

Filed on behalf of Becton, Dickinson and Company

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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 of
U.S. Patent No. 9,149,626 to Woehr et al.

IPR Trial No. IPR2017-01587

**PETITION FOR INTER PARTES REVIEW
OF CLAIMS 11, 20 OF U.S. PATENT NO. 9,149,626
UNDER 35 U.S.C. §312 AND 37 C.F.R. §42.104**

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I. Introduction

Petitioner Becton, Dickinson and Company requests institution of an *inter partes* review to cancel claims 11 and 20 (“Challenged Claims”) of U.S. Patent No. 9,149,626 (“the ’626 patent”). For the reasons set forth below, there is a reasonable likelihood that the Challenged Claims are unpatentable as obvious over (1) Woehr ’108 in view of Tauschinski (Ground I), (2) Woehr ’108 in view of Tauschinski and further in view of Arnett (Ground II), and (3) Van Heugten (Ground III), and (4) Van Heugten in view of Arnett (Ground IV).

II. Mandatory Notices

A. Real Parties in Interest

Becton, Dickinson and Company and Becton Dickinson Infusion Therapy Systems, Inc. are real-parties-in-interest are real-parties-in-interest.

B. Related Matters

The Challenged Claims have been asserted against Petitioners in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.) Additionally, *Inter Partes* Review petitions are being concurrently filed on U.S. Patent Nos. 8,328,762; 8,333,735; 8,337,463; 8,540,728; 8,597,249; 8,460,247; and 9,370,641, all of which have also been asserted in the same litigation.

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Petitioners agree to accept service by email.

III. Certification of Grounds for Standing

Petitioner certifies pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review on the grounds identified in this Petition.

IV. Overview of Challenge and Relief Requested

A. Grounds of Challenge

Under Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioners request cancellation of claim 11, 20 of the '626 patent as unpatentable under 35 U.S.C. §103 based on the following grounds.

Ground	35 U.S.C. §	Claims	References
I	103	11, 20	Woehr '108 in view of Tauschinski
II	103	11, 20	Woehr '108 in view of Tauschinski, and further in view of Arnett
III	103	11, 20	Van Heugten
IV	103	11, 20	Van Heugten in view of Arnett

B. Relief Requested

Petitioners request that the Board cancel the Challenged Claims because they are unpatentable under 35 U.S.C. §103.

V. Overview of the '626 Patent

A. State of the Art

As described in more detail in the Declaration of Jack Griffis, since at least the 1980s, catheter insertion assemblies have been designed to include needle safety to minimize the potential of healthcare workers being stuck by needles and

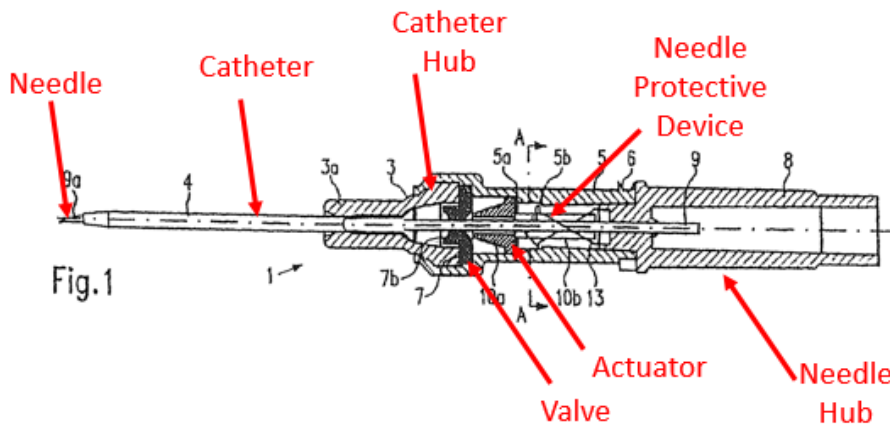
thereby injured or infected by blood borne pathogens. (Ex. 1002, Griffis Decl. ¶¶31-34.) In addition to many books, papers, and patents that identified the need for needle safety and suggested designs to achieve it, Congress also recognized this need. (*Id.*) The 1991 OSHA Bloodborne Pathogens Standard, 56 Fed. Reg. 64004 at 64114 (Dec. 6, 1991) identified “self-sheathing needles” as an engineering control to reduce employee exposure to hazardous pathogens. (*Id.*) Further, the Needlestick Safety and Prevention Act of 2000 recognized that “the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.” (Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901, 1902 (2000).) The 2000 Act also updated the bloodborne pathogens standard to include the term “Sharps with Engineered Sharps Injury Protections” to be “a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.” (*Id.*; *see also* Ex. 1002, Griffis Decl. at ¶¶31-34.)

It was also recognized, for example in U.S. Patent No. 5,053,014 (“Van Heugten”), that during use of an I.V. catheter assembly it is desirable to minimize

“any blood leakage from the assembly so as to reduce the risk of transmitting blood-borne diseases to medical personnel.” (Ex. 1006, Van Heugten at 1:15-18.)

B. Brief Description of the '626 Patent in View of the State of the Art

The '626 patent was filed as a patent application on January 22, 2014, and claims priority to a German patent application filed on July 4, 2002. The '626 patent describes an over-the-needle catheter insertion device. Figure 1, reproduced below, demonstrates the various claimed features of the catheter assembly.



The device claimed in the '626 patent is composed of various, standard features in catheter assemblies. The '626 patent acknowledges that catheter assemblies including a catheter hub, a needle guard element, and a hollow needle that engages with a needle guard element were also known. (*Id.* at 1:11-19).

The '626 patent identifies two objectives for the disclosed catheter assembly: (1) to prevent an outflow of blood from the catheter after removal of the hollow needle; and (2) to cover the tip of the needle as the needle is withdrawn so

that operating personnel cannot injure themselves on the needle tip. (Ex. 1001, '626 patent at 1:26-36). These “objectives” were also well known in the art. (Ex. 1002, Griffis Decl. ¶¶35-40; Ex. 1006, Van Heugten at claim 1.)

The '626 patent accomplishes blood control by a check valve that seals as the needle is withdrawn from the catheter hub, but can be opened when an external force pushes a valve actuating element in a distal direction into the slit. (Ex. 1001, '626 patent at 2:21-33, 37-45.) By 2002, catheter insertion devices that included check valves and valve actuating elements to prevent blood leakage were well known. (Ex. 1002, Griffis Decl. at ¶¶31-40, 50, 73-75.) In order to cover the needle tip to prevent injury, the '626 patent discloses a spring clip that closes around the needle tip as it is withdrawn from the catheter hub. (*E.g.*, Ex. 1001, '626 patent at 2:21-29.) The same spring clip disclosed in the '626 patent was also known as of 2002. (Ex. 1002, Griffis Decl. at ¶¶39-40.) Further, catheter insertion devices with the combination of blood control and needle protection were well known by 2002. (*Id.*)

VI. POSA

A person of ordinary skill in the art (“POSA”) in 2002 would been either a (i) 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 (ii) 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. (Ex. 1002, Griffis Decl. at ¶ 30)

VII. Claim Construction

Generally in an *inter partes* review, the Board construes claim terms in an unexpired patent according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b).

A. “needle protective device”

A claim term defined by the performance of a function that does not recite sufficient structure for performing the function is construed under 35 U.S.C. § 112, ¶ 6. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc). In *Williamson*, the Federal Circuit held that there was no “heightened evidentiary showing” to overcome the presumption that a claim phrase that does not use the term “means” is not governed by § 112, ¶ 6. *Id.* at 1349. Instead, “[where] the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function,’” the claim is governed by § 112, ¶ 6 whether or not the word “means” is used. *Id.* at 1348; *see also Adlens USA, Inc. v. Superfocus Holdings LLC*, 2016 WL 7992047, IPR2016–01824, Paper 42 (Final Decision) at *4 (Dec. 27, 2016); *Verizon Servs.*

Corp. v. AIP Acquisitions LLC, 2015 WL 9899021, IPR2015-01106, Paper 10 (Institution of Inter Partes Review) at *10 (Oct. 15, 2015); *Apple Inc. v. Immersion Corp.*, 2017 WL 376909, IPR2016-01372, Paper 7 (Institution of Inter Partes Review) at *6 (Jan. 11, 2017).

Once it is determined that a claim term is a means-plus-function term, a two-step analysis under § 112, ¶ 6 applies. *Williamson*, 792 F.3d at 1351-52; *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc). The first step requires identifying the claimed function. *Id.* The second step is identifying the structure in the patent specification that performs the claimed function. *Id.* The claim term is construed to cover those structures and all equivalents thereof. *Id.*

Claims 11 and 20 recite a “a catheter insertion device comprising . . . a needle protective device . . . to prevent unintended needle sticks.” The use of the word “device” in the claims does not impart any structure and is tantamount to using the word “means.” *Williamson*, 792 F.3d at 1350. The term “needle protective device” is not used, nor is it defined, in the specification of the ’626 patent.

The Board may look to the modifiers of a nonce term to see if they impart structure. *Williamson*, 792 F.3d at 1351 (“The prefix ‘distributed learning control’ does not impart structure into the term ‘module.’”). If the modifier has no dictionary definition and no generally understood structural meaning in the art,

then the term is a means-plus-function term. *See MIT & Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) (“[T]he term ‘colorant selection,’ which modifies ‘mechanism’ here, is not defined in the specification and has no dictionary definition, and there is no suggestion that it has a generally understood meaning in the art.”).

Here, the modifier “needle protective” does not impart any structure to the term “device.” The 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.” (Ex. 1002, Griffis Decl. ¶¶ 41-50); *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1359-60 (Fed. Cir. 2004). As Mr. Griffis explains, devices and mechanisms that prevent needle sticks are described by a wide variety of phrases, such as needle shield, safety mechanism, safety feature, protective device, and needle stick prevention device, but these functional phrases do not convey any structural meaning to those in the art. (Ex. 1002, Griffis Decl. ¶ 46.) As Mr. Griffis also explains, at the time of the alleged invention, different safety devices were being developed at a fast pace and new structures and methods were being continually introduced in the art. *Id.* Thus, a POSA would not understand the term “needle protective device” to define any particular structure or class of structures at the time of the claimed invention. (Ex. 1002, Griffis Decl. ¶ 47); *see Micron*

Tech., Inc. v. Innovative Memory Sys., Inc., 2016 WL 5027747; IPR2016-00324, Decision Denying Institution at *5 (June 13, 2016) (finding “error correction module” is governed by §112 ¶ 6 when nothing in the specification or claims indicated that a skilled artisan would understand the term as a name for structure).

The term “needle protective device” is therefore a means-plus-function term. The function, which is recited in the claims, is “to prevent unintended needle sticks.” (Ex. 1002, Griffis Decl. ¶ 49.)

In accordance with 37 C.F.R. § 42.104(b)(3), the structure identified in the specification to perform the function is a spring clip as more completely described at:

- ’626 patent at Figs. 1-2, 4, 5, 7a 7d, 8, 9a, 10
- ’626 patent at 2:29-30
- ’626 patent at 2:21-29
- ’626 patent at 3:4-16
- ’626 patent at 3:23-27
- ’626 patent at 3:56-63
- ’626 patent at 4:26-40
- and structural equivalents thereof.

(Ex. 1002, Griffis Decl. ¶ 50.)

VIII. Ground I: The Challenged Claims Are Obvious over Woehr '108 in view of Tauschinski.

The Challenged Claims are obvious over U.S. Patent No. 6,117,108 to Woehr et al., “Spring Clip Safety IV Catheter,” filed June 12, 1998, issued Sept. 12, 2000 (“Woehr '108”) (Ex. 1003), in view of U.S. Patent No. 4,387,879 to Tauschinski, “Self-Sealing Connector for Use with Plastic Cannulas and Vessel Catheters,” filed July 16, 1981, issued June 14, 1983 (“Tauschinski”) (Ex. 1004). (Ex. 1002, Griffis Decl. ¶¶61-77.) Woehr '108 and Tauschinski qualify as prior art to the '626 patent under 35 U.S.C. § 102(b), and are cited on the face of the patent.

Woehr '108 discloses a safety IV catheter with the same spring clip shown in the '626 patent to prevent needle sticks. Tauschinski describes a well-known valve and valve actuator that are used with catheters to prevent the emergence of blood.

During prosecution of App. No. 10/520,325, to which the '626 patent claims priority, the examiner discussed Woehr '108 and Tauschinski, but did not address them in combination. Later, during prosecution of the application that issued as U.S. Pat. No. 8,328,762 to which this patent also claims priority, the applicant argued that a prior art device with a valve and a valve actuator (as disclosed in U.S. Pat. No. 4,917,668 to Haindl) could not be modified to accommodate a needle guard (as disclosed in Woehr '108) because “there would be no room to

accommodate the needle guard in a ready position” and making an accommodation of this nature would necessitate that “the catheter hub ... be made longer” thus positioning “the sliding member ... too far distally for a male Luer tip made to industry standard size to actuate the sliding member.” (Ex. 1008, Nov. 4, 2011 Office Action Response at 10). The Grounds present a new combination of references that has not previously been considered, and it provides additional evidence that was not before the examiner, including the testimony of Jack Griffis (Ex. 1002) and testimony by Patent Owner’s own expert that there were no design concerns about combining Introcan Safety, which is the embodiment of Woehr ’108, and Tauschinski.

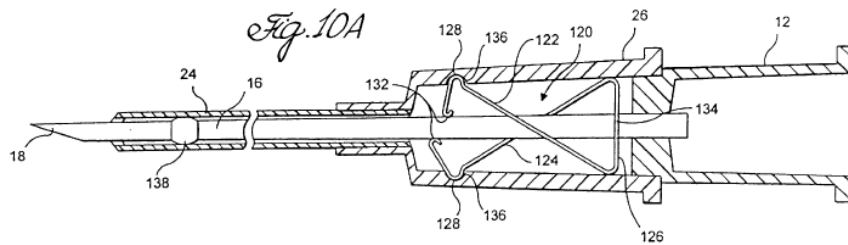
The Challenged Claims recite features long known by engineers who design IV catheters. The structures in the claimed catheter assembly all have known functions that perform in expected ways. Based on the prior art described below, the claim limitations perform known functions with predictable results and there is no unexpected result on which to base the patentability of the claims. (Ex. 1002, Griffis Decl. ¶ 60.)

A. Independent Claim 11

1. Element 11p. “A catheter insertion device comprising:”

To the extent this preamble is limiting, Woehr ’108 discloses a “catheter insertion device.” As shown and described in connection with Figures 1-7C, 7D,

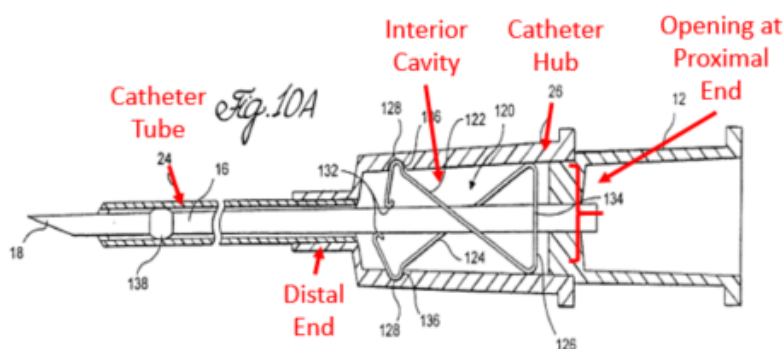
and 10A, Woehr '108 discloses a catheter insertion device (*e.g.*, safety IV catheter 10). (*See, e.g.*, Ex. 1003, Woehr '108 at 2:25-26 (“It is accordingly an object of the present invention to provide a safety IV catheter...”); *id.* at 3:26-28 (“FIGS. 1A and 1B are views in partial cross-section of a safety IV catheter in accordance with a first embodiment of the invention...”); *id.* at Fig. 10A (shown below); *see also id.* at 1:14-18, 4:8-18, 4:36-42, Figs. 1A-7C, 7D, and 10A; Ex. 1002, Griffis Decl. ¶ 61.)



2. Element 11a. “a catheter hub...;”

Woehr '108 discloses “a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached to a distal end.” As shown and described in connection with Figures 1A, 1C, 2A, 3A, 4A, 5A, 6A, 7A, 7B, 7C, 7D, 7E, and 10A, Woehr '108 discloses a catheter hub (*e.g.*, element 26) comprising an interior cavity, an opening at a proximal end, and a catheter tube (*e.g.*, element 24) attached to a distal end (*e.g.*, element 28). (*See, e.g.*, Ex. 1003, Woehr '108 at 4:13-27 (“As is also conventional, the needle 16 is received within a hollow tubular catheter 24, the proximal end of which is concentrically affixed

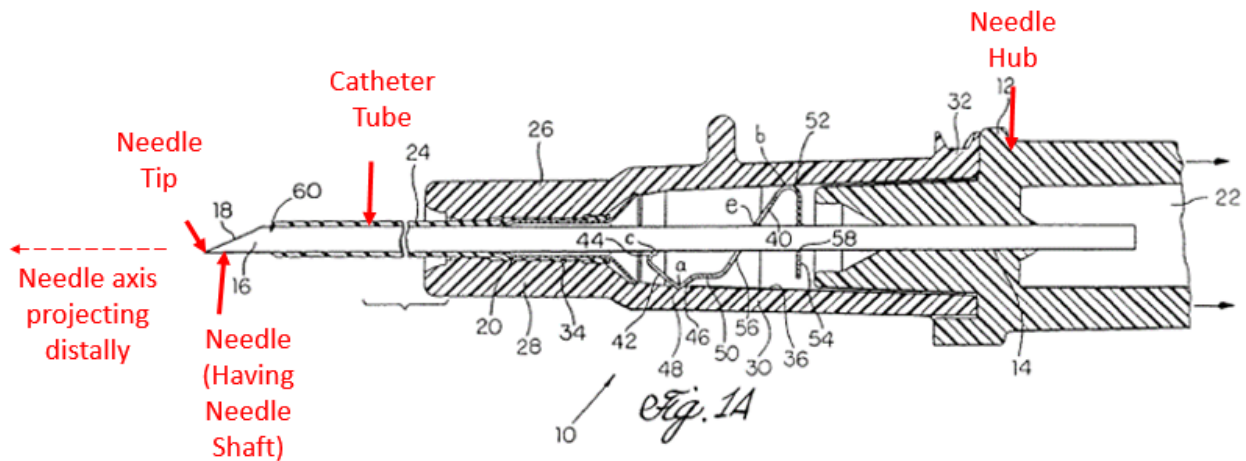
within the distal end of a catheter hub 26 having a distal section 28 and a contiguous, larger diameter proximal section 30.”); *id.* at Fig. 1A and 10A (annotated below); *see also id.* at Figs. 1A, 1C, 2A, 3A, 4A, 5A, 6A, 7A, 7B, 7C, 7D, and 7E; 3:26-28, 4:8-34; Ex. 1002, Griffis Decl. ¶ 62.)



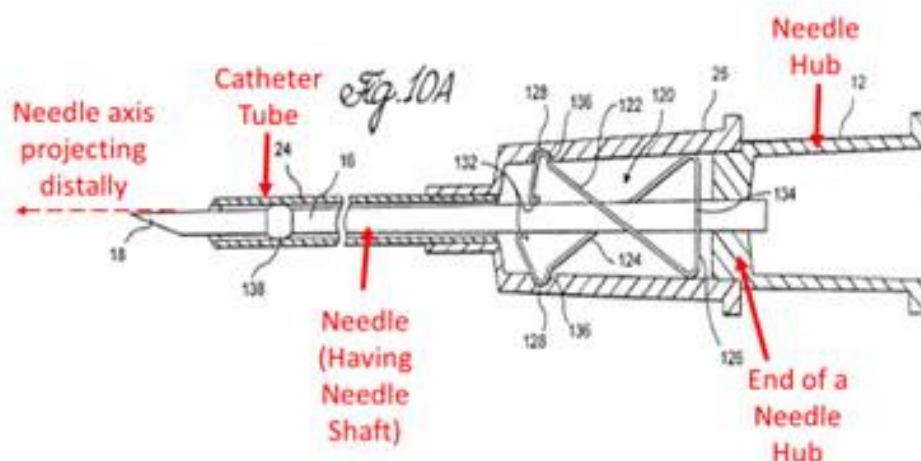
3. Element 11b. “a needle...;”

Woehr '108 discloses “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.” As shown and described in connection with Figures 1-10, Woehr '108 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). (*See, e.g.*, Ex. 1003, Woehr '108 at 4:8-18, Fig. 1A (annotated below); *see also id.* at Figs. 1-10, 4:35-42; Ex. 1002, Griffis Decl. ¶¶63-64.) Woehr '108 describes, “The safety IV catheter of the invention, generally

designated 10, in the embodiment illustrated in Figures 1A and 1B, includes a needle hub 12 that includes an axial opening 14 which securely receives the proximal end of a needle 16 having a sharpened tip 18. . . . As is also conventional, the needle 16 is received within a hollow tubular catheter 24, the proximal end of which is concentrically affixed within the distal end of a catheter hub 26. . . .” (Ex. 1003, Woehr ’108 at 4:8-18.)



The same elements are used to describe the needle, needle tip, catheter tube, and needle hub in Figure 10A.



Thus, a POSA would understand that the same description of these elements for Fig. 1A also applies to Figure 10A. (Ex. 1002, Griffis Decl. ¶ 64.)

4. Element 11c. “a valve...;”

Woehr in view of Tauschinski renders obvious “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.” (Ex. 1002, Griffis Decl. ¶¶65-67.)

As shown and described in connection with Figures 2 and 3, 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) and comprises a wall

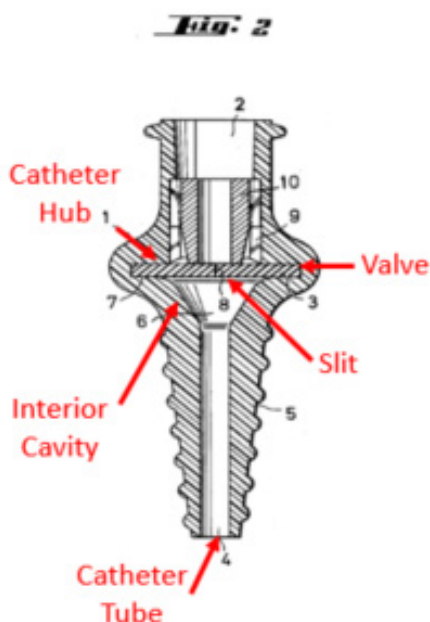
surface comprising a slit (e.g., element 8); said valve (e.g., element 3) remaining inside the interior cavity when the needle is removed from the catheter tube (e.g., element 4) and the catheter hub (e.g., element 1). *See, e.g.*, Ex. 1004, Tauschinski at 2:7-19, stating:

[I]t is an object of the present invention to provide a connector which is of the kind mentioned first hereinbefore and through which a metal cannula or a vessel catheter can be pushed without obstruction but which will close automatically as soon as the metal cannula or the catheter or the cone fitting of a supply hose has been pulled from such connector. The connector is intended to close as the metal cannula, the vessel catheter or the cone fitting of the supply hose are pulled out of the fitting or inadvertently fall from the same, and the closed connector is intended to prevent an emergence of blood or an ingress of air through the fitting.”

Tauschinski also discloses a slit: “A metal cannula or a catheter hose can be inserted through the central slit of the rubber-elastic, plane disc of the connector according to the invention, and when the cannula or hose has been pulled out the slit is tightly closed to seal the passage, owing to the elasticity of the disc.” (Ex. 1004, Tauschinski at 2:26-31; *see also id.* at Fig. 2

(annotated below), Fig. 3, 2:7-37, 3:14-19, 3:20-32; Ex. 1002, Griffis Decl.

¶¶65-67.)



It would have been obvious for a POSA to combine the catheter insertion device of Woehr '108 with the valve as disclosed in Tauschinski. A POSA would have been motivated to modify Woehr '108 based on the teaching in Tauschinski that the valve prevents the emergence of blood or ingress of air. One of the goals of the Woehr '108 device is to have a protective needle guard “automatically snap[] into a retracted position in which it blocks access to the distal needle tip” thereby preventing “accidental contact by the health care practitioner with the needle tip” and potential exposure to diseases in patient’s blood. 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.) As Patent Owner's expert, Dr. Haindl, admitted in another proceeding, he had no design concern regarding the combination of the Braun Introcan Safety with the Fresenius type valve.¹ (Ex. 1010, Australian Tr. at 587:5-11.) For at least these reasons 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.

5. Element 11d. “a valve actuating element...;”

The combination of Woehr '108 and Tauschinski discloses “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 and a plunger end extending proximally of the

¹ Dr. Haindl explains that he is “of the view that the Fresenius valve seems to be based on the Tauschinski patent.” (*Id.* at 517:11-12.) The Tauschinski patent in the Australian proceeding is the same as cited here. (*Id.* at 146:28-35.) Further, B.Braun lists the '108 patent as a patent covering the Introcan Safety IV Catheter. (Ex. 1009, B.Braun Brochure at 6.)

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.”

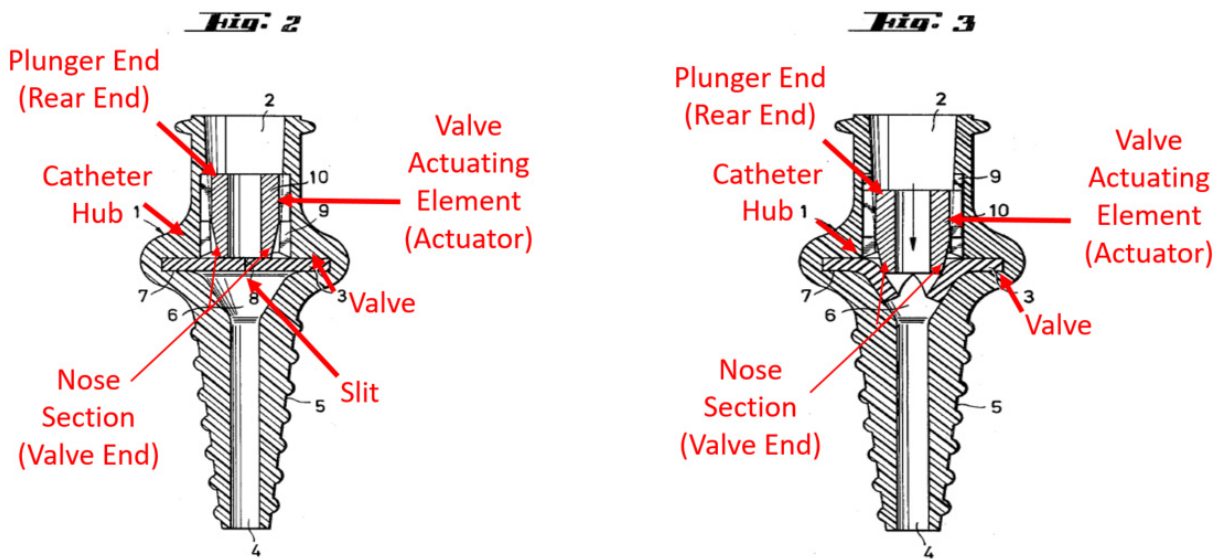
As shown and described in Figures 2 and 3, Tauschinski discloses a valve actuating element (e.g., element 10) slidably disposed in the catheter hub (e.g., element 1) to actuate the valve (e.g., element 3), the valve actuating element (e.g., element 10) comprising a nose section having a tapered end for pushing the valve (e.g., element 3) to open the slit (e.g., element 8) 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 (e.g., element 3) to open the slit (e.g., element 8) when pressed upon. *See, e.g.*, Ex. 1004, Tauschinski at 3:21-36 (describing Figures 2 and 3).

[T]he inside surface of the hollow-conical portion 2 is formed with two or more axial guide grooves 9, which are engaged by mating splines of a member 10, which is axially slidable between limits. . . . The member 10 has a central through bore and has a square rear end face whereas its forward end portion is frustoconical. In the position shown in FIG. 2 the forward end of the member 10 just contacts the disc 3, which has sprung back to its plane position, so that the slit 8 of the disc 3 is tightly closed. In FIG. 3 the member 10 is shown in a position to which it has been advanced by a [sic]

oval fitting, not shown, of a supply hose. In that position the slit 8 is open because it has been expanded.

See also *id.* at Figs. 2, 3 (annotated below); *id.* at 2:42-56, 3:20-36, 3:47-58;

Ex. 1002, Griffis Decl. ¶¶68-72.



It 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. As discussed above, it would have been obvious for a POSA to combine the catheter insertion device of Woehr '108 with the valve as disclosed in Tauschinski. A valve actuating element would have been an obvious and readily implementable solution to opening and closing a valve in view of the well-recognized problem of mitigating blood outflow from a catheter insertion device. Similarly, adding a valve actuator for controlling flow of a fluid through the valve

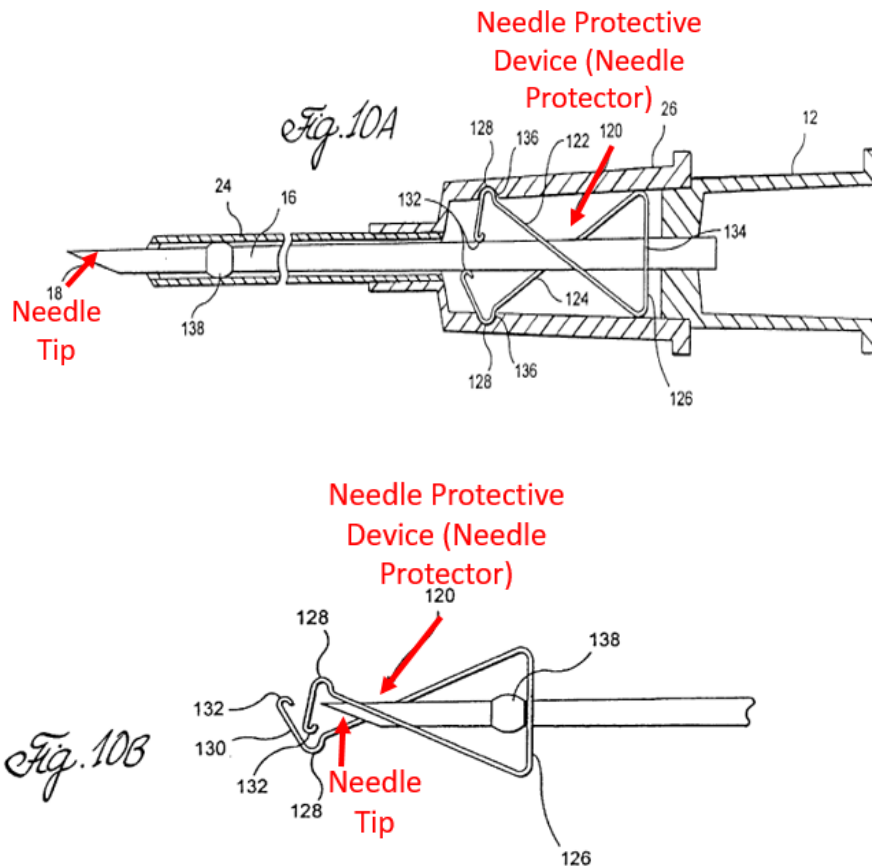
would have been an uncomplicated design choice in view of the teaching in Tauschinski that such valves can be opened with the application of force. It would have been apparent to a POSA that positioning such an actuator in mechanical communication with a deflectable valve could be implemented in the catheter insertion device of Woehr '108 without compromising the function of the instrument, while at the same time, providing a readily implementable solution to the well-recognized problem of mitigating blood outflow from a catheter insertion device. It is routine design optimization. Further, as previously noted, Patent Owner's expert, Dr. Haindl, admitted in another proceeding, he had no design concern regarding the combination of the Braun Introcan Safety with the Fresenius type valve. (Ex. 1010, Australian Tr. at 587:5-11.) For the same reasons discussed in Section IX.A.4 (valve), it would have been obvious to combine the valve and valve actuator of Tauschinski with the spring clip safety IV catheter of Woehr '108. (Ex. 1002, Griffis Decl. ¶¶68-72.)

6. Element 11e. “a needle protective device....”

Woehr '108 discloses “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.” As shown and described in connection with Figures 1-11, Woehr '108 discloses a needle protective device (e.g., element 120) spaced from the needle tip (e.g., element 18) in the ready

position and movable relative to the needle tip (e.g., element 18), at least in part distally of the needle tip (e.g., element 18) to prevent unintended needle sticks.

See, e.g., Ex. 1003, Woehr '108 at 4:43-49; Figs. 10A and 10B (annotated below); Figs. 1-11, 4:43-57, 8:16-29, 8:43-9:8; Ex. 1002, Griffis Decl. ¶¶73-75.



The function of the needle guard (e.g., “spring clip”) in Figure 10A is to prevent accidental needle sticks. (*See, e.g.*, Ex. 1003, Woehr '108 at 8:53-62 (“When the needle is retracted axially within the catheter hub... the needle guard... form[s] a barrier that prevents inadvertent contact with the needle tip.”)).

Therefore, the “spring clip” needle guard in Woehr ’108 provides the same function as the as the “needle protective device” identified in the ’626 patent specification described at 2:19, 2:21-40, 3:4-16, 3:23-27, 3:56-63, and 4:26-40. (Ex. 1002, Griffis Decl. ¶¶73-75.) Further, as described in Woehr ’108, the spring clip needle guard 220 is the same structure with two spring arms that cover the needle tip to protect it. (*Compare, e.g.*, Ex. 1001, ’626 patent at 2:34-41, Figs. 1 and 2 *with* Ex. 1003, Woehr ’108 at 8:16-29, Figs.10A and 10B; Ex. 1002, Griffis Decl. at 74.) Thus, Woehr ’108 discloses the needle protective device claimed in the ’626 patent. (Ex. 1002, Griffis Decl. at 74.) Further, Woehr ’108 describes the spring clip in a ready and protective position:

In the ready position illustrated in FIG. 10A, the needle shaft passes through the needle guard and applies an outward radial force on resilient arms 122, 124 by means of its engagement with lips 132, so as to urge the curved protrusions 128 of each of the arms into the annular groove 136, so as to retain needle guard 120 in a fixed position within the inner wall of catheter hub 26. . . . When the needle is retracted axially within the catheter hub, and moves past the end lips 132 of the needle guard, the radial force previously exerted on arms 122, 124 of needle guard 120 is suddenly released. This causes the distal end walls 130 of the needle guard to be released from their seat in the annular groove 136 and to pivot inwards into the catheter hub until, as seen in FIG. 10B, the end walls 130 overlap one another at a location distally in front of the needle tip, thereby to form a barrier that prevents inadvertent contact with the needle tip. At the same time, the

clamping edges 146 of the needle guard (FIG. 11B) are urged against the needle tip to restrict further axial movement of the needle. As also shown in FIG. 10B, the needle guard 120 and the needle clamped to the needle guard after needle retraction can be removed from the catheter hub as a unitary assembly, and safely discarded.

(Ex. 1003, Woehr '108 at 8:43-9:2; Ex. 1002, Griffis Decl. ¶¶73-75.)

For these reasons, Woehr '108 in view of Tauschinski renders obvious all of the limitations in claim 11. (Ex. 1002, Griffis Decl. at ¶¶73-75.)

B. Dependent Claim 20

Claim 20 depends from claim 11, and the analysis for claim 11 in Section VIII.A is incorporated by reference. Further, Tauschinski discloses that “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.” As shown and described in connection with Figures 2, 3, Tauschinski discloses the catheter insertion device of claim 11, wherein the catheter hub further comprises a shoulder (*e.g.*, element 9) in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element (*e.g.*, element 10). (*See, e.g.*, Ex. 1004, Tauschinski at 4:50-57, 8:16-29, 8:43-9:8; Ex. 1002, Griffis Decl. ¶¶76-77.) Tauschinski explains, “The embodiment shown in Figures 2 and 3 differs from the embodiment shown in Figure 1 in that the inside surface of the hollow-conical portion 2 is formed with two or more axial guide grooves 9, which are engaged by

mating splines of a member 10, which is axially slidable between limits.” (Ex. 1004, Tauschinski at 3:16-25.) Tauschinski recognizes that the grooves or another suitable means can be used to prevent the actuator from falling out of the connector. (*Id.* at 3:47-50.) The edge of the groove creates a shoulder in the connector body to prevent the actuator from falling out of the connector. (Ex. 1002, Decl. ¶¶76-77.)

It would have been obvious to a POSA to modify the catheter hub of Woehr ’108 to add a shoulder being a stop for the valve actuating element as described in Tauschinski. Adding another shoulder and groove to the catheter hub of Woehr ’108 would be a known modification with a known advantage of keeping the actuator in the catheter hub, and the shoulder and groove would perform its intended purpose of interacting with another element to retain the actuator in the catheter hub. (*Id.*) For this reason, Woehr ’108 in view of Tauschinski renders obvious all of the limitations in claim 20.

IX. Ground II: The Challenged Claims Are Obvious over Woehr ’108 in view of Tauschinski, and further in view of Arnett.

The Challenged Claims are obvious over U.S. Patent No. 6,117,108 to Woehr et al., “Spring Clip Safety IV Catheter,” filed June 12, 1998, issued Sept. 12, 2000 (“Woehr ’108) (Ex. 1003), in view of U.S. Patent No. 4,387,879 to Tauschinski, “Self-Sealing Connector for Use with Plastic Cannulas and Vessel

Catheters,” filed July 16, 1981, issued June 14, 1983 (“Tauschinski”) (Ex. 1004), in further view of U.S. Patent No. 5,817,069 to Arnett, “Valve Assembly,” (“Arnett”) (Ex. 1005) (Ex. 1002, Griffis Decl. ¶¶87-92).

As described in Section VIII, Ground I, Woehr ’108 and Tauschinski are prior art under 35 U.S.C. § 102(b). Arnett (U.S. Patent No. 5,817,069), “Valve Assembly,” filed February 28, 1996 and issued October 6, 1998 (Ex. 1005), is prior art under 35 U.S.C. § 102(b) and is cited on the face of the patent.

Arnett also discloses a catheter device that includes needle protection, a valve and actuator assembly to prevent leakage, where the actuator has a second actuator end with gaps that transfers force to actuate the valve.

A. Independent Claim 11

1. Element 11p. “A catheter insertion device comprising:”

The analysis at VIII.A.1 is incorporated by reference here. (See Section VIII.A.1 (Ground I, Element 11p); Ex. 1002, Griffis Decl. ¶ 78).

2. Element 11a. “a catheter hub...;”

The analysis at VIII.A.2 is incorporated by reference here. (See Section VIII.A.2 (Ground I, Element 11a); Ex. 1002, Griffis Decl. ¶ 79).

3. Element 11b. “a needle...;”

The analysis at VIII.A.3 is incorporated by reference here. (See Section VIII.A.3 (Ground I, Element 11b); Ex. 1002, Griffis Decl. ¶¶ 80).

4. Element 11c. “a valve...;”

The analysis at VIII.A.4 is incorporated by reference here. (*See* Section VIII.A.4 (Ground I, Element 11c); Ex. 1002, Griffis Decl. ¶ 81).

5. Element 11d. “a valve actuating element...;”

The combination of Woehr '108, Tauschinski and Arnett renders obvious “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.”

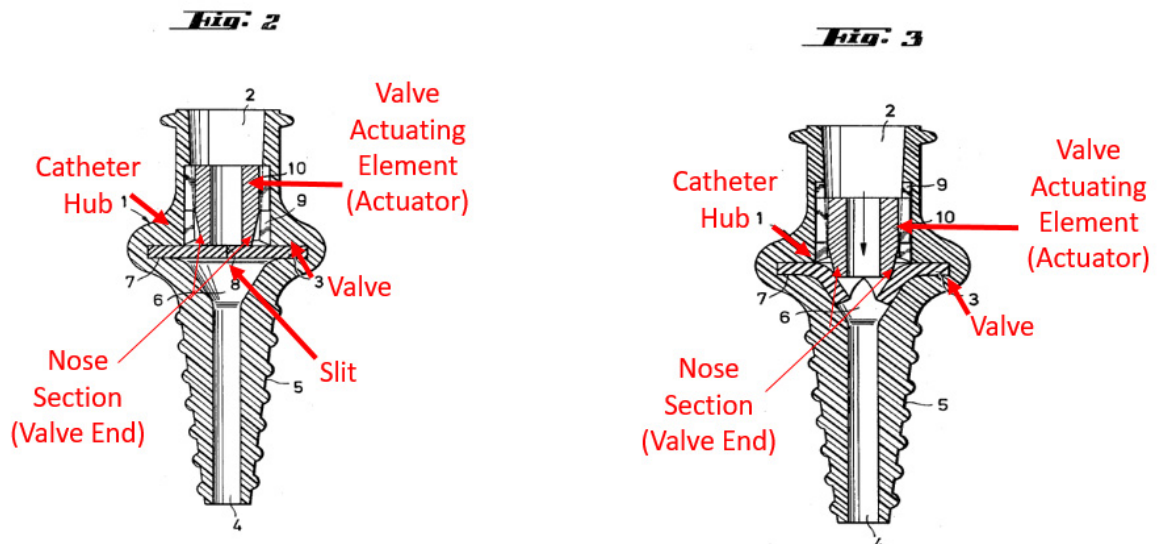
As shown and described in Figures 2 and 3, Tauschinski discloses a valve actuating element (e.g., element 10) slidably disposed in the catheter hub (e.g., element 1) to actuate the valve (e.g., element 3), the valve actuating element (e.g., element 10) comprising a nose section having a tapered end for pushing the valve (e.g., element 3) to open the slit (e.g., element 8) and also discloses that the valve actuating element transferring a distally directed force to the nose section to push the valve (e.g., element 3) to open the slit (e.g., element 8). *See, e.g.*, Ex. 1004, Tauschinski at 3:21-36, describing Figures 2 and 3:

[T]he inside surface of the hollow-conical portion 2 is formed with two or more axial guide grooves 9, which

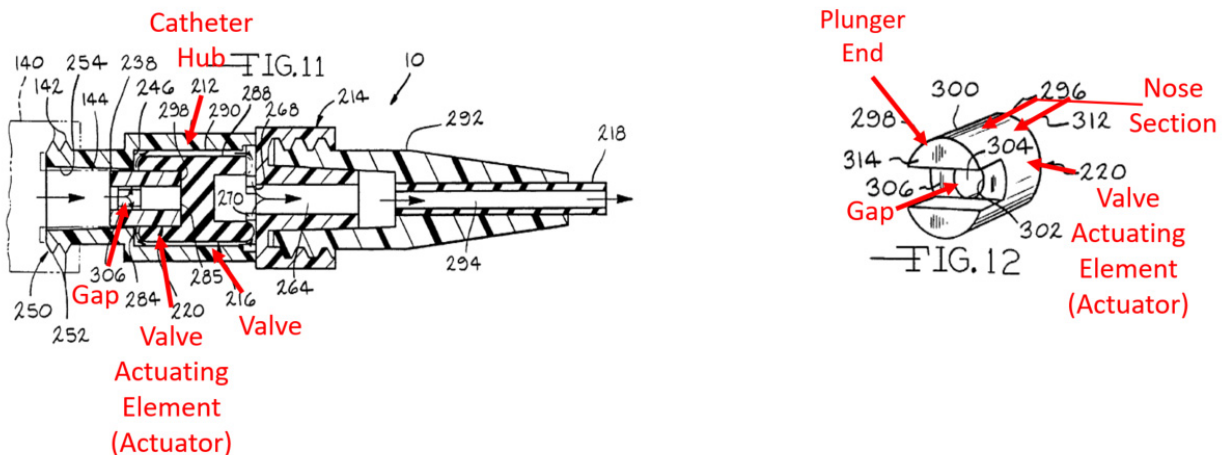
are engaged by mating splines of a member 10, which is axially slidable between limits. . . The member 10 has a central through bore and has a square rear end face whereas its forward end portion is frustoconical. In the position shown in FIG. 2 the forward end of the member 10 just contacts the disc 3, which has sprung back to its plane position, so that the slit 8 of the disc 3 is tightly closed. In FIG. 3 the member 10 is shown in a position to which it has been advanced by a [sic] oval fitting, not shown, of a supply hose. In that position the slit 8 is open because it has been expanded.

See also id. at Figs. 2 and 3 (annotated below); *id.* at 2:42-56, 3:20-36, 3:47-

58; Ex. 1002, Griffis Decl. ¶¶ 82-90.



As shown and described in connection with Figs. 1-15, Arnett also discloses a valve actuating element (e.g., element 220) slidingly disposed in the catheter hub (e.g., element 212) to actuate the valve (e.g., element 216), the valve actuating element (e.g., element 220) comprising a nose section (e.g., element 296 and/or element 312) for pushing the valve (e.g., element 216) and a plunger end (e.g., element 314) extending proximally of the nose section (e.g., element 296 and/or element 312); the plunger end (e.g., element 314) transferring a distally directed force to push the valve (e.g., element 216) when pressed upon. (See, e.g., Ex. 1005, Arnett at 7:30-54, 8:26-49.)



Arnett explains:

“Referring to FIGS. 9 and 12, the actuator 220 includes a first actuator end 296, a second actuator end 298, an exterior actuator surface 300, and an interior actuator surface 302. The interior actuator surface 302 defines a

needle passageway 304 extending between the first actuator end 296 and the second actuator end 298. The interior actuator surface 302 defines a fluid passageway 306 adjacent the second actuator end 298. As shown in FIGS. 9 and 12, the actuator exterior surface 300 defines an annular septum contact surface 312 and an opposed fitting contact surface 314. A portion of the exterior surface 300 and the septum contact surface 312 engage the actuator recess 285 of the septum 216.”

(Ex. 1005, Arnett at 7:30-45.) Thus, the actuator 220 has a proximal, second actuator end that has two plungers. (*Id.* at 7:34-36; Ex. 1002, Griffis Decl. ¶¶ 82-90.)

It 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 and Arnett. For the same reasons discussed in Section IX.A.4 (valve), it would have been obvious to combine the valve and valve actuator of Tauschinski with the spring clip safety IV catheter of Woehr '108. A plunger would help transfer external force from a male luer connector or other similar instrument to the valve, so that the valve opened. (Griffis Decl. ¶¶ 82-90.)

Further, it would have been obvious to modify the actuator disclosed in Tauschinski 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.

Arnett discloses a safety catheter device with a valve, actuator, and needle protection. 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.)

6. Element 11e. “a needle protective device....”

The analysis at VIII.A.6 is incorporated by reference here. (*See* Section VIII.A.6 (Ground I, Element 11e); Ex. 1002, Griffis Decl. ¶ 91).

For these reasons, Woehr '108 in view of Tauschinski renders obvious all of the limitations in claim 11.

B. Dependent Claim 20

The analysis at VIII.B is incorporated by reference here. (*See* Section VIII.B (Ground I, Dependent Claim 20); Ex. 1002, Griffis Decl. ¶ 92).

X. Ground III: The Challenged Claims Are Obvious over Van Heugten.

In the event that the Board determines that “needle protective device” should not be construed under 35 U.S.C. § 112, ¶ 6, then the Challenged Claims are obvious over U.S. 5,053,014 to Van Heugten,² “Catheter with Controlled Valve,” filed Feb. 1, 1990, issued Oct. 1, 1991 (“Van Heugten”) (Ex. 1006). (Ex. 1002, Griffis Decl. ¶¶ 93-109.) Van Heugten qualifies as prior art to the ’626 patent under 35 U.S.C. §102(b) and was cited on the face of the patent.

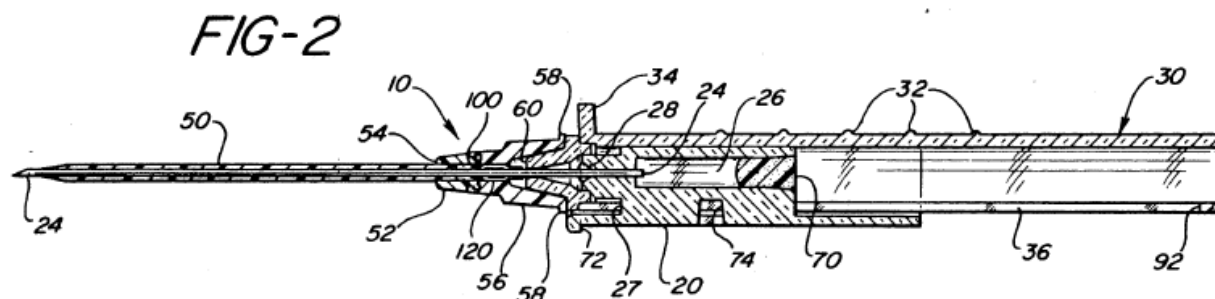
Van Heugten discloses a catheter assembly including a catheter, a catheter hub, a needle, a needle hub, a septum, an actuator, and tubular needle protection.

² Petitioner believes that “needle protective device” should be construed under 35 U.S.C. § 112, ¶ 6, and has presented Grounds I and II to invalidate the challenged claims under that construction. Patent Owner disagrees with applying § 112, ¶ 6 in the concurrent litigation. If the Board agrees with Patent Owner and gives the term its plain and ordinary meaning under the BRI standard, then all of the Grounds in this petition invalidate the challenged claims.

A. Independent Claim 11

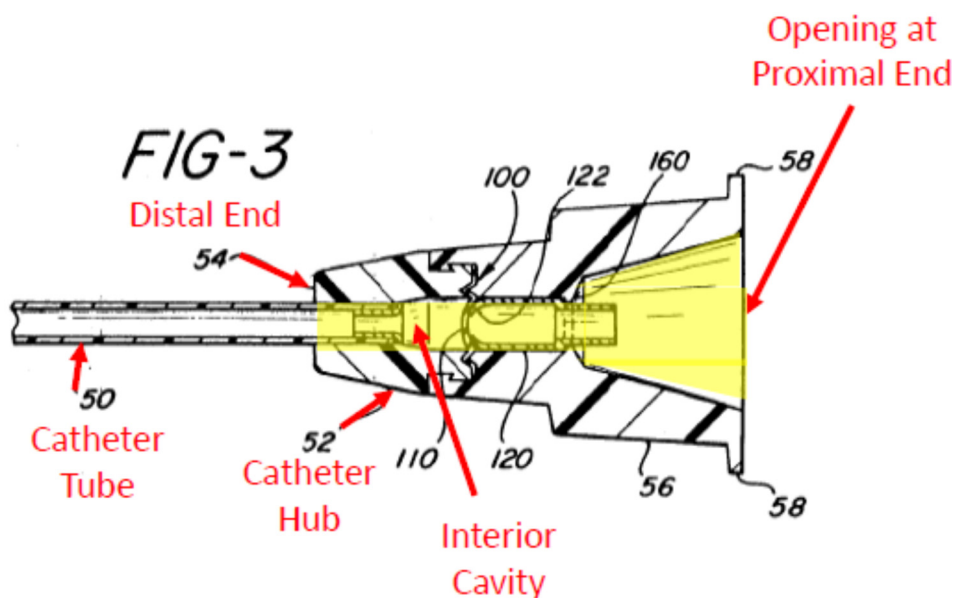
1. Element 11p. “A catheter insertion device comprising:”

To the extent this preamble is limiting, Van Heugten discloses a “catheter insertion device.” As shown and described in connection with Figures 1-4, Van Heugten discloses a catheter insertion device (*e.g.*, element 10). (Ex. 1006, Van Heugten at 2:45-46, 3:25-48, Fig. 2 (shown below); *see also id.* at 1:7-27, 1:46-68, 2:6-15, 2:19-21, Figs. 1, 3-4; Ex. 1002, Griffis Decl. ¶ 94.) The patent opens by stating, “This invention relates to I.V. catheters. ...” and refers to a catheter assembly 10 (Ex. 1006, Van Heugten at 1:4, 2:19.)



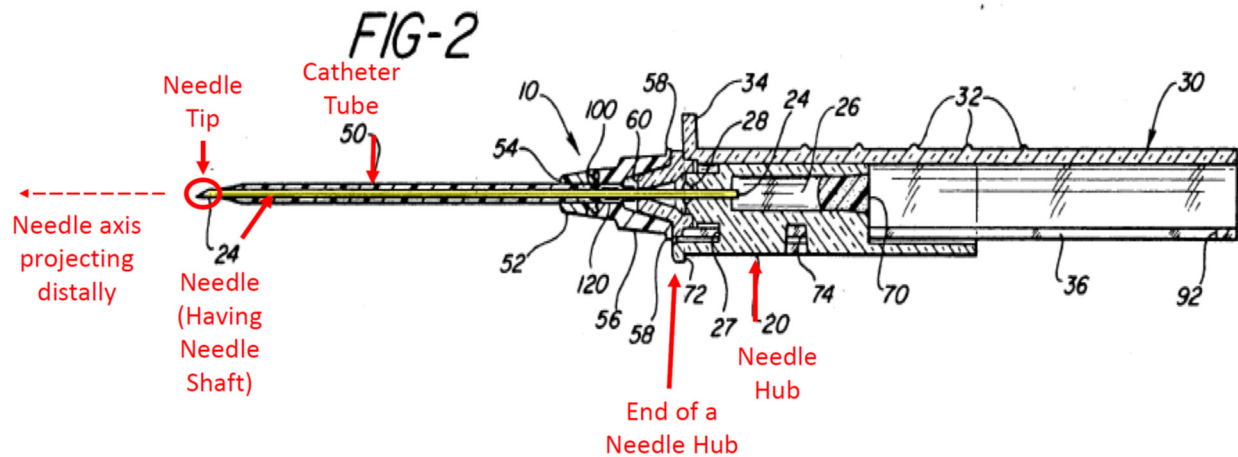
2. Element 11a. “a catheter hub...;”

Van Heugten discloses a catheter hub (*e.g.*, element 52) comprising an interior cavity, an opening at a proximal end, and a catheter tube (*e.g.*, element 50) attached to a distal end (*e.g.*, element 54). (Ex. 1006, Van Heugten at 2:45-55, 2:6-15, Fig. 3 (annotated below); *see also id.* at Figs. 1-2, 4; Ex. 1002, Griffis Decl. ¶ 95.)



3. Element 11b. “a needle...;”

Van Heugten a needle (e.g., element 24) having a needle shaft defining a needle axis projecting distally of an end of a needle hub (e.g., element 20), said needle projecting through the catheter tube (e.g., element 50) in a ready position and comprises a needle tip. (Ex. 1006, Van Heugten at 2:19-23, 2:36-40, 2:56-62, Figs. 1, 2 (annotated below); *see also id.* at 1:64-68, 2:6-15, 2:45-50, Figs. 3-4; Ex. 1002, Griffis Decl. ¶ 96.) For example, Van Heugten describes Figure 2, stating, “This drawing shows the catheter 50 and its catheter hub 52 mounted on the distal end of the needle guard 30. The point of the needle 24 is seen to extend from the distal tip of the catheter 50.” (Ex. 1006, Van Heugten at 2:37-40.)

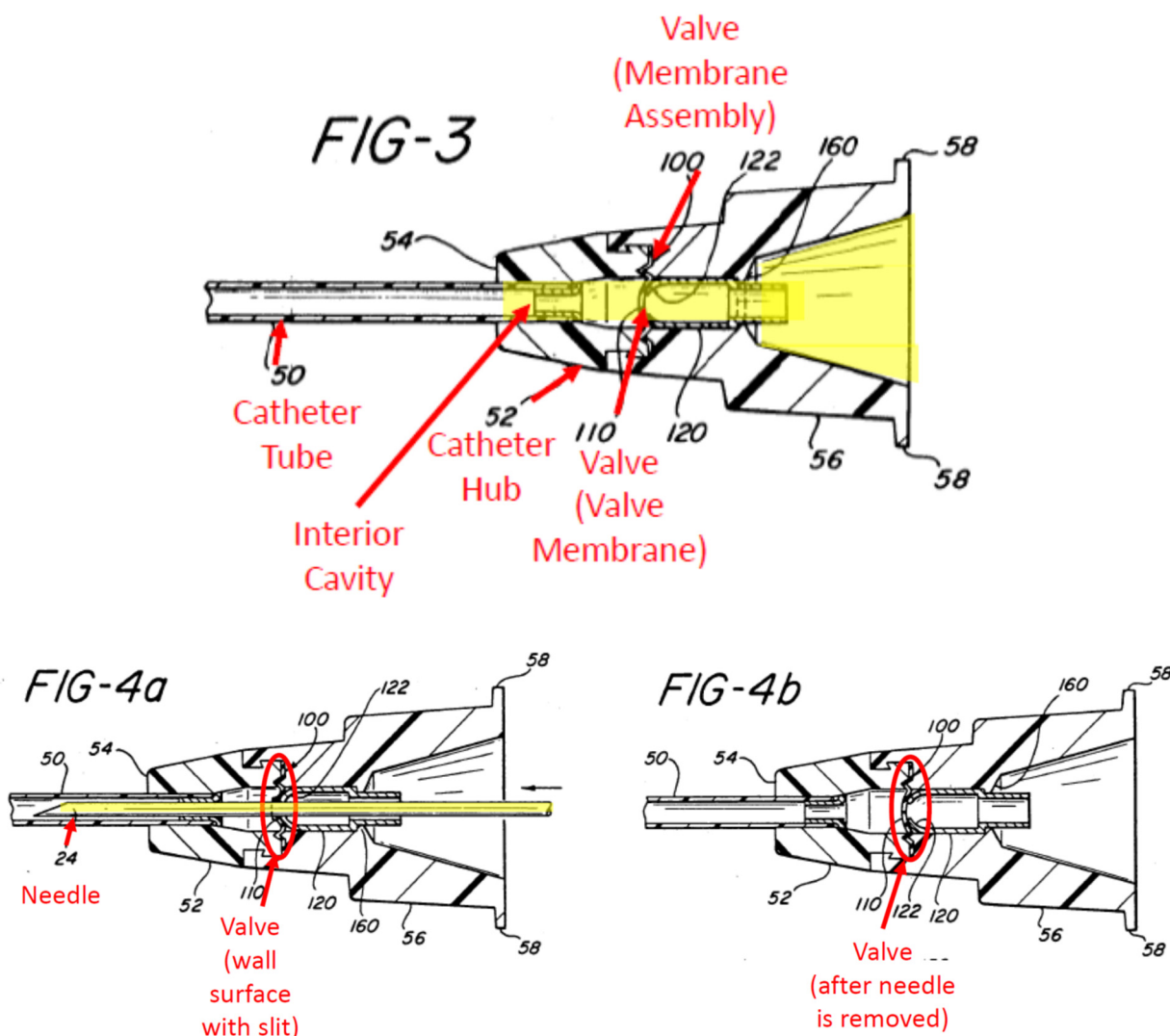


4. Element 11c. “a valve...;”

Van Heugten renders obvious “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.” (Ex. 1002, Griffis Decl. ¶¶ 97-99.)

As shown and described in connection with Figures 1-4, Van Heugten discloses a valve (e.g., elements 100, 110) positioned inside the interior cavity of the catheter hub (e.g., element 52) and in contact with the interior cavity; said valve being sized and shaped to obstruct fluid flow through the catheter hub and comprises a wall surface comprising a slit; said valve remaining inside the interior cavity when the needle (e.g., element 24) is removed from the catheter tube (e.g., element 50) and the catheter hub. For example, Van Heugten describes the membrane assembly 100 and valve membrane 110 in connection with Figures 3,

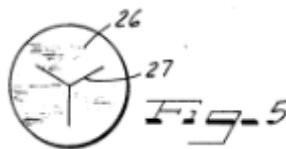
4a-4b. (Ex. 1006, Van Heugten at 3:59-4:3, 4:6-30, Figs. 3, 4a-4b (annotated below).)



(See also *id.* at 1:9-26, 1:46-56, 1:60-2:4, 2:6-15, Figs. 1-2, 4; Ex. 1002, Griffis Decl. ¶ 98.)

Van Heugten also describes that the valve membrane 110 can be configured in multiple ways. (Ex. 1002, Griffis Decl. ¶ 99.) In a first way, the valve is originally sealed, and upon insertion of a needle, the valve is punctured. (Ex. 1006, Van

Heugten at 3:64-4:3). In a second way, the valve is configured as a “duck-bill” valve or a valve of similar configuration, which a POSA would understand as having a slit. (*Id.* at 4:23-27.) In a third way, the valve is configured to have multiple slits. For example, Van Heugten explains the desirability of applying the valve principle of U.S. Patent No. 3,585,996 (“Reynolds”) to a catheter assembly. (Ex. 1006, Van Heugten at 1:28-32 (describing a “self-sealing disc valve ... with several fine slits”), 1:47-57.) More particularly, Reynolds discloses a valve (e.g., element 26) having slits in the form of a “Y” (e.g., element 27). (Ex. 1007, Reynolds at 2:56-60, Fig. 5 (shown below); Ex. 1002, Griffis Decl. ¶¶99.)



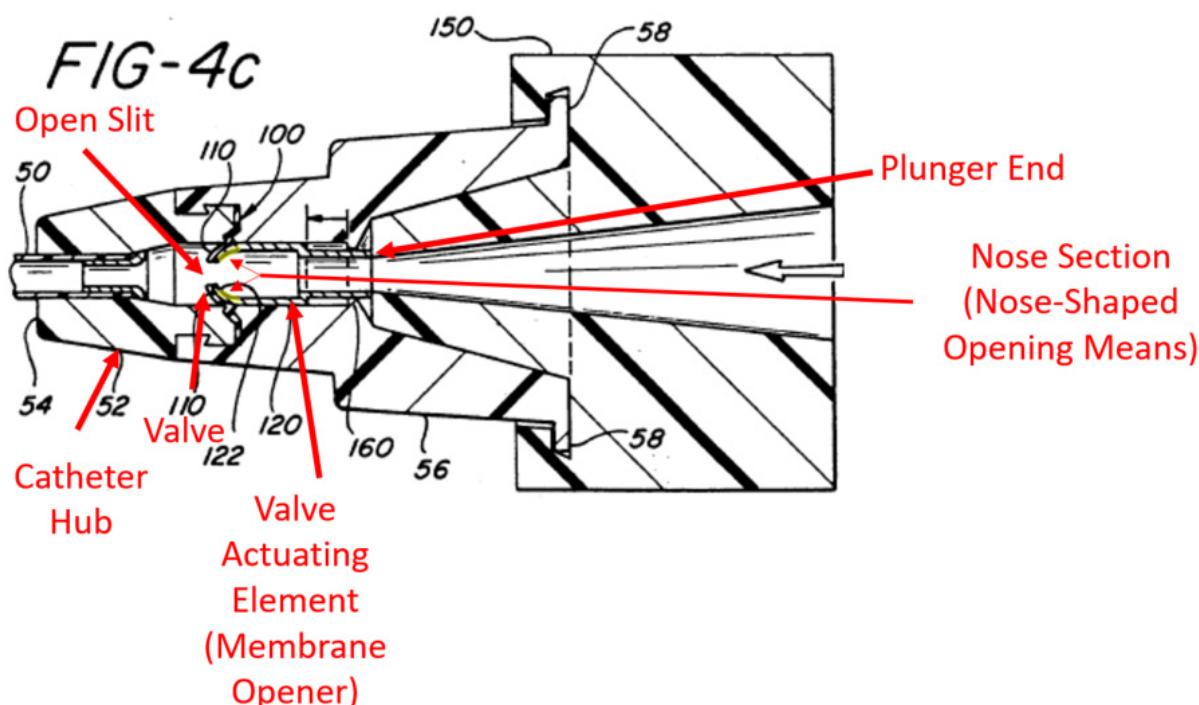
Thus, a POSA would have understood Van Heugten to disclose the valve membrane 110 having a slit. (Ex. 1002, Griffis Decl. ¶¶ 97-99.)

5. Element 11d. “a valve actuating element...;”

Van Heugten discloses “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. 1002, Griffis Decl. ¶¶ 100-103.)

As shown and described in connection with Figures 1-4, Van Heugten discloses 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); the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon. For example, Van Heugten describes the membrane opener 120 in connection with Figure 4c, stating, “Membrane opener 120 is generally cylindrical in shape and contains nose-shaped opening means 122. These nose shaped opening means 122 fit comfortably within valve membrane 110 when so inserted.” (Ex.1006, Van Heugten at 4:31-36, *see also* 4:43-49, Fig. 4c (annotated below).)



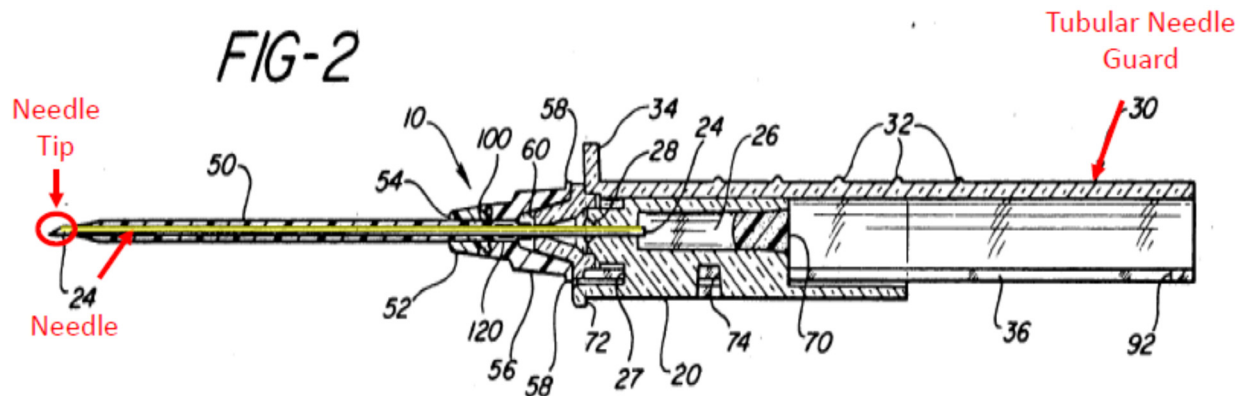
Van Heugten further describes the membrane opener 120 as a valve opener that is “slideably emplaced” in the catheter hub so that when a luer assembly is attached to the hub the “valve opener contacts said luer assembly and slides to open said valve.” (*Id.* at 5:12-19, 6:20-23.) (*See also id.* at 1:62-2:4, 2:6-15, 4:31-58, Figs. 1-4; Ex. 1002, Griffis Decl. ¶¶ 100-103.) Thus, a POSA would understand that the portion of the valve opener proximal to the nose section and that transfers a distally directed force from a luer to push open the slit is the claimed plunger end. (Ex. 1002, Griffis Decl. ¶¶ 100-103.)

6. Element 11e. “a needle protective device....”

Van Heugten discloses a tubular needle guard 30 spaced from the needle tip (e.g., end of element 24) 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.

For example, Van Heugten describes the tubular needle guard 30, which includes a needle guard tip 60, in connection with Figure 2. (Ex. 1006, Van Heugten at 2:36-44, Fig. 2 (annotated below).)



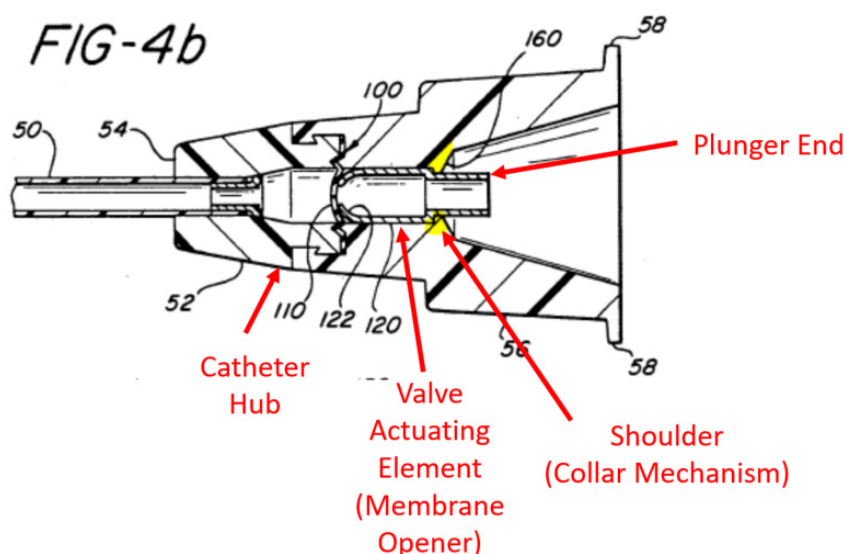
Van Heugten further discloses that when the needle is retracted, the user pushes on push-off tab 34 and the tubular needle guard 30 advances in a distal direction and moves relative to the needle tip to a protective position distally of the needle tip to prevent inadvertent injury to the user. (*Id.* at 3:34-58.) (*See also id.* at 2:6-12, 2:25-35, 2:53-55, 2:64-3:7, 5:4-6, 6:4-8, Figs. 1, 3; Ex. 1002, Griffis Decl. ¶¶ 104-105).

For these reasons, Van Heugten renders obvious all of the limitations in claim 11.

B. Dependent Claim 20

Claim 20 depends from claim 11, and the analysis for claim 11 in Section X.A is incorporated by reference. Further, Van Heughten 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.” As shown in FIGS. 1-4, Van Heughten 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).

Van Heugten explains, “hub 52 also contains membrane opener 120. Membrane opener 120 is generally cylindrical in shape and contains nose-shaped opening means 122. These nose shaped opening means 122 fit comfortably within valve membrane 110 when so inserted. Also attached to catheter hub 52 is collar mechanism 160. This collar mechanism 160 holds membrane opener 120 in place when luer assembly 150 is attached to catheter hub 52. . . .” (Ex. 1006, Van Heugten at 4:31-58, Fig. 4b and 4c (annotated below).)



Figs. 4a and 4b shows that in the ready position collar mechanism 160 acts as a stop for membrane opener 120 because it interacts with the projection on the membrane opener 120. (Ex. 1002, Griffis Decl. ¶ 106-109).

For this reason, Van Heugten renders obvious the limitation in claim 20.

XI. Ground IV: The Challenged Claims Are Obvious over Van Heugten in view of Arnett.

In the event that the Board determines that “needle protective device” should not be construed under 35 U.S.C. § 112, ¶ 6, then the Challenged Claims are obvious Van Heugten in view of Arnett (Ex. 1005). (Ex. 1002, Griffis Decl. ¶ 110-122.) Van Heugten and Arnett qualify as prior art to the ’626 patent under 35 U.S.C. § 102(b), and both were cited on the face of the patent.

Van Heugten discloses a catheter assembly including a catheter, a catheter hub, a needle, a needle hub, a septum, an actuator, and tubular needle protection.

Arnett discloses a catheter device that includes needle protection, a valve and actuator assembly to prevent leakage, where the actuator has a second actuator end with gaps that transfers force to actuate the valve.

A. Independent Claim 11

1. Element 11p. “A catheter insertion device comprising:”

The analysis at X.A.1 is incorporated by reference here. (*See* Section X.A.1 (Ground III, Element 11p); Ex. 1002, Griffis Decl. ¶ 111).

2. Element 11a. “a catheter hub...;”

The analysis at X.A.2 is incorporated by reference here. (*See* Section X.A.2 (Ground III, Element 11a); Ex. 1002, Griffis Decl. ¶ 112).

3. Element 11b. “a needle...;”

The analysis at X.A.3 is incorporated by reference here. (*See* Section X.A.3 (Ground III, Element 11b); Ex. 1002, Griffis Decl. ¶ 113).

4. Element 11c. “a valve...;”

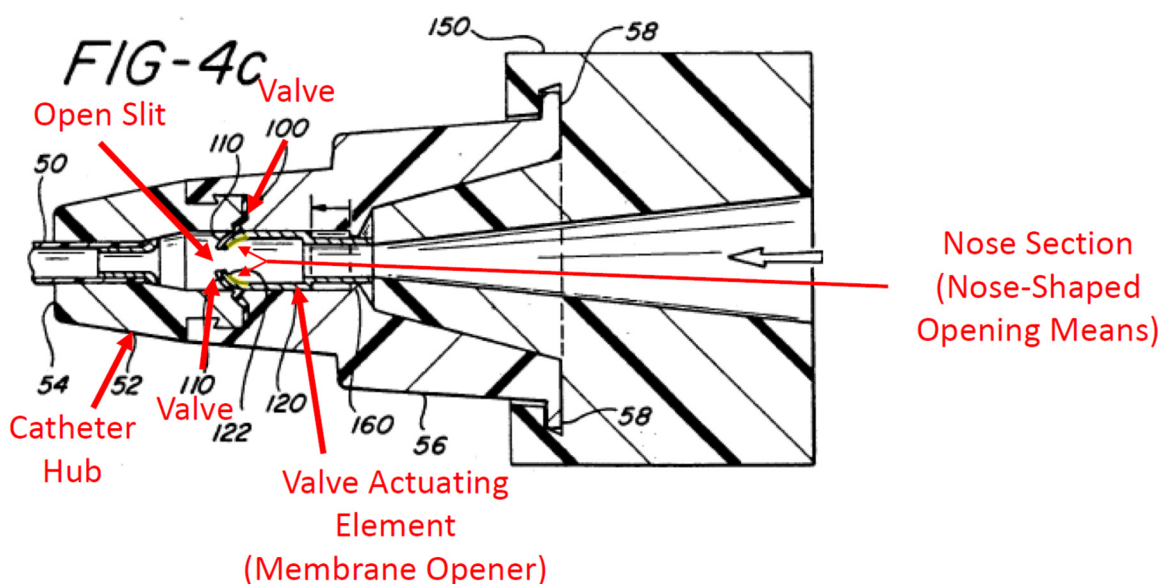
The analysis at X.A.4 is incorporated by reference here. (*See* Section X.A.4 (Ground III, Element 11c); Ex. 1002, Decl. ¶ 114).

5. Element 11d. “a valve actuating element...;”

The combination of Van Heugten and Arnett discloses “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

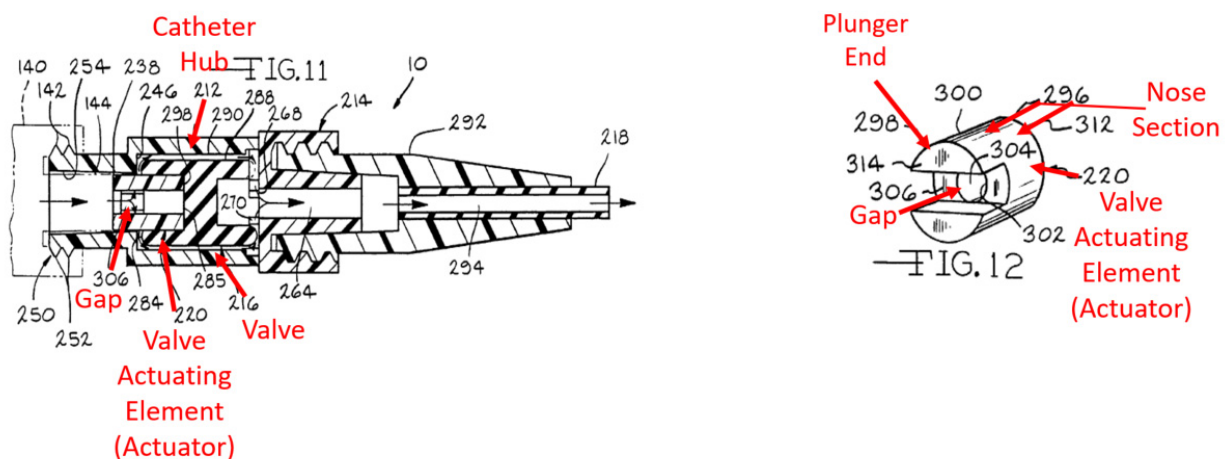
valve to open the slit and a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon.” (Ex. 1002, Decl. ¶ 115-120.)

As shown and described in connection with Figures 1-4, Van Heugten discloses 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; the valve actuating element transfers a distally directed force to the nose section to push the valve to open the slit when pressed upon. For example, Van Heugten describes the membrane opener 120 in connection with Figure 4c, stating, “Membrane opener 120 is generally cylindrical in shape and contains nose-shaped opening means 122. These nose shaped opening means 122 fit comfortably within valve membrane 110 when so inserted.” (Ex. 1006, Van Heugten at 4:31-36, *see also* 4:43-49, Fig. 4b (annotated below).)



Van Heugten further describes the membrane opener 120 as a valve opener that is “slideably emplaced” in the catheter hub. (*Id.* at 5:12-14, 6:20-23.) (*See also id.* at 1:62-2:4, 2:6-15, 4:31-58, Figs. 1-4; Ex. 1002, Griffis Decl. ¶¶ 115-120.)

As shown and described in connection with Figures 1-15, Arnett discloses a valve actuating element (e.g., element 220) slidably disposed in the catheter hub (e.g., element 212) to actuate the valve (e.g., element 216), the valve actuating element (e.g., element 220) comprising a nose section (e.g., element 296 and/or element 312) for pushing the valve (e.g., element 216) to open the valve and a plunger end (e.g., element 298) extending proximally of the nose section (e.g., element 296 and/or element 312); the plunger end (e.g., element 314) transferring a distally directed force to push the valve (e.g., element 216) when pressed upon. (*See, e.g.*, Ex. 1005, Arnett at 7:30-54, 8:26-49, Figs. 11-12 (annotated below).)



The actuator 220 has a proximal, second actuator end that has two plungers and a gap therebetween, which creates fluid passageway 306 that permits fluid to flow therethrough. (Ex. 1005, Arnett at 7:34-36; Ex. 1002, Griffis Decl. ¶ 118.) There is also a central passageway through the length of the actuator, described as needle passageway 304. (Ex. 1005, Arnett at 7:32-34; Ex. 1002, Griffis Decl. ¶ 119.)

Arnett explains:

Referring to FIGS. 9 and 12, the actuator 220 includes a first actuator end 296, a second actuator end 298, an exterior actuator surface 300, and an interior actuator surface 302. The interior actuator surface 302 defines a needle passageway 304 extending between the first actuator end 296 and the second actuator end 298. The interior actuator surface 302 defines a fluid passageway 306 adjacent the second actuator end 298. As shown in FIGS. 9 and 12, the actuator exterior surface 300 defines an annular septum contact surface 312 and an opposed

fitting contact surface 314. A portion of the exterior surface 300 and the septum contact surface 312 engage the actuator recess 285 of the septum 216.

(Ex. 1005, Arnett at 7:30-45.)

It would have been obvious for a POSA to combine the catheter insertion device of Van Heugten with the valve actuating elements disclosed in 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 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.)

6. Element 11e. “a needle protective device....”

The analysis at X.A.6 is incorporated by reference here. (*See* Section X.A.6 (Ground III, Element 11e); Ex. 1002, Griffis Decl. ¶ 121).

For these reasons, Van Heugten in view of Faust renders obvious all of the limitations in claim 11.

B. Dependent Claim 20

The analysis at X.B is incorporated by reference here. (*See* Section X.B (Ground III, Dependent Claim 20); Ex. 1002, Griffis Decl. ¶ 122).

XII. Secondary Considerations of Nonobviousness Do Not Negate the Above Obviousness Grounds.

Any attempt by Patent Owners to rely on alleged secondary considerations of nonobviousness cannot overcome the showing of obviousness detailed above. Where, as here, there is a strong showing of obviousness, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011). In any event, Patent Owners cannot satisfy their burden of demonstrating a nexus between any alleged secondary consideration and the alleged invention of the '512 patent. *Cf. Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013).

XIII. Conclusion

Based on the foregoing, there is a reasonable likelihood that claims 11 and 20 of the '626 patent are unpatentable as obvious. Petitioners request institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the type-volume limitation of 37 C.F.R. §42.24(a)(1)(i) because, according to the “word count” function of Microsoft Word 2010, the Petition contains 9,161 words, excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

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CERTIFICATE OF SERVICE

I hereby certify that, on June 16, 2017, I caused a true and correct copy of the following materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 9,149,626
- Exhibits 1001-1024
- Fee Authorization Page
- Power of Attorney
- Certificate of Compliance
- List of Exhibits

to be served via Federal Express on the following attorney of record as listed on PAIR:

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A courtesy copy of this Petition and supporting material was also served upon litigation counsel for Patent Owner via email:

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U.S. Patent No. 9,149,626
Petition for *Inter Partes* Review IPR2017-01587

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Petitioner’s Appendix of Exhibits

Pet’rs’ Ex. No.	Description
1001.	U.S. Patent No. 9,149,626 (issued Oct. 6, 2015) (“the ’626 patent”)
1002.	Declaration of Mr. Griffis (“Griffis Decl.”)
1003.	U.S. Patent No. 6,117,108 to Woehr et al. (issued Sept. 12, 2000) (“Woehr ’108”)
1004.	U.S. Patent No. 4,387,879 to Tauschinski (issued Jun. 14, 1983) (“Tauschinski”)
1005.	U.S. Patent No. 5,817,069 to Arnett (issued Oct. 6, 1998) (“Arnett”)
1006.	U.S. Patent No. 5,053,014 to Van Heugten (issued Oct. 1, 1991) (“Van Heugten”)
1007.	U.S. Patent No. 3,585,996 to Reynolds et al. (issued Jun. 22, 1971) (“Reynolds”)
1008.	U.S. Patent Application No. 12/790,630 Prosecution History, Response of Nov. 4, 2011
1009.	B. Braun Interventional Systems Inc., <i>Accel™ Valved Safety Centesis Catheter With Introcan Safety™ Technology</i> (2016) (“B.Braun Brochure”)
1010.	Excerpts from Dr. Haindl, Australian Transcript (June 9, 2017) (“Australian Tr.”)
1011.	Intravenous Therapy Clinical Principles and Practices 317 (Judy Terry et al. eds., 1995) (“Terry”)

Pet'rs' Ex. No.	Description
1012.	A.M. Rivera et al., <i>The history of peripheral intravenous catheters: How little plastic tubes revolutionized medicine</i> , 56 Acta Anaesth. Belg. 271, (2005) (“Rivera”)
1013.	U.S. Patent No. 5,858,002 to Jesch (issued Jan. 12, 1999) (“the ’002 patent”)
1014.	U.S. Patent No. 4,850,961 to Wanderer et al. (issued Jul. 25, 1989) (“the ’961 patent”)
1015.	U.S. Publication No. 2001/0053895 to Vaillancourt, published Jan. 20, 2001 (“Vaillancourt”)
1016.	OSHA Bloodborne Pathogens Standard, 56 Fed. Reg. 64004 (Dec. 6, 1991) (“OSHA Standard”)
1017.	Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000) (“Needlestick Prevention Act”)
1018.	N.Y. STATE, DEP’T OF HEALTH, <i>PILOT STUDY OF NEEDLESTICK PREVENTION DEVICES</i> , Report to the New York State Legislature, (March, 1992) (“Pilot Study”)
1019.	Hanrahan & Reutter, <i>A critical review of the literature on sharps injuries: epidemiology, management of exposures and prevention</i> , 25 J Adv. Nursing 144-154 (1997) (“Hanrahan”)
1020.	<i>Plumer’s Principles & Practice of Intravenous Therapy</i> , Ch. 11, 193 (7th ed. 2001) (“Plumer’s”)
1021.	Fran Powers, <i>Effectively Evaluating and Converting Your Organization to the Use of Infusion Safety Products</i> , 25 J. of Infusion Nursing S10 (2002) (“Powers”)

Pet'rs' Ex. No.	Description
1022.	FDA, <i>Guidance for Industry and FDA Staff—Medical Devices with Sharps Injury Prevention Features</i> (Aug. 9, 2005) (“FDA Guidance”)
1023.	International Standard, ISO 594-2, <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings</i> (Sept. 1, 1998) (“ISO 594-2”)
1024.	U.S. Patent No. 5,458,658 to Sircom (issued Oct. 17, 1995) (“Sircom”)