

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATRIUM MEDICAL CORPORATION,
Petitioner,

v.

BARD PERIPHERAL VASCULAR, INC.,
Patent Owner.

IPR2021-01200
Patent 7,947,022 B2

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

TARTAL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Atrium Medical Corporation (“Petitioner”)¹ filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–14, 16, and 18–20 (“the Challenged Claims”) of U.S. Patent No. 7,947,022 B2 (Ex. 1001, “the ’022 patent”). Paper 2 (“Pet.”). Bard Peripheral Vascular, Inc. (“Patent Owner”)² filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). 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 for leave, authorized Petitioner to file a preliminary reply to the Patent Owner Preliminary Response, as requested, and further authorized Patent Owner to file a sur-reply thereto. *Id.* Subsequently, as authorized, Petitioner filed a Reply (Paper 9, “Prelim. Reply”) and Patent Owner filed a Sur-reply (Paper 10, “Prelim. Sur-reply”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . 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). The Board has discretion to deny a request for institution when the information presented shows that the petitioner raises “the same or substantially the same prior art or arguments previously presented to the Office,” for example, during patent examination or

¹ Petitioner identifies only itself as a real party in interest. Pet. 65.

² Patent Owner identifies itself, C.R. Bard, Inc., and Becton, Dickinson and Company, as real parties in interest. Paper 5, 1.

re-examination. 35 U.S.C. § 325(d) (“Section 325(d)”). For the reasons stated below, upon consideration of the arguments and evidence, we exercise our discretion to deny institution of *inter partes* review of the ’022 patent under Section 325(d).

II. BACKGROUND

A. The ’022 Patent

The ’022 patent, titled “Access Port Identification Systems and Methods,” issued from Application No. 12/420,028, filed on April 7, 2009, a continuation of Application No. 11/368,954 (“the ’954 App.”), filed on March 6, 2006, which issued as U.S. Patent No. 7,785,302 (the ’302 patent”). Ex. 1001 codes (21), (22), (54), (63). The ’022 patent also refers back to Provisional Application No. 60/658,518 (“the ’518 App.”), filed on March 4, 2005. *Id.* at code 60. The ’022 patent states that both the ’954 App. and the ’518 App. are each “incorporated, in its entirety.” *Id.* at 1:6–13.

The ’022 patent states that it is directed to “an access port for subcutaneous implantation,” and more specifically, to “an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient.” *Id.* at 2:67–3:2, 3:31–34. The ’022 patent discloses that its “access port may be injected by hand (e.g., via a syringe including a needle) for example, or may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port).” *Id.* at 3:12–18. Thus, the “at least one identifiable feature of an access port may be correlative with the access port being power injectable.” *Id.* at 3:46–48. In one embodiment, the “at least one identifiable feature may be perceived via X-ray or ultrasound imaging.” *Id.* at 3:58–59.

Figure 1A, reproduced below, shows an access port in accordance with the disclosure of the '022 patent:

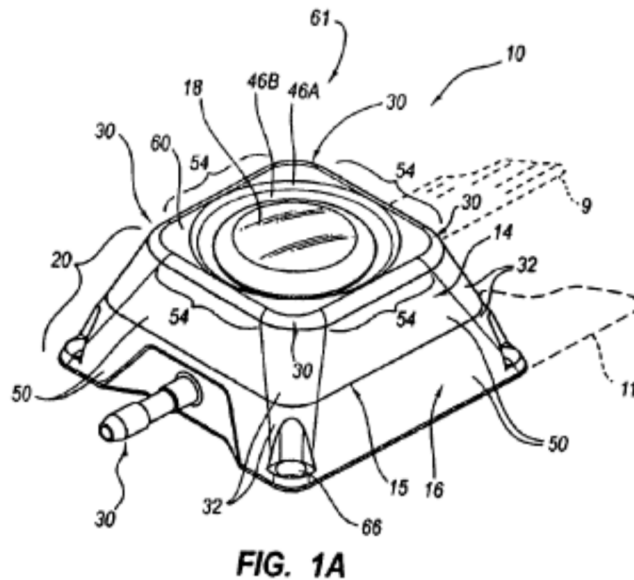


Figure 1A is a perspective view of an access port. Ex. 1001, 3:63–4:5; Fig. 1A. Access port 10 has body 20, defined by cap 14 and base 16 that “may be configured for capturing therebetween septum 18.” *Id.* at 4:5–8. Cap 14, base 16, and septum 18 may “collectively define a cavity 36 in fluid communication with a lumen 29 and outlet stem 31” (shown in Figure 1B). *Id.* at 4:14–16. Once body 20 is implanted, the upper surface of septum 18 “may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the cavity 36.” *Id.* at 4:21–26. Outlet stem 31 (shown in Figure 1B) provides “a fluid-communicative passageway” from cavity 36 to the interior of a patient. *Id.* at 4:26–29.

Figure 52, reproduced below, shows an access port in accordance with an embodiment described in the '022 patent:

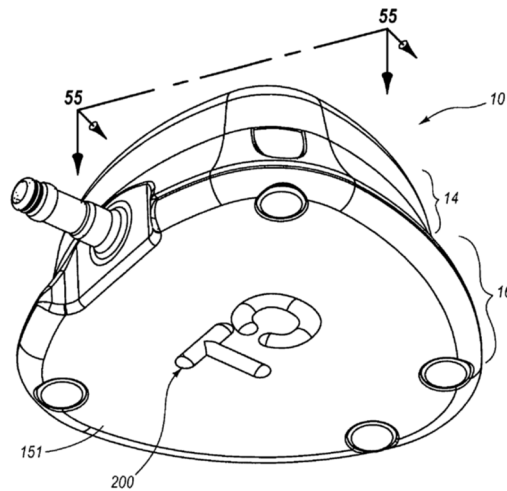


FIG. 52

Figure 52 shows “a bottom perspective view of an access port 10,” including lower surface 151 of base 16 with identification feature 200. *Id.* at 11:11–22. “[I]dentification feature 200 can be one or more alphanumeric characters, such as the ‘CT’ depicted [in Figure 52].” *Id.* at 11:22–24. “[T]he identification feature 200 can convey information to a practitioner regarding the power-injectability of the implanted access port.” *Id.* at 11:30–33. The '022 patent further explains that “[t]he ‘CT’ is engraved mirror-reversed so that when imaging technology, such as X-ray imaging, is used to identify a subcutaneously implanted access port, the ‘CT’ will be visible in the proper orientation.” *Id.* at 11:43–47.

B. Illustrative Claim

Petitioner challenges claims 1–14, 16, and 18–20 of the '022 patent. Pet. 1. Claims 1, 10, and 16 are independent and each is directed to an “access port assembly for providing subcutaneous access to a patient.” Ex. 1001, 15:12–21, 16:1–9, 16:24–32. Claims 2–9 depend from claim 1,

claims 11–14 depend from claim 10, and claims 18–20 depend from claim 16. *Id.* at 15:22–46, 16:10–20, 16:36–44. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. An access port for providing subcutaneous access to a patient, comprising:
 - a body defining a fluid cavity accessible by inserting a needle through a septum; and
 - at least one radiopaque identification feature of the access port observable via imaging technology subsequent to subcutaneous implantation of the access port, the at least one radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power-injectable.

Id. at 15:12–21.

C. *Asserted Grounds of Unpatentability*

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §	References/Basis
1–14, 16, 18–20	103	Eliassen, ³ Melsky, ⁴ Lee ⁵
1–14, 16, 18–20	103	Bardport, ⁶ Herts, ⁷ Lee

³ U.S. Patent App. Pub. No. 2004/0204692 A1, published October 14, 2004 (Ex. 1009, “Eliassen”).

⁴ U.S. Patent No. 5,045,060, issued September 3, 1991 (Ex. 1008, “Melsky”).

⁵ U.S. Patent No. 5,203,777, issued April 20, 1993 (Ex. 1010, “Lee”).

⁶ Various screenshots of webpages within the Bardaccess.com website collected by Petitioner purportedly describing Bard Access System’s suite of access port devices (Exs. A and B of Ex. 1012, “Bardport”).

⁷ Herts et al., *Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, and Efficacy*, AMERICAN JOURNAL OF ROENTGENOLOGY 176:447–54, February 2001 (Ex. 1020, “Herts”).

Pet. 6. Petitioner relies on the supporting Declaration of Boris Leschinsky, dated July 12, 2021 (Ex. 1003).

D. Related Proceedings

The parties identify a number of proceedings as related matters. Pet. 65; Paper 5, 1–2. According to the parties, the '022 patent is a subject of: (1) *C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. v. Medical Components*, No. 2:12-cv-00032 (D. Utah) (the “MedComp Action”); (2) *C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. v. Smiths Medical ASD, Inc.*, No. 1:20-cv-01543 (D. Del.); and (3) *C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. v. AngioDynamics*, No. 1:20-cv-01544 (D. Del.) (the “AngioDynamics Action”).⁸ Pet. 65; Prelim. Resp. 11; Paper 5, 1. Petitioner states that it is not a party to any of these district court proceedings. Pet. 65. According to Patent Owner, the MedComp Action and the AngioDynamics Action “have been pending since 2012.” Prelim. Resp. 14–15, 53. In the MedComp Action the district court “invalidated challenged claims 1, 3, 5, 8–10, 12, and 14 of the '022 patent under 35 U.S.C. § 101 at the summary judgment stage” and that determination “has been certified for appeal to the Federal Circuit.” Prelim. Resp. 53; PO Sur-Reply 6; *see also* Pet. Reply 1 (stating that Patent Owner appealed the decision in the MedComp Action and that the defendant in the AngioDynamics Action “has requested dismissal to allow it to participate in a coordinated appeal” of the decision in the MedComp Action) (citing Exs. 1047–1049).

⁸ According to Patent Owner, the AngioDynamics Action was filed in Utah and captioned *C.R. Bard, Inc. v. AngioDynamics Inc.*, No. 2:12-cv-00035 (D. Utah) prior to being transferred to Delaware. Prelim. Resp. 11 n.1.

Additional related matters identified by Patent Owner include U.S. Patent Application Nos. 16/389,732, 17/102,316, and 17/164,560, which claim priority to the '518 App. Paper 5, 2. The parties also note that the '302 patent is the subject of *Atrium Medical Corp. v. Bard Peripheral Vascular, Inc.*, IPR2021-01199, and that U.S. Patent No. 7,959,615, which claims priority to the '302 patent as a continuation, is the subject of *Atrium Medical Corp. v. Bard Peripheral Vascular, Inc.*, IPR2021-01197. Pet. 65; Paper 5, 2

III. ANALYSIS

Below we briefly summarize the scope and content of the asserted prior art, as well as the procedural history of the '022 patent, and then address discretionary denial of the Petition under Section 325(d). We conclude that discretionary denial of the Petition is appropriate under the circumstances for the reasons provided below.

A. Scope and Content of the Asserted Prior Art

Petitioner relies on Eliasen, Melsky, Lee, Bardport, and Herts, each of which we briefly summarize in relevant part below.

1. Summary of Eliasen

Eliasen, titled "Implantable Vascular Access Device," relates to "an implantable access port having a needle-penetrable, self-sealing septum which affords repeated access to a fluid cavity in communication with a catheter." Ex. 1009, code (54), ¶ 1. According to Eliasen, "[c]ontinual access involves the use of a non-coring needle attached to an ambulatory-type pump or a gravity feed IV bag suspended above the patient" and "[t]he ambulatory-type pump or the IV bag continually feeds the medication or fluid through the needle to the fluid cavity in the access port and from there through the catheter to the entry point into the venous system." *Id.* ¶ 14.

Figure 2 of Eliassen, reproduced below, shows an exemplary implantable access port:

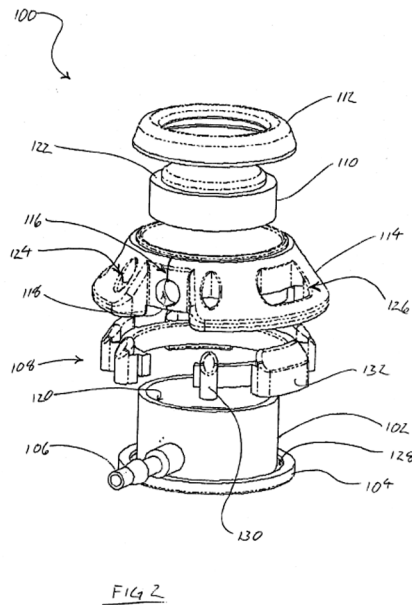


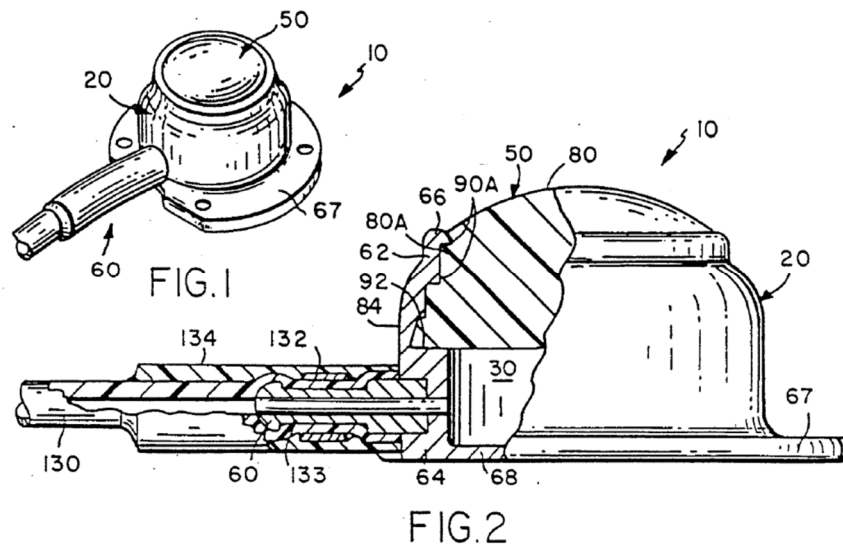
Figure 2 is an exploded perspective view of an implantable access port. *Id.* ¶ 32. Single access port 100 includes septum 110 surrounded by ring cap 112, suture ring or body component 114 that defines the overall profile and geometry of the access port, and stem 106 that extends from a sidewall of the access port and is “in fluid communication with a fluid chamber internal of the access port.” *Id.* ¶ 40. Access port 100 also includes chamber body 102 that “defines an open-ended fluid chamber” and has bottom portion 104. *Id.* ¶¶ 41–42. Septum 110 “may allow ingress and egress of needles to deliver fluid to the fluid chamber.” *Id.* ¶ 49. Further, septum 110 “may be provided with tactile features allowing percutaneous identification of a specific port.” *Id.*

2. Summary of Melsky

Melsky, titled “Implantable Infusion Device,” relates to a device “which can be implanted for drug delivery within a patient’s body, and supplied with infusate without the need for surgical removal.” Ex. 1008,

code (54), 1:5–9. Melsky discloses that, using ports as described, “[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’s device 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.

Figures 1 and 2 of Melsky are 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” and states that “while known prior art infusion devices can handle internal pressures

of 125 psi,” the arrangement described in Melsky “can safely accommodate pressures of 200 psi or more.” *Id.* at 6:33–38.

3. *Summary of Lee*

Lee, titled “Radiopaque Marker System for a Tubular Device,” teaches “a tubular device meant to be inserted into an object and imaged with an X-ray source,” which “is especially suited for use in a medical environment.” Ex. 1010, code (54), 1:6–8, 1:11–12. Lee discloses that in order to properly place devices such as a cannula within a patient’s body, “a physician or radiologist typically uses an X-ray photograph or a fluoroscope to examine the location of the cannula within the body.” *Id.* at 1:49–59. Lee provides a tubular device that comprises “a body having an outer circumference and including a distal end and a radiopaque marker located on the body adjacent the distal end thereof.” *Id.* at 2:49–52. In one embodiment, a device is provided with “a diamond shaped marker.” *Id.* at 7:42–43. In another embodiment, a device is provided with a radiopaque marker in the form of a “letter E.” *Id.* at 8:3–4.

4. *Summary of Bardport*

Petitioner identifies Bardport as “a collection of related publically available webpages within the Bardaccess.com website describing Bard’s suite of access port devices.” Pet. 18. Specifically, Petitioner directs us to Exhibit 1012 as an affidavit “demonstrating that the related webpages were publically available,” along with “screenshots of the Bardport webpages and the dates on which they were publicly available.” *Id.* The first two pages of Exhibit 1012 are an “Affidavit of Duncan Hall” stating that: (1) the pages attached to the affidavit as “Exhibit A” are “true and accurate copies of screenshots of the Internet Archive’s records of the archived files for the URLs and the dates specified in the attached coversheet of each printout,”

and (2) the pages attached to the affidavit as “Exhibit B” are “true and accurate copies of the Internet Archive’s records of the archived files for the URLs and the dates specified in the attached coversheet of each file.” Ex. 1012, 1–2. The Petition cites to Exhibit 1012 as “Bardport” (*see, e.g.*, Pet. 18 (referring to “Ex. 1012 (Bardport)”), yet in the “List of Exhibits” in the Petition, Exhibit 1012 is identified as having a “Short Name” of “Internet Archive Records & Affidavit” (*see* Pet. v). Further potentially confusing what Petitioner contends is “Bardport,” Petitioner cites to various other exhibits in conjunction with its discussion of Bardport. *Id.* at 19 (citing Exs. 1030, 1033, 1037).

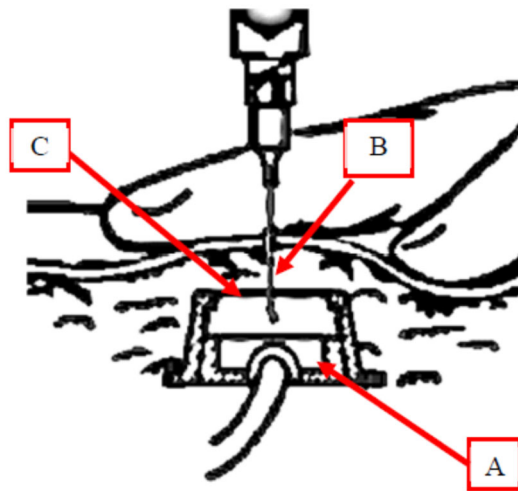
With regard to the sufficiency of Petitioner’s identification of “Bardport,” Patent Owner asserts as follows:

It is unclear which specific exhibits the Petition considers to be part of the “Bardport” reference since it variably cites to Exhibits 1012 and 1030–1040. The Petition and Dr. Leschinsky’s declaration (Ex. 1003) include the Bardport IFU 2003 (Open-Ended) as Exhibit 1019, but do not appear to cite to this exhibit at any point, or indicate whether it forms part of the “Bardport” reference.

Prelim. Resp. 14 n.2. In its Reply to the Preliminary Response, Petitioner does not clarify to what it contends “Bardport” corresponds. *See generally* Prelim. Reply. Based on the Petition, we understand Petitioner to intend its use of “Bardport” to correspond to the webpages that appear in “Exhibit A” and “Exhibit B” of Exhibit 1012. *See, e.g.*, Pet. 20 (discussing webpages that appear in “Exhibit A” and “Exhibit B” of Exhibit 1012 and asserting that “the webpages comprise a single printed publication for purposes of § 102(b)”); *see also id.* at 21 n.4 (asserting that “if the Bardport webpages are found not to be a single prior art publication, then the Bardport webpages

(within the bardaccess.com website attached as Exhibits 1030–1040) individually qualify as prior art references”).

Petitioner contends that Bardport discloses implantable vascular access ports, as shown in the following portion of a figure annotated by Petitioner in the Petition from Bardport taken from a document labeled as “BardPort Implanted Ports with Groshong Catheters Instructions For Use”:



Pet. 21–22 (citing Ex. 1012, 44). According to Petitioner, Bardport discloses the structure of the Bardport device as having “a body defining a fluid cavity (A) accessible by inserting a needle (B) through septum (C).” *Id.* (citing Ex. 1012, 44; Ex. 1040, 6).

Also included by Petitioner as part of Bardport is a screenshot of a webpage with the heading “Frequently Asked QUESTIONs Regarding Bard Catheters,” which includes the following:

QUESTION: Can catheters be used in the Radiology Department with the Power Injector?

ANSWER: Catheters have not been evaluated with the use of Power Injectors. The recommended psi for all Access products is 25 psi. There are many different power injectors and many cannot be set in millimeters of Mercury (mmHg). The formula, $51.7 \text{ mmHg} = 1 \text{ psi}$ may help to determine the ability to utilize the injector. Two articles on

the subject may be of help: 1) *Power Injection of Intravenous Contrast Material Through Central Venous Catheters*; Herts, B.; RADIOLOGY; Volume 200; Number 3, 1996 and 2) *Power Injection with Peripherally Inserted Central Catheters*; Rivitz, S.M., Sambuto, J.A.: Scientific Paper; Session 7; 1996

Ex. 1012, 27–28.⁹ We note from the question and answer in Bardport reproduced above that the only article identifying “Herts” as the author has the following citation:

Power Injection of Intravenous Contrast Material Through Central Venous Catheters; Herts, B.; RADIOLOGY; Volume 200; Number 3, 1996.

Id. In the Petition, Petitioner relies on a reference it identifies as Herts with the following citation:

Herts *et al.*, *Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, and Efficacy*, American Journal of Roentgenology 176 (February 2001).

Pet. vi. Although both citations above refer to “Herts” as an author, it is apparent that the citations to the two articles provide different article titles, different publications, and different publication dates. Accordingly, Petitioner’s assertion that “Bardport specifically identifies Herts as ‘on the subject’ of, and ‘of help’ regarding, the use of power injectors with Bard’s venous access port assembly,” is incorrect, because the article Petitioner relies on as Herts is not the article cited in Bardport authored by “Herts.” *See* Pet. 22 (citing Ex. 1012, 27–28; Ex. 1038, 1–2). Mr. Leschinsky’s testimony regarding Bardport on this point is likewise incorrect. *See* Ex. 1003 ¶ 94. Mr. Leschinsky states that “[i]t is my opinion that a [person of ordinary skill in the art] would have been motivated to combine the

⁹ The identical question and answer appears on multiple pages of Exhibit 1012. *See* Ex. 1012, 21–22, 27–28, 33–34.

teachings of Herts . . . because Bardport itself acknowledges Herts’ findings,” and “in response to a ‘frequently asked question’ titled ‘[c]an catheters be used in the Radiology Department with the Power Injector?’ Bardport cites to Herts.” *Id.* (citing Ex. 1012, 21–22). As explained above, Bardport does not cite to Herts, the reference relied upon by Petitioner, but instead refers to a different article identifying “Herts” as the author.

5. *Summary of Herts*

Herts, titled “Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, and Efficacy,” dated 2001, discloses a study of “power-injecting IV contrast media through central venous catheters for CT examinations.” Ex. 1020, 447.¹⁰

Table 1 of Herts is reproduced below:

TABLE 1 Technical Specifications of Central Venous Catheters Evaluated				
Catheter	Size (French)	Internal Diameter (mm)	Pressure Limit (psi)	Flow Rate (mL/sec)
Bardport ^a	9.6	1.6	25	1.5
Leonard ^a double lumen	9.6	1.3	25	2.5
Hickman ^a triple lumen	10	1.0	25	2.0
Arrow ^b triple lumen	7	1.05 (16 gauge × 1)	15	2.0
		0.8 (18 gauge × 2)	15	1.6

^aBard, Salt Lake City, UT.

^bArrow, Reading, PA.

Table 1 shows technical specifications of central venous catheters that were used in the study, which includes a Bardport catheter. *Id.* at 448, Table 1. The “pressure limit” of the Bardport catheter is shown in Table 1 to be 25 psi. *Id.* Herts states that “[s]lower flow rates and lower-iodine-concentration contrast material with lower viscosity were used with central venous catheters to remain within manufacturer’s guidelines of maximum

¹⁰ Citations are to the original pagination of Herts.

pounds per square inch at the inflow into the device.” *Id.* at 449. According to Herts, “vascular enhancement is less for the pulmonary artery and thoracic aorta when injecting through the Bardport and triple-lumen Hickman catheters,” which “should be because of both a reduced concentration of contrast material and slower flow rates.” *Id.* at 451. Herts concludes as follows:

In summary, power injection of IV contrast media through central venous catheters is feasible and safe as a means of IV access when central venous catheters are accessed according to hospital protocols. Power injection of contrast media through indwelling central venous catheters provides an alternative to obtain a bolus IV contrast-enhanced examination when peripheral IV access is inadequate. Careful adherence to protocols and hospital risks to the patient. We suggest that before radiology departments use central venous catheters for power injection, policy guidelines be formed for the use, the monitoring of complications related to the use, and the devices used for the injection of contrast media.

Id. at 452.

B. The '022 Patent's Procedural History

The prosecution of the '022 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. *See generally* Ex. 1002. 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 of an implantable access port that has a radiopaque alphanumeric message to indicate that this port is specifically power injectable.” Ex. 1002, 1052. The '022 patent issued in 2011.

Patent Owner states that, in 2012, the '022 patent and related patents were asserted in the MedComp Action and the AngioDynamics Action, and that in response to the AngioDynamics Action, the defendant in that case requested and was granted *inter partes* reexamination subjecting all claims of the '022 patent to Reexamination No. 95/002,090 (the “AngioDynamics Reexam”). Prelim. Resp. 11. In 2013 the Examiner issued a Right of Appeal Notice rejecting claims 1–20 of the '022 patent, stating in part that “the prior art is not required to teach a power injectable pump since a power injectable pump is not structurally claimed and the alphanumeric message indicating that the assembly is power injectable is not afforded any patentable weight.” Ex. 2011, 26.¹¹

The Examiner’s decision on the claims in reexamination was appealed to the Board. *AngioDynamics, Inc. v. C.R. Bard, Inc.*, Appeal No. 2015-004554, (PTAB March 28, 2016). The Board affirmed the Examiner’s decision rejecting claims 1–20. *Id.* The references relied upon in the proposed and adopted rejections did not include the references Petitioner asserts in this proceeding. *Id.*; *see also* Ex. 2011 (Right of Appeal Notice). In rendering its decision, the Board found that “the recitation limiting the subject matter of claim 1 to an access port having a radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power-injectable port does not limit claim 1 to a power injectable port.” *Id.* at *13.

Patent Owner appealed the Board’s decision. *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748 F. App’x 1009 (Fed. Cir. 2018) (unpublished). As applicable to the '022 patent, the Federal Circuit found that all claims of

¹¹ Citations are to the original pagination of Exhibit 2011.

the '022 patent “mean that the claimed access port is power injectable,” and noted that the prosecution history makes clear that the applicant and the Examiner “both believed the claim language covered power injectable ports, which is consistent with the plain language of the claim.” *Id.* at 1016–17. The Federal Circuit vacated and remanded the Board’s decision with respect to claims 1–20. *Id.* The Federal Circuit’s remand to the Board was for the purpose of determining “whether, under a construction requiring the ports to be power injectable, these claims are obvious in view of the prior art of record.” *Id.* at 1021.

On remand, the Board found that none of the “references relied upon in the proposed and adopted rejections, disclose a power injectable access port,” and that “[p]rior art evidence as to a power injectable access port is missing from the rejections at issue.” *AngioDynamics, Inc. v. C.R. Bard, Inc.*, Appeal 2015-004554 (PTAB Jan. 28, 2019). The Board, therefore, reversed the Examiner’s rejections of claims 1–20 of the '022 patent. *Id.*

Patent Owner further states as follows:

The Examiner then issued a Notice of Intent to Issue a Reexamination Certificate. Ex. 2012 (5/23/19 Notice of Intent). At no point did AngioDynamics submit any comments to the Examiner or petition for reconsideration after the Notice of Intent to Issue a Reexamination Certificate with respect to the power injectability limitation of all claims. *See* MPEP § 2687.01 (permitting comments and noting availability of petitions under 37 C.F.R. § 1.182 for reconsideration on the merits). In short, the Board’s reversal was not challenged and the Office allowed the claims of the '022 patent to stand.

Prelim. Resp. 13.

C. Discretionary Denial of the Petition Under Section 325(d)

Patent Owner asserts that we should deny the Petition under Section 325(d) because the Petition presents the same art and arguments that

the Office previously analyzed and Petitioner fails to show that the Office materially erred. Prelim. Resp. 19–32. Petitioner did not address in the Petition whether discretionary denial under Section 325(d) was warranted. *See generally* Pet. As noted above, Petitioner requested and was granted leave to file a preliminary reply to the Patent Owner Preliminary Response, but Petitioner only requested leave to address whether discretionary denial under 35 U.S.C. § 314(a) was warranted. *See* Ex. 2030, 1–2 (email correspondence between counsel for Petitioner and the Board seeking leave to file replies “to address Patent Owner’s arguments under 35 U.S.C. § 314(a)” and receiving from the Board leave to do so). Consistent with Petitioner’s request for leave to file a reply to address discretionary denial under 35 U.S.C. § 314(a), Petitioner’s Reply to the Patent Owner Preliminary Response does not explicitly address Section 325(d), but it does present arguments pertinent to the exercise of our discretion, which we have taken into consideration and address below. *See generally* Prelim. Reply.

1. Legal Framework of Section 325(d)

We have discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). Section 325 governs AIA proceedings as they relate to other proceedings and actions, and part (d) states as follows:

(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.¹² *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.

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;

¹² The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

- (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 a 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.

2. *Consideration of Whether the Same or Substantially the Same Art Was 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. Petitioner argues that its “grounds are new,” that “the Board’s determinations in the earlier AngioDynamics reexam did not involve any of Petitioner’s primary or secondary references,” and that the Petition is “the first time the Board has been asked to evaluate the patentability of the claims under prior art disclosing ‘power-injectable access ports’—as required by the

Federal Circuit.” Prelim. Reply 5–6. Petitioner’s arguments are unavailing with regard to whether the first part of the two-part framework of *Advanced Bionics* is satisfied.

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 ’022 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. Below we address each of the references relied upon by Petitioner and conclude, based on the information presented, that each of Eliassen, Melsky, Lee, Bardport, and Herts is the same or substantially similar to art previously presented to the Office.

a. Eliassen, Melsky, and Lee

Eliassen, Melsky, and Lee are each cited on the face of the ’022 patent and, therefore, are each the same art previously presented to the Office. Ex. 1001, code (56). Eliassen, Melsky, and Lee each appear on an

Information Disclosure Statement initialed by the Examiner to indicate that each reference was considered during the prosecution of the '022 patent. *See* Ex. 1002, 943, 947, 948. Eliassen, Melsky, and Lee were also each presented during the AngioDynamics Reexam, and marked as considered by the Examiner. Ex. 2013, 5, 6, 17. Patent Owner argues, and we agree, that “[a]ny one of these presentations to the Office is sufficient to satisfy the first prong of *Advanced Bionics*.” Prelim. Resp. 22 (citing *Advanced Bionics*, Paper 6 at 7–8 (“Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent”)).

b. Bardport

Bardport, a collection of screenshots of websites assembled by Petitioner, does not, itself, appear in the prosecution history of the '022 patent. *See generally* Ex. 1002; Ex. 1012. Patent Owner argues that “substantially similar references” to Bardport were before the Patent Office during examination and the AngioDynamics Reexam. Prelim. Resp. 22. According to Patent Owner, Bardport “describes the BardPort, X-Port and SlimPort devices.” *Id.* Patent Owner directs us to the “Extreme Access Bard™ Access Systems, Inc. Product Brochure,” dated 2003 (Exhibit 2021, the “Extreme Access Brochure”), listed on the face of the '022 patent as disclosing the radiopaque rings on the catheters of the X-Port and SlimPort devices. Prelim. Resp. 22; Ex. 1001, code (56). The Extreme Access Brochure was also presented during the AngioDynamics Reexam, and marked as considered by the Examiner. Ex. 2013, 26. Additionally, Patent Owner directs us to the “Bard Access Systems, BardPort, SlimPort, X-Port Instructions for Use,” dated May 2003 (Exhibit 1019, the “Bardport IFU”),

presented to the Office during the AngioDynamics Reexam. Prelim. Resp. 22–23; Ex. 2014, 5. Patent Owner states that the Bardport IFU “discloses much of the same information supposedly taught by the ‘Bardport’ reference, including (1) the BardPort, SlimPort, and X-Port implanted port devices; (2) their pressure limit of 25 psi (Ex. 1019 at 23); and (3) the use of a catheter having a radiopaque ring (*id.* at 2, 17).” Prelim. Resp. 14 n.2. Petitioner offers no argument or evidence to rebut Patent Owner’s assertions regarding the substantial similarity between Bardport and either the Extreme Access Brochure or the Bardport IFU.

Accordingly, we agree with Patent Owner that information previously presented to the Office in the Extreme Access Brochure and in the Bardport IFU is substantially similar to Bardport for the reasons provided above. Petitioner offers no argument or evidence to rebut Patent Owner’s assertions. Moreover, to the extent Petitioner relies on Bardport as disclosing a citation to an article by Herts not included in the Extreme Access Brochure or the Bardport IFU, we find that not to be a persuasive distinguishing feature because, as explained above, the reference relied upon by Petitioner as Herts is not the article cited in Bardport authored by “Herts.” *See supra* Section III.A.4.

c. Herts

Herts does not appear in the prosecution history of the ’022 patent. *See generally* Ex. 1002. Patent Owner argues that “substantially similar references” to Herts were before the Patent Office during examination and the AngioDynamics Reexam. Prelim. Resp. 22. First Petitioner identifies

Costa,¹³ which appears on the face of the '022 patent and is listed on an Information Disclosure Statement as a reference considered by the Examiner during examination and during the AngioDynamics Reexam. *Id.* at 23 (citing Ex. 2008; Ex. 2013); Ex. 1001, code (56). Patent Owner explains in detail how Herts is substantially similar to Costa, as follows:

Costa summarizes and cites to Herts, disclosing that “Herts *et al.* published an *in vivo* study of power injection using central venous catheters in 2001.” Ex. 2029 (Costa) at 38, col. 1. Costa further explains that the implanted ports of Herts “were successfully power injected when pressure limits were set to 100 psi and rates were limited from 1.5 to 2.5mL/sec.” *Id.* at 38, cols. 1–2. Costa also describes that “[t]he authors [of Herts] offer the caveat that each hospital should establish safety protocols for power injection with central venous catheters, as their study included several safeguards that may not be applicable in all clinical settings.” *Id.* at 38, col. 1. Costa thus summarizes the same disclosures of Herts that are relied upon by [Petitioner]. *See, e.g.*, Petition at 23–24 (“Herts concluded that ‘[p]ower injection of contrast media through central venous catheters for CT examination is feasible and safe when set hospital guidelines and injection protocols are followed.’” (citing Herts at 477, 452)).

Prelim. Resp. 23–24.

Second, Patent Owner identifies Sanelli,¹⁴ which appears on the face of the '022 patent and was cited on an Information Disclosure Statement

¹³ Costa, “More Than Skin Deep: An Overview of Iodinated Contrast Media,” J. Ass’n Vascular Access, Vol. 8, No. 4, 2003 (Ex. 2029, “Costa”).

¹⁴ Sanelli, et al., “Safety and Feasibility of Using a Central Venous Catheter for Rapid Contrast Injection Rates.” Am. J. Roentgenology, Vol. 183, Dec. 2004 (Ex. 2025, “Sanelli”). We note that the reference to the “American Journal of Radiology” in the citation to Sanelli on the face of the '022 patent appears to be a typographical error as all of the additional information in the citation corresponds to the article identified as Ex. 2025 appearing in the American Journal of Roentgenology.

during examination and during the AngioDynamics Reexam. Prelim. Resp. 24 (citing Ex. 2008; Ex. 2013); Ex. 1001, code (56). Patent Owner asserts that Sanelli “explicitly cites Herts and discusses its findings,” and that “[c]onsistent with Herts’ own conclusions, Sanelli states that power injection procedures with a Bard device require reduced concentration contrast media, resulting [in] inferior image quality.” *Id.* at 24, 43 (citing Ex. 2025, 1833, col. 1). According to Patent Owner, Sanelli also states that “power injectable ports” were still not available. *Id.* at 43 (quoting Ex. 2025, 1829–30 (“Despite the recent need for central venous access for rapid contrast injection, the manufacturers of both power injectors and central venous catheters have made no recommendations regarding the use of the two devices together”).

Petitioner offers no argument or evidence to rebut Patent Owner’s assertions. We agree with Patent Owner that information previously presented to the Office in Costa and Sanelli is substantially similar to Herts for the reasons provided above.

In sum, Petitioner asserts two grounds of unpatentability, each of which relies on Lee, which was indisputably previously presented to the Office, along with Eliassen and Melsky. Patent Owner also identifies art before the Office that was substantially similar to Bardport and to Herts, which Petitioner does not refute. Accordingly, in view of the above, we find that the statutory purpose of Section 325(d) is implicated for each of the asserted grounds.

3. *Consideration of Whether Petitioner Has Shown the Office Erred in a Manner Material to Patentability*

As explained above, because the information presented shows that the same or substantially the same art that is the basis for Petitioner’s challenges

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. *See Advanced Bionics*, Paper 6 at 8, 10; *see also id.* at 21 (“Petitioner must demonstrate that the Examiner erred in the evaluation of the prior art, for example, by showing that the Examiner misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims”). For the reasons that follow, we find that Petitioner has not made the necessary showing of material error by the Office.

Patent Owner argues, and we agree, 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. 29. Patent Owner further asserts, and we agree, that Petitioner “does not attempt to point to any error by the Examiner in the original prosecution, notwithstanding the fact that Eliassen, Melsky, and Lee were before the Office,” and that Petitioner “likewise does not point to any error by the Board in its decision following remand in the AngioDynamics Reexam, including with respect to the Examiner’s decision not to issue a new ground for rejection.” *Id.* at 30. Based upon our review of both the Petition and Petitioner’s Preliminary Reply, we find that Petitioner has not identified any specific teaching in any reference that the Examiner misapprehended or overlooked. *See generally* Pet.; Prelim. Resp. Although the Petition addresses the prosecution history, reexamination, and Federal Circuit appeals concerning the ’022 patent, we find no express assertion that any error was committed by the Office in ultimately allowing and upholding the patentability of the claims in the ’022 patent. *Id.*

As discussed above, Petitioner argues in reply that its “grounds are new” and that “the Board’s determinations in the earlier AngioDynamics reexam did not involve any of Petitioner’s primary or secondary references.” Prelim. Reply 5–6. We evaluate these arguments that particular references and combinations were not applied by the Examiner in weighing whether the Examiner erred in the evaluation of the prior art, which corresponds to *Becton, Dickinson* factor (c) (i.e., “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection”). The references Petitioner relies upon were not relied upon as a basis for rejection by the Examiner or in the AngioDynamics Reexam. Nevertheless, as detailed above, Eliassen, Melsky, and Lee, as well as prior art substantially similar to Bardport and Herts was presented to the Office both during examination and reexamination as prior art, and the issue raised by Petitioner—whether the prior art taught ports to be power injectable—was expressly before the Office. *See C.R. Bard*, 748 F. App’x at 1021 (remand to the Board for the purpose of determining “whether, under a construction requiring the ports to be power injectable, these claims are obvious in view of the prior art of record”).

Also in this regard, Patent Owner states that Petitioner relies on, for example, Eliassen as teaching power injectable ports, and asserts the portion of Eliassen cited by Petitioner is identical to a disclosure in Tallarida¹⁵ cited by the Examiner during prosecution of the ’302 patent, the parent of the ’022 patent. *Id.* at 26–28 (citing Pet. 15; Ex. 1003 ¶ 66; Ex. 2015 at 2 (office action during prosecution of the ’302 patent in which the Examiner rejected claims as obvious over Tallarida and another reference); Ex. 2019, 2:49–56).

¹⁵ US 6,527,754 B1, issued March 4, 2003 (Ex. 2019, “Tallarida”).

According to Patent Owner, the '302 patent and the '022 patent were examined by the same Examiner and were pending in parallel for several years, which are relevant considerations in determining whether to exercise discretion to deny a petition as provided in *Becton, Dickinson*. Prelim. Resp. 26 n.5 (citing *Becton, Dickinson* at 22–23). Whether a reference was the basis for a rejection may be probative of whether the Examiner misapprehended or overlooked a specific teaching contained in the reference; however, it is not dispositive here where Petitioner does not identify any specific teaching that the Examiner misapprehended or overlooked.

Becton, Dickinson factor (f) asks whether new evidence that was not before the Examiner justifies the Office reconsidering the patentability of the claims. *Becton, Dickinson*, Paper 8 at 17–18. As discussed above, Patent Owner argues that Costa and Sanelli were before the Examiner and each discusses Herts, providing a substantially similar disclosure as Herts. Prelim. Resp. 23–24. To the extent Herts is “new evidence,” Petitioner does not rely on Herts to fill a missing structural element of the Challenged Claims, which are directed to an apparatus, not a method, but instead relies on Herts to show what Bardport purportedly discloses. *See, e.g.*, Pet. 31 (“Herts specifically discloses the use of a power-injection method with a Bardport catheter.”). As discussed above (*see supra* Section III.A.4), the portion of Bardport cited by Petitioner expressly states that “[c]atheters have not been evaluated with the use of Power Injectors.” Ex. 1012, 27–28. Additionally, as explained above, Petitioner and Mr. Leschinsky misidentify a 1996 article by “Herts” as the 2001 reference Petitioner calls Herts. *See supra* Section III.A.4. Thus, Petitioner’s basic premise that Bardport cites Herts (the reference relied upon by Petitioner) is wrong, and the information

presented fails to show that Petitioner's reliance on Herts is sufficient new evidence to support reconsidering the patentability of the Challenged Claims. Similarly, to the extent the declaration Petitioner provides from Mr. Leschinsky (Exhibit 1003) is "new evidence," Petitioner does not explain how this testimony serves to show that the Examiner erred, particularly where Mr. Leschinsky also misidentified the article cited in Bardport authored by "Herts" in 1996 as the reference Petitioner relies on as Herts, dated 2001.

In sum, to the extent Petitioner implies error by the Office with regard to whether the prior art teaches a power injectable pump, we find that the prosecution history demonstrates that the Examiner engaged with the prior art and, specifically with the power injectable port limitations. As discussed above, for example, the Examiner during prosecution of the '302 patent, the parent of the '022 patent, applied Tallarida in a rejection where the relevant disclosure was identical to the disclosure of Eliassen upon which Petitioner relies with regard to power injectable ports. *See* Prelim Resp., 26–28 (citing Pet. 15; Ex. 1003 ¶ 66; Ex. 2015 at 2; Ex. 2019, 2:49–56). *Advanced Bionics* explains that "if 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." *Advanced Bionics*, Paper 6 at 9. Having considered the arguments and the evidence of record, we conclude that even if Petitioner disagrees with how the Examiner applied the prior art, Petitioner has not shown that the Examiner's consideration of the prior art was unreasonable and has not shown that the Office materially erred in evaluating any claimed feature.

IV. CONCLUSION

For the reasons set forth above, we exercise our discretion under Section 325(d) to deny institution of trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all Challenged Claims of U.S. Patent No. 7,947,022 B2 for all asserted grounds, and no trial is instituted.

IPR2021-01200
Patent 7,947,022 B2

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