

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATRIUM MEDICAL CORPORATION,
Petitioner,

v.

BARD PERIPHERAL VASULCAR, INC.,
Patent Owner.

IPR2021-01197
Patent 7,959,615 B2

Before GRACE KARAFFA OBERMANN, JAMES A. TARTAL,
and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. §§ 314, 325(d)

Atrium Medical Corporation (“Petitioner”) filed a Petition for *inter partes* review challenging claims 8, 9, and 11 of U.S. Patent 7,959,615 B2 (Ex. 1001, “the ’615 patent”). Paper 2 (“Pet.”). Bard Peripheral Vascular, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). Petitioner filed an authorized Preliminary Reply and Patent Owner filed an authorized Preliminary Sur-Reply. Paper 9 (“Prelim. Reply”); Paper 10 (“Prelim. Sur-Reply”).¹

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314 (2018). However, the Board has discretion to deny a request for institution when the information presented shows a petitioner raises “the same or substantially the same prior art or arguments previously presented to the Office.” 35 U.S.C. § 325(d).

After reviewing the parties’ submissions, for the reasons stated below, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

¹ Petitioner requested leave to file a reply “to address Patent Owner’s arguments under 35 U.S.C. § 314 (a).” Ex. 2030, 1–2 (email correspondence between counsel for Petitioner and the Board dated November 11, 2021, and November 12, 2021). The Board granted Petitioner’s request and authorized Petitioner to file a reply and Patent Owner to file a sur-reply. *Id.*

I. INTRODUCTION

A. REAL PARTIES-IN-INTEREST

Petitioner and Patent Owner each, respectively, identifies itself as a real party-in-interest. Pet. 45; Paper 7, 1. Patent Owner also identifies “C.R. Bard, Inc., and Becton, Dickinson and Company” as real parties-in-interest. Paper 7, 1.

B. RELATED MATTERS

Petitioner states “[t]he ’615 Patent is currently subject to two ongoing litigations: *C.R. Bard v. Medical Components*, No. 2:12-cv-00032 (D. Utah), and *C.R. Bard v. AngioDynamics*, No. 1:20-cv-01544 (D. Del.). Petitioner is not a party to either litigation.” Pet. 46. Patent Owner identifies these same district court litigations as related matters. Paper 7, 1. Patent Owner also identifies that IPR2021-00199 directed to U.S. Patent 7,785,302, and IPR2021-01200 directed to U.S. Patent 7,047,022, are related matters because the patents are in the same family as the ’615 patent. *Id.* at 1–2.

C. THE ’615 PATENT

The ’615 patent issued on June 14, 2011, from U.S. Application 12/023,280, which was filed on January 31, 2008. Ex. 1001, codes (45), (21), (22). On its face, the ’615 patent ultimately claims priority to U.S. Provisional 60/658,518, filed on March 4, 2005. *Id.* at code (60), 1:6–13.²

1. *The ’615 Patent’s Claimed Invention and Disclosure*

The ’615 patent concludes with 11 claims, of which claims 1 (not challenged), 8, and 10 (not challenged) are independent claims. Ex. 1001,

² Petitioner does not dispute that the ’615 patent is entitled to priority to this provisional application. *See* Pet. 13.

12:52–14:29. Claim 8 is illustrative of the challenged claims and is reproduced below:

8. An access port for providing subcutaneous access to a patient, comprising:

a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and

at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

Id. at 13:23–14:7. Challenged claim 9 depends from claim 8 and challenged claim 11 depends from unchallenged independent claim 10, which is similar to claim 8, but is directed to a method of identifying the access port by palpating its structural features. *Id.* at 14:8–29.

The '615 patent's Abstract states:

An access port for subcutaneous implantation is disclosed. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, the access port may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation. Methods of identifying a subcutaneously implanted access port are also disclosed. For example, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted

access port may be identified in response to perceiving the at least one feature.

Id. at Abstract.

For context, the '615 patent explains, as background, that “[a]ccess ports provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures,” that such ports “permit the infusion of medicine, parenteral solutions, blood products, or other fluids” and “may also be used for blood sampling.” *Id.* at 1:16–23. The '615 patent further explains that when “a port is implanted within the body [its] the catheter is routed to a remote area where a fluid is desired to be delivered” and “to deliver the fluid, a caregiver locates the septum of the port by palpation of a patient’s skin” and “percutaneously insert[s] a needle . . . through the septum of the port and into the reservoir” to inject fluid. *Id.* at 1:31–37. The '615 patent explains that such ports may be used, for example, for chemotherapy, blood sampling, or saline infusion, may be surgical or cosmetic, and may or may not be “power injectable.” *Id.* at 1:37–2:21. The '615 patent explains that “power injectable” means that the access port “may be injected and pressurized by mechanical assistance,” as opposed to by hand via a syringe and needle. *Id.* at 3:45–49.

An exemplary access port as described and claimed, as it would be implanted in a patient, is illustrated by the '615 patent at Figure 1B, reproduced below:

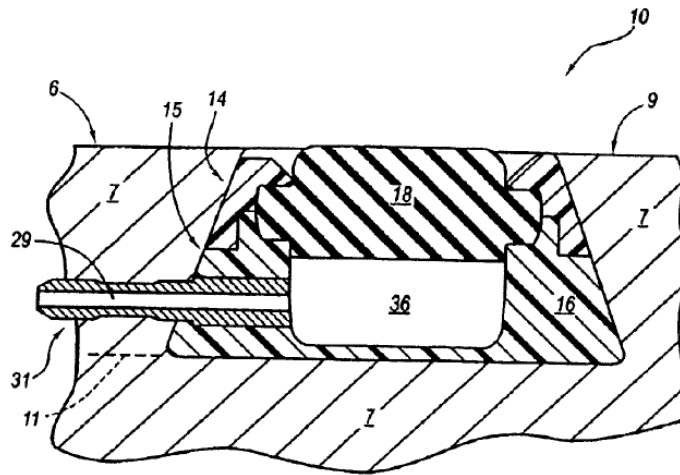
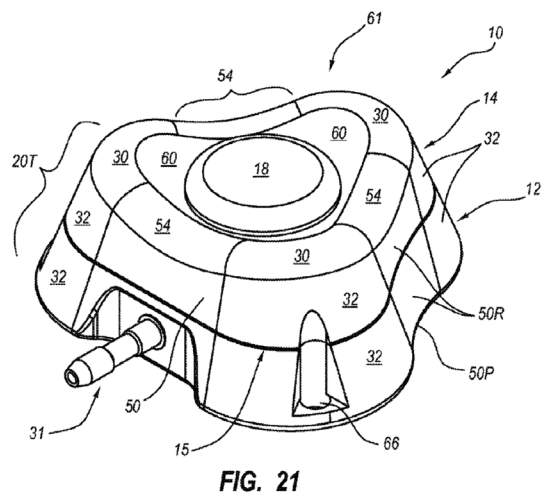
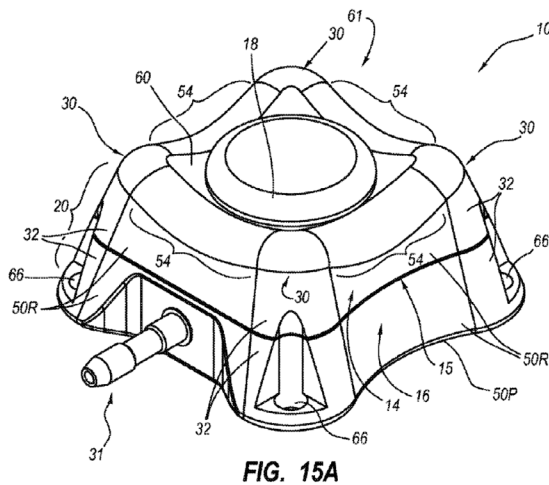


FIG. 1B

Figure 1B, above, “shows a schematic side cross-sectional view” of “an access port according to the ’615 patent’s disclosure.” *Id.* at 2:32–35.

Figure 1B illustrates the percutaneous nature of access port 10 in use as it shows it disposed in cavity 36 subcutaneously within a patient’s tissue 7. *Id.* at 4:27–5:46. Access port 10 is shown to include cap 14 and base 16 with mating line 15, septum 18, and outlet stem 31 with lumen 29. *Id.*

More detailed, perspective views of such injection ports, as claimed, are illustrated by the ’615 patent at Figures 15A and 21, which are reproduced below:



Figures 15A (above-left) and 21 (above-right) show two embodiments of access port 10 having different shapes. *Id.* at 2:64–65, 3:11–12. Figure 15A shows access port 10 having housing 20, cap 14, base 16, septum 18, and outlet stem 31 (as in Fig. 1B, above). *Id.* at 4:27–5:46, 8:62–9:9. Figure 15A shows access port 10 to be defined by four side surfaces 50 connected to each other by radii 32, and having upper topography 61 defined by upper surface 60 and rounded corner regions 30. *Id.* Figure 21 shows access port 10 having all these same features, but rather than being defined by four sides, its structure is “generally triangularly-shaped” and is “defined by three side surfaces” 50. *Id.* at 10:22–41. Both embodiments include “a concave portion 50P of a bottom perimeter that bounds or shapes a bottom surface of the access port” and this concave shape extends up side surface 50R. *Id.* at 9:4–9, 10:35–37. In each embodiment, the upper topography 61, upper surface 60, side regions 54, and rounded corner regions 30, or the concave bottom 50P and side(s) 50R “is identifiable after implantation” or “provides a configuration “having at least one feature that may be perceived by palpation.” *Id.* at 9:7–9, 10:37–41.

The '615 patent describes that the perceivable feature of its access ports, which is perceivable after the port is implanted in a patient, may correlate to information about the access port such as manufacturer, model or design, port type, catheter type, manufacture date, material lots, part numbers, or whether the access port is power injectable. *Id.* at 3:62–4:12. The '615 patent further describes that the perceivable feature may be perceived by palpation (touch), visual observation, x-ray, ultrasound imaging, magnetic energy, light, radio energy, or “communication” with the access port. *Id.* at 4:17–26.

2. *The '615 Patent's Procedural History*

The unique procedural history of the '615 patent warrants discussion. As noted above, prosecution of the application that became the '615 patent began January 31, 2008. During prosecution, numerous references were submitted to or uncovered by the Examiner and are listed on the face of the '615 patent as having been considered by the Examiner, including U.S. Patent 5,045,060 (Ex. 1008, “Melsky”) and U.S. Publication 2005/0075614 (Ex. 1007, “Bunodiére”), each of which are prior art references asserted in Petitioner's challenges in this proceeding. Ex. 1001, code (56), 2, 4; Ex. 2006, 1, 2; Ex. 2007, 1, 2; Pet. 6. Although indicated as considered by the Examiner, neither Melsky nor Bunodiére were expressly cited in any office action or rejection of the claims during prosecution. *See generally* Ex. 1002 (prosecution history). The prosecution of the '615 patent involved several office actions where the Examiner rejected the claims over prior art and otherwise, and several responses to those office actions including claim amendments. *Id.* Ultimately, the application and its claims were allowed by the Examiner, who indicated that “the prior art of record fails to disclose

either singly or in combination the claimed device and method of identifying an implanted access port that has concave sides, including the interface between the side and the base being concave.” *Id.* at 1290. This Examiner’s statement of reasons for allowance was disavowed by the Applicant. *Id.* at 1316. The ’615 patent subsequently issued on June 14, 2011, as noted above. *See id.* at 1337; Ex. 1001, code (45).

In the year following its issuance, the ’615 patent was subject to *Inter Partes* Reexamination No. 95/002,092 where all claims (1–11) were challenged as unpatentable over European Patent Application Publication EP 1 238 682 A2 (Ex. 1005, “Reuter”), U.S. Patent 4,626,244, and the “Representative Knowledge” of the ordinarily skilled artisan as illustrated by U.S. Patent 5,919,160 (Ex. 1006, “Sanfilippo”), Bunodiére, Patent Application WO2004/004800, Patent Application WO 2004/091434 (Ex. 2014), and U.S. Patent 5,476,460. Ex. 2008, 1–3, 27–35.³ Of this reexam-cited prior art, Reuter, Sanfilippo, and Bunodiére are asserted in Petitioner’s challenges in this proceeding. Pet. 6; *see also infra* Section I.D. (summary of asserted grounds for unpatentability). Ultimately, this reexamination resulted in the Office determining claims 1–10 (and not 11) were unpatentable over this prior art. Ex. 1009, 11–16.

The Examiner’s decision on the claims in reexamination was appealed to the Board. *Angiodynamics, Inc. Respondent v. C.R. Bard, Inc.*, Appeal No. 2015-004506, 2016 WL 1166545 (PTAB March 24, 2016). The Board affirmed-in-part the Examiner’s rejections of the ’615 patent’s claims,

³ Although not expressly cited in a challenge or rejection of the claims on reexamination, Melsky was before and considered by the Examiner. Ex. 2012, 5.

affirming the rejection of claims 1–5 and 8–10 over Reuter, Sanfilippo, and Bunodiére, and reversing all other rejections. *Id.* Of note, in rendering the decision, the Board construed the claim language “at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation,” recited in claim 8, as *encompassing structural features capable of identifying an access port as power injectable after implantation*; however, in analyzing the claims in view of the prior art, the Board found that “claim 8 does not recite that the claimed access port assembly is power injectable.” *Id.* at *7, *13. In its decision, the Board provided an analysis of the relevant teachings of Reuter, Sanfilippo, and Bunodiére. *Id.* at *7–*10.

Patent Owner appealed the Board’s decision to the U.S. Court of Appeals for the Federal Circuit. *C.R. Bard, Inc., v. Angiodynamics, Inc.*, 748 F. App’x 1009 (Fed. Cir. 2018) (unpublished). As applicable to the ’615 patent, the Federal Circuit vacated the Board’s decision that claims 8 and 9 of the ’615 patent were obvious and remanded for further consideration by the Board. *Id.* Central to the Federal Circuit’s decision was its determination that the language of claim 8 requires that the claimed access port is “power injectable,” contrary to the Board’s analysis. *Id.* at 1015–17. The Federal Circuit’s remand to the Board was for the purpose of determining whether, under the correct claim construction requiring power injectable access ports, the claims would have been obvious over the prior art of record. *Id.* at 1021.

On remand from the Federal Circuit, the Board modified its original decision and reversed the Examiner’s rejection on the obviousness of claims 8 and 9. *Angiodynamics, Inc. Respondent v. C.R. Bard, Inc.*, Appeal No.

2015-004506, 2019 WL 411126 (PTAB Jan. 29, 2019). Pursuant to the Federal Circuit’s claim construction, the Board found that “the [C]ourt’s decision is clear ‘that the claimed access port is power injectable,’” and that the Board’s “review of the record does not indicate that Reuter, or any of the other references relied upon in the proposed and adopted rejections of claims 8 and 9, disclose a power injectable access port. Prior art evidence as to a power injectable access port is missing from the rejections at issue.” *Id.* at *2.

D. SUMMARY OF ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts the following grounds for the unpatentability of claims 8, 9, and 11 of the ’615 patent:

Ground	Claims Challenged	35 U.S.C. § ⁴	Reference(s)/Basis
1	8, 11	103	Reuter, Sanfilippo, Melsky
2	9	103	Reuter, Sanfilippo, Melsky, Bunodiene

See Pet. 6. In support of the grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Boris Leschinsky (Ex. 1003).

We review Petitioner’s asserted prior art below.

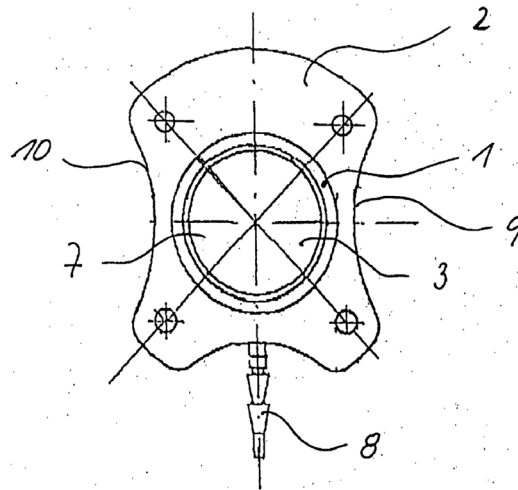
E. REUTER

Reuter is a European Patent Office Application published on September 11, 2002, filed as Application No. 02004983.9 on March 6, 2002. Ex. 1005, codes (43), (21), (22). Reuter’s Abstract states that:

⁴ The ’615 patent has a filing and issue date before March 16, 2013, which is date the AIA revisions to 35 U.S.C. § 103 took effect. 35 U.S.C. § 100 (note). Therefore, pre-AIA § 103 applies. Our decision, however, is not impacted by which version of the statute applies.

The invention relates to a port for an implantable port system comprising at least one port with a housing (1), a catheter connection (8), and catheter. The housing (1) of the port has, on both sides, at least one concave cut-out (9, 10) parallel to the axis of the catheter connection (8). In one embodiment the concave cut-outs (9, 10) are arranged in a base plate (2) on the housing (1).

Id. at Abstract. For context, Reuter includes the following, single illustration of such a port:



The figure above illustrates a port, seemingly viewed from above, as described in the above-quoted Abstract, including reference numbers to indicate housing 1, base plate 2, septum 3, catheter connection 8, concave cut-outs 9, 10. *Id.* ¶¶ 12–14. Reuter states that “[t]he advantage of the port . . . consists in that the port can be handled securely during implantation and especially during the fastening of the catheter.” *Id.* ¶ 10. Moreover, Reuter invites the structural design of its concave cut-outs 9, 10 in “existing ports . . . through equivalent cut-outs.” *Id.* ¶ 16.

F. SANFILIPPO

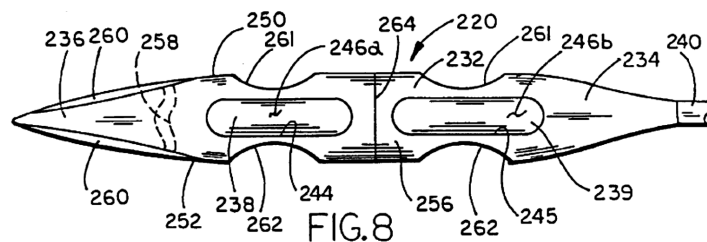
Sanfilippo issued on July 6, 1999, from U.S. Application 08/728,825, which was filed on October 10, 1996. Ex. 1006, codes [45], [21], [22].

Sanfilippo's Abstract states:

A vascular access device is provided which can be used for chronic venous or organ access. When implanted, the device facilitates repeated intermittent infusions of medical treatment while reducing the risk of infection at the implant site. The vascular access device comprises an elongated body and a delivery tube coupled to the elongated body for delivering the medical treatment to a preselected site in a patient's body, which permits subcutaneous implanting of the device with a minimally invasive procedure. . . .

Id. at Abstract. Sanfilippo states that its invention “provides an access opening to the access chamber that is elongated longitudinally with the implant body,” where “tactile identification structures in registry with the access opening of the implant body facilitate locating the access opening once implanted, and two separate access chambers with a tactile differentiation structure permit two separate access, openings to be located and distinguished after implanting.” *Id.* at 3:18–25.

A vascular access device is illustrated by Sanfilippo at Figure 8, which is reproduced below:



The reference states that “FIG. 8 is a plan view of [an] embodiment of the vascular access device of the present invention.” *Id.* at 4:49–50. Figure 8

shows vascular access device 220 with elongated implant body 232 and two access openings 244, 245, where curved indentations 261, 262 are in sidewalls 250, 252 to assist a medical practitioner in tactilely identifying the precise location of elongated access openings 244, 245 once vascular access device 220 is implanted. *Id.* at 8:4–17. Further, “[r]aised ridge 264 permits a medical practitioner to tactilely differentiate between access openings 244 and 245 in order to ensure that a needle is inserted into the correct access chamber 238, 239.” *Id.* at 8:35–39.

G. MELSKY

Melsky issued September 3, 1991, from U.S. Application 343,914, which was filed on April. 26, 1989. Ex. 1008, codes [45], [21], [22].

Melsky’s Abstract states its invention is directed to

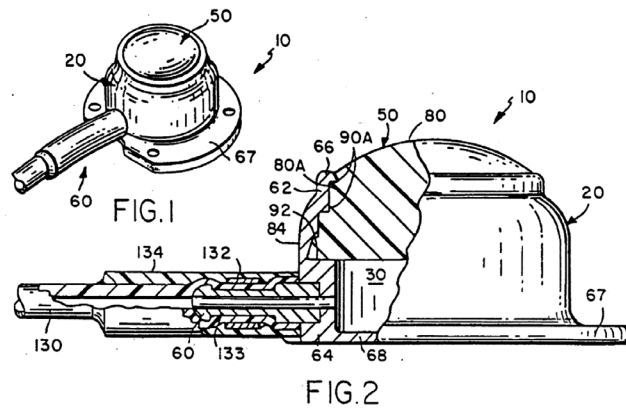
An improved infusion device is of the type which can be implanted for drug delivery within a patient’s body, and supplied with infusate without the need for surgical removal. The infusion device has a housing forming a chamber and an entry port into the chamber. The entry port is closed by a septum. The septum has a convex top section extending from the housing, and a frusto-conical section which matingly engages a similarly shaped interior surface of the housing. The interior surface can be provided with a plurality of notches with which the septum engages by material flexure. This arrangement improves retention of the septum and operation of the infusion device, and permits advances in the method by which such devices are manufactured.

Id. at Abstract.

Melsky discloses that, using ports as described in the Abstract, “[i]nfusate is injected into the port by means of a conventional hypodermic syringe,” through a septum, into a chamber. *Id.* at 1:11–2:25. Melsky indicates its invention provides an infusion port or portal with an improved

septum and housing configuration, with a rounded-smooth atraumatic profile, eliminating dead space where body fluid or fibrin can collect. *Id.* at 3:50–59.

An illustration of such an infusion port is provided by Melsky at Figures 1 and 2, reproduced below:



Figures 1 and 2, above, show an infusion port, with Figure 1 showing it from a perspective view and Figure 2 showing it from a side, partial-cut-away view. *Id.* at 4:41–45. The figures show infusate portal 10 with cup-like housing 20, and self-sealing septum 50 covering chamber 30. *Id.* at 4:56–68. Melsky explains that “[t]he infusion portal 10 is accessed by means of a conventional hypodermic syringe (not shown)—i.e., the syringe needle penetrates the septum 50 and injects a fresh charge of infusate into the chamber 30.” *Id.* at 5:3–7. Figure 2 shows interfitting notches 80A and 90A that retain the septum 50, and Melsky explains that the “interfitting notches 80A and 90A prevent blowouts due to internal pressure. Thus, while known prior art infusion devices can handle internal pressures of 125 psi, the

improved retention arrangement just described can safely accommodate pressures of 200 psi or more.”⁵ *Id.* at 6:33–38.

H. BUNODIERE

Bunodiére is the April 7, 2005, publication of U.S. Application 10/692,727, which was filed October 27, 2003. Ex. 1007, codes (43), (21), (22). Bunodiére’s Abstract states:

The invention relates to a chamber for the infusion of a medicament, which chamber comprises a reservoir (15), an outer casing (17) having a base wall (19) and a lateral wall (21), a region for access to the reservoir, and a duct (27) for the diffusion of the medicament. According to the invention, the contour of the base wall is substantially triangular, the casing (17) has a shape tapered in a direction (Y), and the terminal portion (27a) of the diffusion duct extends transversely, and preferably perpendicularly, to the direction of tapering.

Id. at Abstract.

⁵ It is specifically this portion of Melsky that Petitioner cites as teaching a power-injectable access port, as claimed. *See* Pet. 27, 31, 36; *see also* Ex. 1003 ¶¶ 66, 70, 74 (analyzing Melsky and concluding it teaches a power injectable port, as claimed). We note that Melsky never expressly mentions a power injectable port. *See generally* Ex. 1008. Petitioner’s witness relies on Melsky’s disclosure that its port can withstand pressures of 200 psi or more as inherently disclosing a power injectable port; however, the witness merely concludes this without citation to supporting evidence. This is meager evidence of an alleged inherent disclosure intended to be a foundation of Petitioner’s challenges in this proceeding. “Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.” 37 C.F.R. § 42.65(a); *see TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358–59 (Fed. Cir. 2019) (“conclusory expert testimony is inadequate to support an obviousness determination on substantial evidence review.”).

proceedings as they relate to other proceedings and actions, and part (d) states:

(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

Thus, Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office.⁶ *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

In evaluating the exercise of discretion to deny institution under Section 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, Paper 6 at 8.

⁶ The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

In applying the two-part framework, we consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
- (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”).

Becton, Dickinson factors (a), (b), and (d) relate to whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we consider whether petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this

framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

B. SAME OR SUBSTANTIALLY THE SAME ART OR ARGUMENTS
PREVIOUSLY PRESENTED TO THE OFFICE

Under the *Advanced Bionics* framework, we first consider whether Petitioner asserts the same or substantially the same art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8. Here, undeniably, the same prior art was previously presented to the Office.

We discussed the unique procedural history of the ’615 patent above at Section I.C.2 and identified that the prior art asserted by Petitioner, i.e., Reuter, Sanfilippo, Melsky, and Bunodiére, was presented and of record before the Office. Melsky and Bunodiére were first cited in an Information Disclosure Statement during the prosecution of the application that would issue as the ’615 patent, they were then indicated by the Examiner as having been considered, and were then listed among the references cited during prosecution on the face of the ’615 patent once it issued. Ex. 2006, 1, 2; Ex. 2007, 1, 2; Ex. 1001, code (56), 2, 4. As also discussed above, Reuter, Sanfilippo, and Bunodiére were cited in and were a primary focus of *Inter Partes* Reexamination No. 95/002,092 concerning the ’615 patent, and were analyzed by the Examiner, the Board, and the Federal Circuit. *See* Ex. 2008, 1–3, 27–35; *Angiodynamics*, Appeal No. 2015-004506, 2016 WL 1166545; *C.R. Bard*, 748 F. App’x 1009; *Angiodynamics*, Appeal No. 2015-004506, 2019 WL 411126; Ex. 2008; Ex. 2009; Ex. 2011; Ex. 2012, 5, 10, 14, 21; *see also* Ex. 2012, 5 (Melsky was of record and considered as well).

Under *Advanced Bionics*,

The factors set forth in *Becton, Dickinson* should be read broadly, however, to apply to any situation in which a petition

relies on the same or substantially the same art or arguments previously presented to the Office during a proceeding pertaining to the challenged patent. For example, although *Becton, Dickinson* factors (a) and (b) pertain to art evaluated “during examination,” these factors more broadly provide guidance as to whether the art presented in the petition is the “same or substantially the same” as the prior art previously presented to the Office during *any* proceeding, including prior AIA proceedings. Similarly, although *Becton, Dickinson* factor (d) pertains to arguments made “during examination,” this factor more broadly provides guidance as to whether the arguments presented in the petition are “the same or substantially the same” as the arguments previously presented to the Office during *any* proceeding.

Advanced Bionics, Paper 6 at 10. Thus, if the prior art asserted by Petitioner here was presented to the Office during *any* proceeding concerning the ’615 patent (or its application), e.g., during prosecution, a reexamination, or a prior AIA proceeding, *Advanced Bionics* requires us to consider *Becton, Dickinson*’s factors (a) and (b) as satisfied.⁷

Because Reuter, Sanfilippo, Melsky, and Bunodiene, i.e., the same prior art as asserted here, were before the Office during prosecution of the ’615 patent and during reexamination and the subsequent related proceedings, we find that the same or substantially the same art was

⁷ We note Petitioner’s assertion that “this IPR is the first time the Board has been asked to evaluate the patentability of the claims under prior art disclosing “power-injectable access ports,” however, this is not the first time the issue was considered by the Office. Prelim. Reply 5. To the contrary, during prosecution of the application that would issue as the ’615 patent, the applicant and Examiner each addressed whether the claim limitation regarding the “access port as being power injectable” was obvious. *See* Ex. 1002, 12, 1134, 1225–26.

previously presented and we move on to the second part of the *Advanced Bionics* framework.

C. WHETHER PETITIONER HAS SHOWN THE OFFICE ERRED IN A
MANNER MATERIAL TO PATENTABILITY

Because we find that the same or substantially the same art that is the basis for Petitioner's challenges here was previously presented to the Office, we turn to analyzing whether Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 8, 10; *see Becton, Dickinson*, Paper 8 at 24. We conclude that Petitioner has failed to do so.

Patent Owner argues that Petitioner has "failed to identify any material error in the examination or reexamination that would have led to rejection of the challenged claims." Prelim. Resp. 22. Moreover, according to Patent Owner, Petitioner "does not attempt to point to any error by the Examiner in the original prosecution, notwithstanding the fact that Melsky was before the Office" and Petitioner "likewise does not point to any error by the Board in its decision following remand in the *AngioDynamics* Reexam, . . . or the Examiner's decision not to issue a new ground[] for rejection." *Id.* Patent Owner is correct.

Having searched the Petition, we discern no express assertion that *any* error was committed by the Office in ultimately allowing and upholding the patentability of the claims in the '615 patent. Petitioner discusses the '615 patent's prosecution, reexamination, Board appeal, Federal Circuit appeal, and Board remand at length and in detail, urges that the findings by the Office, Board, and Federal Circuit concerning the prior art were correct concerning certain prior art asserted (Reuter, Sanfilippo, and Bunodiére), notes that other prior art (i.e., Melsky) was not expressly analyzed, but never

expressly asserts, or even mentions that any error or mistake occurred. Pet. 1–3, 9–16; *see also* Prelim. Reply (Petitioner’s Reply was authorized on *every* issue expressly requested by Petitioner, which did not include the dispute or evidence concerning Section 325(d)—*see infra* n.1).

Petitioner leaves the Board to guess or develop its own theory on what error may have been committed in prior proceedings over the ’615 patent where the now-asserted prior art was at issue. Under the circumstances here, we find such speculation unwarranted. To the extent that Petitioner implies that the Examiner erred by failing to recognize that Melsky inherently teaches a power injectable port, we do not agree. *See supra* note 5.

Moreover, we agree with Patent Owner that, even if Melsky was not previously singled out in any proceeding before the Office, the prosecution history demonstrates that the Examiner engaged with the prior art and the “power injectable” limitation, and that Petitioner has not sufficiently demonstrated how the Examiner erred in the evaluation of this claimed feature. *See* Prelim Resp. 20–21; *Advanced Bionics*, Paper 6 at 9 (“[I]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”). For example, in an office action response dated January 8, 2010, the applicant expressly pointed out the claim limitation the “access port as being power injectable,” arguing the Examiner’s rejection conceded the cited prior art failed to disclose the feature. Ex. 1002, 12. This was followed by more than one Office Action where the Examiner indicated that a power injectable access port was still obvious to the ordinarily skilled artisan, thus expressly addressing the issue for which Melsky is now asserted. Ex. 1002, 1134, 1225–26.

Thus, we find that Petitioner has not persuasively shown that the Office erred in a manner material to the patentability of the challenged claims.

D. CONCLUSION ON SECTION 325(d)

For the reasons set forth above, we exercise our discretion to not institute review of claims 8, 9, and 11 of the '615 patent because, under 35 U.S.C. § 325(d), the same or substantially the same art previously was presented to the Office, and Petitioner has not shown that the Office erred in a manner material to patentability.

III. CONCLUSION

For the foregoing reasons, we exercise discretion not to institute *inter partes* review under 35 U.S.C. § 325(d).

ORDER

Accordingly, it is hereby:

ORDERED that the Petition is *denied* and no *inter partes* review is instituted.

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Patent 7,959,615 B2

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