

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner,

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00116
Patent 11,754,077 B1

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

HAMANN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Abbott Laboratories (“Petitioner”) filed a petition for *inter partes* review of claims 1–5, 7, 10, 16–24, 26, and 28 (“the challenged claims”) of U.S. Patent No. 11,754,077 B1 (Ex. 1001, “the ’077 patent”). Paper 1 (“Pet.”). Miracor Medical SA (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (2024); *see* 37 C.F.R. § 42.108 (2024). Upon consideration of the papers, we conclude that the information presented shows that there is a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one challenged claim of the ’077 patent.

A. *Real Parties in Interest*

Petitioner states that itself and Thoratec LLC are real parties in interest. Pet. 3. Patent Owner states that it is the real party in interest. Paper 4, 2.

B. *Related Matters*

The parties identify *Miracor Medical SA v. Abbott Laboratories*, 1:23-cv-16257 (the “parallel litigation”) as a matter that may affect, or be affected by, a decision in this proceeding. Pet. 4; Paper 4, 2. Petitioner also submits that IPR2025-00096 and IPR2025-00112–IPR2025-00115 are directed to patents that are related to the challenged patent. Pet. 3–4.

C. *The Challenged Patent*

The ’077 patent provides “[a] device to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via a

magneto coupling.” Ex. 1001, code (57). The ’077 patent explains that conventional external pumps that assist the performance of a heart do not provide the desired pressure at particular locations due to fluid flow of blood being affected by mechanical stress. *Id.* at 1:64–2:24. In response, the ’077 patent teaches improving fluid flow by providing “[a] completely impervious separation of [a] rotor from [a] drive wheel” via “a magneto coupling” to “eliminate[] axial passages between the drive wheel and the rotor lying distally on the outside.” *Id.* at 2:24–28.

The ’077 patent states that “[t]he rotor itself can follow design principles such as described for example in WO 01/70300 A1.” *Id.* at 2:29–30. According to the ’077 patent, “[t]he rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is not directly suitable for incorporation into a catheter.” *Id.* at 2:30–34. The ’077 patent discloses that for the desired conveying capacity with the axial pump, the rotor needs to have “guide surfaces to produce centrifugal flow components.” *Id.* at 2:34–38.

Figure 1 “shows a diagrammatic illustration of the arrangement of the pump and of the drive” of the ’077 patent and is reproduced below. *Id.* at 3:1–3.

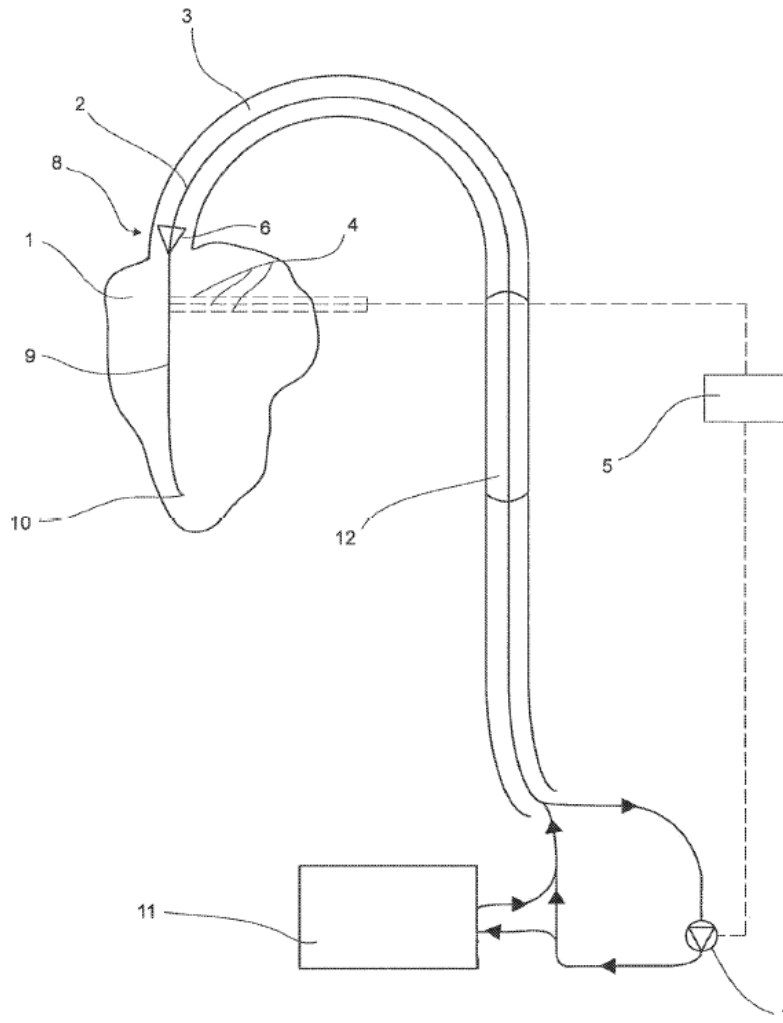


Fig. 1

Figure 1 illustrates heart ventricle catheter 2 introduced into heart 1 via aortic arch 3. *Id.* at 3:10–13. Catheter 2 carries into heart 1 sensors 4 “via which the volume can be determined” such that measurement signals are passed to control arrangement 5. *Id.* at 3:11–15. Catheter 2 has several lumina that supply fluid to drive a rotor at its distal end, which forms pump 6 to assist the blood circulation at position 8. *Id.* at 3:15–23. “The driving medium for the rotor or the pump is guided in a circular flow by means of . . . fluid pump 7 which can be regulated in a synchronized manner as a function of the control signals generated in control arrangement 5.” *Id.* at

3:23–26. Catheter 2 has at its distal end tube 9 that leads to suction end 10. *Id.* at 3:26–29. Reservoir 11 for driving fluid provides additional driving medium for filling balloon 12 that serves for an occlusion of the artery, “and which receives again the volume of driving medium occurring on deflation of the balloon.” *Id.* at 3:29–34. Control arrangement 5 provides corresponding fixed values, “such as for example a defined cardiac output, which is referred to on deviation of the measured cardiac output to control the pump.” *Id.* at 3:39–43. The ’077 patent discloses that “[a] retroperfusion can take place via a conventional balloon catheter which is occluded in a correspondingly synchronized manner, so that the directed return is in fact guaranteed during the diastole.” *Id.* at 3:44–47.

Figure 2, reproduced below, “shows a diagrammatic illustration of the distal end of a catheter” in accordance with the ’077 patent. *Id.* at 3:3–4.

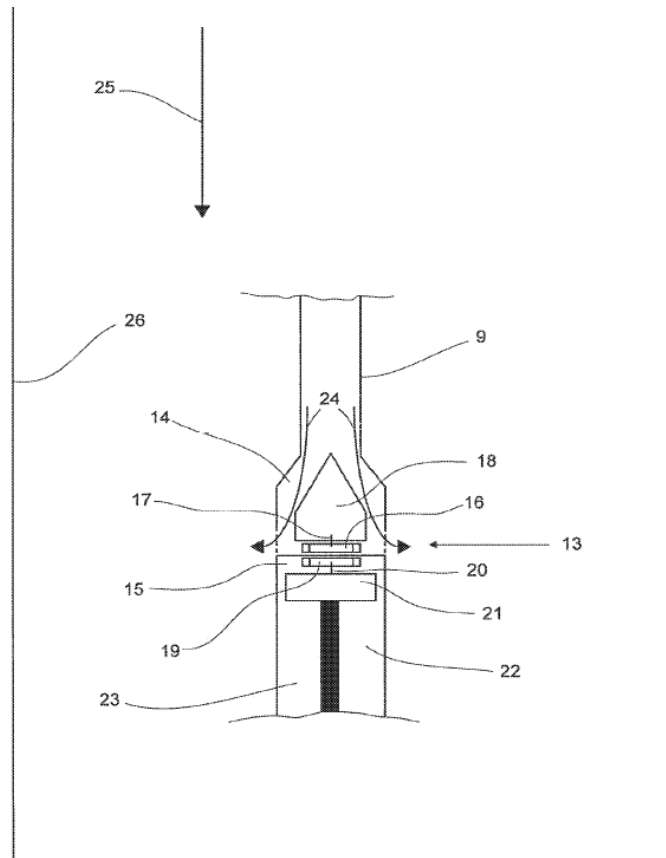


Fig. 2

Figure 2 shows the distal end of catheter 2 having end side 13 with two pocket-shaped chambers 14 and 15, “in which bar magnets [16 and 19] are respectively arranged.” *Id.* at 3:50–53. Bar magnet 16 “is connected here at the distal end outwards” via shaft 17 with rotor 18, whereas bar magnet 19 “lying on the inside is connected” via shaft 20 with drive wheel 21. *Id.* at 3:53–56. Drive wheel 21 “is formed here as a paddle wheel and is acted upon with fluid via lumen 22,” in which “this fluid flows off again via . . . lumen 23 of the catheter.” *Id.* at 3:56–59. The rotation of paddle wheel 21 “is regulated here accordingly by corresponding control of the fluid pressure” in lumen 22 serving for the supply of fluid, in which magnet 19, “which is connected so as to be locked against relative rotation” with drive

wheel 21, “is set into corresponding rotation.” *Id.* at 3:59–64. The ’077 patent discloses that “[a]t the outer side, which is completely sealed with respect to the lumina 22 and 23, the magnet 16 is subsequently entrained accordingly and drives the rotor 18 via the shaft 17, whereby a flow is formed in the region of the tube 9, as is indicated by the arrows 24, and which assists the natural blood flow in the vessel 26, illustrated by the arrow 25.” *Id.* at 3:64–4:3.

D. The Challenged Claims

Petitioner challenges claims 1–5, 7, 10, 16–24, 26, and 28 in this proceeding. Claims 1 and 16 are independent claims. Claim 1 is illustrative of the challenged claims and is reproduced below:

1. A system for assisting the blood circulation of a heart, comprising:

a heart assist pump device deliverable to the heart and comprising:

an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart;

a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle, the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor having guide surfaces to produce centrifugal flow components, the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;

a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device while being spaced

apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly, the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor;

a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly, wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and

an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output, wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

Ex. 1001, 4:29–5:11.

E. Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims of the '077 patent are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–5, 7, 10, 16–24, 26, 28	103(a)	Wampler, ² Bourque ³
1–5, 7, 10, 16–24, 26, 28	103(a)	Wampler
1–5, 7, 10, 16–24, 26, 28	103(a)	Akamatsu ⁴
1–5, 7, 10, 16–24, 26, 28	103(a)	Akamatsu, Schima ⁵

Pet. 6, 16–145. Petitioner submits in support of its arguments the Declaration of Peter Crosby (Ex. 1003).

II. LEVEL OF ORDINARY SKILL IN THE ART

To determine whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In assessing 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) (citing *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962–63 (Fed. Cir. 1986)). “[O]ne or more factors may predominate.” *Id.*

¹ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because the ’077 patent issued from an application claiming an effective filing date before March 16, 2013, we apply the pre-AIA version of the statutory basis for unpatentability.

² US 2002/0102169 A1, published Aug. 1, 2002 (Ex. 1008, “Wampler”).

³ Kevin Bourque et al., HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor, *ASAIO J.* 401–05 (2001) (Ex. 1007, “Bourque”).

⁴ Chisato Nojiri 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”).

⁵ US 2003/0124007 A1, published July 3, 2003 (Ex. 1005, “Schima”).

Petitioner argues that one of ordinary skill in the art “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). At this stage, “Patent Owner takes no position regarding the appropriate level of skill for a person of ordinary skill in the art.” Prelim. Resp. 1.

For purposes of this Decision, we adopt Petitioner’s definition of the level of skill for one of ordinary skill in the art. Pet. 6. We view this definition for the level of ordinary skill as consistent with the ’077 patent and the asserted prior art, and we apply it in our analysis below.

III. CLAIM CONSTRUCTION

Because the Petition was filed after November 13, 2018, we apply the same claim construction standard that would be used in a civil action under 35 U.S.C. § 282(b), following the standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b); 83 Fed. Reg. 51,340, 51,340–41, 51,343 (Oct. 11, 2018). In applying such standard, claim terms generally are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention and in the context of the entire patent disclosure. *Phillips*, 415 F.3d at 1312–13. “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner argues that “magneto coupling” and “by a gap sized for passage of the blood” are terms that Patent Owner has construed in the parallel litigation differently from their plain and ordinary meaning. Pet. 7–9. In response, Patent Owner argues that Petitioner’s proposed constructions incorrectly narrow the scope of these terms. Prelim. Resp. 2–5.

Notably, Petitioner argues that the claims are “unpatentable under any interpretation, [and, thus,] the Board need not construe the claim terms.” Pet. 7. And Patent Owner does not dispute, at this stage, that the cited art teaches the limitations corresponding to these terms. *See* Prelim. Resp. Thus, for purposes of institution, we do not need to construe these terms, and we afford them their plain and ordinary meaning. *See, e.g., Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’”).

However, we need to address the parties’ dispute as to the meaning of “axially adjacent.” In particular, Petitioner argues in connection with mapping cited art to challenged claims for the Wampler and Akamatsu asserted grounds that “a magnetic element sealed within a rotor is . . . ‘*axially adjacent.*’” Pet. 20 n.6. Petitioner fails to point to any intrinsic evidence to support this construction. Rather, Petitioner alleges that Patent Owner took this position in the parallel litigation in a chart mapping claim 1 to accused products. *Id.* (citing Ex. 1019,⁶ 5–7). Petitioner does not explain how Patent Owner’s chart supports Petitioner’s construction here. *See id.* at

⁶ Petitioner identifies this exhibit as “Exhibit 13 of Complaint, dated November 27, 2023,” which comprises a claim chart mapping accused products to claim 1.

20–22. Simply put, we find nothing in Patent Owner’s chart that supports when “a magnetic element [is] sealed within a rotor,” it necessarily means being “axially adjacent,” as Petitioner alleges. *See* Ex. 1019. Rather, we agree with Patent Owner that this chart instead labels product components that are adjacent to one another as measured along a central axis. Prelim. Resp. 21 (citing Ex. 1019, 6–7).

In addition, we agree with Patent Owner that “[t]his [mapping] 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.” *Id.* We note that Petitioner applies the plain and ordinary meaning of “axially adjacent” for other asserted grounds, arguing that components which are adjacent to one another along a central axis are “axially adjacent.” *E.g.*, Pet. 55–57.

Accordingly, we find, for purposes of this Decision, that the plain and ordinary meaning of “axially adjacent” is being adjacent to one another as measured along a central axis, and does not mean a magnetic element sealed within a rotor. *Id.* at 20.

IV. PRINCIPLES OF LAW

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). 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) objective evidence

of non-obviousness, if present.⁷ *See Graham*, 383 U.S. at 17–18. When evaluating a claim for obviousness, we also must “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

V. ALLEGED OBVIOUSNESS OVER WAMPLER AND BOURQUE

Petitioner argues that the combination of Wampler and Bourque renders claims 1–5, 7, 10, 16–24, 26, and 28 obvious. Pet. 52–88. For the reasons that follow, we determine that Petitioner establishes a reasonable likelihood that it would prevail in showing that this combination renders at least one of these claims obvious.

A. *Summary of Wampler*

Wampler relates “to continuous flow pumps of rotary design, suitable for permanent implantation in humans for use as chronic ventricular assist devices.” Ex. 1008 ¶ 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 using pumps that provide cyclic or pulsating blood flow. *Id.* ¶ 5. 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.* To address this issue, Wampler discloses an improved rotary blood pump that eliminates the need for a driveshaft seal. *Id.* ¶ 6.

⁷ Patent Owner does not present arguments or evidence of such objective evidence of non-obviousness. *See* Prelim. Resp.

B. Summary of Bourque

Bourque relates to a long-term, compact LVAD “featuring a centrifugal pump with a magnetically levitated rotor.” Ex. 1007, 1.⁸ Bourque explains that second generation LVAD research has focused on continuous flow pumps over positive displacement pumps because the former which have inherently fewer mechanical parts, are smaller, and lower cost. *Id.* Bourque teaches further improving second generation LVADs by employing a pump with no mechanical bearings. *Id.* Instead, “[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.” *Id.*

C. Challenged Claim 1

Petitioner argues that the combination of Wampler and Bourque renders claim 1 obvious. Pet. 52–73, 81–88. Patent Owner argues that (i) the combination fails to teach that a rotor assembly and inflow tube are axially aligned, and (ii) Petitioner fails to show that one of ordinary skill in the art would have combined Wampler and Bourque’s teachings as Petitioner proposes. Prelim. Resp. 10–11, 41–52. We address these arguments below.

1. Rotor Assembly Axially Aligned with Inflow Tube

Claim 1 recites having a “rotor assembly configured to be axially aligned with the inflow tube.” Ex. 1001, 4:35–36. Petitioner argues that the combination of Wampler and Bourque teaches this limitation in two ways. Pet. 52–57. Petitioner first argues that Bourque, alone, teaches a rotor “axially aligned” with the inflow tube, and, second, that Bourque, in combination with Wampler, teaches this limitation. *Id.*

⁸ We cite to the page numbers of the exhibit as added by Petitioner.

As to Petitioner’s argument based on Bourque, alone, on the current record, we find that Petitioner does not sufficiently show that Bourque teaches a rotor “axially aligned” with an inflow tube. Petitioner contends that Figure 3 of Bourque teaches a heart assist pump device (“HeartMate III LVAD”) with an inflow tube (“an inflow subassembly . . . that includes a left ventricular (LV) cannula”) that is deliverable to the heart so that the inflow cannula is “implanted . . . via left ventricular apical cannulation.” *Id.* at 52–54 (citing Ex. 1003 ¶ 411; Ex. 1007, 1, 3, Fig. 1A, Fig. 3).

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

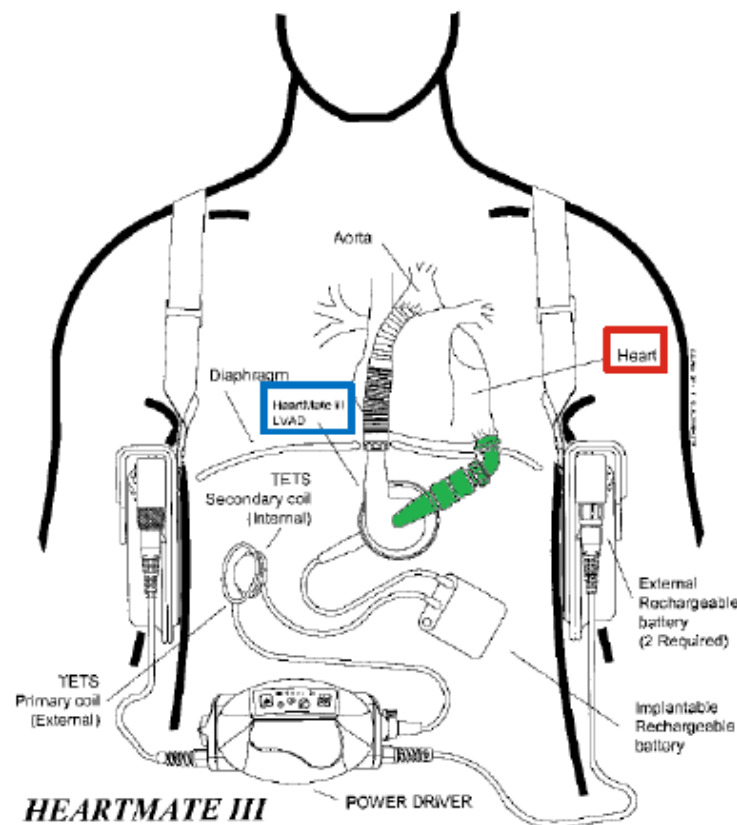
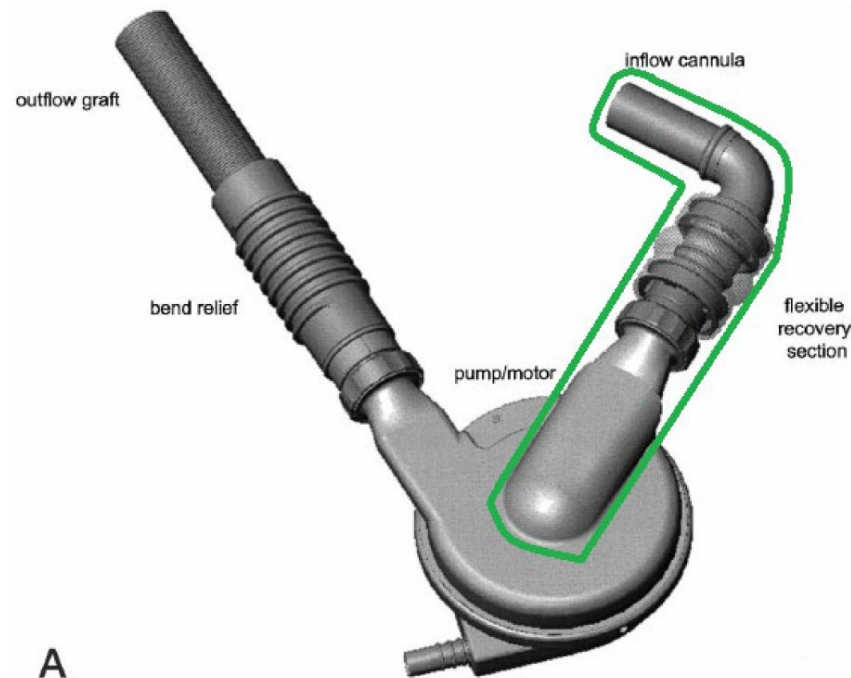


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Id. at 54; Ex. 1007, Fig. 3. This figure shows a human chest region with internal features identified as the “Heart” (labeled as such in a red outline)

and an implanted heart assist pump device (labeled “HeartMateIII LVAD” in a blue outline). *Id.* Petitioner identifies an element colored green in as “an inflow subassembly . . . that includes a left ventricular (LV) cannula,” which Petitioner asserts corresponds to “an inflow tube defining a blood inflow path,” as required by claim 1 of the ’077 patent. *Id.* (emphasis omitted).

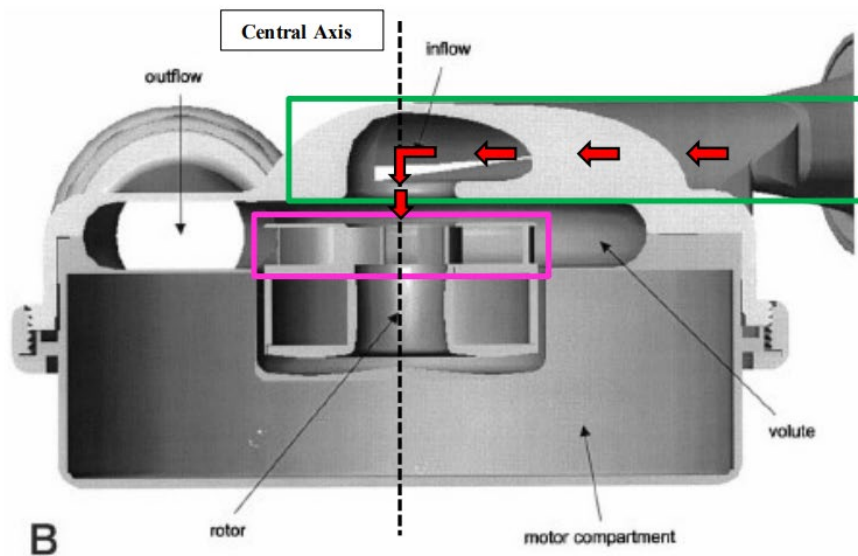
Petitioner also provides an annotated version of Figure 1A of Bourque, reproduced below.



Id. at 53. Figure 1A 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” or “inflow subassembly.” Pet. 52–54. Figure 1A illustrates that the “inflow

cannula” and “flexible recovery section” form a right angle prior to the connection with the “pump/motor.” *Id.* at 53.

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 axis” of the “inflow subassembly” (corresponding to the recited “inflow tube”).



Id. at 55–56. Petitioner’s annotated version of Figure 1B 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, ¶ 471. 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, ¶421.

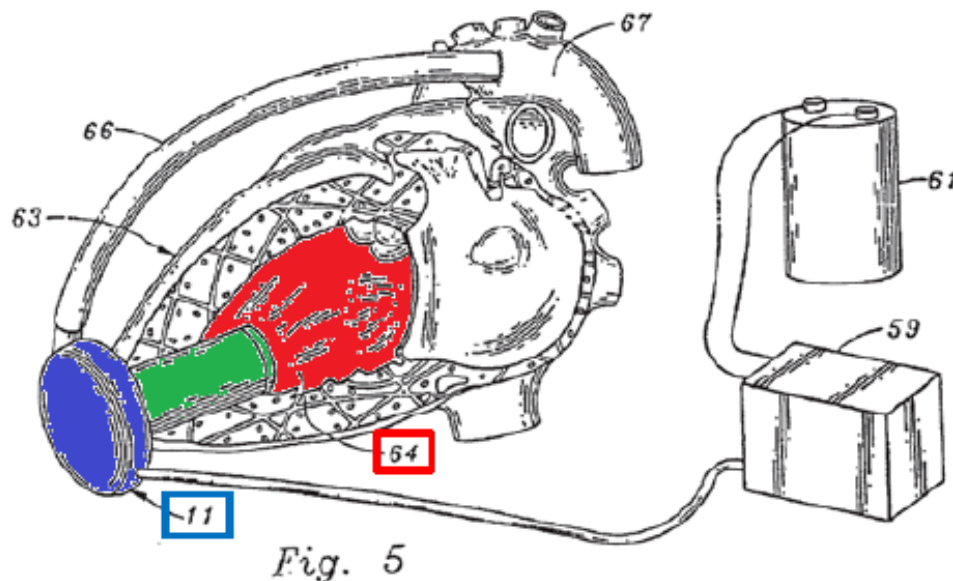
Id. (emphases omitted). Petitioner identifies the entire inflow subassembly of Bourque as corresponding to the recited “inflow tube,” and it is plainly clear from Figures 1A and 1B of Bourque that the central/inflow axis of Bourque’s inflow subassembly is not axially aligned with the rotor. To show the 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.* (emphasis omitted, alteration in original). We find on the current record Petitioner’s arguments unconvincing.

As Patent Owner explains, “the rotor’s axis in Bourque is perpendicular to the inflow tube,” and “Bourque recognizes that this configuration, with the inflow tube perpendicular to the rotor, ‘resulted in a sharp bend in the flow before it enters the impeller.’” Prelim. Resp. 43–44 (citing Ex. 1007, 2). We also agree with Patent Owner that the claim language requires “that the inflow tube and the rotor are axially aligned—not the flow.” *Id.* at 44. 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 appear likely to reflect reality. As Patent Owner explains, it is known that “the blood does not make a 90 degree turn as illustrated by Petitioner,” because “Petitioner published a computational fluid dynamics analysis of the HeartMate III pump (including Mr. Bourque

as an author), showing that the flow is not so simple.” *Id.* at 45–46 (citing Ex. 2005,⁹ 874, 878, Fig. 6).

In sum, on the current record we agree with Patent Owner that Petitioner fails to sufficiently show that Bourque, alone, teaches a rotor “axially aligned” with the inflow tube, as required by claim 1. Petitioner, however, alternatively also relies on Wampler as teaching a rotor “axially aligned” with an inflow tube and the “inflow axis” of the inflow tube, which we turn to next.

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



Pet. 56. 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.* Patent Owner does not dispute

⁹ Greg W. Burgreen et al., *Computational Fluid Dynamics Analysis of a Maglev Centrifugal Left Ventricular Assist Device*, 28 *Artificial Organs* 874–80 (2004).

Petitioner’s contention that the inflow tube is axially aligned with the rotor taught by Wampler. We find Petitioner sufficiently shows, at this stage, how Wampler teaches a rotor assembly is “axially aligned” with the inflow tube, as required by claim 1.

2. *Combining Wampler and Bourque*

Petitioner offers several reasons a person of ordinary skill in the art would have found it obvious to include Wampler’s “techniques related to its *axially aligned inflow tube*” in the HeartMateIII device taught by Bourque. Pet. 81–88. Petitioner argues that Wampler teaches an arrangement for which “[g]ood anatomic compatibility is possible . . . fitting well between the apex of the heart and the adjacent diaphragm.” *Id.* at 83 (quoting Ex. 1008 ¶ 76) (alterations in original). Petitioner reasons that applying Wampler’s arrangement to Bourque combines old elements performing known functions yielding expected results. *Id.* at 83–84. According to Petitioner, a person of ordinary skill in the art would have known from Wampler that an axial inflow, as taught by Wampler, would have improved blood flow for the device of Bourque by eliminating the flow restrictive elbow in Bourque. *Id.* at 84 (citing Ex. 1003 ¶¶ 648–649; Ex. 1007, 2; Ex. 1008 ¶¶ 75–76). Petitioner contends that Bourque recognized certain components, including inflow components, were the cause of clinical troubles, and that Wampler “taught how to eliminate these components that caused clinical troubles—using the inlet to also ‘serve[] as the inflow canula.’” *Id.* at 85–86 (citing Ex. 1003 ¶¶ 741–747; Ex. 1007, 1, 5; Ex. 1008 ¶¶ 75–76).

Petitioner also argues that a person of ordinary skill in the art would have understood Wampler’s arrangement would have reduced “rates of infection” by avoiding placement of the pump in a preperitoneal pocket

position, as taught by Bourque. *Id.* at 84–85. According to Petitioner, a person of ordinary skill in the art “would have adhered to the express teachings of [Wampler], which focused on ‘[g]ood anatomic compatibility’ so that the device ‘fit[s] 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.” *Id.* at 86–87 (citing Ex. 1003 ¶¶ 651–654; Ex. 1008 ¶ 76) (second and third alterations in original).

Petitioner reasons that a person of ordinary skill in the art would have had a reasonable expectation of success because the asserted combination of Bourque and Wampler “would ‘fit[] well between the apex of the heart and the adjacent diaphragm’ due to the pump’s ‘development as a compact’ device and the existence of several similar LVADs that fit well at that position.” *Id.* at 87 (citing Ex. 1003 ¶¶ 652–655; Ex. 1007, 5). Lastly, Petitioner argues that the asserted combination would have been obvious to try, because “there were a finite number (i.e., two) [of] 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 ¶ 656).

At this stage, we find Petitioner’s arguments persuasive, and find that Petitioner has provided sufficiently articulated reasoning with rational underpinning to support combining Wampler and Bourque’s teachings in the manner Petitioner does.

At this stage, we find unavailing Patent Owner’s arguments that Petitioner’s rationale for the asserted combination is insufficient because: (1) Petitioner ignores the “reasons, stated expressly in Bourque, for keeping the HeartMate III pump where it is, instead of moving it as required by the proposed combination,” and (2) “the Bourque pump is too big to fit” in the

position taught by Wampler that Petitioner relies upon. Prelim. Resp. 47–50.

As to the first argument, Patent Owner directs us to portions of Bourque that state the pump is placed in the “least obtrusive position,” uses a “sharp bend” in the inflow to allow for placement in that location, and provides “freedom of movement” to reduce “potential tissue trauma.” *Id.* at 47–49 (citing Ex. 1007, 2, 5; Ex. 2004,¹⁰ 387; Ex. 2006,¹¹ 310, 311). At this stage, the evidence discussed by Patent Owner suggests that the named inventor of Bourque may have believed that the placement of the pump of Bourque provided certain benefits. It does not, however, address, for example, whether those benefits would have been lost in the asserted combination or whether a person of ordinary skill in the art would have understood the benefits of the asserted combination outweighed any detriments. Patent Owner’s arguments are unsupported by expert testimony, and are not convincing on the current record.

For similar reasons, Patent Owner’s bodily incorporation argument that Bourque’s pump would not fit in the location of Wampler is not convincing on the current record. Patent Owner argues that Wampler’s pump fits between the apex of the heart and the adjacent diaphragm because “the pump casing is compact and disk-shaped.” *Id.* at 50 (quoting Ex. 1008 ¶ 76). Patent Owner then makes the unsupported, conclusory assertion that

¹⁰ Howard M. Loree II et al., *The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device*, 25 *Artificial Organs* 386–391 (2001).

¹¹ David J. Farrar et al., *Design Features, Developmental Status, and Experimental Results With the Heartmate III Centrifugal Left Ventricular Assist System With a Magnetically Levitated Rotor*, *American Society of Artificial Internal Organs (ASAIO) Journal* 310–315 (2007).

“Bourque does not have such a compact disc,” and that due to “the size of its ‘motor compartment,’” Bourque’s pump “will not fit well between the apex of the heart and the adjacent diaphragm.” *Id.* at 51. Further, according to Patent Owner, “Petitioner has admitted that significant, patentable, engineering changes needed to be made in order to reduce the size of HeartMate III so that it would fit in the way that Wampler does.” *Id.* at 51–52 (citing Ex. 2007,¹² 5–7; Ex. 2008,¹³ 375; Ex. 2009;¹⁴ Ex. 2010,¹⁵ 5).

We have considered the evidence identified by Patent Owner and find Patent Owner’s characterization of that evidence as an “admission” is not supported. For example, relying on a later patent to show that it included “inventive activity to redesign the pump to be small enough to work,” is not an admission by Petitioner “that significant, patentable, engineering changes needed to be made in order to reduce the size of HeartMate III so that it would fit in the way that Wampler does.” *See id.*

And, the arguments raised by Patent Owner, based in part on attorney argument and mischaracterized evidence, does not convince us that Petitioner’s rationale supporting the asserted combination is insufficient for

¹² Abbott, *A Father of HeartMate 3 Wants A Bigger Family*, available at <https://www.abbott.com/corpnewsroom/productsand-innovation/a-father-of-heartmate-3-wants-a-biggerfamily.html> (December 16, 2021).

¹³ Kevin Bourque et al., *Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System for Hemocompatibility*, ASAIO J. 375–83 (2016).

¹⁴ US 10,500,321 B2, issued Dec. 10, 2019.

¹⁵ American Heart Association News, *The past, present and future of the device keeping alive Carew, thousands of HF patients*, available at <https://www.heart.org/en/news/2018/06/13/the-past-present-and-future-of-the-device-keeping-alive-carew-thousands-of-hf-patients> (June 13, 2018).

purposes of institution. In addition, we find unavailing Patent Owner’s argument that “Petitioner essentially includes a laundry list of obviousness buzzwords but does not actually provide a coherent rationale for the contended combination.” *Id.* at 10 (citing Pet. 81–88). As we discuss above, at this stage, we find Petitioner has provided sufficiently articulated reasoning with rational underpinning.

3. Remaining Limitations

Patent Owner does not dispute that the combination of Wampler and Bourque teaches the remaining limitations of claim 1. *See* Prelim. Resp. After reviewing Petitioner’s arguments and cited evidence, at this stage, we are persuaded that Petitioner sufficiently demonstrates, with citations to Wampler and Bourque’s specific teachings and the testimony of Mr. Crosby, that all of the limitations of claim 1 are taught. And, we thus find unavailing Patent Owner’s argument that Petitioner “fails to meet its burden of identifying ‘with particularity’ the evidence that supports its asserted obviousness grounds.” *Id.* at 12.

4. Summary

In sum, at this stage, we determine that Petitioner shows a reasonable likelihood that it would prevail in showing that claim 1 would have been obvious to one of ordinary skill in the art in view of Wampler and Bourque.

D. Challenged Claims 2–5, 7, 10, 16–24, 26, and 28

At this stage, Patent Owner does not provide separate, additional arguments addressing Petitioner’s arguments and evidence as to how the

combination of Wampler and Bourque teaches claims 2–5, 7, 10, 16¹⁶–24, 26, and 28. *See* Prelim. Resp.

After reviewing Petitioner’s arguments and cited evidence, at this stage, we find Petitioner’s showing for these claims sufficient for institution. Pet. 74–80. And, we find unavailing Patent Owner’s argument that Petitioner fails to identify with particularity the evidence that supports its arguments for these claims. Prelim. Resp. 12. At this stage, we find Petitioner’s cross references to its arguments are sufficiently clear.

VI. ALLEGED OBVIOUSNESS OVER WAMPLER

Petitioner contends that the subject matter of claims 1–5, 7, 10, 16–24, 26, and 28 would have been obvious over Wampler. Pet. 16–52. Petitioner already has demonstrated a reasonable likelihood of success in proving that at least one claim is unpatentable. *See supra* Section V.C. We, however, provide the below guidance to the parties for this asserted ground.

The parties dispute, among other things, whether Wampler teaches “a first magnetic device that is . . . axially adjacent to a rotor,” as required by claim 1. Pet. 20–22; Prelim. Resp. 20–23. As explained above (*supra* Section III), for purposes of this Decision, we find Petitioner incorrectly argues that a magnetic element sealed within a rotor equates to being axially adjacent. And Petitioner’s argument that Wampler teaches this limitation is premised on Petitioner’s incorrect construction. Pet. 20–22. Thus, Petitioner’s showing is insufficient.

Moreover, we agree with Patent Owner that “Wampler cannot teach or suggest a first magnetic device that is axially adjacent to a rotor based on

¹⁶ Our reasoning for claim 1 also applies to Patent Owner’s arguments made concerning similar limitations of independent claim 16. *See supra* Section V.C.1–2.

the positioning of its magnet segments 88 and impeller 74 because these components are not adjacent to one another as measured along the central or inflow axis of the device.” Prelim. Resp. 23 (citing Ex. 1008 ¶ 18, Figs. 3, 4, 7, 9, 11, 13, 15, 17, 19).

Accordingly, at this stage, we find Patent Owner’s argument refuting Petitioner’s contention that the challenged claims would have been obvious over Wampler has substantial merit.

VII. ALLEGED OBVIOUSNESS OVER AKAMATSU

Petitioner argues that claims 1–5, 7, 10, 16–24, 26, and 28 would have been obvious over Akamatsu. Pet. 16–52. Petitioner already has demonstrated a reasonable likelihood of success in proving that at least one claim is unpatentable. *See supra* Section V.C. We, however, provide the below guidance to the parties for this asserted ground.

A. *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, 1.¹⁷ Akamatsu explains that “the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, [and] it is expected to be one of the most durable blood pumps.” *Id.*

B. *First Magnetic Device Axially Adjacent to Rotor*

The parties dispute, among other things, whether Akamatsu teaches “a first magnetic device that is . . . axially adjacent to a rotor,” as required by

¹⁷ We cite to the page numbers of the exhibit as added by Petitioner.

claim 1. Pet. 93–94; Prelim. Resp. 56–58. As explained above (*supra* Section III), for purposes of this Decision, we find Petitioner incorrectly argues that a magnetic element sealed within a rotor equates to being axially adjacent. And Petitioner’s argument that Akamatsu teaches this limitation appears premised on Petitioner’s incorrect construction. Pet. 20–22. Thus, Petitioner’s showing is insufficient.

Moreover, we agree with Patent Owner that Akamatsu instead teaches that “the permanent magnets [(i.e., first magnetic device)] and impeller [(i.e., rotor)] are aligned with, and overlap, one another as measured along the central or inflow axis [in Akamatsu’s] configuration.” Prelim. Resp. 58 (citing Ex. 1006, Fig. 2).

Accordingly, at this stage, we find Patent Owner’s arguments refuting Petitioner’s contention that the challenged claims would have been obvious over Akamatsu have substantial merit.

VIII. ALLEGED OBVIOUSNESS OVER AKAMATSU AND SCHIMA

Petitioner argues that claims 1–5, 7, 10, 16–24, 26, and 28 would have been obvious over the combination of Akamatsu and Schima. Pet. 115–145. Petitioner already has demonstrated a reasonable likelihood of success in proving that at least one claim is unpatentable. *See supra* Section V.C. We, however, provide the below guidance to the parties for this asserted ground.

A. *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 its 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.

*B. Independent Claim 1*¹⁸

Petitioner argues that Schima discloses “a rotary pump for moving blood” that is “deliver[ed] to the heart.” Pet. 115–118 (emphasis omitted). Petitioner relies on Schima as teaching or suggesting the features of the pump of claim 1, including, for example, that Schima’s pump “has ‘inlet 13’ [‘an inflow tube defining a blood inflow path along an inflow axis’],” a “rotor 1” that “holds rotor magnets 6 that preferably transfer rotation energy” (“magnetically driven rotor”), a first magnetic device “rotor magnets 6” and “the magnetically driven rotor (‘rotor 1’) ‘being rigidly coupled and axially adjacent to a first magnetic device (‘rotor magnets 6’) that is axially aligned with the inflow axis.’” *Id.* at 118–122 (citing Ex. 1005 ¶ 12, Fig. 2) (emphasis omitted). Petitioner argues that inlet 13 of Schima’s pump corresponds to an inflow tube with a suction end “insertable into a left ventricle [of the heart].” *Id.* at 116–118. According to Petitioner, a person of ordinary skill in the art would have had reason to “implant [Schima’s] pump” in the configuration described by Akamatsu “because the teachings are complimentary,” and “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 145 (citing Ex. 1003 ¶¶ 1128–1129, 1139–1140).

¹⁸ Our reasoning also applies to independent claim 16, for which the parties provide similar arguments.

Petitioner concedes that Schima “does [not] expressly disclose” an “external control unit . . . to regulate operation,” as required by claim 1. *Id.* at 133; *see also id.* at 134–135. Petitioner relies on Akamatsu as teaching the recited control unit. *Id.* at 134 (citing Ex. 1006, Fig. 1). According to Petitioner, a person of ordinary skill in that art “would have had a reasonable expectation of success that [Schima’s] pump would be controlled and implanted according to [Akamatsu’s] teachings” because “[e]xternal controllers were commonly employed to regulate operation of LVADs” and “LVADs were routinely delivered to the heart with a suction end inserted into the left ventricle.” *Id.* at 145 (citing Ex. 1003 ¶¶ 1129, 1139–1140; Ex. 1008 ¶¶ 72, 75; Ex. 1007 1–3; Ex. 1006, 4).

In opposition, Patent Owner argues that Schima is deficient because it is “silent regarding placement of its disclosed pump, and includes no disclosure regarding delivery of its disclosed pump to a heart.” Prelim. Resp. 68. However, claim 1 does not require placement in a body or actual delivery of the device to the heart. In fact, claim 1 merely requires “a system” that includes a device “deliverable to the heart” and an inflow tube “insertable” into a ventricle of the heart. Similarly, Patent Owner’s argument that “[t]here is simply no teaching or suggestion in Schima that it would have even been possible to implant its disclosed pump within the body” is misplaced. *Id.* at 69. Nor does Petitioner need to show that Schima’s inlet tube was “designed to be . . . inserted into a ventricle of the heart,” as Patent Owner suggests. *Id.* at 69–70. The relevant issue is whether a person of ordinary skill would have known that the apparatus disclosed by Schima would have been “deliverable to the heart” and that Schima’s inflow tube would have been “insertable into a ventricle of the

heart.” Accordingly, Patent Owner’s arguments appear on the current record to be outside the scope of claim 1.

Patent Owner also argues “[i]t is simply not clear from Akamatsu that the reference discloses delivering its pump to a heart such that an inflow tube is inserted into a ventricle of the heart.” *Id.* at 70–71. Patent Owner, however, only provides attorney argument purporting to explain how a person of ordinary skill in the art would have understood what is shown, for example, in Figure 1 of Akamatsu. Moreover, Patent Owner’s arguments, as explained above, appear on the current record to be outside the scope of claim 1.

Patent Owner also argues that neither reference teaches or suggests, an external control unit connectable to the pump. *Id.* at 72–73. For example, Patent Owner argues that Petitioner “should not be allowed” to rely on Figure 1 of Akamatsu because it is “a low-resolution conceptual illustration of a potential ‘future’ system.” *Id.* at 73. Patent Owner’s argument lacks evidence of how a person of ordinary skill in the art would have understood the teachings of Akamatsu. By contrast, Mr. Crosby supports Petitioner’s contention and offers an explanation for why a person of ordinary skill in the art would have understood Akamatsu to disclose an external controller. *See* Ex. 1003 ¶¶ 982–990.

IX. WORD COUNT LIMITS

Petitioner’s Certificate of Compliance states that the Petition “complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,911 words (as determined by the Microsoft Word word-processing system used to prepare the brief and including annotated figures), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.” Pet. 149.

Patent Owner argues that we should deny the Petition because it uses

improper formatting to circumvent the 14,000-word count limit set by 37 C.F.R. § 42.24. Prelim. Resp. 74–75. In particular, Patent Owner asserts that the “Petition regularly omits a space when citing to exhibits (e.g., ‘Ex.1001’ vs. ‘Ex. 1001’), the expert’s declaration (e.g., ‘¶¶54–55’ vs. ‘¶¶ 54–55’), and statutes (e.g., ‘§102’ vs. ‘§ 102’).” *Id.* at 74 (citing *Axon Enterprise, Inc., v. Digital Ally, Inc.*, IPR2017-00375, Paper 9 at 2 n.2 (PTAB June 6, 2017)). According to Patent Owner, “these citations occur so frequently that at least 1,036 words have been improperly undercounted” (*id.* at 74–75), and “[t]he result is an advantage to Petitioner and undue prejudice to Patent Owner” (*id.* at 75).

Patent Owner further asserts that “the Petition attempts an additional massive circumvention of the word count limit by omitting analysis for about half of the challenged claims.” *Id.* at 76. According to Patent Owner, in each of the asserted grounds, Petitioner addresses certain claims by referencing non-identical elements of other claims, “in most cases without any additional analysis.” *Id.* at 76–77.

With respect to Patent Owner’s assertions about word count limits, the Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 (“Consolidated TPG”) states that “deleting spacing between words, or using excessive acronyms or abbreviations for word phrases, in order to circumvent the rules on word count, may lead to a party’s brief not being considered.” Consolidated TPG, 40 (citing *Pi-Net Int’l, Inc. v. JPMorgan Chase & Co.*, 600 F. App’x 774 (Fed. Cir. 2015)). As the basis for denying the Petition, Patent Owner alleges “undue prejudice.” Prelim. Resp. 75. Patent Owner, however, did not raise with the Board, prior to filing its Preliminary Response, any concern with the manner in which Petitioner formatted its Petition. As a result, Patent Owner did not avail itself of the

opportunity to seek relief to address any alleged undue prejudice short of denying the Petition through, for example, an increase in the word count for its own brief. *See* 37 C.F.R. § 42.24(a)(2).

Under the circumstances presented, we do not find denial of the Petition warranted based on the alleged improper formatting.¹⁹

X. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown a reasonable likelihood that it would prevail in proving the unpatentability of at least one of the challenged claims of the '077 patent. We thus institute an *inter partes* review of all of the challenged claims on all grounds asserted in the Petition.

Any findings or conclusions in this Decision are made only for the purposes of institution and are not dispositive of any issue. We have not made a final determination with respect to the patentability of any challenged claim. Our final determination will be based on the record as fully developed during trial, including any evidence or argument timely presented by the parties under our Rules.

XI. ORDER

In consideration of the foregoing, it is hereby:

¹⁹ Patent Owner also broadly argues that the Petition should be denied as “incomplete” because Petitioner did not identify differences between the prior art and the challenged claims, did not propose modifications to the asserted art, and failed to assert rationales for obviousness. Prelim. Resp. 1, 8–16 (arguing, additionally, that the Petition lacks particularity and that Mr. Crosby’s declaration “often” mirrors the Petition). We have considered all of Patent Owner’s arguments and have determined Petitioner made a sufficient showing in the Petition to support institution, as explained herein.

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '077 patent is instituted on all of the challenged claims and all grounds asserted in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial commences on the entry date of this Decision.

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