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Paper No. 8
Entered: January 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B. BRAUN MELSUNGEN AG,
Patent Owner.

Case IPR2017-01589
Patent 8,597,249 B2

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

KINDER, *Administrative Patent Judge.*

DECISION

Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Becton, Dickinson and Company ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting *inter partes* review of claims 1 and 4 of U.S. Patent No. 8,597,249 B2 ("the '249 patent"). Pet. 1. B. Braun Melsungen AG ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.") in response to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 1.

We have jurisdiction under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the arguments and the evidence presented, for the reasons described below, we institute an *inter partes* review based on the ground identified in the Order section of this Decision.

A. Related Proceedings

The parties represent that the '249 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1; Paper 5, 2. Petitioner also represents that petitions for *inter partes* review were also filed challenging related patents US. Patent Nos.: 8,328,762; 8,333,735; 8,337,463; 8,540,728; 8,597,249; 8,460,247; 9,149,626, and 9,370,641. *Id.* The following chart associates each *inter partes* review with its corresponding patent:

IPR Number	Patent Number
IPR2017-01583	8,333,735
IPR2017-01584	8,540,728
IPR2017-01585	8,337,463
IPR2017-01586	8,328,762
IPR2017-01587	9,149,626
IPR2017-01588	8,460,247
IPR2017-01589	8,597,249
IPR2017-01590	9,370,641

B. The '249 Patent (Ex. 1001)

The '249 patent, titled "Catheter Assembly and Components Thereof," discloses catheter assemblies having "a tip protector, a valve, a valve opener, and . . . a needle wiper." Ex. 1001, [54], [57]. The '249 discusses the need to prevent accidental needle sticks following withdrawal of the needle from a patient's vein, and to minimize the risk of dangerous blood-borne pathogens. *Id.* at 1:34–43. The '249 patent discusses a desire to cover needles immediately following use, and to provide a valve to minimize blood exposure following successful catheterization. *See id.* at 1:52–58.

To illustrate a particular embodiment of the '249 patent's catheter insertion device, we reproduce Figures 13 and 14 of the '249 patent, below:

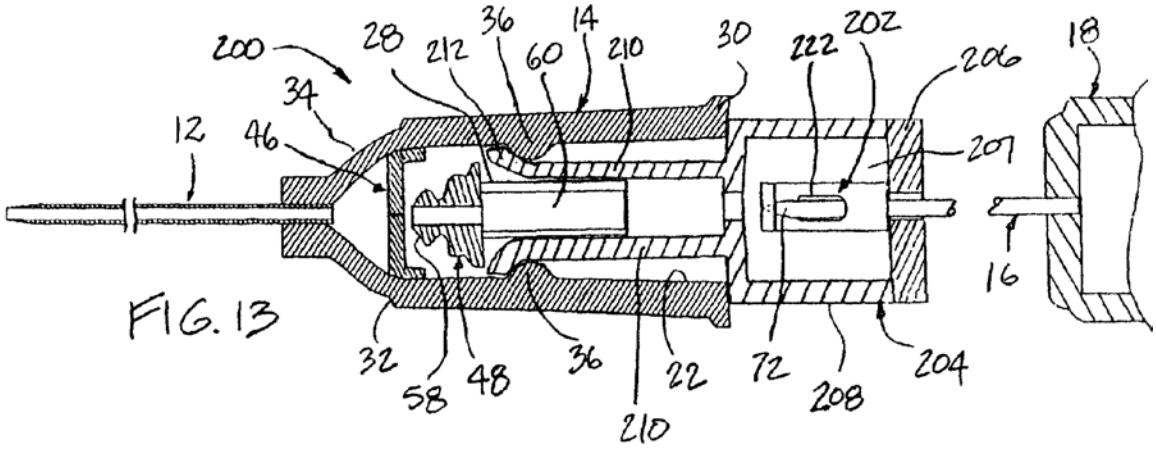


FIG. 13

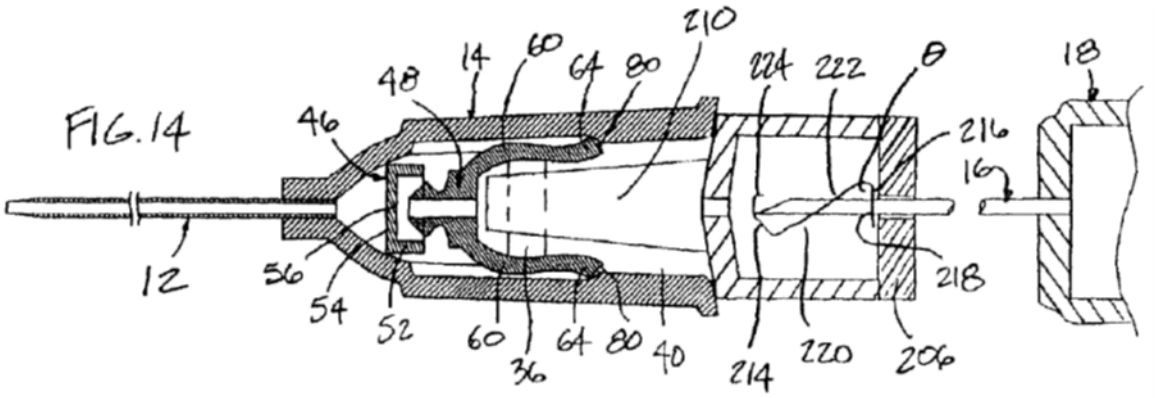


FIG. 14

Figures 13 and 14 depict a particular embodiment of Patent Owner's catheter assembly with a *third housing*. *Id.* at 4:36–41. Figure 14 "is a cross-sectional side view" of Figure 13's catheter assembly "taken along an orthogonal plane." *Id.* at 4:40–41. In particular, Figures 13 and 14 depict catheter assembly 200, including catheter tube 12, catheter hub 14, needle 16 with needle tip 72, needle hub 18, hemostatic valve 46, and valve opener 48. *Id.* at 11:4–16. Valve opener 48 comprises a pair of legs 60 positioned in corresponding channels 28. *Id.* at 11:10–12. In this particular embodiment, third housing 204 (Fig. 13) is provided to "accomodat[e] the tip protector." *See id.* at 11:16–19. Third housing 204 incorporates pair of arms 210, each of which comprises hook 212. *Id.* at 11:33–34. The two hooks 212 are configured to engage two bumps 36 to retain third housing 204 to catheter

hub 14 in a "ready to use position," and are preferably flexible to provide a gripping force against bumps 36. *Id.* at 11:34–38. Needle 16 extends through valve 46 and through catheter tube 12, and after withdrawal of needle 16 from catheter tube 12 and valve 46, valve 46 closes to prevent an outflow of blood. *See id.* at 7:5–15.

Following a successful catheterization, needle 16 is retracted away from catheter tube 12, and in the rightward direction as shown in Figures 13 and 14. *Id.* at 11:45–48. As needle tip 72 moves to the right of distal wall 214 of tip protector 202, tip protector 202 engages needle 16 and further movement of needle 16 causes tip protector 202 to pull on rear plate 206 of third housing 204, which then disengages hooks 212 from two bumps 36. *Id.* at 11:49–54. Needle 16 is covered by both tip protector 202 and third housing 204 to minimize the risk of injury from needle tip 72. *Id.* at 2:25–34; 11:46–57.

C. Challenged Claims

Claim 1 is independent and claim 4 depends from claim 1. *Id.* at 12:40–67, 13:8–10. Each claim is reproduced below:

> 1. A catheter assembly comprising:
>
> a first hub comprising an interior cavity, an opening at a proximal end, and a catheter tube having a distal end opening extending distally of the first hub;
>
> a needle having a needle shaft defining a needle axis projecting distally of an end of a second hub, said needle projecting through the catheter tube and comprising a needle tip;
>
> a valve comprising a slit for obstructing fluid flow and a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first

> hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the first hub;
>
> a valve opener disposed in the first hub for actuating the valve, the valve opener comprising a nose section for pushing the valve to open the slit when activated and a leg element extending proximally of the nose section; wherein the leg element is slidable distally within the interior cavity of the first hub by a male implement to transfer a distally directed force to the nose section to push the valve to open the slit;
>
> a needle protective device spring loaded in a ready to use position and positioned proximally of the valve and at least in part around the needle to prevent unintended contact with the needle tip in a protective position; and
>
> a third hub positioned substantially proximally of the first hub.
>
> 4. The catheter assembly of claim 1, further comprising a second leg element spaced from the leg element for fluid flow therebetween.

Id.

D. References Relied Upon

The Petitioner relies in relevant part on the following references (Pet. 3):

Name	Reference	Ex. No.
Woehr[1]	PCT WO 2004/004819 A1, published Jan. 15, 2004	Exs. 1003, 1005
Basta	US 2005/0043684 A1, published Feb. 24, 2005	Ex. 1004
Callaway	US 2006/0178635 A1, published Aug. 10, 2006	Ex. 1006

[1] Exhibit 1005 is the English language translation of Exhibit 1003, and our citations to Woehr are to Exhibit 1005.

Villa	US 2004/0225260 A1, published Nov. 11, 2004	Ex. 1007
Rogers	WO Publication No. 1995/022364, published Aug. 24, 1995	Ex. 1008

E. Requirements for Affidavit under 37 C.F.R. §§ 42.2 and 42.63(b)

With respect to the German language publication Woehr (Ex. 1003), Patent Owner argues that we should deny institution because Petitioner has failed to provide a compliant affidavit attesting to the accuracy of the English translation (Ex. 1005), of the original German language publication Woehr (Ex. 1003). Prelim. Resp. 21; *see also id.* at 21–25 (arguing Woehr should not be considered as evidence).

"When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an *affidavit* attesting to the accuracy of the translation must be filed with the document." 37 C.F.R. § 42.63 (emphasis added). Pursuant to 37 C.F.R. § 42.2, an "[a]ffidavit means affidavit *or* declaration under § 1.68 of this chapter." (emphasis added). Patent Owner's contentions seem to misplace the requirements for a "declaration" (under § 1.68) onto a sworn affidavit. These are distinct documents. For example, the requirements of 28 U.S. Code § 1746 are for "Unsworn declarations." If a document is sworn, the additional requirements of § 1746 would seemingly not apply. *See also* 37 C.F.R. § 1.68 ("Declaration *in lieu of oath*"). It appears to us that the translation of Woehr (Ex. 1005) was sworn testimony before a notary public, and as such, would qualify as an affidavit – sworn testimony under oath. *See* Ex. 1005, final page (stating "*Sworn* to before me this August 9, 2016" (emphasis added)). Every state provides for a variety of

officials, civil servants, and others with special status to give oaths, with notaries public being the most common. Based on the record before us, Petitioner's translation (Ex. 1005) is a compliant affidavit because it was administered as a sworn affidavit before a notary public pursuant to the laws of the State of New York. *See Berry v. United States*, 86 Fed. Cl. 750, 754, n.10 (2009) (quoting "Black's Law Dictionary 62 (8th ed. 2004) (defining 'affidavit' as '[a] voluntary declaration of facts written down and sworn to by the declarant before an officer authorized to administer oaths, such as a notary public'"); *see, e.g.*, N.Y. Comp. Codes R. & Regs. tit. 19, Part 182 § 135 (2017) ("Every notary public duly qualified is hereby authorized and empowered within and throughout the State to administer oaths and affirmations, to take affidavits.").

F. Alleged Grounds of Unpatentability

Petitioner contends that claims 1 and 4 of the '249 patent are unpatentable under the following grounds:

References	Basis	Claim(s)
Woehr, Basta, and Callaway	§ 103(a)	1 and 4
Woehr, Basta, and Villa	§ 103(a)	1 and 4
Woehr, Rogers, and Callaway	§ 103(a)	1 and 4
Woehr, Rogers, and Villa	§ 103(a)	1 and 4

Pet. 3. Petitioner also relies on the declaration testimony of Jack Griffis, III (Ex. 1002) in support of its Petition. Patent Owner relies on the declaration testimony of Richard Meyst (Ex. 2001) in support of its Preliminary Response.

II. ANALYSIS

A. Claim Construction

As a first step in our analysis, we determine the meaning of the claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach). Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). For purposes of this Decision, we determine it necessary to construe the term "needle protective device."

Needle Protective Device

Independent claim 1 requires "[a] catheter assembly comprising . . . a needle protective device spring loaded in a ready to use position and positioned proximally of the valve and at least in part around the needle to prevent unintended contact with the needle tip in a protective position." Ex. 1001, 12:62–65. Petitioner contends the term needle protective device invokes 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Pet. 10–14. Petitioner acknowledges that a presumption exists that the limitation is not in means-plus-function format, yet Petitioner contends that the "use of the word 'device' in the claims does not impart any structure and is tantamount to using the word 'means'" and

further contends that "the modifier 'needle protective' does not impart any structure to the term 'device.'" *Id.* at 12 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc)). Petitioner's argument is supported by the declaration of Mr. Griffis, who testifies that "[t]he phrase 'needle protective device' is not defined in any technical dictionaries or engineering handbooks, nor is it 'used in common parlance or by persons of skill in the pertinent art to designate structure.'" *Id.* at 13 (quoting Ex. 1002 ¶ 44).

Patent Owner disagrees that the needle protective device limitation should be construed in means-plus-function format. Prelim. Resp. 4–17. Patent Owner contends that "[t]he claim language following 'needle protective device' . . . indicates the term is structural." *Id.* at 16. According to Patent Owner:

> Claim 1 requires that the "needle protective device" be "positioned proximally of the valve and at least in part around the needle to prevent unintended contact with the needle tip in a protective position." Dependent claim 5 requires that the "needle protective device is positioned adjacent to the leg element." Independent claim 10 indicates that the tip protector comprises "a tip protector housing; and an arm extending from the tip protector housing to . . . retain the tip protector in a ready to use position and wherein the tip protector is spring loaded and in the ready to use position." By describing the location of the "needle protective device," how it cooperates with the needle, and that it may comprise a tip protector housing, a POSITA would understand it to be structural.

Id. (citing Ex. 2001 ¶¶ 62–63; *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 649 F.3d 1350, 1356 (Fed. Cir. 2011)).

Based on the record before us, we are not convinced that the needle protective device limitation should be construed as a means-plus-function

term. Because the term "means" is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. Rather, as pointed out by Patent Owner, we determine that the needle protective device limitation and the claims as a whole recite sufficient structure. *See Williamson, LLC*, 792 F.3d 1349 (explaining that the presumption is overcome when "the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'"). Further, Mr. Meyst explains how a person of ordinary skill in the art "would recognize that the claimed 'needle protective device' refers to the class of structures included in safety IV catheters that prevent unintended needle-sticks by covering (*i.e.*, protecting or guarding) the needle tip." Ex. 2001 ¶ 56 (citing Ex. 2014, which is cited in the '249 patent, *see* Ex. 1001, [56]). Based on the current record before us, we find Mr. Meyst's testimony persuasive as to this issue.

Based on the record before us, the term "needle protective device" should not be construed under § 112 ¶ 6. Instead, we adopt Patent Owner's proposed construction that the term "needle protective device" means *a device configured to prevent unintended needle sticks*. *See* Prelim. Resp. 17.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art;

(2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17.

Petitioner relies upon the declaration of Mr. Griffis (Ex. 1002) and contends that a person of ordinary skill in the art ("POSITA") would have been either "a medical practitioner with experience using vascular access devices and with training, experience and/or familiarity applying principles of engineering to the design, development, and/or testing of vascular access devices," or "an engineer having at least a bachelor of science degree and with several years of experience in the design, development, and/or testing of vascular access devices and their clinical use; a higher level of education could reduce the number of years of experience required." Pet. 9 (citing Ex. 1002 ¶ 30).

Patent Owner, on the other hand, relies upon the declaration of Mr. Meyst (Ex. 2001) and contends that a POSITA would have had "at least an associate's degree in engineering or Physics or the equivalent, and at least

five years of experience with IV catheters. Alternatively, more education, such as a Bachelor of Science degree, could reduce the number of years of experience to at least two years of experience." Prelim. Resp. 2 (citing Ex. 2001 ¶¶ 26–28).

Based on our review of the '249 patent, the types of problems and solutions described in the '249 patent and applied prior art, and the testimony of Mr. Griffis and Mr. Meyst, we determine that a POSITA would be either a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Petitioner's Citations to Sutton (Ex. 1033)

We address at the outset Petitioner's references to Sutton (Ex. 1033) and Patent Owner's objection that such references to Sutton makes the Petitioner unclear and defective. *See* Pet. 8, 27, 30, 34; *see also* Prelim. Resp. 26.

The Petition refers at several points to Sutton as disclosing 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.'" Pet. 8 (citing Ex. 1033 ¶ 11). The Petition, citing to Mr. Griffis testimony, explains that Sutton is an example of what was known to those of skill in the art, namely, that "[i]t 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." *See, e.g.*, *id.* at 27 (citing Ex. 1002 ¶ 89).

We agree with Patent Owner that the Petition does not include Sutton in any ground. We do not, however, find the allusion to Sutton particularly unclear. According to Mr. Griffis' testimony, Sutton, like Villa and Callaway, apparently shows that "[c]atheters having three (or additional) hubs or housing structures were well known as of 2006." Ex. 1002 ¶ 89. We understand that Mr. Griffis relies on Sutton as evidence to bolster his testimony that one of skill in the art would have understood that such housing structures "provide[] the benefit of 'reduc[ing] the likelihood of inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub.'" *Id.* (quoting Ex 1033 ¶ 11).

To what extent, or not, Sutton may aid the credibility of Mr. Griffis's testimony is a matter to be developed during trial and does not, at this point, render the Petition unclear or defective.

E. Obviousness of Claims 1 and 4 over Woehr, Basta, and Callaway

Petitioner contends that claims 1 and 4 are unpatentable over Woehr, Basta, and Callaway. Pet. 3. For the reasons set forth below, Petitioner has shown a reasonable likelihood that these claims would have been obvious over Woehr, Basta, and Callaway.

1. Woehr (Ex. 1005)

Woehr is a PCT Patent Publication titled "Catheter Insertion Device." Ex. 1005, [54]. To illustrate an embodiment of Woehr's device, we reproduce Figure 1, below:

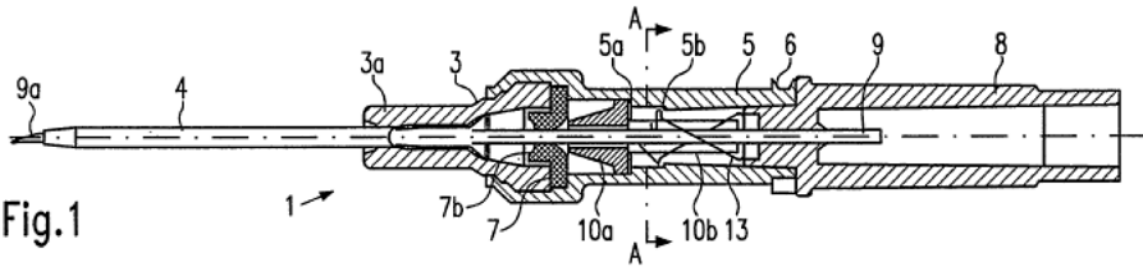


Fig.1

Woehr describes Figure 1 as depicting its catheter insertion device 1 in a ready-to-use position. *Id.* at 1, 2. Device 1 comprises distal hub 3, catheter 4, hub element 5, and a check valve in the form of valve disk 7. *Id.* at 2. In the ready-to-use position, needle hub 8 is inserted into hub element 5, and hollow needle 9 extends through valve disk 7 and catheter 4, such that needle point 9a is exposed. *See id.* Valve actuating element 10 (shown as elements 10a, 10b) is arranged in hub element 5 between needle hub 8 and valve disk 7. *Id.*

To illustrate Woehr's catheter insertion device 1 with hollow needle 9 withdrawn, we reproduce Figure 2, below:

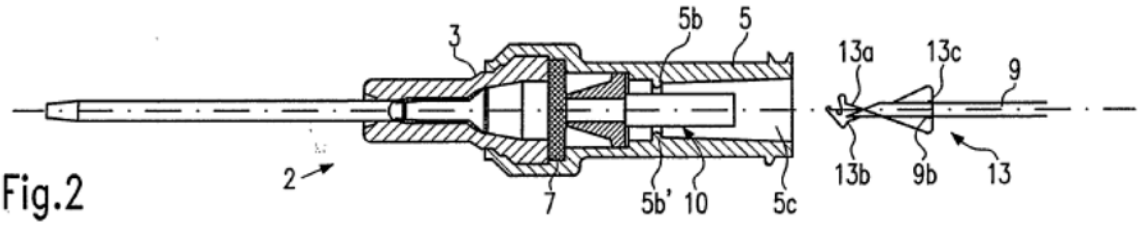


Fig.2

Woehr describes Figure 2 as depicting hollow needle 9 withdrawn from catheter insertion device 1. *Id.* at 1. During needle 9 withdrawal, spring clip 13 is drawn out of hub 5 along with needle 9, and spring arms 13a and 13b of spring clip 13 "lie around . . . and completely cover and block" needle point 9a. *See id.* at 2, Fig. 1. In this separated position, valve disk 7, due to its elasticity, closes the through opening for needle 9 such that "no blood may discharge through catheter 4." *Id.* at 2–3.

Woehr's catheter insertion device may also be attached to an "injection," as depicted in Figure 3, below:

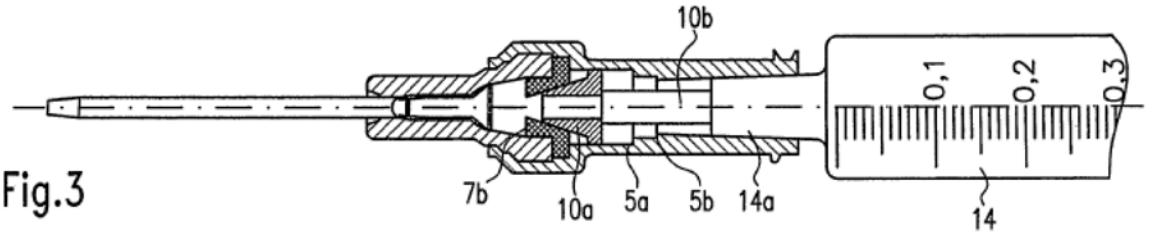
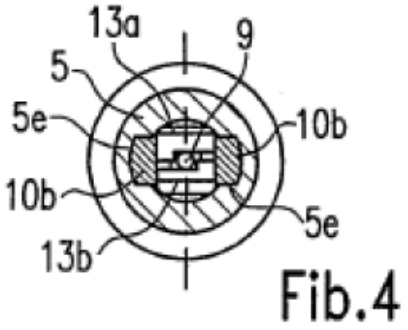


Fig.3

Woehr describes Figure 3 as depicting insertion of injection 14 into Woehr's catheter hub, with neck section 14a of injection 14a contacting plunger section 10b of valve actuating element 10. *Id.* at 3. Upon insertion of injection 14, cone-shaped contact section 10a of valve actuating element 10 presses against valve disk 7 to open the valve so that fluid may be supplied from injection 14 and into catheter 4. *Id.*

To better illustrate valve actuating element 10 and its arrangement within hub 5, we reproduce Woehr's Figure 4, below:



Fib.4

Woehr describes Figure 4 as depicting a side view along line A-A of Figure 1. *Id.* at 1. In particular, Figure 4 depicts two plungers 10b of valve actuating element 10 as being guided in longitudinal grooves 5e of hub element 5, such that plungers 10b form a contact surface for neck section 14a of injection 14. *Id.* at 3, Fig. 3. Figure 4 further depicts spring clip 13 fixed within hub 5 and with spring arms 13a, 13b in a position to "spring

back inward to cover" needle point 9a upon the withdrawal of needle 9 from hub 5. *See id.* at 3–4, Fig. 2.

2. Basta (Ex. 1004)

Basta is a U.S. Patent Publication titled "Needle with Sealing Valve," and it discloses a needle that is attached to a needle hub. Ex. 1004, [57]. The disclosed needle hub contains a valve that closes to stop fluid flowing through the needle hub. *Id.* ¶ 9. Basta also discloses plunger 146 that is slidable and can bias the valve to an open position to allow fluid communication. *Id.* ¶¶ 9, 25, 27. For example, as shown in Figure 2 below, Basta discloses valve 140 comprising through-opening 150 for obstructing fluid flow and seal 142, or skirt section, positioned inside the interior cavity of the hub such that the skirt section contacts the interior cavity of the hub. *See id.* ¶¶ 24, 25.

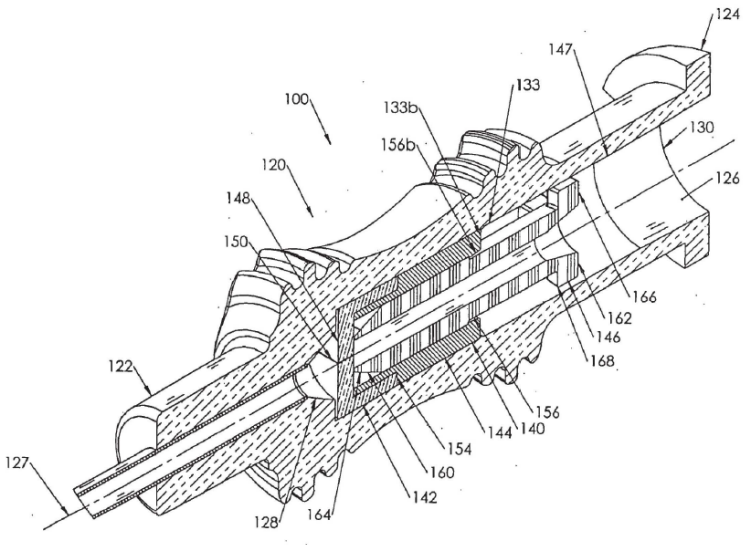
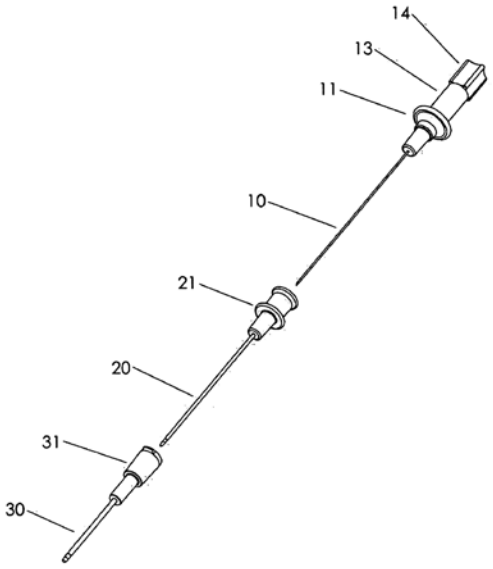


FIG. 2

Figure 2 of Basta is an enlarged perspective view of the needle hub shown with a hub valve in a closed position. *Id.* ¶ 14.

3. Callaway (Ex. 1006)

Callaway is a U.S. Patent Publication titled "Easy Entry Catheters." Ex. 1006, [54]. To illustrate a particular embodiment of Callaway's catheter, we reproduce Figure 5, below:



Callaway describes Figure 5 as depicting its catheter insertion device "with the three major parts disassembled from each other" and "separated along their common axis." *Id.* ¶¶ 37, 57. In particular, Figure 5 depicts needle 10, proximal hub 11, and flash chamber 13 on the right, and with outer catheter 30 and its hub 31 on the left. *Id.* ¶ 57. Figure 5 also depicts small catheter 20 and its hub 21 in the center. *Id.* In summary, Figure 5 depicts three hubs: proximal hub 11; small catheter hub 21; and outer catheter hub 31. *Id.* Callaway further discloses:

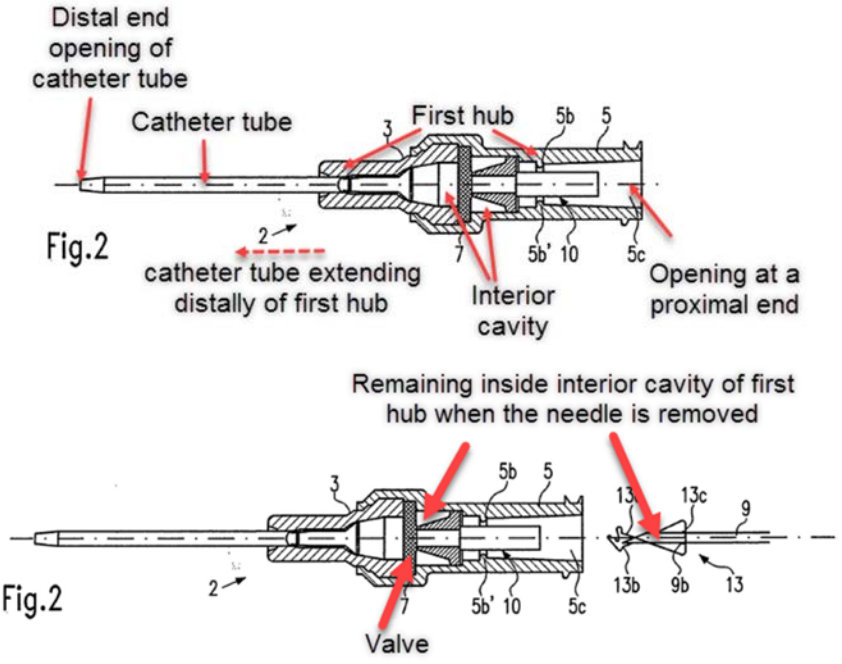
> [T]he catheter assembly could be integrated with an existing needle protection device . . . . This needle safety device includes a metal clip in the hub (21) of the inner catheter which, upon withdrawal of the needle (10), captures and contains the needle tip within the hub (21) of the inner catheter. *The clip and hub (21) protect users from the sharp tip of the needle (10).*

Id. ¶ 61 (emphasis added).

4. Petitioner's Challenge

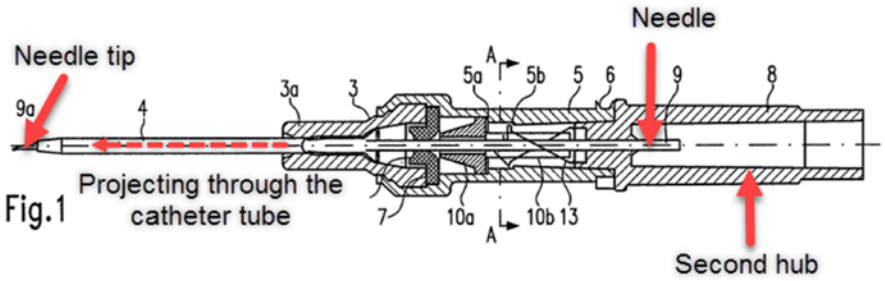
In challenging the claims, Petitioner submits that "Woehr discloses a catheter insertion device that has a needle protective device in the form of a spring clip, and a valve that stops fluid from flowing out of the catheter hub after the needle is removed." Pet. 15. Petitioner relies on Callaway as disclosing an embodiment where a needle safety device in the form of a spring clip is placed in the middle of three hubs. *Id.* at 16. Petitioner contends "Basta discloses a needle that is attached to a needle hub" with "a valve that closes to stop fluid" and "a plunger that is slidable" that "can bias the valve to an open position to allow fluid communication." *Id.*

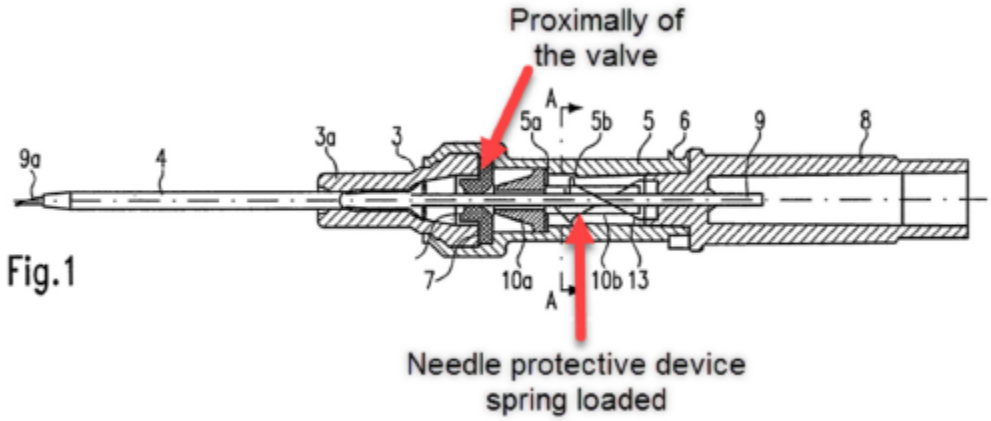
Examining each of the elements of claim 1, Petitioner contends Woehr also discloses a "catheter assembly comprising" the claimed "first hub," "second hub," "a needle having a needle shaft", "valve," "valve opener," and "a needle protective device." *See* Pet. 17–27. To illustrate these findings, Petitioner submits annotated versions of Woehr's Figure 2 (*id.* at 19, 21), copies of which we reproduce below:



According to Petitioner, annotated Figure 2 depicts a "safety catheter assembly" comprising the claimed "first hub" 2 (*id.* at 18, 19), "valve" 7 (*id.* at 20), and "a valve opener" 10 comprising a "nose section having a tapered end" 10a (*id.* at 24). *See also* Ex. 1005, Fig. 1.

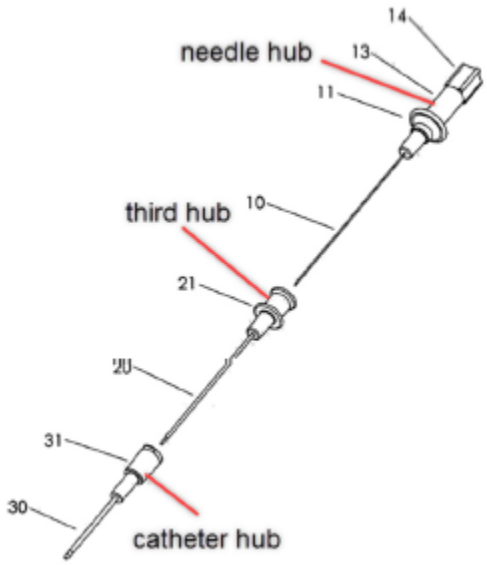
Petitioner also submits two annotated versions of Woehr's Figure 1 (*id.* at 19, 27), copies of which we reproduce below:





According to Petitioner, and as shown above in the annotated versions of Woehr's Figure 1, Woehr discloses its safety catheter assembly as also comprising the claimed "a needle having a needle shaft" 9 (*id.* at 19), "second hub" 8 (*id.*), and "needle protective device" 13 (*id.* at 25–27).

In addressing the claimed "third hub," Petitioner cites, *inter alia*, to Callaway's annotated Figure 5 (*see id.* at 28), which we reproduce below:



According to Petitioner, annotated Figure 5 depicts Callaway's "third hub (e.g., element 21) positioned substantially proximally of the first hub (e.g., element 31)." *Id*. Petitioner asserts that Callaway "explains that a needle safety device in the form of a metal clip can be placed into" third hub 21 (*id.* at 27) and that "Callaway teaches that 'clip and hub (21) protect users from the sharp tip of the needle (10)'" (*id.* at 28). *See also* Ex. 1006 ¶ 61 ("The clip and hub (21) protect users from the sharp tip of the needle (10)").

In combining Woehr with Callaway, Petitioner reasons that a person having ordinary skill in the art would have found it obvious "to combine the catheter insertion device of Woehr with a third hub that houses a metal clip form of needle protection, such as that disclosed in Callaway." Pet. 29. Petitioner argues "that the third hub, in addition to the metal clip, provides more secure protection from the needle tip," and also that "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." *Id.* at 30 ("A POSA would have found it obvious to improve Woehr by adding protective elements, such as a third hub to also prevent unintended contact with the tip protector

itself and/or contact with any fluids remaining on the needle after it is removed.").

In addressing the claimed valve and "a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first hub," Petitioner relies on Basta. *Id.* at 20–23. In particular, Petitioner submits annotated version of Basta's Figure 2 (*id.* at 23), which we reproduce below:

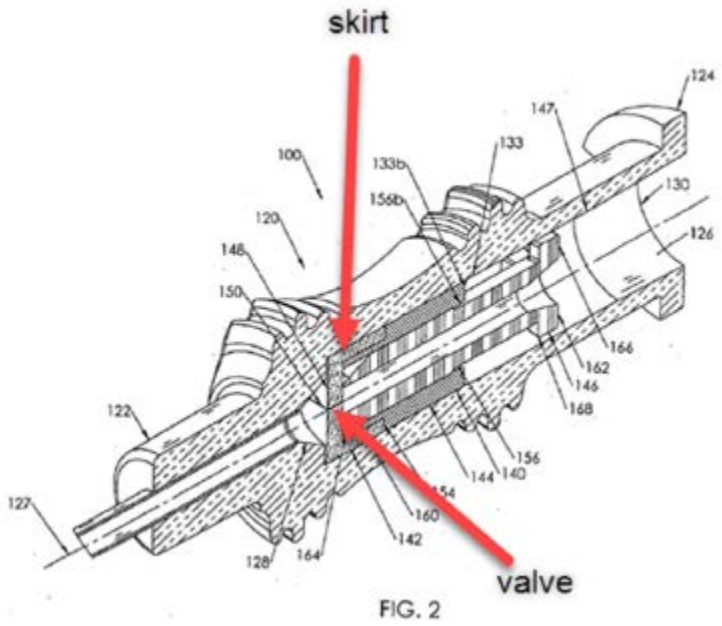


FIG. 2

According to Petitioner, annotated Figure 2 depicts Basta's skirt section 142 and valve 140. *Id.* at 22–23. Petitioner contends Basta teaches "a valve (e.g., element 140) comprising a slit (e.g., element 150) for obstructing fluid flow and a skirt section (e.g., element 142) positioned inside the interior cavity of the hub (e.g., element 120 and/or element 200) such that the skirt section contacts the interior cavity of the hub." *Id.* at 22.

In combining Basta with Woehr and Callaway, Petitioner reasons that "[i]t would have been obvious for a POSA to combine the catheter insertion

device of Woehr with a skirt section positioned inside the interior cavity of the hub, such as that disclosed in Basta." *Id.* (citing Ex. 1004 ¶ 39; Ex. 1002 ¶ 83). Petitioner further contends that "[a] POSA would have been motivated to modify Woehr based on the knowledge and motivations in the art as well as the specific teaching in Basta that the valve seals the passageway to prevent fluid flow therethrough." *Id.* (citing Ex. 1002 ¶ 83). According to Petitioner, adding Basta's skirt would create a distinct valve that could be reliably closed after withdrawing the hollow needle from the catheter, such that a blood discharge is prevented. *Id.* (citing Ex. 1005, 1; Ex. 1002 ¶ 83). As such, it would have been "obvious to improve Woehr by substituting one known element, a valve with a skirt, for another, a valve without a skirt, to hold the valve in place and improve its fluid obstruction capabilities, based on the knowledge and motivations in the art and the specific, known technique disclosed in Basta to improve a similar catheter insertion device." *Id.* at 23–24.

Petitioner contends Woehr teaches claim 4's requirement of "a second leg element spaced from the leg element for fluid." Pet. 31. Petitioner relies on Woehr's disclosure that element 10b "is formed by two plungers spaced apart" through which fluid may be supplied from the injector into the catheter. Ex. 1005, 2–3; Ex. 1002 ¶ 99.

5. Patent Owner's Argument

Patent Owner presents numerous arguments in contesting Petitioner's challenge. Prelim. Resp. 26–39. In particular, Patent Owner first argues that modifying Woehr's two-hub device to include a third hub, as disclosed by Callaway, would render Woehr inoperable for its intended purpose. *Id.* at

26–38. For example, Patent Owner alleges that Callaway's middle hub and its inner catheter are physically inseparable. *Id.* at 34.

Patent Owner also argues that Petitioner's reason for combining Woehr with Callaway is based on improper hindsight reconstruction. *Id.* at 38–40.

Patent Owner also contends that a person of ordinary skill in the art would not find it obvious to add "a skirt section" to Woehr. *Id.* at 53–58. Specifically, Patent Owner argues that the proposed rationale for modifying Woehr's valve to include a "skirt" based on Basta is nonsensical and faulty and adding a skirt section would degrade, not improve, Woehr's device. *Id.*

At this stage of the proceeding, we do not find Patent Owner's arguments persuasive, and instead determine that the information presented in the Petition establishes a reasonable likelihood that the Petitioner would prevail.

6. Analysis (claims 1 and 4)

With regards to Patent Owner's first argument, we are not persuaded that modifying Woehr to include a third hub would somehow render Woehr inoperable for its intended purpose. Patent Owner's arguments appear to be premised on the physical combinability of Woehr with Callaway. However, "it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). Rather, the relevant inquiry is whether the claimed subject matter would have been obvious to those of ordinary skill in the art in light of the combined teachings of those references. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Based on the record before us, we are persuaded that a person having ordinary skill in the art would have

modified Woehr to include a third hub, as taught by Callaway, for the purpose of further preventing unintended contact with Woehr's needle and any fluids remaining on the needle after removal. *See* Pet. 27–30.

Furthermore, Patent Owner's argument is based on the assertion that Callaway's principle of operation "requires two nested catheter hubs." Prelim. Resp. 29. We are not persuaded that Woehr's principle of operation requires two hubs. Rather, we find that Woehr's principle of operation is to provide a needle protecting element that prevents blood from discharging from the catheter after removal of a hollow needle. *See, e.g.*, Ex. 1005, 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"). At this stage of the proceeding, we are not persuaded that adding a third hub would render Woehr inoperable for its intended purpose of preventing blood discharge from the catheter.

Patent Owner also argues that Callaway's "third hub" 21 is physically inseparable from its catheter 20, and that the proposed combination would render *Callaway's device inoperable* and unsuitable for its intended purpose. Prelim. Resp. 35–38. Here, Patent Owner's argument is based on a misapplication of Petitioner's challenge. Petitioner does not propose to modify Callaway's device to remove its catheter, but instead proposes to modify Woehr's device to include a third hub that itself does not include Woehr's inseparable catheter. *See* Pet. 27–30. Accordingly, Patent Owner's argument is not responsive to Petitioner's ground of unpatentability.

With regards to Patent Owner's hindsight argument, we disagree with the assertion that Petitioner's combination of Woehr and Callaway is based

on impermissible hindsight. Prelim. Resp. 38–40. In the present case, Petitioner's reasoning does not rely only on knowledge gleaned from the '249 patent's disclosure. *See In re McLaughlin*, 443 F.2d 1392 1313–14 (CCPA 1971) ("Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and *does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper" (emphasis added)). As pointed out by Petitioner, Callaway expressly teaches the use of its "third hub" 21 in conjunction with a protective needle clip for the purpose of protecting users from the sharp needle tip. Pet. 28–29 (citing Ex. 1006 ¶ 61); *see also* Ex. 1006 ¶ 61 ("The clip and hub (21) protect users from the sharp tip of the needle (10)."). Accordingly, Petitioner's reasoning for modifying Woehr to add 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" is explicitly taught by Callaway and is articulately reasoned with some rational underpinning. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*, 550 U.S. at 418) ("rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

Based on the current record, we also do not find persuasive Patent Owner's contention that Petitioner's proposed rationale for modifying Woehr's valve to include a "skirt" based on Basta is faulty. *See* Prelim. Resp. 54–58. Patent Owner speculates that "[u]sing a skirt valve would

interfere with the ability of the actuator to fully insert into, and open, the valve" of Woehr. *Id.* at 57. Specifically, "[a]dding a skirt section to the distal side of valve (7) would make it difficult for the actuator (10) to open the valve (7) because the skirt material would interfere with the valve's flaps, restricting the flaps from opening." *Id.* Patent Owner's speculative design approach is parroted by Mr. Meyst, but no further technical explanation is provided as to why the skirt configuration would not allow the valve's slit to open normally. *See* Ex. 2001 ¶¶ 100–103; *see also* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Petitioner has presented persuasive evidence and testimony demonstrating that it would have been obvious to improve Woehr by substituting one known element, a valve with a skirt, for another, a valve without a skirt. Specifically, this would be done to hold the valve in place and improve its fluid obstruction capabilities, and such was a known technique disclosed in Basta to improve a similar catheter insertion device. *See* Ex. 1002 ¶ 83.

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner's asserted reasons for combining Woehr, Callaway, and Basta and Petitioner's showing that the proposed combination satisfies the limitations recited in independent claims 1 and 4, as well as teaching each claim as a whole. At this stage of the proceeding, Patent Owner has not challenged Petitioner's evidence with respect to claim 4, and we find Petitioner's evidence and argument for claim 4 persuasive on this record. *See* Pet. 31.

F. Obviousness of Claims 1 and 4 over Woehr, Basta, and Villa

Petitioner contends that claims 1 and 4 are unpatentable over Woehr, Basta, and Villa. Pet. 3, 32–38. For the reasons set forth below, Petitioner has shown a reasonable likelihood that these claims would have been obvious over Woehr, Basta, and Villa.

1. Villa (Ex. 1007)

Villa is a U.S. Patent Publication entitled "Protective Device for a Needle." Ex. 1007, [54]. To illustrate a particular embodiment of Villa's device, we reproduce Figure 7, below:

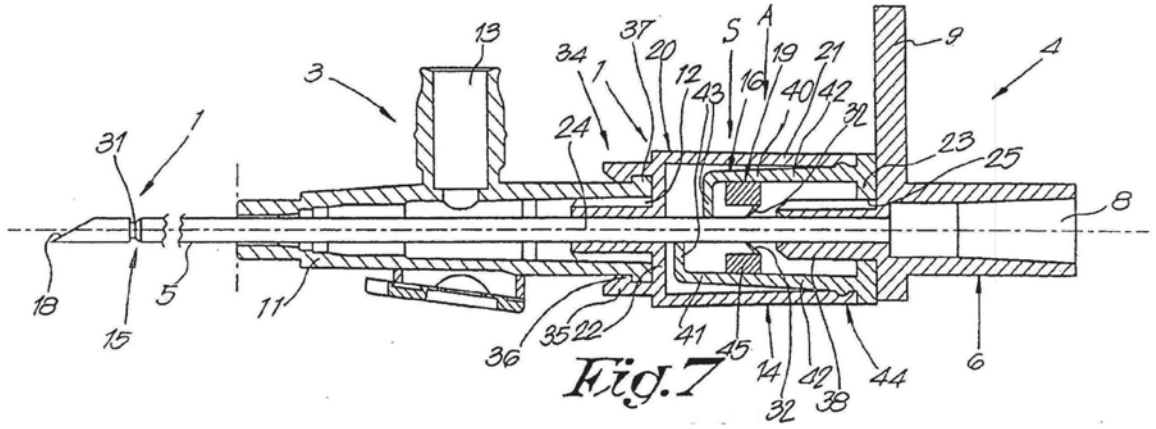


Fig. 7

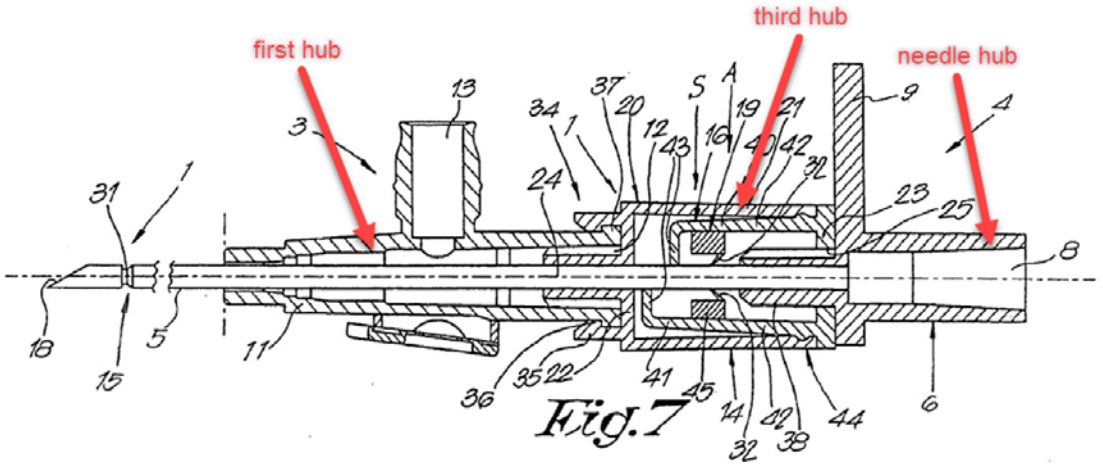
Figure 7 depicts a cross-sectional view of a cannula needle assembly with Villa's protective device. *See id.* ¶¶ 32, 38, 66. In particular, Figure 7 depicts protective device 1 with protective means 14, which slidably fits onto needle 5. *Id.* ¶ 45. Protective means 14 comprises safety means 16 and blocking means 19, which are preferably incorporated in housing 20, and which have openings 24, 25 for needle 5. *See id.* ¶¶ 46, 47. Housing 20 may include coupling means 34 at end wall 22, which allows for a releasable connection with the catheter hub. *Id.* ¶ 53. During passage from the non-operative state to the operative state, needle 5 slides through scraping means 33 to dry needle 5 from liquids that are adhered to needle 5, and the liquids

are retained in hollow body 20. *Id.* ¶ 63. Although hollow body 20 is not completely closed, the fluids retained in housing 20 by scraping means 33 "are practically completely held inside," even if needle 5 "were to undergo shocks or vibrations." *Id.*

2. Petitioner's Challenge (claims 1 and 4)

As with the prior ground based on Woehr and Callaway, Petitioner asserts that Woehr discloses a "catheter assembly" comprising the claimed "first hub," "second hub," "needle having a needle shaft," "valve," "valve opener," and "needle protective device." *See* Pet. 32–34 (incorporating by reference analysis based on Woehr with Basta and Callaway).

In addressing the claimed "third hub," Petitioner cites, *inter alia*, to Villa's Figure 7 (*see id.* at 35), a copy of which we reproduce below:



According to Petitioner, Figure 7 depicts Villa's "third hub" 20. *Id.* at 35. Petitioner asserts that "Villa discloses 'a protective device for a needle' that 'is intended to be used in combination with a catheter introducing needle . . . [and] discloses a 'hollow body or housing 20' that houses safety means 16 and blocking means 19." *Id.* at 36 (citing Ex. 1007 ¶¶ 1, 2, 47).

In combining Woehr with Villa, Petitioner reasons that a person having ordinary skill in the art would have found it obvious to modify Woehr by moving its spring clip into a third hub "based on the specific teaching in Villa that a housing for the protective means presents a number of advantages over the Woehr spring clip alone." *Id.* at 37. Petitioner further reasons that doing so would considerably reduce the risk of contact with a patient's bodily fluids or drugs on the needle, and would further prevent accidental pricking with the needle. *See id.* (citing Ex. 1007 ¶¶ 15, 80).

Petitioner relies on its previous analysis of Woehr discussed above to explain how the combination of references teach the limitations of claim 4. *See id.* at 38.

3. Patent Owner's Argument

Patent Owner argues that the proposed combination changes the principle of operation of each of these references and results in inoperability. *See* Prelim. Resp. 40–53. In particular, Patent Owner presents the following arguments:

> (1) Patent Owner argues that the Petitioner provides inadequate explanation as to how Woehr's needle guard element 13 is moved into Villa's housing without disrupting the housing's essential features (*id.* at 42–44);
>
> (2) Patent Owner argues that Petitioner's combination would render Villa's housing 20 inoperable and unsatisfactory for its intended purpose (*id.* at 45–50);
>
> (3) Patent Owner argues that the proposed combination would render Woehr's device inoperable and unsuitable for its intended purpose (*id.* at 50–53); and,
>
> (4) Patent Owner argues (as addressed above) that Petitioner's rationale for adding a "skirt" to Woehr based on Basta is nonsensical and faulty (*id.* at 54–57).

At this stage of the proceeding, we do not find Patent Owner's arguments persuasive, and instead determine that the information presented in the Petition establishes a reasonable likelihood that the Petitioner would prevail.

4. Analysis (claims 1 and 4)

With regards to Patent Owner's argument (1), at this stage, we are persuaded that Petitioner provides sufficient explanation as to how to move Woehr's needle guard element 13 into Villa's housing 20. As discussed above with the prior ground based on Woehr, Basta, and Callaway, Patent Owner's argument appears to be premised on the physical combinability of Woehr with Villa. However, "it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *Sneed*, 710 F.2d at 1550. Rather, the relevant inquiry is whether the claimed subject matter would have been obvious to those of ordinary skill in the art in light of the *combined teachings* of those references. *See Keller*, 642 F.2d at 425; *see also In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) ("Combining the *teachings* of references does not involve an ability to combine their specific structures."). Based on the record before us, and as Mr. Griffis testifies, we are persuaded that a person having ordinary skill in the art would have modified Woehr to include a third hub, as taught by Villa, and to place Woehr's needle guard element 13 into the third hub for the purpose further reducing the risk of contact with a patient's bodily fluids (or drugs) on Woehr's needle, and that the proposed modification would further prevent accidental pricking with the needle. *See* Pet. 37; Ex. 1002 ¶ 110.

With regards to Patent Owner's argument (2), we find it to be unresponsive to Petitioner's proposed combination. In particular, we are not persuaded that Petitioner's proposed combination would render Villa's housing 20 inoperable and unsatisfactory for its intended purpose (Prelim. Resp. 45–49), as Petitioner does not propose to modify Villa's housing—as Patent Owner's argument presumes—but rather proposes to modify Woehr by adding a third hub, as taught by Villa. *See* Pet. 36–37. Patent Owner's argument is also unpersuasive as it appears to be premised on the physical combinability of Woehr's and Villa's specific structures. *Nievelt*, 482 F.2d at 968.

In response to Patent Owner's third argument, at this stage of the proceeding, we find it unpersuasive. As discussed above, Patent Owner's argument focuses overly on the physical combinability of Villa's particular structure (Villa's housing 20) and Woehr's particular structure (Woehr's needle guard 13), overlooking the general teachings of Villa. *See, e.g.*, Prelim. Resp. 51 ("there is nothing in Villa's housing (20) to hold Woehr's needle guard (13) in place"); *see also, e.g., id.* at 52 ("[a]dding Villa's housing to Woehr's catheter hub would cause Woehr's actuator (10) to be pushed distally, activating Woehr's valve (7), never allowing the valve to close upon removal of the needle"). As explained above, "[c]ombining the teachings of references does not involve an ability to combine their specific structures." *Nievelt*, 482 F.2d at 968.

At this stage of the proceeding, we credit Mr. Griffis's testimony that "a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching of Woehr with those of Villa." Ex. 1002 ¶ 112.

Finally, for the reasons set forth above and based on the current record, we find unpersuasive Patent Owner's contention related to adding a skirt to Woehr. *See* Prelim. Resp. 53–58. We are also persuaded at this stage of the proceeding by Petitioner's asserted reasons for combining Woehr, Basta, and Villa, and Petitioner's showing that the proposed combination satisfies the limitations recited in claims 1 and 4, as well as teaching each claim as a whole.

G. Obviousness of Claims 1 and 4 over Woehr, Rogers, and Callaway

Petitioner contends that claims 1 and 4 are unpatentable over Woehr, Rogers, and Callaway. Pet. 39–44. For the reasons set forth below, Petitioner has shown a reasonable likelihood that these claims would have been obvious over Woehr, Rogers, and Callaway.

Petitioner incorporates its analysis from the Woehr, Basta, and Callaway combination contending that the combination of Woehr and Callaway teach the claimed "catheter assembly," "first hub," "a needle having a needle shaft," "a valve opener," "a needle protective device," and "a third hub." *Id.* at 39, 40, 43, 44. Petitioner substitutes Rogers for Basta in the prior combination and relies on Woehr and Basta to teach "a valve comprising a slit for obstructing fluid flow and a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first hub." *Id.* at 40. Because Petitioner's contentions with respect to Woehr and Callaway are repeated, as well as Patent Owner's arguments against this combination (Prelim. Resp. 26, 53), we address below only the arguments specific to Rogers.

1. Rogers (Ex. 1008)

Rogers is titled "Catheter Check Valve Assembly," and it discloses a catheter check valve assembly that prevents unintended back flow of body fluids through a catheter when a trocar is removed from the assembly. Ex. 1008, [54], 1:10–13; *see also* Ex. 1002 ¶ 73. Rogers discloses a duckbill valve that seals after an introducing trocar is removed. *Id.* at 2:22–25. The duckbill valve can be opened by a disclosed separator that has an elongated cylindrical probe that can open the slit of the duckbill valve when it is distally advanced. *Id.* at 2:25–31.

2. Analysis (claims 1 and 4)

Petitioner relies on Woehr and Rogers to teach "a valve comprising a slit for obstructing fluid flow and a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first hub." Pet. 40. According to Petitioner,

> Rogers discloses a valve (e.g., element 14) comprising a slit (e.g., element 48) for obstructing fluid flow and a skirt section (e.g., elements 50 and/or 49 and/or 47) positioned inside the interior cavity of the hub (e.g., elements 11 and 15) such that the skirt section contacts the interior cavity of the hub; said valve remaining inside the interior cavity when the needle (e.g., element 17) is removed from the catheter tube (e.g., element 16) and the first hub (e.g., elements 11, 15).

Id. at 40–41 (citing Ex. 1008, [57], 1, 3, 6, Claim 1; Ex. 1002 ¶ 119).

Relying on Mr. Griffis's testimony, Petitioner reasons that "[i]t would have been obvious for a POSA to combine the catheter insertion device of Woehr with a skirt section positioned inside the interior cavity of the hub, such as that disclosed in Rogers." *Id.* at 42 (citing Ex. 1002 ¶ 120). According to Petitioner, a person of ordinary skill in the art would have been

motivated to modify Woehr because Rogers's valve "prevents unintended back flow of body fluids through the catheter and that the skirt and ribs on the valve ensure that the valve remains closed." *Id.* (citing Ex. 1008, 6:13–18). Petitioner also contends improving Woehr by substituting one known element, a valve with a skirt, for another, a valve without a skirt, to hold the valve in place and improve its fluid obstruction capabilities, would have been obvious based on the teachings in Rogers in order to improve a similar catheter insertion device. *Id.* at 43.

Patent Owner challenges the combination of Woehr and Callaway on the basis that the combination would change the principle of operation of both references and result in their inoperability. Prelim. Resp. 26–40. For the reasons set forth above, we find these arguments unpersuasive.

Patent Owner also contends that a person of ordinary skill in the art would not have found it obvious to add "a skirt section" to Woehr. *Id.* at 53. With respect to Rogers, Patent Owner argues "Petitioner's proposed rationale for modifying Woehr's valve to include a 'skirt' based on Rogers is also nonsensical and faulty." *Id.* at 55. Patent Owner argues that Petitioner's rationale is not supported because "Woehr's valve already prevents unintended backflow, so Petitioner's asserted motivation is nonsensical." *Id.* at 56.

Based on the record before us, we are not convinced by Patent Owner's arguments. As discussed above, Patent Owner speculates that "[u]sing a skirt valve would interfere with the ability of the actuator to fully insert into, and open, the valve" of Woehr. *Id.* at 57. Petitioner, however, has presented persuasive evidence and testimony demonstrating that it would

have been obvious to improve Woehr by substituting one known element, a valve with a skirt, for another, a valve without a skirt. *See* Ex. 1002 ¶ 120.

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner's asserted reasons for combining Woehr, Rogers, and Callaway, and Petitioner's showing that the proposed combination satisfies the limitations recited in independent claims 1 and 4. At this stage of the proceeding, Patent Owner has not challenged Petitioner's evidence with respect to claim 4, and we find Petitioner's evidence and argument for claim 4 persuasive on this record. *See* Pet. 43.

H. Obviousness of Claims 1 and 4 over Woehr, Rogers, and Villa

Petitioner contends that claims 1 and 4 are unpatentable over Woehr, Rogers, and Villa. Pet. 44–45. For the reasons set forth below, Petitioner has shown a reasonable likelihood that these claims would have been obvious over Woehr, Rogers, and Villa.

Petitioner incorporates its analysis from the combination of references discussed above. For example, Petitioner contends that Woehr teaches the claimed "catheter assembly," "first hub," "a needle having a needle shaft," "a valve opener," "a needle protective device," and "a third hub." Pet. 44–45. Petitioner relies on Woehr and Rogers to teach "a valve comprising a slit for obstructing fluid flow and a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first hub." *Id.* at 44 (incorporating the analysis from *id.* at 40–43). Petitioner contends that Woehr and Villa teach the claimed "a third hub." *Id.* at 45 (incorporating the analysis from *id.* at 34–38). Petitioner's rationales for combining both Rogers and Villa with Woehr are set forth above.

Patent Owner challenges the combination of Woehr, Rogers, and Villa for the same reasons previously addressed. Specifically, Patent Owner challenges the combination of Woehr and Villa on the basis that such a combination would change the principle of operation of each reference and result in their inoperability. Prelim. Resp. 40. As addressed above, Patent Owner also contends that Petitioner's proposed rationale for modifying Woehr's valve to include a "skirt" based on Rogers is nonsensical and faulty. *Id.* at 55.

Based on the record before us, we are not convinced by Patent Owner's arguments. Each of these contentions was addressed in turn above. For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner's asserted reasons for combining Woehr, Rogers, and Villa, and Petitioner's showing that the proposed combination satisfies the limitations recited in independent claims 1 and 4. At this stage of the proceeding, Patent Owner has not challenged Petitioner's evidence with respect to claim 4, and we find Petitioner's evidence and argument for claim 4 persuasive on this record. *See* Pet. 45.

III. SUMMARY

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail on the alleged grounds of unpatentability with respect to each of claims1 and 4 of the '249 patent. The Board has not made a final determination on the patentability of any challenged claims.

IV. ORDER

For the reasons given, it is

ORDERED that *inter partes* review of the '249 patent is hereby instituted as to claims 1 and 4 on the ground that claims 1 and 4 are obvious over Woehr, Basta, and Callaway;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1 and 4 of the '249 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Basta, and Villa;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1 and 4 of the '249 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Rogers, and Callaway;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1 and 4 of the '249 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Rogers, and Villa;

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

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

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