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

PETITIONER'S NOTICE OF APPEAL

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
P.O. Box 1450
Alexandria, VA 22314-5793

Pursuant to 35 U.S.C. §§ 141-44 and 319, and 37 C.F.R. § 90.2-90.3, notice is hereby given that Petitioner Becton, Dickinson and Company appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered December 12, 2018 (Paper 70) in IPR2017-01590 (Exhibit A), and all prior and interlocutory rulings related thereto or subsumed therein.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner further indicates that the issues on appeal include, but are not limited to, whether the Patent Trial and Appeal Board erred in its claim construction of the term "safety device" as recited in U.S. Patent No. 9,370,641 and/or in Patent Owner's proposed substitute claims; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that claims 15, 17, 18, 20, and 22 of U.S. Patent No. 9,370,641 are unpatentable under 35 U.S.C. § 103 over the combination of Woehr and Callaway; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that proposed substitute and amended claims of U.S. Patent No. 9,370,641 fail to satisfy the written description and enablement requirements of 35 U.S.C. § 112; whether the Patent Trial and Appeal Board erred in determining that

Patent Owner's proposed substitute claims meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that proposed amended claim 31 unpatentable over the combination of Woehr, Villa, and Nakajima; whether the Patent Trial and Appeal Board erred in granting Patent Owner's Motion to Amend with respect to proposed substitute claims 32 and 33; whether the Patent Trial and Appeal Board erred in granting Patent Owner's Motion to Amend with respect to proposed amendments to claims 20, 21, and 23; whether the Patent Trial and Appeal Board erred in granting Owner's Motion to Amend with respect to claims 19, 22, and 24, whereby claims 19, 22, and 24 only depend from claim 32; and any finding or determination supporting or related to those issues, as well as all other issues decided adversely to Petitioner in the Final Written Decision and any prior and interlocutory orders, decisions, rulings, and opinions.

Pursuant to 37 C.F.R. § 90.3, this Notice of Appeal is timely, having been duly filed within 63 days after the date of the Final Written Decision.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), a copy of this Notice of Appeal is being filed simultaneously with the Patent Trial and Appeal Board, the Clerk's Office for the United States Court of Appeals for the Federal Circuit, and the Director of the Patent and Trademark Office.

Dated: February 8, 2019

Respectfully submitted,

/Heather M. Petruzzi/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 90.2(a)(1) and 104.2(a), I hereby certify that, in addition to being filed electronically through the Patent Trial and Appeal Board's End to End (PTAB E2E), a true and correct original version of the foregoing PETITIONER'S NOTICE OF APPEAL is being filed by Express Mail (Express Mail Label EK 703738766 US) on this 8th day of February 2019, with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 90.2(a)(2) and Federal Circuit Rule 15(a)(1), and Rule 52(a), (e), I hereby certify that a true and correct copy of the foregoing PETITIONER'S NOTICE OF APPEAL is being filed in the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF filing system on this day, February 8, 2019, and the filing fee is being paid electronically using pay.gov.

I hereby certify that on February 8, 2019 I caused a true and correct copy of the PETITIONER'S NOTICE OF APPEAL to be served via e-mail on the following attorneys of record:

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EXHIBIT A

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Paper No. 70
Filed: December 28, 1018

NON-PUBLIC VERSION - BOARD AND PARTIES ONLY

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 IPR2017-01590
Patent 9,370,641 B2

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

Opinion Concurring by *Administrative Patent Judge* DANIELS.

WOODS, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

ORDER ADDRESSING MOTION TO AMEND
37 C.F.R. § 42.121

I. INTRODUCTION

Becton, Dickinson and Company ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting *inter partes* review of claims 15, 17, 18, 20, and 22 of U.S. Patent No. 9,370,641 B2 ("the '641 patent"). Pet. 1. We issued a Decision to Institute an *inter partes* review of the challenged claims of the '641 patent under all grounds. Paper 8, 28 ("Decision to Institute").

After institution of trial, B. Braun Melsungen AG ("Patent Owner") filed a Patent Owner Response (Paper 21, "PO Resp."), to which Petitioner replied (Paper 41, "Pet. Reply"). Patent Owner also filed a Sur-Reply (Paper 42, "PO Sur-Reply #1"), to which Petitioner filed a Petitioner's Sur-Reply Response (Paper 45, "Pet. Sur-Reply"), and to which Patent Owner replied (Paper 51, "PO Sur-Reply #2").

Patent Owner also filed a Motion to Amend (Paper 22, "Amend Mot."), to which Petitioner opposed (Paper 39, "Amend Opp."), which Patent Owner replied (Paper 40, "PO Amend Reply"), and to which Petitioner filed a sur-reply (Paper 52, "Pet. Amend Sur-Reply").

Oral argument was conducted on September 21, 2018, and the transcript of the hearing has been entered as Paper 68.

We have jurisdiction under 35 U.S.C. § 318(a). After considering the evidence and arguments of both parties, and for the reasons set forth below, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 15, 17, 18, 20, and 22 of the '641 patent are unpatentable.

We grant in part Patent Owner's Motion to Amend. In particular, we grant Patent Owner's proposed amendments to claims 20, 21, and 23 and proposed substitute claims 32 and 33. We deny Patent Owner's proposed

amendment to claim 31, but grant proposed amendment to claims 19, 22, and 24 such that these three claims shall depend from claim 32, only. We also grant Patent Owner's proposed amendment to cancel claim 16.

A. Related Proceedings

Petitioner represents that the '641 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. Petitioner also represents that petitions for *inter partes* review were filed challenging related patents U.S. Patent Nos.: 8,328,762 B2; 8,337,463 B2; 8,540,728 B2; 9,149,626 B2; 8,597,249 B2; 8,333,735 B2; and 8,460,247 B2. *Id.* Below is a chart that associates the *inter partes* reviews with each patent:

IPR Number	Patent Number
IPR2017-01583	8,333,735 B2
IPR2017-01584	8,540,728 B2
IPR2017-01585	8,337,463 B2
IPR2017-01586	8,328,762 B2
IPR2017-01587	9,149,626 B2
IPR2017-01588	8,460,247 B2
IPR2017-01589	8,597,249 B2
IPR2017-01590	9,370,641 B2

We declined to institute review in IPR2017-01583, IPR2017-01584, and IPR2017-01585. We instituted review, however, in the other listed *inter partes* reviews.

B. The '641 Patent (Ex. 1001)

The '641 patent, titled "**CATHETER ASSEMBLY AND COMPONENTS THEREOF**," discloses catheter assemblies having a "tip protector, a valve, a valve opener, and optionally a needle wiper." Ex. 1001, (54), (57). The '641 patent 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 1:38–46. The '641 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 1:57–60.

To illustrate a particular embodiment of the '641 patent's catheter insertion device, we reproduce Figures 13 and 14 of the '641 patent, below:

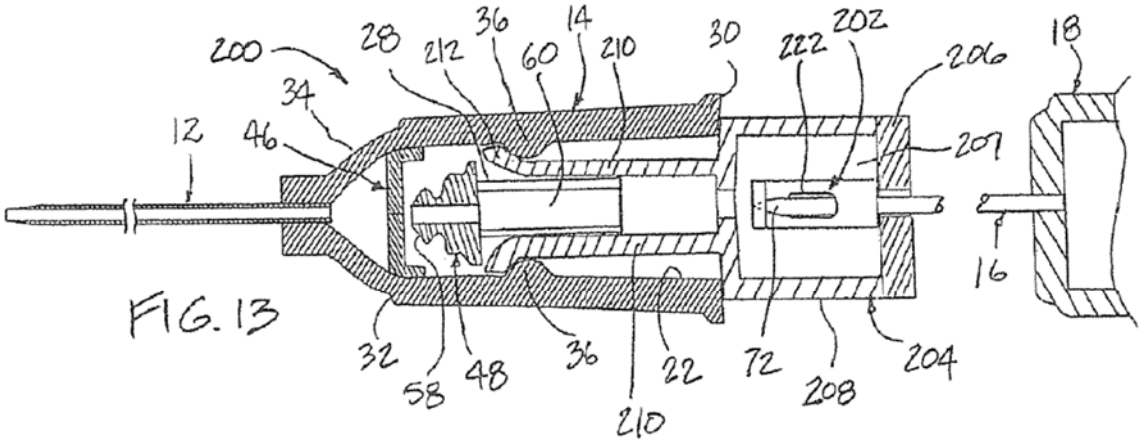


FIG. 13

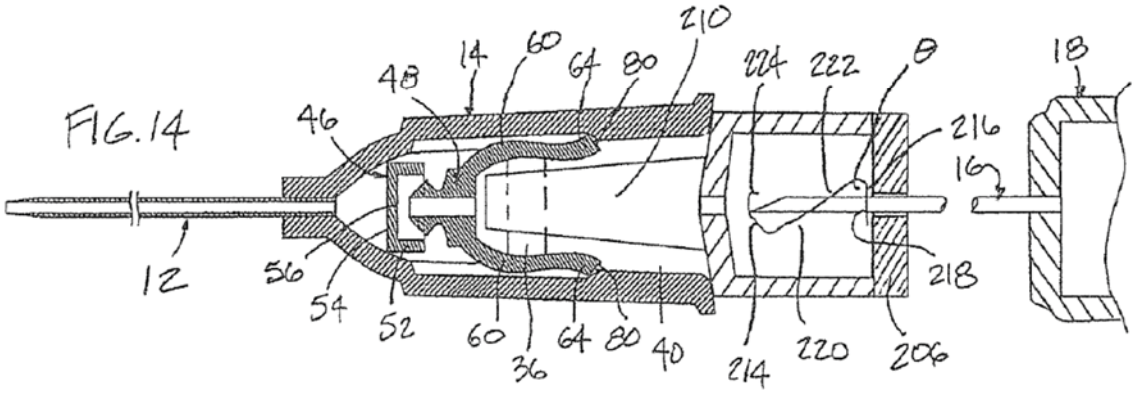


FIG. 14

Figures 13 and 14 above depict a particular embodiment of Patent Owner's catheter assembly with a *third housing 204* positioned between the catheter and needle hubs. *Id.* at 4:41–46. Figure 14 "is a cross-sectional side view" of Figure 13's catheter assembly "taken along an orthogonal plane." *Id.* at 4:45–46. 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 11:13–24. Valve opener 48 comprises a pair of legs 60 positioned in corresponding channels 28. In this particular embodiment, third housing 204 is provided to "accommodat[e] the tip protector." *See id.* at 11:25–27. Third housing 204 incorporates pair of arms 210, each of which comprises hook 212. *Id.* at

11:41–42. 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 11:42–44. 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 7:13–16.

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 11:53–56. 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 bear on rear plate 206 of third housing 204, which then disengages hooks 212 from two bumps 36. *Id.* at 11:56–61. With third housing 204 disengaged from catheter hub 14, 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 11:53–64, Figs. 13, 14.

C. Illustrative Claim

Of the challenged claims, claim 15 is independent. Each of dependent claims 17, 18, 20, and 22 depend directly from claim 15. *Id.* at 5:1–8:28. Claim 15 illustrates the claimed subject matter and is reproduced below, with emphasis added to a particular limitation discussed in this Decision:

> 15. A safety catheter assembly comprising:
>
> 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;

> 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;
>
> a valve for limiting fluid flow and a valve opener in cooperative arrangement therewith positioned in the interior cavity of the catheter hub;
>
> *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*; and
>
> 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.

Id. at 13:55–14:8 (emphasis added).

D. References Relied Upon

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

Name	Reference	Ex. No.
Woehr[1]	PCT WO 2004/004819 A1, published Jan. 15, 2004	Exs. 1003, 1005
Callaway	US 2006/0178635 A1, published Aug. 10, 2006	Ex. 1004
Villa	US 2004/0225260 A1, published Nov. 11, 2004	Ex. 1006

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

E. Alleged Grounds of Unpatentability

This proceeding includes the following grounds:

References	Basis	Claim(s)
Woehr and Callaway	§ 103(a)	15, 17, 18, 20, and 22
Woehr and Villa	§ 103(a)	15, 17, 18, 20, and 22

Paper 8, 28.

Petitioner also relies on the declaration testimony of Jack Griffis, III (Exs. 1002, 1064) and Marty Stout (Ex. 1065). Patent Owner relies on the declaration testimony of Richard Meyst (Exs. 2001, 2028).

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) (2017); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach).[2] Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the

[2] On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. *See* CHANGES TO THE CLAIM CONSTRUCTION STANDARD FOR INTERPRETING CLAIMS IN TRIAL PROCEEDINGS BEFORE THE PATENT TRIAL AND APPEAL BOARD, 83 Fed. Reg. 51340 (Oct. 11, 2018). This rule change, however, applies to petitions filed after November 13, 2018, and does not apply to this proceeding. *Id*.

art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In our Decision to Institute, we determined that the only term that required construction for purposes of that decision was "safety device." Paper 8, 9–11. In that Decision, we construed "safety device" to mean "a device for preventing accidental needle sticks by protecting the needle tip." *Id.* at 11.

Petitioner disagrees with our construction of "safety device," and argues that "safety device" is a "purely functional phrase" and we have provided a "purely functional interpretation." Pet. Reply 2–3. Petitioner acknowledges, however, that Woehr discloses a "safety device" whether the term is construed as a means-plus-function term or not. *See* Pet. Reply 3 n.1 ("The cited prior art reference, Woehr (Ex. 1003, Ex. 1005)[,] discloses a 'safety device' under any of the proposed claim constructions").

Patent Owner, on the other hand, does not dispute the construction of "safety device" from our Decision to Institute (PO Resp. 3), but "clarifies" that the term is "a device for preventing accidental needle sticks by protecting ***a user from*** the needle tip" (*id.*).

We conclude that the safety device limitation recites sufficient structure and should not be construed as a means-plus-function term. As explained in greater detail, below, we maintain the construction of the term "safety device" as explained in our Decision to Institute.

1. "safety device"

Independent claim 15 and dependent claim 20 each recites a "safety

device." Ex. 1001, 14:1, 25. Petitioner contends the term "safety device" invokes 35 U.S.C. § 112, sixth paragraph, and that it should be construed as a means-plus-function limitation. Pet. 10–16; Pet. Reply 2–6. 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'" (Pet. 12 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc)) and further contends that "the modifier 'safety' does not impart any structure to the term 'device'" (*id.*)). Petitioner's argument is supported by the Declaration of Mr. Griffis, who testifies that "[t]he 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." *Id.* at 12–13 (citing Ex. 1002 ¶¶ 54–56) (internal citations omitted).

We are not convinced that the safety 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, sixth paragraph, and Petitioner has not overcome this presumption.

As explained in our Decision to Institute, the challenged claims do not merely recite a "safety device." Paper 8, 9–11. Rather, independent claim 15 requires the "safety device" "cover[s] the needle tip [and] compris[es] a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub." Ex. 1001, 13:55–14:8. Dependent claim 20 recites further that the "safety device" "comprises a resilient portion made from a metal material[, i.e., a tip protector,] and the tip protector housing surrounding the resilient portion." *Id.* at 14:24–27. These structural

recitations provide definite scope as to the components comprising the device confirming that § 112, sixth paragraph, does not apply. *Inventio AG v. ThyssenKrupp Elevator Am. Corp*., 649 F.3d 1350, 1359 (Fed. Cir. 2011) (finding sufficient structure when claims "delineate the components that the . . . device is connected to, describe how the . . . device interacts with those components, and describe the . . . [function] that the . . . device performs"); *see also Williamson, LLC*, 792 F.3d at 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.'").

As to Patent Owner's "clarification" that the "safety device" is "a device for preventing accidental needle sticks by protecting ***a user from*** the needle tip," we are not persuaded. PO Resp. 3. Patent Owner does not explain who the "user" is and we do not know if the user is limited to the medical technician inserting the needle into the patient. Patent Owner also fails to explain why the claim should be construed to protect only users, rather than all medical professionals who may come into contact with the safety device, and long after the needle is removed from the patient. *See id.* To the contrary, the Specification provides that "all needles should be covered immediately following use to ensure *greater worker safety*." Ex. 1001, 1:57–58 (emphasis added). Patent Owner's proposed construction that only "users" are protected, rather than a larger subset of workers, is not supported by the explicit claim language and is seemingly inconsistent with

the Specification. Accordingly, we do not agree with Patent Owner's further "clarification."

Accordingly, the term "safety device" should not be construed under §112, sixth paragraph, and should not be construed to protect only "users." Instead, the term "safety device," as recited in the challenged claims, means a device for preventing accidental needle sticks by protecting the needle tip, and that the device comprises a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub.[3] Ex. 1001, 13:55–14:8.

2. Other Claim Terms

We determine that no other claim term requires express construction for the purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fec. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy'") (internal quotation marks omitted).

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

[3] We agree with Petitioner, however, that whether the term is construed as a means-plus function term does not impact the outcome of this Decision. *See* Pet. Reply 3 n. 1 (acknowledging that "Woehr . . . discloses a 'safety device' under any of the proposed claim constructions.").

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) (internal quotation marks and citation omitted). 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).

Furthermore, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* It is not enough to show that a POSITA *could* have combined the prior art without explaining why a POSITA *would* have made the combination. *See Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (finding that a skilled artisan would have understood that prior art could be combined insufficient; "it does not imply a motivation to pick out those two references and combine them to arrive at the claimed invention"). Additionally,

> [i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

In re Wesslau, 353 F.2d 238, 241 (CCPA 1965).

"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 our Decision to Institute, we determined the level or ordinary skill in the pertinent art at the time of the invention. Paper 8, 12–13.

Neither Patent Owner nor Petitioner dispute our initial determination of a person having ordinary skill in the art ("POSITA"), and we see no reason to revisit it here. *See*, *generally*, PO Resp.; *see also*, *generally*, Pet. Reply.

Accordingly, and as explained in our Decision to Institute, we determine that a POSITA would include 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. Paper 8, 12–13.

D. Woehr and Callaway

Petitioner contends that claims 15, 17, 18, 20, and 22 are unpatentable over Woehr and Callaway. Pet. 2–3. Claims 17, 18, 20, and 22 depend from independent claim 15. Ex. 1001, 13:55–14:34.

1. Woehr (Exs. 1003, 1005)[4]

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:

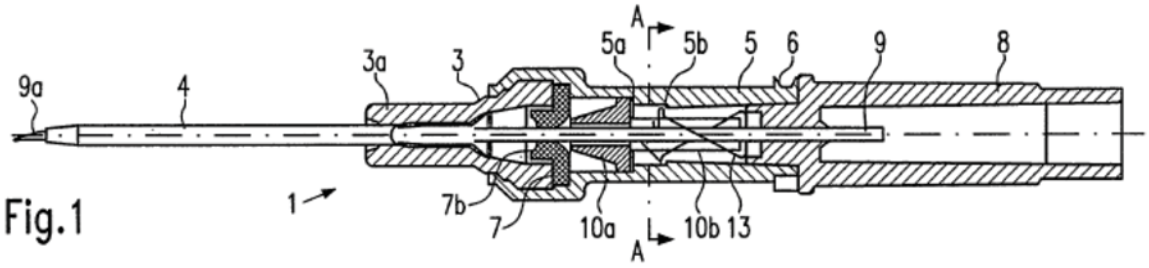


Fig.1

Woehr describes Figure 1 above 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:

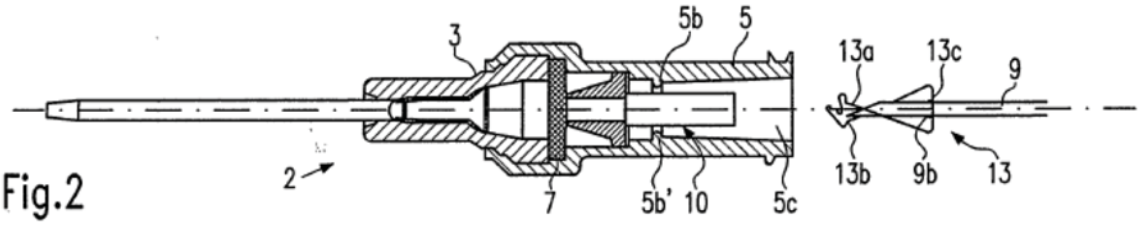


Fig.2

[4] *See supra* n.1.

Woehr describes Figure 2 above 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:

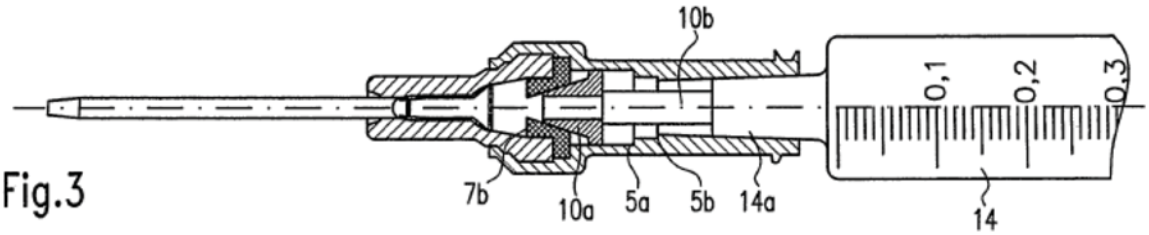
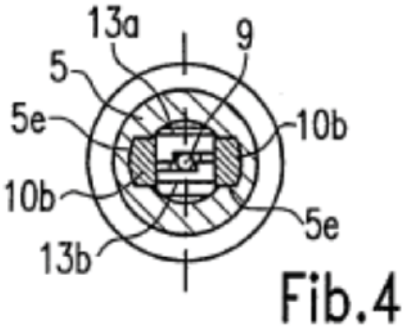


Fig.3

Woehr describes Figure 3 above as depicting insertion of injection 14 into Woehr's catheter hub, with neck section 14a of injection 14 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

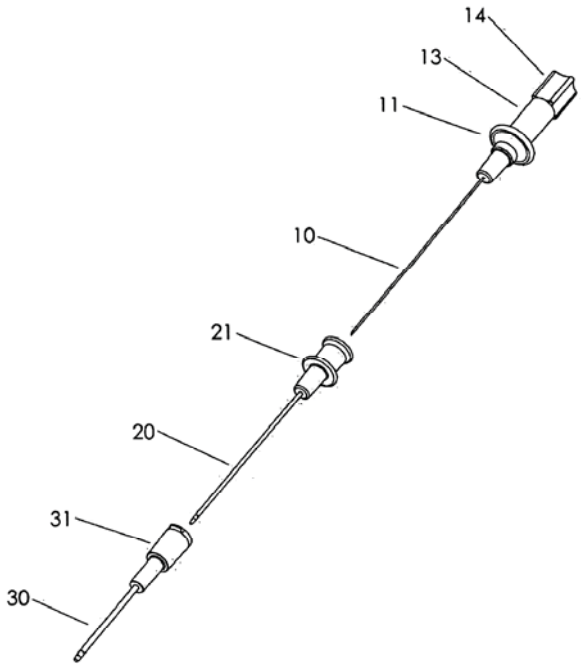
Woehr describes Figure 4 above as depicting a side view along line A–A of Figure 1. *Id.* at 1. In particular, Figure 4 depicts two plungers 10b of valve actuating element 10 as being guided in longitudinal grooves 5e of hub element 5, such that plungers 10b form a contact surface for neck section 14a 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. Callaway (Ex. 1004)

Callaway is a U.S. Patent Publication titled "**EASY ENTRY CATHETERS**." Ex. 1004, (54). Callaway depicts and describes *at least three embodiments*: (1) the embodiment of Figures 1–8 (*see id.* ¶¶ 33–40); (2) the embodiment of Figure 9 with the needle safety device disclosed in Woehr-630, but further comprising "a clip within the hub of the inner catheter (*see id.* ¶ 41; *see also id.* ¶ 61 (describing Figure 9 as "show[ing] the catheter assembly with a needle safety device disclosed in . . . [Woehr-630]"); and (3) the embodiment of Figures 10–16, or the "second type of needle device" (*see id.* ¶¶ 42–48; *see also id.* ¶ 62 (describing Figures 10–16 as depicting a

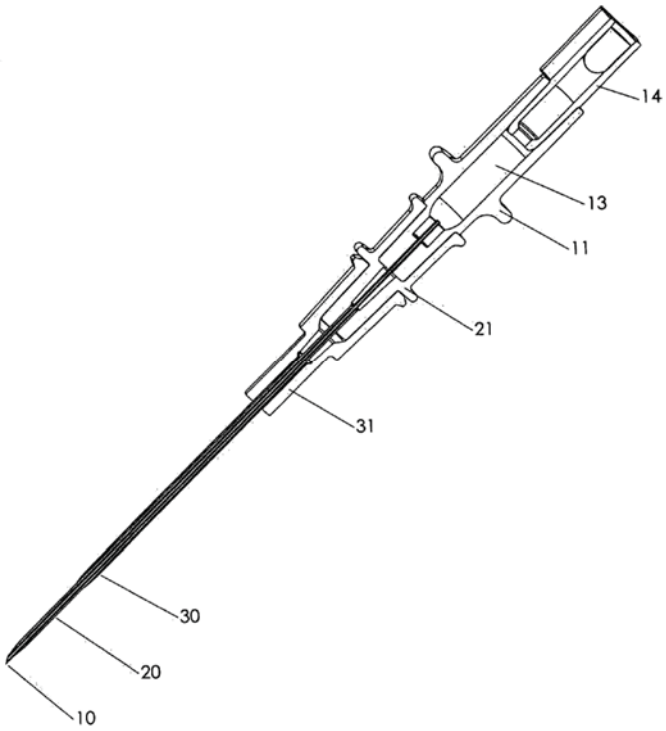
catheter assembly with the needle safety system disclosed in U.S. Patent Nos. 5,000,740 and 5,092,845)).

To illustrate the *first embodiment* of Callaway's catheter, we reproduce Figure 5, below:



Callaway describes Figure 5 above 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 small catheter 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.*

Figure 3, reproduced below, depicts a cross-sectional view of Callaway's catheter insertion assembly (*id.* ¶ 35):



Callaway describes Figure 3 above (along with Figures 1, 2, and 4) as depicting proximal hub 11 attached to hollow needle 10, which extends beyond the distal ends of catheters 20, 30. *Id.* ¶ 53. Middle hub 21 is attached to inner catheter 20, which is shorter than needle 10, but longer than outer catheter 30. *Id.* Distal hub 31 is attached to outer catheter 30 and inner hub 21 has fittings that engage with and attach to standard intravenous tubing. *Id.* Callaway further discloses that "[t]he hubs fit together with slight friction which *prevents unintentional separation*." *Id.* ¶ 55 (emphasis added).

We reproduce Callaway's *second embodiment*, shown in Figure 9, alongside one of Callaway's first embodiment views, shown in Figure 6, below:

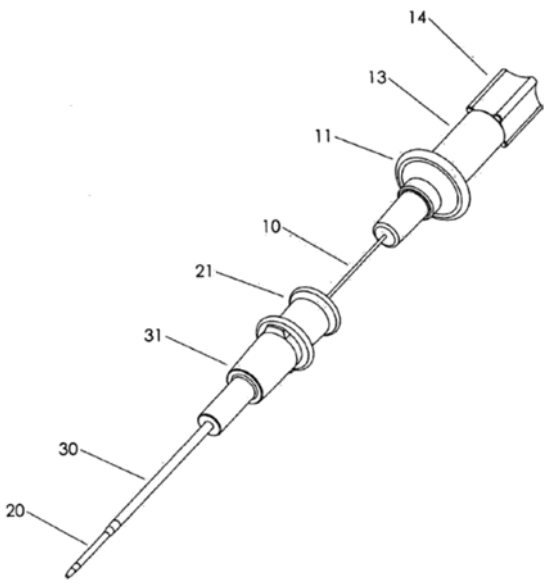


Figure 6

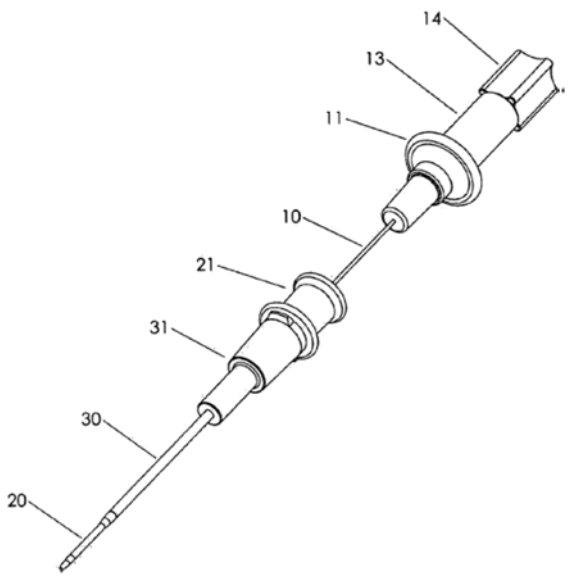


Figure 9

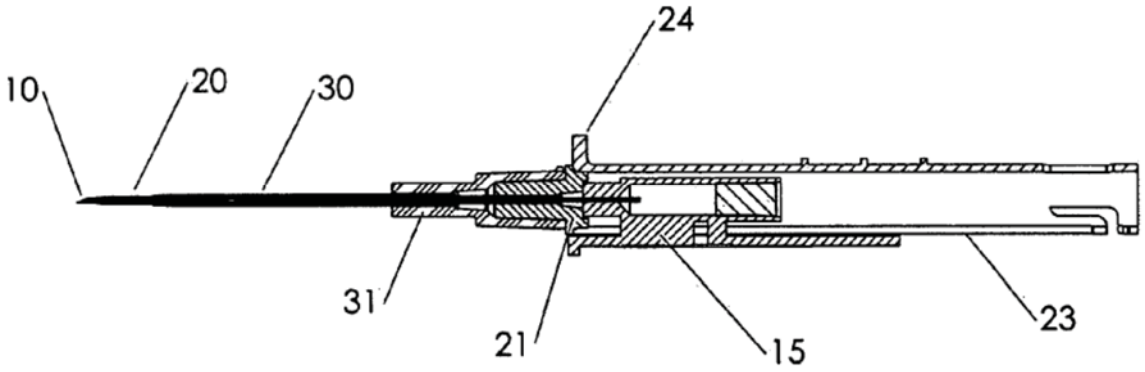
Callaway's first embodiment, Figure 6 (above left side), and second embodiment, Figure 9 (above right side), are reproduced above. As can be seen, Figure 6 is identical to Figure 9 and neither figure depicts a needle safety device, despite Callaway's express disclosure that Figure 9 "depicts a catheter assembly with one type of needle safety device comprised of a clip within the hub of the inner catheter which captures the end of the needle as it is withdrawn from the inner catheter." *Id.* ¶ 41; *see also* Ex. 2028 ¶ 61 ("FIG. 9 is also supposed to illustrate the integration of the Callaway device with a spring clip, but it does not actually show a spring clip."). Callaway further describes:

> **FIG. 9** shows the catheter assembly with a needle safety device disclosed in . . . [Woehr-630], hereby incorporated by reference in the entirety. **FIG. 9** illustrates how the catheter assembly could be integrated with an existing needle protection device. In **FIG. 9** the catheters (**20** and **30**) and their hubs (**21** and

> **31**) have been partially advanced off the needle (**10**). 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**). In one version, the needle (**10**) and attached clip could be withdrawn from the hub (**21**). In the preferred version, the inner catheter (**20**), its hub (**21**) and the needle (**10**) remain attached together and are discarded together in a safe manner.*

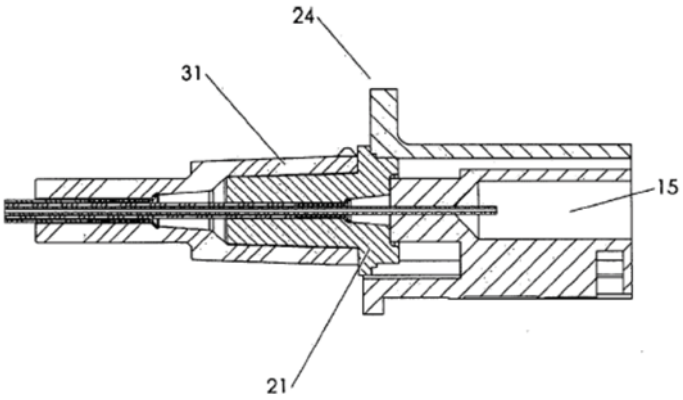
Ex. 1004 ¶ 61 (emphasis added). Notably, Callaway's Figure 9 embodiment itself describes two versions: "one version" in which "the needle (**10**) *and attached clip* could be withdrawn from . . . hub (**21**)"; and a "preferred version," which *does not reference a safety clip*, but discloses that "the inner catheter (**20**), its hub (**21**) and the needle (**10**) remain attached together and are discarded together in a safe manner." *Id.* (emphasis added).

Callaway also discloses a *third embodiment* in Figures 10 through 16, which together "illustrate how the catheter assembly could be integrated with an existing needle protection device [of U.S. Patent Nos. 5,000,740 and 5,092,845]." *Id.* ¶ 62. Patent Owner references this third embodiment as the "*Critikon version*," and for consistency of references, we adopt it here. *See* Ex. 2028 ¶ 60 (explaining that Critikon was the original assignee of the patents referred to in this embodiment). Unlike Callaway's second embodiment (shown in Figure 9), however, Callaway actually depicts a needle protection device in the Critikon embodiment, including in Figure 13, reproduced below:



As described in Callaway, Figure 13 depicts above "a cross section view of a catheter insertion assembly with a needle safety device, prior to use." *Id.* ¶ 45. In particular, this figure (along with Figures 10–12 and 14–16) depicts needle 10 attached to flash chamber 15, which has finger-grip extensions 16 (numbered in Figure 10) with texturing for handling. *Id.* ¶ 62. Inner catheter 20 is attached by tapered hub 21 to an elongated cylindrical needle guard 23, which is clear to allow visualization of flash chamber 15. *Id.* In use, needle 10 is advanced until it enters a blood vessel and blood is seen in flash chamber 15. *Id.* In operation, a user holds flash chamber extensions 16 in a fixed position, while pushing on flange 24 of cylinder 23 to advance inner catheter 20 and outer catheter 30 together, and catheters 20, 30 are then advanced together off needle 10 and into the lumen of the blood vessel. *Id.* As cylinder 23 and catheters 20, 30 are advanced, cylinder 23 contains needle 10. *Id.* When catheters 20, 30 are fully advanced off needle 10, flash chamber 15 and cylinder 23 snap into a locked configuration that contains needle tip 12 within hub 21 of inner catheter 20, needle shaft 10, and a portion of flash chamber 15. *Id.*

We further reproduce Figure 14 of Callaway, below:



According to Callaway, Figure 14 above depicts a sectional detail view of the middle hub of a catheter assembly with a safety device demonstrating that the middle hub 21 has been cemented or joined with cylindrical needle guard 23. *Id.* ¶¶ 46, 67.

We further reproduce Callaway's Figure 15, below:

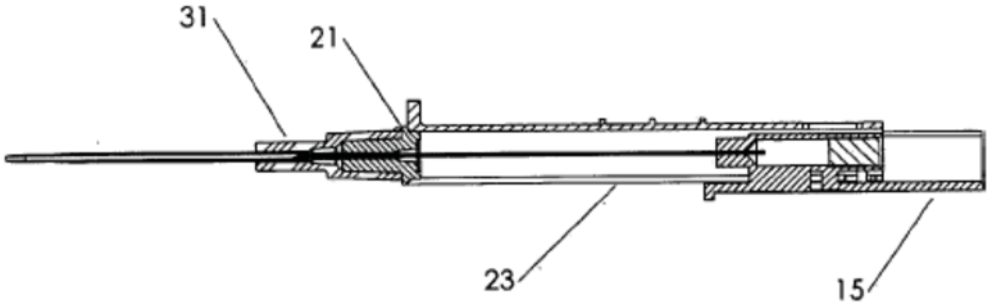
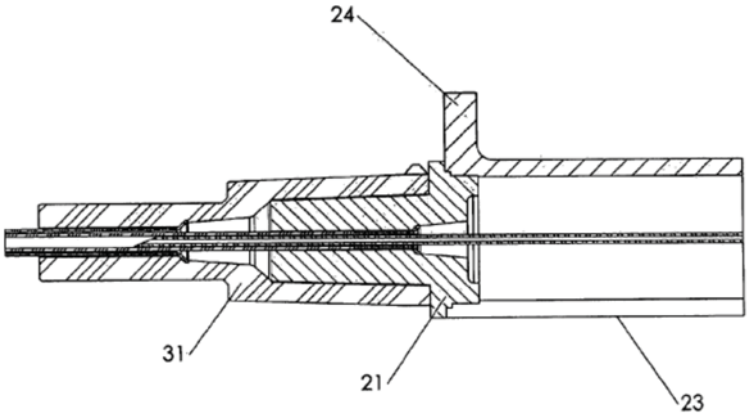


Figure 15 above depicts "a section[ed] view of a catheter assembly with a safety device with the needle in a protected position within the cylindrical needle guard." *Id.* ¶ 47. In particular, Figure 15 depicts catheter assembly with a needle safety device in the "safe" position, with middle hub 21 and clear cylindrical needle guard 23 "contain[ing] the needle and some of" flash chamber 15 after catheters 20, 30 have been deployed off the needle. *Id.*

¶ 68. We find that needle guard 23 and inner hub 21 together form the "safety device" referenced in Callaway. *See id.*; *see also* Ex. 2028 ¶ 86 ("Callaway's Critikon version, then, involves a needle moving into a safety device – needle guard cylinder 23 and inner catheter hub (21)").

We further reproduce Callaway's Figure 16, below:



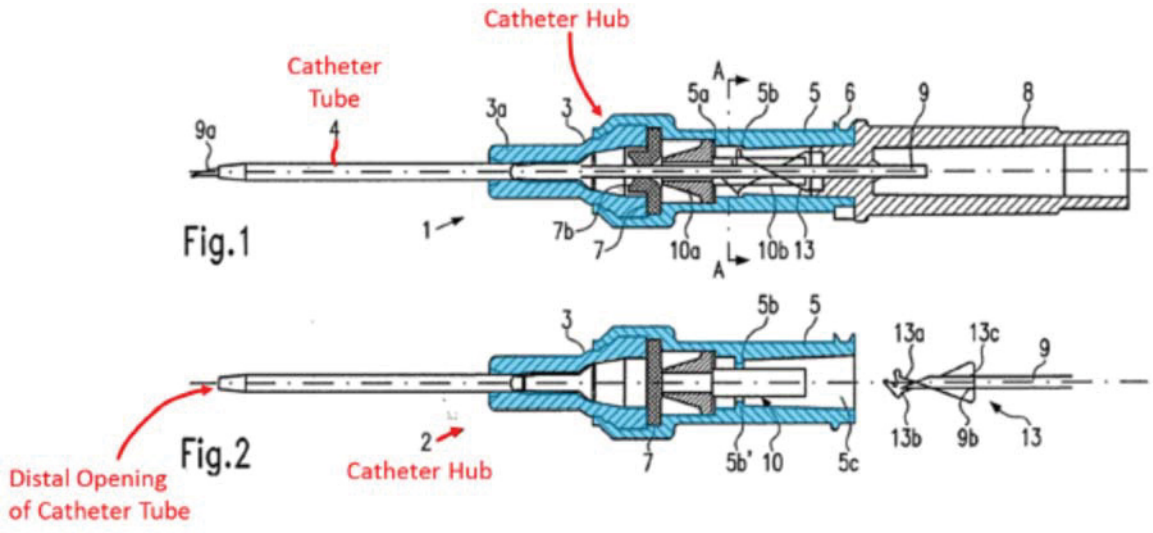
Callaway describes Figure 16 above as depicting "the middle hub of a catheter assembly with a safety device demonstrating how the needle tip is contained within the hub of the inner catheter when the assembly is in the protected position." *Id.* ¶ 48. In particular, Figure 16 depicts needle safety device in a "safe" position and shows how the tip of the needle is contained within the middle hub 21 after flash chamber 15 has been snapped into the "safe position" relative to clear cylindrical needle guard 23. *Id.* ¶ 69.

3. Petitioner's Challenge

Petitioner contends that claims 15, 17, 18, 20, and 22 are unpatentable over Woehr and Callaway. Pet. 2–3. Claims 17, 18, 20, and 22 depend from independent claim 15. Ex. 1001, 13:55–14:34. As such, our analysis begins with Petitioner's challenge of independent claim 15.

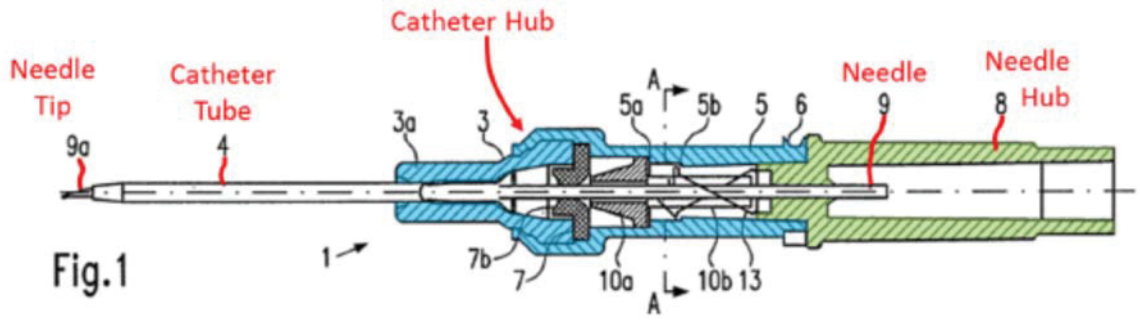
In challenging independent claim 15, Petitioner argues that Woehr discloses "[a] safety catheter assembly" comprising several of the claimed elements, and submits several annotated figures to illustrate these findings. *See* Pet. 19–26.

To address the claimed "catheter hub comprising a housing . . . ," Petitioner submits an annotated version of Woehr's Figures 1 and 2 (*id.* at 21), which we reproduce, below:



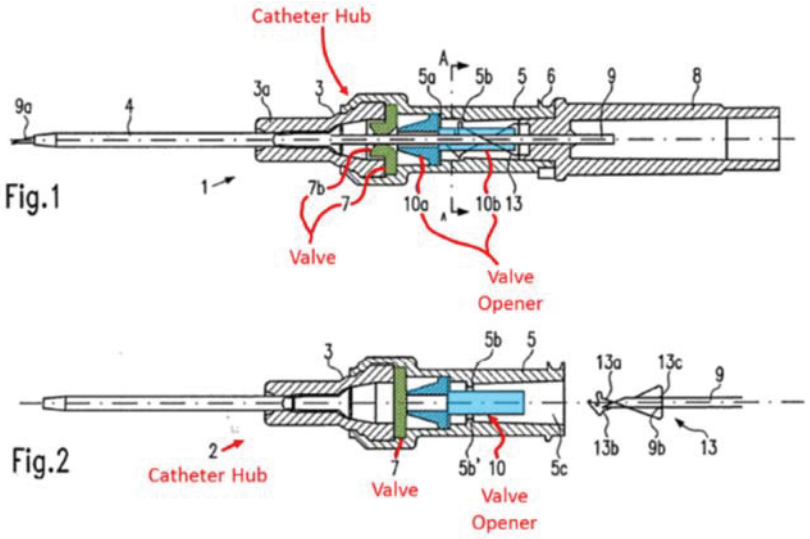
According to Petitioner, and as shown above in the annotated Figures 1 and 2, Woehr discloses catheter hub 2 with a housing and having catheter tube 4 having a distal opening and attached to distal end 3a of catheter hub 2. *Id.* at 20 (internal citations omitted).

To address the claimed "needle hub having a needle . . . ," Petitioner submits another annotated version of Woehr's Figure 1 (*id.* at 22), which we reproduce below:



According to Petitioner, the above Figure 1 depicts Woehr's needle 9 and needle tip 9a attached to needle hub 8 and projecting distally therefrom and into catheter tube 4. *Id.* at 21.

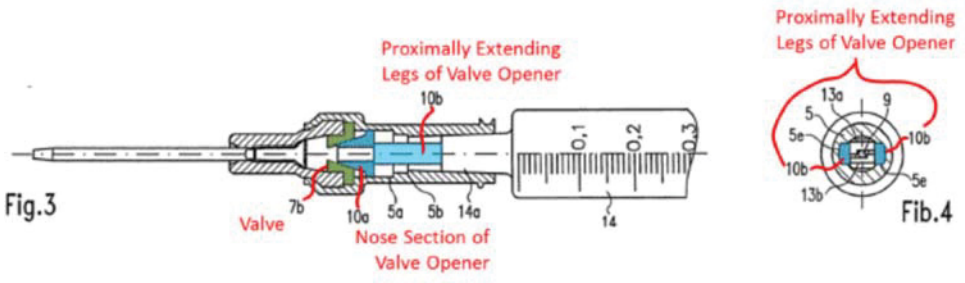
To address the claimed "valve for limiting fluid flow and a valve opener . . . ," Petitioner submits an annotated version of Woehr's Figures 1 and 2 (*id.* at 23), which we reproduce below:



According to Petitioner, the above Figures 1 and 2 depict Woehr's valve 7 and valve opener 10 positioned within the interior cavity of catheter hub 2. *Id.* at 22 (internal citations omitted).

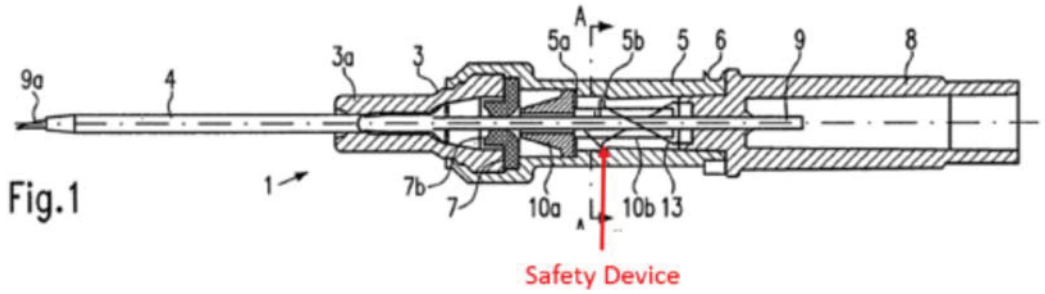
To address the claimed "wherein the valve opener comprises two proximally extending legs having a gap therebetween . . . ," Petitioner

submits an annotated version of Woehr's Figures 3 and 4 (*id.* at 30), which we reproduce below:



According to Petitioner, and as shown in the above Figures 3 and 4, Woehr's valve opener 10 comprises two proximally extending legs 10b having a gap therebetween. *Id.* at 29 (internal citations omitted).

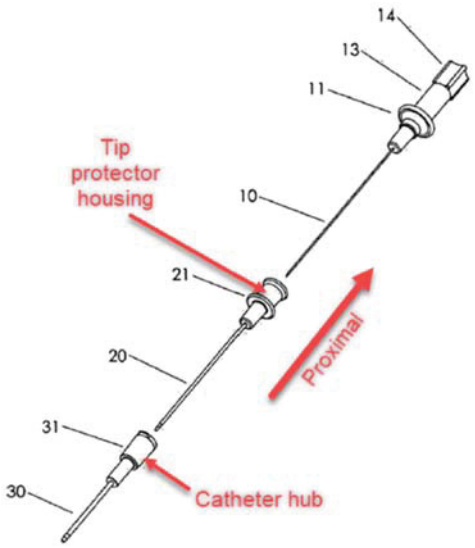
To address the claimed "safety device for covering the needle tip," Petitioner submits an annotated version of Woehr's Figure 1 (*id.* at 25), which we reproduce below:



According to Petitioner, the above Figure 1 depicts Woehr's "safety device" 13, described as a spring clip that lies around the needle point. *See id.* at 24 (citing in-part Ex. 1005, 2).

Petitioner acknowledges, however, that *Woehr does not disclose* the claimed "tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub." *Id.* at 25. To address this

missing limitation, Petitioner relies on Callaway, and submits an annotated version of Callaway's Figure 5 (*id.* at 26), which we reproduce, below:



According to Petitioner, and as shown in the above-annotated Figure, Callaway discloses tip protector housing 21 having a housing section positioned proximally of a proximal end of catheter hub 31. *Id.* at 26 (internal citations omitted).

In combining Woehr with Callaway's "tip protector housing" 21, Petitioner cites to Callaway's disclosure that "clip and hub (21) protect users from the sharp tip of the needle (10)." *Id.* at 27 (citing Ex. 1004 ¶ 61). Mr. Griffis testifies that the clip described and incorporated in Callaway "is the same clip that is included in the Woehr device." Ex. 1002 ¶ 89.

Petitioner reasons that it would have been obvious for a POSITA to have modified 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." Pet. 28 (citing Ex. 1002 ¶¶ 90–91). Petitioner further reasons that a

POSITA "would understand [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" and that a POSITA

> would have found it obvious to improve Woehr by adding protective elements, such as . . . [the] third hub disclosed in Callaway, to also prevent unintended contact with the tip protector itself and/or [any] 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*.

Id. (emphasis added).

4. Patent Owner's Arguments

In its Response to Petitioner's challenge under Woehr and Callaway, Patent Owner presents numerous arguments. PO Resp. 3–41. In particular, Patent Owner argues that "Petitioner mischaracterizes Callaway" (*id.* at 30) and that a POSITA would not have modified Woehr to add Callaway's inner catheter hub 21, as Petitioner proposes (*see id.* at 29–38).

For the reasons discussed below, Patent Owner's argument is persuasive.

5. Analysis

Because Callaway does not teach a spring clip retained in its inner hub 21 *after* the needle is withdrawn, we are not persuaded by Petitioner's reasons for combining Woehr and Callaway.

The issue before us involves the proper interpretation of Callaway, and whether Petitioner (and its expert, Mr. Griffis) or Patent Owner (and its

expert, Mr. Meyst) interprets Callaway correctly. To make matters difficult, we find that Callaway itself is ambiguous, conflates multiple distinct embodiments, and fails to provide *any* detail on how the "second embodiment"—which Petitioner relies on—actually works as Petitioner asserts it does. *See supra* Part II.D.2.

Petitioner proposes 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*." Pet. 28 (emphasis added). Petitioner reasons that a POSITA "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*." *Id.* (citing Ex. 1002 ¶¶ 90–91) (emphasis added). Specifically, Petitioner reasons that a POSITA "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*" (*id.* (emphasis added)) and that a POSITA

> 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.

Id. (emphasis added).

Notably, Petitioner's reasoning relies on *Callaway specifically teaching* that its "tip protector housing, in addition to the metal clip, provides more secure protection from the needle tip," and that "the third hub

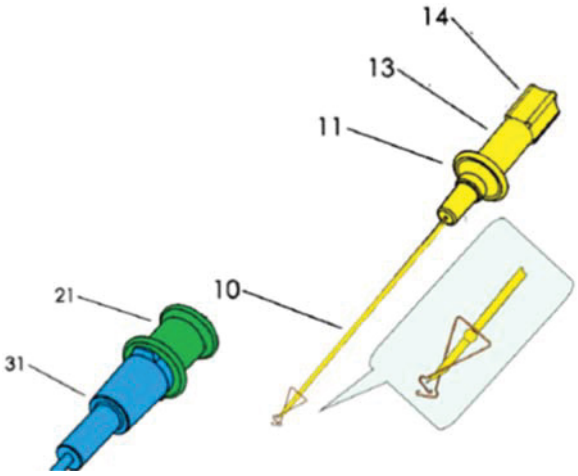
of Callaway provides a secure cover to keep the tip protector in place on the needle tip *after* the needle has been withdrawn." *Id.* (emphasis added).

At first glance, Petitioner's interpretation has merit. Indeed, Callaway explicitly discloses that its Figure 9 embodiment includes a "needle safety device [that] 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" and that the "clip and hub (**21**) protect users from the sharp tip of the needle (**10**)." Ex. 1004 ¶ 61. Callaway further discloses that "[t]he clip disclosed . . . [in Woehr-630] may be incorporated into the hub of the inner catheter, thus making the catheter and clip both cover the sharp end of the needle" (*id.* ¶ 76) and that "[i]n some versions of the assembly, the inner catheter hub is designed to contain the needle after it is withdrawn" (*id.* ¶ 84). Moreover, Mr. Griffis testifies that "Callaway teaches that when the clip from the '630 patent is 'incorporated into the hub of the inner catheter . . . the catheter and clip both cover the sharp end of the needle.'" Ex. 1002 ¶ 91 (citing Ex. 1004 ¶ 76). This disclosure and testimony support Petitioner's interpretation of Callaway.

We are mindful, however, that "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Wesslau*, 353 F.2d at 241. We find that Petitioner picks and chooses certain statements in Callaway, while ignoring

other teachings, to support its hindsight reconstruction of the claimed invention.

Patent Owner provides a more comprehensive analysis of Callaway, and asserts that a POSITA "would know that . . . [Callaway's] catheter hub merely retains the spring clip until the needle is retracted . . . [and] would also know that . . . [Callaway's] catheter hub itself provides no protection relative to the needle tip, as is expressly recognized in Callaway." PO Resp. 10 (citing Ex. 1004 ¶¶ 53, 77, Ex. 2028 ¶ 64). Below, we reproduce an annotated figure (Callaway's Figure 6) that Patent Owner's expert, Mr. Meyst, provides (Ex. 2028 ¶ 71):



In referencing Callaway's annotated Figure 6, Mr. Meyst testifies that "Callaway's inner catheter hub (21) retains the Woehr-630 spring clip *until the needle is removed*, at which time the spring clip engages and covers the needle tip as it releases from the inner catheter hub so a user can safely dispose of the needle." Ex. 2028 ¶ 71 (citing Ex. 1004 ¶ 61) (emphasis added).

In addressing the difference between the "one version" and the "preferred version" of Callaway's second embodiment, Patent Owner asserts that the "preferred version" reference in paragraph 61 is merely a transition to the Critikon embodiment discussed immediately following in paragraph 62. *See* PO Resp. 28 ("The other reasonable interpretation of the conclusion to Callaway's ¶61 is that the '*one version'* versus '*preferred version'* language was actually meant to be a transition from the Callaway spring clip version ('one version') to the Critikon version ('preferred version') discussed in the very next paragraph."). Mr. Meyst testifies that the most likely interpretation of Callaway's "preferred version" is that

> a POSITA would understand the conclusion of ¶61 to be a transition from Callaway's spring clip version ('one version') to the Critikon version ('preferred version"). A POSITA would have this understanding because the Critikon version is discussed in the very next paragraph, where considerably more detail is provided than with respect to the spring clip version.

Ex. 2028 ¶ 104.

We agree, credit Mr. Meyst's testimony, and find that this is the most plausible interpretation of Callaway. Accordingly, we find that in Callaway's "one version," hub 21 does not itself provide any additional protection once the needle and clip are withdrawn, and in the "preferred version," the discussion relates to the very different safety device and hub 21 of the Critikon embodiment.

As discussed above (*see supra* Part II.D.2), Callaway discloses at least three embodiments, with the second embodiment apparently describing two "versions." The second embodiment (Figure 9) appears almost identical to the first embodiment (Figures 1–8), and Petitioner cites to both embodiments

in its challenge. *See, e.g.*, Pet. 26–27 (citing in part Ex. 1004, Fig. 5 (first embodiment), ¶ 61 (second embodiment)).

Callaway's first described embodiment, shown in Figures 1–8, depicts a catheter assembly *without* a needle safety device. Ex. 1004 ¶ 53.

Regarding Callaway's second embodiment, Callaway discloses that Figure 9 "illustrates how the catheter assembly could be integrated with an existing needle protective device," namely, the spring clip of Woehr-630. *Id.* ¶ 61. As discussed above, however, we find that Figure 9 itself fails to show any such spring clip, or how it may be "integrated." *See id.*; Fig. 9; *see also* Ex. 2028 ¶ 61 ("FIG. 9 is also supposed to illustrate the integration of the Callaway device with a spring clip, but it does not actually show a spring clip"). Moreover, in the two "versions" of this second embodiment, the spring clip is only mentioned in the "one version," and not the "preferred version," which Petitioner specifically relies on. *See* Ex. 1004 ¶ 61; *see also* Pet. Reply 9 ("The 'preferred version' of the catheter assembly is relevant here."). Importantly, although Callaway discloses that "[i]n one version, the needle (**10**) *and attached clip* could be withdrawn from the hub (**21**)," the "preferred version" makes no such mention of an attached clip, instead disclosing in-full that "[i]n the preferred version, the inner catheter (**20**), its hub (**21**) and the needle (**10**) remain attached together and are discarded together in a safe manner." Ex. 1004 ¶ 61 (italicized emphasis added). We find that the absence of a reference to "spring clip" in the "preferred version" supports Patent Owner's interpretation of Callaway, namely, it is the "one version" that includes the Woehr-630 safety clip in catheter hub 21, *only*, and that hub 21 merely retains the spring clip until the needle is

retracted. *See* PO Resp. 12 ("a POSITA reading Woehr-630 would know that the catheter hub merely retains the spring clip until the needle is retracted. A POSITA would also know that a catheter hub itself provides no protection relative to the needle tip, as is expressly recognized in Callaway") (citing Ex. 1004 ¶¶ 53, 77; Ex. 2028 ¶ 64); *see also* PO Resp. 16 ("The 'sequential removal' option is the only safe option when employing the Woehr-630 spring clip") (citing Ex. 2028 ¶ 75). Accordingly, we find that in the "one version," hub 21 does not itself provide any additional protection once the needle and clip are withdrawn, and in the "preferred version," the discussion relates to hub 21 of the Critikon embodiment. *See* PO Resp. 29

The third, Critikon embodiment, shown in Figures 10–16, indeed discloses "how the catheter assembly could be integrated with an existing needle protection device" (Ex. 1004 ¶ 62), illustrating precisely "how the tip of the needle is contained within the middle hub (**21**) after the flash chamber (**15**) has been snapped into the 'safe' position" (*id.* ¶ 69 (referencing Figure 16)). The Critikon embodiment, however, does not integrate the spring clip of Woehr-630 (*see supra* Part II.D.2.) and Petitioner does not rely on Callaway's Critikon embodiment, instead relying only on Callaway's first two embodiments. *See* Pet. 26–27 (relying on Callaway's embodiments that include the Woehr-630 safety clip); *see* Ex. 1004, Fig. 5, ¶ 61.

As mentioned above, in addition to paragraph 61, Petitioner also cites to Callaway's paragraph 84 in support of its assertion that Callaway expressly discloses that in at least some versions, the inner catheter hub is designed to contain the needle after it is withdrawn. Pet. Reply 9–10 (citing Ex. 1004 ¶ 84). Callaway's disclosure in paragraph 84 states, "[i]n some

versions of the assembly, the inner catheter hub is designed to contain the needle after it is withdrawn." Ex. 1004 ¶ 84. We find that paragraph 84 *refers to the Critikon version*, and not the first and second embodiments that Petitioner relies on. We find that the description in paragraph 84 is consistent with the reading of the Critikon embodiment discussed in Callaway's paragraphs 62 to 69, and credit Mr. Meyst's testimony regarding the same. *See* Ex. 2028 ¶ 89 ("Callaway's statement in ¶ 84 . . . refers to the Critikon version"). Accordingly, paragraph 84 does not support Petitioner's interpretation of Callaway.

Petitioner also references paragraph 76 to support its assertion that "Callaway further explains that a needle safety device in the form of a metal clip can be placed into a 'middle hub.'" Pet. 26–27; *id.* at n.7 (citing Ex. 1004 ¶¶ 61, 76). Paragraph 76 recites, in relevant part, "[t]he [Woehr-630] clip . . . may be incorporated into the hub of the inner catheter, *thus making the catheter and clip both cover the sharp end of the needle*." Ex. 1004 ¶ 76 (emphasis added). We find that this disclosure is ambiguous, as we do not see how Callaway's "catheter and clip" can both cover the needle tip. Nevertheless, this paragraph does not disclose that *Callaway's hub 21* and the Woehr-630 safety clip both simultaneously cover the needle upon withdrawal, which is what Petitioner would have us believe. If anything, Callaway is ambiguous, and we are mindful not to read into Callaway that which is not disclosed; such hindsight bias has no role in an obviousness analysis. Accordingly, we find that Callaway's paragraph 76 does not support Petitioner's interpretation of Callaway.

Callaway further discloses that "[v]arious structures may be employed to control movement of the needle and catheters relative to one another. For example, as depicted in **FIG. 1**, hubs may be used. *One or more of the hubs may be replaced with safety devices*, tubes, or pegs." *Id.* ¶ 77 (italicized emphasis added). We further find that this paragraph supports Patent Owner's argument that hub 21 itself provides no protection, and hub 21 is instead used to "control movement of the needle and catheters relative to one another." *Id.*; *see also* PO Resp. 10 ("[a] POSITA would also know that a catheter hub itself provides no protection relative to the needle tip, as is expressly recognized . . . [by] Callaway"). In other words, if Callaway taught using a hub in combination with a needle safety device so that both structures provide needle tip protection after the needle is withdrawn, as Petitioner asserts (Pet. 27), we do not understand why Callaway would disclose *replacing* hubs with a needle safety device. Accordingly, we find that Callaway's paragraph 77 supports Patent Owner's interpretation of Callaway.

Finally, we note that nothing in Callaway's Figures 1–9 discloses any structure that would support Petitioner's position that Callaway's hub 21 could retain the Woehr-630 safety clip after the needle is withdrawn. *See supra* Part II.D.2. Indeed, as shown in Callaway's Figure 3, reproduced above, the back wall of Callaway's hub 21 is completely open, and we agree with Mr. Meyst that a "POSITA would also know that Callaway's inner catheter hub does not provide protection because it has an open back." Ex. 2028 ¶ 97. Callaway's failure to disclose such structure weighs against Petitioner's proposed interpretation.

Further, we have considered Mr. Griffis's testimony that it would have been a matter of *routine design* to "design a device that retains the spring clip in the inner catheter hub after the spring clip is activated" (Ex. 1064 ¶ 35), but we do not find it persuasive. First, this is a new argument not presented in the original Petition. The Petition makes no mention that modifying Callaway and/or Woehr to include structure that would retain the Woehr-630 clip as a simple matter of routine design. *See*, *generally*, Pet. Petitioner's Sur-Reply is not the place to raise new arguments or evidence. *See* 37 C.F.R. § 42.23(b) ("A reply may only respond to arguments raised in the corresponding opposition . . . or patent owner['s] response."); *see also* PO Sur Reply 1–2 (arguing the same). Second, even if Petitioner's "routine design" argument was presented in the Petition, which it was not, we do not find it persuasive. As discussed above, Callaway and Woehr disclose distinctive catheter devices (*compare supra* Part II.D.1, *with supra* Part II.D.2), and we do not see how it would be a matter of routine design, without more explanation, to incorporate Callaway's inner hub 21 with Woehr, while also modifying Callaway's hub 21 so that it can retain Woehr-630's spring clip after removal of the needle. We find that such a combination and modification is not routine, but would instead involve significant restructuring of Callaway's hub 21 and Woehr's catheter assembly.

Having considered Callaway in its entirety, and after weighing the competing testimony of Mr. Griffis and Mr. Meyst, we agree with Patent Owner and credit its expert that Callaway's inner hub 21 would do "nothing more than hold the spring clip in place until the needle is withdrawn," and

that the "only embodiment in which the inner catheter hub (21) potentially adds any needle protection is in the Critikon version" (PO Resp. 34), which does not integrate Woehr-630's safety clip (Ex. 1004 ¶ 62) and which Petitioner does not rely on (*see* Pet. 26–27).

After considering the evidence and arguments of both parties, and for the reasons set forth above, we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that independent claim 15, and its dependent claims 17, 18, 20, and 22, of the '641 patent are unpatentable over Woehr and Callaway.

E. Woehr and Villa

Petitioner also contends that claims 15, 17, 18, 20, and 22 are unpatentable over Woehr and Villa. Pet. 2–3. As distinguished from the challenge based on Woehr and *Callaway*, Petitioner relies on *Villa* for addressing the claimed "tip protector housing." *See id.* at 39–43 (setting forth Petitioner's challenge of independent claim 15 based on Woehr and Villa).

1. Villa (Ex. 1006)

Villa is a U.S. Patent Publication entitled "**PROTECTIVE DEVICE FOR A NEEDLE**." Ex. 1006, (54). To illustrate a particular embodiment of Villa's device, we reproduce Figure 7, below:

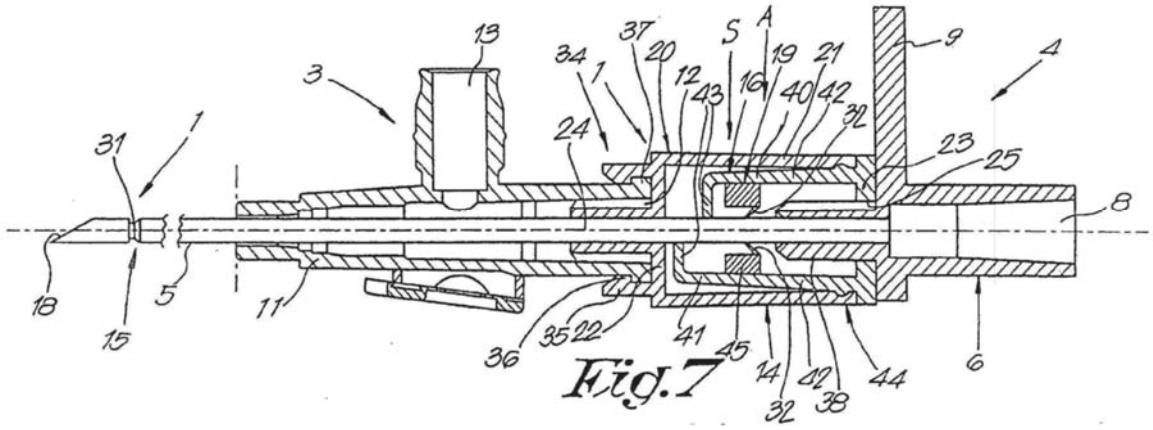


Fig.7

Figure 7 above 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. During passage from the non-operative state to the operative state, needle 5 slides through scraping means 33 (not shown) 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.*

Villa further discloses:

> 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*. To this end, in the represented embodiment, said couple means **34** comprise a number of elastically bendable fins

> **35**, having locking portions **36** which can cooperate with a collar **37** at the rear edge of the rear portion of the cannula **3**.

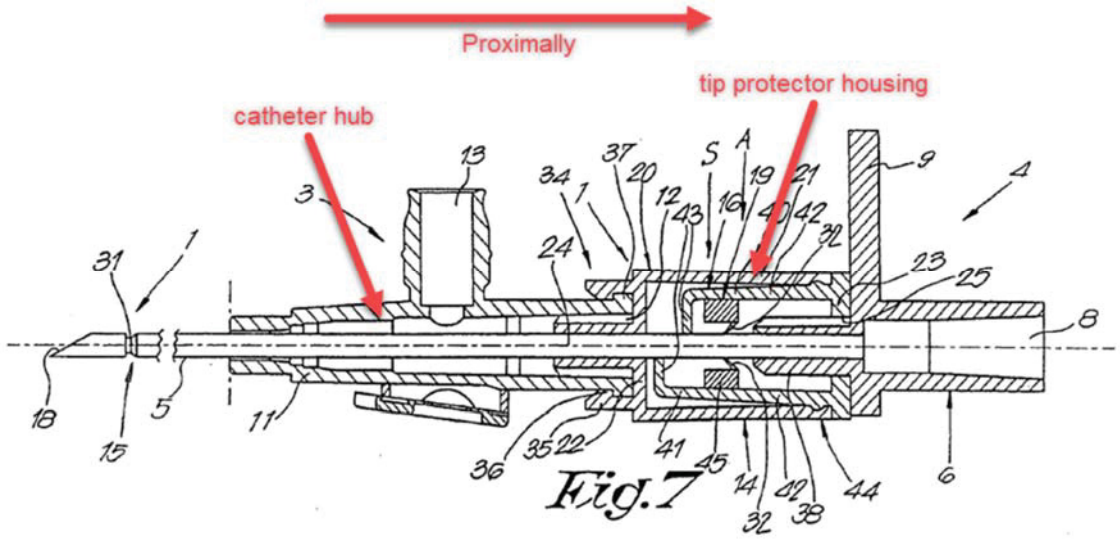
Ex. 1006 ¶ 53 (italicized emphasis added).

2. Petitioner's Challenge

As with the prior ground based on Woehr and Callaway, Petitioner asserts that Woehr discloses a "safety catheter assembly" comprising the claimed "catheter hub," "needle hub," and "valve." *See* Pet. 39 (incorporating by reference analysis based on Woehr and Callaway).

a) Claim 15

In addressing independent claim 15, specifically, the claimed "safety device for covering the needle tip comprising a tip protector housing," Petitioner relies on a combination of Woehr and Villa and cites, *inter alia*, to an annotated version of Villa's Figure 7 (*see id.* at 41), a copy of which we reproduce below:



According to Petitioner, Figure 7 above depicts Villa's "tip protector housing" 20. *See id.* at 40 ("Villa discloses a tip protector housing (e.g., element 20)." 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 41 (citing Ex. 1006 ¶¶ 1, 2, 47; Ex. 1002 ¶ 116).

In combining Woehr with Villa, Petitioner reasons that a person having ordinary skill in the art would have found it obvious to modify Woehr "to include a spring clip in a housing" (*id.* at 42 (citing Ex. 1002 ¶ 117)) and by moving

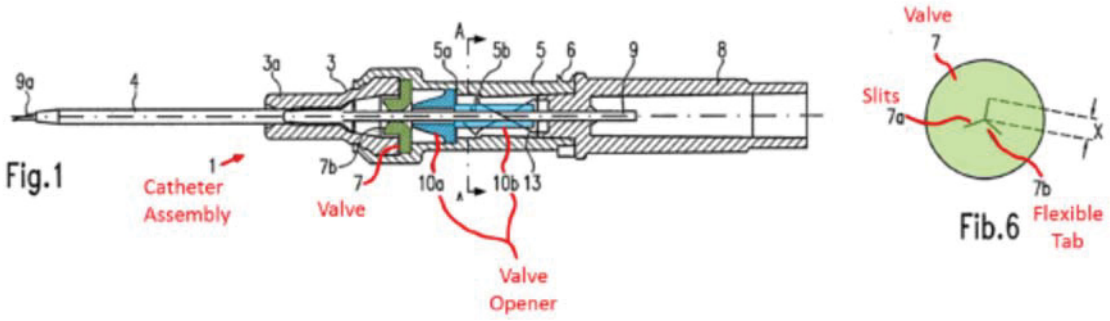
> the safety device in Woehr into a tip protector housing . . . such as the one disclosed in Villa, based on the knowledge and motivations in the art as well as the specific teaching . . . [in] Villa that a tip protector housing accomplishes the predictable result of minimizing blood exposure risks and needle sticks for operators

(*id.* at 43 (citing Ex. 1002 ¶ 118)). Petitioner explains that the modification "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." *Id.* (citing Ex. 100 ¶ 118).

b) Claim 17

Claim 17 depends from claim 15 and further recites, "wherein the valve comprises *one or more slits* that are deflectable by a distal end of the valve opener." Ex. 1001, 14:13–15 (emphasis added).

To address this claim, Petitioner relies on the same analysis relied upon in presenting its challenge based on Woehr and Callaway. Pet. 43. Petitioner further submits an annotated version of Woehr's Figures 1 and 6 (*id.* at 31), which we reproduce, below:

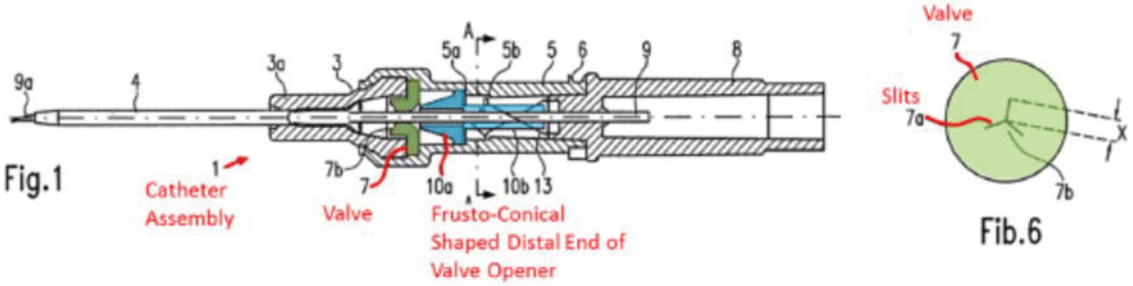


According to Petitioner, and as shown in the above Figures 1 and 6, Woehr's valve 7 comprises slits 7a that are deflectable by distal end of valve opener 10. *Id.* at 30–31.

c) Claim 18

Claim 18 depends from claim 17 and further recites, "wherein the distal end of the valve opener comprises a *nose section having a frusto-conical shape* for projecting through the slits." Ex. 1001, 14:16–19 (emphasis added). To address this claim, Petitioner relies on the analysis relied upon in presenting its challenge based on Woehr and Callaway. Pet. 44.

Petitioner submits an annotated version of Woehr's Figures 1 and 6 (*id.* at 31), copies of which we reproduce, below:



According to Petitioner, and as shown above in Woehr's Figures 1 and 6, Woehr's valve opener 10 has a nose section with a frusto-conical shape 10a for projecting through slits 7a. *Id.* at 32.

d) Claim 20

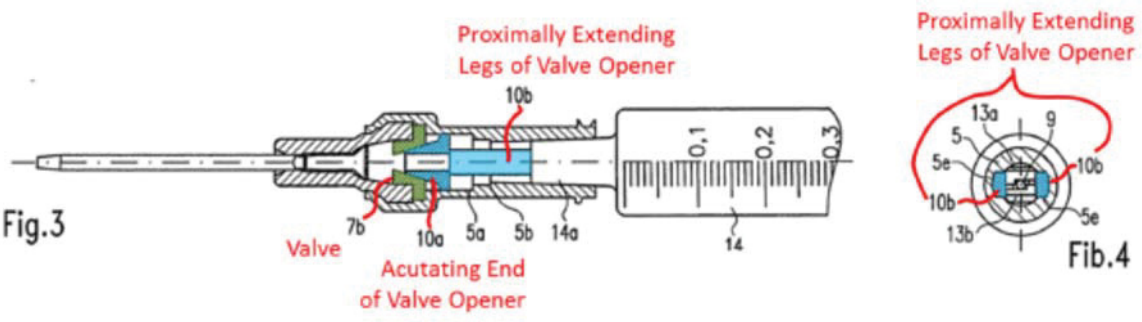
Claim 20 depends from claim 18 and further recites, "wherein the safety device for covering the needle tip comprises a resilient portion made from a metal material and the tip protector housing surrounding the resilient portion." Ex. 1001, 14:24–27. To address this claim, Petitioner relies on the same analysis relied upon in presenting its challenge based on Woehr and Callaway. Pet. 44.

Petitioner asserts that Woehr's spring clip 13 covers the needle tip and comprises a resilient portion made from a metal material. *Id.* at 33 (citing Ex. 1002 ¶¶ 100–105); *see also* Ex. 1005, 4 ("the two spring arms 13a, 13b may release from shoulder 5b and spring back inward to cover the needle point."). Petitioner also asserts that the spring clip is made from metal, because it is the same spring clip disclosed in Woehr-630, and Woehr-630 discloses that its "unitary spring clip . . . is preferably made of a resilient metal." Ex. 1007, 5:54–56.

e) Claim 22

Claim 22 depends from claim 15 and further recites, "wherein the valve opener comprises an actuating end for opening the valve and *one or more legs* extending proximally of the actuating end." Ex. 1001, 14:31–34 (emphasis added). To address this claim, Petitioner relies on the same analysis relied upon in presenting its challenge based on Woehr and Callaway. Pet. 45.

Petitioner submits an annotated version of Woehr's Figures 3 and 4, which we reproduce (*id.* at 37), below:



According to Petitioner, and as shown in the above Figures 3 and 4, Woehr discloses valve opener 10 with actuating end 10a for opening valve 7 and one or more legs 10b extending proximally of the actuating end. *Id.* at 26–37.

3. Patent Owner's Arguments

In contesting the ground based on Woehr and Villa, Patent Owner does not argue any of dependent claims 17, 18, 20, or 22 separately. *See* PO Resp. 41–54. Rather, Patent Owner contests Petitioner's challenge of independent claim 15 under the following arguments, which apply to all of the challenged claims:

a) Petitioner's proposed combination is unclear and the Petitioner has failed to plead its obviousness case with particularity (*id.* at 44);

b) A POSITA would not have combined Woehr with Villa as Petitioner has done, because Woehr already prevents needlesticks (*id.* at 45); and

c) Petitioner's proposed combination would render the primary reference inoperable (*id.* at 52–53).

4. Analysis

Having considered Patent Owner's arguments and Petitioner's analysis, we find Petitioner's analysis persuasive. Petitioner establishes that Woehr and Villa teach all elements of the challenged claims, and that a POSITA would have had reason to combine those teachings with a reasonable expectation of success.

We address each of Patent Owner's arguments separately, below.

a) Patent Owner's argument that Petitioner has failed to plead its claim with particularity

Patent Owner argues that "Petitioner's actual combination remains unclear" (PO Resp. 42) and Petitioner's challenge fails to plead its obviousness case with the necessary particularity (*id.* at 44). In support of this argument, Patent Owner argues that Petitioner's combination is based on either (1) using "Villa's housing and its essential features," or (2) using "the housing alone with the Woehr-819 device." *Id.* at 42 (citing Pet. 42–43).

Patent Owner's argument misconstrues Petitioner's proposed combination as relying on Villa's housing, either alone or with its "essential features." *See id.* Patent Owner bases this argument on taking certain statements from the Petition and Petitioner's expert out of context. *See id.* at 43–44. We find nothing inconsistent in these statements, however. In particular, we find no persuasive evidence in these statements that support a finding that Petitioner's challenge relies on using Villa's "essential features."

> Instead, we find that the Petition clearly sets forth that a POSITA would have been motivated to *move the safety device in Woehr into a tip protector housing . . . 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.

Pet. 43 (emphasis added). In other words, Petitioner's proposed combination simply relies on Villa's teaching of using a tip protector housing, and proposes to move Woehr's safety device into a tip protector housing, "such as" Villa's tip protector housing, but not with Villa's "essential features," which Patent Owner's argument presumes. *See* PO Resp. 42.

Accordingly, we find that Petitioner's proposed challenge based on Woehr and Villa is pleaded with the requisite particularity.

b) Patent Owner's argument that Woehr already prevents needlesticks

Patent Owner also argues that "a POSITA would not combine . . . [Woehr's safety device] with Villa's housing . . . because Woehr[] already

prevents needlesticks via . . . [its safety device]." PO Resp. 45. Patent Owner further argues that moving Woehr's safety device "into Villa's housing does not address a fluid exposure problem." *Id.*

We disagree with Patent Owner. Although Woehr's safety device helps to prevent needle sticks, we are persuaded by Petitioner's reasoning that a POSITA would have improved Woehr by placing its needle protective device into a tip protector housing to *further reduce the risk* of needle sticks and to reduce the risk of exposing operators with undesirable blood exposure. Pet. 43. For example, *even if* Woehr's safety device covers the tip of the used needle, we agree with Petitioner and credit Mr. Griffis's testimony that Woehr's device is improved by moving it into a tip protector housing, as doing so would reduce exposure by holding the potentially-contaminated blood. Ex. 1002 ¶ 117 (testifying that placing Woehr's safety device in a tip protector housing presents a number of advantages, including reducing the risk of contact with a patient's bodily fluids or with drugs on the needle); Ex. 1064 ¶ 57 ("a person of ordinary skill in the art would still recognize that a housing could reduce exposure to fluids by capturing and holding the catapulted fluids inside the housing.").

In support of its argument, Patent Owner cites to various disclosures within Villa that bear little relevance to Petitioner's proposed combination. For example, Patent Owner cites to an embodiment (Villa's "first embodiment" shown in its Figures 1–6) where Villa's safety means never touches, or only slightly touches, the needle. PO Resp. 48 (quoting Ex. 1006 ¶ 61 (referencing the embodiment of Figures 1–6)).

Patent Owner's citations to these various disclosures within Villa, however, do not successfully rebut Petitioner's challenge. Petitioner relies on the alternative embodiment of Figures 7 and 8. *See* Pet. 41 (annotating Villa's Figure 7); *see also* Ex. 1006 ¶¶ 32–38 (explaining that Figures 7 and 8 relate to a different embodiment from that shown in Figures 1–6). Petitioner does not rely on Villa's first embodiment in which its safety means never (or only slightly) touches the needle. *Id.*

We further note that Patent Owner's cited disclosure of Villa does not *criticize, discredit, or otherwise discourage* placing a safety device in Villa's housing, which would persuade us of nonobviousness in the combination. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) ("A reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed."); *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("mere disclosure of alternative designs does not teach away"). As pointed our correctly by Petitioner, "there is no basis for . . . [Patent Owner's] suggestion that Villa's first embodiment with a tongue that does not touch the needle would lead a . . . [POSITA] to conclude that the housing . . . would not be an improvement if added to Woehr." Pet. Reply 23.

Having considered Villa in its entirety, and after weighing the competing testimony of Mr. Griffis and Mr. Meyst, we agree with Petitioner and credit Mr. Griffis that a POSITA "would have been motivated to use the Villa housing in the Woehr device to house [Woehr's] spring clip to reduce the risk of exposure to fluids and blood." Ex. 1064 ¶ 58.

Patent Owner also argues that Petitioner's combination is based on impermissible hindsight, as it requires the removal of "Villa's essential safety means (16) and scraping means (33)" (PO Resp. 50) and that "[e]liminating these safety [means] (16) and scraping (33) means in favor of . . . [Woehr's safety device] makes fluid contamination worse" (*id.* at 51).

Patent Owner's argument, however, is premised on replacing Villa's safety means 16 and scraping means 33 with Woehr's safety device, and misconstrues Petitioner's proposed combination, which is simply to move Woehr's safety device into a tip protector housing. *Compare id.*, *with* Pet. 43. Stated differently, Petitioner does not propose to modify Villa, as Patent Owner's argument presumes. As such, we do not agree with Patent Owner's assertion that placing Woehr's spring clip into a tip protector housing would make contamination worse.

c) Patent Owner's inoperability argument

Patent Owner further argues that a "POSITA would not use both the spring clip and Villa's safety means in the housing." PO Resp. 52 (emphasis omitted). In particular, Patent Owner argues that "the claimed combination cannot change the principle of operation of the *primary reference* or render the reference inoperable for its intended purpose." *Id.* at 52–53 (quoting MPEP § 2145(III)) (emphasis added). Patent Owner argues that a "POSITA would have no reason to add Woehr-819's . . . [safety device] to Villa's housing with all of its essential components retained because Villa's essential components already prevent needlesticks and fluid contamination." *Id.* at 53 (internal citations omitted).

As discussed above, however, Patent Owner's argument is based on a mischaracterization of Petitioner's combination. Petitioner does not propose to use Villa's "essential components." Pet. 43. Petitioner is simply relying on Villa's teaching of using a housing for minimizing blood exposure risks and needle sticks. *Id.*

Moreover, Villa is not the *primary reference* that Petitioner proposes to modify, and Patent Owner's argument that the proposed combination would render Villa inoperable for its intended purpose is off point. *See* PO Resp. 52–53 (explaining that the claimed combination cannot change the principle of operation of the *primary reference* or render the reference inoperable for its intended purpose). As explained above (*supra* Part II.E.2), Petitioner relies primarily on Woehr for disclosing the claimed structure, with the exception of a "tip protector housing," which Petitioner proposes to combine with Woehr based on Villa's teaching "that a tip protector housing accomplishes the predictable result of minimizing blood exposure risks and needle sticks for operators" (Pet. 43). Accordingly, Patent Owner's extensive analysis that the proposed combination would render *Villa* inoperable for its intended purpose misses the point.

d) Summary

We have reviewed Petitioner's cited evidence and agree with and adopt Petitioner's mapping of the combination of Woehr and Villa to claims 15, 17, 18, 20, and 22. We further determine that a POSITA would have combined Woehr with Villa as Petitioner proposes.

Accordingly, and as set forth in the Petition supported by the underlying evidence cited therein, we are persuaded that a preponderance of

the evidence supports the conclusion that claims 15, 17, 18, 20, and 22 would have been obvious over Woehr and Villa.

III. MOTION TO AMEND

Patent Owner filed a contingent Motion to Amend to replace, respectively, unpatentable claims 15, 17, and 18 with proposed substitute claims 31–33. Paper 22, 3 ("Amend Mot."). Patent Owner also seeks to cancel dependent claim 16 and amend dependent claims 19–24 to depend from one of substitute claims 31–33. *Id.* Petitioner filed an opposition to Patent Owner's motion (Paper 39 ("Amend Opp.")), to which Patent Owner filed a reply (Paper 40 ("PO Amend Reply")). Petitioner also filed a sur-reply in response to Patent Owner's reply. Paper 52 ("Pet. Amend Sur-Reply").

Because we find claims 15, 17, 18, 20, and 22 unpatentable, we address Patent Owner's contingent Motion to Amend. For the reasons discussed below, we *deny* the Motion to Amend as to claim 31, but *grant* the Motion to Amend as to claims 16, 20, 21, 23, 32, and 33. We also grant the Motion to Amend claims 19, 22, and 24, but only to the extent that they depend from claim 32.

A. U.S.C. § 316(d) and 37 C.F.R. § 42.121

Pursuant to 35 U.S.C. § 316(d)(3), "[a]n amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter." *See Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1340–41 (Fed. Cir. 2017) ("Part III of this opinion sets forth the judgement of this court on

what the Board may and may not do with respect [to] the burden of production on remand in this case," and "[t]here is no disagreement that the patent owner bears a burden of production in accordance 35 U.S.C. § 316(d)."); *see also, e.g.*, *id.* at 1305−06 (explaining that "patent owner must satisfy the Board that the statutory criteria in § 316(d)(1)(a)–(b) and § 316(d)(3) are met and that any reasonable procedural obligations imposed by the Director are satisfied"). Similarly, 37 C.F.R. § 42.121(a)(2)(ii) provides that a motion to amend may be denied where the amendment seeks to enlarge the scope of the claims of the patent or introduces new subject matter. *See* USPTO Memorandum, "GUIDANCE ON MOTIONS TO AMEND IN VIEW OF *AQUA PRODUCTS*" ("Guidance") (Nov. 21, 2017), https://go.usa.gov/xQGAA (stating that, in addition to the requirements of 35 U.S.C. § 316(d), a motion to amend must meet the requirements of 37 C.F.R. § 42.121). In addition, with its motion to amend, a patent owner must set forth "support in the original disclosure of the patent for each claim that is added or amended." 37 C.F.R. § 42.121(b)(1).

B. Proposed Substitute Claims and Written Description Support

Patent Owner seeks to replace three unpatentable claims (15, 17, and 18) with substitute claims (31–33). Amend Mot. 3; *id.* at Claims App. A. Each substitute claim 31, 32, and 33 adds limitations that narrow the scope of the original claim it replaces. Amend Mot. 3; *id.* at Claims App. A. Patent Owner also identifies disclosures in the originally-filed application (Ex. 2041) and a parent application (Ex. 2040, "Parent Application") that

provide written description for the proposed substitute claims. Amend Mot. 7–19 (citing Exs. 2040, 2041).

1. Substitute Claim 31

Substitute claim 31 is independent and replaces original independent claim 15. Amend Mot. 3. Claim 31 adds several new limitations, discussed below. *Id.*

a) Single Catheter Hub

Patent Owner adds "single" to the originally-claimed "catheter hub," so that the claim requires only a "single catheter hub." *Id.* at 9. Patent Owner identifies written description support for this new limitation by citing, in-part, Figures 1–4, 5a, 5b, 8c, 9d, 13, and 14 of the originally-filed application and the Parent Application. *Id.* (citing in-part Exs. 2040, 2041).

b) Plurality of Slits

Patent Owner adds "wherein the valve comprises a face having a plurality of slits therein" (*id.* at 10) and "wherein the plurality of slits are deflectable by a distal end of the valve opener" (*id.* at 11). Patent Owner identifies written description support for this limitation in Figures 13 and 14 of the originally-filed application and in paragraph 42 of the Parent Application, which describes "'[t]he hemostatic valve 46 . . . [having] a top 54 having a cut-out 56 comprising a plurality of slits . . . for expanding the cut-out when deflected.'" *Id.* at 11 (quoting Ex. 2040 ¶ 42); *see also id.* (citing Ex. 2041, Figs. 13, 14). Figures 13 and 14 of the originally-filed

application depict a slit in the face of the valve. *See id.* (reproducing annotated versions of Figures 13 and 14 of Ex. 2041).

c) Skirt Section with Air Flow Gaps

Patent Owner adds "wherein the valve comprises a skirt section . . . ; wherein *one or more air flow gaps are incorporated into the skirt* section for ensuring sufficient air flow between the skirt section and an interior surface of the single catheter hub." *Id.* at 12 (emphasis added). Patent Owner cites to the Parent Application's description that "a plurality of bumps, stretched ridges, or protuberances may be incorporated around the external circumference of the skirt section . . . for ensuring sufficient air flow between the valve skirt . . . and the inside surface . . . of the catheter hub for purposes of blood flashback." *Id.* (citing in-part Ex. 2040 ¶ 7).

2. Substitute Claim 32

Substitute claim 32 depends from claim 31 and replaces original dependent claim 17. Amend Mot. 3, 13. Claim 32 further recites, "wherein an arm extends distally of the tip protector housing, wherein the arm is located at least in part in the single catheter hub in the ready position." *Id.* at 14. Patent Owner identifies, in-part, Figures 13 and 14 of the originally-filed application. *Id.* Figures 13 and 14 (reproduced *supra* Part I.B) depict bumps 36 that retain third housing 204 to catheter hub 14. Further, the Patent Owner also cites the Parent Application, which expressly describes, "[t]he two hooks 212 are configured to engage the two bumps 36 to retain

the third housing 204 to the catheter hub 14 in a ready to use position." *Id.* (citing Ex. 2040 ¶ 8).

3. Substitute Claim 33

Substitute claim 33 depends from claim 32 and replaces original dependent claim 18. Amend Mot. 3, 15. Claim 33 further recites, "wherein the skirt section comprises a uniform circumference." *Id.* at 15. Patent Owner identifies Figures 13 and 14 of the original application for depicting a uniform circumference around the skirt section of valve 46. *See id.* at 16 (submitting partially-annotated views of Figures 13 and 14).

C. Petitioner's Opposition

As discussed above, Patent Owner does not have the burden of persuasion with respect to the patentability of the substitute claims presented in its Motion to Amend. *See Aqua Prods.*, 872 F.3d at 1327; Guidance. We determine whether the substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including Petitioner's Opposition. *See Aqua Prods.*, 872 F.3d at 1325–26; *see* Guidance.

For the reasons explained below, considering the entirety of the record before us, we determine that the preponderance of the evidence shows the proposed claim 31 is not patentable over the prior art of record, but that proposed claims 32 and 33 are patentable. We further grant the proposed amendment to claims 16, 20, 21, and 23, and grant in-part the proposed amendment to claims 19, 22, and 24.

We address each of Petitioner's arguments in opposition to Patent Owner's Motion to Amend, below.

1. Petitioner's argument that "air flow gaps" lacks written description support

Petitioner first argues that the new claim limitation "wherein one or more air flow gaps are incorporated into the skirt section" lacks written description support. Amend Opp. 1 (citing 35 U.S.C. § 112). In particular, Petitioner argues that the Specification only discloses structures that "***extend from*** the outside surface of the skirt valve" and that it "does not disclose structures which are ***'incorporated in'*** the skirt valve." *Id.* at 1–2. As to the claimed "one or more airflow gaps," Petitioner also argues that "there is no support for only one gap." *Id.* at 2.

We address each of Petitioner's sub-arguments separately, below.

Regarding Petitioner's first sub-argument, Petitioner asserts that the claimed phrase "air flow gaps are incorporated into the skirt section" "is arguably limited to" "skirt valves that have channels, cutouts, or other indentations in the skirt surface." *Id.* at 3 (citing Ex. 1064 ¶ 69).

We disagree with Petitioner's first sub-argument. Petitioner's argument that the claimed "incorporated into the skirt section" is limited to "channels, cutouts, or other indentations in the skirt surface" is not supported by the record. The parent application explicitly describes, "a plurality of bumps, stretched ridges, or protuberances may be *incorporated around the external surface of the skirt* section 52 for ensuring sufficient air flow between the valve skirt 52 and the inside surface 22 of the catheter hub for purposes of blood flashback." Ex. 2040 ¶ 42 (emphasis added). We find

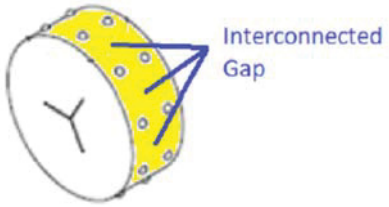
that this description provides support for the claimed "one or more air flow gaps are incorporated into the skirt section for ensuring sufficient air flow between the skirt section and an interior surface of the single catheter hub." Amend Mot. 12. As argued persuasively by Patent Owner in its reply, "[t]here is no *in haec verba* requirement" and newly added claim limitations may be supported by "express, ***implicit***, or inherent disclosure." PO Amend Reply 1–2 (quoting MPEP § 2163). Having reviewed the Specification, including that from the Parent Application, and after weighing the competing testimony of Mr. Griffis and Mr. Meyst, we credit Mr. Meyst's testimony that

> [a] POSITA would instantly recognize that one or more air flow gaps must necessarily be present if a "plurality of bumps, stretched ridges, or protuberances" are "incorporated around the external circumference of the skirt section" "for ensuring sufficient air flow between the valve skirt 52 and the inside surface 22 of the catheter hub."

Ex. 2028 ¶ 167.

Regarding the second sub-argument, Petitioner asserts that "[t]he specification only describes a valve that has multiple air flow gaps" and there is no written description support for the claimed "**one or** more air flow gaps." Amend Opp. 6. In support of this argument, Petitioner asserts that adding a "plurality of bumps, stretched ridges, or protuberances" to the skirt of the valve would result in multiple air flow gaps. *Id.*

Petitioner's second sub-argument is not persuasive. In its reply, Patent Owner submits a figure to illustrate why Petitioner's argument is incorrect, a copy of which we reproduce below (PO Amend Reply 3):



According to Patent Owner, the above-figure depicts how a valve skirt with "a plurality of bumps creates one large, interconnected airflow gap." *Id.* We agree with Patent Owner's understanding.

2. Petitioner's argument that "sufficient air flow" is indefinite

Petitioner argues that the phrase "sufficient air flow" is indefinite, because the "claims do not recite what the air flow must be sufficient to accomplish." Amend Opp. 8. Petitioner acknowledges that the Specification discusses "blood flashback," but argues that "it would be improper to import the concept of flashback from the specification into the claims" and that a POSITA "would have no way of knowing what the purpose is to assess whether the air flow is sufficient to meet that goal." *Id.*

We disagree with Petitioner. The Parent Application expressly describes:

> The hemostatic valve 46 . . . generally speaking comprises a skirt section 52 . . . . In accordance with aspects of the present invention, a plurality of bumps, stretched ridges, or protuberances may be incorporated around the external circumference of the skirt section 52 for ensuring sufficient air flow between the valve skirt 52 and the inside surface 22 of the catheter hub *for purposes of blood flashback*.

Ex. 2040 ¶ 42 (emphasis added). We find that one of ordinary skill in the art would have understood from reading the Specification that the sole purpose

for the "sufficient air flow" is for allowing blood flashback. Furthermore, Patent Owner's proposed construction does not impermissibly read a limitation from the Specification into the claims, but simply reads the claims in light of the Specification. *Translogic*, 504 F.3d at 1257. As Patent Owner correctly argues, a POSITA "reading the claims in view of the specification would understand 'sufficient air flow' to refer to purposes of blood flashback." PO Amend Reply 4 (citing *Tinnus Enters., LLC v. Telebrands Corp.*, 733 F. App'x 1011, 1021 (Fed. Cir. 2018) ("the claims, in the context of the specification, 'notify the public of what is within the protections of the patent, and what is not'") (internal citation omitted)).

Petitioner also argues that "even if the air flow is for 'flashback,' neither the claims nor the specification recites where this blood flashback must occur." Amend. Opp. 8 (citing Ex. 1064 ¶ 83). We disagree. The record clearly provides that blood flashback occurs when the vein is punctured during catheter insertion, and the increased pressure in the vein results in blood entering the chamber or catheter. *See, e.g.*, Ex. 1015, 318 ("When the stylet punctures the vein . . . is immediately relieved into the catheter stylet with a show of blood in the chamber"). We credit Mr. Meyst's testimony that, as shown in Figures 13 and 14 of the '641 patent, "blood flashback occurs proximally (to the right of) the valve in the needle hub." Ex. 2049 ¶ 22 (citing Ex. 1001, 7:61–65, 9:4–7).

Petitioner further argues that a claim using a "word of degree" like "sufficient" can only be definite where the patent provides some objective boundary for measuring that degree. Amend Opp. 9 (internal citation omitted). Although Petitioner cites the correct standard, we find that the

Specification provides a specified goal for measuring "sufficient air flow," that is, for the purposes of allowing blood flashback. Having weighed the competing testimony of Mr. Griffis and Mr. Meyst, we credit Mr. Meyst's testimony that a "POSITA reading the specification would understand that blood flashback is a functional/qualifiable result that is visually achieved via the flashback chamber when blood flashback occurs after the vein is penetrated." Ex. 2049 ¶ 21.

3. Petitioner's argument that "sufficient air flow" is not enabled

Petitioner argues that the "claims are not enabled because they do not teach a . . . [POSITA] how to make and use 'air flow gaps for ensuring sufficient air flow.'" Amend Opp. 10. Petitioner cites the *Wands* factors and asserts that a ". . . [POSITA] would not be able to make and use the claimed invention without undue experimentation." *Id.* (citing in-part *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)); *see also id.* at 10–12 (analyzing each of the *Wands* factors).

The Federal Circuit explained in *Wands* that the claim was not enabled if undue experimentation was required to practice the claimed invention. *Wands*, 858 F.2d at 736–739. "The key word is 'undue,' not experimentation." *Id.* at 737 (internal citation omitted). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* One of these factors is the *quantity of experimentation necessary*. *Id.*

Petitioner asserts that "[d]etermining how to design such a valve required extensive experimentation." Amend Opp. 12 (citing Ex. 1064

¶ 93). In support of this assertion, Petitioner submits the testimony of Mr. Stout, who is an Associate Marketing Director of Petitioner, but "was a Principal R&D Engineer and a member of the R&D core team" during a project to develop Petitioner's IAG BC catheter device. Ex. 1065 ¶ 2.

Mr. Stout testifies that the purpose of the IAG BC project was to develop a product [redacted] (*id.* ¶ 6 (internal citation omitted)) and that the [redacted] (*id.* ¶ 7 (internal citation omitted)). Mr. Stout further testifies that

[redacted]

Id. ¶ 9. Mr. Stout explains that there were several issues that arose [redacted].

Mr. Stout further testifies that [redacted] *Id.* ¶ 14 (citing Ex. 1047).

Mr. Stout also testifies that they used a silicone rubber material [redacted] *Id.* ¶ 15 (citing Ex. 1050, 10). Mr. Stout explains that [redacted]

[redacted] *Id.* ¶ 17 (citing Exs. 1056, 1091). Mr. Stout testifies that [redacted] *Id.* ¶ 15 (citing Ex. 1050, 10).

Mr. Stout also testifies that

[redacted]

Id. ¶ 19.

Although Mr. Stout's testimony supports a finding that Petitioner devoted significant resources and experimentation to create Petitioner's IAG BC product, we do not find this evidence to support a finding that undue experimentation was required to practice Patent Owner's claimed invention, which is the issue before us.

The claim limitation at issue simply requires that "one or more air flow gaps are incorporated into the skirt section for ensuring sufficient air flow between the skirt section and an interior surface of the single catheter hub." Claim 31 *does not* require that the air flow gaps are designed to a level of perfection that Petitioner's product may have sought, such as by preventing leaks. Unlike Petitioner's IAG BC product, claim 31 does not

require that [redacted]. Nor does claim 31 require [redacted] Indeed, Petitioner's IAG BC product appears to be [redacted] *See* Ex. 1065 ¶ 14 (citing Ex. 1047) [redacted]

We find that Petitioner's substantial efforts in developing the IAG BC product, as testified by Mr. Stout, [redacted]. Ex. 1065 ¶ 6 (testifying that Petitioner sought [redacted] Accordingly, even though Petitioner devoted [redacted] (*id.* ¶ 19), this does not support Petitioner's assertion that Patent Owner's claimed "gaps" for blood flashback would require undue experimentation. Having weighed the competing testimony of Mr. Griffis and Mr. Meyst, we credit Mr. Meyst's testimony that "determining the size of gaps is straightforward trial and error with a finite number of variables and that a POSITA would have a reasonable expectation of success in determining the proper size of gap(s) to allow for blood flashback." Ex. 2049 ¶ 26.

4. Petitioner's argument that "tip protector housing" is not described

Petitioner argues that "[i]f the Board construes the claims not to require a tip protector, then the substitute claims lack written description support." Amend Opp. 14. Petitioner explains that the "disclosed tip protector housings do not have any structure that protects the tip of the needle without a tip protector." *Id.* at 15.

We construe claim terms only to the extent necessary to resolve this proceeding. *Wellman,* 642 F.3d at 1361. In resolving the particular prior art challenges before us, we need not determine whether the claims require a "tip protector" separate from the "tip protector housing."

Turning to the claim language itself, namely, the recited "tip protector housing," Figures 13 and 14 provide written description support for the claimed limitation. To illustrate this point, Patent Owner submits an annotated version of these figures (PO Amend Reply 8), which we reproduce, below:

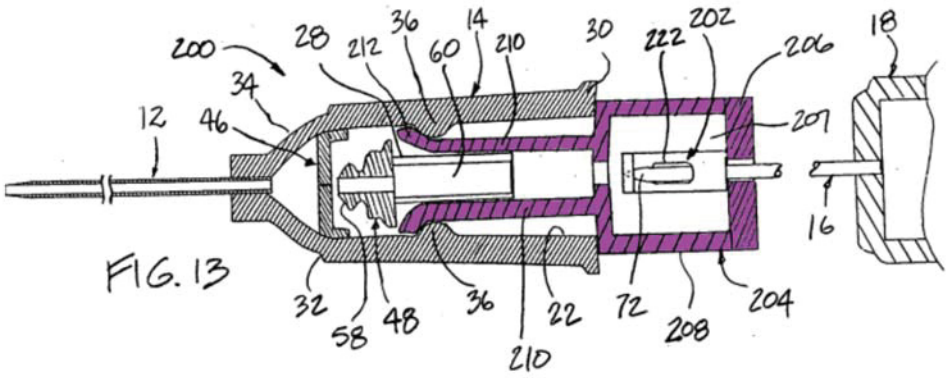
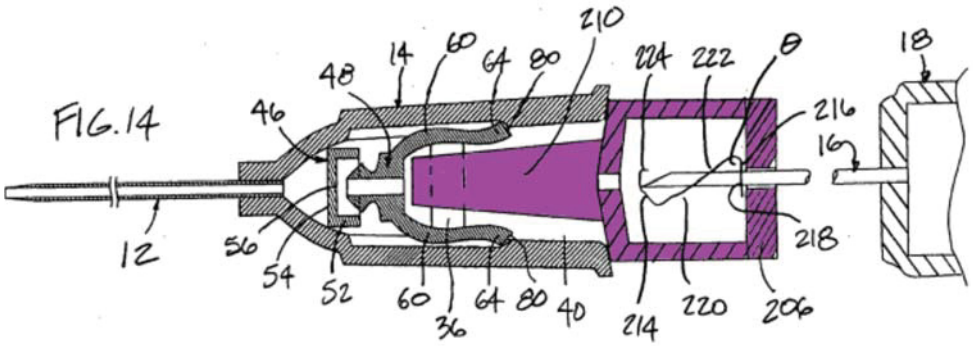


FIG. 13



As shown in the above Figures 13 and 14, and as discussed above (*supra* Part I.B), Figures 13 and 14 depict catheter assembly 200, including catheter tube 12, catheter hub 14, needle 16 with needle tip 72. Ex. 1001, 11:13–24. Needle 16 is covered by third housing 204 (purple) to minimize the risk of injury from needle tip 72. *Id.* at 11:53–64.

Accordingly, and because third housing 204 provides written description support for the claimed "tip protector housing," Petitioner's argument is unavailing.

5. Petitioner's argument that substitute claim 33 improperly broadens claim 32 or 31

Petitioner argues that claim 33, which requires the skirt section to comprise "a uniform circumference," improperly broadens its independent claim 31, which recites "one or more air flow gaps are incorporated into the skirt section." Amend Opp. 16; Amend Mot. 12, 15.

We disagree.

Simply because claim 31 requires "one or more air flow gaps incorporated into the skirt section" does not mean that it cannot be further narrowed to require the skirt section to have a "uniform circumference." In

other words, claim 31 may be interpreted to cover skirt sections that have a non-uniform circumference, such as a conical shape. *See* PO Amend Reply 8 ("Claim 31 . . . is broad enough to cover a valve with a skirt with a uniform circumference or a valve with a skirt with a conical shape"). Claim 33 does not recite a surface void of any air flow gaps, as Petitioner's argument presumes. Amend Opp. 16.

6. Petitioner's argument that substitute claim 31 is unpatentable over Prior Art

Petitioner argues that independent claim 31 would have been obvious over the combination of Woehr, Callaway, and Nakajima and Woehr, Villa, and Nakajima. Amend Opp. 16–17. Petitioner relies on Nakajima to address the claimed "one or more air flow gaps," but otherwise generally relies on the same reasoning and findings discussed above with regard to Woehr and Callaway and Woehr and Villa. *See id.* at 17–22.

For the same reasons discussed above (*supra* Part II.D.5), Petitioner's challenge under the combination of Woehr, *Callaway*, and Nakajima is not persuasive. Accordingly, our analysis focuses only on the challenge based on Woehr, *Villa*, and Nakajima.

a) Petitioner's Position

To address the newly claimed "single catheter hub," Petitioner asserts that "Woehr discloses a single catheter hub (e.g., element 2)." Amend Opp. 19 (citing in-part Ex. 1005, Abstract; Ex. 1064 ¶¶ 123, 124). Mr. Griffis testifies that "[t]he addition of the word 'single' *does not change my analysis*" and explains that "[a]lthough the catheter hub in Woehr is formed

from two pieces, it is still a single catheter hub." Ex. 1064 ¶ 123 (emphasis added).

To address the newly claimed "valve comprising a skirt section," Petitioner asserts that "Nakajima discloses a valve that comprises a skirt section" (Amend Opp. 19 (citing Ex. 1066 ¶ 32) and reasons that a POSITA would have modified "Woehr to use a valve having a skirt section" (*id.* at 20). Petitioner reasons that "[i]t was known in the art that a skirt valve helps keep the slit reliably closed because at least in part, the walls of the skirt valve exert a force against the slits." *Id.* (citing Ex. 1076, 1:48–58). Petitioner further reasons that using a skirt could help hold the valve in place and prevent buckling. *Id.* (citing Ex. 1064 ¶ 133).

To address the newly claimed "one or more air flow gaps are incorporated into the skirt section for ensuring sufficient air flow between the skirt section and an interior surface of the single catheter hub," Petitioner relies on Nakajima for teaching a valve with gaps to allow air flow. *Id.* at 21 (citing Ex. 1066 ¶ 32). Nakajima discloses that

> [a] plurality of gaps **3***c* is defined between an outer periphery of the elastic valve **3** and the inner surface **1***a* of the catheter body **1**. Distal and proximal spaces divided by the elastic valve **3** communicate with each other through the gaps **3***c*. Thus the elastic valve **3** slides smoothly with air passing through the gaps **3***c*.

Ex. 1066 ¶ 32. Petitioner reasons that it would have been obvious for a POSITA "to add the Nakajima skirt valve with air flow gaps to the slit-valve device in Woehr to allow air flow around the valve, which was understood to provide better blood flashback." Amend Opp. 22.

b) Our Analysis

Having considered Patent Owner's arguments and Petitioner's analysis, we find Petitioner's analysis persuasive.

We address each of Patent Owner's arguments separately, below.

Patent Owner first argues that Petitioner improperly incorporates by reference arguments made in the Petition and Petitioner's Reply. PO Amend Reply 10–11. In presenting this argument, Patent Owner explains that Petitioner's obviousness analysis is inadequate. *See id.* at 11–12.

Patent Owner's first argument is not persuasive. As pointed out correctly by Petitioner, we consider the entirety of the record when assessing the patentability of amended claims. Pet. Amend Sur-Reply 10 (citing *Aqua Prods.*, 872 F.3d at 1296). Accordingly, when raising prior art challenges to newly amended claims, it is appropriate for Petitioner to refer to arguments and analyses presented in its Petition.

Patent Owner further argues that Woehr does not teach a "single catheter hub," as it has "two hub elements 3 and 5." PO Amend Reply 12 (citing Ex. 1005, 2) (emphases omitted).

We disagree.

Woehr discloses a single catheter hub, denoted by reference numeral 2. Ex. 1005 (Figure 1 shows a catheter insertion device 1 comprising a catheter hub 2); *see also id.* at Figs. 1, 2 (depicting a single catheter hub 2). Although Woehr's catheter hub 2 is formed of two *hub elements* 3 and 5, this does not support Patent Owner's assertion that Woehr's *hub elements* are each catheter hubs. PO Amend Reply 12. We credit Mr. Griffis's

uncontroverted testimony that "[a]lthough the catheter hub in Woehr is formed from two pieces, it is still a single catheter hub." Ex. 1064 ¶ 123.

If Patent Owner seeks to claim the catheter hub as a single, integral, and gaplessly continuous piece, so as to preclude Woehr's two-piece construct, Patent Owner must adopt such language, or similar limiting language, within the claim itself. *See, e.g.*, *Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 784–85 (Fed. Cir. 1983) (holding that "a single integral and gaplessly continuous piece" is not obvious in light of similar bolted prior art structures"); *see also Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1336 (Fed. Cir. 2011) ("'integral'" as used means "'formed or cast of one piece'" (internal citation omitted)).

Petitioner establishes that Woehr, Villa, and Nakajima teach all elements of claim 31, including the new limitations, and why a POSITA would have had reason to combine those teachings with a reasonable expectation of success. We are persuaded that a preponderance of the evidence supports the conclusion that substitute claim 31 would have been obvious over Woehr, Villa, and Nakajima.

7. Petitioner's argument that substitute Claims 32 and 33 are unpatentable over the prior art

Petitioner asserts that substitute claims 32 and 33 are unpatentable over Woehr, Villa, Nakajima, and Sutton. Amend Opp. 22.

Claim 32 recites, in relevant part, "wherein an arm extends distally of the tip protector housing, wherein the arm is located at least in part in the single catheter hub in the ready position." Amend Mot. 14. Claim 33 depends from claim 32 and, through this dependency, also requires the

claimed "arm." *Id.* at 15. To address this limitation, Petitioner relies on Sutton and proposes to modify the Woehr/Villa device "to include an arm extending distally into a catheter hub as disclosed in Sutton to hold the catheter hub and the tip protector housing together." Amend Opp. 23 (citing in relevant part Ex. 1064 ¶¶ 192–197).

Sutton is a U.S. Patent Publication titled "**NEEDLE GUARD MECHANISM WITH SHROUD**." Ex. 1014, (54). Sutton describes "needle guards to protect users and others from the sharp tip of the needle after withdrawal from a patient." *Id.* ¶ 1. To illustrate a particular embodiment of Sutton's needle guard, we reproduce Figure 3C, below:

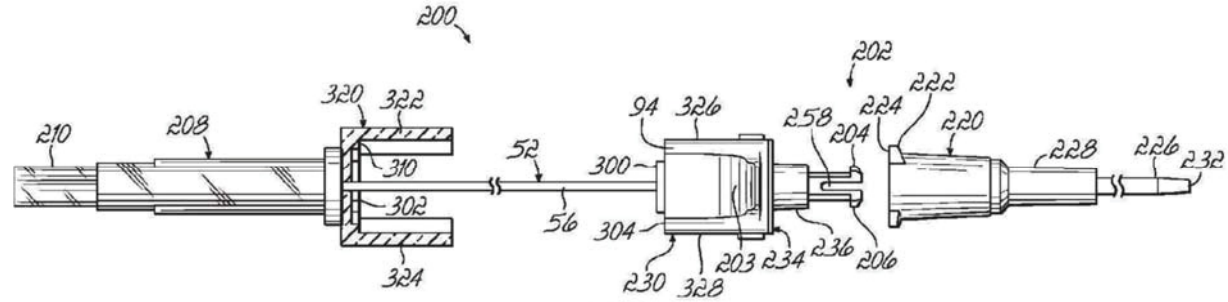


FIG. 3C

Sutton's Figure 3C above depicts catheter assembly 200 with needle guard 202 for protecting needle tip 58. *Id.* ¶ 39. In this particular embodiment, finger tab 203 is provided with duckbills 204 and 206, which allow housing 230 to be released from catheter hub 220. *See id.* ¶ 40. In operation, needle support 208 is pulled relative to needle guard 202, and movement of needle 52 brings tip 58 (shown in Figure 6A) into housing 230 "to be protected in the secured position thereof." *Id.*

We also reproduce Sutton's Figure 6A, below:

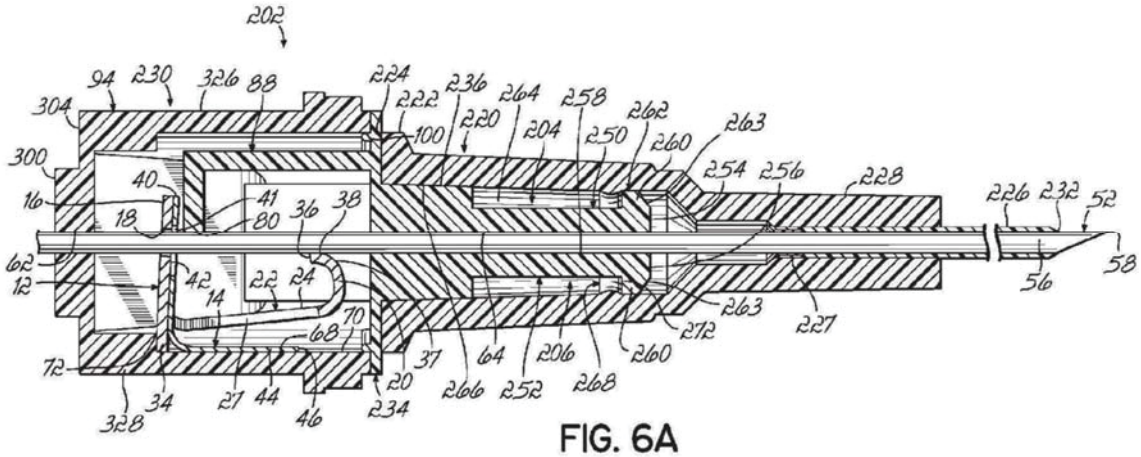


FIG. 6A

Sutton describes Figure 6A above as a cross-sectional view of the catheter assembly embodiment shown in Figure 3C, including operation of a duckbill catheter hub release mechanism. *Id.* ¶ 23. In particular, Figure 6A depicts needle guard duckbills 204, 206, and catheter hub rib 268 that cooperate to define a duckbill release mechanism. *Id.* ¶ 47. Sutton discloses that duckbill release mechanism may be combined with a canting-plate clip, or other clip designs, to protect needle tip 58. *See id.* Sutton describes reference numerals 12 and 14 as depicting a canted-plate clip and spring member, respectively. *See id.* ¶ 28 (referencing Fig. 1).

Petitioner reasons that it would have been obvious to a POSITA "to include an arm extending distally into a catheter hub as disclosed in Sutton to hold the catheter hub and the tip protector housing together." Amend Opp. 23 (citing Ex. 1064 ¶¶ 180–183, 192–197). Petitioner asserts that "the hub-connection mechanisms of . . . *Villa had disadvantages such as either allowing premature separation or requiring too much manipulation* that could be improved by using the easy-to-release arms in Sutton." *Id.* (citing

Ex. 1064 ¶¶ 181, 193) (emphasis added). In support of its assertion that Villa had "disadvantages," Mr. Griffis testifies that

> [a] person of ordinary sill [sic] in the art would understand that the snap connection in *Villa may require excessive manipulation* to separate the tip protector housing from the catheter hub, thus potentially compromising the catheter position within the vessel, or damaging the vessel itself due to *aggressive manipulation*. For example, a person of ordinary skill in the art understood that IV catheters should not be disturbed because doing so can lead to phlebitis or inflammation of a patient's vein.

Ex. 1064 ¶ 193 (citing Ex. 1040, 354) (emphases added).

Upon reviewing Mr. Griffis's testimony and Exhibit 1040, however, we find that Villa has no such "disadvantages." Accordingly, Petitioner's reasoning lacks rational underpinnings, and a POSITA would not have replaced Villa's releasable connection with Sutton's connection.

Villa explicitly discloses that "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 ¶ 53 (emphasis added).

Although Mr. Griffis testifies that "the snap connection in Villa may require *excessive manipulation* to separate the tip protector housing from the catheter hub, thus potentially compromising the catheter position within the vessel, or damaging the vessel itself due to *aggressive manipulation*," Mr. Griffis does not cite to any evidence to support his assertion that Villa's snap fit itself requires undesirable manipulation. *See* Ex. 1064 ¶ 193 (citing Ex. 1066, 354) (emphases added). Rather, the evidence that Mr. Griffis cites states that "[m]echanical irritation, causing a phlebitis or inflammation of the

vein can be attributed to use of too large a cannula in a small vein . . . [and m]anipulation of the catheter during infusion causes irritation of vein wall . . . [and that t]echnical expertise of the person inserting the cannula influences the risk for mechanical phlebitis." Ex. 1040, 354. Although this supports a finding that using smaller cannulas and utilizing medical technicians with increased expertise reduces the risk for mechanical phlebitis, the cited evidence does not support a finding that Villa's snap fit requires more manipulation than Sutton's duck-bill release mechanism. Rather, we find that Villa's snap fit and Sutton's duck bill mechanisms are similar, in that both use flexible, resilient members for connecting to their respective hubs. *See supra* Part II.E.1.

"Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." 37 C.F.R. § 42.65(a); *see also* Fed. R. Evid. 702(b) ("A witness who is qualified as an expert . . . may testify . . . if . . . the testimony is based on sufficient facts or data"). Because the record does not support Mr. Griffis's testimony that Villa's snap fit requires more manipulation than Sutton's duck bill release mechanism, Mr. Griffis's testimony is not persuasive.

For the foregoing reasons, we are not persuaded that a POSITA would have modified Woehr and Villa to include Sutton's "arms," as Petitioner proposes. As such, the preponderance of the evidence fails to establish that the cited art would have rendered proposed substitute claim 32 or 33 obvious to a person of ordinary skill in the art at the time of the invention.

8. Petitioner's argument that Patent Owner failed to meet its duty of candor

Petitioner argues that Patent Owner failed to meet its duty of candor by failing to "disclose to the Board information of which the patent owner is aware that is material to the patentability of substitute claims." Amend Opp. 24 (citing 37 C.F.R. § 42.11).

We are not persuaded that Patent Owner failed to meet its duty of candor. Patent Owner asserts that "the information alleged to be material is at best cumulative," and we have no reason to doubt Patent Owner. PO Amend Reply 9.

9. Petitioner's argument that amending dependency of claims 19, 22, and 24 is improper

Petitioner points out that Patent Owner seeks to amend dependent claims 19, 22, and 24 from single dependent claim format to multiple dependent claim format, and argues that the proposed amendment is improper because Patent Owner seeks to increase the number of claims. *See* Amend Opp. 25.

Our Rules require that "[a] motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims. *The presumption is that only one substitute claim would be needed to replace each challenged claim*." 37 C.F.R. § 42.121(a)(3) (emphasis added).

In seeking to amend claims 19, 22, and 24 from single dependent format to multiple dependent format, Patent Owner seeks to amend claims 19, 22, and 24 to depend from either claim 31 or 32. *See* Amend Mot., Claims App. A, 2–3 (amending claims 19, 22, and 24 from single

dependency to depend from claim 31 or 32). As discussed above, however (*supra* Part III.C.6), substitute claim 31 would have been obvious over Woehr, Villa, and Nakajima. As such, newly amended claims 19, 22, and 24 now only depend from a single patentable claim, claim 32, and we do not find Patent Owner's proposed amendment to conflict with 37 C.F.R. § 42.121(a)(3).

IV. CONCLUSION

In consideration of the foregoing, it is hereby:

ORDERED that, by a preponderance of the evidence, claims 15, 17, 18, 20, and 22 of the '641 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend is *granted* with respect to proposed substitute claims 32 and 33, but *denied* with respect to proposed substitute claim 31;

FURTHER ORDERED that Patent Owner's Motion to Amend is *granted* with respect to proposed amendments to claims 20, 21, and 23;

FURTHER ORDERED that Patent Owner's Motion to Amend is *granted* with respect to claims 19, 22, and 24, but claims 19, 22, and 24 shall only depend from claim 32;

FURTHER ORDERED that Patent Owner's Motion to Amend is *granted* with respect to the cancellation of claim 16; and

FURTHER ORDERED that this is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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 IPR2017-01590
Patent 9,370,641 B2

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

DANIELS, *Administrative Patent Judge,* concurring.

I concur in the majority's judgment granting Patent Owner's Motion to Amend as it relates to substitute dependent claims 19, 22, and 24, but I write separately to express my belief that the presumption of a one-for-one replacement of substitute claims under 37 C.F.R. § 42.121(a)(3) is not a steadfast requirement, but a guidepost subject to the reasonableness requirements expressed in 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 42.121(a)(3).

By Rule, there is a rebuttable presumption that more than one substitute claim per challenged claim is unreasonable, and that presumption "may be rebutted by a demonstration of need." 37 C.F.R. § 42.121(a)(3). According to 35 U.S.C. § 316(d)(1)(B) a Patent Owner may "[f]or each challenged claim, propose a reasonable number of substitute claims." Thus, the Statute using the plural noun "substitute claims" clearly expresses the reasonableness of multiple replacement claims for each claim canceled. What the Board may determine to be "reasonable" is constrained by 37 C.F.R. § 42.121(a)(3) and the rebuttable presumption of no more than one substitute claim per challenged claim. I agree entirely with the Board's determination in other cases, that an *inter partes* review is not a vehicle for unfettered multiple claim substitution nor "an opportunity to start anew with a fresh set of claims at trial." *adidas AG v. Nike, Inc*., Case IPR2013-00067, Paper 69 at 14 (PTAB Sept. 18, 2018) ("*adidas*"). I further agree with our cases that espouse the Board's discretionary provisions under our Rules when deciding matters and circumstances evidencing multiple substitute claims. *See, e.g., Idle Free Sys., Inc. v. Bergstrom*, Case IPR2012-00027, Paper 26 at 8–9 (PTAB June 11, 2013) ("*Idle Free*").[5]

In this case, Patent Owner simply amended dependent claims 19, 22, and 24 in their original form to be multiple dependent claims, i.e., dependent upon both substitute claims 31 and 32, without changing the scope and

[5] *Idle Free's* informative designation was withdrawn on June 1, 2018, for reasons other than the Board's discretionary review of multiple substitute claims. *See* USPTO BULLETIN, June 1, 2018, https://content.govdelivery.com/accounts/USPTO/bulletins/1f442f5 (last visited Aug. 8, 2018).

substantive content of the existing dependent claims in any manner. Assuming both substitute claims 31 and 32 had been determined patentable, such an amendment could be understood as adding three more claims to the patent then were being canceled, and hence potentially running afoul of the rebuttable one-for-one presumption under 37 C.F.R. § 42.121(a)(3). As I stated, however, in my Concurrence in *adidas*:

> A strategic goal of the reasonableness requirement in both the statute and our rules is to facilitate the goals of keeping the review process within the statutorily directed time limits (*see* 35 U.S.C. § 316(a)(11)) and "secur[ing] the just, speedy, and inexpensive resolution of every proceeding" (37 C.F.R. § 42.1(b)). A tactical goal is to maintain the scope of the claims within bounds which maintain *inter partes* review as an adjudicatory, rather than a prosecutorial, process. *Abbot Labs v. Cordis Corp.*, 710 F.3d 1318, 1326 (Fed. Cir. 2013).

adidas, APJ Daniels Concurrence, 3–4. In this case, the addition of three dependent claims in Patent Owner's Motion to Amend beyond a one-for-one substitution, without change in scope or content of those dependent claims, is manifestly reasonable and does not impact either of the Board's goals of timely resolving the proceeding under 35 U.S.C. § 316(a)(11) and ensuring the proceedings do not become overly prosecutorial. Although the majority decision in this case couches the amendment of claims 19, 22, and 24 as proper because the end result found claim 31 to be unpatentable, even if claim 31 was found to be patentable, the addition of three dependent claims as multiple dependent claims applies neither a substantive nor procedural burden on the board and is therefore reasonable and within the Board's discretion to permit.

To the extent Patent Owner did not in its Motion to Amend express a specific demonstration of need for the multiple dependent claims, in this case, the addition of three dependent claims as multiple dependent claims without any change to the scope and substantive content of the dependent claims was reasonable and within the Board's discretion to permit. This is also because, in this case, the formal amendment of claims 19, 22, and 24 as multiple dependent claims was naturally intended to ensure that if claim 30 were found unpatentable, as it was, the dependent claims would potentially remain in the patent as dependent upon claim 31. An express demonstration of need, however, can, and almost always will be crucial in the exercise of our discretion under 37 C.F.R. § 42.121(a)(3). Fulfilling this provision of our rules should never be overlooked by a Patent Owner seeking to add multiple substitute claims beyond a one-for-one substitution.

Consequently, while I concur in the majority's judgment, I do not believe correct an interpretation that the rebuttable presumption of one-for-one substitute claims as set forth in our Rules always dictates what the Board determines to be a reasonable number of substitute claims.

IPR2017-01590
Patent 9,370,641 B2

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