argues that it is “assuming” Patent Owner's assertion in the Parallel Litigation that “a fixed speed or lower speed limit (*e.g.* output as measured in liters of blood per minute) are ‘*measurement values indicative of cardiac output of the heart.*’” Pet. 77. As support, Petitioner

¹⁵ Although the ground at issue is Bourque in combination with Wampler, Petitioner does not rely on Wampler in its contentions for how the asserted combination teaches the additional limitations of claim 5 and does not provide any reasoning for why a person of ordinary skill in the art would have had reason to apply Wampler's teachings to Bourque for purposes of showing the unpatentability of claim 5 with regard to this limitation. *See* Pet. 77.

cites to page 29 of Exhibit 1019. *See id.* Exhibit 1019 has only 15 pages, and we find no support in Exhibit 1019 for Petitioner’s assertion.

Mr. Crosby similarly states that he is adopting the construction of “measurement values of cardiac output” from Petitioner’s contentions in the Parallel Proceeding, citing Exhibit 1019 (with no page reference). Ex. 1003 ¶ 428. From our review, the term “measurement values of cardiac output” does not appear in Exhibit 1019 and there is no basis for the assumption made by Mr. Crosby. On this basis, alone, Petitioner fails to show in the Petition how Bourque teaches the requirements of claim 5.

Additionally, Patent Owner argues that Bourque “indicates prescribing rpm rates for the pump adjusted based on *pump* output flow rates,” and that “[t]here is no indication that the pump was controlled in response to any measured value indicative of *cardiac output* of the heart—especially where the pump is assisting, not replacing, the heart.” PO Resp. 43 (citing Ex. 2015 ¶ 172). In Reply, Petitioner fails to address Patent Owner’s argument, and instead asserts that “the speed of the pump is a direct proxy indicative of cardiac output because it corresponds to blood outflow.” Petitioner neglects to address what “blood flow” the speed of the pump is indicative of and fails to distinguish between blood flow from the pump and blood flow as a “measurement value” that is indicative of cardiac output of the heart. In other words, there is no evidence to suggest that pump speed is indicative of cardiac output if, for example, cardiac output of the heart is decreasing at the same time the speed of the pump (and the “blood flow” of the pump) remains the same. Petitioner also asserts that in Bourque the speed and motor parameters can be “adjusted to maintain volume flow

rates.” Pet. Reply 27 (citing Ex. 1007, 3¹⁶). Bourque states that “[t]he pump was prescribed to run at 3,500 rpm perioperatively, then gradually adjusted to maintain volume flow rates at 5 ± 1 L/min throughout the study.”

Ex. 1007, 403. Petitioner fails to direct us to any indication in Bourque that the “volume flow rates” referred to are anything other than the pump volume flow rate. Contrary to Petitioner’s argument, Bourque states that “[p]ump volume flow rates were consistently maintained between 3 L/min and 6 L/min during sedentary periods and elevated to a range of 6 L/min to 11 L/min during treadmill exercise.” Ex. 1007, 403–404. Based on our review and consideration of Petitioner’s arguments and evidence directed to claim 5, we find that Petitioner has not shown by a preponderance of the evidence that the asserted combination of Bourque and Wampler teaches or suggests each of the limitations of claim 5.¹⁷

3. Dependent Claim 7

Claim 7 depends from claim 1 and further requires “providing feedback signals to the external control unit from one or more sensors.” Ex. 1001, 6:26–28. According to Petitioner, Bourque teaches that “measurements were made with an ultrasonic flow probe...[and] catheter-

¹⁶ Petitioner’s citation to page 3 of Bourque corresponds to page 403 of Bourque’s original pagination, which Petitioner uses elsewhere.

¹⁷ Petitioner attempts to assert its arguments concerning claim 5 are “undisputed” because Patent Owner did not address claim 5 in its Sur-reply. Tr. 32:14–17. We explained to Patent Owner that arguments raised in the Patent Owner Response are not waived merely because Patent Owner does not address Petitioner’s Reply in Patent Owner’s Sur-reply. *Id.* at 34:15–21. Indeed, the burden is on Petitioner to show unpatentability and where, as here, Petitioner fails to show how a limitation of a claim is taught in the asserted prior art, Petitioner fails to satisfy that burden, regardless of whether any issue is addressed by Patent Owner in its Sur-reply.

type pressure transducers.”¹⁸ Pet. 78 (quoting Ex. 1007, 403). Claim 7, however, is directed to a “method for assisting the blood circulation of a heart in a body” and requires “delivering a heart assist pump device to the heart.” The portions of Bourque relied upon by Petitioner concern “*in vitro* characterization,” where “the pump was attached to a mock physiologic laboratory flow loop.” Ex. 1007, 403. Bourque states that as part of this “*in vitro* characterization,” “[f]low measurements were made with an ultrasonic flow probe and pressure measurements were made with solid-state, catheter-type pressure transducers.” *Id.* Bourque does not suggest that either the “ultrasonic flow probe” or the “pressure transducers” used in the “*in vitro* characterization” studies were part of the heart assist pump device, as opposed to being used separate from the device as part of the “mock physiological laboratory flow loop.”

Patent Owner argues that Bourque provides “no indication that any feedback signal from a sensor was provided to an external control unit that was responsible for controlling the pump.” PO Resp. 44 (citing Ex. 2015 ¶ 174). We agree with Patent Owner that Petitioner fails to show that the “ultrasonic flow probe” or the “pressure transducers” used in the “*in vitro* characterization” provide feedback signals to the external control unit. In fact, for *in vivo* testing Bourque makes no mention of the use of the “ultrasonic flow probe” or the “pressure transducers” to provide feedback signals to the external control unit. *See, e.g.*, Ex. 1007, 403 (stating that

¹⁸ Although the ground at issue is Bourque in combination with Wampler, Petitioner does not rely on Wampler in its contentions for how the asserted combination teaches the additional limitations of claim 7 and does not provide any reasoning for why a person of ordinary skill in the art would have had reason to apply Wampler’s teachings to Bourque for purposes of showing the unpatentability of claim 7. *See* Pet. 78.

during *in vivo* testing “[t]he animals were continuously monitored for general welfare, and certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded”).

In support of Petitioner, Mr. Crosby states that Bourque “discloses that the electronics for power and control of the LVAD and for data acquisition resided on a shelf,” and that “[s]peed and motor parameters were set and controlled using software.” Ex. 1003 ¶ 439; *see also* Pet. Reply 27 (asserting that Bourque teaches feedback signals including “‘flow measurements,’ ‘pressure measurements,’ and the monitoring of ‘[s]peed and motor parameters,’ all of which would have been provided to Bourque’s ‘electronics for power and control’”). According to Mr. Crosby, a person of ordinary skill in the art “would have understood based on the disclosure of this setup that these speed and motor parameters were monitored by a sensor providing feedback to the controller.” *Id.* Mr. Crosby identifies no support for this opinion, which we give it little weight. The mere fact that Bourque’s pump used software to control speed and motor parameters does not show that Bourque used “one or more sensors” to provide feedback signals to the external control unit. Indeed, Petitioner fails to identify any evidence that Bourque used any “sensor” to monitor “speed and motor parameters.” Mr. Crosby also states that “[e]ach of the ‘ultrasonic flow probe’ and the ‘solid-state catheter-type pressure transducer’ described in [Bourque] is a sensor as recited in Claim 7 that provides feedback signals to the external control unit (e.g., ‘electronics for power and control’ and ‘data acquisition’).” *Id.* ¶ 440. Mr. Crosby’s opinion is again unsupported by the evidence, because, as explained above, there is no teaching in Bourque that either the “ultrasonic flow probe” or the “pressure transducers” used in the

“in vitro characterization” studies were part of the heart assist pump device. Based on our review and consideration of Petitioner’s arguments and evidence directed to claim 7, we find that Petitioner has not shown by a preponderance of the evidence that the asserted combination of Bourque and Wampler teaches or suggests each of the limitations of claim 7.

4. Dependent Claims 2–4, 6, 10, 12, and 13

Petitioner contends that Bourque teaches each additional limitation of dependent claims 2–4, 6, 10, 12, and 13. Pet. 75–80. Patent Owner does not dispute that the additional limitations of these dependent claims are taught by Bourque, apart from relying on its arguments contesting the alleged obviousness of claim 1. *See generally* PO Resp. Based on our review and consideration of Petitioner’s arguments and evidence directed to claims 2–4, 6, 10, 12, and 13, we find that Petitioner has shown by a preponderance of the evidence that the asserted combination of Bourque and Wampler teaches or suggests each of the limitations of dependent claims 2–4, 6, 10, 12, and 13.

5. Rationale in Support of Asserted Combination

Petitioner shows, and there is no dispute, that Bourque and Wampler are directed to the same field of endeavor and are analogous art. *See* Pet. 82–83; PO Resp. 22–45. In the asserted combination, Petitioner argues that “it would have been obvious to modify [Bourque’s] ‘impeller’ to ‘*be axially aligned with*’ the ‘inflow subassembly’” in view of Wampler. Pet. 55. Petitioner emphasizes that, according to Wampler, use of a centrifugal pump enables “a 90 degree redirection of the blood . . . without the necessity of a flow-restrictive elbow fitting,” thereby allowing for “a considerable amount of flexibility during implantation.” *Id.* at 56 (citing Ex. 1008 ¶ 76).

From this, Petitioner asserts that a person of ordinary skill in the art “would have been motivated with a reasonable expectation of success to modify” Bourque’s “‘inflow subassembly’ to serve as the ‘inflow cannula...placed into the apex of the left ventricle’ as taught by [Wampler], resulting in an ‘*axially aligned...inflow tube*.’” *Id.* (citing Ex. 1003 ¶ 331; Ex. 1007, 402; Ex. 1008 ¶ 76, Fig. 5); *see also id.* at 81–82 (arguing that Wampler’s pump “has an ‘inlet tube 16 [that] serves as the inflow cannula and is placed into the apex of the left ventricle 64,’ thereby eliminating the need for any elbow or additional inflow assembly”). According to Petitioner, Wampler states that “[w]ith this design, ‘[g]ood anatomic compatibility is possible...fitting well between the apex of the heart and the adjacent diaphragm.’” *Id.* at 81 (quoting Ex. 1008 ¶ 76); *see also id.* at 82 (asserting that a person of ordinary skill would have been motivated to apply Wampler to Bourque “to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex of the left ventricle as expressly taught by” Wampler) (citing Ex. 1003 ¶ 470). Petitioner also argues that the proposed combination of Bourque and Wampler “would have been the arrangement of old elements (an inflow subassembly, inlet tube, and inflow cannula) with each performing the same function it has been known to perform (allowing blood to flow from the ventricle to the pump) and yielding no more than one would expect from such an arrangement (blood flowing from the ventricle to the pump) as [Wampler] demonstrates.” *Id.* at 83 (citing Ex. 1003 ¶ 468 Ex. 1007, 401; Ex. 1008 ¶ 75).

In considering Petitioner’s contentions, we find a fundamental problem with the premise upon which its arguments are based. Petitioner purports to rely on Wampler as teaching that a centrifugal pump allows a 90-degree redirection of blood flow without the need for an elbow fitting.

See, e.g., Pet. 56. However, Bourque—just like Wampler—utilizes a centrifugal pump that redirects blood flow 90-degrees. *See id.* at 50 (stating that Bourque discloses “a centrifugal pump”) (citing Ex. 1007, 401). In fact, in its discussion of the motivation in support of the combination, Petitioner acknowledges that “by virtue of the ‘centrifugal design,’ both [Bourque’s] and [Wampler’s] pump comprise ‘axial inflow and radial outflow’ that result in ‘a 90 degree redirection of the blood.’” *Id.* at 80 (citing Ex. 1003 ¶ 459; Ex. 1007, 402; Ex. 1008 ¶¶ 75–76).

Petitioner fails to show that there is any “teaching” in Wampler that is being used to modify Bourque, as both references use a centrifugal pump to redirect blood 90-degrees. By using a centrifugal pump Wampler does not “teach” the elimination of an elbow from Bourque as Bourque also uses a centrifugal pump. Unlike Wampler, Bourque further includes an elbow leading to the centrifugal pump not because Bourque failed to appreciate that an elbow was unnecessary, but precisely because adding the elbow was *necessary* to place the Bourque’s centrifugal pump in “the least obtrusive position.” Ex. 1007, 402. Accordingly, Petitioner fails to show why a person of ordinary skill in the art would have modified Bourque based on a teaching in Wampler (the use of a centrifugal pump to redirect blood flow) that was *already known* and applied in Bourque’s device, which uses a centrifugal pump to redirect blood flow 90-degrees. Because, contrary to Petitioner’s contentions, Wampler does not “teach” eliminating an elbow by using a centrifugal pump in light of Bourque’s identical use of a centrifugal pump, Petitioner fails to support the purported modification of Bourque to replace Bourque’s flow-restrictive elbow fitting with Wampler’s straight inflow. On this basis, alone, the reason for Petitioner’s asserted modification of Bourque based on Wampler fails.

In addition to finding that a preponderance of the evidence does not support Petitioner’s asserted modification of Bourque based on Wampler, we further consider Petitioner’s purported rationales that allegedly support such a modification and likewise find them to be lacking in sufficient evidentiary support or persuasive reasoning. *See* Pet. 83–88. Petitioner argues that Bourque recognized that “its ‘elbow’ was flow restrictive” and that “the flow had to be ‘accelerate through this elbow’ ‘[t]o minimize the losses in this transition.’” *Id.* at 83 (quoting Ex. 1007, 402). Petitioner ignores why Bourque states that it used an elbow with its centrifugal pump. More completely, the portion of Bourque that Petitioner refers to states as follows:

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, 402. Petitioner nonetheless argues that because Wampler “teaches that this type of elbow [*i.e.*, the elbow used with Bourque’s centrifugal pump] was unnecessary,” applying Wampler to Bourque would have improved “blood flow.” Pet. 83 (citing Ex. 1003 ¶¶ 469–470; Ex. 1007, 402; Ex. 1008 ¶¶ 75–76). As explained above, Wampler does not teach that “this type of elbow” was unnecessary. Bourque uses a centrifugal pump with an additional elbow specifically so that the centrifugal pump may be oriented “in the least obtrusive position.” Ex. 1007, 402. Moreover, there is no persuasive evidence to support Petitioner’s assertion that eliminating the elbow from Bourque would improve “blood flow.” Mr. Crosby’s declaration provides no additional explanation or support to show how

“blood flow” would have been improved. *See* Ex. 1003 ¶ 470. Nor does Mr. Crosby address the fact that Bourque expressly states that “flow is slightly accelerated” through the elbow to “minimize losses in this transition.” Ex. 1007, 402. Eliminating the elbow from Bourque, as Petitioner and Mr. Crosby propose, would mean the pump could no longer be placed in “the least obtrusive position,” according to Bourque and there is no persuasive evidence that such a modification would improve blood flow.

Next, Petitioner asserts that eliminating Bourque’s inflow tube elbow would have eliminated components that caused clinical troubles and would have been complimentary to Bourque’s “fundamental goal” of designing the pump “in the simplest possible way.” Pet. 83–84 (citing Ex. 1003 ¶¶ 464–470; Ex. 1007, 401, 405; Ex. 1008 ¶¶ 75–76). According to Petitioner, Bourque “itself recognized that peripheral hardware, such as its ‘inflow...components’ and ‘recovery section,’ ‘account for most of the...clinical troubles.’” *Id.* at 83 (citing Ex. 1007, 405). We disagree with Petitioner’s characterization of Bourque based on a truncated quotation that rearranges the disclosure in Bourque. The portion of Bourque relied on by Petitioner states that Bourque’s “pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components)” were developed “concurrently.” Ex. 1007, 405. Bourque further states that “[a]lthough generally regarded as secondary in importance when setting out on a new pump design (compared to the primary purpose of ‘pumping’), items such as cannula, grafts, articulating mechanical joints, valves (if any), connectors, and cables can account for most of the propensity for clinical troubles when implanted.” *Id.* Later, Bourque states that “a flexible ‘recovery section’ between the pump and apical cannula” allows the pump to “be removed, leaving behind the cannula.” *Id.*

We reject Petitioner’s argument, because it is unsupported by Bourque, which does not state or suggest that the inflow tube Petitioner proposes modifying accounted for “most” of the “clinical troubles” discussed in Bourque. *See* Ex. 1007, 405. We also find unavailing Petitioner’s assertion that Wampler “taught how to eliminate these components that caused clinical troubles—using the inlet to also ‘serve[] as the inflow cannula.’” Pet. 83–83 (citing Ex. 1003, ¶¶ 464–470; Ex. 1008 ¶¶ 75–76). The premise of Petitioner’s alleged “teaching” in Wampler is the same as discussed above, i.e., that Wampler uses a centrifugal pump to redirect blood flow 90-degrees, *just like Bourque*.

We also give Mr. Crosby’s supporting testimony little weight as it is based only on the same mischaracterized disclosure in Bourque. *See, e.g.*, Ex. 1003 ¶ 470. Mr. Crosby states that Bourque “taught that the number of components of its inflow assembly caused ‘clinical troubles.’” *Id.* (citing Ex. 1007, 405). Bourque, however, only identifies a number of components that “can account for most of the propensity for clinical troubles.” *See* Ex. 1007, 405. Bourque does not state that it is “the” number of components that cause clinical troubles. *See id.* Thus, the very premise of Mr. Crosby’s opinion is unsupported by the only disclosure Mr. Crosby purports to rely upon. Mr. Crosby also suggests that Bourque recognized its elbow was a “flow-restrictive elbow” and opines that this is “the exact type of elbow [Wampler] taught to eliminate.” Ex. 1003 ¶ 470 (citing Ex. 1007, 402). Neither Petitioner nor Mr. Crosby show that Wampler proposed eliminating *any* components related to the inflow tube and rotor, much less an elbow used in Bourque precisely for the purpose of being able to place the pump in “the least obtrusive position.”

Additionally, Mr. Crosby also suggests that Bourque identified the goal of making a pump that provided “optimal” performance in “the simplest possible way,” from which he states a person of ordinary skill “would have been motivated to reduce the ‘clinical troubles’ by designing the pump ‘in the simplest possible way’ and by eliminating the flow-restrictive elbow and other components of the inflow assembly—i.e., the axially aligned inflow tube technique of [Wampler].”¹⁹ *Id.* The idea that Bourque recognized its elbow caused “clinical troubles” is completely unfounded, as explained above, and even if that were true, there is no persuasive evidence that adding Wampler’s “axially aligned inflow tube technique” would have been “the simplest possible way” to design a pump, particularly in light of Bourque’s express goal of placing the pump in “the least obtrusive position.” We find Petitioner’s line of reasoning unpersuasive because it is based on mischaracterizations of both Bourque and Wampler and on unsupported expert testimony.

Petitioner contends that a person of ordinary skill “would have further been motivated to reduce rates of infection by adhering to [Wampler’s] focus on ‘[g]ood anatomic compatibility’ over [Bourque’s] focus on ‘borrowing’ from ‘presently available Heart-Mate systems’ like the ‘HeartMate II.’” Pet. 84 (citing Ex.1007, 403, 405).²⁰ At the outset,

¹⁹ Mr. Crosby does not identify what “other components” he is referring to, and makes no mention of the “recovery section” in Bourque referred to in the Petition. To the extent the “recovery section” is the “other component” Mr. Crosby proposes eliminating from Bourque, he does not explain how, then, the pump could be easily recovered, which, as taught by Bourque, depends on the recovery section. *See* Ex. 1007, 405.

²⁰ Petitioner cites to page 403 of Bourque, which provides no support for Petitioner’s arguments.

Petitioner has once again mischaracterized Bourque. The portion of Bourque relied upon by Petitioner on page 405 of Bourque states as follows:

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems.

Ex. 1007, 405. Petitioner distorts Bourque’s disclosure concerning “borrowing from the enormous clinical experience,” to instead assert that Bourque was focused on “borrowing” from an early system instead of anatomic compatibility.²¹ *See, e.g.*, Pet. 85 (misquoting Bourque to assert Bourque’s pump placement was due to Bourque’s “‘borrowing’ ‘inflow and outflow components’ from the predecessor systems”); *see also* Ex. 1003 ¶ 171 (Mr. Crosby making the same mischaracterization of Bourque). Nor is there any support for Petitioner’s basic premise that Wampler was focused on “good anatomic compatibility,” and that Bourque was not, despite Bourque’s express disclosure that it used an elbow with a centrifugal pump to “orient the pump in the least obtrusive position.” Ex. 1007, 402.

Petitioner also asserts that “[i]nstead of borrowing parts from predecessor systems, a [person of ordinary skill] would have adhered to the express teachings of [Wampler], which focused on ‘good anatomic compatibility’ so that the device ‘fits well between the apex of the heart and the adjacent diaphragm,’ eliminating the need for a peritoneal pocket dissection associated with increased rates of infection.” Pet. 86–87 (citing

²¹ Petitioner also cites to page 403 of Bourque, from which we fail to discern any support for Petitioner’s arguments.

Ex. 1003 ¶¶ 472–475; Ex. 1008 ¶ 76). Mr. Crosby also states that a person of ordinary skill in the art would have been motivated to combine Bourque with “the axially aligned inflow tube technique” of Wampler “based on the teachings that placement of LVADs in the preperitoneal pocket position were associated with increased infections rates and decreasing the size of LVADs was associated with reduced infection rates.” Ex. 1003 ¶ 471 (further stating that “the second-generation devices were smaller ‘and d[id] not require a great deal of surgical dissection,’ they had a ‘low[er] infection rate’”) (citing Ex. 1014, 842). Thus, Mr. Crosby ties reducing infection rates to *reducing the size of the LVAD*, not to the teaching in Wampler. Petitioner purports to rely on (i.e., eliminating the elbow in Bourque’s inflow based on Wampler’s use of a centrifugal pump (*just like Bourque*)). In other words, even if the elbow of Bourque were eliminated based on Wampler, as Petitioner proposes, Petitioner offers no evidence that infection rates would be reduced unless the size of the pump in Bourque was decreased.

Lastly, Petitioner argues that the asserted combination would have been obvious to try, because “there were a finite number (i.e., two) options for LVAD implantation: the device would be implanted at a [preperitoneal] pocket, or at the cardiac apex.” *Id.* at 87–88 (citing Ex. 1003 ¶ 477). Implicitly, Petitioner is arguing that without the elbow, which Bourque uses to place the pump in “the least obtrusive position,” (Ex. 1007, 402), Bourque’s pump could have been placed in one other location that would have been better. First, there is no evidence that there were only “two” options for LVAD implantation, even if LVADs were only routinely implanted in one of two locations. Second, Petitioner does not adequately address in the Petition any need to reduce the size of Bourque’s pump to support the asserted combination with Wampler, which we find problematic

in light of the obligation on Petitioner to address “any differences between the claimed subject matter and the prior art.” *See Graham*, 383 U.S. at 17–18. Where the size of the pump is a critical distinction between Bourque and Wampler, Petitioner is required to address it to show why a person of ordinary skill would have had reason to modify Bourque in light of Wampler. That is, Petitioner suggests the only proposed modification of Bourque is eliminating an elbow and moving the pump to a new location, but Petitioner fails to address the very reason why Bourque’s pump is placed where it is, i.e., that it was in the in “the least obtrusive position.”

Patent Owner argues that Bourque’s pump is “too ‘large and heavy’” to be placed at the apex of the heart, in the manner taught by Wampler. PO Resp. 27 (citing Ex. 2015 ¶ 139; Ex. 2017 ¶ 45). Patent Owner also directs us to disclosures in Bourque that explain why Bourque’s placement of the pump in the preperitoneal pocket corresponded to the “least intrusive position.” *Id.* at 27–28 (citing Ex. 1007, 405 (stating 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’”). According to Dr. Gallegos, even at the time of invention of the ’356 patent, other devices continued to place the blood pump “remote from the heart and coupled to the heart using the same technique” as Bourque. Ex. 2017 ¶ 56 (citing Ex. 2006, 311, Fig.1).

Patent Owner explains that the “good anatomical compatibility” referred to in Wampler is only “possible since [Wampler’s] pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm.” PO Resp. 30–31 (citing Ex. 1008 ¶ 76); *see also* Pet. 16 (recognizing that it was Wampler’s “compact and disc-shaped” pump that

allowed placement between “the apex of the heart and the adjacent diaphragm”). Patent Owner states that Bourque “does not have such a compact disc” and argues that Bourque’s pump “will not fit well between the apex of the heart and the adjacent diaphragm.” PO Resp. 31 (citing Ex. 2015 ¶¶ 147–149; Ex. 2017 ¶ 54). According to Patent Owner, “[Dr.] Wampler proposed an LVAD that could be small enough to fit to the apex of the heart—but it was 10 years after Wampler’s publication and 5 years after the priority date of the challenged patent that an LVAD was made small enough to fit there.” *Id.* at 33 (citing Ex. 2015 ¶ 150; Ex. 2017 ¶ 52; Ex. 2014, 52).

In Reply, Petitioner argues that “whether the pump is placed above or below the diaphragm” is not part of the claims and that obviousness does not require bodily incorporation. Pet. Reply 17–18. Petitioner also asserts that a year before the priority date of the ’356 patent, clinical trials of devices with axially aligned inflows placed at the apex of the heart above the diaphragm had begun. *Id.* at 18 (citations omitted). The issue, however, is not whether Patent Owner argues “bodily incorporation,” but whether Petitioner has shown a reason in support of the asserted combination. Here, Petitioner argues that a person of ordinary skill would have had reason to eliminate the elbow from Bourque’s pump device so that *Bourque’s pump* could be implanted at the apex of the heart. Petitioner does not propose replacing Bourque’s pump with some other device, and does not show that Bourque’s device could be placed at the apex of the heart without other significant modifications that Petitioner neglects to address. In short, a preponderance of the evidence does not support Petitioner’s assertion that it would have been obvious to try the modification of Bourque that Petitioner proposes (i.e., eliminating the elbow from Bourque) in light of the very reasons why

Bourque uses an elbow with a centrifugal pump based on the size of Bourque's pump.

6. Conclusion

Upon consideration of the arguments and evidence of record, we conclude, for the reasons provided above, that the Petitioner fails to show by a preponderance of the evidence that Bourque, alone or in combination with Wampler, teaches the limitations of claims 5 and 7. We also find that Petitioner fails to provide a sufficient rationale for the asserted combination of Bourque and Wampler, and, therefore does not show by a preponderance of the evidence that any of claims 1–7, 10, 12, and 13 of the '356 patent would have been obvious over Bourque and Wampler.

G. Alleged Obviousness over Akamatsu

Petitioner contends that the subject matter of claims 1–7, 10, 12, and 13 of the '356 patent would have been obvious over Akamatsu. Pet. 88–115; Pet. Reply 28–30. Petitioner relies on the testimony of Mr. Crosby in support of its contentions. Ex. 1003 ¶¶ 479–627. In opposition, Patent Owner argues, among other things, that Petitioner fails to show how Akamatsu teaches “a magnetically driven rotor . . . coupled to a first magnetic device . . . at a position axially adjacent to the magnetically driven rotor,” as required by claim 1. PO Resp. 50–52. Patent Owner relies on the testimony of Mr. Leschinsky as support for its arguments. Ex. 2015 ¶¶ 176–204.

As explained above (*supra* Section III.D.3), we find “at a position axially adjacent” to mean at a position “adjacent to one another as measured along a central axis,” and that components embedded or sealed within one another and components that overlap or occupy the same portion of an axis are not “axially adjacent” components. Petitioner's entire analysis in the

Petition consists of an annotated version of Figure 2 of Akamatsu depicting permanent magnets in purple housed within an impeller shown as a pink box. Pet. 99. The annotated version of Figure 2 of Akamatsu provided by Petitioner is reproduced below:

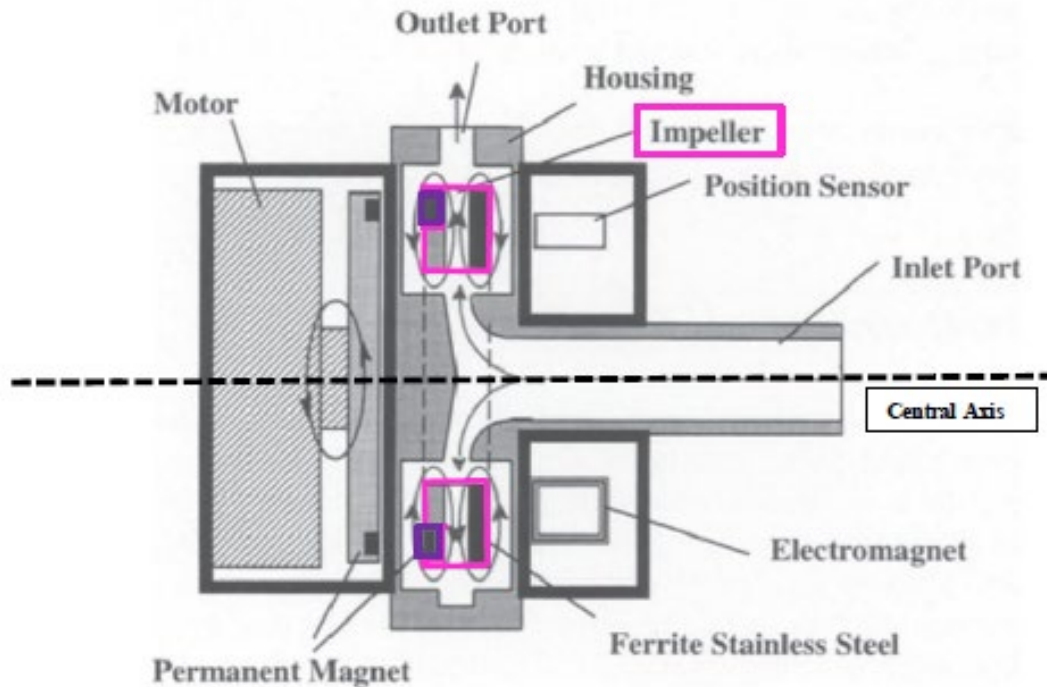


Fig. 2. Schematic cross section of the MSCP

Id. Petitioner’s annotated version of Figure 2 of Akamatsu, showing a schematic cross section of a MSCP, identifies the impeller (outlined in pink) and “the impeller’s ‘[p]ermanent [m]agnet’” (outlined in purple). *Id.* Petitioner offers no explanation of its contention other than a conclusory assertion that the permanent magnet is “at a position axially adjacent” to the impeller. *Id.* As noted in our Institution Decision, we understand Petitioner to be arguing that “a magnetic element sealed within a rotor is ‘at a position axially adjacent to the magnetically driven rotor,’” which we find unconvincing as explained above. *See supra* Section III.D.3; Inst. Dec. 38–39; Pet. 26–27, 99.

In its Reply, Petitioner makes clear that its contentions based on Akamatsu are based on a claim construction that Petitioner alleges Patent Owner asserted in the Parallel Proceeding, which is the same argument we rejected above. *See supra* Section III.D.3; Pet. Reply 29–30. We are especially troubled by Petitioner’s false assertion that Mr. Leschinsky “admitted” that Akamatsu’s magnet and impeller are “axially adjacent,” and strongly caution counsel against misrepresenting deposition testimony, which contains no such admission. Pet. Reply 29 (citing Ex. 1040, 77:18–78:17). In discussing Akamatsu, Mr. Leschinsky explains, and Petitioner does not dispute, that a person of ordinary skill in the art would not have understood “axially adjacent” to have included “components that are embedded within one another such that they overlap or occupy the same space as measured along a central axis.” Ex. 2015 ¶ 189.

There is no dispute that the permanent magnets of Akamatsu relied upon by Petitioner as the recited “first magnetic device” are embedded in Akamatsu’s impeller, corresponding to the recited rotor. *See* Ex. 1006, Fig. 2; *see also* Ex. 1003 ¶ 527 (Mr. Crosby describing the components of Akamatsu relied on by Petitioner as comprised of “a permanent magnet embedded in the impeller” (citing Ex. 1006, 4, Fig. 2)). Accordingly, because Petitioner’s contentions are premised on an unsupported claim construction that we reject, Petitioner fails to show how Akamatsu teaches or suggests “a magnetically driven rotor . . . coupled to a first magnetic device . . . *at a position axially adjacent* to the magnetically driven rotor,” as required by claim 1, as well as by claims 2–7, 10, 12, and 13, which depend from claim 1. For the preceding reasons, Petitioner fails to show by a preponderance of the evidence that the subject matter of any Challenged Claim would have been obvious over Akamatsu.

H. Alleged Obviousness over Schima and Akamatsu

Petitioner contends that the subject matter of claims 1–7, 10, 12, and 13 of the ’356 patent would have been obvious over the combination of Schima and Akamatsu. Pet. 115–149; Pet. Reply 31–32. Petitioner relies on the testimony of Mr. Crosby in support of its contentions. Ex. 1003 ¶¶ 628–801. Petitioner argues that Schima discloses “a rotary pump for moving blood” that is “an LVAD designed to be ‘delivered to the heart.’” Pet. 115–116. Petitioner relies on Schima as teaching or suggesting the features of the pump of claim 1, including, for example, that Schima’s pump teaches a rotor axially aligned with inlet 13, corresponding to an inflow tube. *Id.* at 120–121 (citing Ex. 1005 ¶ 12, Fig. 2). Petitioner argues that inlet 13 of Schima’s pump corresponds to an inflow tube with a suction end that is “inserted into a ventricle of the heart.” *Id.* at 115–116. Petitioner asserts “it would have been obvious” to a person of ordinary skill “to implant Schima’s device in the configuration described by [Akamatsu].” Pet. 115–116. Petitioner also relies on Akamatsu as teaching an external control unit. *Id.* at 136. Petitioner additionally addresses the motivation to combine Schima and Akamatsu. *Id.* at 147–149.

In opposition, Patent Owner primarily argues that neither reference teaches limitations [1A], 1[N], and 1[O], and that Petitioner fails to provide a sufficient rationale for the asserted combination of Schima with Akamatsu. PO Resp. 56–65. Patent Owner also contends the additional limitations of dependent claims 5 and 7 are not taught by either Schima or Akamatsu. *Id.* at 65–67. Patent Owner does not dispute that Schima teaches limitation [1C] (i.e., a magnetically driven rotor axially aligned with the inflow tube) and limitation [1H] (i.e., a rotor coupled to a first magnetic device at a position axially adjacent to the rotor). Patent Owner relies on the testimony of

Mr. Leschinsky (Ex. 2015 ¶¶ 205–243) and the testimony of Dr. Gallegos (Ex. 2017 ¶¶ 36–40, 70–91) as support for its arguments.

1. Independent Claim 1

We focus our discussion below on the disputed limitations of claim 1.

(a) Whether Schima and Akamatsu Teaches [1A] “delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart”

Petitioner contends that Schima teaches a pump with a rotor axially aligned with an inlet, corresponding to an inflow tube, and that the rotor magnets are located in a ring at the base of the rotor at a position axially adjacent, as required by claim 1. Pet. at 120–121, 127–128 (citing Ex. 1005 ¶ 12, Figs. 2, 7). According to Petitioner, Schima teaches a rotary pump for moving blood, but Schima “does not expressly state where its pump is placed.” *Id.* at 115. According to Petitioner, “Mr. Crosby explains that Schima suggests that its pump is an LVAD [i.e., a left ventricular assist device] and is designed to be delivered to the heart with an inlet tube 13 (the “suction end of an inflow tube,” as recited by claim 1) inserted into a ventricle of the heart. Pet. 115–116 (citing Ex. 1003 ¶¶ 634–635; Ex. 1005 ¶ 12, Fig. 2). Petitioner, however, directs us to no portion of Schima that uses the words “heart,” “ventricle,” “LVAD,” or in any other way describes delivering a heart assist pump device to the heart, much less that an inflow tube is inserted into a ventricle of the heart. Instead, Mr. Crosby reasons that because Schima discusses other prior art pumps that were used as heart assist pump devices with inflow tubes inserted into ventricles of the heart, and Schima describes “overcoming” disadvantages with the pumps used in those devices, “Schima is describing that its ‘present invention’ is also a ‘heart assist pump device.’” Ex. 1003 ¶ 641. Schima, however, discusses

problems with prior art devices specifically with regard to features of the pump itself, not with an inflow tube or delivery to the heart. *See* Ex. 1005 ¶¶ 3–9 (describing, for example, concerns with the operation of the rotor in prior art pumps).

Patent Owner argues that Schima provides “no disclosure regarding delivery of its disclosed pump such that a suction end of an inflow tube is inserted into a ventricle of the heart.” PO Resp. 56 (citing Ex. 1042 ¶¶ 630, 780). Indeed, Petitioner concedes that “Schima focuses on pump design alone.” Pet. 117–18. We are not persuaded by Petitioner’s assertion that Schima, alone, teaches an insertion of a suction end of an inflow tube of a heart assist pump device into a ventricle of the heart merely because Schima refers to prior art that may teach these features where Petitioner does not rely on that prior art in the asserted combination.

In the alternative, Petitioner contends that “it would have been obvious to implant Schima’s device in the configuration described by [Akamatsu] (i.e., “*an inflow tube of the heart assist pump device is inserted into a ventricle of the heart*”).” Pet. 116. The only “description” of a configuration in *Akamatsu* that Petitioner relies on is Figure 1, which Petitioner provides with annotations, as reproduced below:

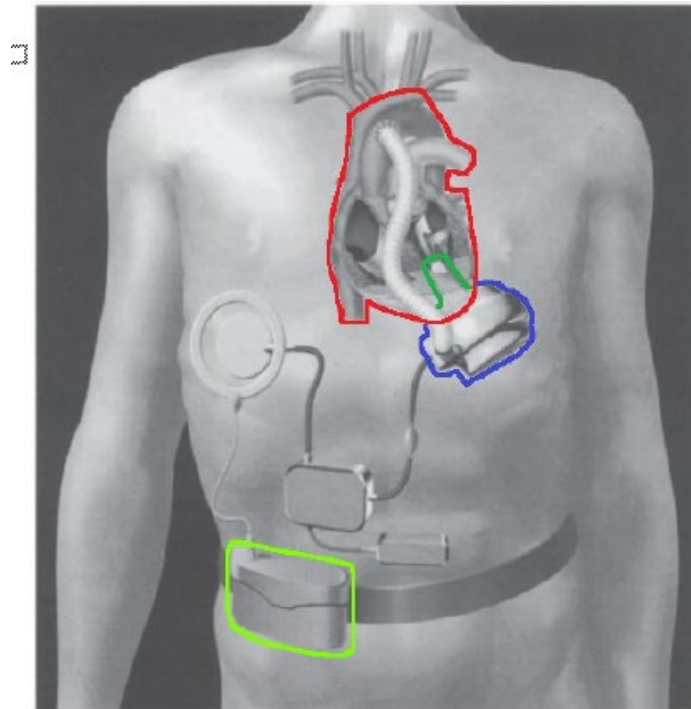


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Pet. 117, 137. The image above shows Petitioner’s annotated version of Figure 1 of Akamatsu with a red box generally corresponding to an outline of the heart of a patient, a dark green line highlighting where Petitioner contends the suction end of an inflow tube is located, and a blue line around a heart assist pump device. Pet. 117, 137; *see also id.* at 91 (identifying the annotations in the same figure). According to Petitioner, “[i]n the Schima/Akamatsu combination, Schima’s pump is “*deliver[ed]...to the heart*” so that its inlet 13 is “inserted into the left ventricle,” as taught by [Akamatsu].” *Id.* (citing Ex. 1003 ¶ 644; Ex, 1006, Fig. 1).

Patent Owner argues that the asserted combination of Schima and Akamatsu fails to teach or suggest features of claim 1 for several reasons, each of which we find unavailing for the reasons that follow. PO Resp. 56–63. First, Patent Owner argues that there is “no teaching or suggestion in Schima to suggest that its pump is configured for use in the

body, [or] even capable of being positioned at the heart in the manner claimed at all.” PO Resp. 57 (citing Ex. 2015 ¶ 208; Ex. 2017 ¶ 71). According to Patent Owner, because Schima describes a pump “suitable for use in ‘moving blood and other shear sensitive liquids,’” Schima “teaches away from a device specifically configured for implantation in the body.” *Id.* at 57–58 (citing Ex. 2015 ¶¶ 210; Ex. 2017 ¶ 71).

As support, Patent Owner argues that the fitting illustrated in Schima would have been understood to be used with “tubing and clamps,” not “to interface with the heart or other anatomical features,” Pet. 57–58 (citing Ex. 2015 ¶ 212; Ex. 2017 ¶ 78). According to Patent Owner, “another reference directed to a multi-fluid-application pump design like Schima . . . acknowledges contemplated use only extracorporeally or in industrial settings outside the medical field.” *Id.* (citing Ex. 1011, 3–4, Figs. 4, 5); *see id.* (further arguing that “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”) (citing Ex. 2015 ¶ 214; Ex. 2017 ¶ 72). Patent Owner also asserts that a 2009 paper described Schima’s pump as performing “‘in the range of contemporary extracorporeal bearingless blood pumps,” from which Patent Owner argues that “the pump in Schima is an extracorporeal blood pump not intended for implantation in the body.” *Id.* at 58–59 (citing Ex. 2015 ¶¶ 217–218; Ex. 2017 ¶¶ 75–77; Ex. 2022, 256–57).

Prior art may teach away if it criticizes, discredits, or otherwise discourages the solution claimed. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Patent Owner states that “Petitioner admits that Schima is silent regarding placement of its disclosed pump, and includes no disclosure

regarding delivery of its disclosed pump such that a suction end of an inflow tube is inserted into a ventricle of the heart. PO Resp. 56 (citing Pet. 115); *see also* Pet. 117–118 (stating that “Schima focuses on pump design alone”). Patent Owner directs us to no disclosure in Schima that “criticizes, discredits, or otherwise discourages” the use of the teachings from Schima that Petitioner relies upon to show how the combination with Bourque teaches or suggests a heart assist pump device deliverable to the heart. The mere fact that the pump described by Schima could be used outside of the body or with fluids other than blood does not constitute a “teaching away” of a device “specifically configured for implantation in the body,” as Petitioner asserts. *See* PO Resp. 57. Contrary to Patent Owner’s argument, the fact that Schima describes a pump in the context of prior art pumps that were intended to be implanted in the body would have suggested to a person of ordinary skill that Schima’s pump was likewise intended to be implanted in a body even if it could also be used outside of the body in other applications. *See* Pet. Reply 31 (citing Ex. 1003 ¶¶ 635–641; Ex. 1040, 207:2–9 (Mr. Leschinsky confirming that Schima discloses a device that “may be used as an LVAD”).

Second, Patent Owner argues that “Ppetitioner’s reliance on Akamatsu as providing the required teaching to implant the device of Schima is incorrect,” because “it is simply not clear from Akamatsu that the reference discloses delivering its pump so that a suction end of an inflow tube is inserted into a ventricle of the heart.” PO Resp. 59. Patent Owner argues that Figure 1 of Akamatsu, relied upon by Petitioner, is “conceptual” and “low resolution,” and that Akamatsu “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,” thereby “suggesting Akamatsu’s pump is not itself inserted into a ventricle of the heart.” PO Resp. 59–60 (citing Ex. 2015 ¶¶ 220–221; Ex. 2017 ¶ 81; Ex. 1006, 4).

Although Dr. Gallegos states that Akamatsu “does not describe the placement of the pump shown in [Figure] 1 in any detail and it is not clear from the image exactly how or where the pump is positioned,” he further concedes that “to the extent [Figure] 1 of Akamatsu shows placement of a pump at the apex of the heart with an inflow tube inserted into a ventricle of the heart, this would have been an illustration of an aspirational intention for the future, not an implantation technique that was feasible at the time of the invention.” Ex. 2017 ¶¶ 81–82; *see also* Ex. 2015 ¶¶ 176, 186 (Mr. Leschinsky describing Figure 1 of Akamatsu as “a conceptual and aspirational drawing of an implantable left ventricular assist system that they had not actually made” and that Akamatsu’s pump must have been implanted “in a preperitoneal or intrabdominal pocket”). There is no evidence that Figure 1 of Akamatsu illustrates a pump implanted in a preperitoneal or intrabdominal pocket, and no other disclosure in Akamatsu of placement in those locations. Patent Owner’s argument is not persuasive as it is not consistent with what is expressly shown in Figure 1 of Akamatsu, i.e., “delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart,” as required by claim 1. On this record, Petitioner has shown

by a preponderance of the evidence that Schima, in combination with Akamatsu, teaches limitation 1[A] of claim 1.²²

- b) Whether Schima and Akamatsu Teaches [1N] “connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor via the magneto coupling with the first magnetic device,” and [1O] “the external control unit being positioned exterior to the body while the inflow tube of the heart assist pump device is in the heart”

Petitioner concedes that Schima does not expressly disclose connecting an external control unit and relies, instead, on Akamatsu.²³ *Id.* at 136–37 (citing Ex. 1003 ¶¶ 719–720; Ex. 1006 3–4, Fig. 1). Petitioner contends that Figure 1 of Akamatsu teaches an external control unit, as identified in the lime green box in the annotated version of Figure 1 of Akamatsu reproduced above. *Id.* In regard to determining what is shown in Figure 1 of Akamatsu, we note that Akamatsu identifies three prototype models: the “paracorporeal Model I,” the implantable Model II,” and the “modified Model II.” Ex. 1006, 4. “The Model I and the modified Model II had dual electric wires separately connected to the motor and the electromagnets, and the “Model II had a single electric wire, with the

²² To the extent Patent Owner argues that the size of Schima’s pump argues against the asserted combination with Akamatsu, those arguments are addressed in the context of the rationale for the combination addressed below and do not refute Petitioner’s showing that the claimed elements are taught by the asserted prior art combination. *See* PO Resp. 60–61.

²³ We understand Petitioner’s statement in the Petition that “Schima does expressly disclose this element” reflects a typographical error by omitting “not” after “does” in light of the citation to Mr. Crosby’s Declaration, which states, in relevant part, that “Schima does *not* explicitly disclose ‘connecting an external control unit.’” Ex. 1003 ¶ 719 (emphasis added).

intrahousing connectors between the motor and the electromagnets.” *Id.* Akamatsu does not make clear which model is illustrated in Figure 1, describing the illustration only as “the Terumo Implantable Left Ventricular Assist System (T-ILVAS),” which appears to be a general reference to the system under development, not a specific model of the system. *See id.* at 1 (Abstract). By contrast, Figure 3 of Akamatsu illustrates “Implantable Model II MSCP with intrahousing connectors,” and Figure 7 shows “Model III system with an implantable controller.” *Id.* at 4, 7. Petitioner suggests that the discussion of a “next phase” model with an implantable pump contrasts with the “percutaneously driven” Model II’s alleged externally controlled pump. Pet. 107.²⁴ Petitioner also argues that a person of ordinary skill “would have found it obvious to try, because the location of a pump’s controller presented a finite number (i.e., two) options – a controller could be external or implanted.” Pet. 138 (citing Ex. 1003 ¶ 720).

Mr. Crosby explains in this regard as follows:

[Akamatsu] discloses a “controller” (shown to be externally worn in Figure 1) used to provide “electric current” to the “DC brushless motor” and the “electromagnets” located within the centrifugal pump via electric wires. Ex. 1006 at 3, 4. The “Model I” and the “modified Model II” had “dual electric wires separately connect to the motor and electromagnets,” while the “Model II” version of the T-ILVAS “had a single electric

²⁴ In our discussion of Schima in combination with Akamatsu we reference portions of the Petition that discuss obviousness over Akamatsu, alone. That is because Petitioner incorporated these arguments concerning Akamatsu in its analysis based on the combination of Schima and Akamatsu. *See* Pet. 136. Patent Owner similarly relies on arguments directed to Akamatsu, alone, in disputing the combination of Schima and Akamatsu. *See* PO Resp. 81 (stating “Petitioner inherits all of the deficiencies of Akamatsu described above with regard to Ground 3 [i.e., obviousness over Akamatsu, alone], each of which is incorporated by reference here”).

wire, with the intrahousing connectors between the motor and the electromagnets.” Ex.1006 at 4. [Akamatsu] further discloses that during testing, “[t]he pump was operated at a fixed rotational speed” and “[t]he pump was percutaneously driven,” i.e., via the electric wire through the skin. Ex.1006 at 4, 5. In addition, “[a]ortic pressure and pump flow rate were continuously measured throughout the experiments.” Ex.1006 at 4, 5.

Ex. 1003 ¶ 568.

Patent Owner argues that Akamatsu is “silent” regarding what the component identified by Petitioner in the lime green box of annotated Figure 1 is and suggests that because Figure 1 illustrates a “totally implantable” LVAD system,” the controller must be implanted, not external. PO Resp. 53–56 (citing Ex. 2015 ¶ 197); Sur-reply 28. Mr. Leschinsky states that the lime green component in Figure 1 might be a battery as it is “coupled to a wire extending to a ring positioned over what appears to be an implanted disc,” which “may be a transcutaneous energy transfer (TET) system used to transfer electrical power from outside the body to inside the body.” Ex. 2015 ¶ 198 (further noting that the implanted disc appears “is itself coupled to what may be an implanted controller disposed above the lime green outlined component” in Figure 1).

We agree with Mr. Leschinsky that there is no sufficient basis to determine whether the unlabeled component annotated by a lime green box in Figure 1 of Akamatsu is a controller, a battery, or something else. Mr. Leschinsky, however, also recognizes that Akamatsu discloses “aspirations to use ‘a prototype MSCP with . . . an implantable controller,’ as well as ‘a totally implantable LVAS’ including ‘a transcutaneous energy and information transfer system and internal/external batteries.” *Id.*

Mr. Leschinsky also explains as follows:

Further, after identifying what may be an external power source coupled to an implanted controller as the claimed external controller, Petitioner contends that disclosure of the “next phase” Model III pump with an implantable controller shows that earlier disclosure of a “percutaneously driven” Model II pump involves use of an external controller. Paper 1 at 107; Ex. 1003 ¶¶ 568–570. This is speculation by Petitioner without any backing from Akamatsu. For example, a percutaneously driven pump (i.e., with a power source outside the body and drive leads extending into the body) could still utilize an implanted controller coupled to the pump.

Id. at ¶ 200. We disagree with Mr. Leschinsky’s characterization of the express disclosure of Akamatsu as “speculation by Petitioner.” As explained above, Akamatsu contrasts the Model II pump with the Model III pump, and emphasizes in the illustration of the Model III pump that it uses “an implantable controller.” Ex. 1006, 7; *see also id.* at 1 (stating that “[f]urther developments toward a totally implantable system, including an implantable controller and a transcutaneous energy/information transfer system, are under way”). Patent Owner does not dispute Petitioner’s assertion that there are only two options for the location of a controller in regard to whether it is “external” or “implanted,” and notes that Mr. Leschinsky “conceded that ‘the concept of having controllers be either internal or external was known in the prior art to 2007.’” Pet. Reply 30 (citing Ex. 1040, 130:9–12). For the preceding reasons, Petitioner has shown by a preponderance of the evidence Akamatsu teaches an external control unit, as required by limitations [1N] and [1O].

2. Dependent Claim 5

Claim 1 requires “connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device.”

Claim 5 depends from claim 1 and further requires that “the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart.” Ex. 1001, 6:19–21.

Petitioner once again argues that in the Parallel Litigation Patent Owner “asserts that a fixed speed or lower speed limit are ‘*measurement values indicative of cardiac output of the heart.*’” Pet. 112, 143. We rejected this argument by Petitioner based on unsupported allegations of alleged arguments in the Parallel Proceeding in our discussion of alleged obviousness of claim 5 over Bourque and Wampler, and reach the same conclusion here. *See infra* Section III.F.2; *see also* Ex. 1003 ¶ 751 (Mr. Crosby purporting to “adopt” Patent Owner’s “theory of infringement” allegedly asserted in the Parallel Proceeding).

Patent Owner argues that “[d]isclosure of operating a pump at a fixed rotational speed while also taking measurements . . . does not teach or suggest that the measurements are provided to an external controller or that speed is set or adjusted by the external controller in response to the measurements.” PO Resp. 65 (citing Ex. 2015 ¶¶ 242). Patent Owner also maintains that Petitioner provides “no explanation as to how either aortic pressure (an inflow pressure) or a pump speed is indicative of cardiac output.” *Id.*; *see also* Ex. 1003 ¶ (Mr. Crosby stating that Akamatsu discloses “a ‘controller’ to ‘operate[]’ ‘the pump . . . at a fixed rotational speed’ and monitor ‘aortic pressure and pump flow rate [which] were continuously measured’”).

In Reply, Petitioner falsely asserts that Patent Owner “does not dispute that Akamatsu” teaches claim 5. Pet. Reply 32 (citing PO Resp. 45–56). Patent Owner expressly argues in the Patent Owner Response that “No Combination Of Schima And Akamatsu Teaches Or Suggests An External

Control Unit Controlling A Second Magnetic Device In Response To Measurement Values Indicative Of Cardiac Output Of The Heart [Claim 5].” PO Resp. 65. Petitioner then directs us as support for its arguments to a discussion by Mr. Crosby concerning Bourque, which is not at issue in this ground (Pet. Reply 32 (citing Ex. 1003 ¶¶ 429–430)). Petitioner fails to show how Akamatsu’s disclosure of operating a pump at a fixed rotational speed corresponds to control of the pump “in response to measurement values indicative of cardiac output of the heart.” For the foregoing reasons, Petitioner fails to show that Schima, in combination with Akamatsu, teaches or suggests the subject matter of dependent claim 5.

3. Dependent Claim 7

Claim 7 depends from claim 1 and further requires “providing feedback signals to the external control unit from one or more sensors.” Ex. 1001, 6:26–28. Petitioner asserts that Akamatsu “discloses a ‘controller’ and ‘position sensors’ (‘one or more sensors’) that ‘provid[e] feedback signals’ to the ‘controller.’” Pet. 144 (citing Ex. 1003, ¶¶ 762–763; Ex. 1006, 3–4); *see also* Ex. 1006, 3 (stating that “[t]he electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing”).

Patent Owner makes the same argument for claim 7 as claim 1, asserting that Akamatsu does not teach an external control unit. PO Resp. 66–67. Because we determine that Petitioner has sufficiently shown how Akamatsu teaches an external control unit, we find Patent Owner’s argument unconvincing for the same reasons discussed above in regard to claim 1. Based on our review and consideration of Petitioner’s arguments and evidence directed to claim 7, we find that Petitioner has shown by a

preponderance of the evidence that the asserted combination of Schima and Akamatsu teaches or suggests each of the limitations of dependent claim 7.

4. Dependent Claims 2–4, 6, 10, 12, and 13

Petitioner contends that the combination of Schima and Akamatsu teaches or suggests each limitation of claims 2–4, 6, 10, 12, and 13, which depend from claim 1. Pet. 138–147. Patent Owner does not dispute Petitioner’s contentions with respect to claims 2–4, 6, 10, 12, and 13 apart from relying on the arguments contesting the assertions for claim 1. *See generally* PO Resp. Based on our review and consideration of Petitioner’s arguments and evidence directed to claims 2–4, 6, 10, 12, and 13, we find that Petitioner has shown by a preponderance of the evidence that the asserted combination of Schima and Akamatsu teaches or suggests each of the limitations of dependent claims 2–4, 6, 10, 12, and 13.

5. Rationale in Support of the Asserted Combination

Petitioner asserts a person of ordinary skill in the art would have had reason to combine an external controller as taught by Akamatsu, with Schima’s pump, and to implant Shima’s pump such that Schima’s inlet 13 would have been “‘inserted into the left ventricle,’ as taught by” Akamatsu. Pet. 147.

a) Whether Schima and Akamatsu are Analogous Art to the ’356 Patent

Petitioner asserts that Schima and Akamatsu are analogous art to the ’356 patent as they are directed to the same field of endeavor (assisting “the performance of a heart with . . . a rotary pump driven via magneto coupling”). Pet. 147 (citing Ex. 1001, Abstract, 3:50–51; Ex. 1006, 3; Ex. 1008 ¶ 1). Petitioner also contends that Schima and Akamatsu are reasonably pertinent to the problem of “mechanical stress on the blood

during pumping” described by the ’356 patent. *Id.* at 147–48 (citing Ex. 1001, 2:27–32; Ex. 1006, 8; Ex. 1005 ¶¶ 2, 9).

Patent Owner argues that “[t]he identified field of endeavor and pertinent problem are taken at too high a level of abstraction, . . . because they allow false equivalence to be drawn between the implantable pump of Akamatsu and the extracorporeal pump of Schima.” PO Resp. 63–64 (further asserting that a person of ordinary skill “would have immediately appreciated that the pump of Schima cannot be delivered to the heart in the manner disclosed in Akamatsu”) (citing Ex. 2015 ¶¶ 235–236; Ex. 2017 ¶ 86). Patent Owner, however, does not refute Petitioner’s showing that Schima, Akamatsu, and the ’356 patent are all in the field of endeavor of assisting heart performance with a rotary pump driven via magneto coupling and are all pertinent to the problem of reducing mechanical stress on the blood during pumping. Patent Owner provides no legal reasoning and directs us to no supporting case law to suggest that the “level of abstraction” or a “false equivalence” is the proper test for whether a reference is analogous art. Here, Schima concerns “a pump for moving blood,” and Akamatsu concerns the development of “an implantable left ventricular assist system (T-IL VAS) featuring a centrifugal blood pump with a magnetically suspended impeller,” both of which are identical to the field of endeavor of the ’356 patent (i.e., “[a] method and device to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via magneto coupling”). *See* Ex. 1001, code (57); Ex. 1005 code (57); Ex. 1006, 1. Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that Schima and Akamatsu are analogous art to the ’356 patent.

b) Whether Petitioner has Shown a Sufficient Rationale in Support of the Asserted Combination of Schima and Akamatsu

Petitioner argues as follows:

[The] combination would have been an arrangement of old elements (inlet tube; and external controller) with each performing the same function it has been known to perform (allowing blood [to] flow from the ventricle to the pump; and allowing a user to regulate operation) and yielding no more than one would expect from such an arrangement (blood flowing from the ventricle to the pump; and user control of a pump).”

Pet. 148 (citing Ex.1003 ¶¶ 783–785, 792–797; Ex.1005 ¶ 12; Ex. 1006, 4; Ex. 1007, 401–02; Ex. 1008 ¶¶ 72–75). Petitioner contends that Schima’s teachings, focused on “pump design alone,” are “complimentary” to Akamatsu’s teachings focused on pump design, control, and implantation. *Id.* (citing Ex.1003 ¶ 787). Petitioner asserts that because “Schima is silent as to pump implantation and control,” a person of ordinary skill “would have been motivated to use Schima’s advantageous pump design while using [Akamatsu’s] teachings as to pump control (regulating operation via external controller) and implantation (inserted into the left ventricle).” *Id.* at 148–49 (citing Ex. 1003 ¶¶ 787, 789, 798).

Patent Owner argues that a person of ordinary skill “would not have made the contended combination,” because they “would not have considered the extracorporeal pump of Schima deliverable to the heart in the manner contended by Akamatsu,” and that “Akamatsu fails to provide the teaching Petitioner contends based on the size of the disclosed pump in Akamatsu that could not be delivered to the apex of the heart.” PO Resp. 64 (citing Ex. 2015 ¶ 237). According to Patent Owner, the teachings of Schima and Akamatsu are not “complementary,” because a person of ordinary skill would have understood “the inability of Akamatsu to teach or suggest

delivering its pump to the heart as Petitioner contends and the unsuitable nature of Schima for delivery to the heart in the manner Petitioner contends.” *Id.* at 64–65 (citing Ex. 2015 ¶ 238).

Petitioner argues in Reply, and we agree, that Schima’s teachings are not limited to an extracorporeal pump. *See* Pet. Reply 31. As Petitioner notes, although Schima is “silent” as to placement of its pump, Schima expressly discusses “overcoming” issues with prior art implantable LVADs, strongly suggesting that its pump design was intended to be applicable to implanted pumps, which is consistent with Mr. Leschinsky’s testimony that Schima’s pump “may be used as an LVAD, or it may be used for something else.” *Id.*; Ex. 1005 ¶¶ 4–8; Ex. 1040, 207:2–9. We also agree with Petitioner that “even if Schima’s pump is ‘extracorporeal,’ [Patent Owner’s] argument that it cannot be combined ‘with the implantable device of Akamatsu’ amounts to a ‘a legally insufficient bodily incorporation argument.’” Pet. Reply 31–32. In other words, Schima need not expressly state that its pump is implantable for Petitioner to rely upon the teachings of Schima concerning features of the pump to show the obviousness of the Challenged Claims over Schima in combination with Akamatsu, which describes an implantable pump.

Patent Owner argues in its Sur-reply that Akamatsu’s pump “is simply too big to be implanted at the apex of the heart,” thereby undermining “Petitioner’s reasons for motivation.” Sur-reply 25. Patent Owner’s argument is unavailing because Figure 1 of Akamatsu illustrates the pump implanted at the apex of the heart. Patent Owner further argues that the alleged “commercial embodiment” of the Akamatsu pump (the “DuraHeart pump”), which Petitioner asserted had been implanted in 20 patients by 2006 (Pet. Reply 22–23 (citing Ex. 1042 ¶¶ 99–100; Ex. 1046, 4)), was in fact “an

altered version of the Akamatsu pump—set up for implantation in a preperitoneal pocket with a perpendicular inflow tube.” Sur-reply 26–27 (citing Ex. 2026, 1423; Ex. 2028, 38:23–40:21 (Dr. Wieselthaler explaining that the DuraHeart pump was implanted in a preperitoneal pocket and was “definitely too big” to be placed in the pericardial space but could be placed in a “subdiaphragmal position”)). Patent Owner’s reliance on a commercial embodiment of a pump described in Akamatsu is misplaced as obviousness here is based only on what is disclosed in Akamatsu. In short, Akamatsu teaches a pump implanted at the apex of the heart, even if a later commercial embodiment purportedly related to the information disclosed in Akamatsu was implanted elsewhere. For the preceding reasons, Petitioner shows by a preponderance of the evidence a sufficient rationale in support of the asserted combination of Schima and Akamatsu.

c) Whether Petitioner has Shown a Reasonable Expectation of Success in Support of the Asserted Combination of Schima and Akamatsu

Petitioner asserts that “[e]xternal controllers,” as taught by Akamatsu, “were commonly employed to regulate operation of LVADs,” and that “LVADs were routinely delivered to the heart with a suction end inserted into the left ventricle,” as taught by Akamatsu. Pet. 149 (citing Ex. 1003 ¶¶ 788, 798–799; Ex. 1006, 4; Ex. 1008 ¶¶ 72, 75; Ex. 1007, 401–403). Patent Owner argues that a person of ordinary skill in the art would have had no reasonable expectation of success “in attempting to deliver the extracorporeal pump of Schima to the heart.” PO Resp. 65 (citing Ex. 2015 ¶ 239). According to Patent Owner, “Akamatsu fails to teach or suggest delivering its pump to the heart as Petitioner contends,” Akamatsu’s teachings of an external controller are “deficient,” and a person of ordinary

skill “would not have thought that a controller configured to use with Akamatsu’s pump would be suitable for use with the Schima pump,” because “[p]ump-controller pairings for LVADs are specifically tailored and a [person of ordinary skill] would not swap out one side of the pairing with any reasonable expectation of success.” *Id.* (citing Ex. 2015 ¶¶ 239–240; Ex. 2017 ¶¶ 87–91).

Patent Owner does not refute Petitioner’s showing of a reasonable expectation of success concerning the asserted combination of teachings in Schima and Akamatsu relied upon by Petitioner, but instead addresses a combination of their physical embodiments, which is inapposite. *See In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981) (stating that the “test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference”). Here, for example, Petitioner does not propose using the physical controller of Akamatsu with Schima’s pump, but merely applies Akamatsu’s teaching to a person of ordinary skill that a pump such as Schima’s could be controlled with an external controller as taught by Akamatsu with a reasonable expectation of success. Patent Owner’s argument disputing whether “a controller configured to use with Akamatsu’s pump would be suitable for use with the Schima pump” improperly requires bodily incorporation to show obviousness. Accordingly, we find Petitioner has shown by a preponderance of the evidence a reasonable expectation of success in support of the asserted combination of Schima and Akamatsu.

6. Conclusion

Petitioner has shown by a preponderance of the evidence that the asserted combination of Schima and Akamatsu teaches each of the limitations of claims 1–4, 6, 7, 10, 12, and 13. Petitioner has not shown by a

preponderance of the evidence that the asserted combination of Schima and Akamatsu teaches each of the limitations of dependent claim 5. Petitioner has also shown that a person of ordinary skill in the art had sufficient reason to combine the teachings of Schima and Akamatsu in the manner asserted with a reasonable expectation of success. Accordingly, Petitioner has shown that claims 1–4, 6, 7, 10, 12, and 13 would have been obvious over Schima and Akamatsu, but has not shown that dependent claim 5 would have been obvious over Schima and Akamatsu.

IV. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude portions of Dr. Wieselthaler’s Declaration (Exhibit 1041), portions of Mr. Crosby’s Reply Declaration (Exhibit 1042), portions of the deposition transcript of Dr. Wieselthaler Deposition (Ex. 2028), and the exhibits “upon which that testimony is based” (Exhibits 1015, 1038, 1044, 1046, 1049, and 1050). Mot. 1. According to Patent Owner, the Motion was made “to preserve objections previously made in the record.” *Id.* (citations omitted). Patent Owner did not timely move to strike any of the evidence at issue as being outside the scope of reply evidence.

Patent Owner asserts that because an *inter partes* review must be based on prior art consisting of patents or printed publications (citing 35 U.S.C. § 311(b)), the testimony of Mr. Crosby and Dr. Wieselthaler concerning “various physical devices allegedly known” to a person of ordinary skill in the art is inadmissible, along with all of the exhibits (consisting of printed materials such as journal abstracts, press releases, and papers) related to those physical devices. *Id.* at 3–4; *see also* Mot. Reply 1–4 (arguing that “devices that Petitioner’s witnesses assert were in public use prior to the claimed inventions, are not prior art that can form

the basis of an *inter partes* review”). According to Patent Owner, Dr. Wieselthaler was unable to “link two of these physical devices to the printed prior art asserted in this [inter partes review], but those attempts fell apart during his cross examination.” *Id.* at 4. Patent Owner further reasons that because the evidence “cannot be the basis” of an *inter partes* review, it “has no tendency to make any fact of consequence in this trial more or less probable,” “is irrelevant and not admissible,” “presents substantial danger of confusing the issues, causing undue delay, and wasting time in this trial,” and “are not ‘based on sufficient facts[,] the product of reliable principles and methods[, or] ‘a reliable application of the principles and methods to the facts of the case.’” *Id.* at 7 (citing Fed. R. Evid. 401–403, 702) (modification in original).

With regard to Exhibits 1015, 1038, 1044, 1046, 1049, and 1050, Petitioner argues, and we agree, that Patent Owner identifies no plausible legal theory for their inadmissibility based on the contention that they discuss physical devices. *See* Mot. Resp. 3. We also agree with Petitioner that the exhibits are not “the basis for any ground” asserted in this proceeding, and may be properly relied upon by Dr. Wieselthaler and Mr. Crosby as support for their rebuttal testimony directed to Patent Owner’s arguments disputing Petitioner’s asserted motivation to combine the prior art relied upon in the instituted grounds. *See id.* at 3–4.

In regard to the disputed testimony of Dr. Wieselthaler and Mr. Crosby, we also agree with Petitioner that Patent Owner has not disputed their qualifications as experts and fails to show any basis for the exclusion of their testimony. *Id.* at 5. Pursuant to Fed. R. Evid. 402, relevant evidence is admissible and irrelevant evidence is not admissible. Further, evidence is relevant if “it has any tendency to make a fact more or

less probable than it would be without the evidence” and “the fact is of consequence in determining the action.” Fed. R. Evid. 401. Fed. R. Evid. 702 serves “a ‘gatekeeping role,’ the objective of which is to ensure that expert testimony admitted into evidence is both reliable and relevant.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). There is no question that the disputed testimony of Dr. Wieselthaler and Mr. Crosby is relevant to the asserted motivation to combine and reliable, only whether it becomes “not relevant” or “unreliable,” in light of limited scope upon which grounds of unpatentability may be based under 35 U.S.C. § 311(b), because the testimony is based on, or supported by, knowledge of physical devices and publications discussing physical devices. Patent Owner directs us to no support for the notion that an expert’s testimony in an *inter partes* review must be limited to only the prior art relied upon as grounds for unpatentability and may not take into account any knowledge of, or publications concerning, other “physical devices” that would have been known to a person of ordinary skill at the relevant time. *See generally* Mot.²⁵ In sum, we find that Patent Owner has

²⁵ Patent Owner improperly asserts for the first time in its Reply in support of the Motion that “Petitioner in this case is improperly relying on non-prior art evidence.” Mot. Reply 3. This argument was not made in the Motion, and Patent Owner fails to identify what “non-prior art evidence” it seeks to exclude. We recognize that Petitioner appears to raise the argument that “non-prior art evidence” may be relied upon by an expert, but Petitioner also fails to identify what evidence it is referring to and that argument was not responsive to any issue Patent Owner raised in the Motion. *See* Mot. Resp. 5. To the extent the Parties intend “non-prior art evidence” to refer to the testimony of Dr. Wieselthaler and Mr. Crosby, we view the issue as pertaining to the weight afforded that testimony, in light of the supporting evidence relied upon, rather than one of admissibility.

not identified a persuasive basis under any of the Federal Rules of Evidence for the exclusion of evidence in this proceeding and deny the Motion.

V. CONCLUSION²⁶

After reviewing the record and weighing the evidence offered by the Parties, we determine that Petitioner has established by a preponderance of the evidence that claims 1–4, 6, 7, 10, 12, and 13 of the '356 patent are unpatentable, but not claim 5.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–7, 10, 12, 13	103	Wampler		1–7, 10, 12, 13
1–7, 10, 12, 13	103	Bourque, Wampler		1–7, 10, 12, 13
1–7, 10, 12, 13	103	Akamatsu		1–7, 10, 12, 13
1–7, 10, 12, 13	103	Schima, Akamatsu	1–4, 6, 7, 10, 12, 13	5
Overall Outcome			1–4, 6, 7, 10, 12, 13	5

²⁶ Should Patent Owner wish to pursue amendment of the Challenged Claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

VI. ORDER

Upon consideration of the record before us, it is:

ORDERED that Petitioner has established by a preponderance of the evidence that claims 1–4, 6, 7, 10, 12, and 13 of U.S. Patent No. 11,351,356 B2 are unpatentable;

ORDERED that Petitioner has not established by a preponderance of the evidence that claim 5 of U.S. Patent No. 11,351,356 B2 is unpatentable and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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