

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 IPR2017-01587
Patent 9,149,626 B2

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

KINDER, *Administrative Patent Judge*.

DECISION

Instituting *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 11 and 20 of U.S. Patent No. 9,149,626 B2 (“the ’626 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 institute an *inter partes* review based on the ground identified in the Order section of this Decision.

A. *Related Proceedings*

The parties represent that the ’626 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; Paper 6, 4. 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; 8,540,728; 8,597,249; 8,460,247; and 9,370,641. *Id.* The following chart associates each *inter partes* review with its corresponding 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 '626 Patent (Ex. 1001)

The '626 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], 1:20–23.

An embodiment of the '626 patent's catheter insertion device is illustrated in Figure 1 of the '626 patent, as depicted below:

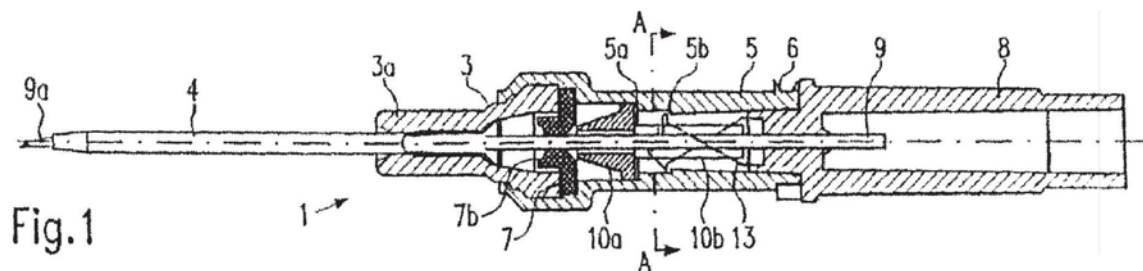


Figure 1 shows a longitudinal section through a catheter insertion device in the ready position. According to the '626 patent, Figure 1 depicts catheter

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. 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 2:9–14. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:15–37. 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 2:21–29.

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

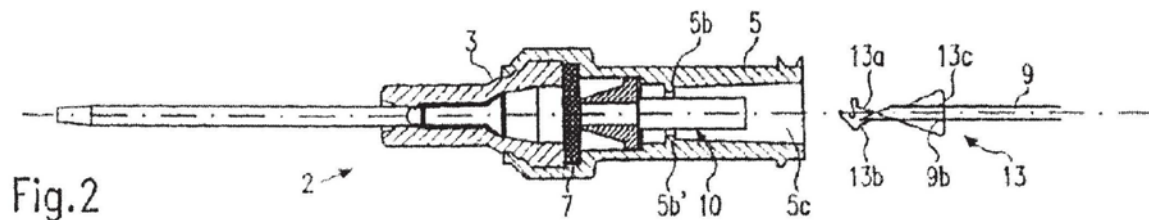


Figure 2 depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:44–45, 2:21–29. As shown above, needle guard element or spring clip 13 is removed from the catheter hub along with needle 9, causing the spring clip’s spring arms 13a, 13b to cover the needle’s tip. *Id.* at 2:26–29. 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 2:30–32.

As depicted in Figure 6 below, valve disc 7 may be provided with three slits 7a that extend radially from the middle over section X.

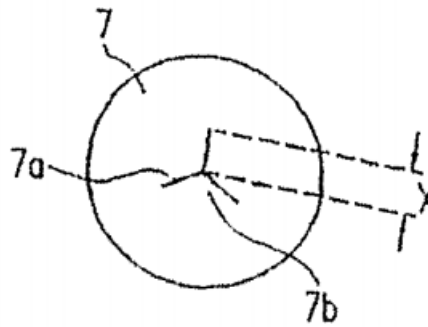


Fig. 6

Figure 6 shows a view of valve disc 7 with slits 7a. *Id.* at 1:44–45. Slits 7a help form elastic flaps 7b, which can be expanded by the insertion of the hollow needle. *Id.* at 2:32–36.

C. Challenged Claims

Claim 11 is independent and claim 20 depends from claim 11. *Id.* at 5:46–6:21, 6:45–48. Each claim is reproduced below:

1. A catheter insertion device comprising:

a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached to 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 in a ready position and comprises a needle tip;

a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow and comprises a wall surface comprising a slit; 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 to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit and a plunger end extending proximally of the nose

section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon; and

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

20. The catheter insertion device of claim 11, wherein the catheter hub further comprises a shoulder in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element.

Id.

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 11 and 20 of the '626 patent are unpatentable under the following grounds:

References	Basis	Claim(s)
Woehr and Tauschinski	§ 103(a)	11 and 20
Woehr, Tauschinski, and Arnett	§ 103(a)	11 and 20
Van Heugten	§ 103(a)	11 and 20
Van Heugten and Arnett	§ 103(a)	11 and 20

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). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). For purposes of

this Decision, we determine it necessary to construe the term “needle protective device.”

Needle Protective Device

Independent claim 11 requires “[a] catheter insertion device comprising . . . a needle protective device spaced from the needle tip in the ready position and movable relative to the needle tip, at least in part distally of the needle tip to prevent unintended needle sticks.” Ex. 1001, 6:18–21. Petitioner contends the term needle protective device invokes 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Pet. 7–10. Petitioner acknowledges that a presumption exists that the limitation is not in means-plus-function format, yet Petitioner contends that the “use of the word ‘device’ in the claims does not impart any structure and is tantamount to using the word ‘means’” (*id.* at 8 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc))) and further contends that “the modifier ‘needle protective’ does not impart any structure to the term ‘device’” (*id.* at 9). Petitioner’s argument is supported by the declaration of Mr. Griffis, who testifies that “[t]he phrase ‘needle protective device’ is not defined in any technical dictionaries or engineering handbooks, nor is it ‘used in common parlance or by persons of skill in the pertinent art to designate structure.’” *Id.* at 9 (quoting Ex. 1002 ¶ 44).

Patent Owner disagrees that the needle protective device limitation should be construed in means-plus-function format. Prelim. Resp. 5–18. Patent Owner contends that “[t]he claim language following ‘needle protective device’ . . . indicates the term is structural.” *Id.* at 16. Patent Owner notes that “[c]laim 11 requires that the ‘needle protective device’ be physically ‘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.” *Id.* Patent Owner also quotes claim 15, which requires that the “needle protective device comprises a proximal wall and two arms that converge to a single point,” and the language of claim 19, which requires that the “needle protective device comprises an arm that is located, at least in part, in the first hub or catheter hub.” *Id.* According to Patent Owner, because this language provides definition to “the location of the ‘needle protective device,’ how it cooperates with the needle, and structural requirements such as a wall and arm(s), a POSITA would understand it to be structural.” *Id.* at 16–17 (citing Ex. 2001 ¶¶ 61–62; *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 649 F.3d 1350, 1356 (Fed. Cir. 2011) (finding sufficient structure when claims “delineate the components that the [device] is connected to, describe how the [device] interacts with those components, and describe the [function] that the [device] performs”)).

Based on the record before us, we are not convinced that the needle protective device limitation should be construed as a means-plus-function term. Because the term “means” is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. Rather, as pointed out by Patent Owner, we determine that the needle protective device limitation and the claims as a whole recite sufficient structure. *See Williamson, LLC*, 792 F.3d 1349 (explaining that the presumption is overcome when “the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’”). Further, Mr. Meyst explains how a person of ordinary skill in the art “would recognize that the claimed ‘needle protective device’ refers to the class of structures included in safety

IV catheters that prevent unintended needle-sticks by guarding (*i.e.*, protecting) the needle tip.” Ex. 2001 ¶ 52 (citing Ex. 2014, which is cited in the ’626 patent). Based on the current record before us, we find Mr. Meyst’s testimony persuasive as to this issue.

Based on the record before us, the term “needle protective device” should not be construed under § 112 ¶ 6. Instead, we agree with Patent Owner that the term “needle protective device” means *a device configured to prevent unintended needle sticks*. See Prelim. Resp. 18.

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. 5 (citing Ex. 2001 ¶¶ 26–28).

Based on our review of the ’626 patent, the types of problems and solutions described in the ’626 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

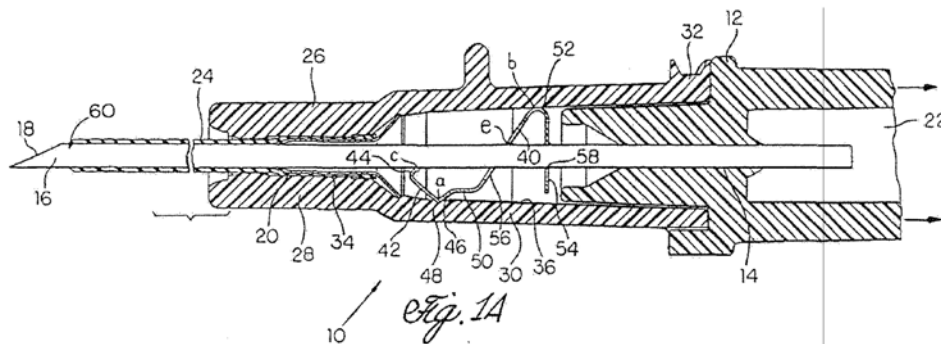
degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Obviousness of Claims 11 and 20 over Woehr and Tauschinski

Petitioner contends that claims 11 and 20 are unpatentable over Woehr and Tauschinski. Pet. 3. For the reasons set forth below, we do not institute trial on this ground.

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:

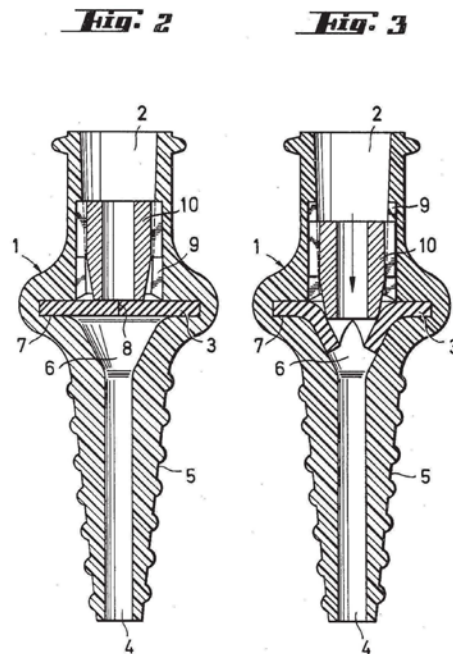


Woehr describes Figure 1A as depicting catheter 10 including needle hub 12, needle 16 with needle tip 18, catheter hub 26, and needle guard 40 in the form of a unitary spring clip. *Id.* at 4:8–28, 50–51. As needle 16 is withdrawn from a patient, needle guard 40 “automatically snaps into a

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. Petitioner's Challenge

In challenging the claims, Petitioner submits that Woehr discloses a “catheter insertion device” comprising a “catheter hub,” “needle,” and “needle protective device.” *See* Pet. 12–15, 22–25 (challenging independent claim 11). To illustrate, Petitioner submits an annotated version of Woehr’s Figure 10A (*id.* at 14), which we reproduce below:

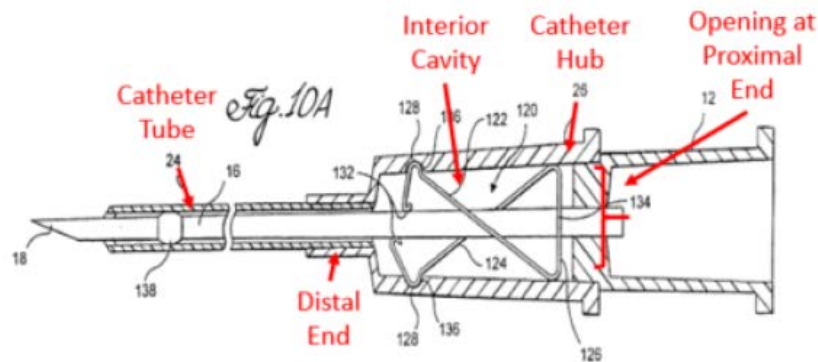


Figure 10A of Woehr shows a partial cross-section of a safety IV catheter in the ready and protected positions. According to Petitioner, and referring to annotated Figure 10A, Woehr discloses the claimed “catheter hub” and “body,” “interior cavity,” (element 26). *Id.* at 13–16. Woehr also “discloses a needle (*e.g.*, element 16) having a needle shaft defining a needle axis projecting distally of an end of a needle hub (*e.g.*, element 12), said needle (*e.g.*, element 16) projecting through the catheter tube (*e.g.*, element 24) in a ready position and comprises a needle tip (*e.g.*, element 18).” *Id.* at 14.

Addressing the claimed “a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity,” and the claimed “a valve actuating element,” Petitioner relies on Tauschinski and reasons that it would have been obvious to modify Woehr to include Tauschinski’s valve. *See id.* at 16–22 (citations omitted). In relying on Tauschinski,

Petitioner submits an annotated version of Tauschinski's Figure 2 (*id.* at 18), which we reproduce below:

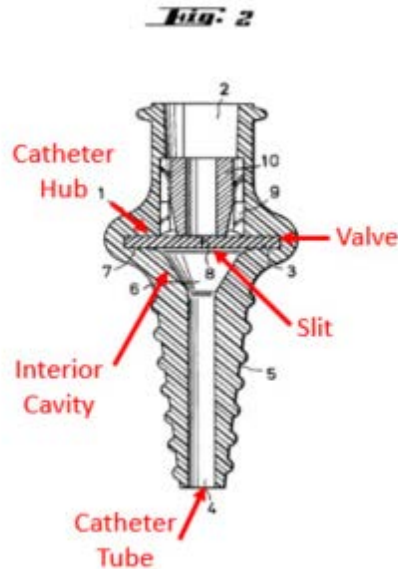
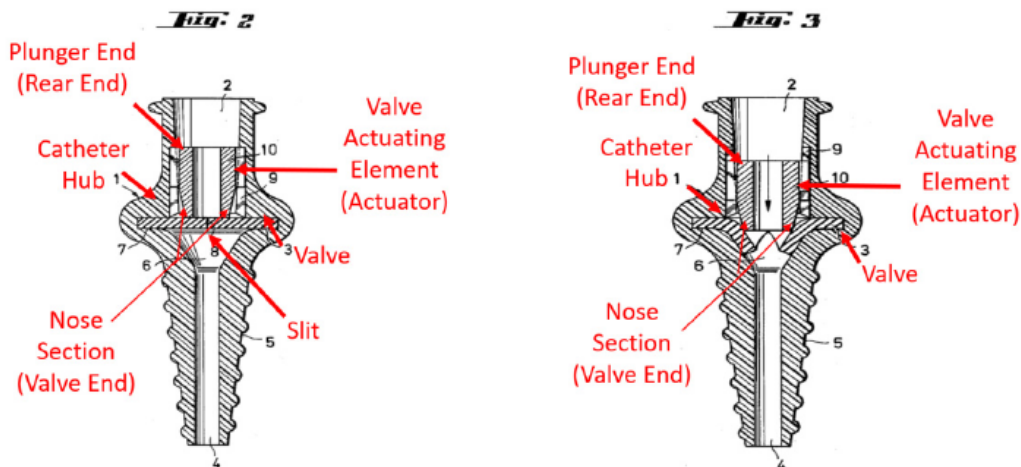


Figure 2 Tauschinski shows a self-sealing connector for catheters. Petitioner asserts that Tauschinski discloses valve 3 with slit 8 configured to obstruct fluid flow through catheter hub 1. *Id.* at 16–18 (citing in-part Ex. 1005, 2:7–37, 3:14–19). Petitioner reasons that it would have been obvious to modify Woehr “by adding protective elements, such as a valve to prevent the emergence of blood,” as disclosed by Tauschinski. *Id.* at 18–19 (citing Ex. 1002 ¶¶ 65–67).

To address the claimed “valve actuating element slidably disposed in the catheter hub to actuate the valve,” Petitioner submits annotated versions of Tauschinski's Figures 2 and 3 (*id.* at 21), which we reproduce below:



Annotated Figures 2 and 3 of Tauschinski depict self-sealing connectors for catheters with labeling added. According to Petitioner, and as shown in the above Figures 2 and 3, Tauschinski discloses valve actuating element 10 slidably disposed in catheter hub 1, and configured to actuate valve 3 to open slit 8. *Id.* at 20 (citing Ex. 1005, 3:21–36).

Petitioner reasons that “[i]t would have been obvious for a POSA to combine the catheter insertion device of Woehr ’108 with the valve actuating elements as disclosed in Tauschinski.” *Id.* at 21. Petitioner contends that

A POSA would have found it obvious to improve Woehr ’108 by adding protective elements, such as a valve to prevent the emergence of blood, based on the known technique disclosed in Tauschinski to improve a similar catheter insertion device. (Ex. 1002, Griffis Decl. ¶¶65–67.) . . . [A] POSA would have recognized a reason to combine the valve with the spring clip safety catheter, and the combination is merely the combination of known elements that that would have been expected to maintain their respective functions after they have been combined.

Id. at 18–19.

4. *Patent Owner's Argument – Discretion Under § 325(d)*

Patent Owner argues that the Office has already considered Woehr and Tauschinski “in connection with U.S. Patent No. 7,736,339 (‘the ’339 patent’), a parent from which the ’626 patent claims priority.” Prelim. Resp. 22. Specifically, during prosecution of the parent application, Woehr was relied upon as the base reference for disclosing a catheter insertion device in the same manner Woehr is used by Petitioner for this ground. *Id.* at 23–24. Conceding that the Examiner did not consider the exact same combination of Woehr and Tauschinski proposed here by Petitioner, Patent Owner contends that “[w]hile Woehr-108 and Tauschinski were never considered together, this appears to be because the Office had already considered the combination of Woehr-108 and U.S. Patent No. 5,405,323 to Rogers.” *Id.* at 23. Patent Owner contends that Rogers, like Tauschinski, discloses a check valve for a catheter insertion device and that now, Woehr and “Tauschinski adds nothing beyond what was already considered and rejected by the Office.”¹ Patent Owner argues that exercise of our discretion under § 325(d) to deny institution of this ground is appropriate here because “Petitioner has failed to present any new evidence or arguments that are substantively different than those already presented by the Office during prosecution of the ’339 patent.” *Id.* at 38.

5. *Analysis*

We start with the premise that institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367

¹ The Examiner also considered Tauschinski’s valve in combination with a different base reference, Bialecki, U.S. Patent No. 6,652,486 (Ex. 2019). *See Ex. 2004*, 314–25.

(Fed. Cir. 2016) (“the PTO is permitted, but never compelled, to institute an IPR proceeding”). In particular, Section 325(d) states that “[i]n determining whether to institute . . . the Director may take into account whether . . . the same or substantially the same prior art or arguments previously were presented to the Office.” In evaluating whether to exercise our discretion when the same or substantially the same prior art or arguments previously were presented to the Office under section 325(d), we have weighed some common *non-exclusive* factors, such as: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.²

² See, e.g., *Palo Alto Networks v. Finjan*, Case IPR2015-01999, slip op. at 6–8 (PTAB Mar. 29, 2016) (Paper 7) (evaluating the similarities between the asserted art and the references relied on during examination and determining the extent arguments considered during examination); *Dorco Co. v. The Gillette Co.*, Case IPR2017-00500, slip op. at 18–19 (PTAB June 21, 2017) (Paper 7) (considering whether Petitioner identifies errors by the Office or explanation of why the Office should revisit the patentability issues considered by the Examiner, and also considering the overlap of arguments).

(a) The Similarities and Material Differences Between the Asserted Art and the Prior Art Involved During Examination

Woehr, relied upon by Petitioner as the base reference here, was also the base reference in the Examiner's Woehr/Rogers obviousness rejection during examination.³ *See* Ex. 2004, 121–24. In this proceeding, Petitioner applies Tauschinski, rather than Rogers as the secondary reference. *See* Pet. 19–22.

As shown and discussed above, Tauschinski discloses valve actuating element 10 slidably disposed in catheter hub 1, and that actuating element 10 slides within the catheter hub to open slit 8 in the valve. *Id.* at 19 (citing Ex. 1005, 3:21–36). Tauschinski's valve is intended to allow a catheter to be inserted through the valve element 10 and, when the catheter is removed, "the closed connector is intended to prevent an emergence of blood or an ingress of air through the fitting." Ex. 1005, 2:17–19. Rogers similarly "relates to a catheter check valve assembly that prevents unintended back flow of body fluids through the catheter when the trocar used in placing the catheter in the body is removed."⁴ Ex. 2018, 1:5–9.

Figure 3 from Rogers is reproduced below.

³ The application (U.S. Pat. Appl'n. No. 14/161,169) which became the '626 patent is a continuation that claims a chain of priority to U.S. Pat. Appl'n. No. 10/520,325 which became the '339 patent. Ex. 1001, [63]. Applicant entered a series of Terminal Disclaimers in each application, including during prosecution of the '169 application, to overcome the Examiner's non-statutory double patenting rejections. *See* Ex. 2003, 147–49.

⁴ A "trocar" is "a sharp-pointed surgical instrument." MERRIAM-WEBSTER ONLINE DICTIONARY <https://www.merriam-webster.com/dictionary/trocar> (last visited Nov. 27, 2017).

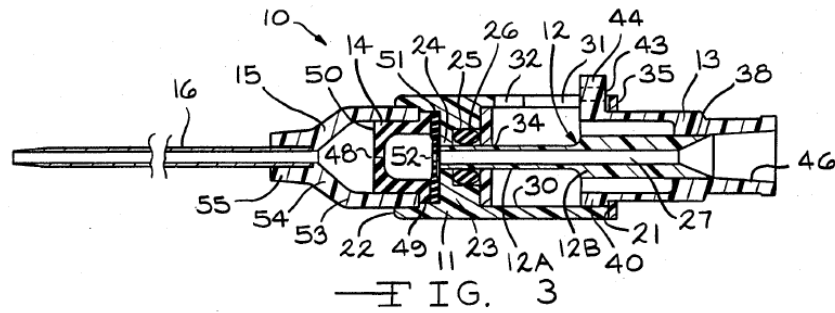
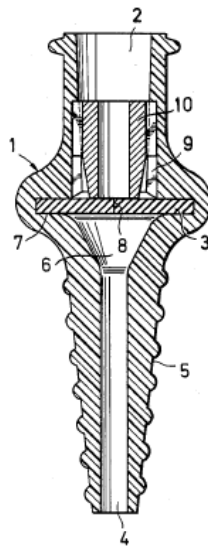


Figure 3 of Rogers illustrates check valve assembly 10 including slit 48 in valve 14, and sliding separator 12. Compare Figure 3 of Rogers with Figure 2 from Tauschinski below.

Fig. 2



Tauschinski's valve, shown above in Figure 2, includes valve disc 3, slit 8, and slidable actuator 10.

Functionally, Rogers and Tauschinski operate the same way, permitting the insertion of a needle, trocar, or catheter through the valve, and then closing the valve against blood or fluid flow upon removal of the needle or catheter. *Compare* Ex. 1005, 2:7–19, *with* Ex. 2018, 1:5–9. From a structural standpoint, both valves include an actuating element defining a

central passage that impacts the valve to open the slit in the valve and then receive and guide a needle through the valve opening. *Compare* Ex. 1005, 3:20–32, *with* Ex. 2018, 4:23–30. The most observable structural difference is that Tauschinski’s actuator has a frustoconical-shaped end portion adjacent the valve disc whereas Rogers actuator, i.e. separator 12, is cylindrical and has a longer body portion 12A extending to an enlarged body portion 12B. Also, Rogers has a duckbill valve 14 with a different cross-section than a simple disc. Ex. 2018, 2:36–41, 50–53. We cannot reasonably consider such differences “material” because, a) these structural differences do not appear to affect, in any meaningful manner, the functioning of the check valve itself, and b) Petitioner has not relied on, or substantively addressed, any particular differences between Rogers and Tauschinski in its assertion of unpatentability in the Petition. We therefore give little weight to the fact that Tauschinski is a different reference from Rogers.

(b) The Cumulative Nature of the Asserted Art and the Prior Art Evaluated During Examination

Patent Owner points out that Tauschinski was substantively evaluated by the Examiner, as combined with Bialecki. Prelim. Resp. 26–29 (citing Ex. 2004, 314–23). During prosecution, Bialecki was relied upon as a base reference disclosing a catheter insertion device, and Tauschinski was relied upon by the Examiner for

a check valve [] disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in, the ready position and which automatically closes after the removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube.

Ex. 2004, 317. Petitioner has relied on Tauschinski, here in its Petition, in combination with Woehr for the same reasons, stating that Tauschinski teaches a

valve (e.g., element 3) for deflecting the valve to permit fluid flow through the interior cavity of the catheter hub . . . wherein the valve (e.g., element 3) remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube (e.g., element 4) and the catheter hub (e.g., element 1).

Pet. 18. Considering these explanations, Tauschinski was, therefore, evaluated substantively by the Examiner during prosecution, even if not in combination with Woehr, in the same manner as Petitioner proposes now. Further, the asserted combination of Woehr and Tauschinski is similar and cumulative in evidentiary context when compared to Woehr and Rogers that was evaluated by the Examiner. Indeed, we are also not apprised of any probative differences between the Examiner's obviousness evaluation over Bialecki and Tauschinski, and the current assertion of Woehr and Tauschinski. Further, Petitioner has not articulated any substantive differences between the prior art alone or in combination, nor do we discern any significant disparity based on our review of these references. Petitioner's rearrangement of previously considered prior art presents little, if any, persuasive new evidence of unpatentability. Thus, we understand these references are primarily cumulative in nature.

(c) The Extent to which the Asserted Art was Evaluated During Examination, Including Whether the Prior Art was the Basis for Rejection

As discussed above and pointed out by Patent Owner, Tauschinski and Woehr were substantively considered, albeit in separate obviousness rejections, during prosecution of the parent application from which the '626

patent issued as a continuation. *See* Ex. 2004, 121–124, 314–323.

However, as we determined above there are few differences between the structure of the check valve elements relied on in Tauschinski and Rogers, nor do we discern a difference in function. And, the asserted prior art for this ground of unpatentability, i.e., Woehr and Tauschinski, were each considered by the Examiner, albeit in separate obviousness rejections, during prosecution. Although each of Woehr and Tauschinski (as well as Arnett and Van Heugten) were cited during the prosecution of the application leading to the '626 patent, *see* Ex. 1001, [56] (References Cited), this is not a case where the prior art was simply listed in an IDS during prosecution. Both Tauschinski and Woehr were included as a basis for, and evaluated with respect to, obviousness rejections in the parent application over claims with scope similar to that of the '626 patent, as evidenced by the Terminal Disclaimers filed by Applicant in the prosecutions leading to allowance of the '626 patent. *See id.* at 314, 344–352, and *see* Ex. 2005, 170–71.

We are not persuaded on this record that rearranging previously substantively considered prior art, and advancing essentially the same positions the Examiner raised concerning these references during prosecution, presents persuasive new evidence of unpatentability that was not evaluated previously by the Office.

(d) The Extent of the Overlap Between the Arguments Made During Examination and the Manner in which Petitioner Relies on the Prior Art

We appreciate, as Petitioner argues that, “[t]he Ground presents a new combination of references that has not previously been considered.” Pet. 12. However, as discussed above, there is significant overlap in the arguments where Petitioner relies on the combination of Woehr and Tauschinski in the

same manner as the Examiner relied on Bialecki and Tauschinski, and Woehr and Rogers. Petitioner has not persuasively explained why the “new combination” leads to any different argument or reasoning than that previously advanced by the Examiner. For example, based on Woehr/Rogers combination, the Examiner reasoned that

[s]ince the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient’s vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr’s cath[e]ter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle.

Ex. 2004, 122. Now, Petitioner argues similarly, based on Woehr/Tauschinski, that

A POSA would have found it obvious to improve Woehr ’108 by adding protective elements, such as a valve to prevent the emergence of blood, based on the known technique disclosed in Tauschinski to improve a similar catheter insertion device.

Pet. 18–19 (citing Ex. 1002 ¶¶ 65–67). Although not verbatim, we find there is substantial overlap in the arguments where Petitioner argues that the prior art “perform[s] known functions with predictable results and there is no unexpected result on which to base the patentability of the claims.” Pet. 12. Based on the Petitioner’s explanation as to how and why a person of skill in the art would have combined the references, and here, considering the same and similar references as applied during examination, we find little if any, different argument than that considered previously by the Office. *See Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior

art elements in the normal course of research and development to yield the claimed invention.”).

(e) Whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art

Petitioner has not pointed to error by the Examiner, or for that matter addressed the evidence and argument presented by Applicant, during the underlying prosecution of the ’626 patent and its parent ’339 patent.

Mainly, as discussed below, Petitioner asserts only that it has new testimonial evidence that has not been considered by the Office.

(f) The Extent to which Additional Evidence and Facts Presented in the Petition Warrant Reconsideration of the Prior Art or Arguments.

Petitioner contends that there is additional evidence “including the testimony of Jack Griffis (Ex. 1002) and testimony by Patent Owner’s own expert” that was not previously considered by the Office. Pet. 12. For its part, Patent Owner asserts that Mr. Griffis has not substantively reviewed the prosecution history of the ’626 patent, and that he “cannot explain, why the new proposed combination of Woehr-108 and Tauschinski is any different than the evidence already of record showing the patentability of the Challenged Claims.” Prelim. Resp. 31.

Mr. Griffis’ declaration addresses the combination of Woehr and Tauschinski with respect to independent claim 11. Ex. 1002 ¶¶ 61–75. Mr. Griffis’ testimony, specifically at ¶ 66, explains that “Tauschinski discloses a valve (e.g., element 3) positioned inside the interior cavity of the catheter hub (e.g., element 1) and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow (e.g., element 1).” *Id.* ¶ 66 (*citing* Ex. 1005, 2:7–32). Mr. Griffis further testifies that it is desirable to make

the proposed combination so “that the valve prevents the emergence of blood or ingress of air.” *Id.* ¶ 67.

We understand that implicit in the Examiner’s obviousness rejection is that a person of ordinary skill in the art would have, and could have, integrated the relevant structures from the references as alleged by Petitioner here. *See* Ex. 2004, 122 (“Since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr’s cath[e]ter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle.”). Applicant overcame this rejection, explaining in significant detail that

the tubular portion 12A disclosed by Rogers would act as a divider or wall and never allow the crimp on the needle to engage the guard to then separate the guard from the catheter hub in a used position to cover the needle tip. Accordingly, the proposed modification is defective and will not operate. As such, the two references cannot be combined to reject the claimed device without undue modification.

Ex. 2004, 241. This is just one example, among others, of Applicant’s detailed arguments presenting evidence and technical explanations that the structures were not compatible, and would not have been combined by one of skill in the art because such a combination would not have operated or functioned in a manner that would have assured a reasonable expectation of success. *See id.* at 239–43.

Mr. Griffis arguably provides a reason to combine Woehr and Tauschinski, that is, to prevent blood leakage from Woehr’s catheter assembly. Ex. 1002 ¶¶ 65–67. What is lacking in Mr. Griffis’ testimony,

however, is sufficient evidentiary underpinnings supporting the combination. Mr. Griffis' reliance on an entirely different reference, Van Heugten, as evidence to support his contention that one of ordinary skill would have combined Woehr and Tauschinski, is not persuasive because Van Heugten discloses a structurally and functionally different needle protection device from Woehr. *See* Ex. 1002 ¶ 68, *and compare* Ex. 1003, Fig. 2, *with* Ex. 1004, Figs. 10A–B. That a valve can be implemented with a catheter and needle protective device, as disclosed in Van Heugten, does not show persuasively why one of skill in the art would combine Woehr and Tauschinski. The simple fact that Woehr could be modified does not satisfy the requirements for a finding of obviousness. *In re Laskowski*, 871 F.2d 115, 117 (Fed. Cir. 1989); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990).

Mr. Griffis' testimony was not considered by the Examiner, this much is true. However, besides the generalized analogy to Van Heugten, Mr. Griffis' testimony presents little persuasive technical evidence or explanation as to why one of ordinary skill in the art would have combined Tauschinski's valve with Woehr's catheter hub and spring needle protective device. Neither Petitioner, nor Mr. Griffis, takes the opportunity to explain why Applicant's arguments made during prosecution were in error, or how those arguments would not apply to this asserted ground. Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). Mr. Griffis' declaration does not provide persuasive facts, data, or analysis to support his stated opinion. Without such testimony, we are not persuaded that the mere existence of the elements in the prior art warrants reconsideration of the prior art and arguments earlier presented to the Office. *See* Ex. 1002 ¶ 75.

(g) Weighing the Factors.

The same base reference, Woehr, was used in this obviousness ground in the same manner as it was during prosecution and it is combined with a secondary reference, Tauschinski, which was also used in the same manner as here by the Examiner. With a different combination of prior art that does not differ substantively from what the Examiner considered and considering that the Petitioner presents the same arguments as were meritoriously overcome by the Applicant during prosecution, based on our evaluation of the non-exclusive factors above, we are persuaded that exercising our discretion under § 325(d) on this particular ground is appropriate.

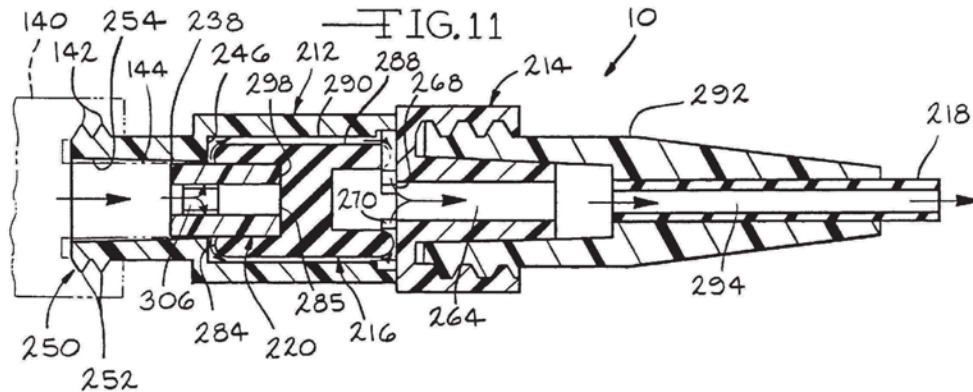
E. Obviousness of Claims 11 and 20 over Woehr, Tauschinski, and Arnett

Petitioner contends that claims 11 and 20 are unpatentable over Woehr, Tauschinski, and Arnett. Pet. 3, 26–32. On the record before us, there is no evidence that Arnett was substantively considered by the Office, we therefore exercise our discretion to reach the merits of this ground consistent with our initial decisions in IPR2017-01583, IPR2017-01584, and IPR2017-01585. For the reasons set forth below, Petitioner has not shown a reasonable likelihood that these claims would have been obvious over Woehr, Tauschinski, and Arnett.

1. Arnett (Ex. 1005)

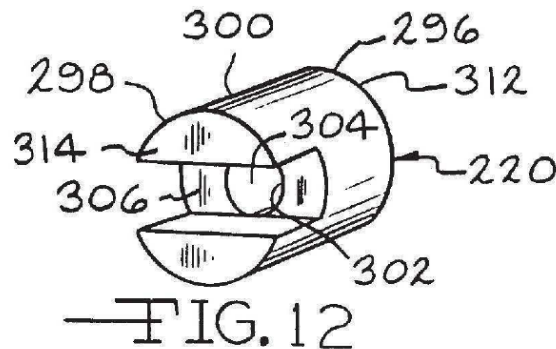
Arnett is a U.S. Patent titled “Valve Assembly” and discloses a “valve assembly having a body, an end cap, a resilient septum, and an actuator.” Ex. 1005, [54], [57]. Arnett discloses that its inventive valve assembly provides a “superior seal” to prevent leakage. *Id.* at 1:12–17. Arnett discloses that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

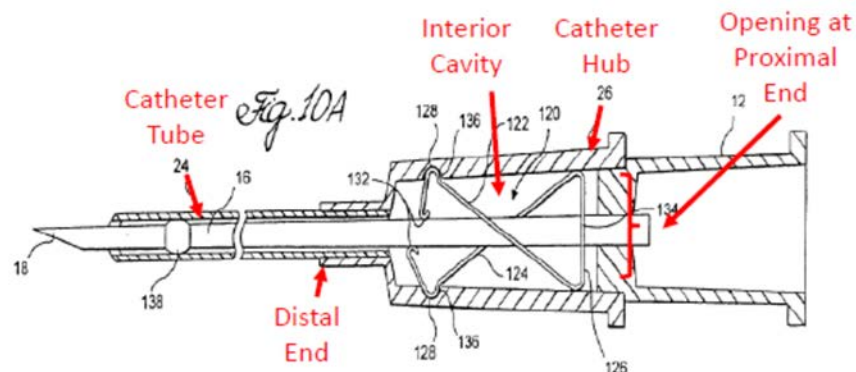
To better illustrate Arnett's actuator 220, we reproduce Figure 12, below:

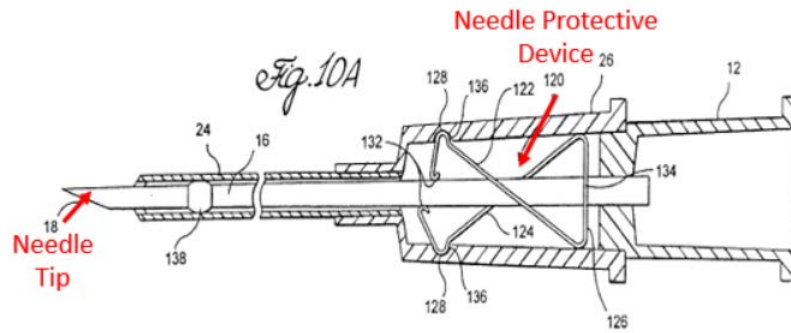


As described by Arnett, Figure 12 depicts actuator 220 including septum contact surface 312, an opposed fitting contact surface 314, and fluid passageway 306. *Id.* at 7:29–39. As discussed above in connection with Figure 11, *fluid passageway 306 allows fluid to flow around septum 216 and through fluid passageways 290.* See *id.* at Fig. 11, 8:41–44.

2. Petitioner's Challenge

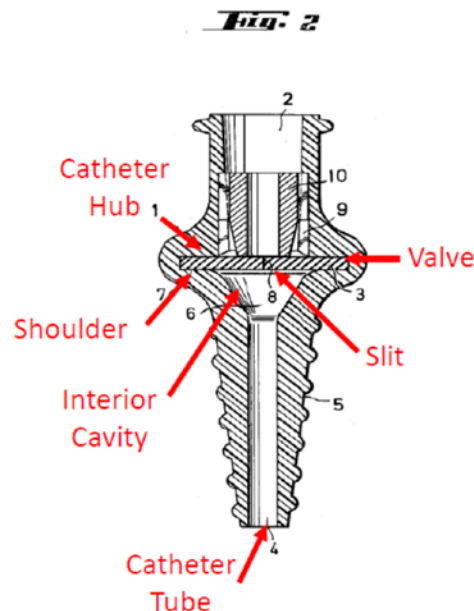
In challenging the claims, Petitioner submits that Woehr discloses a “catheter insertion device” comprising a “catheter hub,” “needle,” and “a needle protective device.” See Pet. 27–32 (referring to analysis of prior ground). To illustrate these contentions, Petitioner submits several annotated Figures, including several annotated figures of Woehr's Figure 10A (*id.* at 14, 23), 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 12–16, 22–24.

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 16–19 (citations omitted). In relying on Tauschinski, Petitioner submits an annotated version of Tauschinski’s Figure 2 (*id.* at 18), which we reproduce below:



As shown in annotated Figure 2, Petitioner asserts that Tauschinski discloses valve 3 with slit 8 configured to obstruct fluid flow through catheter hub 1.

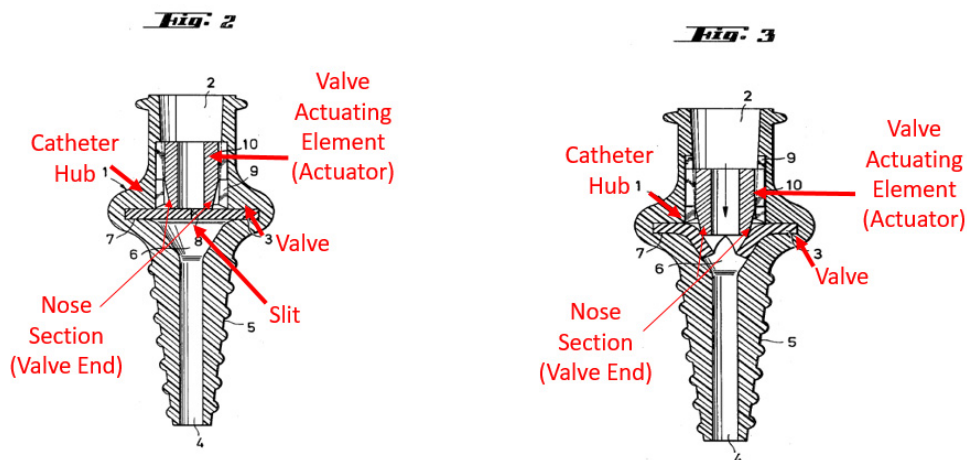
Id. at 16–17 (quoting Ex. 1004, 2:7–19). Petitioner reasons that it would have been obvious to modify Woehr “by adding protective elements, such as a valve to prevent the emergence of blood,” as disclosed by Tauschinski. *Id.* at 18–19 (citing Ex. 1002 ¶¶ 65–67).

In addressing the claimed

a valve actuating element slidably 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 and a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon

(Ex. 1001, 6:11–17), Petitioner relies on both Tauschinski and Arnett. Pet. 28–32.

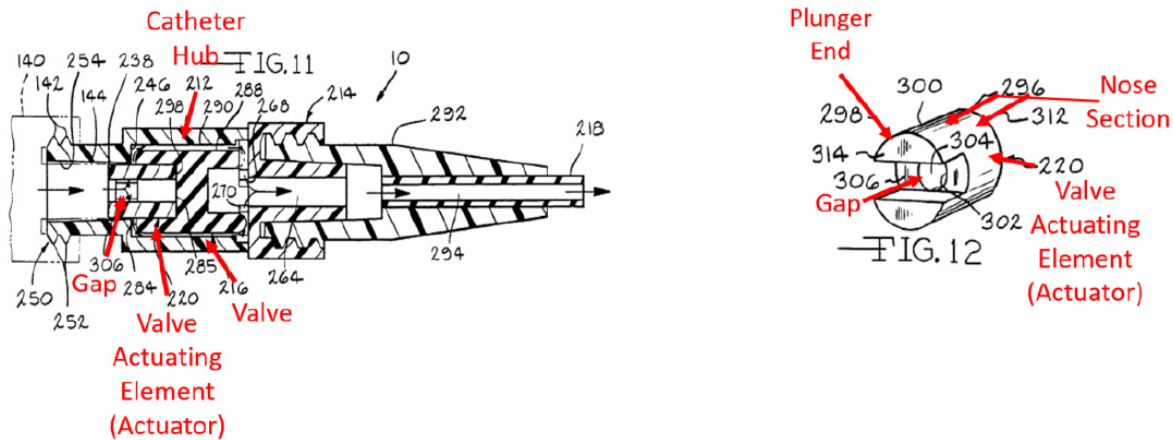
To address the claimed “the valve actuating element (e.g., element 10 of Tauschinski) comprising a nose section having a tapered end for pushing the valve,” Petitioner submits annotated versions of Tauschinski’s Figures 2 and 3 (*id.* at 29), which we reproduce below:



According to Petitioner, and as shown in the above annotated 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 28–29.

To address the claimed “valve actuating element comprising . . . a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon,” Petitioner relies on Arnett and produces annotated versions of Arnett’s Figures 11 and 12 (*id.* at 30), which we reproduce below:



Annotated Figure 11 (left) shows a cross-sectional view of the valve assembly and annotated Figure 12 (right) depicts an actuator. According to Petitioner, Figure 11 depicts valve actuating element 220 comprising a nose section, and as shown in Figure 12, valve actuating element 220 has two end plunger elements 314 extending proximally of the nose section with gap 306 there between to permit fluid to flow. Pet. 30–31 (citing Ex. 1005, 7:30–54, 8:26–49; Ex. 1002 ¶¶ 82–90).

In combining Woehr with Tauschinski and Arnett to arrive at the claimed “valve actuating element,” Petitioner reasons that it would have been obvious to combine the catheter insertion device of Woehr with the valve actuating elements as disclosed in Tauschinski and Arnett, and that it

would have been obvious to modify Tauschinski's actuator "to contain a plunger end on the proximal end of the valve actuating element that is pushed by an external force to open a valve as described in Arnett." *Id.* at 31. In particular, we reproduce Petitioner's reasoning for modifying Tauschinski's valve actuator to include Arnett's two "plunger element," below:

Both Tauschinski and Arnett disclose valves and valve actuators that can be used with catheter devices, and both recognize the need to include such valves and valve actuators to prevent leakage. (Ex. 1002, Griffis Decl. ¶¶ 82-90.) *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 a plunger as described in Arnett, and to include that actuator in the spring clip safety IV catheter of Woehr '108. (Ex. 1002, Griffis Decl. ¶¶ 82- 90.)

Pet. 32 (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 plunger elements 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.*

3. Patent Owner's Argument

Patent Owner argues that Petitioner's reason for adding Arnett's plunger element into Tauschinski is illogical and unsupported. *See Prelim.*

Resp. 32, 49–52. 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 a plunger end based on Arnett.” *Id.* at 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 52; *see also id.* at 50 (presenting annotated Figure 6 of Arnett to demonstrate how fluid flows through side holes and around a septum).

4. *Analysis*

We are not convinced that Petitioner has articulated a persuasive reason and, more specifically, has not shown sufficient evidentiary underpinnings supporting the assertion that a person having ordinary skill in the art would have modified Tauschinski’s actuator to include Arnett’s plunger elements as a matter of simple “design choice” because “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.” Pet. 32

Importantly, Petitioner’s assertion that it is simply a matter of design choice to alter Tauschinski’s actuator with Arnett’s plunger and gap elements lacks rational underpinnings. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418 (“rejections on obvious 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.”). While it may be possible to design Tauschinski’s actuator to include the plunger and

gap elements disclosed by Arnett, Petitioner has not explained adequately *why* one of ordinary skill in the art would have plucked this particular structure from Arnett to add to Tauschinski.

As discussed above, Petitioner reasons initially that a person of skill in the art would add a gap between two plungers as a matter of design choice because “that still allows the actuator to transfer a distally directed force to open the valve slit.” Pet. 32 (citing Ex. 1002 ¶¶ 82–90). This statement, as it is essentially reiterated by Mr. Griffis testimony, articulates a result, a mechanical design that would probably functionally and structurally work to transfer force, but it is not a persuasive reason or explanation as to *why* one of skill in the art would design an actuator with the particular elements from Arnett, as added to Tauschinski. It is not enough that Arnett’s two plunger design and gap structure exists and can impart a valve opening force, there must be a particular reason a person of skill in the art would decide to use such a two plunger and gap design.

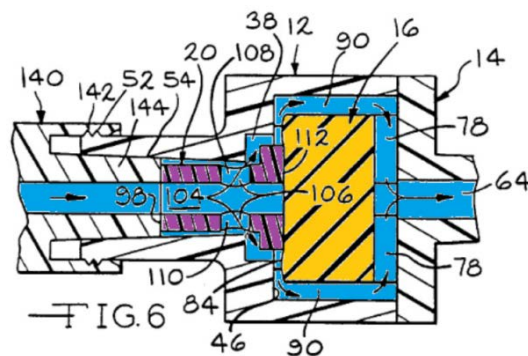
The closest that Petitioner comes to articulating a rationale to use Arnett’s proximal end structure is Mr. Griffis’ assertion that

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.

Ex. 1002 ¶ 89. However, neither Petitioner, nor Mr. Griffis, points to any evidence in the record or reasoning suggesting that the possible approaches to creating space for a spring clip and transferring force to open the valve in a catheter insertion hub are “known and finite.” *See Takeda Chem. Indus. v. Alphapharm Pty.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (discussing the

requirements of an “obvious to try”-type obviousness rejection). Without sufficient evidence or explanation that the structural and technical constraints of accommodating a spring clip within a catheter hub along with a valve and actuator structure was somehow limited, this allegation is simply a hindsight statement based on the invention described in the ’626 patent.

“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 by Patent Owner (*see* Prelim. Resp. 49–52), and as discussed *supra*, Arnett’s actuator and plunger elements “deform[] the septum (16) by pushing it away from surface (46), allowing fluid (depicted in blue) to flow through side holes (104) and around the septum (16).” *Id.* at 49. Patent Owner presents highlighted Figure 6 (depicted below) to demonstrate Arnett’s operation:



Patent Owner's Figure 6 of Arnett shows a cross-sectional view of the assembly in an open position with added highlighting. As shown in Figure 6, and denoted by arrows and blue coloring, fluid flows through side holes 104 and around the septum 16. Patent Owner argues that "the actuator's force is directed to the proximal periphery end surface of the septum (16), as opposed to its center, which is where the needle must pierce the septum." Prelim. Resp. 50; *see also* Ex. 1005, Fig. 11 (gap 306 diverting fluid flow to the periphery channels around septum 216).

As explained above, Petitioner's modification proposes to use Tauschinski's valve. *See* Pet. 32 (citing Ex. 1002 ¶¶ 82–90). Tauschinski's valve 3, however, operates very differently from Arnett's septum (16 or 216), by directing fluid through, and not around, Tauschinski's valve. *See* Prelim. Resp. 50–51. 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, which have gap 306 there between, as Petitioner proposes, and simply as a matter of design choice to "create space." *Id.* at 32. 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.

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 11 and 20.

F. Obviousness of Claims 11 and 20 over Van Heugten

Petitioner contends that claims 11 and 20 are unpatentable over Van Heugten. Pet. 3. For the reason set forth below, and based on the current record before us, Petitioner has shown a reasonable likelihood that claims 11 and 20 would have been obvious in view of Van Heugten.

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:

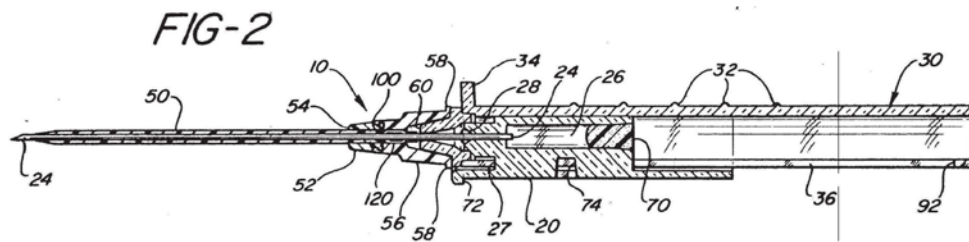
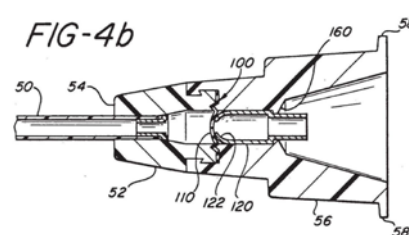
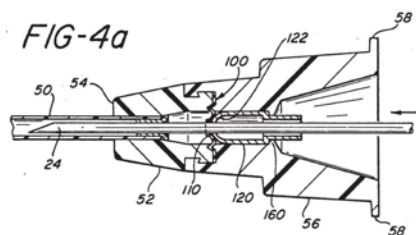


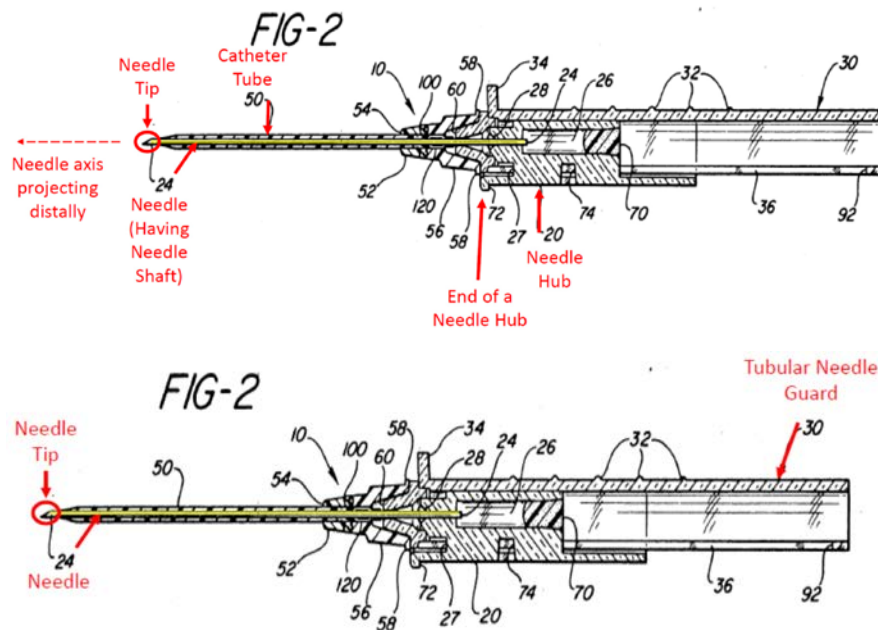
Figure 2 depicts a cross-sectional view of Van Heugten’s catheter assembly 10. *Id.* at 2:6–10, 19–21. In particular, Figure 2 illustrates catheter assembly 10 with catheter 50 and needle 24, which needle guard 30 covers upon retraction of needle 24 to prevent inadvertent needle injury to the user or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

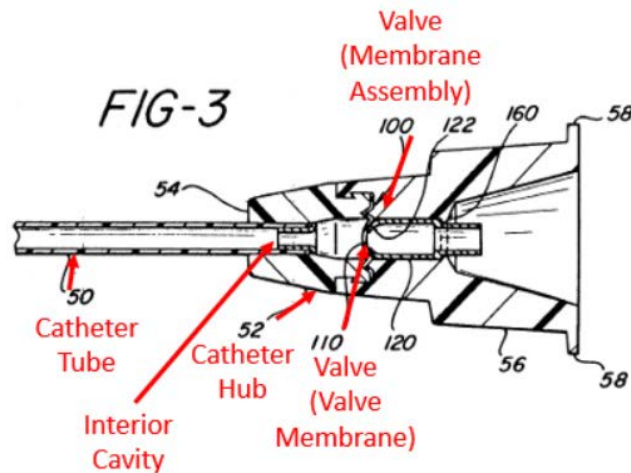
2. *Petitioner’s Challenge to Claims 11 and 20*

Petitioner asserts that Van Heugten discloses a “catheter assembly” comprising the claimed “catheter, a catheter hub, a needle, a needle hub, a septum, an actuator, and tubular needle protection.” Pet. 33–43. In support of these findings, Petitioner submits annotated versions of Van Heugten’s Figure 2 (*id.* at 40, 46), which we reproduce, below:



Annotated versions of Figure 2 of Van Heugten show a cross-sectional view of the catheter assembly. 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 34, 35, 41.

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. 36–38 (“a POSA would have understood Van Heugten to disclose the valve membrane 110 having a slit”) (citing Ex. 1002 ¶¶ 97–99).

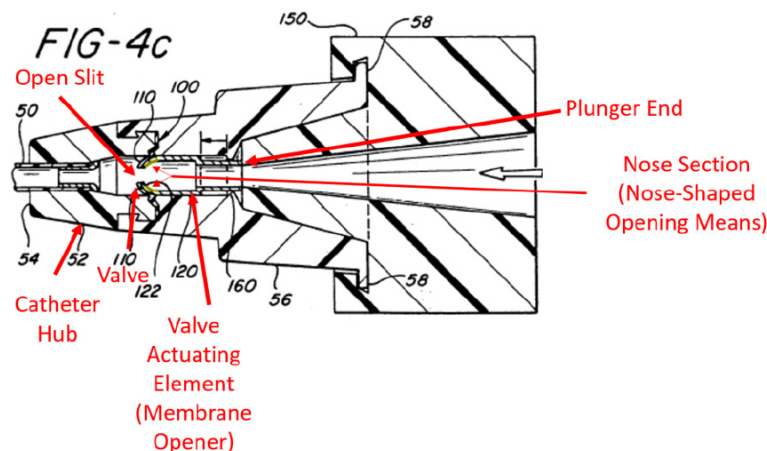
Petitioner contends two embodiments of Van Heugten’s valve membrane meet the “valve . . . comprises a wall surface comprising a slit” limitation required by claim 11. Ex. 1001, 6:5–8; Pet. 36–38 (citing Ex. 1002 ¶ 99). Petitioner argues that when “the valve is configured as a ‘duck-bill’ valve or a valve of similar configuration,” a person of ordinary skill in the art would understand such a configuration to have a slit.” Pet. 38 (citing Ex. 1006, 4:23–27). Petitioner also contends that Van Heugten’s valve

membrane may have multiple slits whereas “Van Heugten explains the desirability of applying the valve principle of U.S. Patent No. 3,585,996 (“Reynolds”) to a catheter assembly.” *Id.* (citing Ex. 1006, 1:28–32, 1:47–57). Petitioner relies on Figure 5 of Reynolds, which depicts a valve element having slits in the form of a “Y,” similar to that of Figure 6 of the ’626 patent.

In addressing the claimed “valve actuating element,” Petitioner relies on Van Heugten for teaching

a valve actuating element (e.g., element 120) slidably disposed in the catheter hub (e.g., element 52) to actuate the valve (e.g., elements 100, 110), the valve actuating element comprising a nose section having a tapered end (e.g., element 122) for pushing the valve to open the slit and a plunger end (e.g., proximal end of element 120 extending past element 160) extending proximally of the nose section (e.g., element 122)[.]

Id. at 39. Petitioner also submits an annotated version of Van Heugten’s Figure 4c (*id.* at 40), 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). Further, according to Petitioner, the plunger end

transfers a distally directed force to the nose section to push the valve to open the slit when pressed upon.

As for claim 20, Petitioner contends that “Van Heug[un]ten renders obvious ‘the catheter hub further comprises a shoulder in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element.’” Pet. 42. Petitioner contends that “Van Heug[un]ten discloses the catheter hub further comprises a shoulder (e.g., shoulder near narrowing portion of the membrane opener shown as element 160) in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element (e.g., element 120).” *Id.* Petitioner relies on collar mechanism 160 attached to catheter hub 52 as acting “as a stop for membrane opener 120 because it interacts with the projection on the membrane opener 120.” *Id.* at 42 (citing Ex. 1002, ¶¶ 106–109).

3. *Patent Owner’s Argument*

Patent Owner argues that Van Heugten does not disclose a valve with slits. Prelim. Resp. 52. In support of this argument, Patent Owner argues that Van Heugten’s “‘duck-bill valve is not required to have slits.’” *Id.* at 53 (citing Ex. 2001 ¶ 82). Instead, Patent Owner contends that a duck-bill valve refers to a one-way valve that prevents backflow. *Id.* According to Patent Owner, “a POSITA would conclude that Van Heugten’s valve membrane does not have slits because it is ‘originally sealed before the needle 24 is inserted in the catheter 50,’ and later ‘punctured’ upon insertion of the needle into the catheter assembly.” *Id.* at 54.

Patent Owner also contends the Van Heugten’s description of Reynolds also fails to teach the claimed slit. *Id.* Patent Owner argues that “Van Heugten teaches away from the Reynolds valve,” because it “expressly

explains the benefits of its valve membrane over the prior art (Ex. 1006 at 4:9-30), including the Reynolds valve, which is discussed in the Background.” *Id.* Patent Owner differentiates the slits describes in Reynolds because Reynolds’ valve is for use in arterial catheters, which are different from intravenous catheters. *Id.*

4. *Analysis*

Petitioner has sufficiently shown, based on the current record before us, that Van Heugten teaches a valve with a slit. First, we note that Patent Owner contends Van Heugten fails to disclose multiple “slits,” but the claim requires only “a slit.” *See, e.g.*, Prelim. Resp. 53 (“because a duck-bill valve is not required to have slits”). Claim 11 requires “a wall surface comprising a slit” and later “the valve to open the slit,” but the language does not require multiple “slits.” Ex. 1001, 6:8, 6:14. The issue before us is whether Van Heugten’s valve (e.g., 110) could incorporate a slit, or whether, as Patent Owner contends, the valve would not have a slit because it has to be punctured.

Van Heugten states that Reynolds (’996 patent) discloses “a self-sealing disc valve ... with several fine slits.” Ex. 1006, 1:28–32. Immediately after describing Reynolds’ disc valve, Van Heugten goes on to state that “[i]t would be desirable to apply the valve principle of the ’996 patent to a catheter assembly to enable the catheter to automatically open when an insertion needle is passed through the catheter, then automatically close when the needle is withdrawn from the catheter” *Id.* at 1:47:53. Contrary to Patent Owner’s contentions, this statement of desire to incorporate Reynolds’ “valve principle” is not in the “Background” of the invention. Further, we cannot find any teaching away from the use of

Reynold's valve with slits. To the contrary, specifically stating that "[i]t would be desirable to apply the valve principle of the '996 patent" indicates a desire to incorporate Reynolds' slit valve into Van Heugten's valve assembly. Based on Van Heugten's disclosure incorporating Reynolds' valve principle, we find persuasive Mr. Griffis' testimony that "[o]ne would understand from reading Van Heugten that a valve with several slits, such as shown in Reynolds, was also contemplated for the valve membrane 110." Ex. 1002 ¶ 99.

Further, as to whether Van Heugten's disclosure of "valve membrane 110 is generally configured as a 'duck-bill' valve," (Ex. 1006, 4:23–29) would be understood by a person of ordinary skill in the art as a configuration having a slit, we are faced with competing expert testimony. Petitioner's expert, Mr. Griffis, contends that "a person of ordinary skill in the art would understand such a configuration [duck-bill] to have a slit." Ex. 1002 ¶ 99. Patent Owner's expert, Mr. Meyst, contends that "disclosure of a 'duck-bill' valve does not inherently disclose a slit valve to a POSITA." Ex. 2001 ¶ 82. The conflicting testimony from Mr. Griffis and Mr. Meyst creates a genuine issue of material fact, and "such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute *inter partes* review." 37 C.F.R. § 42.108(c). Petitioner has made a sufficient showing at this stage that a person of ordinary skill in the art would have had understood Van Heugten as teaching a slit as claimed.

We are persuaded on this record that Petitioner has shown a reasonable likelihood that claims 11 and 20 would have been obvious in view of Van Heugten.

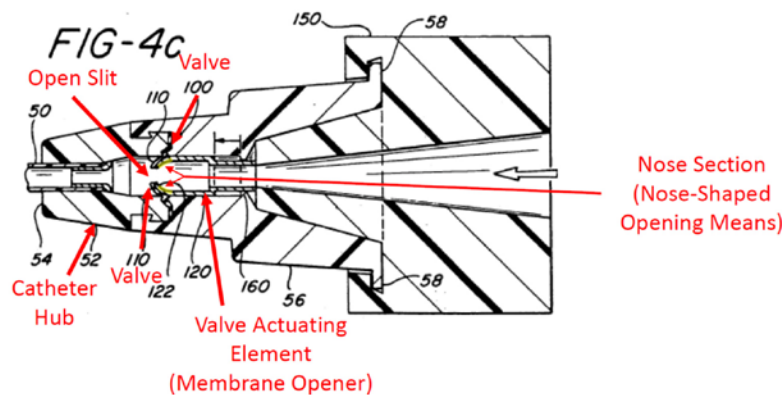
G. Van Heugten and Arnett

Petitioner contends that claims 11 and 20 are unpatentable over Van Heugten and Arnett. Pet. 3. For the reasons set forth below, Petitioner has not shown a reasonable likelihood that these claims would have been obvious over Van Heugten and Arnett.

1. Petitioner's Challenge

Similar to the analysis set forth above based on Van Heugten alone, Petitioner asserts that Van Heugten teaches a “catheter insertion device” comprising the claimed “catheter hub,” “needle,” “valve,” and “needle protective device.” Pet. 44, 48.

In addressing the claimed “valve actuating element,” Petitioner relies on a combination of Van Heugten and Arnett. *Id.* at 44–48. In particular, Petitioner relies on Van Heugten for disclosing a “a valve actuating element (e.g., element 120) slidably disposed in the catheter hub (e.g., element 52) to actuate the valve (e.g., elements 100, 110), the valve actuating element comprising a nose section having a tapered end (e.g., element 122) for pushing the valve to open the slit,” (*id.* at 45) and submits an annotated version of Van Heugten’s Figure 4c (*id.* at 46), which we reproduce, below:



According to Petitioner, Figure 4c “describes the membrane opener 120,” which “is generally cylindrical in shape and contains nose-shaped opening

means 122.” *Id.* at 45. Petitioner notes that Van Heugten describes “the membrane opener 120 as a valve opener that is ‘slideably emplaced’ in the catheter hub.” *Id.* at 46.

Petitioner proposes that “[i]t would have been obvious for a POSA to combine the catheter insertion device of Van Heugten with the valve actuating elements disclosed in Arnett.” *Id.* at 48. To address the claimed “valve actuating element slidingly disposed in the catheter hub to actuate the valve . . . having a tapered end for pushing the valve to open the slit and a plunger end extending proximally of the nose section,” and as with the previous ground with Arnett, Petitioner relies on Arnett’s actuator 220 with “two plungers with a gap between these elements.” *Id.* at 47. Petitioner reasons that it would have been obvious to combine the catheter insertion device of Van Heugten with the valve actuating elements disclosed in Arnett as follows:

It would have been obvious to a POSA to modify Van Heugten’s valve actuating element to put a plunger end 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, Griffis Decl. ¶¶ 115-120.)

Id. at 48 (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.* (emphasis added).

2. *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. 53, 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 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 57–58 (citing Ex. 2001 ¶¶ 85–89).

3. *Analysis*

As with the prior ground based on Woehr and Arnett, 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 “two plungers and a gap there between.” Pet. 47, 48.

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. 48 (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 with Arnett, 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. 45–46 (citing Ex. 1006, 4:31–36, 4:43–49, Fig. 4[c]). 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.* at 46 (annotated Fig. 4c). 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 create two plungers with a gap between these elements,” as Petitioner proposes. *See id.* at 48. 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.

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 11 and 20.

III. SUMMARY

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail on at least one alleged ground of unpatentability with respect to each of claims 11 and 20 of the '626 patent. The Board has not made a final determination on the patentability of any challenged claims.

IV. ORDER

For the reasons given, it is

ORDERED that *inter partes* review of the '626 patent is hereby instituted as to claims 11 and 20 on the ground that claims 11 and 20 are obvious over Van Heugten;

FURTHER ORDERED that no ground other than those specifically granted above is authorized for the *inter partes* review; and

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

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Patent 9,149,626 B2

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