

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B. BRAUN MELSUNGEN AG,
Patent Owner.

Case IPR2017-01583
Patent 8,333,735 B1

Before SCOTT A. DANIELS, MICHAEL L. WOODS, and
ROBERT L. KINDER, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Becton, Dickinson and Company (“Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting *inter partes* review of claims 1, 9–11, 18, 19, and 24 of U.S. Patent No. 8,333,735 B1 (“the ’735 patent”). Pet. 1. B. Braun Melsungen AG (“Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”) in response to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 1.

We have authority under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that 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.” Having considered the arguments and the evidence presented, for the reasons described below, we do not institute an *inter partes* review of any of the challenged claims.

A. Related Proceedings

Petitioner represents that the ’735 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1. Petitioner also represents that petitions for *inter partes* review were filed challenging related U.S. Patent Nos.: 8,328,762; 8,337,463; 8,540,728; 9,149,626; 8,597,249; 8,460,247; and 9,370,641. *Id.* Below is a chart that associates the *inter partes* reviews with each patent:

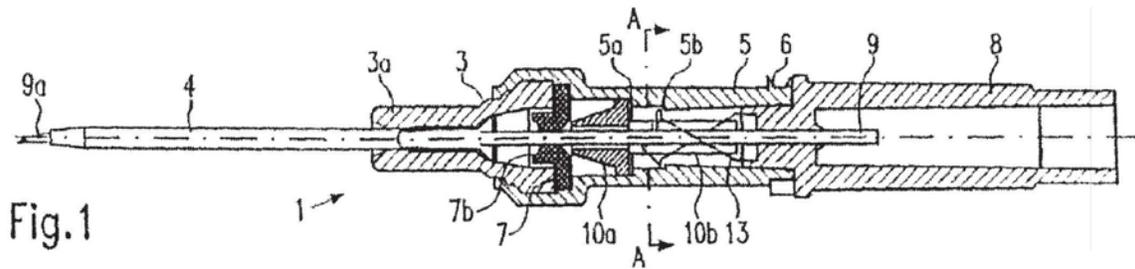
IPR Number	Patent Number
IPR2017-01583	8,333,735
IPR2017-01584	8,540,728
IPR2017-01585	8,337,463
IPR2017-01586	8,328,762

IPR2017-01587	9,149,626
IPR2017-01588	8,460,247
IPR2017-01589	8,597,249
IPR2017-01590	9,370,641

B. The '735 Patent (Ex. 1001)

The '735 patent, titled “Catheter Insertion Device,” states that an intended goal is to prevent “an outflow of blood from the catheter . . . after removal of the hollow needle with [a] needle guard element.” Ex. 1001, [54], 1:33–36.

To illustrate an embodiment of the '735 patent's catheter insertion device, we reproduce Figure 1 of the '735 patent, below:



According to the '735 patent, Figure 1 depicts catheter insertion device 1 with catheter 4, needle hub 8, to which hollow needle 9 is fixed and which needle 9 extends through valve disc 7. Ex. 1001, 2:8–9, 19–22. Between needle hub 8 and valve disc 7 is valve actuating element 10 (depicted as 10a and 10b), which has a truncated cone-shaped section 10a, which serves to open valve disc 7, and a plunger section 10b. *Id.* at 2:22–26. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:28–32. Needle guard element 13 serves to cover needle tip 9a upon withdrawal of needle 9 from the catheter hub, thereby “completely protecting and blocking it,” as shown in Figure 2. *See id.* at 2:33–41.

To illustrate the removal of needle 9 from catheter hub 2, we reproduce Figure 2, below:

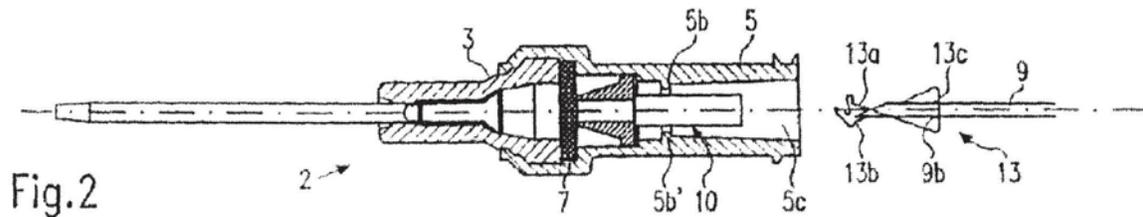


Figure 2 depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:57–58, 2:33–34. As shown above, needle guard element/spring clip 13 is removed from the catheter hub along with needle 9, causing the spring clip's spring arms 13a, 13b to cover the needle's tip. *Id.* at 2:38–41. Figure 2 also depicts valve disc 7—which is elastic—as closing the through-hole from which needle 9 is removed to prevent blood flow from exiting the catheter. *Id.* at 2:41–44.

C. Illustrative Claim

Of the challenged claims, claims 1, 10, and 18 are independent, with claim 9 depending from claim 1, claim 11 depending from claim 10, and claims 19 and 24 depending from claim 18. *Id.* at 5:1–8:28. Claim 1 is illustrative of the subject matter at issue and is reproduced below, with emphasis added to a particular limitation addressed in our Decision:

1. A catheter insertion device comprising:
 - a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve configured to obstruct fluid flow comprising a wall surface comprising a slit positioned inside the interior cavity of

the catheter hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;

a valve actuating element slidably disposed in the catheter hub configured to actuate the valve, *the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit of the valve and at least two plunger elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough*; the two plunger elements configured to transfer a distally directed force to the nose section to push the valve to open the slit;

a needle protective device spaced from the needle tip in a ready position and movable relative to the needle tip to a protective position, at least in part, distally of the needle tip to prevent unintended needle sticks.

Id. at 5:2–5:27 (emphasis added).

D. References Relied Upon

The Petitioner relies in relevant part on the following references (Pet.

3):

Name	Reference	Ex. No.
Woehr	US 6,117,108, issued Sept. 12, 2000	Ex. 1003
Tauschinski	US 4,387,879, issued June 14, 1983	Ex. 1004
Arnett	US 5,817,069, issued Oct. 6, 1998	Ex. 1005
Van Heugten	US 5,053,014, issued Oct. 1, 1991	Ex. 1006
Pike	US 5,954,698, issued Sept. 21, 1999	Ex. 1007
Luther	US 4,842,591, issued June 27, 1989	Ex. 1008
Greene	US 6,221,047 B1, issued Apr. 24, 2001	Ex. 1013

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1, 9–11, 18, 19, and 24 of the '735 patent are unpatentable under the following grounds (Pet. 3):

References	Basis	Claim(s)
Woehr, Tauschinski, and Arnett	§ 103(a)	1, 9–11, 18, 19, and 24
Van Heugten and Arnett	§ 103(a)	1, 9–11, 18, 19, 24
Pike and Luther	§ 103(a)	10, 11, 18, 19, 24
Van Heugten, Arnett, and Greene	§ 103(a)	9

Petitioner also relies on the declaration testimony of Jack Griffis, III (Ex. 1002) in support of its Petition. Patent Owner relies on the declaration testimony of Richard Meyst (Ex. 2001) in support of its Preliminary Response.

II. ANALYSIS

A. Claim Construction

As a first step in our analysis, we determine the meaning of the claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear.” 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach). Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Although Petitioner and Patent Owner disagree about the interpretation of the claim term “needle protective device” (*Compare* Pet. 7–9, *with* Prelim. Resp. 8–9), we determine that no term requires express construction for the purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms

need only be construed ‘to the extent necessary to resolve the controversy’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Here, regardless of the interpretation of the claim term “needle protective device,” we determine that the information presented in the Petition fails to show that there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *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 skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

C. Level of Ordinary Skill in the Art

In determining 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*, 383 U.S. at 17.

Petitioner relies upon the declaration of Mr. Griffis (Ex. 1002) and contends that a person of ordinary skill in the art (“POSITA”) would have been either “a medical practitioner with experience using vascular access devices and with training, experience and/or familiarity applying principles of engineering to the design, development, and/or testing of vascular access devices,” or “an engineer having at least a bachelor of science degree and with several years of experience in the design, development, and/or testing of vascular access devices and their clinical use; a higher level of education could reduce the number of years of experience required.” Pet. 6 (citing Ex. 1002 ¶¶ 28–30).

Patent Owner, on the other hand, relies upon the declaration of Mr. Meyst (Ex. 2001) and contends that a POSITA would have had “at least an associate’s degree in engineering or Physics or the equivalent, and at least five years of experience with IV catheters. Alternatively, more education, such as a Bachelor of Science degree, could reduce the number of years of experience to at least two years of experience.” Prelim. Resp. 4 (citing Ex. 2001 ¶¶ 26–28).

Based on our review of the ’735 patent, the types of problems and solutions described in the ’735 patent and applied prior art, and the testimony of Mr. Griffis and Mr. Meyst, we determine that a POSITA would be either a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical

degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention, for example, Woehr reflects that the field involves catheters and their use by skilled health-care workers. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); Ex. 1003, 1:7–11, 1:60–2

D. Woehr, Tauschinski, and Arnett

Petitioner contends that claims 1, 9–11, 18, 19, and 24 are unpatentable over Woehr, Tauschinski, and Arnett. Pet. 3.

1. Woehr (Ex. 1003)

Woehr is a U.S. patent titled “Spring Clip Safety IV Catheter” and it discloses a “catheter in which the needle tip is automatically covered after needle withdrawal to prevent the health-care worker from making accidental contact with the needle tip.” Ex. 1003, [54], 1:7–11. To illustrate an embodiment of Woehr’s catheter, we reproduce Figure 1A, below:

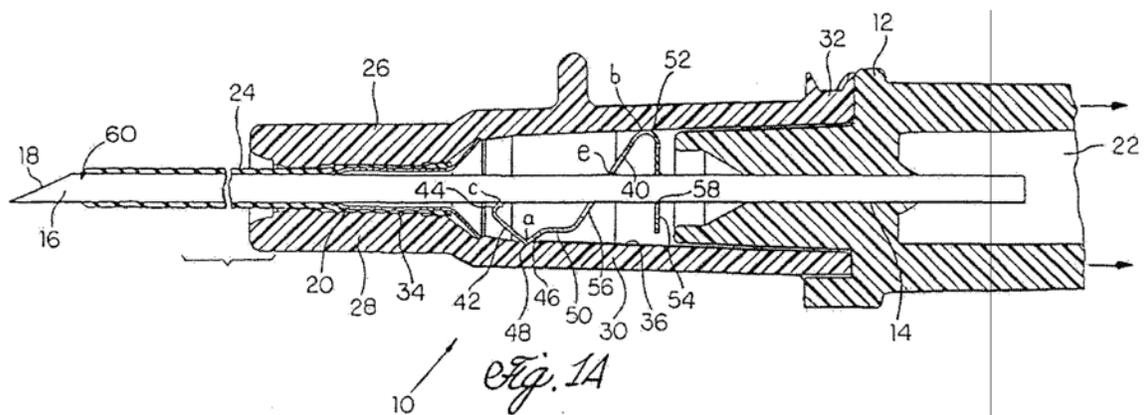
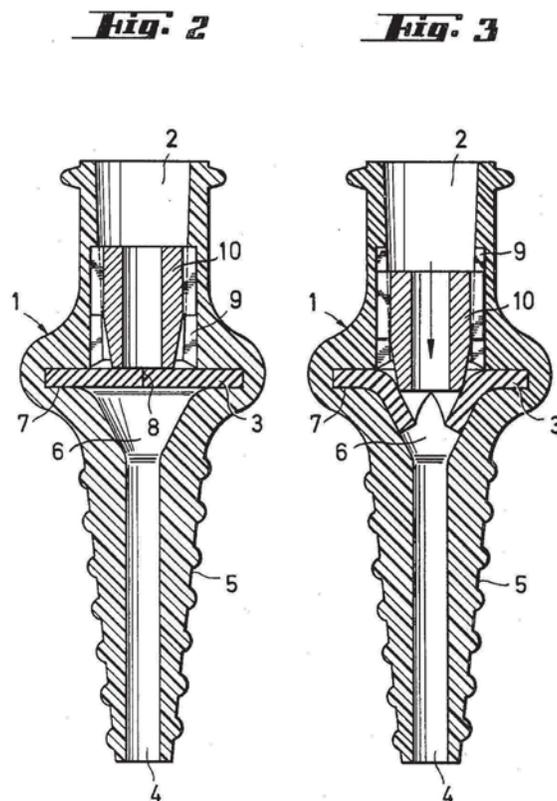


Figure 1A depicts catheter 10 including needle hub 12, needle 16 with needle tip 18, catheter hub 26, and needle guard 40 in the form of a unitary

spring clip. *Id.* at 4:8–28, 50–51. As needle 16 is withdrawn from a patient, needle guard 40 “automatically snaps into a retracted position” to block needle tip 18 to prevent accidental contact to the health care practitioner. *Id.* at 4:43–49.

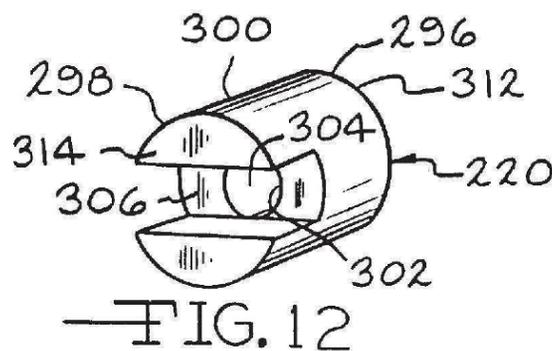
2. *Tauschinski (Ex. 1004)*

Tauschinski is a U.S. patent titled “Self-Sealing Connector for Use with Plastic Cannulas and Vessel Catheters” and it discloses a connector that will close automatically when a corresponding catheter is pulled from the connector, thereby “prevent[ing] an emergence of blood or an ingress of air” through the connector. *See Ex. 1004, [54], 2:7–31.* To illustrate the disclosed connector, we reproduce Tauschinski’s Figures 2 and 3, below:



Arnett describes Figure 11 as depicting a catheter and valve assembly in the open position and when a needle is not used. *See id.* at 2:29–36; *see also id.* at 5:51–58 (describing a different but similar embodiment of Figure 6 “[w]hen the valve assembly 10 is used in a needleless access system . . .”). In particular, Figure 11 depicts valve assembly 10 including septum 216 and actuator 220. Septum 216 “is made of a resilient, compressible elastomeric material . . . that can be compressed or deformed numerous times without losing its original shape.” *Id.* at 7:15–18. In operation, when actuator 220 is pressed against septum 216, a seal between shoulder surface 284 and septum shoulder 246 breaks, thus allowing fluid to flow from luer 140 through fluid passageway 306 and through fluid passageways 290. *See id.* at 8:26–44. Assembly 10 can be resealed by removing luer 140 from body 212, which removes the force applied by actuator 220 onto septum 216, “thereby causing septum 216 to regain its original shape to form a seal between the shoulder surface 284 and the septum shoulder 246.” *See id.* at 8:45–50.

To better illustrate Arnett’s actuator 220, we reproduce Figure 12, below:

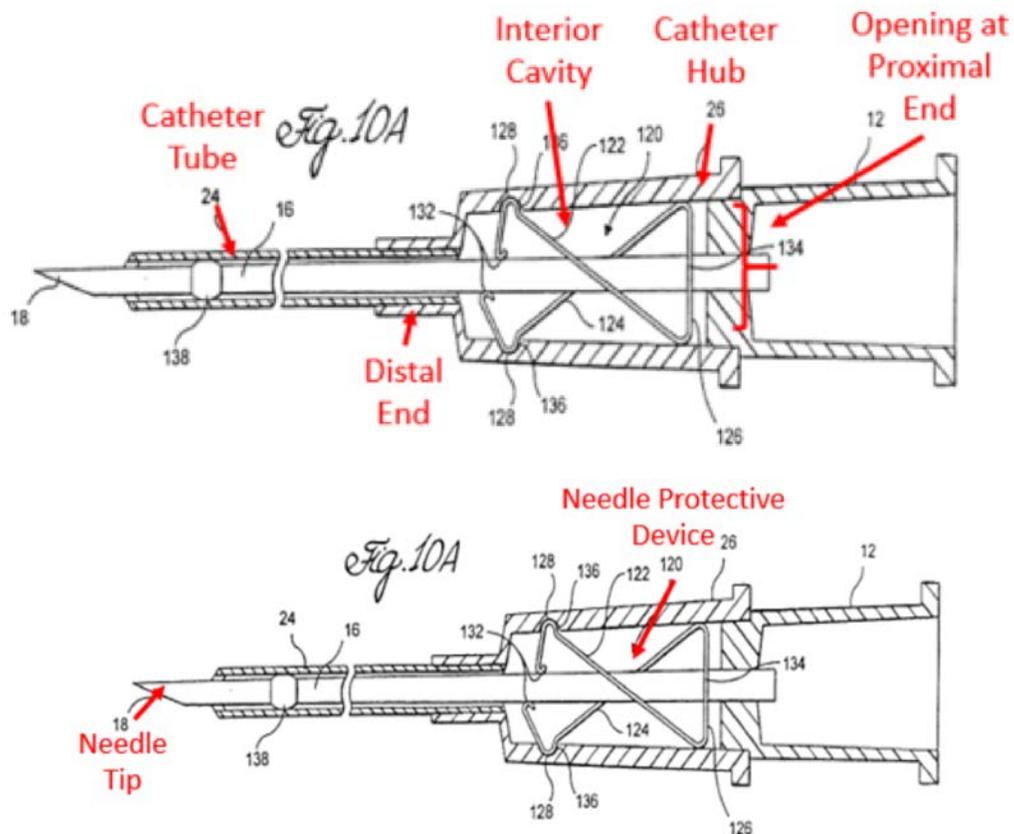


As described by Arnett, Figure 12 depicts actuator 220 including septum contact surface 312, an opposed fitting contact surface 314, and fluid passageway 306. *Id.* at 7:29–39. As discussed above in connection with

Figure 11, *fluid passageway 306 allows fluid to flow around septum 216 and through fluid passageways 290. See id. at Fig. 11, 8:41–44.*

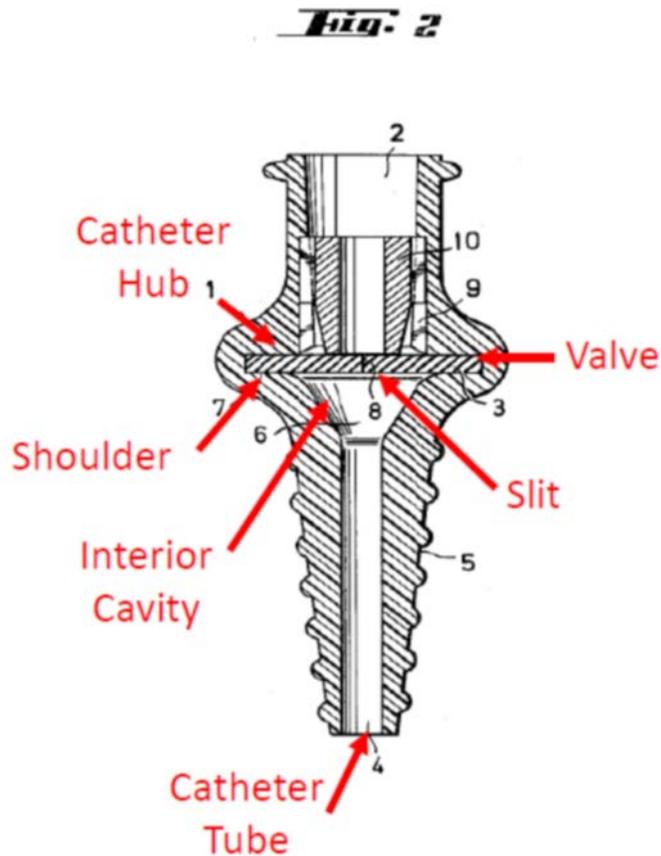
4. *Petitioner’s Challenge*

In challenging the claims, Petitioner submits that Woehr discloses a “catheter insertion device” comprising a “catheter hub” (or “first hub”), “needle,” and “needle protective device.” *See* Pet. 11–13, 21–23 (challenging independent claim 1); *see also id.* at 24–28 (challenging independent claim 10); *id.* at 29–32 (challenging independent claim 18). To illustrate these findings, Petitioner submits several annotated Figures, including several annotated figures of Woehr’s Figure 10A (*id.* at 12, 13, 22), two of which we reproduce, below:



According to Petitioner, and as shown in Figure 10A, Woehr discloses a “catheter insertion device” comprising the claimed “catheter hub” 26, “needle” 16, and “needle protection device” 120. *Id.* at 11–13, 21–23.

In addressing the claimed “valve configured to obstruct fluid flow,” Petitioner relies on Tauschinski and reasons that it would have been obvious to modify Woehr to include Tauschinski’s valve. *See id.* at 13–16 (citations omitted). In relying on Tauschinski, Petitioner submits an annotated version of Tauschinski’s Figure 2 (*id.* at 15), which we reproduce below:

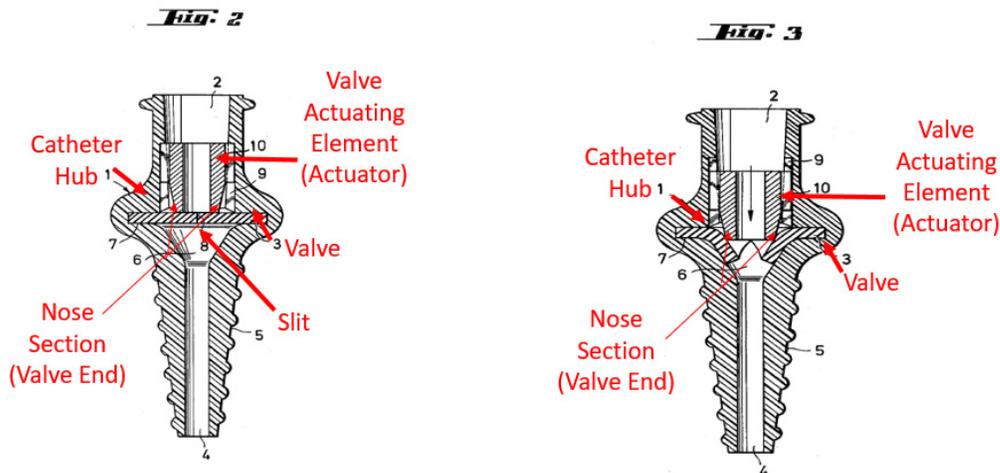


As shown in Figure 2, Petitioner asserts that Tauschinski discloses valve 3 with slit 8 configured to obstruct fluid flow through catheter hub 1. *Id.* at 14 (citing in-part Ex. 1004, 2:7–19). Petitioner reasons that it would have been obvious to modify Woehr “by adding protective elements, such as a valve to

prevent the emergence of blood,” as disclosed by Tauschinski. *Id.* at 15–16 (citing in-part Ex. 1002 ¶¶ 71–73).

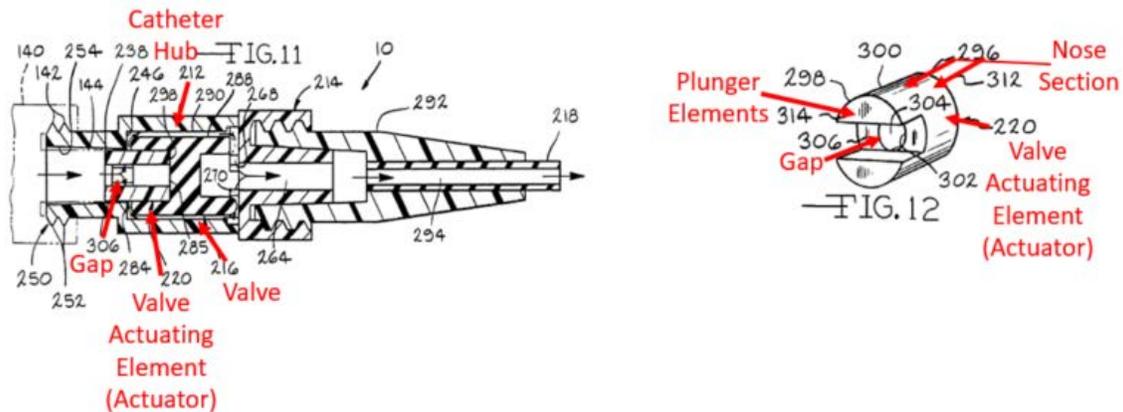
In addressing the claimed “valve actuating element comprising a *nose section having a tapered end . . . and at least two plunger elements extending proximally of the nose section and having a gap therebetween,*” Petitioner relies on both Tauschinski and Arnett. *Id.* at 16–21.

To address the claimed “valve actuating element comprising a *nose section having a tapered end,*” Petitioner submits annotated versions of Tauschinski’s Figures 2 and 3 (*id.* at 18), which we reproduce below:



According to Petitioner, and as shown in the above Figures 2 and 3, Tauschinski discloses valve actuating element 10 with a nose section having a tapered end, slidably disposed in catheter hub 1, and configured to actuate valve 3 to open slit 8. *Id.* at 17 (citing Ex. 1004, 3:21–36).

To address the claimed “valve actuating element comprising . . . at least two plunger elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough,” Petitioner relies on Arnett and submits annotated versions of Arnett’s Figures 11 and 12 (*id.* at 19), which we reproduce below:



According to Petitioner, Figure 11 (above-left) depicts valve actuating element 220, and as shown in Figure 12 (above-right), valve actuating element 220 that has two plungers 314 and gap 306 “therebetween to permit fluid flow to flow therethrough.” Pet. 19 (citing: Ex. 1005, 7:34–36; Ex. 1002 ¶¶ 74–81).

In combining Woehr with Tauschinski and Arnett to arrive at the claimed “valve actuating element,” Petitioner reasons that it would have been obvious to use Tauschinski’s valve actuator, including its tapered nose, in order to actuate Tauschinski’s valve, and that it would have been obvious to modify Tauschinski’s actuator “to contain two plunger elements . . . to open a valve as described in Arnett.” *Id.* at 20. In particular, we reproduce Petitioner’s reasoning for modifying Tauschinski’s valve actuator to include Arnett’s two “plunger elements . . . having a gap therebetween,” below:

Further, it would have been obvious to modify the actuator disclosed in Tauschinski to contain two plunger elements on the proximal end of the valve actuating element that are pushed by an external force to open a valve as described in Arnett. Arnett discloses a safety catheter device with a valve, actuator, and needle protection. Both Tauschinski and Arnett disclose valves and valve actuators with a central passageway that can be used with catheter devices, and both recognize the need to include such valves and valve actuators to prevent

leakage. (Ex.1002, Decl. ¶¶71-81.) Adding another passageway at the proximal end of the actuator is a known *design choice* in IV catheter blood control actuators that still allows the actuator to transfer a distally directed force to open the valve slit. (*Id.*) Further, *adding a gap in the actuator is one of a finite number of predictable solutions for creating space to accommodate the valve, actuator, and spring clip in the catheter hub, while also allowing a male luer to push on the actuator and permit fluid flow in the device.* (*Id.*) Thus, it would have been obvious to a POSA to modify the valve actuator of Tauschinski to add plungers as described in Arnett, and to include that actuator in the spring clip safety IV catheter of Woehr '108. (*Id.*)

Pet. 20–21 (emphases added). In summary, Petitioner reasons that a person having ordinary skill in the art would have modified Tauschinski's actuator to include Arnett's "plungers" and "gap" as a matter of simple "design choice," because it is "one of a finite number of predictable solutions for creating space to accommodate the valve, actuator, and spring clip in the catheter hub." *Id.*

5. Patent Owner's Argument

Patent Owner argues that Petitioner's reason for adding Arnett's "plunger elements . . . having a gap therebetween" "is based on an illogical analysis and mere conclusory statements." *See* Prelim. Resp. 48. In support of this argument, Patent Owner asserts that a "POSITA would have no reason to, and would not want to, modify Tauschinski's existing actuator to include two plunger elements based on Arnett." *Id.* at 48–49. Patent Owner points out that "the mode of operation of the valve actuating element and septum of Arnett is completely different from the valve actuating element and 'disc consisting of elastic material and having a central slit' of Tauschinski." *Id.* at 51.

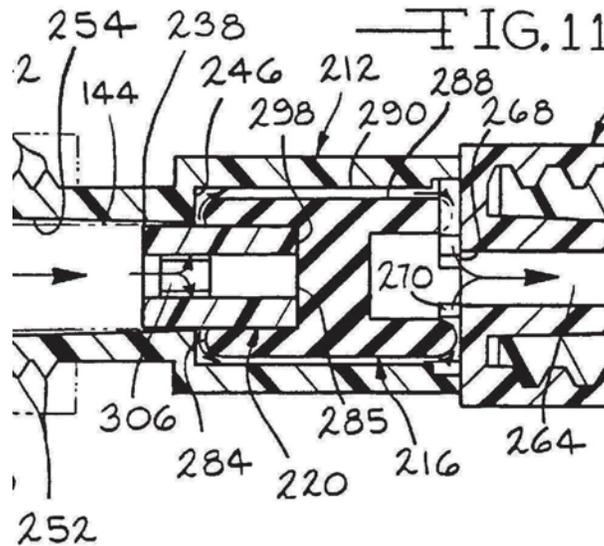
We agree.

6. *Analysis*

We are not persuaded that a person having ordinary skill in the art would have looked to Arnett to modify Tauschinski's actuator to include Arnett's "plunger elements . . . having a gap therebetween" as a matter of simple "design choice" "for creating space" (Pet. 20–21).

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (citation and inner quotes omitted). In the present case, Petitioner's reasoning "picks and chooses" the structure of Arnett's actuator 220 and "gap" 306 to the exclusion of Arnett's extensive disclosure regarding the purpose and operation of these components, an understanding of which is "necessary to the full appreciation of what [Arnett] fairly suggests" (*id.*).

As pointed out correctly by Patent Owner (*see* Prelim. Resp. 48–49), and as discussed *supra*, Arnett's "at least two plunger elements . . . having a gap [306] therebetween" function to direct fluid *around* Arnett's "valve" (septum 216) (*see* Ex. 1005, 8:26–44). To reiterate Arnett's operation, we reproduce a partial view of Arnett's Figure 11, below:



The portion of Figure 11 depicts the assembly in an open position. *See* Ex. 1005, 8:41–43. As shown in Figure 11, and denoted by arrows, when Arnett’s actuator 220 presses against septum 216, a seal between shoulder surface 284 and septum shoulder 246 breaks, thus allowing fluid to flow *through fluid passageway 306 and through fluid passageways 290*. *See id.* (“fluid is free to flow from the luer 140 through the fluid passageway 306 of the actuator 220 to the chamber fluid passageways 290”).

As explained above, Petitioner’s modification proposes to use Tauschinski’s valve. *See* Pet. 20–21 (citing Ex. 1002 ¶¶ 71–81). Tauschinski’s valve 3, however, operates very differently from Arnett’s septum 216, by directing fluid through, and not around, Tauschinski’s valve. *See id.* Because fluid is not directed around Tauschinski’s valve, and Petitioner has not provided a persuasive reason why such fluid flow would be desirable for Tauschinski’s valve, we are not persuaded that a person having ordinary skill in the art would have looked to Arnett to modify Tauschinski’s actuator to include Arnett’s “plunger elements . . . having a gap [306] therebetween,” as Petitioner proposes, and simply as a matter of

design choice to “create space.” *Id.* Rather, we find that Petitioner’s reasoning selectively ignores Arnett’s general disclosure regarding the operation of Arnett’s “gap” 306 and fails to give full appreciation to what Arnett’s “gap” fairly suggests to a person having ordinary skill in the art. *In re Hedges*, 783 F.2d at 1041.

Moreover, independent claims 1 and 18 do not simply recite a “gap,” but recite a “gap . . . to permit fluid flow to flow therethrough” or “therebetween.” Ex. 1001, 5:2–27, 6:37–64. Petitioner fails to explain how, under the proposed modification, Arnett’s “gap” 306 would “permit fluid flow to flow therethrough,” when the proposed modification utilizes Tauschinski’s valve, which itself *does not* direct fluid around the valve. *See* Pet. 18–21 (citing Ex. 1002 ¶¶ 71–81; *see also* Ex. 1002 ¶ 79 (citing Ex. 1005, 7:34–36)). In other words, although we agree with Petitioner that Arnett’s fluid passageway 306—the claimed “gap”—permits fluid to flow therethrough (*see* Pet. 19), as discussed above, fluid flows through passageway 306 *only to the extent* that passageway 306 is directing fluid to flow around Arnett’s “valve” (septum 216) and through Arnett’s passageways 290. *See* Ex. 1005, 8:26–44, Fig. 11. Accordingly, we are not persuaded that the proposed combination would result in a “gap . . . to permit fluid flow to flow therethrough” or “therebetween,” as further required by independent claims 1 and 18. Ex. 1001, 5:2–27, 6:37–64.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Woehr, Tauschinski, and Arnett render obvious claims 1, 9–11, 18, 19, and 24.

E. Van Heugten and Arnett

Petitioner contends that claims 1, 9–11, 18, 19, and 24 are unpatentable over Van Heugten and Arnett. Pet. 3.

1. *Van Heugten (Ex. 1006)*

Van Heugten is a U.S. Patent titled “Catheter with Controlled Valve.” Ex. 1006, [54]. Van Heugten discloses a “catheter hub assembly . . . wherein the assembly contains a membrane useful in preventing backflow of blood.” *Id.* at [57]. To illustrate Van Heugten’s catheter assembly, we reproduce Figure 2, below:

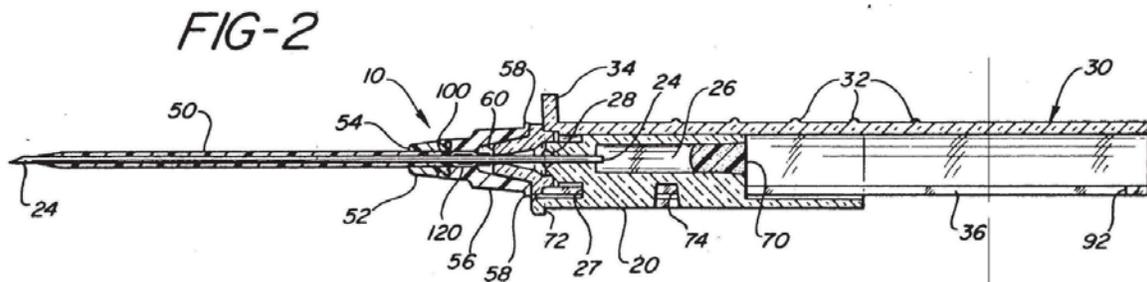
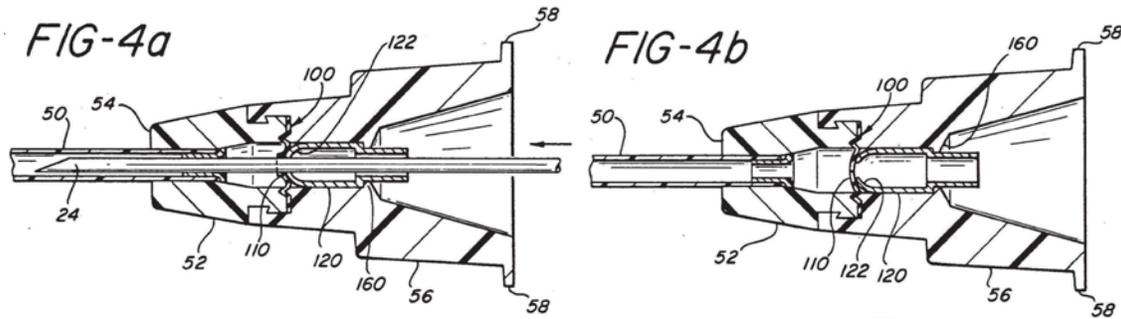


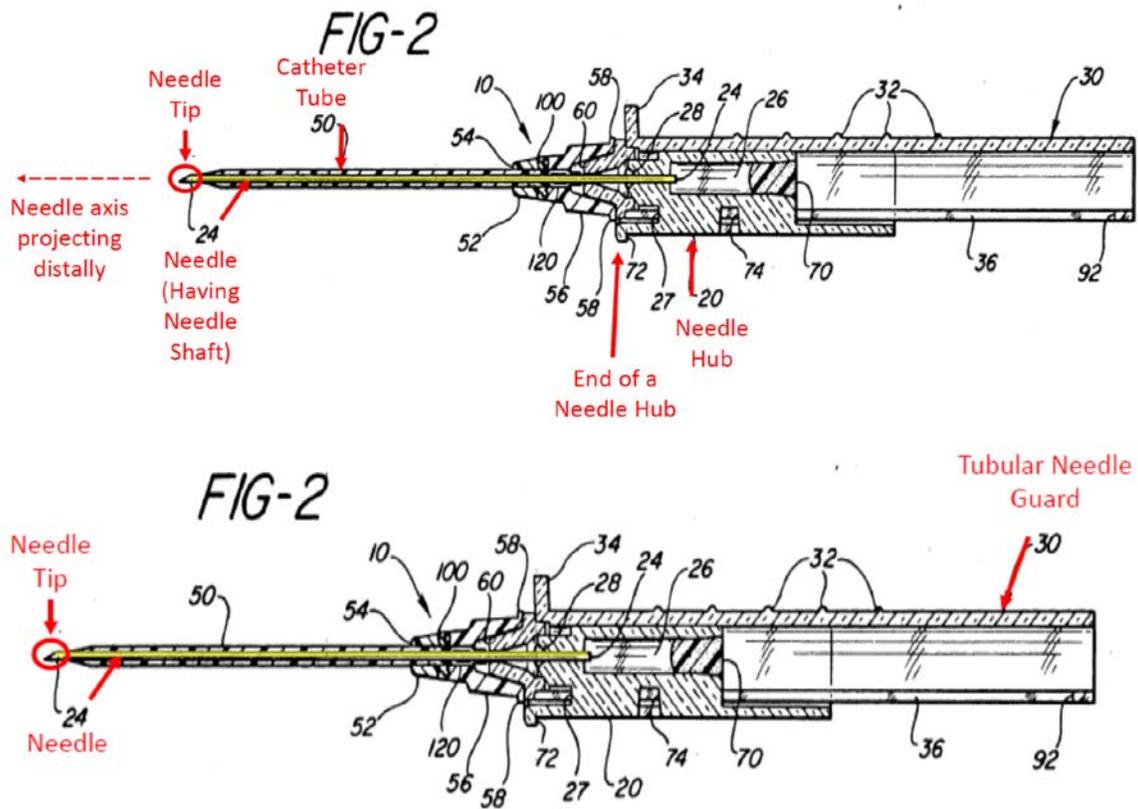
Figure 2 depicts a cross-sectional view of Van Heugten’s catheter assembly 10. *Id.* at 2:6–10, 19–21. In particular, Figure 2 illustrates catheter assembly 10 with catheter 50 and needle 24, which needle guard 30 covers upon retraction of needle 24 to prevent inadvertent needle injury to the user or others. *See id.* at 2:36–39, 3:34–58. Catheter assembly 10 also includes valve membrane 110, which is illustrated in Figures 4a and 4b, which we also reproduce, below:



As disclosed in Van Heugten, Figures 4a and 4b further show membrane assembly 100 comprising a one-directional valve membrane 110. *Id.* at 3:59–64. Figure 4a (above-left) depicts membrane 110 as being “punctured” by needle 24 (*id.* at 3:59–4:3), while Figure 4b (above-right) depicts needle 24 removed, where upon “removal from the catheter hub 52, the valve membrane closes” (*id.* at 4:6–9). Valve member 110 is “generally configured as a ‘duck bill’ valve or a valve of similar configuration and smoothly allows removal of . . . needle 24[, so that upon] removal of the needle 24 from the catheter 50, the valve membrane unidirectionally closes so that blood will not flow into flash chamber 26.” *Id.* at 4:23–30.

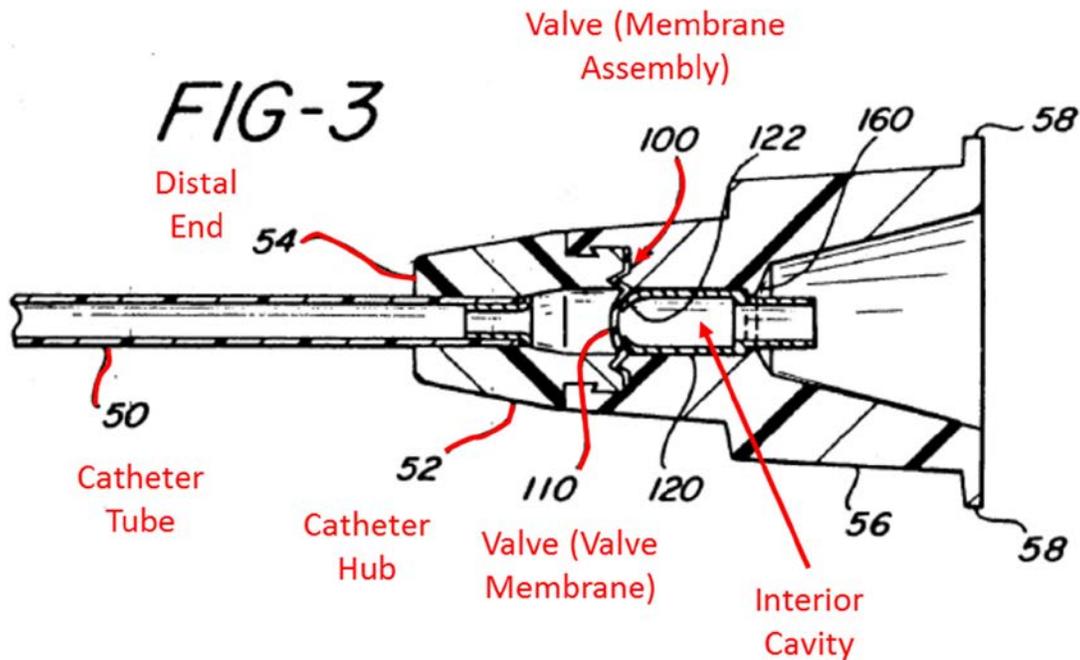
2. *Petitioner’s Challenge*

Petitioner asserts that Van Heugten discloses a “catheter insertion device” comprising the claimed “catheter hub” or “first hub,” “needle,” “valve,” and “needle protective device.” Pet. 35–39, 42 (independent claim 1); *id.* at 44–45, 47–48 (independent claim 10); *id.* at 49–51, 52–53 (independent claim 18). In support of these findings, Petitioner submits annotated versions of Van Heugten’s Figure 2 (*id.* at 37, 42), which we reproduce, below:



According to Petitioner, and as shown above, Figure 2 depicts Van Heugten’s “catheter hub” 52, “needle” 24, and “needle protective device” 30. *Id.* at 35, 36, 42.

Petitioner also submits an annotated version of Van Heugten’s Figure 3 (*id.* at 38), which we also reproduce, below:



According to Petitioner, and as shown in Figure 3, Van Heugten also discloses the claimed “valve” 100, 110. *See id.* at 38–39 (“a POSA would have understood Van Heugten to disclose the valve membrane 110 having one or more slits”) (citing Ex. 1002 ¶¶ 118–121).

In addressing the claimed “valve actuating element,” Petitioner relies on a combination of Van Heugten and Arnett. *Id.* at 39. In particular, Petitioner relies on Van Heugten for disclosing a “valve actuating element comprising a nose section having a tapered end” 122 for “pushing the valve to open the slit of the valve,” and submits an annotated version of Van Heugten’s Figure 4c (*id.* at 40), which we reproduce, below:

allow fluid to flow from an external infusion set. A POSA would have found it obvious to improve Van Heugten by adding an actuator based on the known technique disclosed in Arnett *to improve a similar catheter insertion device actuator that could be used for its intended purpose of actuating the valve and promoting fluid flow.* (Ex.1002, Decl. ¶¶122-126.)

Pet. 41 (emphases added). In summary, Petitioner proposes to modify Van Heugten’s actuator because Arnett’s “two plungers with a gap between these elements was a known configuration . . . [and] *it had a known advantage to allow fluid to flow from an external infusion set.*” *Id.*

3. Patent Owner’s Argument

Patent Owner argues that “there is no reason to modify the already existing actuator of Van Heugten based on Arnett.” Prelim. Resp. 55. In support of this argument, Patent Owner points out that in Van Heugten, fluid flows through the center of its valve membrane, whereas Arnett’s actuator pushes on the periphery of its septum “to allow fluid to flow around its thick, deformable septum.” *See id.* at 57–58 (emphasis omitted)). Patent Owner argues that Petitioner’s proposed modification “would weaken [Van Heugten’s] device, and the side openings would detract from fluid through the center of the device; such detracted flow would dead-end and stagnate on the interior walls of the Van Heugten catheter hub.” *Id.* at 58 (citing Ex. 2001 ¶¶ 86–90).

Patent Owner’s argument is persuasive.

4. Analysis

As with the prior ground, we are not persuaded that a person having ordinary skill in the art would have looked to Arnett to modify Van

Heugten's actuator to include Arnett's "plunger elements . . . having a gap therebetween."

The Federal Circuit has stated that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418. In the present case, Petitioner proposes to modify Van Heugten's actuator because Arnett's "two plungers with a gap between these elements was a known actuator configuration . . . [and] *it had a known advantage to allow fluid to flow from an external infusion set.*" Pet. 41 (emphasis added). Petitioner's reasoning implies that Van Heugten's device is not able to connect to an "external infusion set," and that Arnett's "plunger elements" advantageously provide for such a connection. *See id.* Upon reviewing Van Heugten, however, we find that Van Heugten's actuator is already configured for connection to an infusion set. *See, e.g.*, Ex. 1006, 2:50–53 ("The larger diameter proximal portion 56 of the catheter hub 52 is flanged at its proximal end for connection to an infusion set"). Accordingly, Petitioner's reasoning is not supported by some rational underpinning. *See KSR*, 550 U.S. at 418.

Furthermore, and as discussed above in the previous ground, Petitioner's reasoning "picks and chooses" the structure of Arnett's actuator 220 and "gap" 306 to the exclusion of Arnett's extensive disclosure regarding the purpose and operation of these components, an understanding of which is "necessary to the full appreciation of what [Arnett] fairly suggests." *In re Hedges*, 783 F.2d at 1041. Petitioner's modification proposes to use Van Heugten's valve membrane 110, which upon insertion

of membrane opener 120, is opened. *See* Pet. 40 (citing Ex. 1006, 4:31–36, 4:43–49, Fig. 4c). Van Heugten’s valve membrane 110, however, operates very differently from Arnett’s septum 216, by directing fluid through, and not around, membrane 110. *See id.* Because fluid is not directed around Van Heugten’s valve membrane 110, we are not persuaded that a person having ordinary skill in the art would have looked to Arnett to modify Van Heugten’s membrane opener 120 to include Arnett’s “plunger elements” “having a gap [306] therebetween,” as Petitioner proposes. *See id.* at 41, 19. Rather, we find that Petitioner’s reasoning selectively ignores Arnett’s extensive disclosure regarding the operation of Arnett’s “gap” 306 and fails to give full appreciation to what Arnett’s “gap” fairly suggests to a person having ordinary skill in the art. *In re Hedges*, 783 F.2d at 1041.

Moreover, independent claims 1 and 18 do not simply recite a “gap,” but recite a “gap . . . to permit fluid flow to flow therethrough” or “therebetween.” Ex. 1001, 5:2–27, 6:37–64. Petitioner fails to explain how, under the proposed modification, Arnett’s “gap” 306 would “permit fluid flow to flow therethrough,” when the proposed modification utilizes Van Heugten’s valve membrane 110, which itself *does not* direct fluid around the membrane. *See* Pet. 41 (citing Ex. 1002 ¶¶ 122–126); *see also* Ex. 1002 ¶ 125 (incorporating by reference discussion of Arnett from prior ground). In other words, although we agree with Petitioner that Arnett’s fluid passageway 306—the claimed “gap”—permits fluid to flow therethrough (*see* Pet. 19), as discussed above, fluid flows through passageway 306 *only to the extent* that it is directing fluid to flow around Arnett’s “valve” (septum 216) and through Arnett’s passageways 290. *See* Ex. 1005, 8:26–44, Fig. 11. Because the proposed modification does not direct fluid to flow around

a valve, we are not persuaded that the proposed combination would result in a “gap . . . to permit fluid flow to flow therethrough” or “therebetween,” as further required by independent claims 1 and 18. Ex. 1001, 5:2–27, 6:37–64.

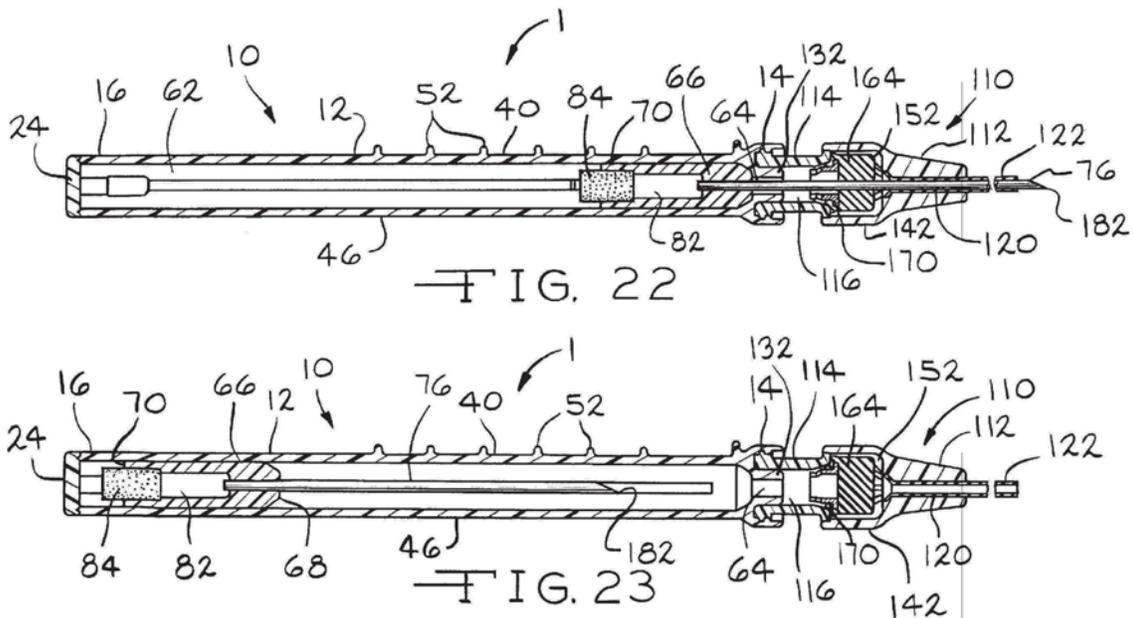
Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Van Heugten and Arnett render obvious claims 1, 9–11, 18, 19, and 24.

F. Pike and Luther

Petitioner contends that claims 10, 11, 18, 19, and 24 are unpatentable over Pike and Luther. Pet. 3.

1. Pike (Ex. 1007)

Pike is a U.S. patent titled “Catheter Apparatus Having Valved Catheter Hub and Needle Protector.” Ex. 1007, [54]. To illustrate Pike’s catheter apparatus, we reproduce Figures 22 and 23, below:



Figures 22 and 23 are cross-sectional views of catheter apparatus 1, including needle protector 10. *Id.* at 2:45–52, 4:38–39, 4:49–50. Figure 22 depicts needle 76 in a position ready for insertion, and Figure 23 depicts needle 76 retracted within needle protector 10 and within interior space 62. *See id.* at 6:26–36.

Pike also discloses that “[t]he primary object of the present invention is to provide a catheter apparatus that includes a valve for regulating flow in the catheter hub.” *Id.* at 1:47–49 (emphasis added).

To depict Pike’s inventive valve, we reproduce Figure 19, below:

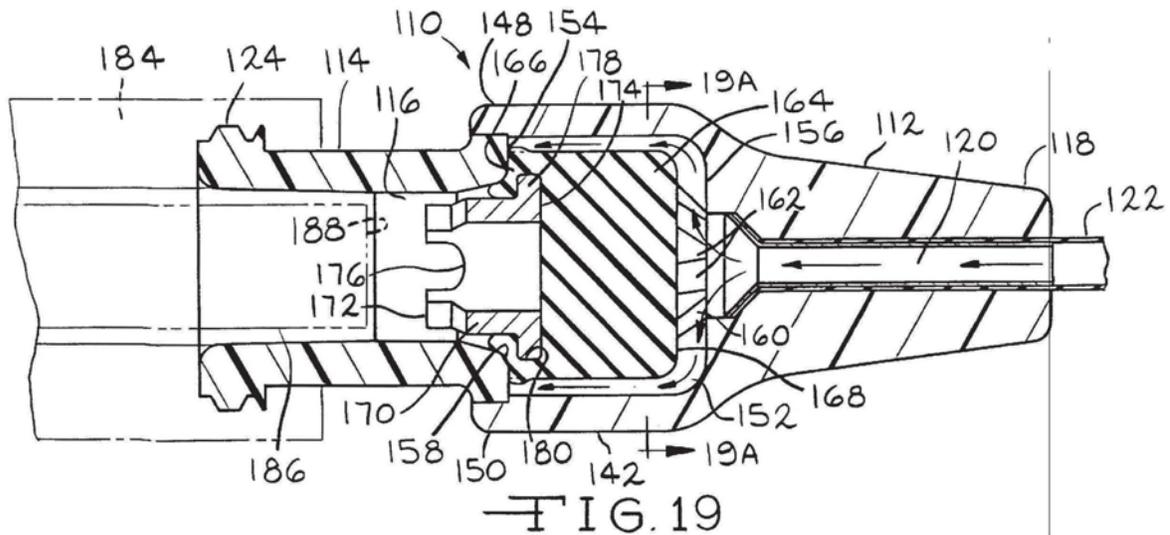
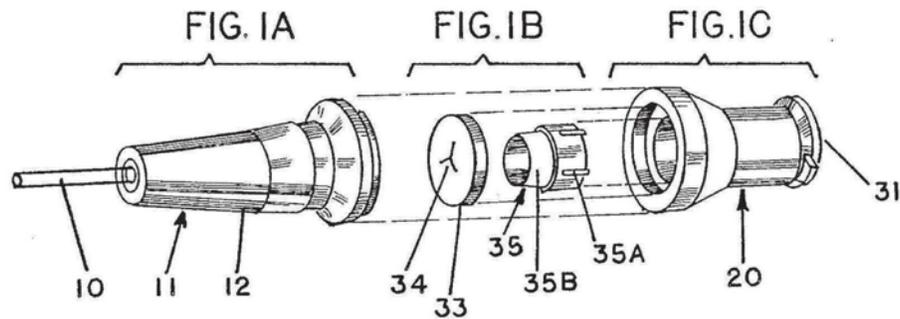


Figure 19 is a cross-sectional view with valve 164 in its normally closed position. *Id.* at 2:35–36, 5:26–27. Valve 164 is composed of a resilient material (*id.* at 5:32–33), which can be deformed to open the valve upon application of force by luer 184 to actuator 170, which moves freely from left-to-right within fluid passageway 116 (*see id.* 5:37–38, 6:61–67, Fig. 20). “[A]nnular flange 178 provides the structural support for the valve 164 at the actuator end 166 so that a superior seal is formed.” *Id.* at 5:45–47 (emphasis added). The arrows denote the flow of blood, including through chamber 152, and blood is “prevented from entering the first fluid passageway 116 due to the seal created between the valve 164 and the annular shoulder 158.” *Id.* at 6:44–50.

We also reproduce Figure 20, below:

2. *Luther (Ex. 1008)*

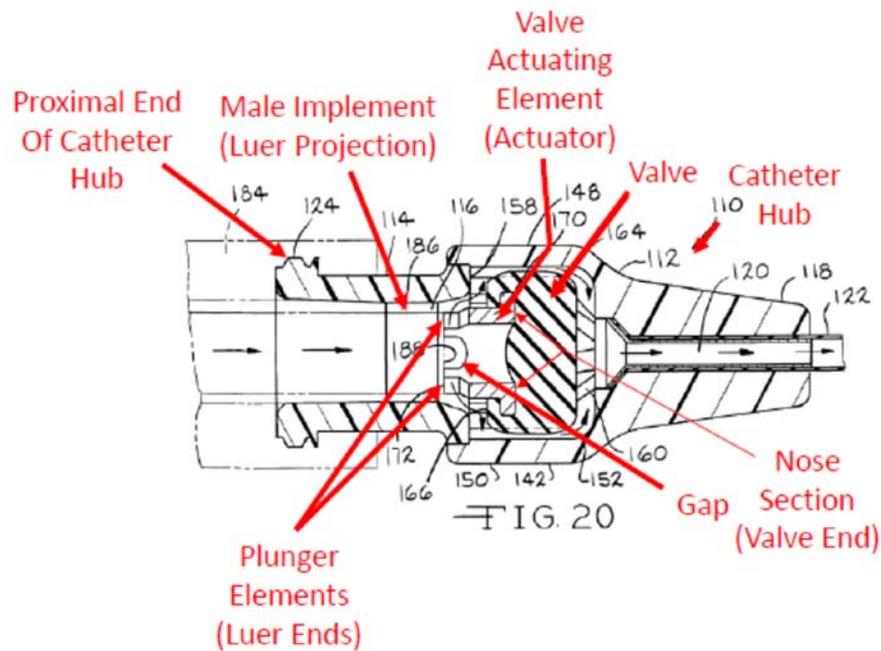
Luther is a U.S. patent titled “Connector with One-Way Septum Valve, and Assembly.” Ex. 1008, [54]. To illustrate Luther’s one-way septum valve, we reproduce Figures 1A, 1B, and 1C, below:



As shown in Figures 1A, 1B, and 1C, Luther discloses a resilient septum 33 that includes slit 34; septum 33 can be deformed by either moveable plug 35 (which itself rests in fitting 20) or by a needle (not shown). *Id.* at 2:20–23. Luther also discloses flange 31 formed at the end of fitting 20 “to engage with a luer locking type of device.” *Id.* at 2:15–17.

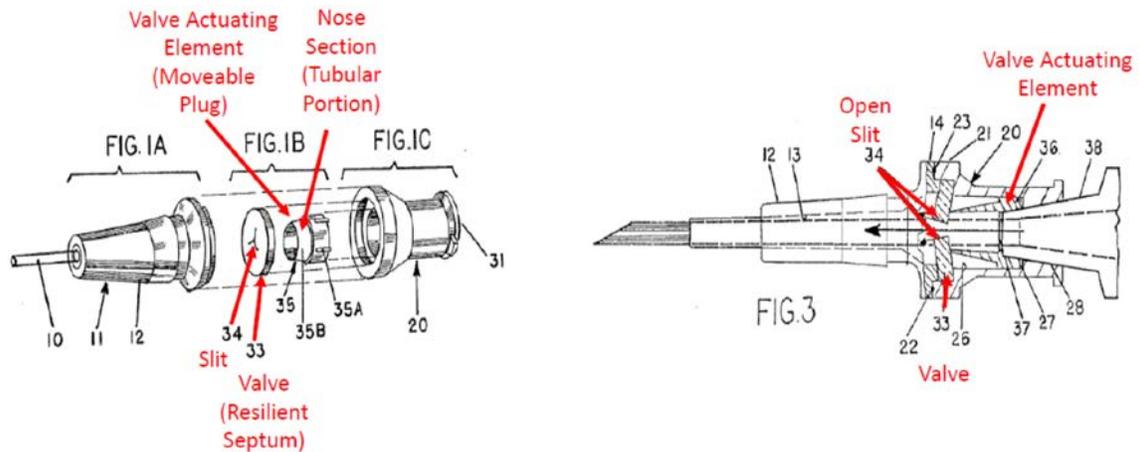
3. *Petitioner’s Challenge*

Petitioner asserts that Pike discloses a “catheter insertion device” comprising the claimed “catheter hub” or “first hub,” “needle,” and “needle protective device.” Pet. 55–57, 64–65 (independent claim 10); *id.* at 67–68, 71 (independent claim 18). To illustrate these findings, Petitioner submits annotated versions of Pike’s Figure 22 (*id.* at 57, 65), which we reproduce, below:



According to Petitioner, Figure 20 depicts Pike’s “valve” 164, “valve actuating element” 170 comprising a “nose section” 174 and “at least two plunger elements [172] . . . having a gap therebetween,” which Petitioner explains is the “u-shaped opening between element 172.” *Id.* at 61 (citations omitted).

In support of its assertion that Luther also discloses a valve and valve actuating element, Petitioner submits annotated versions of Luther’s Figures 1A, 1B, 1C, and 3 (*id.* at 63), the four of which we reproduce, below:



According to Petitioner, Luther's Figures 1A, 1B, 1C, and 3 depict "valve" 33 with slit 34, and "valve actuating element" 35 comprising a nose section having tapered end 35B and configured to push valve 33 to open slit 34. *Id.* (citations omitted).

In combining Pike with Luther to satisfy the claimed "valve," Petitioner reasons that it would have been obvious to "modify Pike based on the teaching in Luther . . . [by] *using a slit valve instead of a deformable valve.*" *Id.* at 60 (emphasis added, citations omitted). We reproduce Petitioner's reason for replacing Pike's valve, below:

It would have been obvious for a POSA to combine the catheter insertion device of Pike with the valve having a slit positioned on a shoulder in the hub as disclosed in Luther. A POSA would have been motivated to modify Pike based on the teaching in Luther that the resilient septum seal "prevent[s] blood leakage from the patient and back through the connector," has "good sealing and sterility properties," and "can be used a number of times while still maintaining these properties." (Ex. 1008, Luther at 1:6-18; Ex.1002, Decl. ¶¶161-166.) One of the goals of the Pike catheter assembly is to have "a 'bloodless' catheter apparatus that includes an internal valve in the catheter hub to regulate fluid flow." (Ex. 1007, Pike at 1:12-25; Ex.1002, Decl. ¶¶161-166.) A POSA would have found it obvious to improve Pike by adding protective elements, such as a valve to prevent the emergence of blood, based on the *known technique disclosed in Luther to improve a similar catheter insertion device.* (Ex.1002, Decl. ¶¶161-166.) *A POSA would have recognized other advantages with this design: it reduced the risk of an air embolism forming, it involved a simple construction, and it was easy to use.* (*Id.* ¶¶161-166.) A POSA would have understood that there are a finite number of ways to provide a valve configured in this way in a catheter device, and using a slit valve instead of a deformable valve is the combination of known prior art elements according to known methods to yield predictable results, and was obvious to try.

Pet. 60 (*emphases added*). In summary, Petitioner reasons that replacing the valves would have been obvious as Luther's design "reduced risk of an air embolism forming, it involved a simple construction, and it was easy to use." *Id.* (citing Ex. 1002 ¶¶ 161–166).

In combining Pike with Luther to satisfy the claimed "valve actuating element," Petitioner proposes to modify Pike's "actuator" "by adding a nose section to the actuator to open a slit valve because there was a known reason to do so to facilitate opening the valve, and doing so would allow the actuator and valve to retain their known functions." *Id.* at 64 (citing Ex. 1002 ¶¶ 161–166).

4. Patent Owner's Argument

Patent Owner argues that "there is no reason to use a slit valve in the Pike catheter." Prelim. Resp. 59. Patent Owner points out that "Pike *already has a valve to control blood flow and works for its intended purpose*" (*id.* at 63), and notes that Pike's valve, when open, permits fluid to flow around the valve, unlike Luther's valve (*see id.* at 60–61 (citing in part Ex. 1007, 7:3–7)). Patent Owner asserts that Petitioner's combination "wholly redesign[s] Pike" and that replacing Pike's valve for Luther's valve would require: (1) swapping the valves; (2) redesigning the interior chamber of Pike's catheter hub, including its proximal sealing shoulder and ribs; and (3) redesigning Pike's actuator. *Id.* at 63. Patent Owner also questions, "[w]hy would a POSITA use the Pike actuator, which has openings in the sides, if there is no longer a flow path around the valve?" *Id.* at 59.

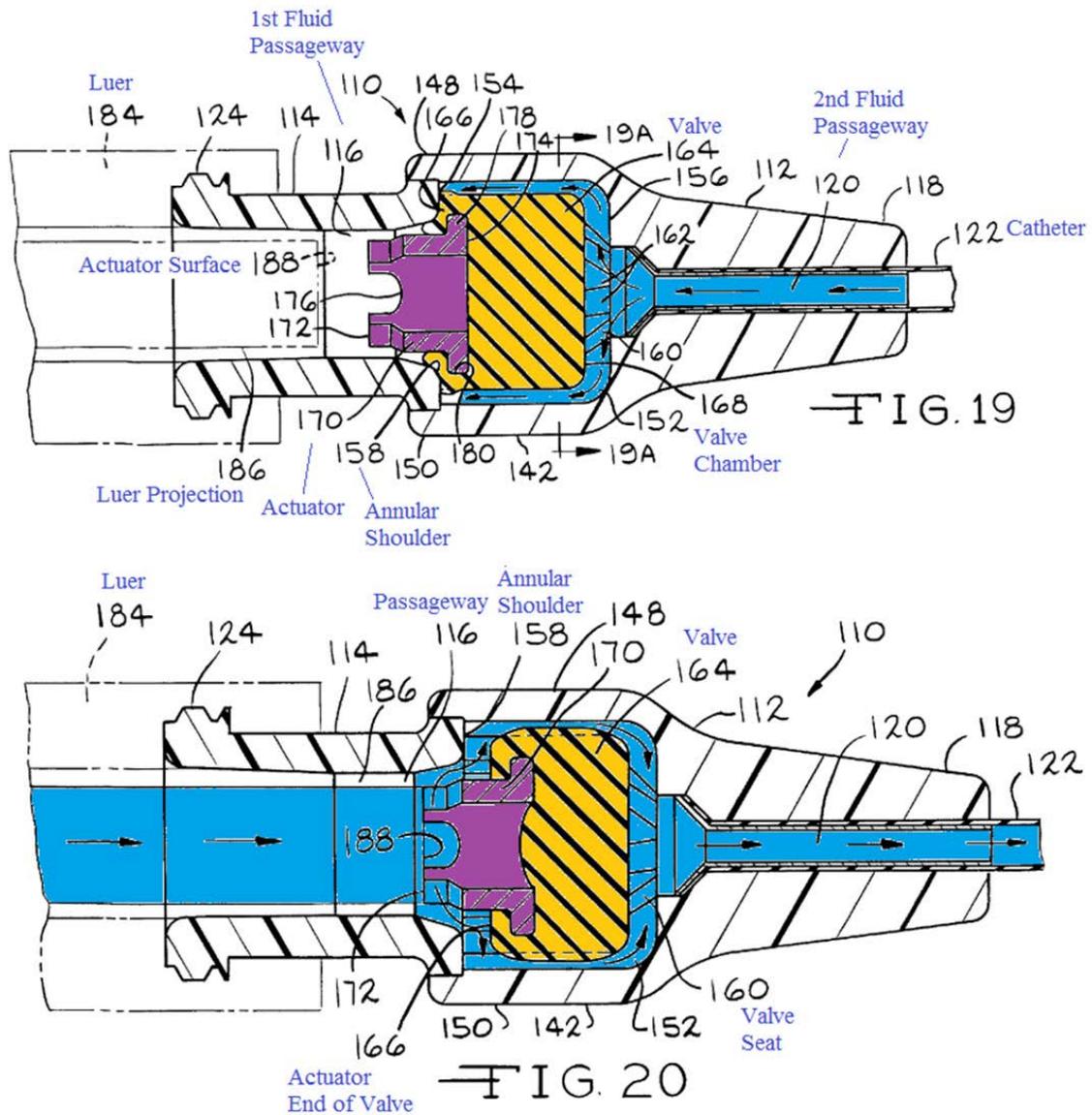
Patent Owner's arguments are persuasive.

5. *Analysis*

We agree with Patent Owner that Petitioner’s proposed combination would “wholly redesign Pike.” Prelim. Resp. 63. Petitioner’s proposed combination appears to be premised on an impermissible use of hindsight after review of the ’735 patent, rather than on a supported reason to combine the references. *See KSR*, 550 U.S. at 421 (stating that the fact finder must be aware “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”). For example, we are not persuaded that a person having ordinary skill in the art would have replaced Pike’s valve 164 with Luther’s valve 33, while only partially modifying Pike’s actuator 170, as Petitioner proposes. *See* Pet. 60, 63–64. In particular, we are not persuaded that a person having ordinary skill in the art would have modified Pike’s actuator 170, while keeping Pike’s “u-shaped openings” (the claimed “gaps”), for any reason other than to meet the claimed limitations. *See id.*

To fully satisfy the claimed “valve actuating element comprising at least two plunger elements . . . having a gap therebetween,” Petitioner relies on Pike’s “plunger elements” 172 as having u-shaped openings, which Petitioner asserts meet the claimed “gaps” therebetween. *Id.* at 61 (citations omitted). As argued correctly by Patent Owner, however, “Why would a POSITA use the Pike actuator, which has openings in the sides, if there is no longer a flow path around the valve?” Prelim. Resp. 59. Stated differently, Pike’s “u-shaped openings” or “gaps” function to direct fluid around Pike’s valve 164, but Petitioner’s proposed modification eliminates this feature.

To illustrate this point, we reproduce Pike’s Figures 19 and 20, which Patent Owner annotates (Prelim. Resp. 61), below:



As pointed out correctly by Patent Owner and its expert, Mr. Meyst, when valve 164 is open (Figure 20), fluid flows in valve chamber 152 and around valve 164. Prelim. Resp. 60–61; Ex. 2001 ¶ 92; *see* Ex. 1007, 6:57–7:15. Like Arnett, discussed above, arrows denote the flow of fluid, and a comparison of Figures 19 (depicting valve 164 as closed) and 20 (depicting valve 164 as open), along with a review of Pike’s associated description, show that “u-shaped openings” between “plunger elements” 172 function to

direct fluid flow to valve chamber 152 and around valve 170. *See* Ex. 1007, 6:57–7:15. Petitioner’s combination proposes to replace Pike’s valve 164 with Luther’s valve 33, but Luther’s valve 33 does not direct fluid around itself, so we are not persuaded that a person having ordinary skill in the art would have modified Pike’s actuator while also maintaining Pike’s “u-shaped openings.” Accordingly, we are not persuaded that a person having ordinary skill in the art would have combined Pike and Luther to arrive at a device comprising “plunger elements with a gap therebetween,” as Petitioner proposes.

Moreover, Petitioner’s reasoning is not supported by some rational underpinning. *KSR*, 550 U.S. at 418. In the present case, Petitioner’s reasoning is premised on an assertion that Luther’s valve 33 is an improvement over Pike’s valve 164, as Luther’s valve advantageously “reduced the risk of an air embolism forming” and was easier to manufacture and easier to use. *See* Pet. 60 (citing Ex. 1002 ¶¶ 161–166); *see also* Ex. 1002 ¶ 166. We find nothing in the cited portion of Mr. Griffis’ declaration, however, that sets forth the underlying facts or data to support a finding that Luther’s valve is an improvement over Pike’s valve 164. *See, e.g.*, Ex. 1002 ¶¶ 161–166; *see also* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). Rather, Pike discloses that “[t]he primary object of the present invention is to provide a catheter apparatus that includes a valve for regulating fluid flow” (Ex. 1007, 1:48–50 (emphasis added)) and that “annular flange 178 provides structural support for the valve 164 at the catheter end 166 so that a superior seal is formed” (*id.* at 5:45–47 (emphasis added)). In light of Pike’s disclosure, we are not

persuaded that Petitioner presents a sufficient rationale to show that it would have been obvious for a person of ordinary skill in the art to have replaced Pike's "superior sealing" valve 164, which itself is "the primary object" of Pike's invention, with Luther's valve, as Petitioner contends. Pet. 60.

Furthermore, independent claim 18 does not simply recite a "gap," but recites "one or more gaps to permit fluid flow to flow therebetween." Ex. 1001, 6:37–64. Petitioner fails to explain how, under the proposed modification, Pike's u-shaped openings would "permit fluid flow to flow therebetween," when the proposed modification utilizes Luther's valve 33, which itself *does not* direct fluid around the valve. *See* Pet. 61–64 (citations omitted). In other words, although we find that Pike's "u-shaped openings" "permit fluid flow to flow therebetween" (*see, e.g.*, Ex. 1007, Fig. 20), as discussed above, fluid flows between "u-shaped openings" *only to the extent* that they are directing fluid to flow around Pike's valve 164 and within valve chamber 152. *Compare* Ex. 1007, Fig. 19, *with id.* at Fig. 20. Accordingly, we are not persuaded that the proposed combination would result in "one or more gaps to permit fluid flow to flow therebetween," as further required by independent claim 18. Ex. 1001, 6:37–64.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Pike and Luther render obvious claims 10, 11, 18, 19, and 24.

G. Van Heugten, Arnett, Greene

Petitioner contends that dependent claim 9 is unpatentable over Van Heugten and Arnett, as discussed above, and in further view of Greene. Pet.

73–74. Claim 9 depends from claim 1, and Petitioner relies on the same findings and reasoning based on Van Heugten and Arnett, discussed above. *Id.*

For the same reasons that Petitioner has not established a reasonable likelihood of prevailing on its contentions under the grounds based on Van Heugten and Arnett, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that claim 9 is unpatentable over Heugten, Arnett, and Greene.

III. ORDER

For the reasons given, it is
ORDERED that no *inter partes* review is instituted.

IPR2017-01583
Patent 8,333,735 B1

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