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Paper No. 8
Entered: November 29, 2017

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 IPR2017-01584
Patent 8,540,728 B2

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, 2, 9, 10, 24, 27, and 28 of U.S. Patent No. 8,540,728 B2 ("the '728 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 jurisdiction 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 '728 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 also filed challenging related patents US. Patent Nos.: 8,328,762; 8,333,735; 8,337,463; 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 '728 Patent (Ex. 1001)

The '728 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], 1:31–34.

To illustrate an embodiment of the '728 patent's catheter insertion device, we reproduce Figure 1 of the '728 patent, below:

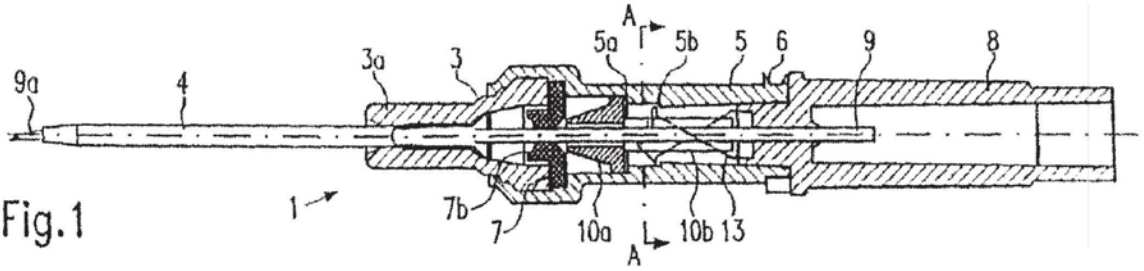


Fig.1

According to the '728 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, 2:6–9, 17–20. Between needle hub 8 and valve disc 7 is valve actuating element 10 (depicted as 10a, 10b), which has a truncated cone-shaped section 10a, which serves to open valve disc 7. *Id.* at 2:20–24. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:26–29. 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 2:31–39.

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

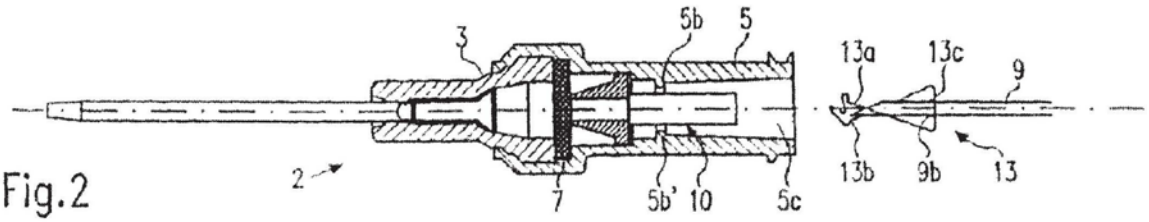


Fig.2

Figure 2 depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:55–56, 2:31–37. 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 2:36–39. 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 2:40–42.

C. Illustrative Claim

Of the challenged claims, claims 1, 9, and 24 are independent, with claim 2 depending from claim 1, claim 10 depending from claim 9, and claims 27 and 28 depending either directly or indirectly from claim 24. *Id.* at 4:63–8:28. 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 sized and shaped to obstruct fluid flow comprising a wall surface comprising a slit positioned inside the interior cavity of the catheter hub and in contact with the interior cavity; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub and abuts a shoulder formed in the interior cavity of the catheter hub;
>
> a valve actuating element slidingly disposed in the catheter hub 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 a plunger end having 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 being sufficiently rigid 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 4:64–5:25 (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

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1, 2, 9, 10, 24, 27, and 28 of the '728 patent are unpatentable under the following grounds:

References	Basis	Claim(s)
Woehr, Tauschinski, and Arnett	§ 103(a)	1, 2, 9, 10, 24, 27, and 28
Van Heugten and Arnett	§ 103(a)	1, 2, 9, 10, 24, 27, and 28

Pet. 3.

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 claimed term "needle protective device" (*Compare* Pet. 7─10, *with* Prelim. Resp. 6─8), 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 claimed 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. 6–7 (citing Ex. 1002 ¶¶ 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 '728 patent, the types of problems and solutions described in the '728 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. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Woehr, Tauschinski, and Arnett

Petitioner contends that claims 1, 2, 9, 10, 24, 27, and 28 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 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], 1:8–11. To illustrate an embodiment of Woehr's catheter, we reproduce Figure 1A, below:

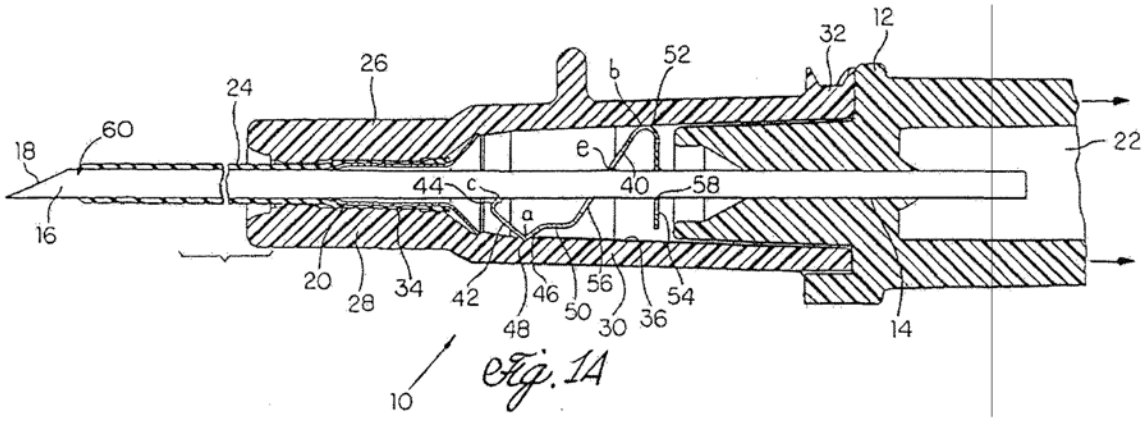
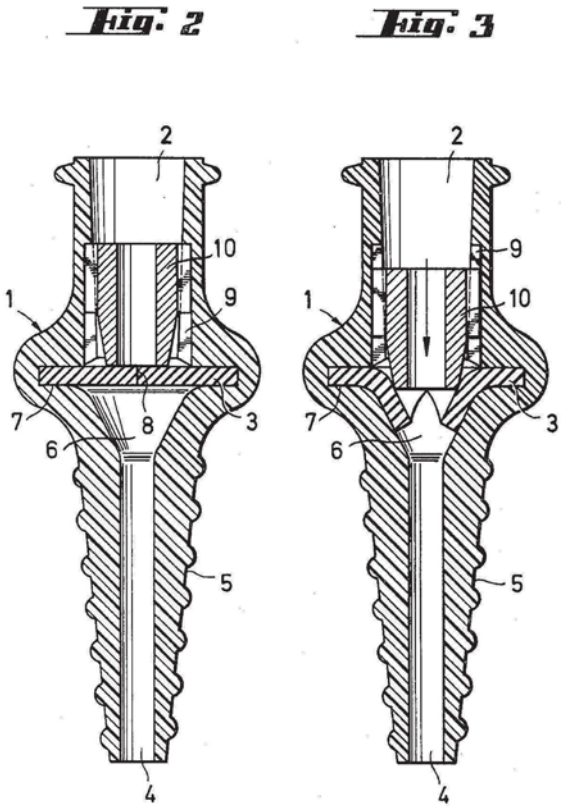


Fig. 1A

Woehr describes Figure 1A as depicting 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 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:

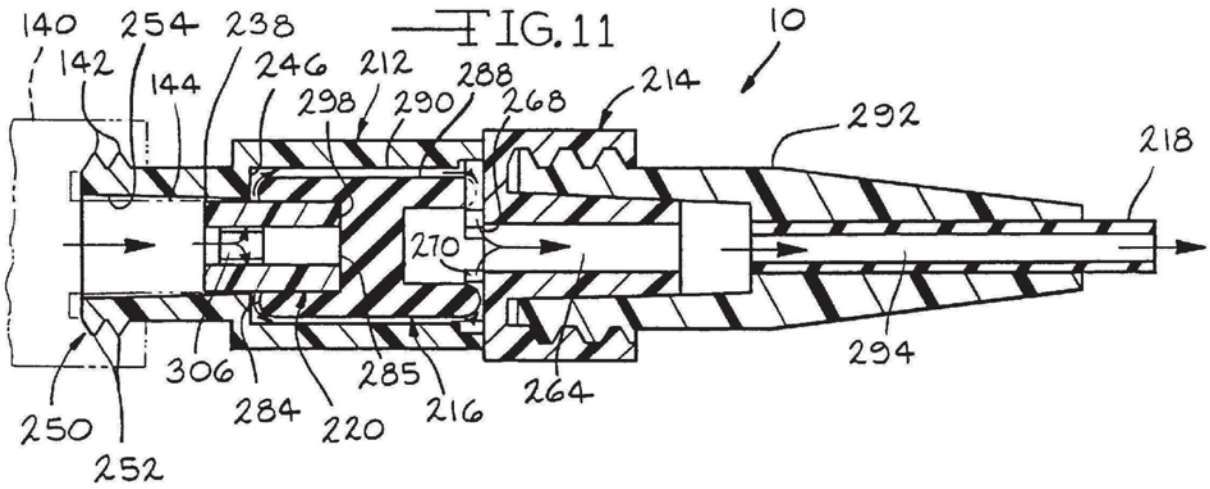


According to Tauschinski, Figures 2 and 3 depict a connector with a slit sealing disc. *See id.* at 2:62–68. In particular, these figures depict member 10 slidable within hollow-conical portion 2 and disc 3 provided with central slit 8. *See id.* at 3:17–25. Figure 2 depicts disc 3 as closed, with Figure 3 depicting member 10 advanced downward and within slit 8 of disc 3 to open the slit. *See id.* at 3:29–36.

3. Arnett (Ex. 1005)

Arnett is a U.S. Patent titled "Valve Assembly" and discloses a "valve assembly having a body, an end cap, a resilient septum, and an actuator." Ex. 1005, [54], [57]. Arnett discloses that its inventive valve assembly provides a "superior seal" to prevent leakage. *Id.* at 1:12–17. Arnett discloses that its "actuator moves the shoulder surface of the septum away

from the septum shoulder of the body to allow fluid to flow through the body fluid passageway, the chamber fluid passageways and the end cap fluid passageway." *Id.* at 1:51–55. To illustrate an embodiment of Arnett's invention—which Petitioner itself relies upon (Pet. 20–21)—we reproduce Figure 11 of Arnett, 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 needless 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:

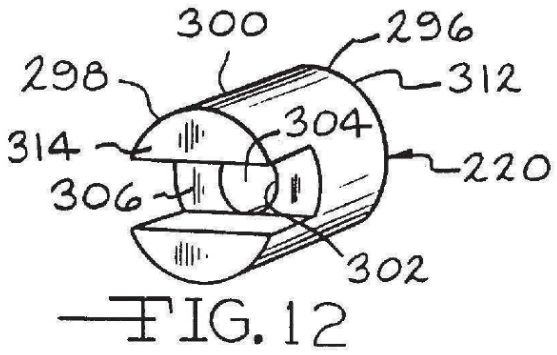
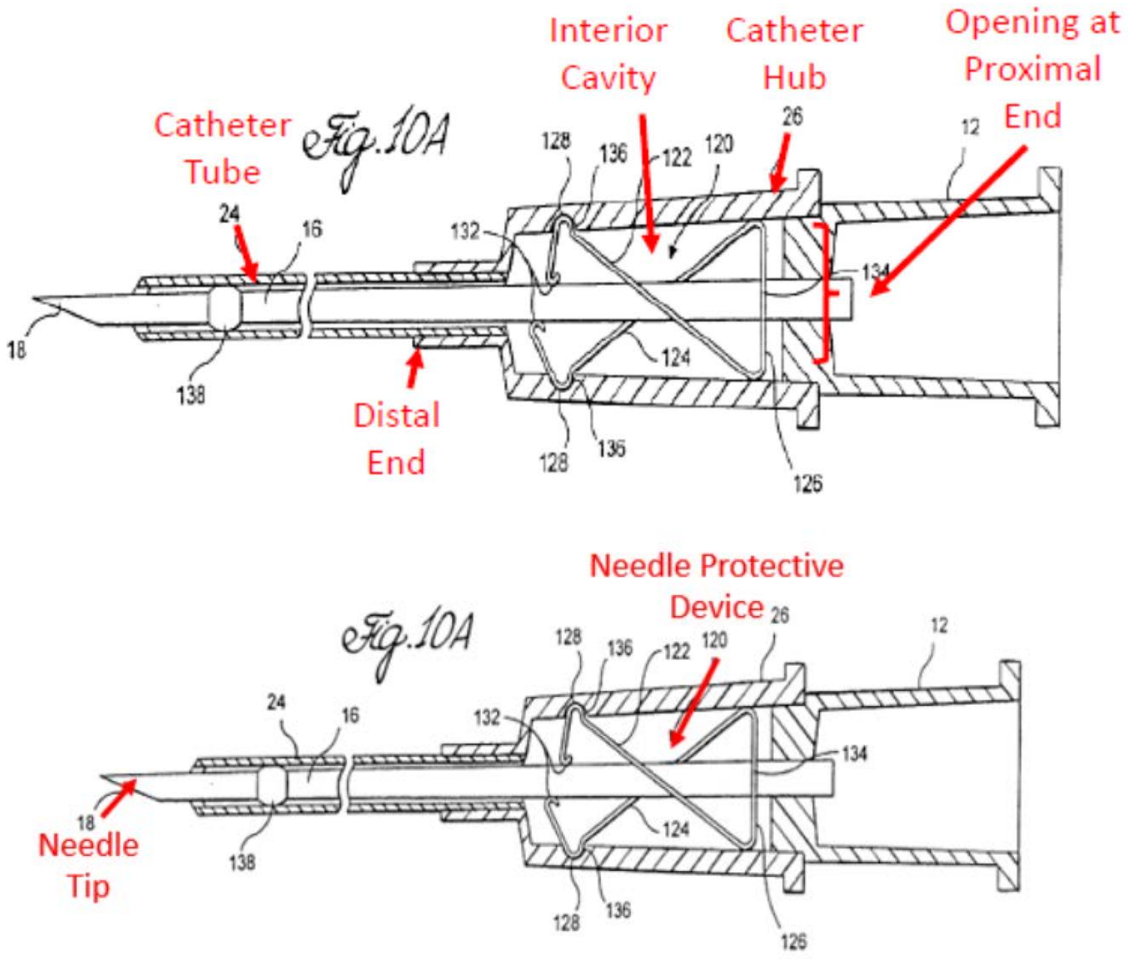


FIG. 12

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

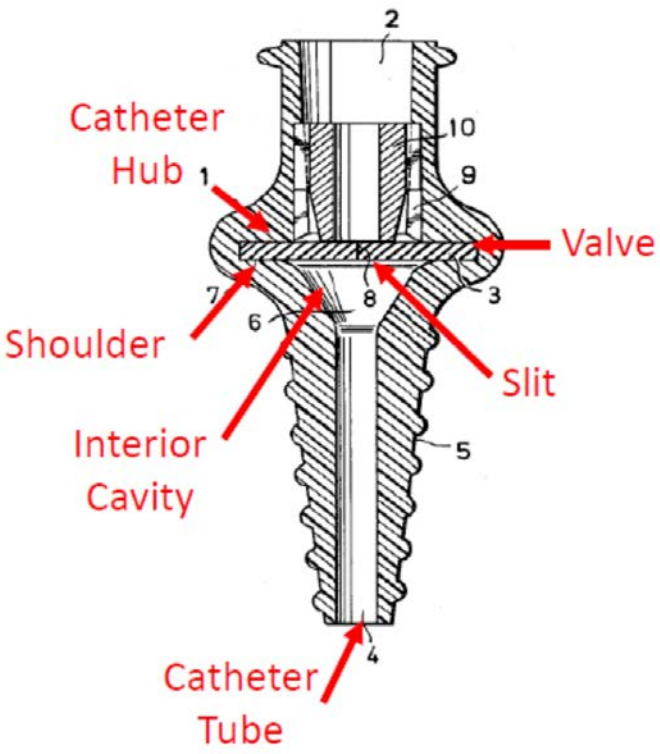
In challenging the claims, Petitioner submits that Woehr discloses a "catheter insertion device" comprising a "catheter hub" (or "first hub"), "needle," and "needle protective device." *See* Pet. 12–15, 23–26 (challenging independent claim 1); *see also id.* at 27–28, 30–31 (challenging independent claim 9); *see also id.* at 32–33, 35 (challenging independent claim 24). To illustrate these findings, Petitioner submits several annotated Figures, including several annotated figures of Woehr's Figure 10A (*id.* at 14, 15, 24), 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 12–14, 23–24.

In addressing the claimed "valve," Petitioner relies on Tauschinski and reasons that it would have been obvious to modify Woehr to include Tauschinski's valve. *See id.* at 16–18 (citations omitted). In relying on Tauschinski, Petitioner submits an annotated version of Tauschinski's Figure 2 (*id.* at 17), which we reproduce below:

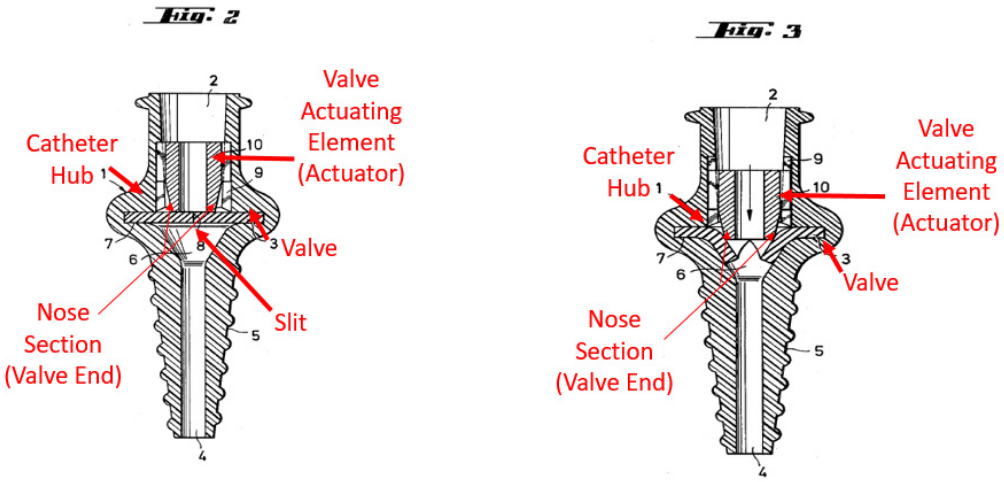
Fig. 2



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 16 (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 17–18 (citing in-part Ex. 1002 ¶ 73).

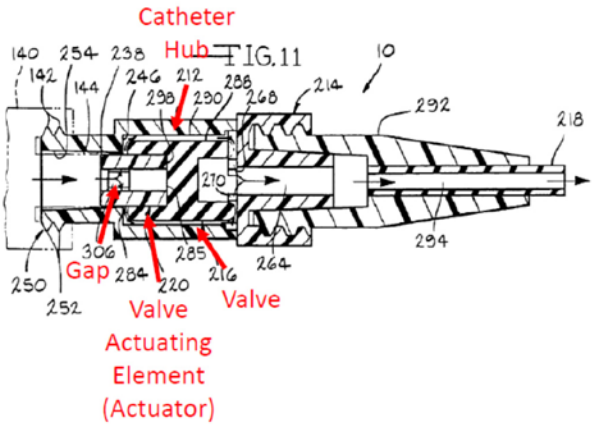
In addressing the claimed "valve actuating element comprising a *nose section having a tapered end* . . . and a plunger end having at least two plunger elements . . . having *a gap therebetween to permit fluid flow to flow therethrough*," Petitioner relies on both Tauschinski and Arnett. *Id.* at 18–23.

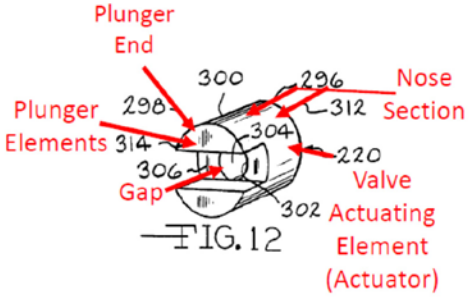
To address the claimed "valve actuating element comprising a *nose section having a tapered end*," Petitioner submits annotated versions of Tauschinski's Figures 2 and 3 (*id.* at 20), which we reproduce below:



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, slidingly disposed in catheter hub 1, and configured to actuate valve 3 to open slit 8. *Id.* at 19 (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 20─21), 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 has two plunger elements and gap 306 "therebetween . . . that permits fluid to flow therethrough." Pet. 21 (citing: Ex. 1005, 7:29–36; Ex. 1002 ¶ 79).

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 22–23. 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. ¶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.* ¶¶74, 82-83.).

Pet. 22–23 (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.

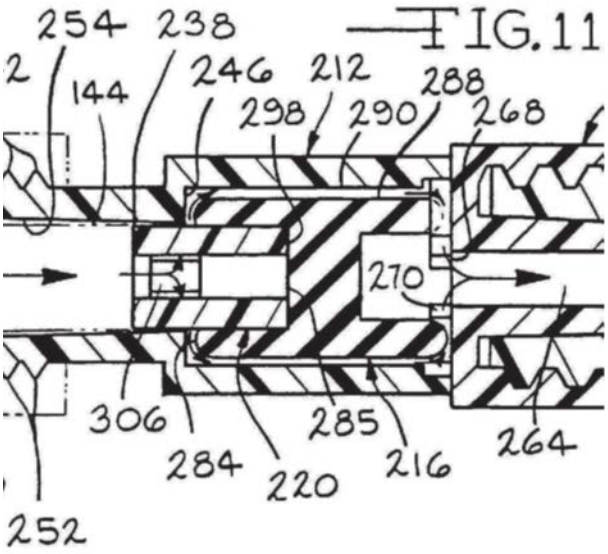
We agree.

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. 22–23.

"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, which understanding of 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. 17–18 (citing Ex. 1002 ¶ 72). 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, 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.* at 22–23. 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 24 do not simply recite a "gap," but recite a "gap . . . to permit fluid flow to flow therethrough" or "thereacross." Ex. 1001, 4:64–5:25, 7:11–8:9. 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. 18–23 (citing Ex. 1002 ¶¶ 74–83; *see also* Ex. 1002 ¶ 79 (citing Ex. 1005, 7:29–36)). In other words, although we agree with Petitioner's finding that Arnett's fluid passageway 306—the claimed "gap"—permits fluid to flow therethrough (*see* Pet. 21), 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 "thereacross," as further required by independent claims 1 and 24. Ex. 1001, 4:64–5:25, 7:11–8:9.

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, 2, 9, 10, 24, 27, and 28.

E. Van Heugten and Arnett

Petitioner contends that claims 1, 2, 9, 10, 24, 27, and 28 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:

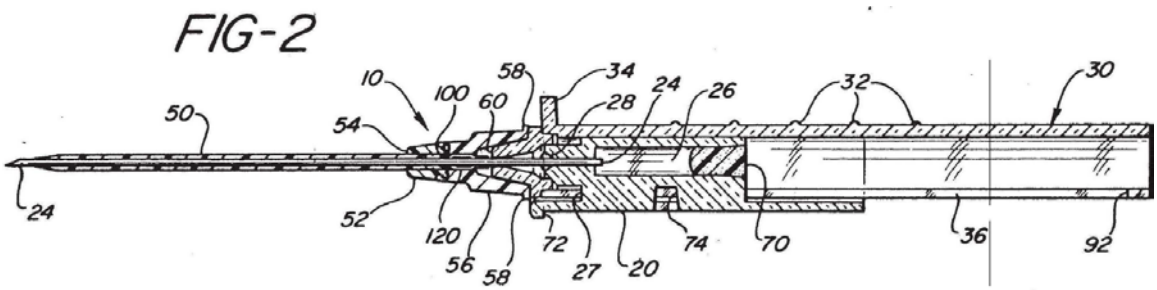
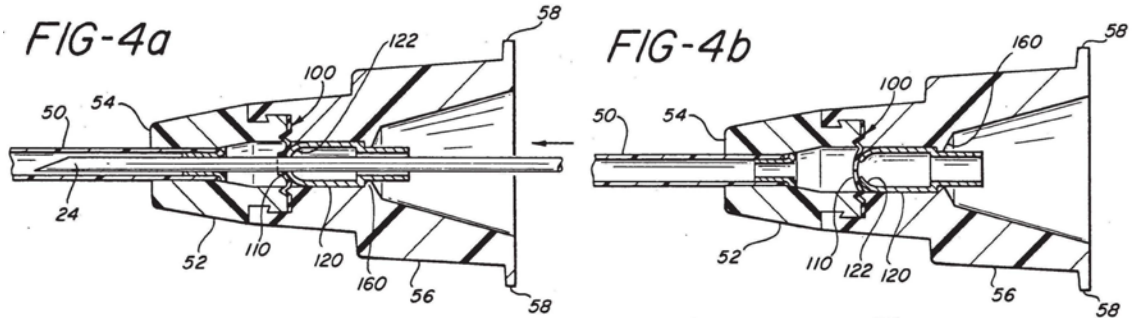


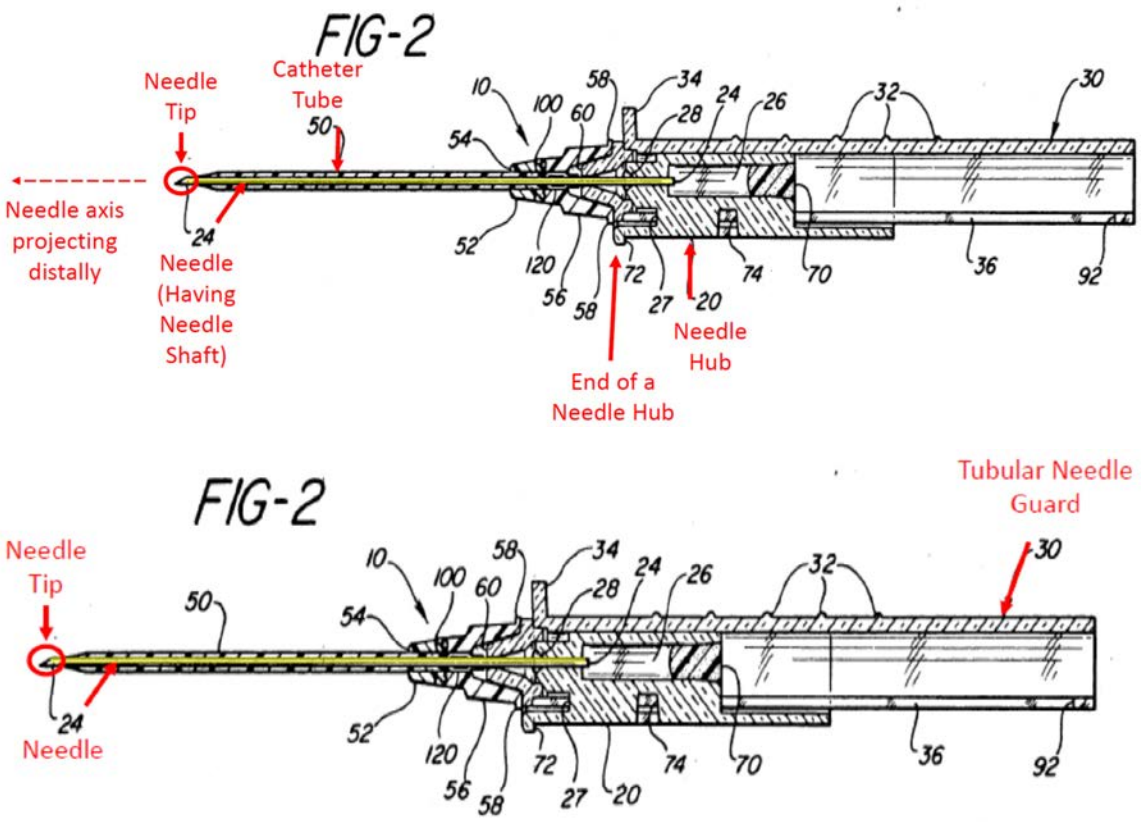
Figure 2 depicts a cross-sectional view of Van Heugten's catheter assembly 10. *Id.* at 2:6–10, 19─21. In particular, Figure 2 illustrates catheter assembly 10 with catheter 50 and needle 24, which needle guard 30 covers upon retraction of needle 24 to prevent inadvertent needle injury to the user or 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.

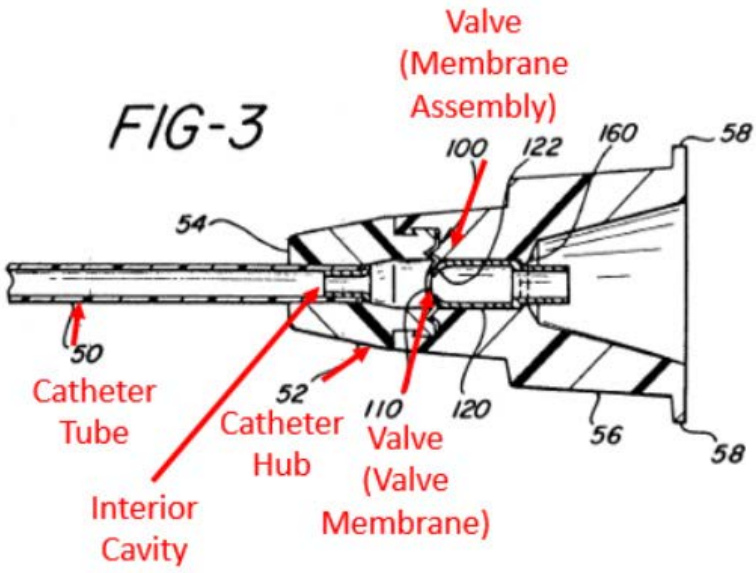
2. Petitioner's Challenge

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. 38–43, 45–46 (independent claim 1); *id.* at 47–49, 51–52 (independent claim 9); *id.* at 53–54, 55 (independent claim 24). In support of these findings, Petitioner submits annotated versions of Van Heugten's Figure 2 (*id.* at 40, 46), which we reproduce, below:



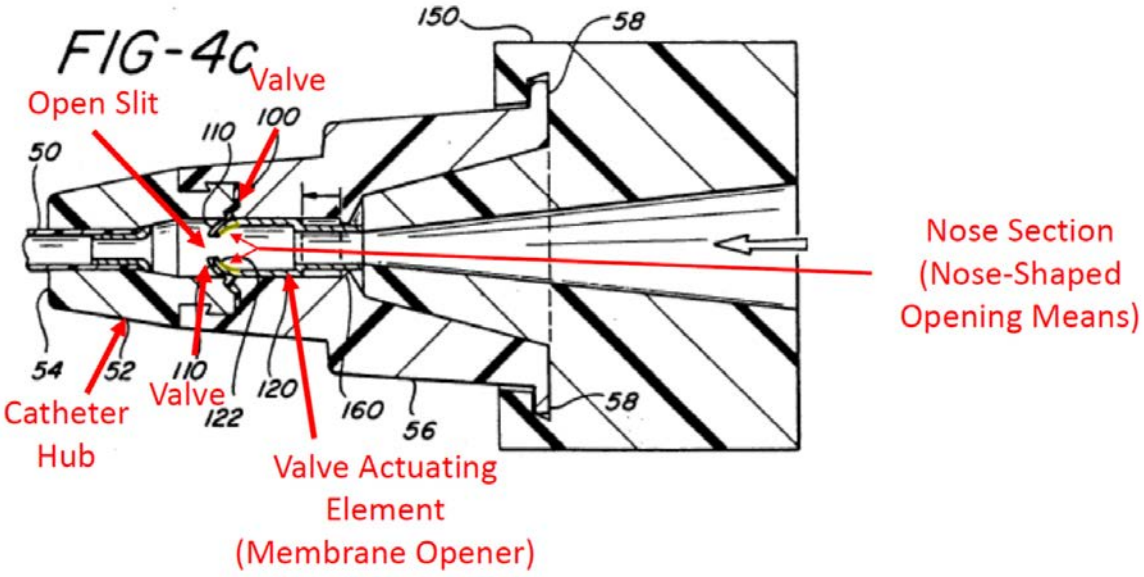
According to Petitioner, and as shown above, Figure 2 depicts Van Heugten's "catheter hub" 52, "needle" 24, and "needle protective device" 30. *Id.* at 38, 39, 45.

Petitioner also submits an annotated version of Van Heugten's Figure 3 (*id.* at 39), which we also reproduce, below:



According to Petitioner, and as shown in Figure 3, Van Heugten also discloses the claimed "valve" 100, 110. *See* Pet. 40–42 ("a POSA would have understood Van Heugten to disclose the valve membrane 110 having one or more slits") (citing Ex. 1002 ¶ 134).

In addressing the claimed "valve actuating element," Petitioner relies on a combination of Van Heugten and Arnett. *Id.* at 45. 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 44), which we reproduce, below:



According to Petitioner, Figure 4c depicts "valve actuating element" 120 comprising a nose section with a tapered end 122. *Id.* at 43–44 (citing Ex. 1006, 4:31–36, 4:43–49).

To address the claimed "valve actuating element comprising . . . at least two plunger elements . . . having a gap therebetween," and as with the previous ground, Petitioner relies on Arnett's actuator 220 with "two plungers with a gap between these elements." *Id.* at 45. Petitioner reasons that it would have been obvious to modify Van Heugten's "valve actuator" 120 to include Arnett's "plungers with a gap," as follows:

> It would have been obvious for a POSA to combine the catheter insertion device of Van Heugten with the valve actuating elements disclosed in Van Heugten and Arnett. Both Van Heugten and Arnett disclose catheter insertion assemblies with a valve, an actuator, and needle protection. It would have been obvious to a POSA to modify Van Heugten's valve actuating element to put two plunger elements on the proximal end that are pushed by an external force to open a valve as described in Arnett. *Adding structure at the end of the actuator to create two plungers with a gap between these elements was a known actuator configuration*. Further, it had a *known advantage to*

> *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. ¶141.)

Id. at 45─46 (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. 54. 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 ¶¶ 85–89).

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. 45 (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, which understanding of 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. 44 (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 45, 21. 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 24 do not simply recite a "gap," but recite a "gap . . . to permit fluid flow to flow therethrough" or "thereacross." Ex. 1001, 4:64–5:25, 7:11–8:9. 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, which itself *does not* direct fluid around the valve. *See* Pet. 43–45 (citing Ex. 1002 ¶¶ 137–141; *see also* Ex. 1002 ¶ 140 (referencing prior ground)). In other words, although we agree with Petitioner's finding that Arnett's fluid passageway 306—the claimed "gap"—permits fluid to flow therethrough (*see* Pet. 21), 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. 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 "thereacross," as further required by independent claims 1 and 24. Ex. 1001, 4:64–5:25, 7:11–8:9.

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, 2, 9, 10, 24, 27, and 28.

III. ORDER

For the reasons given, it is

ORDERED that no *inter partes* review is instituted.

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