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. 9,370,641 to Woehr et al.

IPR Trial No. IPR2017-01590

PETITION FOR INTER PARTES REVIEW OF CLAIMS 15, 17, 18, 20, 22 OF U.S. PATENT NO. 9,370,641 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

Table of Contents

Table of Authorities

Page(s)

Cases

Statutes

Rules

Regulations

I. Introduction

Petitioner requests institution of an *inter partes* review to cancel claims 15, 17, 18, 20, and 22 ("Challenged Claims") of U.S. Patent No. 9,370,641 ("the '641 patent"). For the reasons set forth below, there is a reasonable likelihood that the Challenged Claims are unpatentable as obvious over (1) Woehr in view of Callaway (Ground I), and (2) Woehr in view of Villa (Ground II).

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.). Additionally, IPRs are being filed on U.S. Patent Nos. 8,328,762; 8,333,735; 8,337,463; 8,540,728; 9,149,626; 8,460,247; and 8,597,249.

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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 claims 15, 17, 18, 20, 22 of the '641 patent as unpatentable under 35 U.S.C. § 103 based on the following grounds.

Ground	35 U.S.C. §	Claims	References
I	103	15, 17, 18, 20, 22	Woehr in view of Callaway
II	103	15, 17, 18, 20, 22	Woehr in view of Villa

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 '641 Patent

A. The State of the Art

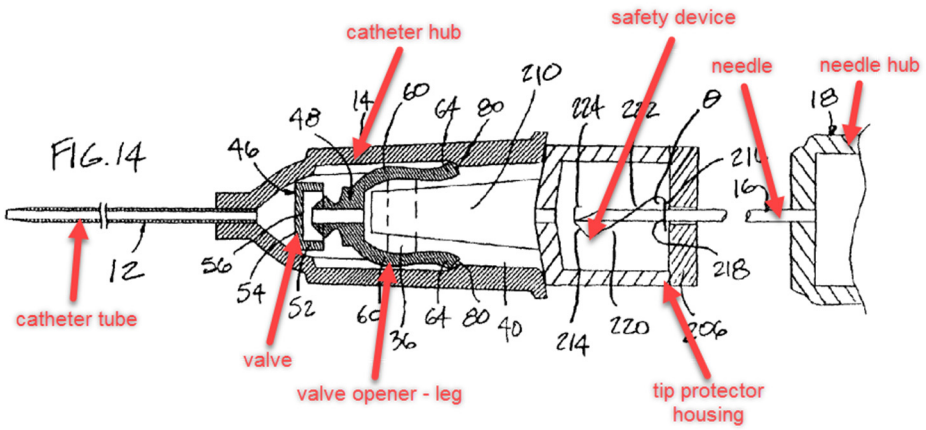
The '641 patent concerns a particular design for a catheter assembly. (Ex. 1002, Griffis Decl. ¶ 31). The term intravenous catheter is commonly used to describe the combination of a small gauge needle with a sharp tip used in combination with a plastic fitted tube to gain access to the vasculature and to withdraw or administer fluids. (Ex. 1002, Griffis Decl. ¶ 31). Modern IV catheters have been in use since the 1950s when first introduced by Dr. David Massa at the Mayo Clinic. (Ex. 1002, Griffis Decl. ¶ 31).

Since their introduction, IV catheters have undergone evolutionary changes. (Ex. 1002, Griffis Decl. ¶ 32). In the 1970s, improvements were primarily focused on catheter tubing materials making them softer, more flexible and less traumatic to the vessels during insertion. (Ex. 1002, Griffis Decl. ¶ 32).

Since well before 2006, catheter assemblies incorporated blood control features such as valves and flash-back chambers. (Ex. 1002, Griffis Decl. ¶ 33). Catheter assemblies also incorporated safety features intended to reduce the risk of accidental needle sticks since well before 2006. (Ex. 1002, Griffis Decl. ¶¶ 33, 34). These improvements in ease of use and safety have also been driven by the move from a doctor-dominated to a nurse-dominated use environment. (Ex. 1002, Griffis Decl. ¶ 33).

B. Brief Description of the '641 Patent

The '641 patent was filed as a patent application on October 24, 2013, and claims priority to a U.S. patent application filed on November 3, 2006. (Ex. 1001). The '641 patent describes an over-the-needle catheter insertion device. (Ex. 1002, Griffis Decl. ¶¶ 35, 36). Figure 14, reproduced below, demonstrates the various claimed features of the catheter assembly, as annotated below. (Ex. 1002, Griffis Decl. ¶ 35).



The ’641 patent identifies three objectives for the disclosed catheter assembly. (Ex. 1002, Griffis Decl. ¶ 36). Ideally, the disclosed catheter should: (1) cover the tip of the needle immediately following use, (2) include a valve to minimize blood exposure following successful catheterization, and (3) incorporate a means for wiping the needle of the deposited blood on the needle as it is withdrawn from the catheter hub. (Ex. 1001, ’641 patent at 1:57-67; Ex. 1002, Griffis Decl. ¶ 38). The devices covered in the challenged claims only accomplish the first two objectives, both of which were known in the art. (Ex. 1002, Griffis Decl. ¶¶ 38, 39).

In order to prevent accidental needle sticks, the ’641 patent discloses a number of tip protectors. (Ex. 1002, Griffis Decl. ¶ 40). Each of the disclosed tip protectors has at least one arm that covers the tip of the needle automatically as it is withdrawn. (Ex. 1002, Griffis Decl. ¶ 40). The ’641 patent also discloses embodiments having a third housing that accommodates the tip protector. (Ex. 1001, ’641 patent at 11:26-29). All of the challenged claims have this feature. (Ex. 1001; Ex. 1002, Griffis Decl. ¶ 411).

Blood control is accomplished by a 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, ’641 patent at 6:3-6:30, 7:13-45, 11:19-20, 11:65-12:10; Ex. 1002, Griffis Decl. ¶ 42). The disclosed valve

is formed from a thermoplastic elastomer that has a plurality of slits. (Ex. 1001, '641 patent at 6:3-8; Ex. 1002, Griffis Decl. ¶ 43). The '641 patent states that the valve closes to form a seal when it is no longer deflected by the needle. (Ex. 1001, '641 patent at 7:13-15; Ex. 1002, Griffis Decl. ¶ 43). Alternatively, the valve can provide a semi-permeable seal, allowing a slow flow of fluid. (Ex. 1001, '641 patent at 7:23-27; Ex. 1002, Griffis Decl. ¶ 43). The specification states that these features provide more time for a health care worker to connect an IV set to the catheter hub. (Ex. 1001, '641 patent at 7:19-27; Ex. 1002, Griffis Decl. ¶ 43).

The specification also discloses a valve opener that has an actuating end with a frusto-conical shape which pushes against the valve to open the valve and allow fluid flow. (Ex. 1001, '641 patent at 6:22-26, 7:40-44; Ex. 1002, Griffis Decl. ¶ 44). The valve opener has a pair of legs that are pushed forward when an IV-set Luer connector pushes into the opening of the catheter hub. (Ex. 1001, '641 patent at 7:40-44). The legs then move the actuating end distally to open the valve. (Ex. 1001, *id*. at 7:44-47).

All of these elements were known as of 2006, alone and in combination. (Ex. 1002, Griffis Decl. ¶¶ 36, 37, 45). The '641 patent acknowledges that catheter assemblies having tip protectors were known by incorporating by reference a number of tip protectors shown in prior art publications. (Ex. 1001, '641 patent at 6:61-7:12; Ex. 1002, Griffis Decl. ¶ 45). Indeed, catheters having many different

tip protector designs to prevent accidental needle sticks and/or to minimize blood exposure risks were well known as of 2006. (Ex. 1002, Griffis Decl. ¶¶ 46-47). Catheters having additional hubs or housing structures to house different tip protector designs were also known. (Ex. 1002, Griffis Decl. ¶ 48).

By 2006, including valves and valve openers in catheter assemblies to prevent blood leakage from a catheter hub after a needle is withdrawn was a well-known idea. (Ex. 1002, Griffis Decl. ¶¶ 33, 47). The '641 patent states that the valve used in the disclosed catheter assembly "is widely commercially available and is a well known component in the relevant art." (Ex. 1001, '641 patent at 6:8-10; Ex. 1002, Griffis Decl. ¶ 49).

All of the above elements, with the possible exception of a third housing that accommodates a tip protector, were disclosed in a 2004 publication of a PCT patent application by one of the named inventors of the '641 patent, Kevin Woehr. (Ex. 1003; Ex. 1005; Ex. 1002, Griffis Decl. ¶ 50). Third housings to accommodate tip protectors are disclosed by the other two references relied on in this petition. (Ex. 1004, Callaway; Ex. 1006, Villa; Ex. 1002, Griffis Decl. ¶ 51). A person skilled in the art would have been motivated to add a tip protector housing to the design disclosed in the Woehr 2004 PCT application to provide additional security for the tip protector so the tip protector can more securely prevent accidental needle sticks and/or to further minimize blood exposure risks by

preventing exposure to any fluids remaining on the needle after it is removed. (Ex. 1002, Griffis Decl. ¶ 51). For example, U.S. Pub. No. 2007/0038186 to Sutton ("Sutton"), discloses that a "shroud" that "substantially encloses the needle guard" provides the benefit of "reduc[ing] the likelihood of inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub." (Ex 1014, Sutton at [0011]; Ex. 1002, Griffis Decl. ¶ 51).

C. Summary of the '641 Patent's Prosecution History

A U.S. family member of the Woehr reference, Application No. 13/451,406, issued as Patent No. 8,333,735, (Ex. 1013) was cited as the basis for a nonstatutory obviousness type double patenting during prosecution of a parent application to the '641 patent. The patentee traversed this rejection by arguing that the '406 application "does not disclose any analogous third hub or housing of the claimed catheter assembly." (U.S. Patent Application No. 13/407,395 Prosecution History, Response dated February 7, 2013) (Ex. 1008).

All of the Grounds in this petition include the Woehr reference in new combinations with references that disclose a tip protector in a third hub of a catheter assembly, and they are supported by new evidence, including the expert testimony of Jack Griffis (Ex. 1002).

VI. Person of Ordinary Skill in the Art

A POSA in 2006 would have been either (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. ¶ 30).

VII. Claim Construction

A. "safety device"[1]

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,

[1] In litigation between Braun and BD, Braun has taken the position that "safety device" is not governed by 35 U.S.C. § 112 because the requirement of a "tip protector housing" provides sufficient structure to perform the claimed function. Because this construction is broader than the means-plus-function construction advanced in this petition and because the prior art cited in this petition discloses tip protectors identical to the tip protector disclosed in the '641 patent, the "safety device" limitation is met under any construction of the claims.

IPR2016–01824, Paper 42 (Final Decision) at *4 (Dec. 27, 2016) ("adjustable connector" construed as a means-plus-function term); *Adlens USA, Inc. v. Superfocus Holdings LLC*, 2016 WL 7992256, IPR2015-01821, Paper 38 (Final Decision) at *4 (Dec. 27, 2016) ("adjustable element" and "controllable spacing member" construed as means-plus-function terms); *Verizon Servs. Corp. v. AIP Acquisitions LLC*, 2015 WL 9899021, IPR2015-01106, Paper 10 (Institution of Inter Partes Review) at *10 (Oct. 15, 2015) ("checking device" and "identifying device" construed as means-plus-function terms); *Apple Inc. v. Immersion Corp.*, 2017 WL 376909, IPR2016-01372, Paper 7 (Institution of *Inter Partes* Review) at *6 (Jan. 11, 2017) ("drive module" construed as a means-plus-function-term).

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); *see also Adlens,* 2016 WL 7992256, at *4; *Willis Elec. Co.. v. Polygroup Macau Ltd. (BVI)*, IPR2017-00330, at 5-6 (May 25, 2017). 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 15, 17, 18, 20, and 22 recite a "safety device for covering the needle tip comprising a tip protector housing having a housing section positioned

proximally of a proximal end of the catheter hub." 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 "safety device" is not used, nor is it defined, in the specification of the '641 patent, nor is there extrinsic evidence demonstrating that the term connotes sufficient structure. (Ex. 1002, Griffis Decl. ¶¶ 53-56).

The Board may also look to the modifiers of a nonce term to see if they impart structure. *Id*. 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."); *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1214 (Fed. Cir. 1998) (affirming the term "lever moving element" did not have a generally understood structural meaning in the art).

Here, the modifier "safety" does not impart any structure to the term "device." (Ex. 1002, Griffis Decl. ¶¶ 53-56). At most, it adds detail to the function that the device must perform – preventing accident needle sticks by

protecting a needle. The phrase "safety 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. ¶¶ 54-56; *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1359-60 (Fed. Cir. 2004).

The further requirement of the claims that the safety device have a "tip protector housing" does not remove them from the requirements of 35 U.S.C. § 112. (Ex. 1002, Griffis Decl. ¶¶ 57-62). In order to avoid 35 U.S.C. § 112, the claim must recite structure sufficient to perform the claimed function. *Williamson,* 792 F.3d at 1348, 115 USPQ2d 1105, 1111 (Fed. Cir. 2015) (*en banc*) (quoting *Watts v. XL Systems, Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)); *see also Samsung Elecs. Co. v. IBEX PT Holding Co.*, 2017 WL 142348, IPR2017-00101, at *3 (Apr. 20, 2017). The function which is recited in the claims, is "covering the needle tip." (Ex. 1002, Griffis Decl. ¶ 66.) The only structures in the specification described as "covering the needle tip" are the tip protectors themselves, not the tip protector housing, which is variously described in the specification as "accommodating" or "surrounding" the tip protector. (Ex. 1001, '641 patent at 6:61-7:3, and 7:65-8:11, *also see*, claims 19, 20, 26, and 28; Ex. 1002, Griffis Decl. ¶¶ 58-62).

Further, without a tip protector, there is no disclosure of how the tip protector would function even to surround the needle tip – the needle would simply be withdrawn from the catheter assembly in an uncovered state. (Ex. 1002, Griffis Decl. ¶¶ 58-62); *cf. McKesson Automation, Inc. v. Swisslog Italia S.P.A.*, 712 F. Supp. 2d 283, 290, 300-01 (D. Del. 2010) (finding that the housing in the claim limitation "picking means for picking packages . . . having a housing" did not perform the stated function and instead enabled the structure that did perform the claimed function, the picking means, to do so); *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 552 F. Supp. 2d 810, 815-16 (N.D. Ill. 2008) (finding that housing in which the spring that performed the claimed function of "holding [a] screen" resided was not part of the means and simply provided an environment for function to be performed).

Claim 20, unlike the other claims at issue, also recites "a resilient portion made from a metal material and the tip protector housing surrounding the resilient portion." Likewise, the requirement that the safety device also include a "resilient portion made from a metal" does not provide any structural limitation which serves to cover the needle tip. It simply defines the physical characteristics of some undefined portion of the safety device. (Ex. 1002, Griffis Decl. ¶ 63). Thus, the additional structure in the claims, while further defining the safety device, does not perform the claimed function.

The term "safety device" is therefore a means-plus-function term. (Ex. 1002, Griffis Decl. ¶ 64). And to the extent the Board finds the "resilient portion" limitation relevant to the issue of whether "safety device" is a means-plus-function term, the "resilient portion" limitation is not present in claims 15, 17, 18, and 22 and, accordingly, the term "safety device" in those claims is a means-plus-function term. *See Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1313 (Fed. Cir. 2001).

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

- '641 patent at Figs. 3, 6, 7, 8C, 9D, 13, 14; *id*. at 2:31-38, 2:52-54, 5:58-6:2, 6:57-64, 7:65-8:11, 10:13-15, 11:23-24, 11:65-12:10, incorporating by reference spring clips disclosed in U.S. Patent No. 6,616,630 (Ex. 1007) at Figs. 1-17, 21, 22; *id*. at 2:47-49, 3:19-20, 3:46-55, 5:54-6:9, 6:27-41, 7:9-13, 7:16-56, 8:23-36, 8:61-9:3, 9:23-35, 9:61-10:4, 10:17-36, 10:58-11:2, 12:20-24;

- '641 patent at 6:64-7:3, 7:65-67, incorporating by reference tip protectors disclosed in U.S. Appl. No. 11/496,769[2] at Figs. 1A, 1B, 2-15; "tip protector," *passim*;
- '641 patent at 7:6-12, incorporating by reference tip protectors with an opening that cants over to grip the needle as disclosed in U.S. Patent No. 6,709,419 (Ex. 1010), U.S. Appl. No. 10/677,810,[3] and U.S. Appl. No. 10/54,041[4] at: Ex. 1010, '419 patent at Figs. 1-5; *id*. at 1:19-28, 1:43-58, 2:41-47, 3:12-30; U.S. Pub. No. 2005/0075609 (Ex. 1011), Figs. 1-8, "needle clip," *passim*; Ex. 1012, '476 patent at Figs. 1-10, *id*. at 1:37-62, 2:54-65, 3:3-11, 3:24-46, 3:57-63, 3:66-4:4, 4:63-5:3, 5:21-6:38, 7:1-8,
- and structural equivalents thereof. (Ex. 1002, Griffis Decl. ¶ 67).

[2] U.S. Appl. No. 11/496,769 issued as U.S. Patent No. 8,382,718 (Ex. 1009), which is cited throughout this document.

[3] U.S. Appl. No. 10/677,810 published as U.S. Publication No. 2005/0075609 (Ex. 1011), which is cited throughout this document.

[4] U.S. Appl. No. 10/954,041 issued as U.S. Patent No. 7,651,476 (Ex. 1012), which is cited throughout this document.

VIII. Ground I: The Challenged Claims Are Obvious over Woehr in View of Callaway.

The Challenged Claims are obvious over WO 2004/004819 to Kevin Woehr et al., "Catheter Insertion Device," published January 15, 2004 ("Woehr") (Ex. 1003)[5] in view of U.S. Pub. No. 2006/0178635 to Callaway, "Easy Entry Catheters," published on August 10, 2006 ("Callaway") (Ex. 1004). Woehr qualifies as prior art to the '641 patent under 35 U.S.C. § 102(b), and is cited on the face of the patent. Callaway qualifies as prior art to the '641 patent under 35 U.S.C. §§ 102(a) and 102(e), and is not cited on the face of the patent.

Woehr discloses a catheter insertion device that has a needle protective device in the form of a spring clip, and a valve that stops fluid from flowing out of the catheter hub after the needle is removed. (Ex. 1005, Woehr at Abstract; Ex. 1002, Griffis Decl. ¶ 70). The disclosed catheter insertion device also has a valve actuator that opens the valve to allow fluid flow when a syringe or other male implement is inserted into the catheter hub. (Ex. 1005, Woehr at 3; Ex. 1002, Griffis Decl. ¶ 70).

[5] All citations to Woehr are to the certified translation (Ex. 1005). The original German document is also provided as Ex. 1003. U.S. Patent No. 8,333,735 is also provided as Ex. 1013.

Callaway discloses a catheter insertion device designed for easy insertion. (Ex. 1004, Callaway at Abstract; Ex. 1002, Griffis Decl. ¶ 72). The device disclosed in Callaway has three hubs: a proximal needle hu, a middle hub, and a distal catheter hub. (Ex. 1004, Callaway at [0053]; Ex. 1002, Griffis Decl. ¶ 72). Callaway discloses an embodiment where a needle safety device in the form of a spring clip is placed in the middle hub. (Ex. 1004, Callaway at [0061]; Ex. 1002, Griffis Decl. ¶ 72).

The challenged claims thus recite features long known by engineers who design IV catheters. (Ex. 1002, Griffis Decl. ¶ 75). The structures in the claimed catheter assembly all have known functions that perform in expected ways. (Ex. 1002, Griffis Decl. ¶ 75). 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. ¶ 75).

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Griffis Declaration (Ex. 1002) show in detail the prior art disclosures that makes the challenged claims obvious.

A. Independent Claim 15 Is Obvious over Woehr in View of Callaway

1. "A safety catheter assembly comprising"

To the extent the preamble is limiting, Woehr discloses "a safety catheter assembly." As shown and described in connection with Figures 1-3, 5, 8, 10, Woehr discloses a safety catheter assembly (e.g., element 1). (*See, e.g.*, Ex. 1005, Woehr at Abstract (describing a catheter insertion device that includes a needle protecting element in the form of a spring clip); Ex. 1005, Woehr at 1 ("The underlying object of the invention is to design a catheter insertion device of the type indicated at the beginning such that a blood discharge from the catheter after removing the hollow needle is prevented by the needle protecting element."); Ex. 1005,Woehr at 2 (describing the catheter insertion device 1 that has needle protection to provide safety); Ex. 1002, Griffis Decl. ¶ 76).

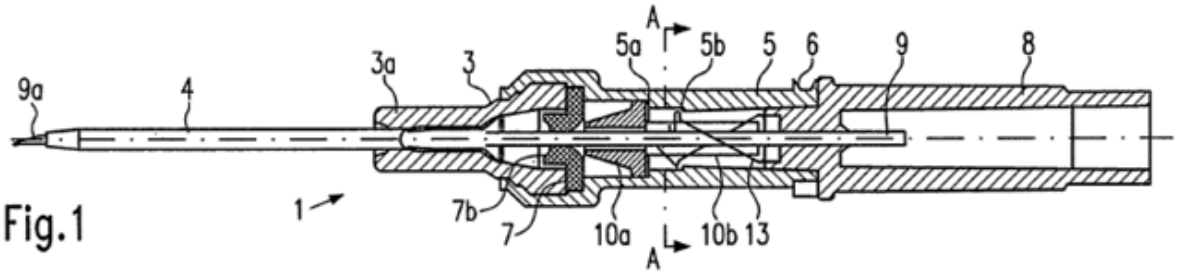
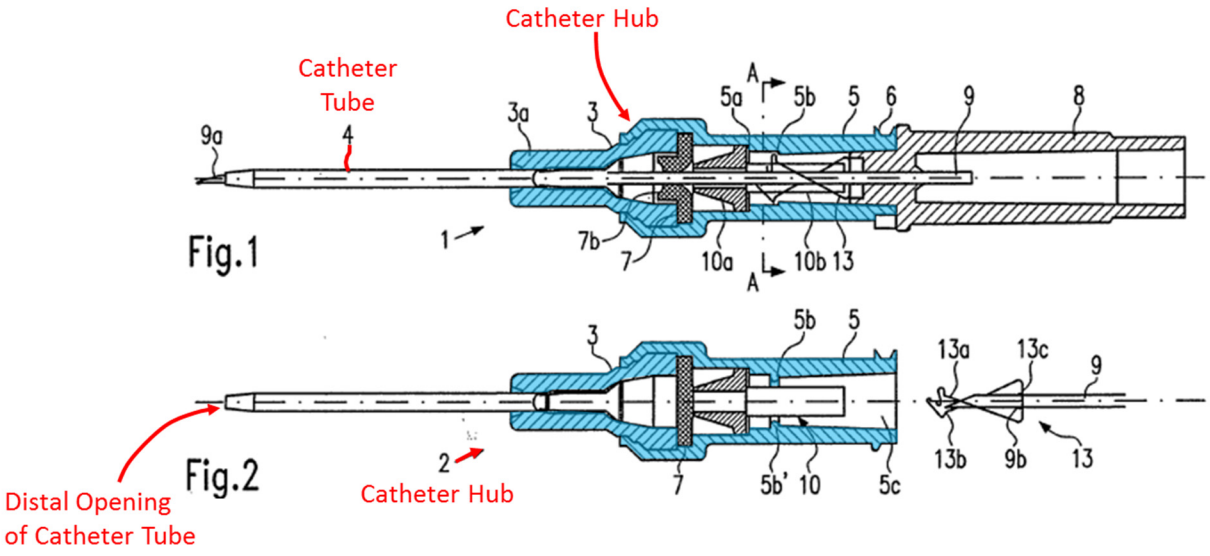


Fig.1

2. Element 15a. "a catheter hub comprising…"

Woehr discloses "a catheter hub comprising a housing comprising an exterior surface and an interior surface defining an interior cavity; said catheter hub having a catheter tube attached to a distal end of the catheter hub and the

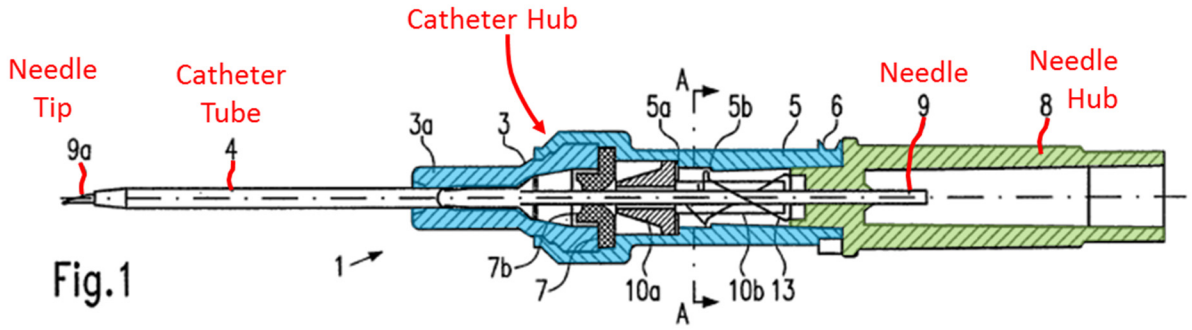
catheter tube comprising a distal opening." As shown and described in Figures 1-3, 5, 8, 10, Woehr discloses a catheter hub (e.g., element 2) comprising a housing comprising an exterior surface and an interior surface defining an interior cavity; said catheter hub (e.g., element 2) having a catheter tube (e.g., element 4) attached to a distal end (e.g., element 3a) of the catheter hub (e.g., element 2) and the catheter tube (e.g., element 4) comprising a distal opening. (*See, e.g.*, Ex. 1005, Woehr at Abstract ("The invention relates to a catheter insertion device comprising: an approximately hollow cylindrical catheter hub (2), at whose distal end a catheter (4) is attached"), Claim 1, Figs. 1-3). Woehr further discloses that catheter tube has a hole at its distal end. (Ex. 1005, Woehr at 3). For example, Woehr states, "In the ready-to-use position according to Figure 1, a needle hub 8 is inserted into catheter hub 2; a hollow needle 9, which extends through valve disk 7 and catheter 4, such that the needle point 9a is exposed, is fixed on the needle hub." (Ex. 1005, Woehr at 2; Ex. 1002, Griffis Decl. ¶ 77).



3. Element 15b. "a needle hub having a needle…"

Woehr discloses "a needle hub having a needle with a needle tip attached to the needle hub and projecting distally of the needle hub and into the catheter tube with the needle tip extending out the distal opening of the catheter tube." As shown and described in connection with Figures 1-3, 5, 8, and 10, Woehr discloses a needle hub (e.g., element 8) having a needle (e.g., element 9) with a needle tip (e.g., element 9a) attached to the needle hub (e.g., element 8) and projecting distally of the needle hub (e.g., element 8) and into the catheter tube (e.g., element 4) with the needle tip (e.g., element 9a) extending out the distal opening of the catheter tube (e.g., element 4). (*See, e.g.*, Ex. 1005, Woehr at Abstract ("a needle hub (8) with a hollow needle (9), which is attached thereto and which extends through the catheter hub (2) and the catheter (4) in the ready-to-use position"); Claim 1). For example, Woehr states, "In the ready-to-use position according to

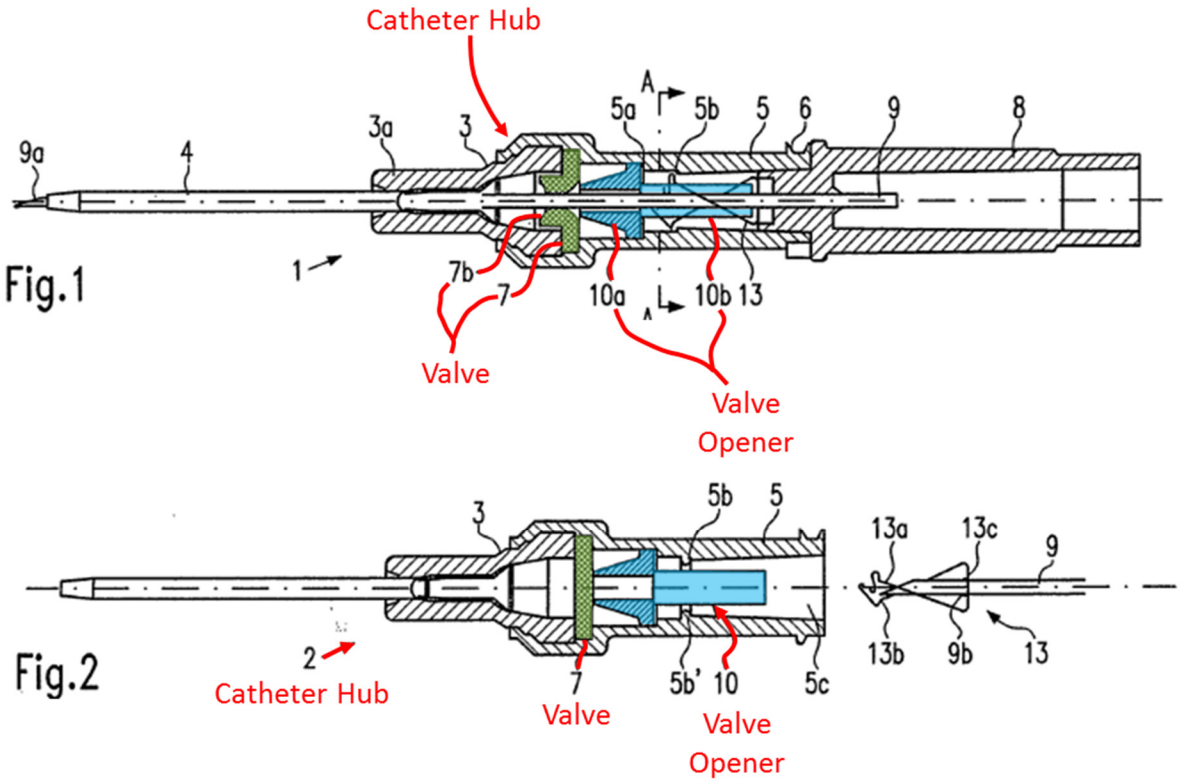
Figure 1, a needle hub 8 is inserted into catheter hub 2; a hollow needle 9, which extends through valve disk 7 and catheter 4, such that the needle point 9a is exposed, is fixed on the needle hub." (Ex. 1005, Woehr at 2; Ex. 1002, Griffis Decl. ¶ 78).



4. Element 15c. "a valve . . ."

Woehr discloses "a valve for limiting fluid flow and a valve opener in cooperative arrangement therewith positioned in the interior cavity of the catheter hub." As shown and described in connection with Figures 1-10, Woehr discloses a valve (e.g., element 7) for limiting fluid flow and a valve opener (e.g., element 10) in cooperative arrangement therewith positioned in the interior cavity of the catheter hub (e.g., element 2). (*See, e.g.*, Ex. 1005, Woehr at Abstract ("A check valve (7, 17) is arranged in the catheter hub (2) between the catheter (4) and the needle protecting element (13). The hollow needle (9) extends through said check valve in the ready-to-use position, and the check valve automatically closes when the needle is withdrawn."); *see also id.* at 1, 2, 3, 6, Claim 1). For example, Woehr

states, "[A] check valve, through which the hollow needle extends, is arranged in the catheter hub between the catheter and the needle protecting element in the ready-to-use position, and this check valve may be reliably closed after withdrawing the hollow needle from the catheter, such that a blood discharge is prevented." (Ex. 1005, Woehr at 1; Ex. 1002, Griffis Decl. ¶¶ 79, 80).



5. Element 15d. "a safety device . . ."

Woehr in combination with Callaway discloses "a safety device for covering the needle tip comprising a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub."[6]

A shown and described in connection with Figures 1, 2, 4, 5, 7, 8, and 10, Woehr discloses a safety device (e.g., element 13) for covering the needle tip (e.g., element 9a). (*See, e.g.*, Ex. 1005 Woehr at Figs. 1, 2, 4, 5, 7, 8, and 10, Abstract, 1-4, Claim 1, Claim 9). For example, Woehr discloses, "When hollow needle 9 is withdrawn from catheter hub 2, an engaging device 9b (Figure 2) in the form of a radial projection, which may be formed by a slight crimping and is provided in the vicinity of needle point 9a, engages with the outer circumference of a hole in the back wall 13c of spring clip 13 such that spring clip 13 is drawn out of the catheter hub with needle 9, while at the same time the spring arms 13a and 13b of the spring clip lie around the needle point and completely cover and block the same." (Ex. 1005, Woehr at 2; Ex. 1002, Griffis Decl. ¶¶ 82-84). The Woehr tip protector

[6] Because Woehr discloses tip protectors identical to the tip protector disclosed in the '249 patent, the "needle protective device" limitation is met under any construction of the claims.

is structurally the same as the claimed "safety device," interpreted pursuant to 35 U.S.C. § 112.

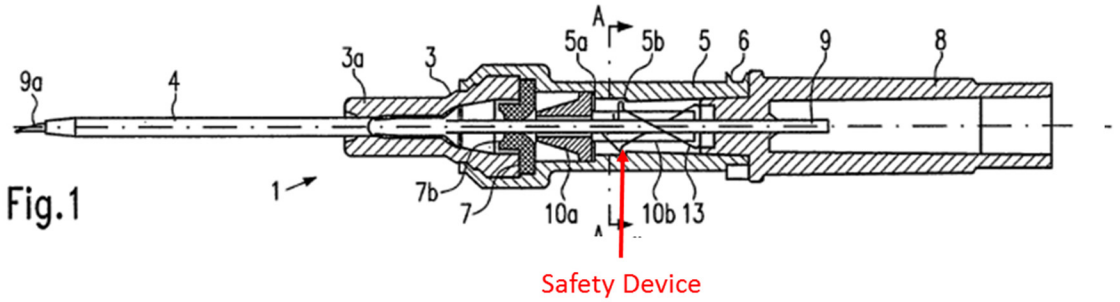


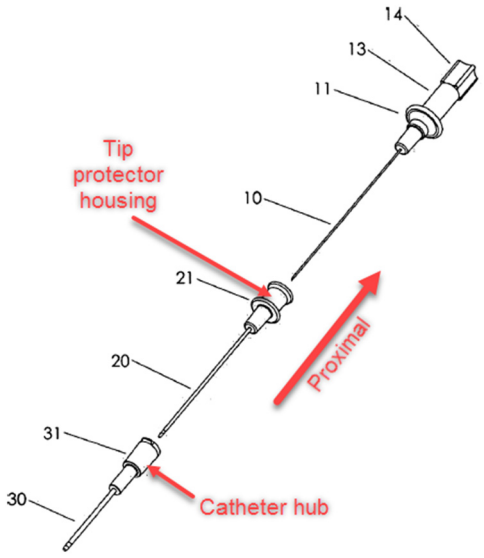
Fig.1

Woehr does not disclose "a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub."

Many different sizes and shapes of "tip protector housings" were known in the art. (Ex. 1002, Griffis Decl. ¶ 85). Catheters having three (or additional) hubs or housing structures were well known as of 2006, including, for example, third hub or housing structures containing tip protectors to prevent accidental needle sticks and/or minimizing blood exposure risks by preventing exposure to any fluids remaining on the needle after it is removed. (Ex. 1002, Griffis Decl. ¶ 85). It was known that hubs or housing structures for the tip protector provided additional security for the tip protector so the tip protector can better prevent accidental needle sticks. (Ex. 1002, Griffis Decl. ¶ 85). For example, U.S. Pub. No. 2007/0038186 to Sutton ("Sutton"), discloses that a "shroud" that "substantially encloses the needle guard" provides the benefit of "reduc[ing] the likelihood of

inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub." (Ex 1014, Sutton at [0011]; Ex. 1002, Griffis Decl. ¶ 85).

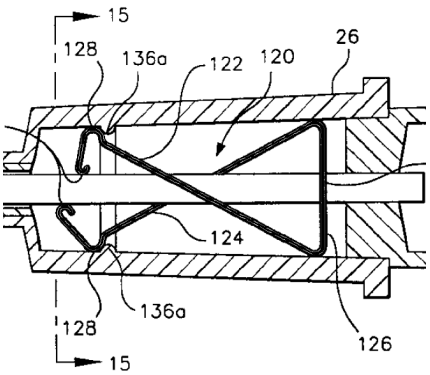
For example, as shown and described in connection with Figures 1, 3, 5, 6, 9-16, Callaway discloses a tip protector housing (e.g., element 21) having a housing section positioned proximally of a proximal end of the catheter hub (e.g., element 31). (*See, e.g.*, Ex. 1004, Callaway at Figs. 1, 3, 5, 6, 9-13, [0053], [0061]; Ex. 1002, Griffis Decl. ¶ 86). As shown, for example, in Figure 5, the middle hub 21 fits into the proximal end of the distal hub 31. (Ex. 1002, Griffis Decl. ¶ 87).



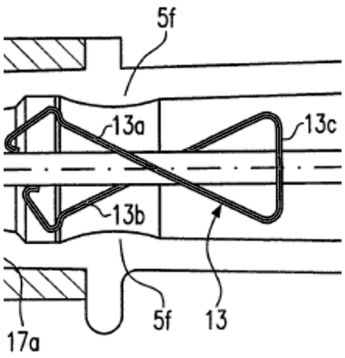
Callaway further explains that a needle safety device in the form of a metal clip can be placed into a "middle hub", and incorporates by reference the metal clip

disclosed in the '630 patent.[7] (Ex. 1004, Callaway at [0061]; Ex. 1002, Griffis Decl. ¶ 88). Callaway teaches that "clip and hub (21) protect users from the sharp tip of the needle (10)." (Ex. 1004, Callaway at [0061]; Ex. 1002, Griffis Decl. ¶ 88).

The clip disclosed in the '630 patent is the same clip that is disclosed in the Woehr device:



(Ex. 1007, '630 patent at Fig. 14)



(Ex. 1005, Woehr at Fig. 10)

(*Compare* Ex. 1007, '630 patent at Fig. 14; Ex. 1005, Woehr at Fig. 10; Ex. 1002, Griffis Decl. ¶ 89).

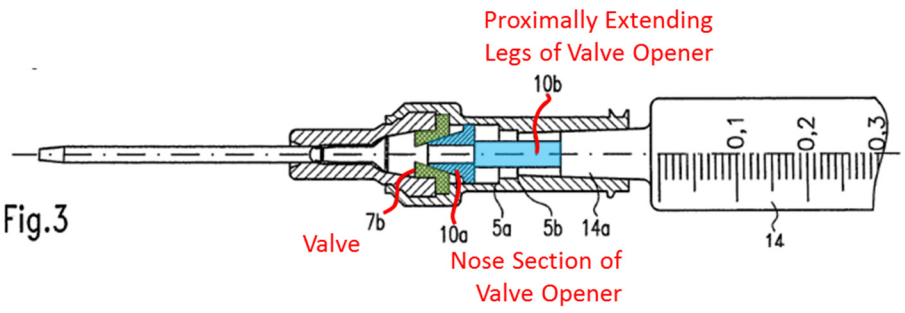
[7] Callaway incorporates the '630 patent by reference by clearly identifying the subject matter which is incorporated – the safety devices in the form of metal spring clips – and where it can be found – the '630 patent. (Ex. 1006, Callaway at [0061], [0076]; Ex. 1002, Griffis Decl. ¶ 88).

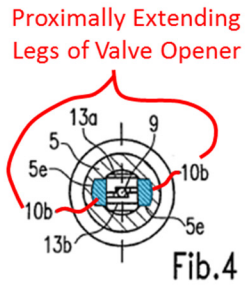
It would have been obvious for a POSA to combine the catheter insertion device of Woehr with a tip protector housing that houses a metal clip form of needle protection, such as the tip protector housing disclosed in Callaway. (Ex. 1002, Griffis Decl. ¶¶ 90-91). A POSA would have been motivated to modify Woehr based on knowledge and motivations in the art as well as the specific teaching in Callaway that the tip protector housing, in addition to the metal clip, provides more secure protection from the needle tip. (Ex. 1002, Griffis Decl. ¶¶ 90-91). A person of skill in the art would understand the third hub of Callaway provides a secure cover to keep the tip protector in place on the needle tip after the needle has been withdrawn. (Ex. 1002, Griffis Decl. ¶¶ 90-91). One of the goals of the Woehr device is to have the needle tip "simultaneously safely covered by the needle protecting element" as the needle is withdrawn from the catheter hub "such that the operating personnel may not be injured on the needle point." (Ex. 1005, Woehr at 1). A POSA would have found it obvious to improve Woehr by adding protective elements, such as a third hub disclosed in Callaway, to also prevent unintended contact with the tip protector itself and/or contact with any fluids remaining on the needle after it is removed, based on the known technique disclosed in Callaway to improve a similar catheter insertion device. (Ex. 1002, Griffis Decl. ¶¶ 90-91).

6. Element 15e. "wherein the valve opener comprises. . . "

Woehr discloses "wherein the valve opener comprises two proximally extending legs having a gap therebetween, the two proximally extending legs being sized and shaped to be pushed distally towards the valve to transfer a force imparted by a male Luer to the valve." As shown and described in connection with Figures 1-10, Woehr discloses a valve opener (e.g., element 10) comprises two proximally extending legs (e.g., element 10b) having a gap therebetween, the two proximally extending legs being sized and shaped to be pushed distally towards the valve (e.g., element 7) to transfer a force imparted by a male Luer to the valve (e.g., element 7). For example, Woehr discloses, "A valve actuating element 10 is displaceably arranged in proximal hub element 5 between needle hub 8 and valve disk 7 and has a truncated cone shaped contact section 10a which functions for opening valve disk 7, as Figure 3 shows. A plunger section 10b connects to contact section 10a on the proximal side and has a cavity for receiving a needle protecting element 13. In the embodiment shown, plunger section 10b is formed by two plungers spaced apart, between which the needle protecting element is inserted in the form of a spring clip 13, as shown in the cross-section view in Figure 4." (Ex. 1005, Woehr at 2). Woehr also discloses, "Figure 3 shows the insertion of an injection 14 into catheter hub 2, wherein the neck section 14a of the injection contacts at plunger section 10b of valve actuating element 10 and presses the same

against valve disk 7 such that truncated cone-shaped contact section 10a presses tabs 7b of the valve disk outward and by this means opens the valve so that a fluid may be supplied from injection 14 into catheter 4. The inclinations of the truncated cone at contact section 10a and the displacement of actuating element 10 relative to valve disk 7 are designed such that tabs 7b press contact section 10a toward the right in Figure 3 due to the elasticity of the material of valve disk 7 when injection 14 is withdrawn from catheter hub 2. By this means, valve disk 7 closes automatically, as the position in Figure 2 shows." (Ex. 1005, Woehr at 3; Ex. 1002, Griffis Decl. ¶¶ 92-93). Thus, claim 15 is obvious.

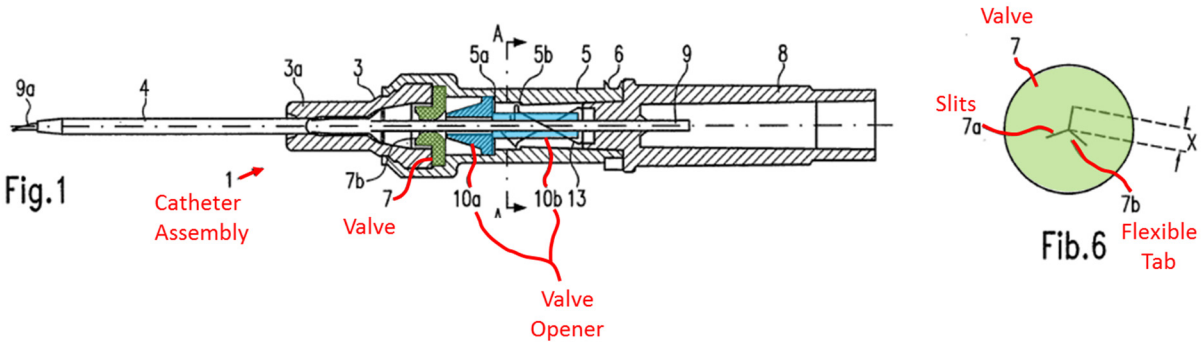




B. Dependent Claim 17 Is Obvious over Woehr in View of Callaway

Claim 17 depends from claim 15, and the analysis for claim 15 in Section VIII.A is incorporated by reference. Claim 17 further limits claim 15 by reciting "wherein the valve comprises one or more slits that are deflectable by a distal end of the valve opener." As shown and described in connection with Figures 1-10, Woehr discloses the safety catheter assembly (e.g., element 1) according to claim

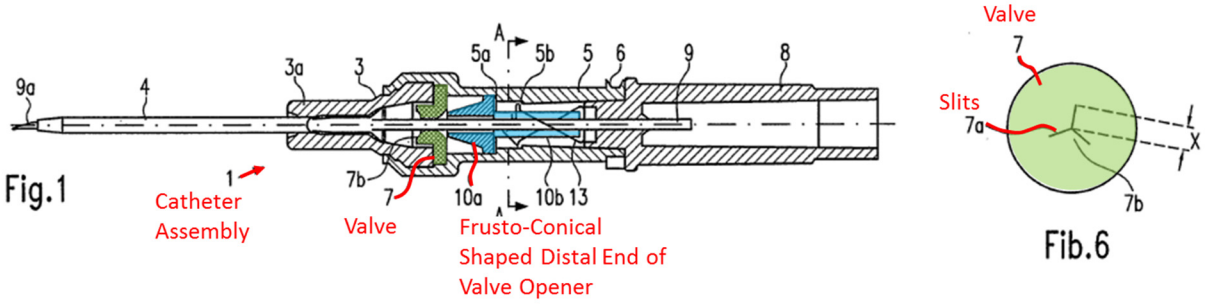
15, wherein the valve (e.g., element 7) comprises one or more slits (e.g., element 7a) that are deflectable by a distal end of the valve opener (e.g., element 10). For example, Woehr discloses, "A valve actuating element 10 is displaceably arranged in proximal hub element 5 between needle hub 8 and valve disk 7 and has a truncated cone shaped contact section 10a which functions for opening valve disk 7, as Figure 3 shows. A plunger section 10b connects to contact section 10a on the proximal side and has a cavity for receiving a needle protecting element 13. In the embodiment shown, plunger section 10b is formed by two plungers spaced apart, between which the needle protecting element is inserted in the form of a spring clip 13, as shown in the cross-section view in Figure 4." (Ex. 1005, Woehr at 2; Ex. 1002, Griffis Decl. ¶¶ 95-96). Thus, claim 17 is obvious.



C. Dependent Claim 18 Is Obvious over Woehr in View of Callaway

Claim 18 depends from claim 17, and the analysis for claim 17 in Section VIII.B is incorporated by reference. Claim 18 further limits claim 17 by reciting the "wherein the distal end of the valve opener comprises a nose section having a

frusto-conical shape for projecting through the slits." As shown and described in connection with Figures 1-10, Woehr discloses the safety catheter assembly according to claim 17, wherein the distal end of the valve opener (e.g., element 10) comprises a nose section having a frusto-conical shape (e.g., element 10a) for projecting through the slits (e.g., element 7a). For example, Woehr states, "Figure 3 shows the insertion of an injection 14 into catheter hub 2, wherein the neck section 14a of the injection contacts at plunger section 10b of valve actuating element 10 and presses the same against valve disk 7 such that truncated cone-shaped contact section 10a presses tabs 7b of the valve disk outward and by this means opens the valve so that a fluid may be supplied from injection 14 into catheter 4." (Ex. 1005, Woehr at 3; Ex. 1002, Griffis Decl. ¶¶ 97-98). Thus, claim 18 is obvious.



D. Dependent Claim 20 Is Obvious over Woehr in View of Callaway

Claim 20 depends from claim 18, and the analysis for claim 18 in Section VIII.C is incorporated by reference. Claim 20 further limits claim 18 by reciting "wherein the safety device for covering the needle tip comprises a resilient portion

made from a metal material and the tip protector housing surrounding the resilient portion." As shown and described in connection with Figures 1, 2, 4, 5, 7, 8, and 10, Woehr discloses a safety device (e.g., element 13) for covering the needle tip comprises a resilient portion made from a metal material. (Ex. 1002, Griffis Decl. ¶¶100-105). The term "resilient" is not defined by the '641 patent. The plain meaning of "resilient" at the time of the alleged invention is "able to recoil or spring back into shape after bending, stretching, or being compressed." (Ex. 1002, Griffis Decl. ¶ 101). Woehr discloses that spring clip 13 has spring arms 13a and 13b that "clip into shoulder 5b due to elastic deformation." (Ex. 1005, Woehr at 4). From this position, "the two spring arms 13a, 13b may release from shoulder 5b and spring back inward to cover the needle point." (Ex., 1005, Woehr at 4). A POSA would understand that the spring arms of the spring clip are elastic and spring into place, so they are a resilient portion. (*E.g.*, Ex. 1002, Griffis Decl. ¶ 101).

A POSA would understand that the spring clip in Woehr is made from a metal material. (Ex. 1002, Griffis Decl. ¶ 102). As shown above in Section VIII.A.5 and incorporated by reference here, the spring clip disclosed in Woehr is the same as the spring clip disclosed in the '630 patent, which is incorporated by

reference in Callaway.[8] (Ex. 1002, Griffis Decl. ¶¶ 102-103). The '630 patent further discloses that "the needle guard 40 is in the form of a unitary spring clip that is preferably made of a resilient metal such as stainless steel." (Ex. 1007, the '630 patent at 5:54-56). Thus, a POSA would understand that the spring clip in Woehr is made from a metal material. (Ex. 1002, Griffis Decl. ¶¶ 102-103).

As shown and described in connection with Figures 1, 3, 5, 6, 9-16 of Callaway by reference to Figures 1A and 1B of the '630 patent, Callaway discloses a tip protector housing (e.g., element 21) surrounding the resilient portion (e.g., metal clip from the '630 patent). (Ex. 1002, Griffis Decl. ¶ 104).

[8] Callaway incorporates the '630 patent by reference by clearly identifying the subject matter which is incorporated – the safety devices in the form of metal spring clips – and where it can be found – the '630 patent. (Ex. 1006, Callaway at [0061], [0076]).

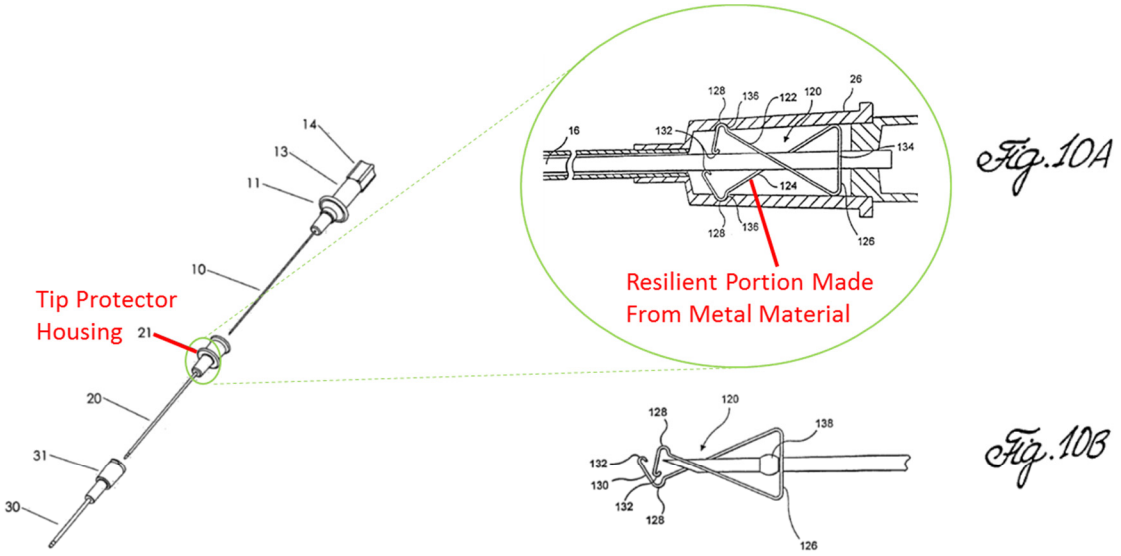


Fig. 5 of Callaway

Figs. 10A and 10B of '630 Patent (incorporated by reference in Callaway)

Callaway discloses that a needle safety device in the form of a metal clip can be placed into a "middle hub", and incorporates by reference the metal clip disclosed in the '630 patent.[9] (Ex. 1004, Callaway at [0061]; Ex. 1002, Griffis Decl. ¶ 104).

It would have been obvious for a POSA to combine the catheter insertion device of Woehr with a tip protector housing that houses a resilient metal spring clip, such as one disclosed in Callaway. (Ex. 1002, Griffis Decl. ¶ 105). A POSA

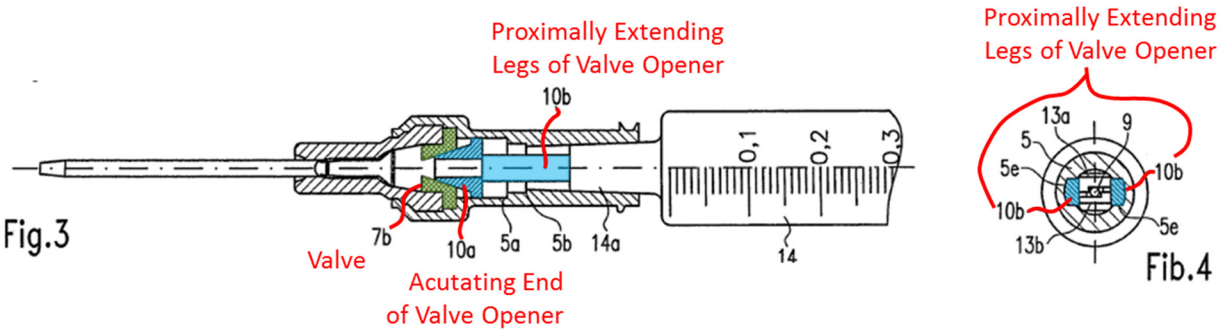
[9] Callaway incorporates the '630 patent by reference by clearly identifying the subject matter which is incorporated – the safety devices in the form of metal spring clips – and where it can be found – the '630 patent. (Ex. 1006, Callaway at [0061], [0076]).

would have been motivated to modify Woehr based on the knowledge and motivations in the art, as well as the specific teaching in Callaway that the tip protector housing, together with the metal clip, "protect users from the sharp tip of the needle." (Ex. 1004, Callaway at [0061]; Ex. 1002, Griffis Decl. ¶ 105). One of the goals of the Woehr device is to have the needle tip "simultaneously safely covered by the needle protecting element" as the needle is withdrawn from the catheter hub "such that the operating personnel may not be injured on the needle point." (Ex. 1005, Woehr at 1). A POSA would have found it obvious to improve Woehr by adding protective elements, such as a third hub to prevent unintended contact with the tip protector itself and/or contact with any fluids remaining on the needle after it is removed, based on the known technique disclosed in Callaway to improve a similar catheter insertion device. (Ex. 1002, Griffis Decl. ¶ 105). Thus, claim 20 is obvious.

E. Dependent Claim 22 Is Obvious over Woehr in View of Callaway

Claim 22 depends from claim 15, and the analysis for claim 15 in Section VIII.A is incorporated by reference. Claim 22 further limits claim 15 by reciting "wherein the valve opener comprises an actuating end for opening the valve and one or more legs extending proximally of the actuating end." In connection with Figures 1-10, Woehr the safety catheter assembly according to claim 15, wherein the valve opener (e.g., element 10) comprises an actuating end (e.g., element 10a)

for opening the valve (e.g., element 7) and one or more legs (e.g., element 10b) extending proximally of the actuating end (e.g., element 10a). For example, Woehr discloses, "Figure 3 shows the insertion of an injection 14 into catheter hub 2, wherein the neck section 14a of the injection contacts at plunger section 10b of valve actuating element 10 and presses the same against valve disk 7 such that truncated cone-shaped contact section 10a presses tabs 7b of the valve disk outward and by this means opens the valve so that a fluid may be supplied from injection 14 into catheter 4." (Ex. 1005, Woehr at 3; Griffis Decl. ¶ 107). Thus, claim 22 is obvious.



IX. Ground II: The Challenged Claims Are Obvious over Woehr in view of Villa.

The Challenged Claims are obvious over WO 2004/004819 to Kevin Woehr et al., "Catheter Insertion Device," published January 15, 2004 ("Woehr") (Ex. 1005)[10] in view of U.S. Pub. No. US 2004/0225260 to Villa, "Protective Device for

[10] All citations to Woehr are to the certified translation.

a Needle," published on November 11, 2004 ("Villa") (Ex. 1006). Woehr qualifies as prior art to the '641 patent under 35 U.S.C. § 102(b), and is cited on the face of the patent. Villa qualifies as prior art to the '641 patent under 35 U.S.C. §§ 102(a) and 102(e), and is cited on the face of the patent.

Villa discloses a protective device for a catheter introducing needle. (Ex. 1006, Villa at Abstract; Ex. 1002, Griffis Decl. ¶ 74). Villa discloses a hollow body or housing that surrounds a safety means in the form of elastic and bendable blocking arms. (Ex. 1006, Villa at [0047], [0066]; Ex. 1002, Griffis Decl. ¶ 74). The hollow body of Villa is formed as "an extension piece, which can be coupled to the catheter hub." (Ex. 1006, Villa at [0053]; Ex. 1002, Griffis Decl. ¶ 74).

The challenged claims thus recite features long known by engineers who design IV catheters. (Ex. 1002, Griffis Decl. ¶ 75). The structures in the claimed catheter assembly all have known functions that perform in expected ways. (Ex. 1002, Griffis Decl. ¶ 75). 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. ¶ 75).

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Griffis Declaration (Ex. 1002) show in detail the prior art disclosures that makes the challenged claims obvious.

A. Independent Claim 15 Is Obvious over Woehr in View of Villa

1. "A safety catheter assembly comprising"

The analysis at VIII.A.1 is incorporated by reference here. (*See* Section VIII.A.1 (Ground I, Element 15-preamble); Ex. 1002, Griffis Decl. ¶ 108).

2. Element 15a. "a catheter hub comprising…"

The analysis at VIII.A.2 is incorporated by reference here. (*See* Section VIII.A.2 (Ground I, Element 15a); Ex. 1002, Griffis Decl. ¶ 109).

3. Element 15b. "a needle hub having a needle…"

The analysis at VIII.A.3 is incorporated by reference here. (*See* Section VIII.A.3 (Ground I, Element 15b); Ex. 1002, Griffis Decl. ¶¶ 110).

4. Element 15c. "a valve . . ."

The analysis at VIII.A.4 is incorporated by reference here. (*See* Section VIII.A.4 (Ground I, Element 15c); Ex. 1002, Griffis Decl. ¶ 111).

5. Element 15d. "a safety device . . ."

Woehr in combination with Villa discloses "a safety device for covering the needle tip comprising a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub."

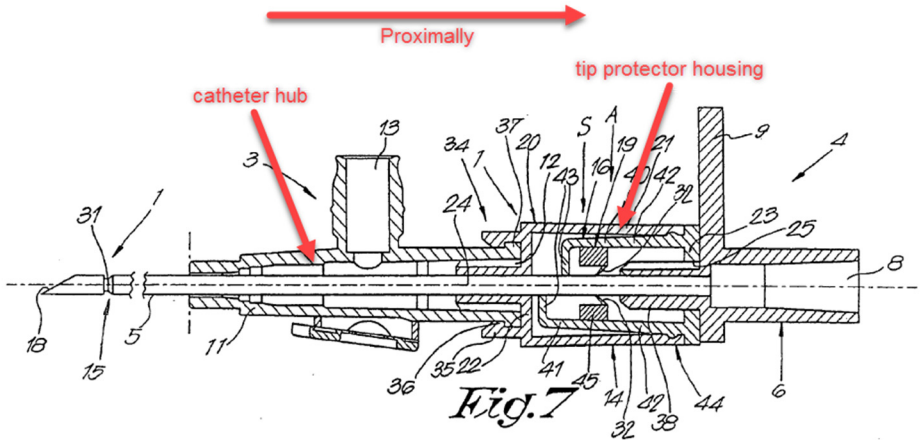
As shown in Section VIII.A.5 and incorporated by reference here, Woehr discloses a safety device (e.g., element 13) for covering the needle tip (e.g.,

element 9a). (*See, e.g.*, Ex. 1005, Woehr at Figs. 1, 2, 4, 5, 7, 8, 10, Abstract, 1-4, Claim 1, Claim 9; Ex. 1002, Griffis Decl. ¶¶ 112-113).

Many different sizes and shapes of "tip protector housings" were known in the art. (Ex. 1002, Griffis Decl. ¶ 114). Catheters having tip protector hubs or housing structures were well known as of 2006, including, for example, tip protector housings to securely protect the tip protectors and prevent accidental needle sticks and/or to minimize blood exposure risks by preventing exposure to any fluids remaining on the needle after it is removed. (Ex. 1002, Griffis Decl. ¶ 114). It was known that hubs or housing structures for the tip protector provided additional security for the tip protector so the tip protector can better prevent accidental needle sticks. (Ex. 1002, Griffis Decl. ¶ 114). For example, Sutton discloses that a "shroud" that "substantially encloses the needle guard" provides the benefit of "reduc[ing] the likelihood of inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub." (Ex 1014, Sutton at [0011]; (Ex. 1002, Griffis Decl. ¶ 114)).

For example, as shown and described in connection with Figures 1-12, Villa discloses a tip protector housing (e.g., element 20) having a housing section positioned proximally of a proximal end of the catheter hub (e.g., element 11 and/or element 3). (*See, e.g.*, Ex. 1006, Villa at Figs. 1-12 [0045]-[0047], [0053], [0058]–[0060], [0066]; Ex. 1002, Griffis Decl. ¶ 115). As shown, for example, in

Figures 7 and 8, tip protector housing 14 fits into the proximal end of the catheter hub 11.



Villa discloses a "protective device for a needle" that "is intended to be used in combination with a catheter introducing needle or a cannula needle. " (Ex. 1006, Villa at [0001], [0002]; Ex. 1002, Griffis Decl. ¶ 116). Villa discloses a hollow body or housing 20 that houses safety means 16 and blocking means 19. (Ex. 1006, Villa at [0047]; Ex. 1002, Griffis Decl. ¶ 116). In one embodiment, safety means 16 are formed as "a pair of opposed elastically bendable safety tongues 40-41, facing each other and fixed to the end wall 23." (Ex. 1006, Villa at [0066]; Ex. 1002, Griffis Decl. ¶ 116). "The safety tongues 40-41 are configured such that by means of their elasticity, they are permanently urged towards a position in which the second portions 43 are located in the path followed by the needle 5." (Ex. 1006, Villa at [0066]; Ex. 1002, Griffis Decl. ¶ 116). Villa shows that the hollow body or housing 20 has an arm that extends into the proximal end

of the catheter hub. "The protective means 14, more particularly the housing 20, is carried out as an extension piece, which can be coupled to the catheter hub. To this end, the housing is provided with coupling means 34 at the end wall 22, allowing a releasable connection with said catheter hub, preferably by means of a snap connection." (Ex. 1006, Villa at [0053]; Ex. 1002, Griffis Decl. ¶ 116).

It would have been obvious to a POSA to modify Woehr to move the safety device in the form of a spring clip into a tip protector housing connected to the catheter hub, such as the tip protector housing disclosed in Villa. (Ex. 1002, Griffis Decl. ¶ 117). As shown for example in Figure 7, the Villa housing contains tongues to cover the tip of the needle and connects to the proximal end of the catheter hub and to the distal end of the needle hub 6. (Ex. 1006, Fig. 7; Ex. 1002, Griffis Decl. ¶ 117). A POSA would have been motivated to modify the Woehr catheter insertion device to include a spring clip in a housing because the Villa housing for the protective means presents a number of advantages over the Woehr spring clip alone. (Ex. 1002, Griffis Decl. ¶ 117). The Villa device "considerably reduce[s] the risk of contact with patient's body fluids or with drugs on the needle[.]" (Ex. 1006, Villa at [0015], [0080]; Ex. 1002, Griffis Decl. ¶ 117).

Villa accomplishes this through a device that has needle protection inside of a housing that "is compact, resulting in that it is also easy to use and in that it is very versatile." (Ex. 1006, *id*. at [0015], [0081]; Ex. 1002, Griffis Decl. ¶ 118).

The Villa device is also "easy to construct and assemble and hence not expensive." (Ex. 1006, Villa at [0016], [0082]; Ex. 1002, Griffis Decl. ¶ 118). Villa describes, "[A]lthough the hollow body 20 is not completely closed, the fluids retained in it by the scraping means 33 are practically completely held inside, even if the needle 5 were to undergo shocks or vibrations." (Ex. 1006, Villa at [0063]; Ex. 1002 Griffis Decl. ¶ 118). This presents an advantage over the device of Woehr, which allows fluids to remain on the needle after it is removed from the catheter tube, thus exposing operators to bodily fluids and drugs on the tip of the needle. (Ex. 1002, Griffis Decl. ¶ 118). Thus, a POSA would have been motivated to move the safety device in Woehr into a tip protector housing attached to the proximal end of the catheter hub, such as the one disclosed in Villa, based on the knowledge and motivations in the art as well as the specific teaching of Villa that a tip protector housing accomplishes the predictable result of minimizing blood exposure risks and needle sticks for operators. (Ex. 1002, Griffis Decl. ¶ 118).

6. Element 15e. "wherein the valve opener comprises . . . "

The analysis at VIII.A.6 is incorporated by reference here. (*See* Section VIII.A.6 (Ground I, Element 15e); Ex. 1002, Griffis Decl. ¶ 119).

B. Dependent Claim 17 Is Obvious over Woehr in View of Villa

The analysis at VIII.B is incorporated by reference here. (*See* Section VIII.B (Ground I, Claim 17); Ex. 1002, Griffis Decl. ¶ 120).

C. Dependent Claim 18 Is Obvious over Woehr in View of Villa

The analysis at VIII.C is incorporated by reference here. (*See* Section VIII.C (Ground I, Claim 20); Ex. 1002, Griffis Decl. ¶ 121).

D. Dependent Claim 20 Is Obvious over Woehr in View of Villa

Claim 20 depends from claim 18, and the analysis for claim 18 in Section IX.B is incorporated by reference here. Claim 20 further limits claim 18 by reciting "wherein the safety device for covering the needle tip comprises a resilient portion made from a metal material and the tip protector housing surrounding the resilient portion."

As discussed and show in Section VIII.D and incorporated by reference here, Woehr discloses a safety device for covering the needle tip and comprises a resilient portion made from a metal material. (Ex. 1002, Griffis Decl. ¶ 123). As discussed and show in Section IX.A.5 and incorporated by reference here, Villa discloses a tip protector housing (e.g., element 20) surrounding a resilient portion. (Ex. 1002, Griffis Decl. ¶ 123). For the same reasons as those set forth in Sections VIII.D and IX.A5, and incorporated by reference here, it would have been obvious to a POSA to modify Woehr to move the safety device in the form of a metal resilient spring clip into a tip protector housing connected to the catheter hub as disclosed in Villa. (Ex. 1002, Griffis Decl. ¶ 124). Thus, claim 20 is obvious.

E. Dependent Claim 22 Is Obvious over Woehr in View of Villa

The analysis at VIII.E is incorporated by reference here. (*See* Section VIII.E (Ground I, Claim 22); Ex. 1002, Griffis Decl. ¶ 125).

X. 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 '641 patent. *Cf. Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013).

XI. Conclusion

Based on the foregoing, there is a reasonable likelihood that claims 15, 17,18, 20, and 22 of the '641 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 9,050 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. 9,370,641
- Exhibits 1001-1030
- 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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Petitioner's Appendix of Exhibits

Pet'rs' Ex. No.	Description
1001.	U.S. Patent No. 9,370,641 (issued Jun. 21, 2016) ("the '641 Patent")
1002.	Declaration of Mr. Griffis ("Griffis Decl.")
1003.	WO Publication No. 2004/004819 to Woehr, published Jan. 15, 2004 ("Woehr")
1004.	U.S. Patent Publication No. 2006/0178635 to Callaway, published Aug. 10, 2006 ("Callaway")
1005.	Certified Translation of WO Publication No. 2004/004819 to Woehr (Ex. 1003)
1006.	U.S. Patent Publication No. 2004/0225260 to Villa et al., published Nov. 11, 2004 ("Villa")
1007.	U.S. Patent No. 6,616,630 to Woehr et al. (issued Sept. 9, 2003) ("the '630 patent")
1008.	U.S. Patent Application No. 13/407,395 Prosecution History, Response of Feb. 7, 2013
1009.	U.S. Patent No. 8,382,718 to Woehr (issued Feb. 26, 2013) ("the '718 patent")
1010.	U.S. Patent No. 6,709,419 to Woehr (issued Mar. 23, 2004) ("the '419 patent")
1011.	U.S. Patent Publication No. 2005/0075609 to Latona, published Apr. 7, 2005 ("Latona")
1012.	U.S. Patent No. 7,651,476 to Kohler (issued Jan. 26, 2010) ("the '476 patent")

Pet'rs' Ex. No.	Description
1013.	U.S. Patent No. 8,333,735 to Woehr et al. (issued Dec. 18, 2012) ("the '735 patent")
1014.	U.S. Patent Publication No. US 2007/0038186 to Sutton et al., published Feb. 15, 2007 ("Sutton")
1015.	Intravenous Therapy Clinical Principles and Practices 317 (Judy Terry et al. eds., 1995) ("Terry")
1016.	A.M. Rivera et al., *The history of peripheral intravenous catheters: How little plastic tubes revolutionized medicine*, 56 Acta Anaesth. Belg. 271, (2005) ("Rivera")
1017.	U.S. Patent No. 5,858,002 to Jesch (issued Jan. 12, 1999) ("the '002 patent")
1018.	U.S. Patent No. 4,850,961 to Wanderer et al. (issued Jul. 25, 1989) ("the '961 patent")
1019.	U.S. Publication No. 2001/0053895 to Vaillancourt, published Dec. 20, 2001 ("Vaillancourt")
1020.	U.S. Patent No. 5,458,658 to Sircom (issued Oct. 17, 1995) ("Sircom")
1021.	OSHA Bloodborne Pathogens Standard, 56 Fed. Reg. 64004 (Dec. 6, 1991) ("OSHA Standard")
1022.	Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000) ("Needlestick Prevention Act")
1023.	International Standard, ISO 10555-5, *Sterile, single-use intravascular catheters; Part 5*, (1996 version).pdf ("ISO 10555-5")
1024.	U.S. Patent No. 5,215,528 to Purdy et al. (issued Jun. 1, 1993) ("Purdy")

Pet'rs' Ex. No.	Description
1025.	U.S. Patent 6,117,108 to Woehr et al. (issued Sept. 12, 2000) ("Woehr '108")
1026.	U.S. Publication No. 2004/0116856 to Woehr, published Jun. 17, 2004 ("the '856 publication")
1027.	U.S. Publication No. 2002/0169418 to Menzi, published Nov. 14, 2002 ("Menzi")
1028.	EP 0 352 928 to Lemieux, published Dec. 30, 1992 ("Lemieux")
1029.	Andrea Mummery, *Be sharp, be safe*, 54 Occupational Health 30 (Sept. 2002).
1030.	The New Oxford American Dictionary (2005) ("Oxford Dictionary")