

Filed on behalf of Becton, Dickinson and Company

By: Heather M. Petruzzi, Reg. No. 71,270 (Lead Counsel)
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
Tel: (202) 663-6000
Email: Heather.Petruzzi@wilmerhale.com

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. 8,328,762 to Woehr et al.

IPR Trial No. IPR2017- 01586

**PETITION FOR INTER PARTES REVIEW
OF CLAIMS 18, 22, 25 OF U.S. PATENT NO. 8,328,762
UNDER 35 U.S.C. §312 AND 37 C.F.R. §42.104**

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I. Introduction

Petitioner requests institution of an *inter partes* review to cancel claims 18, 22, 25 (“Challenged Claims”) of U.S. Patent No. 8,328,762 (“the ’762 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) Van Heugten (Ground II), (3) Van Heugten in view of Lynn (Ground III), and (4) Van Heugten in view of Tauschinski (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.

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.) IPR petitions are being filed on the following patents that are in the same family as the ’762 patent: U.S. Patent Nos. 7,333,735; 8,540,728; 8,337,463; 9,149,626. Additionally, Petitioner is filing IPR petitions on additional patents that may be relevant to this proceeding: U.S. Patent Nos. 8,460,247; 8,597,249; 9,370,641.

C. Counsel

Lead Counsel: Heather M. Petruzzi (Reg. No. 71,270)

Back-up Counsel: Natalie Pous (Reg. No. 62,191)

David L. Cavanaugh (Reg. No. 36,476)

D. Service Information

Email: Heather.Petruzzi@wilmerhale.com;

Natalie.Pous@wilmerhale.com;

David.Cavanaugh@wilmerhale.com;

Post & Hand Delivery: Wilmer Cutler Pickering Hale and Dorr LLP

1875 Pennsylvania Avenue NW, Washington, DC

20006

Tel: (202) 663-6000, Facsimile: (202) 663-6363

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 claims 18, 22, and 25 of the '762 patent as unpatentable under 35 U.S.C. §103 based on the following grounds.

Ground	35 U.S.C. §	Claims	References
I	103	18, 22, 25	Woehr '108 in view of Tauschinski
II	103	18, 22	Van Heugten
III	103	25	Van Heugten in view of Lynn
IV	103	22	Van Heugten in view of Tauschinski

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 State of the Art and the '762 Patent

A. The State of the Art

As described in more detail in the Declaration of Jack Griffis (Ex. 1002), 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. ¶47.) 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. ¶34.)

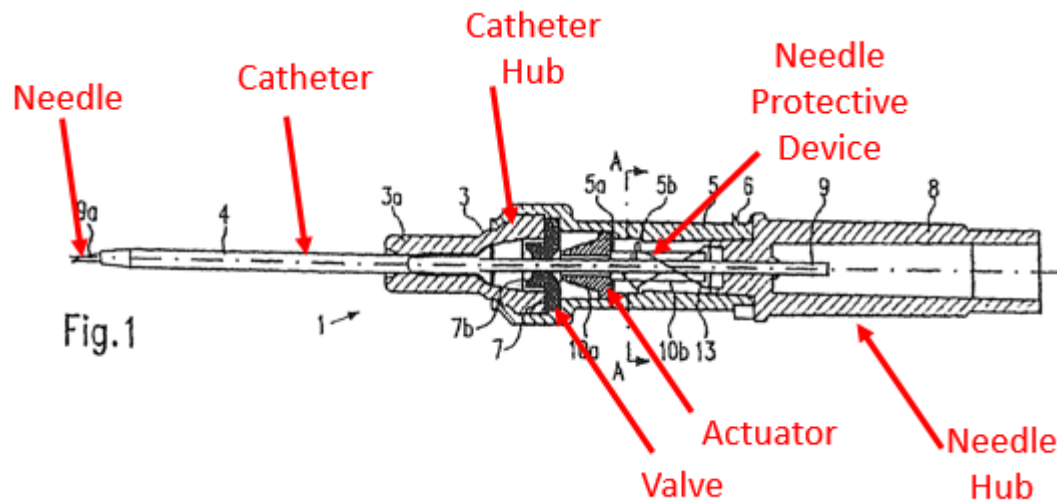
It was also recognized, for example in U.S. Patent No. 5,053,014 (“Van Heugten”) (Ex. 1003), that during use of an I.V. catheter assembly it is desirable to

minimize “any blood leakage from the assembly so as to reduce the risk of transmitting blood-borne diseases to medical personnel.” (Ex. 1003, Van Heugten at 1:15-18.)

B. Brief Description of the '762 Patent in View of the State of the Art

The '762 patent was filed as a patent application on May 28, 2010, and claims priority to a German patent application filed on July 4, 2002.

The '762 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 '762 patent is composed of various, standard features in catheter assemblies. The '762 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. (Ex. 1001, '762 patent at 1:21-26).

The '762 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. (*Id.* at 1:38-46). These “objectives” were also well known in the art. (Ex. 1002, Griffis Decl. ¶¶35-40; Ex. 1003, Van Heugten at claim 1.)

The '762 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. (Ex. 1001, '762 patent at 2:39-54.) By 2002, catheter insertion devices that included check valves and valve actuating elements to prevent blood leakage were well known. (Ex. 1002, Griffis Decl. ¶¶64-68.) In order to cover the needle tip to prevent injury, the '762 patent discloses a spring clip that closes around the needle tip as it is withdrawn from the catheter hub. (*E.g.*, Ex. 1001, '762 patent at 2:31-46.) The same spring clip disclosed in the '762 patent was also known as of 2002. (Ex. 1002, Griffis Decl. ¶¶39, 53, 73.) Further, catheter insertion devices with the combination of blood control and needle protection were well known by 2002. (*Id.*)

VI. Summary of the '762 Patent's Prosecution History

During prosecution of application US Ser. No. 12/790,630, from which the '762 patent issued, the applicant argued against an obviousness rejection of claims 18, 20, and 25 based on the combination of a prior art catheter insertion devices comprising (a) a valve/valve actuating element or (b) a needle protective device. To overcome the rejection of claims 18, 22 and 25, the applicant argued that the prior art device comprising a valve/valve actuator could not be modified to accommodate a needle guard because doing so would require use of a sliding member (for actuating a valve) that would need to be longer than "industry standard size." Claims 18, 20, and 25 issued without further amendment.

VII. POSA

A POSA in 2002 would be 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. ¶¶ 28-30.)

VIII. 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 18, 22, and 25 recite a “a method of manufacturing a catheter insertion device comprising . . . positioning a needle protective device at least partially inside the interior cavity of the catheter hub.” (Ex. 1001, ’762 patent) 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 ’762 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. ¶¶ 116-129); *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. ¶ 118.) 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. ¶¶ 42-50); *see Micron Tech., Inc. v. Innovative Memory Sys., Inc.*, 2016 WL 5027747, IPR2016-00324, Decision Denying Institution at *5 (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:

- ’762 patent, Figs. 1-2, 4, 5, 7a 7d, 8, 9a, 10
- ’762 patent, Col. 2:29
- ’762 patent, Col. 2:31-49
- ’762 patent, Col. 3:13-25
- ’762 patent, Col. 3:32-36
- ’762 patent, Col. 3:65-4:5
- ’762 patent, Col. 4:35-49
- and structural equivalents thereof. (*Id.* ¶50.)

IX. 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, “Spring Clip Safety IV Catheter,” filed Jun. 12, 1998, issued Sep. 12, 2000

(“Woehr ‘108”) (Ex. 1004) in view of U.S. Patent No. 4,387,879 to Tauschinski et al., “Self-Sealing Connector for Use with Plastic Cannulas and Vessel Catheters,” filed Jul. 16, 1981, issued Jun. 14, 1983 (“Tauschinski”) (Ex. 1005). (Ex. 1002, Griffis Decl. ¶¶61-91.) Both Woehr ‘108 and Tauschinski qualify as prior art to the ’762 patent under 35 U.S.C. §102(b).

Woehr ’108 discloses a safety IV catheter with the same spring clip shown in the ’762 patent to prevent needle sticks. Tauschinski describes a well-known valve and valve actuator that is used with catheters to prevent the emergence of blood.

During prosecution of App. No. 10/520,325, to which the ’762 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 the ’762 patent, the applicant again argued that a prior art device with a valve and a valve actuator (as disclosed in US 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. 1006, Nov. 4, 2011 Office Action Response at 10). This petition explains why the

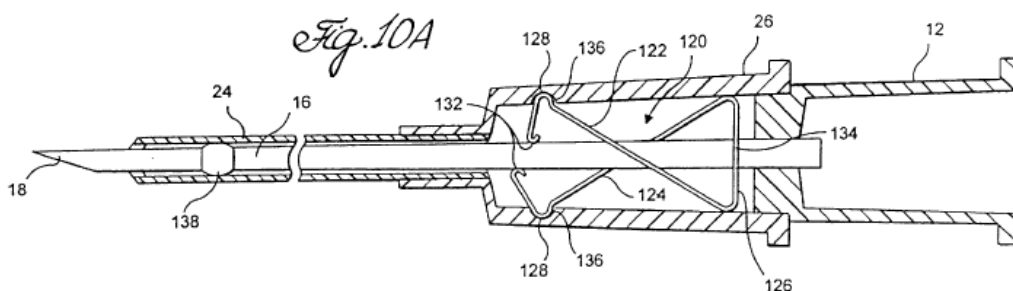
Grounds render the challenged claims obvious. The Ground presents a new combination of references that has not previously been considered, and it provides additional evidence that was not before the examiner, including the testimony of Jack Griffis (Ex. 1002) and testimony by Patent Owner's own expert that there were no design concerns about combining Introcan Safety, which is the embodiment of Woehr '108 (Ex. 1004), and Tauschinski (Ex. 1007.) Further, the as the US Court of Appeals for the Federal Circuit has recognized, it is not necessary for two references to be physically combinable in order to render a patent obvious. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("criterion [is] not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.") (*citing In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc)).

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.

A. Independent Claim 18

1. Element 18p. “A method of manufacturing a catheter insertion device comprising:”

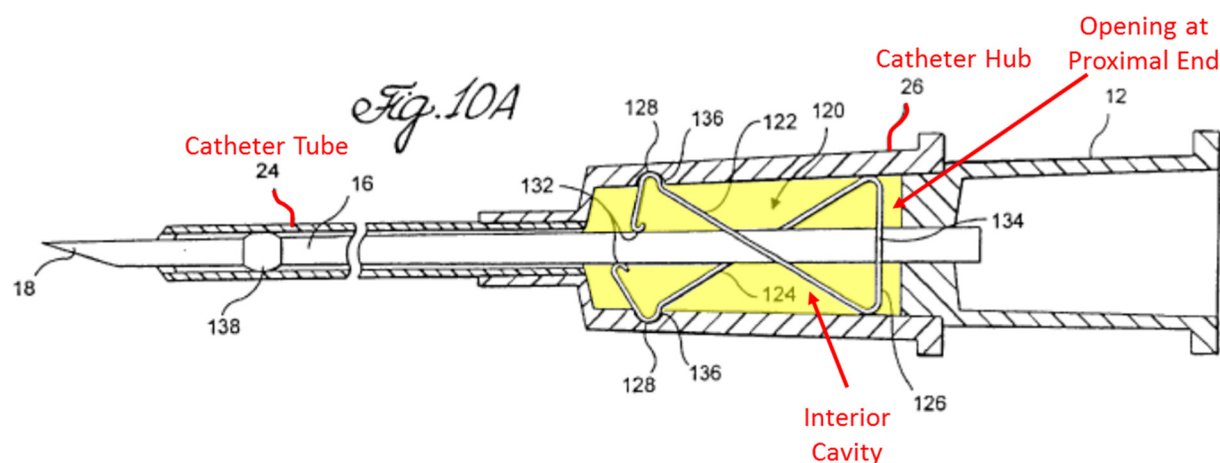
To the extent this preamble is limiting, Woehr ‘108 discloses a method of manufacturing a catheter insertion device (e.g., element 10). (*See, e.g.*, Ex. 1004, Woehr ‘108 at 2:25-28 (“It is accordingly an object of the present invention to provide a safety IV catheter, which reliably and automatically prevents accidental, inadvertent contact with the needle tip after use.”); *see also id.* at 1:14-18, 2:43-46, 4:8-18, 4:36-42, Figs. 1-6, 7C, 7D, 10A; Ex. 1002, Griffis Decl. ¶¶61.) Woehr ‘108 identifies the safety IV catheter as element 10. (*E.g.*, Ex. 1004, Woehr ‘108 at 4:8-10.)



2. Element 18a. “forming a catheter hub...;”

Woehr '108 discloses forming a catheter hub (*e.g.*, element 26) comprising a body comprising an interior cavity with an opening at a proximal end and attaching

a catheter tube (*e.g.*, element 24) thereto. (*See, e.g.*, Ex. 1004, 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.”), Fig. 10A (annotated below); *see also id.* at 3:26-30, 4:8-34, Figs. 1A, 1C, 2A, 3A, 4A, 5A, 6A, 7A, 7B, 7C, 7D, 7E; Ex. 1002, Griffis Decl. ¶62.)

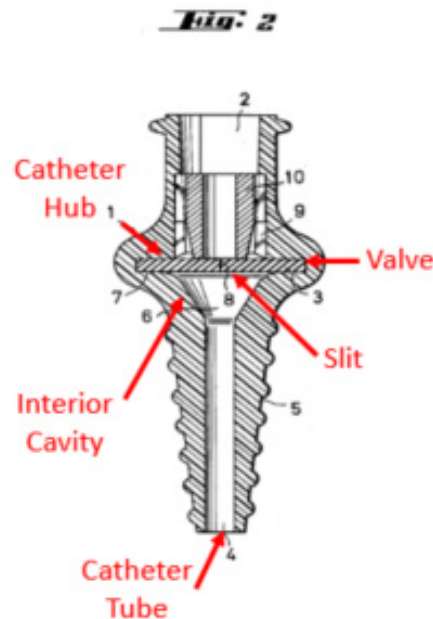


3. Element 18b. “positioning a valve ...;”

The combination of Woehr '108 and Tauschinski renders obvious positioning a valve (*e.g.*, element 3) in sealing communication with the interior cavity of the catheter hub for regulating fluid flow through the interior cavity.

Tauschinski discloses “[a] chamber 6 connects the interior of the hollow-conical

portion 2 to the passage 4 and is provided with a peripheral annular radial groove 7, in which a disc 3 of elastic material is held. The disc 3 is provided with a central slit 8, which terminates short of the edge of the disc.” (Ex. 1005, Tauschinski at 3:14-19, *see also* 2:7-37, 3: 20-32; Fig. 2 (annotated below); Fig. 3; Ex. 1002, Griffis Decl. ¶¶63-68.)



It would have been obvious to a POSA to modify Woehr ‘108 to include a valve in sealing communication with the interior cavity of the catheter hub as described 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. ¶¶63-68.) It would have been apparent to a POSA that such a valve could be introduced into 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. (*Id.*) There are a limited number of ways to position the valve in the catheter hub, and doing so in one of the known arrangements would predictably regulated fluid flow through the interior of the cavity. 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. 1007, 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.

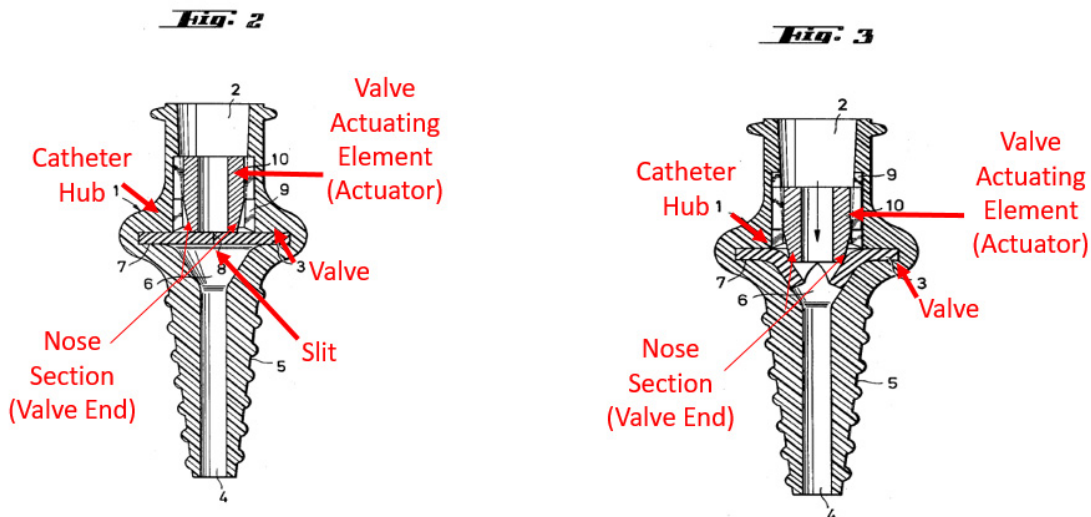
4. Element 18c. “positioning a valve actuating element...;”

The combination of Woehr ‘108 and Tauschinski renders obvious positioning a valve actuating element (e.g., element 10) in mechanical communication with the valve (e.g., element 3) for deflecting the valve to permit fluid flow through the interior cavity of the catheter hub. For example, Tauschinski describes the valve 3, the valve actuating element 10, and connector in connection with Figs. 2 and 3 as follows:

¹ Dr. Haindl explains that he is “of the view that the Fresenius valve seems to be based on the Tauschinski patent.” (Ex. 1007, Australian Tr. at 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. 1008, B. Braun Brochure at 6).

The embodiment shown in FIGS. 2 and 3 differs from the embodiment shown in FIG. 1... 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.

(Ex. 1005, Tauschinski at 3:20-36; also see *id.* at 2:42-56, 3:47-58; Figs. 2 and 3 (annotated below).)



It would have been obvious to a POSA to modify Woehr '108 to include a valve wherein fluid flow through the valve is controlled by a valve actuator. Positioning a valve actuating element in communication with a valve (as described

in section IX.A.3, *supra*), 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 translated through the end(s) of an actuator element. 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 to position the actuator in the device with a needle guard of Woehr '108 such that the actuator can receive an external force once the needle guard is removed. (Ex. 1002, Griffis Decl. ¶¶69-72). As stated above 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. 1007, Australian Tr. at 587:5-11.) As such, a POSA, having considered the solutions proposed in references such as Woehr '108 and Tauschinski would have understood that there are a finite number of ways to actuate a valve, and would

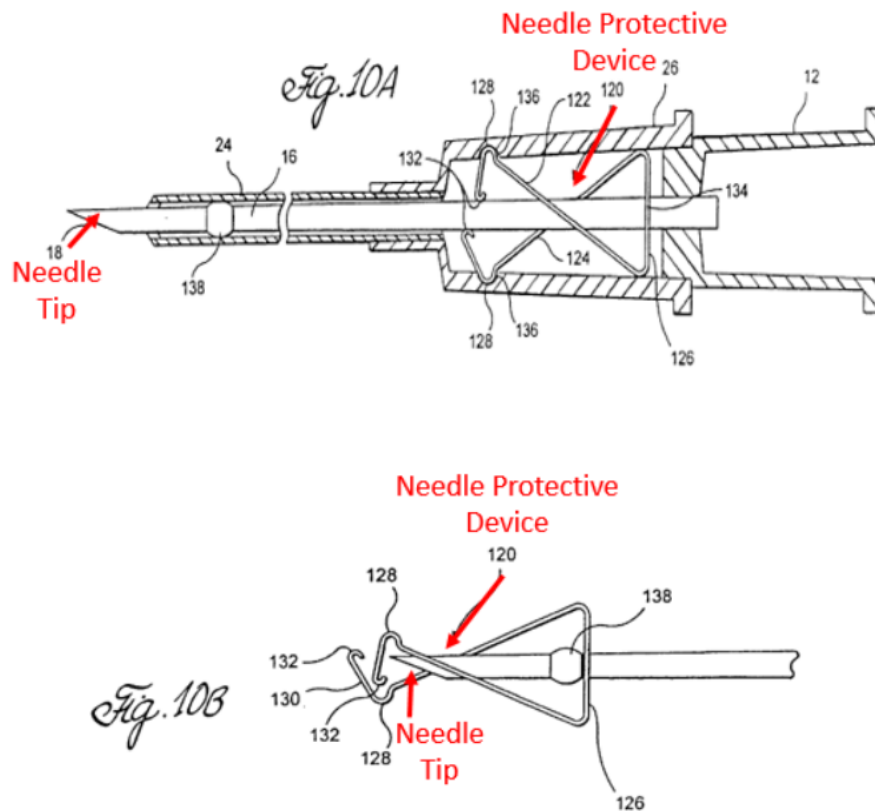
have found this to be a predictable solution based on the combination of known elements that that would have been expected to maintain their respective functions. (Ex. 1002, Griffis Decl. ¶¶69-72.)

5. Element 18d. “positioning a needle protective device....”

The combination of Woehr ‘108 and Tauschinski discloses “positioning a needle protective device at least partially inside the interior cavity of the catheter hub such that the needle protective device is in-line with the catheter hub and the valve actuating element.” As shown and described in connection with Figs. 1-11, Woehr ‘108 discloses positioning a needle protective device (e.g., element 120) at least partially inside the interior cavity of the catheter hub (e.g., element 26) such that the needle protective device is in-line with the catheter hub. (Ex. 1004, Woehr ‘108 at 5:15-24, 8:16-9:8, Fig. 10A (annotated below); see also *id.*, Figs. 1-11); Ex. 1002, Griffis Decl. at ¶¶73-78.).

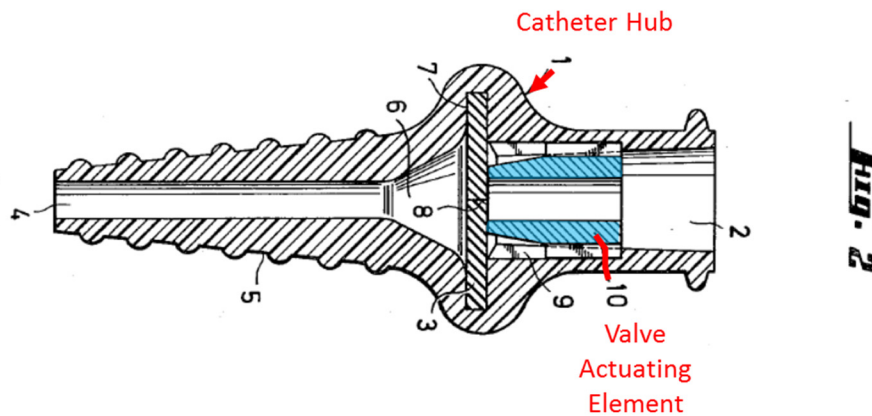
The function of the needle guard (e.g., “spring clip”) in Fig. 10A is to prevent accidental needle sticks. (*See., e.g.*, Ex. 1004, Woehr ‘108 at 8:53-62 (“When the needle is retracted axially within the catheter hub... the needle guard... forms[s] a barrier that prevents inadvertent contact with the 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 ‘762 patent specification described at Col. 2:29, 2:31-49, 3:13-25, 3:32-36, 3:65-4:5, and 4:35-

49. (Ex. 1002, Griffis Decl. at ¶¶41-50, 52, 52, 73-78.) Further, as described in Woehr '108, the spring clip needle guard 120 is the same structure with two spring arms that cover the needle tip to protect it. (*Compare, e.g.,* Ex. 1001, '762 patent at 2:31-39, Figs. 1 and 2 *with* Ex. 1004, Woehr '108 at 8:16-29, Figs. 10A and 10B (annotated below); Ex. 1002, Griffis Decl. ¶¶73-78.) Thus, Woehr '108 discloses the needle protective device claimed in the '762 patent.



As shown in in Fig. 10A of Woehr '108, the needle protective device is positioned inside and along the same axis as the catheter hub, and is therefore “at least partially inside the interior cavity of the catheter hub such that the needle protective device is in-line with the catheter hub.” (Ex. 1002, Decl. at ¶¶73-78.).

Like the needle protective device of Woehr '108, the valve actuating element of Tauschinski is in-line with the catheter hub of the instrument. As shown and described in connection with Figs. 2-3, Tauschinski discloses positioning a valve actuating element (e.g., element 10) in-line with the connector body (e.g., element 1). (Ex. 1005, Tauschinski at 3:47-50; *id.* at Figs. 2 (annotated below) and 3).

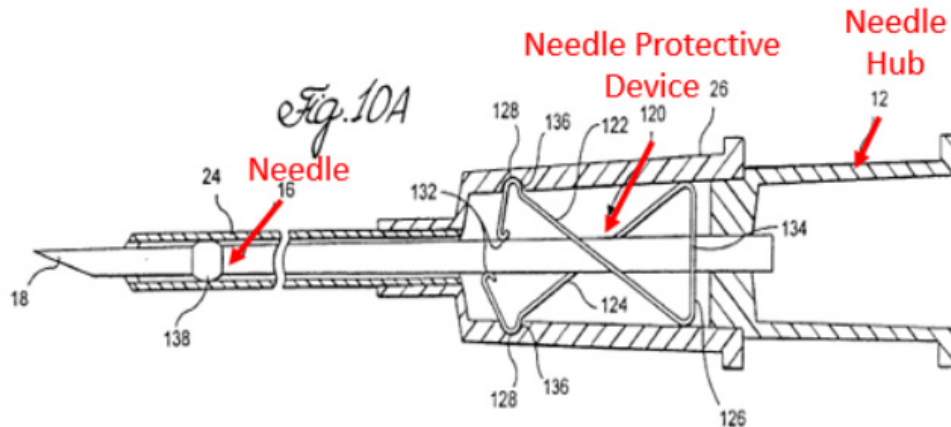


Thus, the combination of the valve actuator in Tauschinski with the spring clip safety IV catheter of Woehr '108 would result in a device with the needle protective device in line with the catheter hub and the valve actuating element. (Ex. 1002, Griffis Decl. ¶¶73-78.) A POSA would have understood that there are a finite number of ways to position a needle protective device and valve actuating element relative to a catheter hub in view of the well-recognized problem of mitigating blood outflow from a catheter insertion device and preventing

accidental needle pricks to health workers. Such a person would also have looked at references directed to a similar problem as the '762 patent, and have considered the solutions proposed in those references, such as Woehr '108 and Tauschinski and would have found positioning a needle protective device in-line with the catheter hub and the valve actuating element to be a predictable solution. (Ex. 1002, Griffis Decl. ¶¶73-78; *see also id.* at ¶38 (addressing the claimed valve having a slit.)

6. Element 18e. “positioning a needle hub....”

Woehr '108 discloses positioning a needle hub (e.g., element 12) having a needle (e.g., element 18) attached thereto proximally of the catheter hub (e.g., element 26) so that the needle projects through the catheter hub and the catheter tube (e.g., element 24). (*See, e.g.*, Ex. 1004, Woehr '108 at 4:8-18 (“The safety IV catheter of the invention, generally designated 10, in the embodiment illustrated in FIGS. 1A and 1B... [t]he needle hub 12, as is conventional, is hollow and includes a flash chamber 22. 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.”), Fig. 10A (annotated below); *see also id.* at Figs. 1C, 2A, 3A, 4A, 5A, 6A, 7A, 7B, 7C, 7D, 7E, 10A; Ex. 1002, Griffis Decl. ¶¶79-80.)



7. Element 18f. “wherein the valve remains inside...”

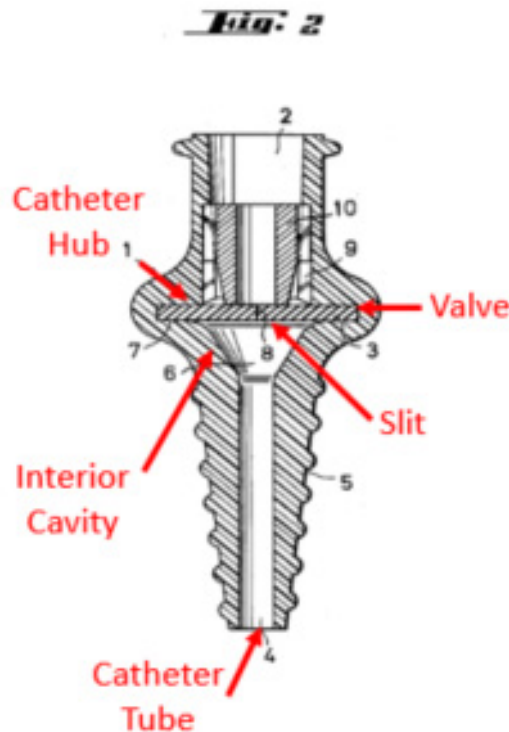
The combination of Woehr ‘108 and Tauschinski discloses a catheter insertion device wherein the valve (e.g., element 3) remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube (e.g., element 4) and the catheter hub (e.g., element 1). For example, Tauschinski describes the valve 3 and catheter tube 4 and the catheter hub 1 in connection with Figs. 2 and 3 as follows:

A plastic connector body shown, in FIG. 1 has at its entrance... . The connector body 1 is provided at its exit end with a cylindrical passage 4, which has a diameter that has been selected in view of the diameter of a cannula or catheter which can be inserted.

(Ex. 1005, Tauschinski at 3:4-11)

In consideration of the diameter, the thickness and the material of the disc, the length of the slit is selected so that metal cannulas and catheter hoses can properly be pushed through the slit and that a tight seal is ensured when such cannula or hose has been removed.

(*Id.* at 2:32-37; 3:20-32, *id.* at Figs. 2 (annotated below) and 3.)



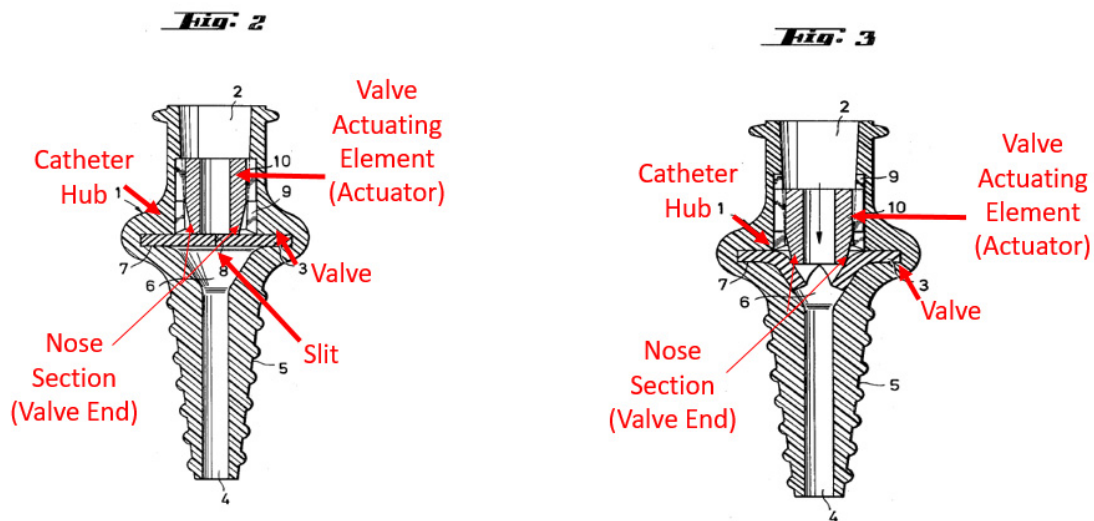
As described above in Section IX.A.3 (valve) and incorporated by reference here, it would have been obvious to a POSA to modify Woehr '108 to include a

valve in view of Tauschinski, and that valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub. A valve that fails to remain in the interior cavity of a catheter after removal of a needle would fail to prevent fluid flow through the device and out of the proximal end of the catheter. (Ex. 1002, Griffis Decl. ¶82.) A POSA would have therefore understood that positioning a valve inside a catheter hub such that the valve remains inside the hub upon removal of the needle from a catheter would be an immediately obvious solution to the problem of mitigating blood outflow from a catheter. A POSA would have understood that there are a finite number of ways to provide a valve configured in this way (such a valve that remains inside the interior cavity of the catheter hub), and would have found this to be a predictable solution.

B. Dependent Claim 22

Claim 22 depends from claim 18, and the analysis for claim 18 in Section IX.A is incorporated by reference. Further, the combination of Woehr '108 and Tauschinski discloses a catheter insertion device wherein the valve actuating element (e.g., element 10) is formed as a hollow cylinder with a truncated cone-shaped distal end section. Tauschinski discloses, “Alternatively, the cylindrical portion of the member 10 may be guided in a mating cylindrical bore. . . . The member 10 has a central through bore and has a square rear end face whereas its

forward end portion is frustoconical.” (Ex. 1005, Tauschinski at 3:25-29, claim 5; *see also* at 3:47-48 (describing the slidable member has having a “cylindrical outside surface”), Fig. 2 and 3 (annotated below); *see also id.* at Figs. 1; Ex. 1002, Griffis Decl. ¶¶84-87.)



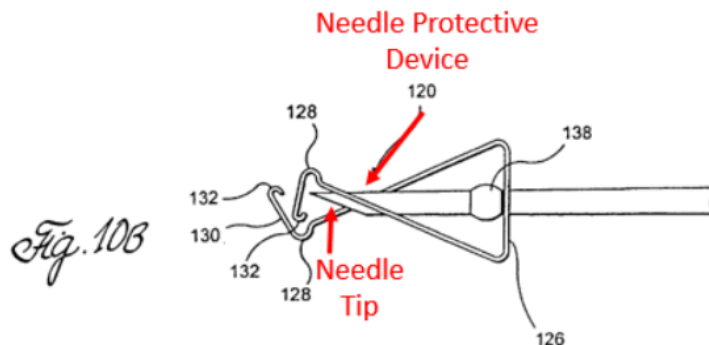
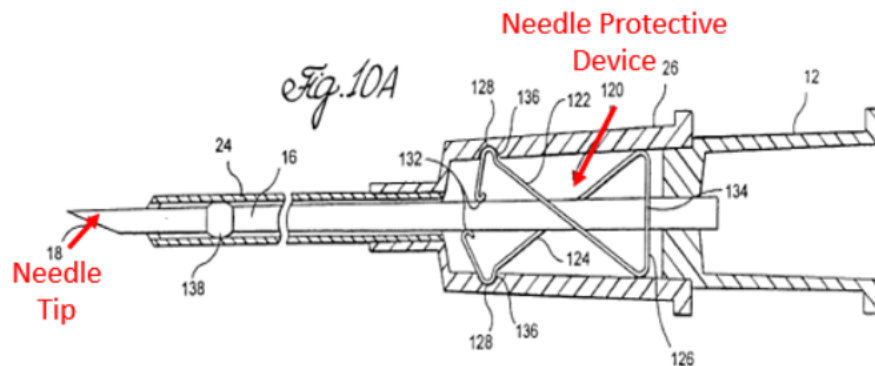
As described above in Section IX.A.4 and incorporated by reference, it would have been obvious to a POSA to modify Woehr ‘108 to include the valve actuating element described in Tauschinski.

C. Dependent Claim 25

Claim 25 depends from claim 18, and the analysis for claim 18 in Section IX.A is incorporated by reference. Further, Woehr ‘108 discloses a catheter insertion device comprising a needle protective device (e.g., elements 120) comprising a resilient portion made from a metallic material for moving the needle

protective device from a ready position to a protected position. Woehr '108

discloses, “the needle guard” is in the form of a spring clip “that is preferably made of a resilient metal such as stainless steel.” (Ex. 1004, Woehr '108 at 4:43-52), *see also* 8:17-9:13, Fig. 10A and 10B (annotated below); Ex. 1002, Griffis Decl. ¶¶88-91.) A POSA would understand that a stainless steel is a metallic material. (Ex. 1002, Griffis Decl. ¶89.)



X. Ground II: Claims 18 and 22 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. 1003). Van Heugten qualifies as prior art to the ’762 patent under 35 U.S.C. §102(b), and Van Heugten was cited on the face of the patent.

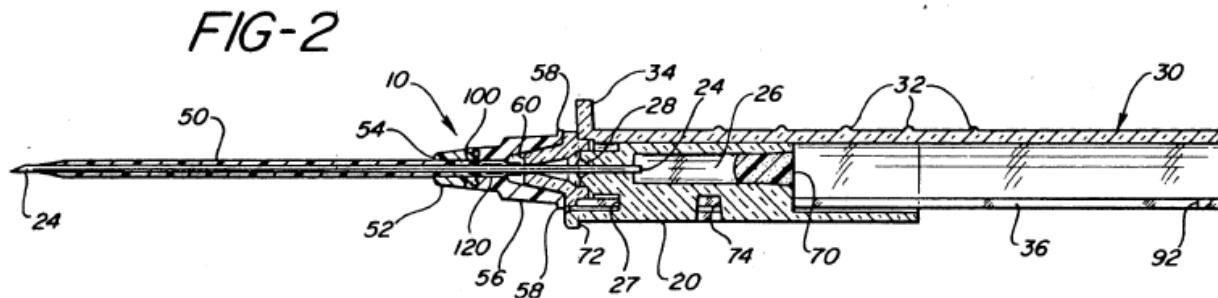
A. Independent Claim 18

1. Element 18p. “A method of manufacturing 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 Figs. 1-4, Van Heugten discloses a catheter insertion device (*e.g.*, element 10). (Ex. 1003, Van

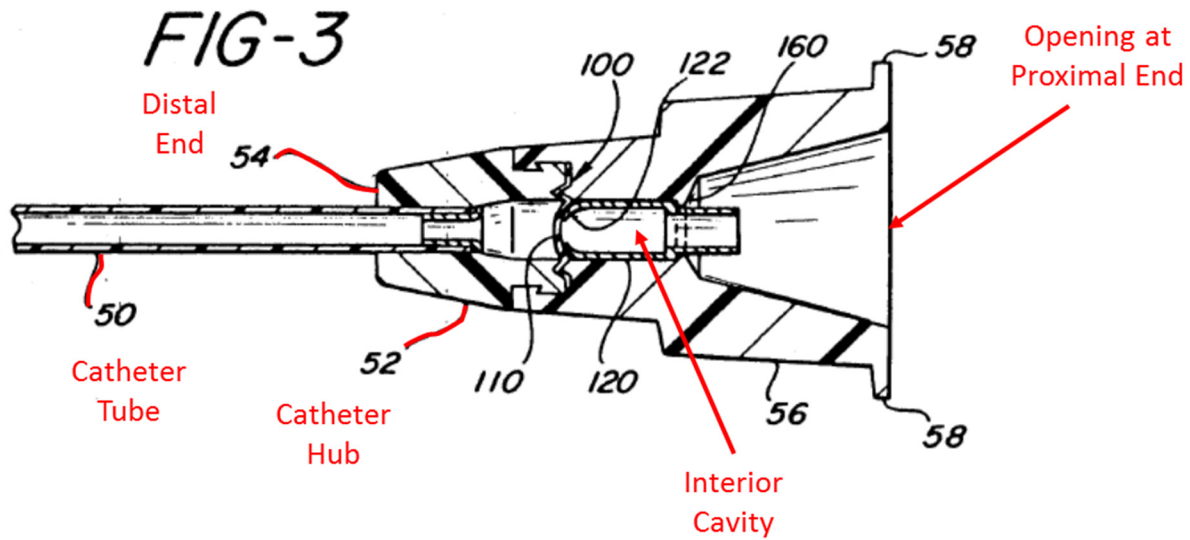
² Petitioner believes that “needle protective device” should be construed under 35 U.S.C. § 112, ¶6, and has presented Ground I to invalidate the challenged claims under that construction. Patent Owner disagrees with applying § 112, ¶6 in the concurrent litigation. If the Board agrees with Patent Owner 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.

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. ¶¶92-93.) The patent opens by stating, “This invention relates to I.V. catheters...” and refers to a catheter assembly 10 (Ex. 1003, Van Heugten at 1:4, 2:19.)



2. Element 18a. “forming a catheter hub...;”

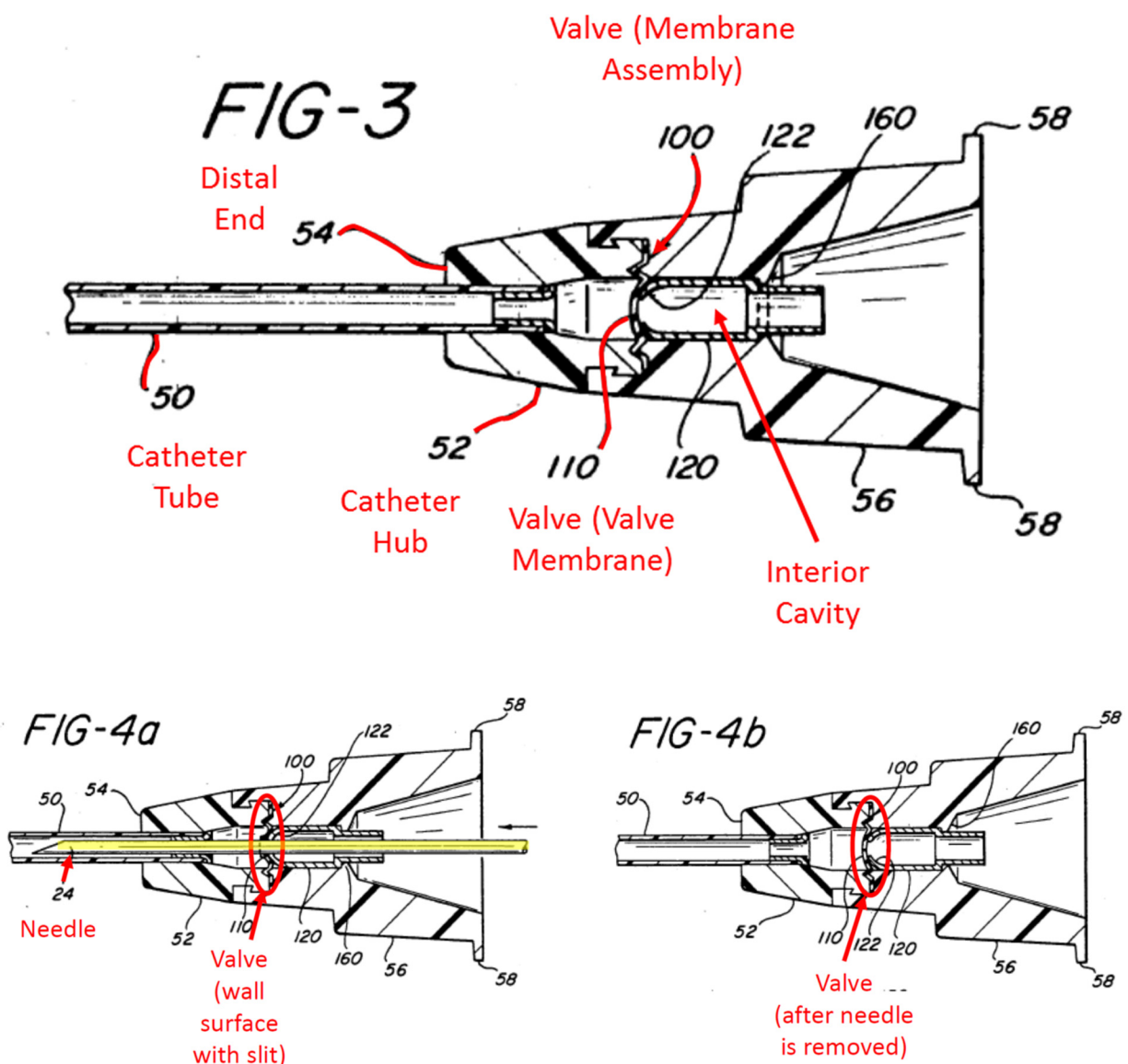
Van Heugten, in connection with Figs. 1-4, discloses forming a catheter hub (e.g., element 52) comprising a body comprising an interior cavity with an opening at a proximal end and attaching a catheter tube (e.g., element 50) thereto. (Ex. 1003, Van Heugten at 2:45-55, 2:6-15, Fig. 3 (annotated below); *see also id.* at Figs. 1-2, 4; Ex. 1002, Griffis Decl. at ¶94.) Van Heugten states, “The catheter 50 is seen to extend from the distal end 54 of the catheter hub 52 and is concentric therewith.” (Ex. 1003, Van Heugten at 2:46-48.)



3. Element 18b. “positioning a valve ...;”

As shown and described in connection with Figs. 1-4, Van Heugten discloses positioning a valve (e.g., elements 100, 110) in sealing communication with the interior cavity of the catheter hub (e.g., element 52) for regulating fluid flow through the interior cavity.

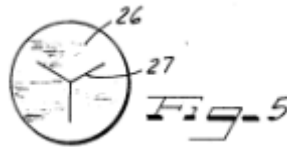
For example, Van Heugten describes the membrane assembly 100 and valve membrane 110 in connection with Figs. 3, 4a-4b. (Ex. 1003, Van Heugten at 3:59-4:3, 4:6-30, Figs. 3, 4a-4b (annotated below).)



(See also *id.* at 1:9-27, 1:28-32, 1:47-57, 2:6-15, Figs. 1, 2, 4, 5; Ex. 1002, Griffis Decl. ¶¶95-96.)

Van Heugten also describes that the valve membrane 110 can be configured in multiple ways. (Ex. 1002, Griffis Decl. ¶¶95-96.) In a first way, the valve is originally sealed, and upon insertion of a needle, the valve is punctured. (Ex. 1003, Van Heugten at 3:64-4:3). In a second way, the valve is configured as a

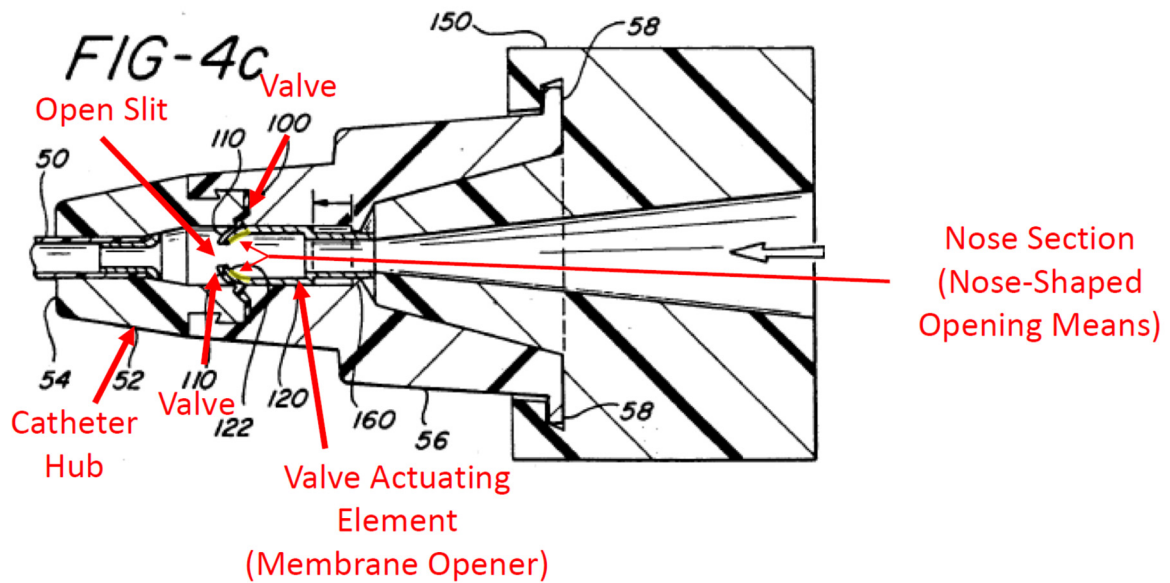
“duck-bill” valve or a valve of similar configuration. (*Id.* at 4:23-27.) In a third way, the valve is configured to have multiple slits. For example, Van Heugten explains the desirability of applying the valve principle of U.S. Patent No. 3,585,996 (“Reynolds”) to a catheter assembly. (Ex. 1003, Van 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. 1009, Reynolds at 2:56-60, Fig. 5 (shown below); Ex. 1002, Griffis Decl. ¶96.) Thus, a POSA would have understood Van Heugten to disclose the valve membrane 110 for regulating fluid flow through the interior cavity because the valves seal and then open to permit fluid flow. (Ex. 1002, Griffis Decl. ¶96)



4. Element 18c. “positioning a valve actuating element...;”

As shown and described in connection with Figs. 1-4, Van Heugten discloses positioning a valve actuating element (*e.g.*, element 120) in mechanical communication with the valve (*e.g.*, elements 110) for deflecting the valve to permit fluid flow through the interior cavity of the catheter hub (*e.g.*, element 52).

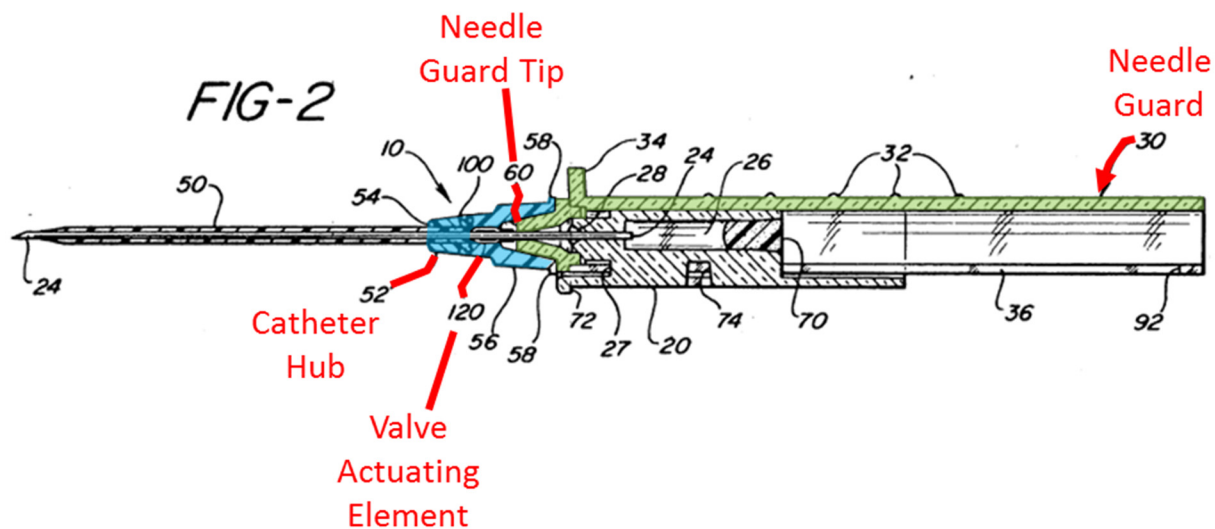
As shown and described in connection with Figs. 1-4, Van Heugten discloses a valve actuating element (*e.g.*, element 120) slidably disposed in the catheter hub (*e.g.*, element 52) configured to actuate the valve (*e.g.*, elements 110), the valve actuating element comprising a nose section having a tapered end (*e.g.*, element 122) for pushing the valve to open the slit of the valve; the valve actuating element is configured to transfer a distally directed force to the nose section to push the valve to open the slit. For example, Van Heugten describes the membrane opener 120 in connection with Fig. 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. 1003, Van Heugten at 4:31-36, *see also* 1:62-2:4; 4:31-36, 4:43-49, Fig. 3, Fig. 4c (annotated below), Ex. 1002, Griffis Decl. ¶¶97-98.) Van Heugten describes that a luer forces membrane opener 120 to open the valve membrane. (Ex. 1003, Van Heugten at 4:31-54; Ex. 1002, Griffis Decl. ¶¶97-98.)



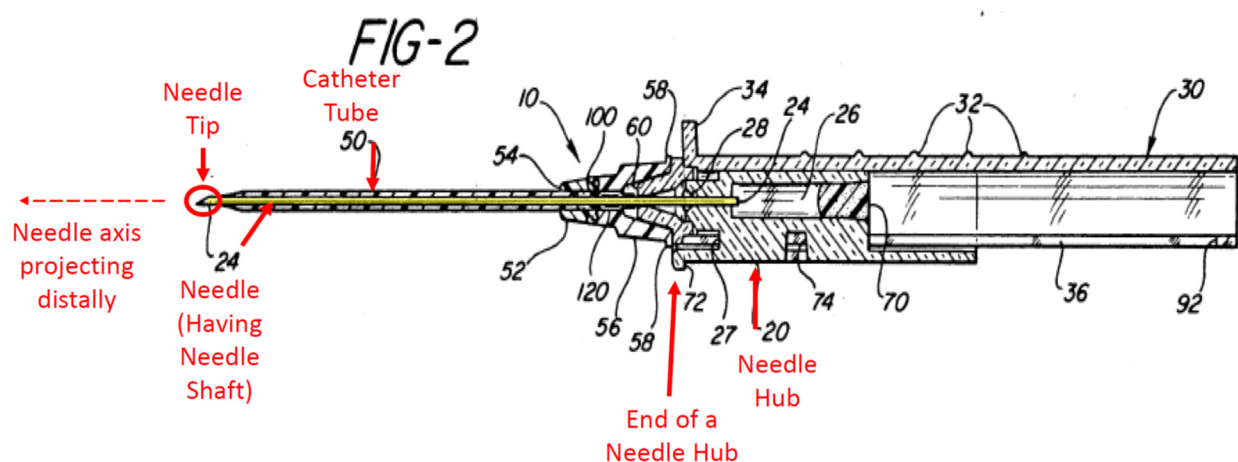
5. Element 18d. “positioning a needle protective device....”

As shown and described in connection with Figs. 1-3, Van Heugten discloses positioning a needle guard 30 with a needle guard tip 60 extending at least partially inside the interior cavity of the catheter hub (e.g., element 52) such that the needle protective device is in-line with the catheter hub and the valve actuating element (e.g., element 120). A person of ordinary skill in the art would understand that elements are in-line if they are oriented along the same axis. (Ex. 1002, Griffis Decl. ¶¶99.) In this case, the needle defines the axis and the catheter hub, actuator, and needle protection are all oriented along that axis. (*Id.*) The needle protective device of Van Heugten is at least partially inside the interior cavity of the catheter hub because the device is configured such that the “larger

diameter proximal portion [] of the catheter hub 52 is flanged at its proximal end for connection to an infusion set, and the inner diameter of the proximal portion of the hub is sized to fit over the distal portion of the needle guard tip 60.” (Ex. 1003, Van Heugten at 2:51-55). Moreover, the needle protective device of Van Heugten is in-line with the catheter hub 52 and the valve actuating element 120 because all of these elements are oriented along the same axis, which is the axis of the needle. (*Id.* at 2:36-44, 4:31-36, Figs. 1-4, *see also* Fig. 2 (annotated below), Ex. 1002, Griffis Decl. ¶99).



1, 2 (annotated below); *see also id.* at 1:64-68, 2:6-15, 2:45-50, Figs. 3-4; Ex. 1002, Griffis Decl. ¶100.) For example, Van Heugten describes Fig. 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. 1003, Van Heugten at 2:37-40.)

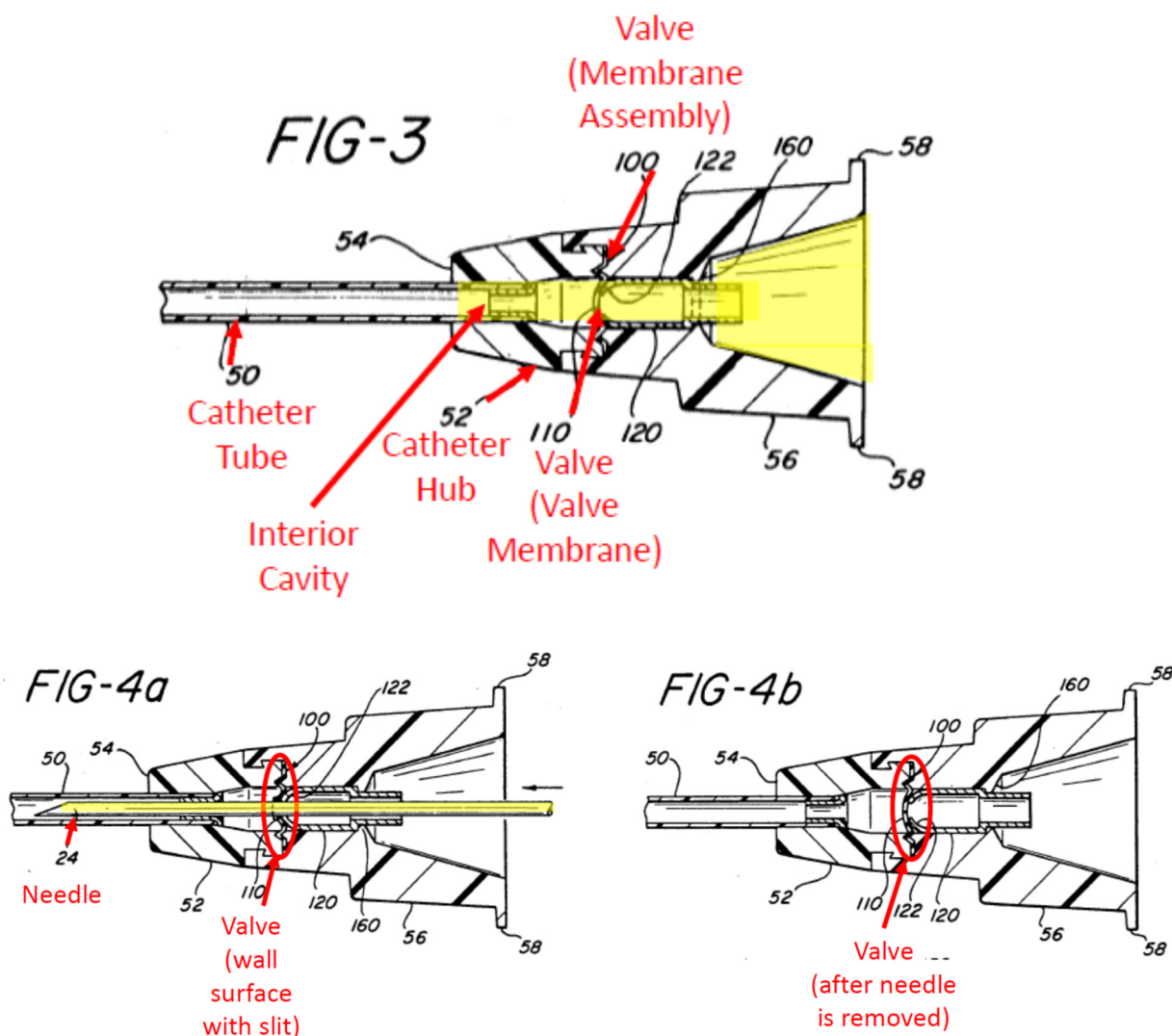


7. Element 18f. “wherein the valve remains inside...”

Van Heugten, in connection with Figs. 2-3, discloses a catheter insertion device wherein the valve (e.g., element 110) remains inside the interior cavity of the catheter hub (e.g., element 52) 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 Figs. 3, 4a-4b. (Ex. 1003, Van Heugten at 1:60-2:4, 3:59-4:3, 4:6-30, Figs. 3, 4a-4b (annotated below), Ex. 1002, Griffis Decl. ¶¶101-102). Van Heugten explains that when the needle is removed from the

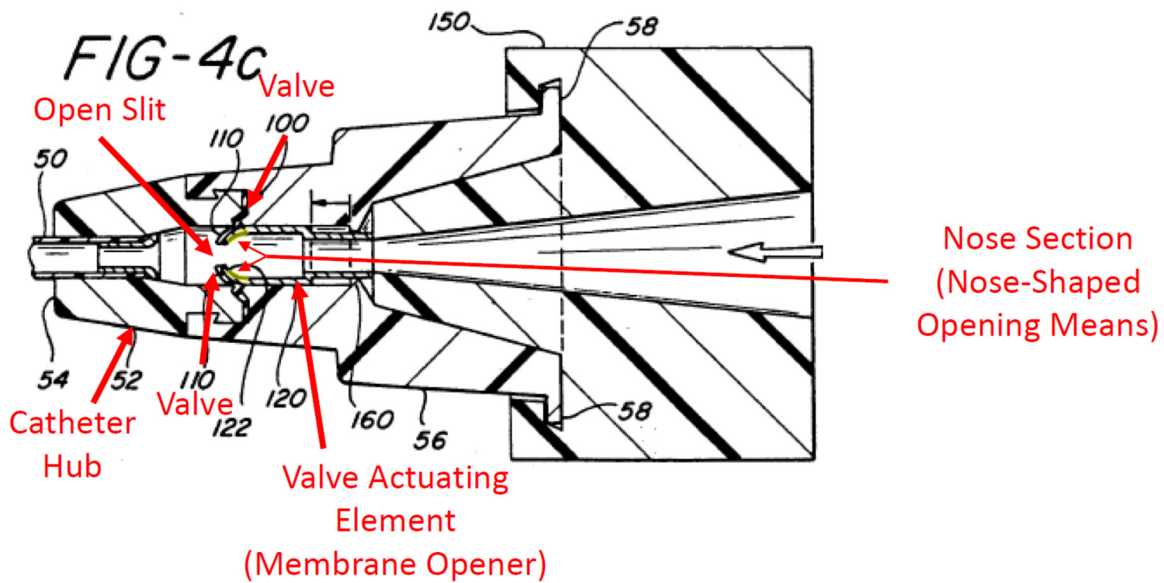
catheter hub 52, the valve closes. (Ex. 1003, Van Heugten at 4:6-9.) This provides a benefit because it prevents blood leakage. (*Id.* at 4:9-14.)



B. Dependent Claim 22

Claim 22 depends from claim 18, and the analysis for claim 18 in Section X(A) is incorporated by reference. Further, Van Heugten, in connection with Figs. 1-4, discloses a catheter insertion device wherein the valve actuating element (e.g.,

element 120) is formed as a hollow cylinder with a truncated cone-shaped distal end section (e.g., element 122). For example, Van Heugten describes the membrane opener having a truncated cone-shaped distal end section 120 in connection with Fig. 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. 1003, Van Heugten at 4:31-36, *see also* 1:62-2:4, 4:43-49, Fig. 4c (annotated below), Ex. 1002, Griffis Decl. ¶¶103-105). The valve actuator of Van Heugten is also configured such that fluids pass through the membrane opener after the nose shaped opening means of the membrane opener opens the valve. (*See, e.g.*, Ex. 1003, Van Heugten at 4:43-49 (“As luer assembly 150 is being attached to catheter hub 52, collar mechanism 160 holds membrane opener 120 in place so that nose-shaped opening means 122 of membrane opener 120 proceed to open valve membrane 110. This is best seen in FIG. 4e. Thus, when the valve membrane 110 is open, nutritional fluids are able to be disposed into the body.”).)



XI. Ground III: Claim 25 is Obvious over Van Heugten in view of Lynn

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 Van Heugten in view of International Patent Application PCT/US00/40638 to Lynn, “Luer Receiving Vascular Access System,” published as WO/01/12249 on Feb. 22, 2001 (“Lynn”) (Ex. 1010). (Ex. 1002, Griffis Decl. ¶¶106-122.) Both Van Heugten and Lynn qualify as prior art to the ’762 patent under 35 U.S.C. §102(b).

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. Lynn discloses a catheter assembly including a catheter, a catheter hub, a needle, a needle hub, a valve, and spring retracted needle protection into a needle receptacle.

A. Dependent Claim 25

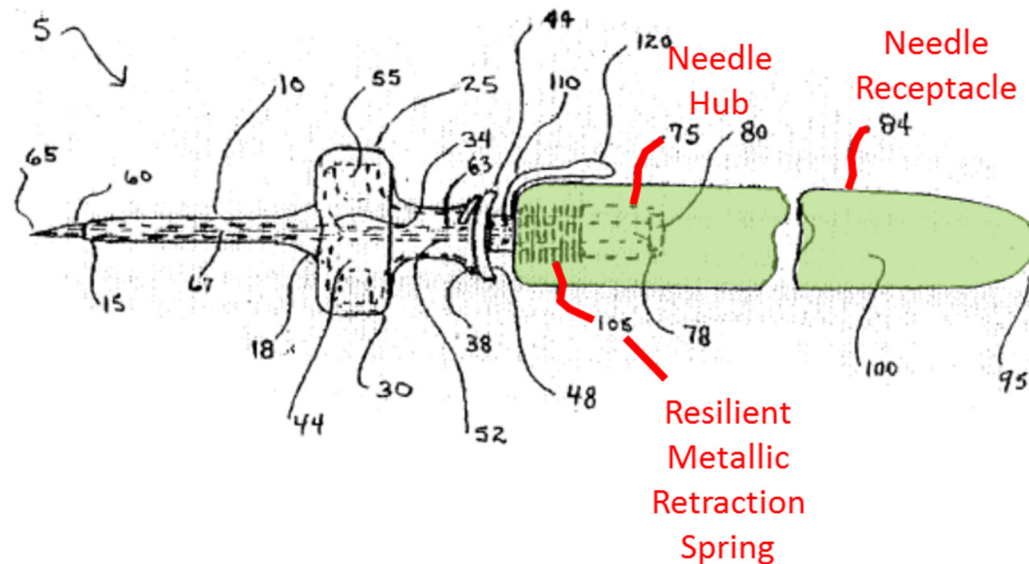
Claim 25 depends from claim 18. As described in Section X.A (Ground II, Claim 18) and incorporated by reference, claim 18 is obvious in view of Van Heugten. The combination of Van Heugten and Lynn renders obvious the method of claim 18, further comprising the limitation wherein “the needle protective device comprises a resilient portion made from a metallic material for moving the needle protective device from a ready position to a protected position.”

As shown as described in connection with, *inter alia*, Fig. 2, the needle protective device of Van Heugten prevents accidental needle sticks when the user of the device applies a linear force to encase the needle tip within the needle protective device described therein. (*See, e.g.*, Ex. 1003, Van Heugten at 3:26-58.)

This same principle is disclosed in Lynn, but is automated. In Lynn accidental needle pricks are prevented by similarly encasing the needle tip in a needle protective device derived from a spring/trigger system. More particularly, as shown and described in connection with Figs. 1-4, Lynn discloses a needle protective device (e.g., elements 75/84/105) comprising a resilient portion for moving the needle protective device from a ready position to a protected position. (*See, e.g.*, Ex. 1010, Lynn at p. 7 ln 15-28 (“The needle hub 75 is contained within a needle receptacle 84, which includes an enclosed proximal end 95 and defines a receptacle chamber 100 for receiving the retracted needle as will be discussed. The

receptacle 84 further contains a retraction spring 105 positioned adjacent the needle hub 75. The retraction spring 105 is held in its compressed position by a trigger retainer 110... The receptacle retainer and spring mechanism can be of the type marketed under the name ‘Autoguard’ by Becton Dickinson.”); *see also id.* at p. 8 ln 9-13, Fig. 1 (annotated below), 2, 3, and 4; Ex. 1002, Griffis Decl. ¶¶116-122.)

Fig. 1



It would have been obvious to a POSA to automate the device of Van Heugten to include a needle protective device comprising a spring (as in Lynn). (Ex. 1002, Decl. ¶121.) A POSA would understand that the needle protective device of Van Heugten could readily be modified to operate according to a

spring/trigger based mechanism to deliver the linear force necessary to encase the needle tip in the protective device rather than relying on force provided by the user. This would simplify actuation of the needle protection by allowing a clinician to activate the needle protection by pressing a button instead of sliding the sheath forward in Van Heugten. (Ex. 1002, Griffis Decl. ¶¶119-122.) As described in Lynn, the purpose of providing “an automatic retractor such as a spring adjacent the needle” is that “the needle can be automatically retracted out of the luer receiving valve hub.” (Ex. 1010, Lynn at p. 4 ln 26-28.) The advantage of automated retraction was well-recognized in the art. For example, US Pat. No. 5,755,709 to Cuppy (“Cuppy”) (Ex. 1011) states that safety needles that require “the operator to manually retract the needle all the way back until it locks into a protective guard” suffer from the disadvantage that “people forget to fully retract the needle into the locked position allowing the needle to slip out of safety tube and again risking a needle stick or puncture of [] the disposal receptacle.” (Ex. 1011, Cuppy at 2:52-58). Cuppy further warns that even where “[s]ome safety needle designs adequately protect the user from needle punctures” they nonetheless result in “residual blood [being] dispersed over the end of the safety guard[.]” (Ex. 1011, Cuppy at 2:58-62).

Lynn further specifies that “[t]he receptacle retainer and spring mechanism can be of the type marketed under the name "Autoguard" by Becton Dickinson.”

(Lynn at p. 7 ln 26-28.) The Autoguard system, which was widely available prior to 2002, protects against inadvertent needle sticks by retracting the needle into a safety barrel after the user presses a button to trigger a spring mechanism within the device. This spring based-system was known to provide “safer handling of a withdrawn needle without reducing its ease of insertion.” (Asai et al., *Anaesthesia*. 2002 Jun; 57(6):572-7 at Abstract, Fig. 2 (below)) (Ex. 1012).

A POSA would further understand that the “retraction spring” held in “a compressed position by a trigger retainer” would most readily be made from a metallic material. (Ex. 1002, Griffis Decl. ¶120.) A POSA would have therefore understood using the catheter assembly of Van Heugten and automating the needle guard to prevent accidental needle sticks as in Lynn would provide a known advantage and require a combination of known elements to function for their intended result. (*Id.*) A POSA would have understood that there are a finite number of ways to provide needle protective device configured in this way, and would have found this to be a predictable solution. (*Id.*)

XII. Ground IV: Claim 22 is Obvious over Van Heugten in view of Tauschinski

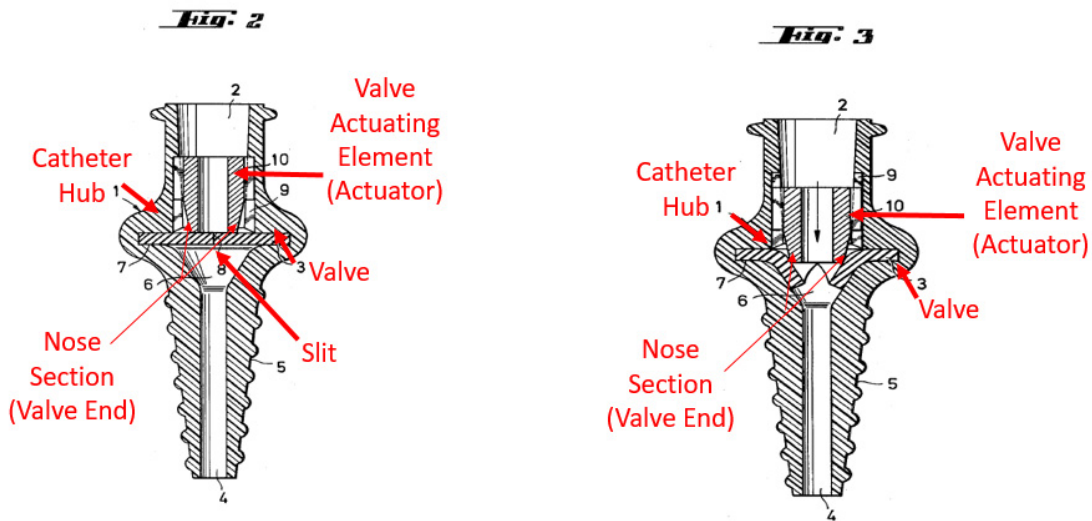
In the event that the Board determines that “needle protective device” should not be construed under 35 U.S.C. § 112, ¶6, then the Challenged Claims are obvious over Van Heugten in view of Tauschinski. (Ex. 1002, Griffis Decl. ¶¶123-

138.) Van Heugten and Tauschinski, qualify as prior art to the '762 patent under 35 U.S.C. §102(b), and are cited in 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. Tauschinski describes a well-known valve and valve actuator with a cone-shpaed nose portion that are used with catheters to prevent the emergence of blood.

A. Dependent Claim 22

Claim 22 depends from claim 18. As described in Section X.A (Ground II, Claim 18) and incorporated by reference, claim 18 is obvious in view of Van Heugten. Van Heugten, in connection with Figs. 1-4, discloses a catheter insertion device wherein the valve actuating element (e.g., element 120) is formed as a hollow cylinder with a truncated cone-shaped distal end section (e.g., element 122). Additionally, Tauschinski discloses an actuator that is cylindrical with a truncated cone-shaped distal end section. Tauschinski discloses, “Alternatively, the cylindrical portion of the member 10 may be guided in a mating cylindrical bore. . . . The member 10 has a central through bore and has a square rear end face whereas its forward end portion is frustoconical.” (Ex. 1005, Tauschinski at 3:25-29, claim 5; *see also* at 3:47-48 (describing the slidable member has having a “cylindrical outside surface”), Fig. 2 and 3 (annotated below); *see also id.* at, Fig. 1; Ex. 1002, Griffis Decl. ¶¶131-138.)



It would have been obvious to a POSA to modify Van Heugten to include the frustoconical distal end of the valve actuating element described in Tauschinski. Both Van Heugten and Tauschinski describe a valve and cylindrical actuator that is used with catheter devices. (Ex. 1002, Griffis Decl. at ¶X.) Both references disclose actuating a slit valve with the distal portion of the actuator, which is tapered. (*Id.*) A POSA would understand that having a truncated cone-shaped distal end section would facilitate entry of the actuator into the slit in the valve to actuate the valve. (*Id.*) A POSA would make modify the distal end of the membrane opener of Van Heugten because there are a limited number of design choices to ensure that the actuator penetrates the slit in the valve, and selecting a truncated, cone-shaped design is one of the known design options that would perform in a predictable way and achieve a known advantage of facilitating entry

into the slit to promote fluid flow. (*Id.*) Thus, claim 22 is obvious over of Van Heugten in view of Tauschinski.

XIII. 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).

XIV. Conclusion

Based on the foregoing, there is a reasonable likelihood that claims 18, 22, and 25 of the '762 patent are unpatentable as obvious. Petitioners request institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

By: /Heather M. Petruzzi/
Heather M. Petruzzi
Registration No. 71,270
Wilmer Cutler Pickering
Hale and Dorr LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006

Customer Number: 24395
Tel: (202) 663-6028
Facsimile: (202) 663-6363

*Counsel for Becton, Dickinson and
Company*

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 8,326 words, excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

/Heather M. Petruzzi/
Heather M. Petruzzi
Registration No. 71,270

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. 8,328,762
- Exhibits 1001-1028
- 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:

KLEIN, O'NEILL & SINGH, LLP
16755 VON KARMAN AVENUE
SUITE 275
IRVINE CA 92606

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

- Scott Bornstein; bornsteins@gtlaw.com
- Joshua Raskin; raskinj@gtlaw.com
- Julie Bookbinder; bookbinderj@gtlaw.com

/Natalie Pous/
Natalie Pous
Registration No. 62,191

Petitioners' Appendix of Exhibits

Pet'rs' Ex. No.	Description
1001.	U.S. Patent No. 8,328,762 (issued Dec. 11, 2012) (“the ’762 patent”)
1002.	Declaration of Mr. Griffis (“Griffis Decl.”)
1003.	U.S. Patent No. 5,053,014 to Van Heugten (issued Oct. 1, 1991) (“Van Heugten”)
1004.	U.S. Patent No. 6,117,108 to Woehr et al. (issued Sep. 12, 2000) (“Woehr ‘108”)
1005.	U.S. Patent No. 4,387,879 to Tauschinski (issued Jun. 14, 1983) (“Tauschinski”)
1006.	U.S. Patent Application No. 12/790,630 Prosecution History, Response of Nov. 4, 2011
1007.	Excerpts from Dr. Haindl, Australian Transcript (June 9, 2017) (“Australian Tr.”)
1008.	B. Braun Interventional Systems Inc., <i>Accel™ Valved Safety Centesis Catheter With Introcan Safety™ Technology</i> (2016) (“B.Braun Brochure”)
1009.	U.S. Patent No. 3,585,996 to Reynolds et al. (issued Jun. 22, 1971) (“Reynolds”)
1010.	WO Publication No. 2001/012249 to Lynn, published Feb. 22, 2001 (“Lynn”)
1011.	US Pat. No. 5,755,709 to Cuppy (issued May 26, 1998) (“Cuppy”)
1012.	Asai et al., <i>Efficacy of catheter needles with safeguard mechanism</i> , <i>Anaesthesia</i> , 57:572-577 (2002) (“Asai”)

Pet'rs' Ex. No.	Description
1013.	Intravenous Therapy Clinical Principles and Practices 317 (Judy Terry et al. eds., 1995) (“Terry”)
1014.	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”)
1015.	U.S. Patent No. 5,858,002 to Jesch (issued Jan. 12, 1999) (“the ’002 patent”)
1016.	U.S. Patent No. 4,850,961 to Wanderer et al. (issued Jul. 25, 1989) (“the ’961 patent”)
1017.	U.S. Publication No. 2001/0053895 to Vaillancourt, published Jan. 20, 2001 (“Vaillancourt”)
1018.	U.S. Patent No. 5,458,658 to Sircom (issued Oct. 17, 1995) (“Sircom”)
1019.	OSHA Bloodborne Pathogens Standard, 56 Fed. Reg. 64004 (Dec. 6, 1991) (“OSHA Standard”)
1020.	Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000) (“Needlestick Prevention Act”)
1021.	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”)
1022.	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”)
1023.	<i>Plumer’s Principles & Practice of Intravenous Therapy</i> , Ch. 11, 193 (7th ed. 2001) (“Plumer’s”)

Pet'rs' Ex. No.	Description
1024.	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”)
1025.	FDA, <i>Guidance for Industry and FDA Staff—Medical Devices with Sharps Injury Prevention Features</i> (Aug. 9, 2005) (“FDA Guidance”)
1026.	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”)
1027.	<i>Resilient</i> , The New Oxford American Dictionary, 1441 (2005) (“resilience Stedman’s”)
1028.	U.S. Patent No. 5,817,069 to Arnett (issued Oct. 6, 1998) (“Arnett”)