UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B.BRAUN MELSUNGEN AG,
Patent Owner of
U.S. Patent No. 8,460,247 to Woehr et al.

IPR Trial No. IPR2017-01588

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 75) in IPR2017-01588 (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 "needle protective device" as recited in U.S. Patent No. 8,460,247; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that claims 12, 13, 20-23, and 29 of U.S. Patent No. 8,460,247 are unpatentable under 35 U.S.C. § 103 over the combinations of Woehr, Callaway, and Sutton and/or Woehr, Villa, and Sutton; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that claim 22 of U.S. Patent No. 8,460,247 is unpatentable under 35 U.S.C. § 103 over the combinations of Woehr, Callaway, Sutton, and Nakajima and/or Woehr, Villa, Sutton, and Nakajima; 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 703738735 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

Trials@uspto.gov
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Paper No. 75
Entered: December 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B. BRAUN MELSUNGEN AG,
Patent Owner.

Case IPR2017-01588
Patent 8,460,247 B2

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

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 12, 13, 20–23, and 29 of U.S. Patent No. 8,460,247 B2 ("the '247 patent"). B. Braun Melsungen AG ("Patent Owner") filed a Preliminary Response. Paper 7, "Prelim. Resp.".

Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, on December 21, 2017, we instituted an *inter partes* review on only four of the eight challenged grounds of unpatentability. *See* Paper 8, 41–42 ("Decision to Institute") (instituting review on only four of the eight grounds presented, concluding that Petitioner failed to demonstrate a reasonable likelihood of prevailing on the four non-instituted grounds).

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). On April 26, 2018, the Office issued Guidance on the Impact of *SAS* on AIA Trial Proceedings, which states that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial. Subsequently, on May 7, 2018, we issued an Order modifying the Decision to Institute to institute on all eight of the grounds presented in the Petition. Paper 28, 2.

On May 14, 2018, the parties filed a joint motion to limit the proceeding to the four originally-instituted grounds, which are allegations of

obviousness under 35 U.S.C. § 103 based on the following combinations of art: (1) Woehr, Callaway, and Sutton; (2) Woehr, Villa, and Sutton; (3) Woehr, Callaway, Sutton, and Nakajima; and (4) Woehr, Villa, Sutton, and Nakajima. Paper 30, 2; *see also infra* Part I.D (listing the references relied upon). We granted the parties' joint motion and limited this proceeding to those four grounds. Paper 32, 4. Accordingly, this Decision addresses only those grounds.

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 22, "PO Resp."), to which Petitioner replied (Paper 38, "Pet. Reply"). Patent Owner also filed a Sur-Reply (Paper 47, "PO Sur-Reply #1"), to which Petitioner filed a Petitioner's Sur-Reply Response (Paper 50, "Pet Sur-Reply"), and to which Patent Owner replied (Paper 56, "PO Sur-Reply #2").

Patent Owner also filed a contingent Motion to Amend. Paper 23.

Oral argument was conducted on September 21, 2018, and the transcript of the hearing has been entered as Paper 73.

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 *not* met its burden of showing, by a preponderance of the evidence, that any of claims 12, 13, 20–23, or 29 of the '247 patent is unpatentable.

Based on our Decision set forth below, Patent Owner's contingent Motion to Amend is considered, but denied as moot.

A. Related Proceedings

Petitioner represents that the '247 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. 1–2. Petitioner also represents that petitions for *inter partes* review were filed challenging related patents US. Patent Nos.: 8,328,762; 8,337,463; 8,540,728; 9,149,626; 8,597,249; 8,333,735; and 9,370,641. *Id.* Below is a chart that associates the *inter partes* reviews with each patent:

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

We denied institution of review in IPR2017-01583, IPR2017-01584, and IPR2017-01585. We instituted review, however, in the other listed *inter partes* reviews.

B. The '247 Patent (Ex. 1001)

The '247 patent, entitled "Catheter Assembly and Components Thereof," discloses catheter assemblies having "a tip protector, a valve, a valve opener, and . . . a needle wiper." Ex. 1001, [54], [57]. The '247

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 1:34–43. The '247 patent also discusses a desire to cover needles immediately following use, and to provide a valve to minimize blood exposure following successful catheterization. *See id.* at 1:52–58.

To illustrate a particular embodiment of the '247 patent's catheter insertion device, we reproduce Figures 13 and 14 of the '247 patent, below:

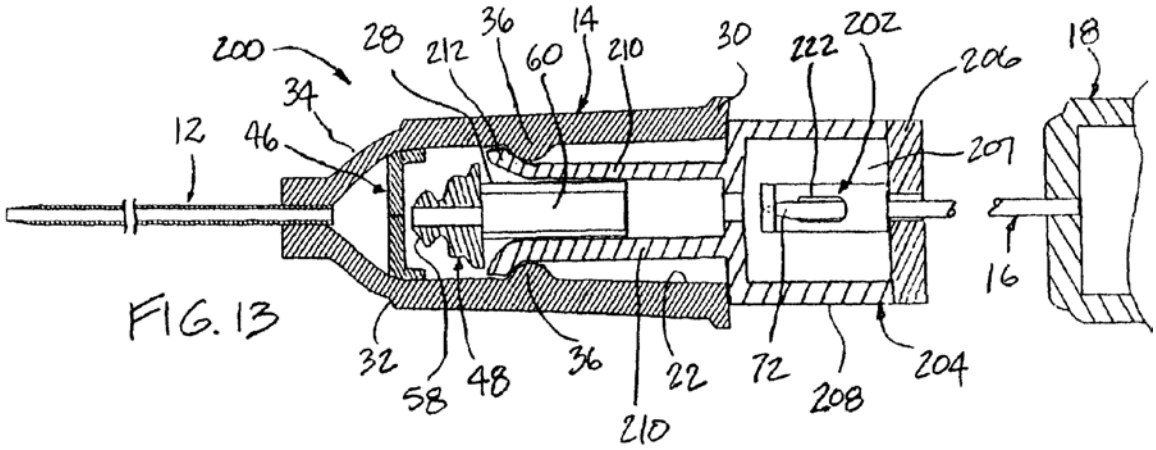


FIG. 13

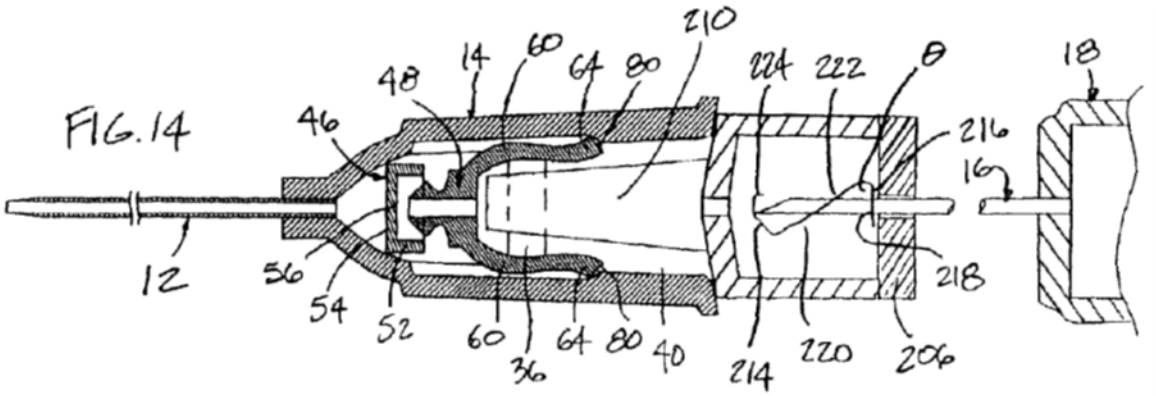


FIG. 14

Figures 13 and 14 depict a particular embodiment of Patent Owner's catheter assembly with a *third housing* positioned between the catheter and needle hubs. *Id.* at 4:36–41. Figure 14 "is a cross-sectional side view" of Figure

13's catheter assembly "taken along an orthogonal plane." *Id.* at 4:40–41. In particular, Figures 13 and 14 depict catheter assembly 200, including catheter tube 12, catheter hub 14, needle 16 with needle tip 72, needle hub 18, hemostatic valve 46, and valve opener 48. *Id.* at 11:4–16. Valve opener 48 comprises a pair of legs 60 positioned in corresponding channels 28. In this particular embodiment, third housing 204 is provided to "accommodat[e] the tip protector." *See id.* at 11:16–19. Third housing 204 incorporates pair of arms 210, each of which comprises hook 212. *Id.* at 11:33–34. The two hooks 212 are configured to engage two bumps 36 to retain third housing 204 to catheter hub 14 in a "ready to use position," and are preferably flexible to provide a gripping force against bumps 36. *Id.* at 11:34–38. Needle 16 extends through valve 46 and through catheter tube 12, and after withdrawal of needle 16 from catheter tube 12 and valve 46, valve 46 closes to prevent an outflow of blood. *See id.* at 7:5–15.

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

C. Illustrative Claim

Of the challenged claims, claims 12 and 23 are independent, with claims 13 and 20–22 depending directly or indirectly from claim 12, and claim 29 depending directly from claim 23. *Id.* at 5:1–8:28. Independent claims 12 and 23 recite similar subject matter and we reproduce claim 12, below, with emphasis added to a particular limitation addressed in our Decision:

> 12. A safety catheter assembly comprising:
>
> a first hub comprising an interior cavity, an opening at a proximal end, and a catheter tube having a distal end opening extending distally of the first hub;
>
> a needle having a needle shaft defining a needle axis projecting distally of an end of a second hub, said needle projecting through the catheter tube and comprising a needle tip;
>
> a valve comprising a slit for obstructing fluid flow positioned inside the interior cavity of the first hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the first hub;
>
> a valve actuating element slidingly disposed in the first hub for actuating the valve, the valve actuating element comprising a nose section having a tapered end with an opening configured to push the valve to open the slit and at least two leg elements extending proximally of the nose section and having a gap therebetween; wherein the at least two leg elements with the gap therebetween are disposed distally of the opening at the proximal end of the first hub and are slidable distally by a male implement projecting into the opening of the first hub to transfer a distally directed force to the nose section to push the valve to open the slit;
>
> a needle protective device positioned proximally of the valve and at least in part around the needle and distal of proximal end of the second hub in a ready position and configured to prevent unintended needle sticks in a protective position;
>
> *wherein an arm extends distally of a third hub and is*

> *located at east [sic] in part in the first hub in a ready position*; and
>
> wherein a portion of the needle protective device springs relative to the needle to move to the protective position.

Id. at 13:33–67 (emphasis added).

D. References Relied Upon

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

Name	Reference	Ex. No.
Woehr[1]	PCT WO 2004/004819 A1, published Jan. 15, 2004	Exs. 1003, 1005
Callaway	US 2006/0178635 A1, published Aug. 10, 2006	Ex. 1004
Villa	US 2004/0225260 A1, published Nov. 11, 2004	Ex. 1006
Sutton	US 2007/0038186 A1, published Feb. 15, 2007	Ex. 1009
Nakajima	US 2002/0128604 A1, published Sept. 12, 2002	Ex. 1007

E. Alleged Grounds of Unpatentability

As discussed above, this proceeding is limited to the following grounds:

References	Basis	Claim(s)
Woehr, Callaway, and Sutton	§ 103(a)	12, 13, 20–23, 29
Woehr, Villa, and Sutton	§ 103(a)	12, 13, 20–23, 29
Woehr, Callaway, Sutton, and Nakajima	§ 103(a)	22
Woehr, Villa, Sutton, and Nakajima	§ 103(a)	22

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

Paper 32, 4.

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. Prosecution History

During prosecution, the examiner did not reject any of the claims based on any of the art relied upon by Petitioner. *See generally* Ex. 2047.[2] The examiner allowed the claims over the prior art of record "because the prior art does not specifically claim or render obvious the claimed third hub." *Id.* (Notice of Allowability, page 2, dated April 3, 2013).

B. 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) (2016); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach).[3] Under that

[2] Exhibit 2047, which is unnumbered, is the file history of the '247 patent.
[3] 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. 51,340 (Oct. 11, 2018). This rule change applies to petitions filed after November 13, 2018, however, and does not apply to this proceeding. *Id.*

standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In our Decision to Institute, we determined that the only terms that required construction for purposes of that decision were: (1) "needle protective device" (claims 12 and 23); and (2) "an arm extends distally of a third hub" (claim 12) and "an arm coupled to a third hub extends distally of the third hub" (claim 23). Paper 8, 9–16; Ex. 1001, 13:34–14:59.

Petitioner disagrees with our construction of "needle protective device"—which we concluded is *not* a means-plus-function term—but acknowledges that Woehr discloses a "needle protective device" whether the term is construed as a means-plus-function term or not. *See* Pet. Reply 3 ("Petitioner disagrees with the Board's construction . . . [because] the term 'needle protective device' is a means plus function term"); *see also id.* at 3 n.1 ("Woehr discloses a 'needle protective device' whether the term is construed as a means plus function term or not.").

Patent Owner, on the other hand, does not dispute the construction of any claim term from our Decision to Institute (PO Resp. 4–5) and agrees that "the Board's prior construction [of needle protective device] remains correct" (*id.* at 5).[4]

[4] Our Decision to Institute was based upon arguments and evidence presented by Patent Owner in its Preliminary Response, and for consistency in this Decision, we cite to those same arguments and evidence here.

Although Petitioner references a district court claim construction and cites to the supplemental declaration of Mr. Griffis, Petitioner does not submit additional argument or otherwise explain why our original construction—as set forth in our Decision to Institute—is in error. *See* Pet. Reply 3 (citing Ex. 1064 ¶¶ 24–26); *see also supra* n.3 (explaining that the Board and federal district court use different claim construction standards for petitions filed before November 13, 2018). Furthermore, Mr. Griffis's supplemental testimony simply relies on "the reasons stated in [his] original declaration" (Ex. 1064 ¶ 25), which we previously considered (*see* Paper 8, 10 (citing Ex. 1002 ¶¶ 53–59)), and does not substantively supplement his testimony (*see* Ex. 1064 ¶¶ 24–26).

Accordingly, and as explained in greater detail, below, we maintain the construction of the terms as explained in our Decision to Institute.

1. "needle protective device"

Independent claims 12 and 23 each recite "a needle protective device positioned proximally of the valve and at least in part around the needle and distal of a proximal end of the second hub [or needle hub] in a ready position and configured to prevent unintended needle sticks in a protective position." Ex. 1001, 13:33–14:59 (hereafter "needle protective device limitation").

Petitioner contends the needle protective device limitation should be construed in means-plus-function format pursuant to 35 U.S.C. § 112 ¶ 6. Pet. 11–15; Pet. Reply 3. Petitioner acknowledges that a presumption exists that the limitation is not in means-plus-function format, yet 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. 13 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc). Petitioner further contends that "the modifier 'needle protective' 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 'needle protective device' is not defined in any technical dictionaries or engineering handbooks, nor is it 'used in common parlance or by persons of skill in the pertinent art to designate structure.'" *Id.* at 14 (citing Ex. 1002 ¶¶ 53–59). Accordingly, Petitioner asserts that the claimed "needle protective device" includes, for example, spring clips described in the Specification and structural equivalents thereof. *See id.* 14–15 (citing in-part, e.g., Ex. 1001, 5:51–55 ("incorporating by reference spring clips disclosed in U.S. Patent No. 6,616,630 [('Woehr-630')]")).

Patent Owner, on the other hand, disagrees that the needle protective device limitation should be construed in means-plus-function format. Prelim. Resp. 8; *see also id.* at 5–17; *see also* PO Resp. 5 ("The record before the Board with respect to this term has not changed, and the Board's prior construction remains correct for the reasons addressed in the [preliminary response and Decision to Institute]."). Patent Owner contends that "[t]he claim language following 'needle protective device' . . . indicates the term is structural." Prelim. Resp. 15. Patent Owner points out that "[c]laim 12 requires that the "needle protective device" be "positioned proximally of the valve and at least in part around the needle and distal of a proximal end of the second hub in a ready position and configured to prevent unintended needle sticks in a protective position." *Id.* Patent Owner further

asserts that several of the dependent claims recite additional structure, such as "[the] protective device comprises a proximal wall and an arm extending distally of the proximal wall" (claim 15), and "[the] needle protective device comprises a resilient portion" (claim 20). *Id.* at 16–17. Patent Owner asserts "[b]y describing the location of the 'needle protective device' and how [the needle protective device] cooperates with the needle, and that it has a wall and an arm and/or a resilient portion, a POSITA would understand it to be structural." *Id.* at 15–16 (citing Ex. 2001 ¶¶ 62–64; *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 649 F.3d 1350, 1356 (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")).

Upon reviewing the prosecution history (Ex. 2047), we find nothing that guides us in our determination of whether the claimed "needle protective device" should be construed under § 112 ¶ 6. We conclude, however, that the needle protective device limitation recites sufficient structure and should not be construed as a means-plus-function term.

Because the term "means" is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. *See Williamson, LLC*, 792 F.3d at 1349 (explaining that the presumption is overcome "if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function'") (internal citation omitted).

The claims do not simply recite a "needle protective device," without

more, but explicitly require that the "needle protective device [be] *positioned proximally of the valve and at least in part around the needle and distal of a proximal end of the second hub in a ready position and configured to prevent unintended needle sticks in a protective position*." Ex. 1001, 13:58–61 (emphasis added to structural limitations of claim 12); *see also id.* at 14:51–55 (reciting similar structure in independent claim 23). Petitioner fails to address these structural limitations in its proposed claim construction, instead focusing only on the three words "needle protective device." *See* Pet. 11–15. Moreover, Petitioner's proposed construction would seemingly render superfluous several of these other claimed structural features.

As argued by Patent Owner, we determine that the needle protective device limitation recites sufficient structure. Mr. Meyst explains how a person of ordinary skill in the art "would recognize that the claimed 'needle protective device' refers to the class of structures included in safety IV catheters that prevent unintended needle-sticks by covering (*i.e.*, protecting or guarding) the needle tip." Ex. 2001 ¶ 56 (citing Ex. 2014, which is cited in the '735 patent). We find Mr. Meyst's testimony persuasive.

Upon reviewing the Specification, the prosecution history, the claim language, and after weighing the competing testimony of Mr. Griffis (Ex. 1002 ¶¶ 53–59; Ex. 1064 ¶¶ 24–26) and Mr. Meyst (Ex. 2001 ¶¶ 29–64), we conclude that the term "needle protective device" should not be construed under § 112 ¶ 6. Instead, we agree with Patent Owner (PO Resp. 4–5) and we credit Mr. Meyst's testimony (specifically, Ex. 2001 ¶ 56) that the term "needle protective device" means *a device configured to prevent*

unintended needle sticks and that it be positioned proximally of the valve and at least in part around the needle and distal of the proximal end of the second hub (claim 12) or needle hub (claim 23) in a ready position.[5]

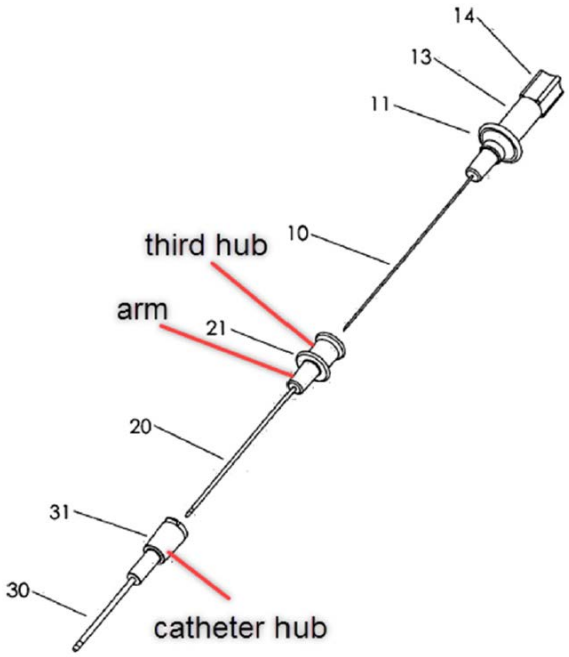
2. "an arm extends distally of a third hub" (claim 12) and "an arm coupled to a third hub extends distally of the third hub" (claim 23)

Petitioner argues that "a POSA would understand 'arm' to mean a part attached to or projecting from something," and asserts that Callaway and Vila each discloses this structure. Pet. 26, 41–42.

Before examining the intrinsic evidence to determine proper claim meaning, we first discuss the significance of the parties' dispute and how Petitioner's interpretation is applied to the art. We do this to show the impact of the claim construction on the issues presented.

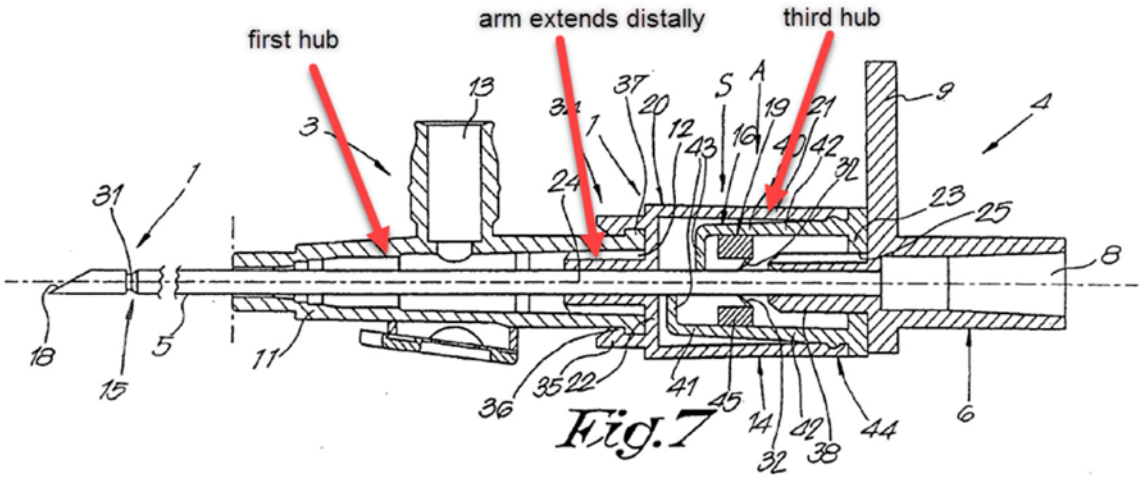
To illustrate Petitioner's interpretation of the claimed term and its application to Callaway, Petitioner submits an annotated version of Callaway's Figure 5 (*id.* at 27), which we reproduce, below:

[5] 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 'needle protective device' whether the term is construed as a means plus function term or not.").



According to Petitioner, and as shown in Callaway's annotated Figure 5, "a POSA would understand that the distal portion of the hub 21 in Callaway is the claimed arm because this element holds the assembly together and projects from hub 21." *Id.* at 26 (citing Ex. 1002 ¶¶ 91–94).

Petitioner also asserts that Villa discloses the claimed "arm," and submits an annotated version of Villa's Figure 7 (*id.* at 41), which we also reproduce below:



According to Petitioner, and as shown in Figure 7, Villa discloses an "arm" 22 that extends distally of "third hub" 20. *Id.* at 41.

Upon reviewing Callaway and Villa, we find that Villa's "third hub" (hollow body 20) appears similar to that of Callaway's "third hub" (hub 21), as each are cylindrical bodies with co-linear cylindrical portions that extend therefrom. *Compare, e.g.*, Ex. 1004, Fig. 5, *with* Ex. 1006 ¶ 49, Fig. 7. Patent Owner describes these co-linear cylindrical portions as noses. *See* Prelim. Resp. 55, 62.

In support of Petitioner's assertion that these co-linear cylindrical portions can be construed as satisfying the claimed "arm," Mr. Griffis testifies that, in applying the broadest reasonable interpretation, "a person of ordinary skill in the art would understand 'arm' to mean '[a] part attached to or projecting from something.'" Ex. 1002 ¶ 93 (citing Ex. 1008, definition of "arm").

In its Preliminary Response—which we relied upon in our Decision to Institute—Patent Owner contends that Callaway's distal section of hub 21 and Villa's walls 22 "noses" cannot reasonably be construed as the claimed

"arm." *See* Prelim. Resp. 55, 62. Patent Owner argues that the Specification depicts the "arms" as being elongated. *See id.* at 56–57 ("*Arms 210 are also elongated*, as FIG. 13 clearly illustrates.") (emphasis added).

We agree with Patent Owner and conclude that Petitioner's interpretation is unreasonably broad and inconsistent with the Specification.

In construing the claimed term "arm," we first focus on the language of the claimed limitation. Here, the claims require the "arm" to extend distally of the third hub. Ex. 1001, 13:34–14:59. "[I]n determining the ordinary and customary meaning of the claim term as viewed by a person of ordinary skill in the art, it is appropriate to consult a general dictionary definition of the word for guidance." *See Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348 (Fed. Cir. 2010) (citation omitted). In consulting general dictionary definitions, including that submitted by Petitioner (Ex. 1008), we find "arm" to be defined as: "any *armlike part or attachment*, as the tone arm of a phonograph" (www.dictionary.com (last visited Nov. 13, 2017) (emphasis added)); "[a] part attached to or projecting from something" (Ex. 1008); "a *long thin piece* that is connected to the main part of a machine, structure, etc., and *that looks or moves like a human arm*" (www.learnersdictionary.com (last visited Nov. 13, 2017) (emphases added)).

We also consult the prosecution history of record. In an amendment dated February 7, 2013, the applicant asserted that "[t]he scope of independent claims [1 and 23] can be found in FIGs. 13 and 14 of the instant application and corresponding written description." Ex. 1010, 10.

We now review the Specification, namely, Figures 13 and 14 and their accompanying description. We find that these figures depict an "arm" extending distally of a "third hub," and to illustrate this structure, we reproduce Figure 13 of the '247 patent, below:

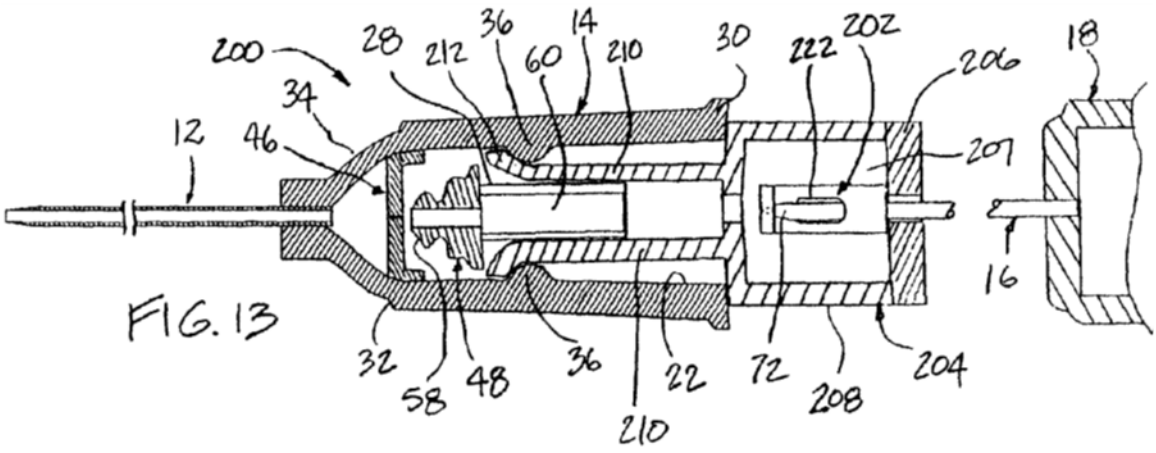


FIG. 13

The '247 patent describes:

> The *third housing **204** incorporates a pair of arms **210** each comprising a hook **212***. The 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. The two arms **210** are preferably flexible to provide a gripping force against the two bumps **36**, which is higher than the frictional force to withdraw the needle through the tip protector **202**, hemostatic valve **46**, and catheter **12**. Alternatively the two arms **210** can be biased radially outward to increase the gripping force. Further, the two arms can be biased inwardly against the needle shaft to decrease the gripping force after the needle is withdrawn proximal of the arms **210**.

Ex. 1001, 11:33–45 (emphasis added).

Upon reviewing the language of the claims, the prosecution history of record, general dictionary definitions, and the Specification, we conclude that the claimed limitations, "arm extends distally of a third hub" (claim 12)

and "arm coupled to a third hub extends distally of the third hub" (claim 23), each require the arm to be a flexible, elongate structure that extends from the claimed "third hub." An example would be Figure 13's elongate arms 210 that extend distally from "third hub" 204. Applying this to the art, we find that the cylindrical co-linear portions (i.e., "noses") of Callaway's "third hub" 21 and Villa's "third hub" 20 (element 22) are not flexible, elongate extensions. Petitioner's proposed interpretation of the claimed term "arm" is inconsistent with the Specification and unreasonably broad, and we do not agree with Petitioner's contentions that Callaway's "third hub" 21 (Pet. 27) and Villa's "third hub" 20" (*id.* at 41–42) have "arms" extending distally therefrom, as required by the claims.

3. 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 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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 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 PersonalWeb 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).

D. Level of Ordinary Skill in the Art

In our Decision to Institute, we determined the level of ordinary skill in the pertinent art at the time of the invention. Paper 8, 17–18.

Neither Patent Owner nor Petitioner disputes 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 be either a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. Paper 8, 17–18.

E. Woehr, Callaway, and Sutton

Petitioner contends that claims 12, 13, 20–23, and 29 are unpatentable over Woehr, Callaway, and Sutton. Pet. 3.

1. Woehr (Exs. 1003, 1005)[6]

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

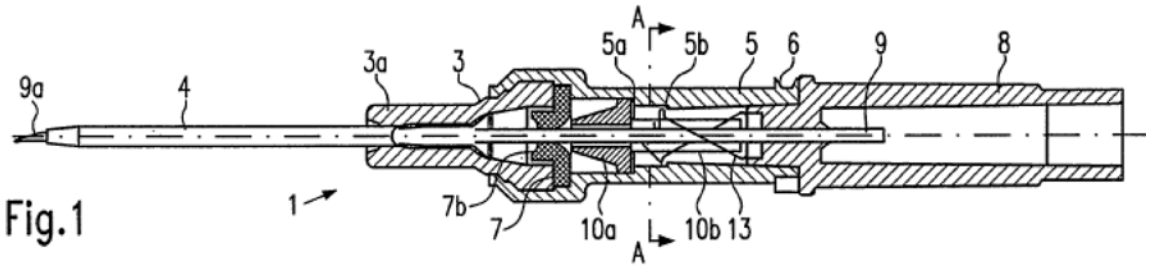


Fig.1

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

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

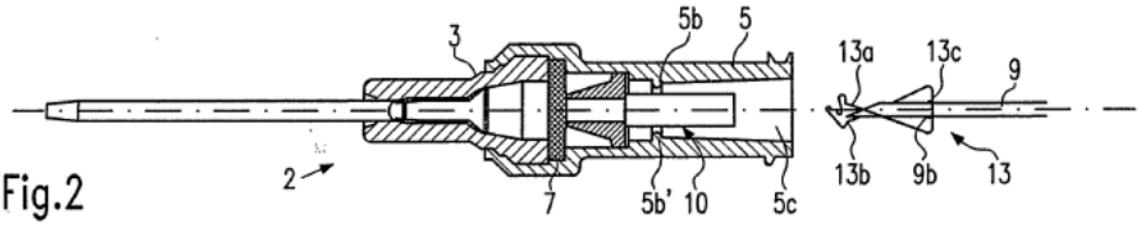


Fig.2

[6] *See supra* n.1.

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

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

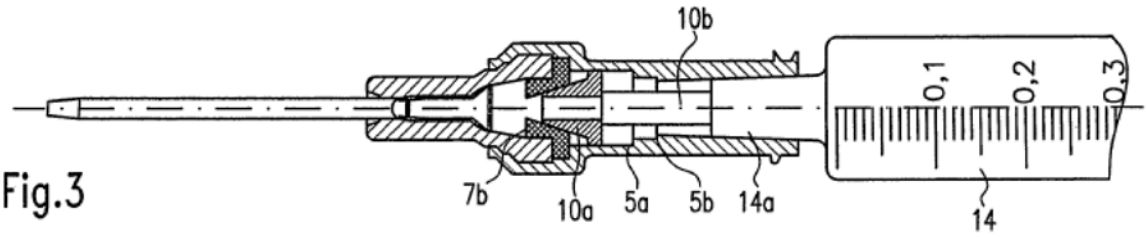
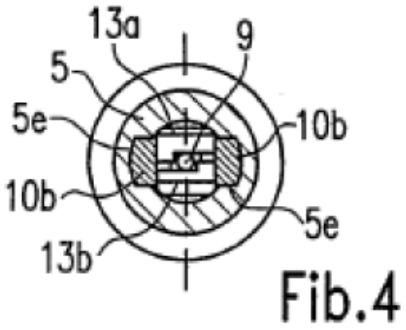


Fig.3

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

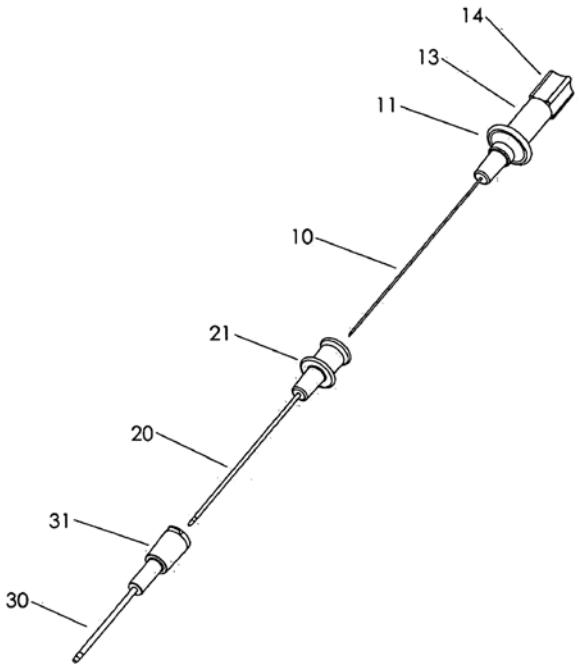
Woehr describes Figure 4 as depicting a side view along line A-A of Figure 1. *Id.* at 1. In particular, Figure 4 depicts two plungers 10b of valve actuating element 10 as being guided in longitudinal grooves 5e of hub element 5, such that plungers 10b form a contact surface for neck section 14a of injection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

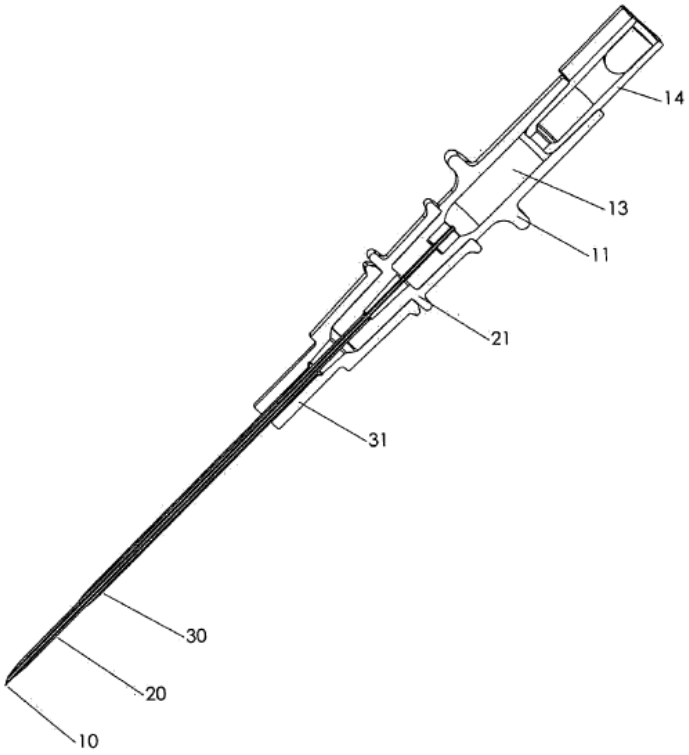
the needle safety system disclosed in U.S. Patent Nos. 5,000,740 and 6,092,845)).

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



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

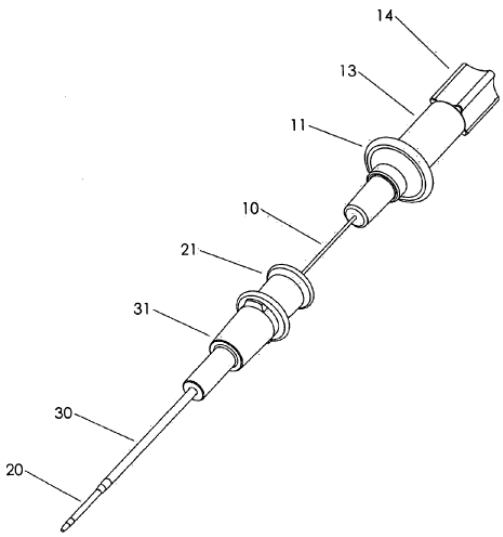


Figure 6

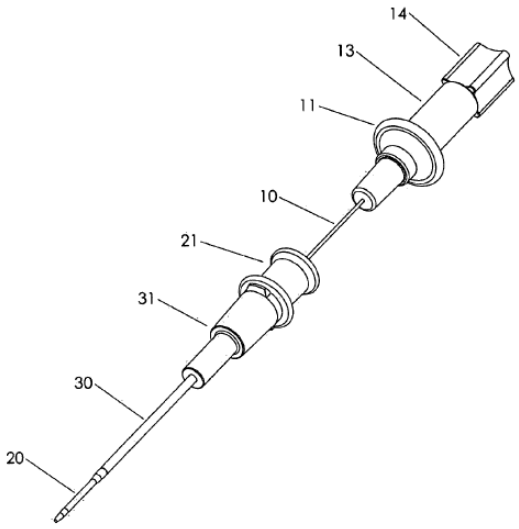


Figure 9

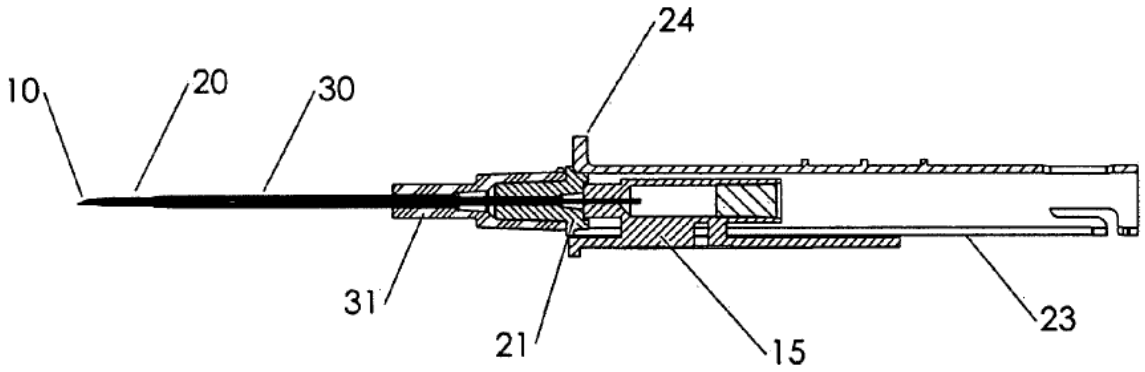
Callaway's first embodiment, Figure 6 (left side), and second embodiment, Figure 9 (right side), are reproduced above. As can be seen, Figure 6 is identical to Figure 9 and neither figure depicts a needle safety device, despite Callaway's express disclosure that Figure 9 "depicts a catheter assembly 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.*

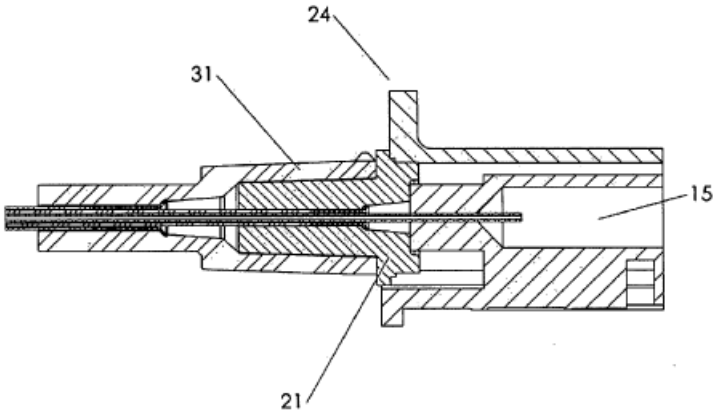
Ex. 1004 ¶ 61 (emphasis added). Notably, Callaway's Figure 9 embodiment itself describes two versions: "one version" in which "the needle (**10**) *and attached clip* could be withdrawn from hub (**21**)"; and a "preferred version," which *does not reference a safety clip*, but discloses that "the inner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

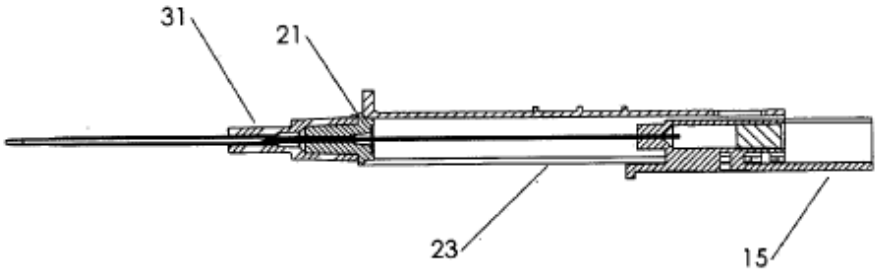
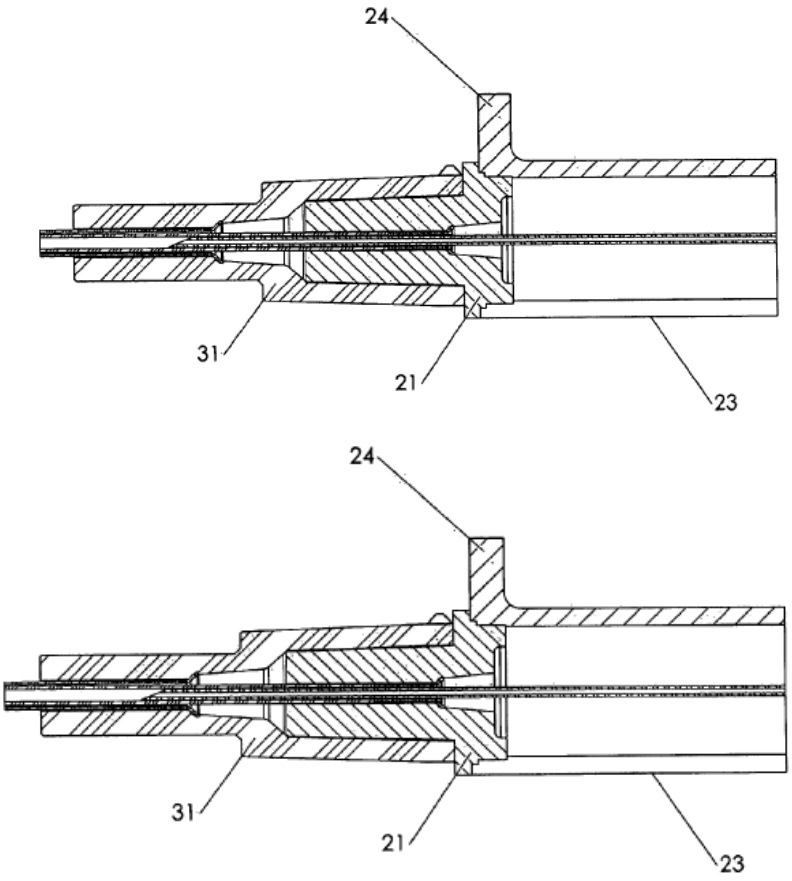


Figure 15 depicts "a sectional view of a catheter assembly with a safety device with the needle in a protected position within the cylindrical needle guard." *Id.* ¶ 47. In particular, Figure 15 depicts catheter assembly with a needle safety device in the "safe" position, with middle hub 21 and clear 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 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. Sutton (Ex. 1009)

Sutton is a U.S. Patent Publication titled "Needle Guard Mechanism with Shroud." Ex. 1009, [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:

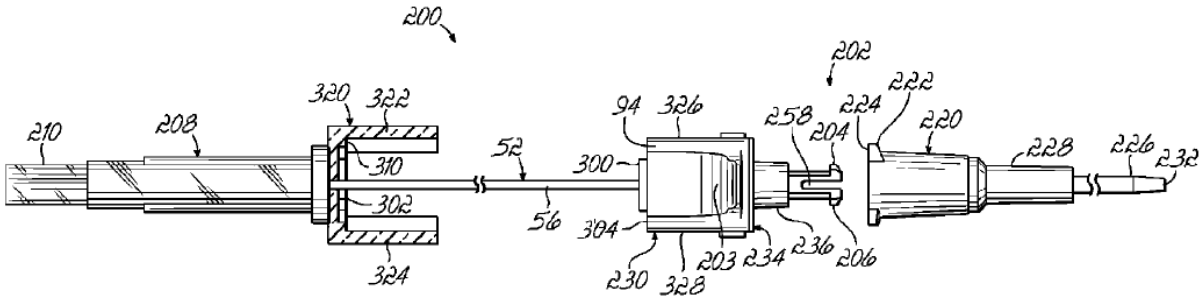


FIG. 3C

Sutton's Figure 3C 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, 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:

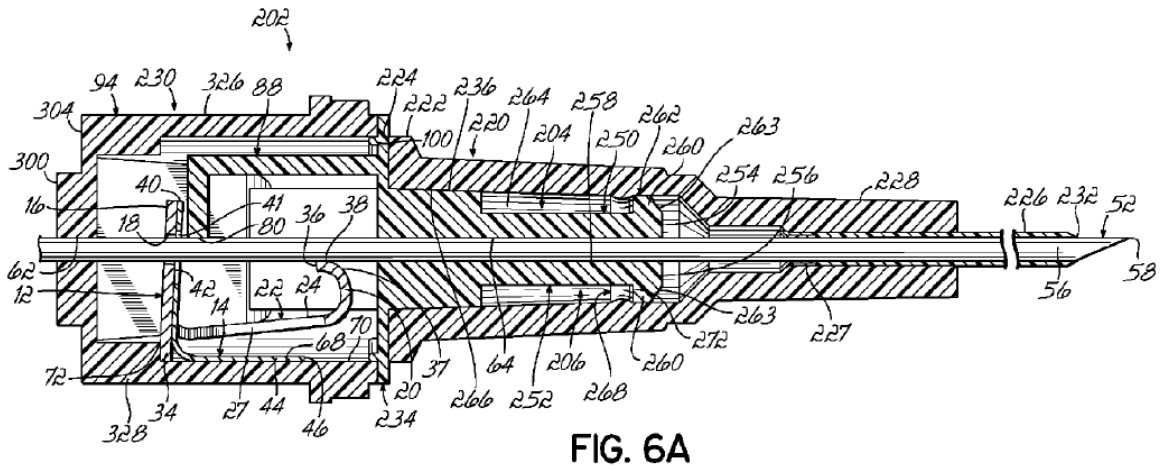


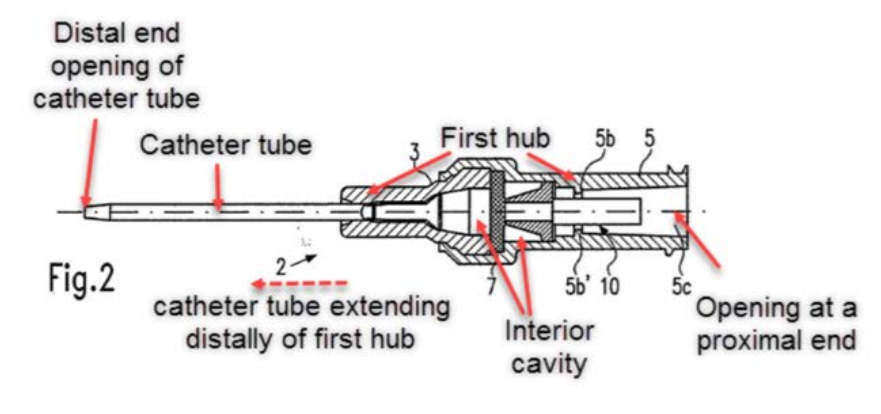
FIG. 6A

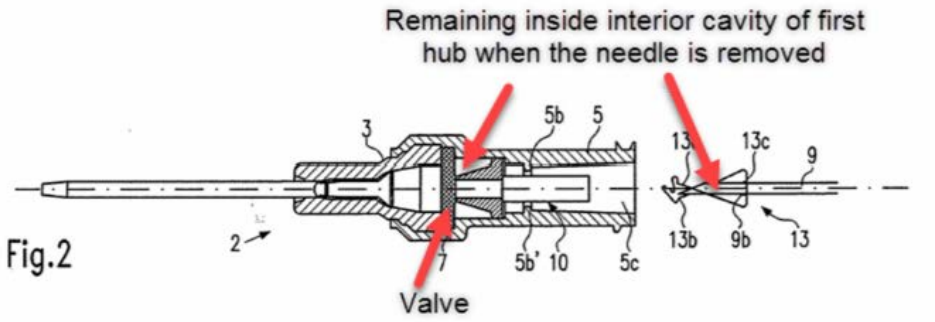
Sutton describes Figure 6A as a cross-sectional view of the catheter assembly embodiment shown in Figure 3C, including operation of a duckbill catheter hub release mechanism. *Id.* ¶ 23. In particular, Figure 6A depicts needle guard duckbills 204, 206, and catheter hub rib 268 that cooperate to define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

4. Petitioner's Challenge

In challenging the claims, Petitioner submits that Woehr discloses a "safety catheter assembly" comprising the claimed "first hub," "second hub," "needle," "valve," "valve actuating element," and "needle protective device." *See* Pet. 49–50 (incorporating by reference analysis based on Woehr and Callaway). To illustrate these findings, Petitioner submits

annotated versions of Woehr's Figure 2 (*id.* at 19, 21), copies of which we reproduce below:





According to Petitioner, the annotated Figures depict a "safety catheter assembly" comprising the claimed "first hub" 2 (*id.* at 17, 18), "valve" 7 (*id.* at 20), and "valve actuating element" 10 comprising a "nose section having a tapered end" 10a (*id.* at 21). *See also* Ex. 1005, Fig. 1.

Petitioner also submits two annotated versions of Woehr's Figure 1 copies of which we reproduce below (Pet. 19, 25):

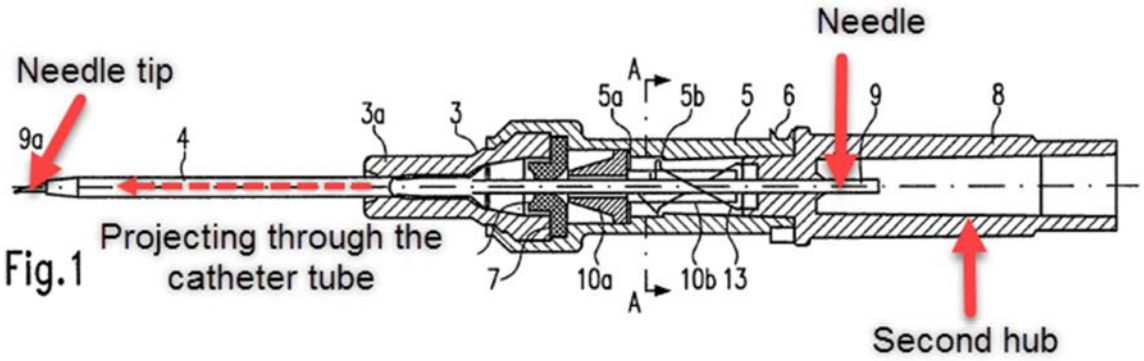


Fig.1

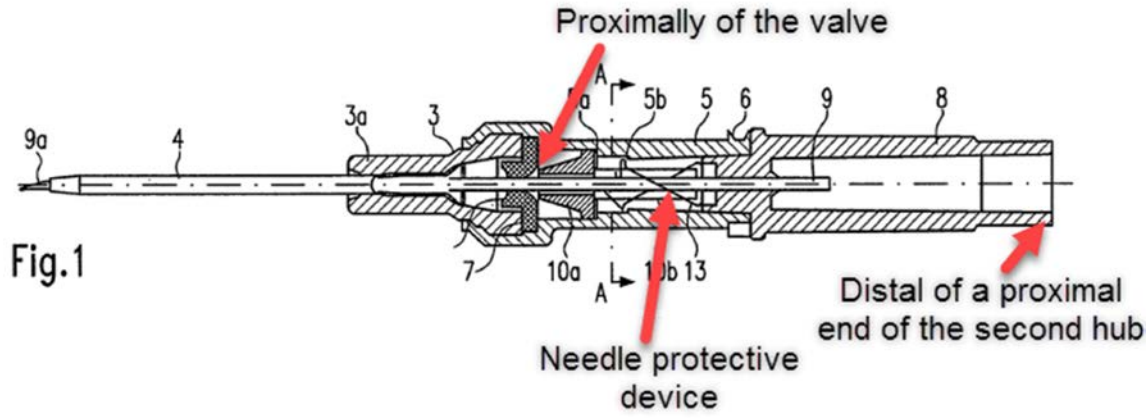


Fig.1

According to Petitioner, and as shown above in the annotated versions of Woehr's Figure 1, Woehr discloses its safety catheter assembly as also comprising the claimed "needle" 9 (*id.* at 19), "second hub" 8 (*id.* at 19), and "needle protective device" 13 (*id.* at 23–24).

In addressing the claimed "third hub," Petitioner cites, *inter alia*, to Callaway's Figures 3 and 5 (*see id.* at 26–27), copies of which we reproduce below:

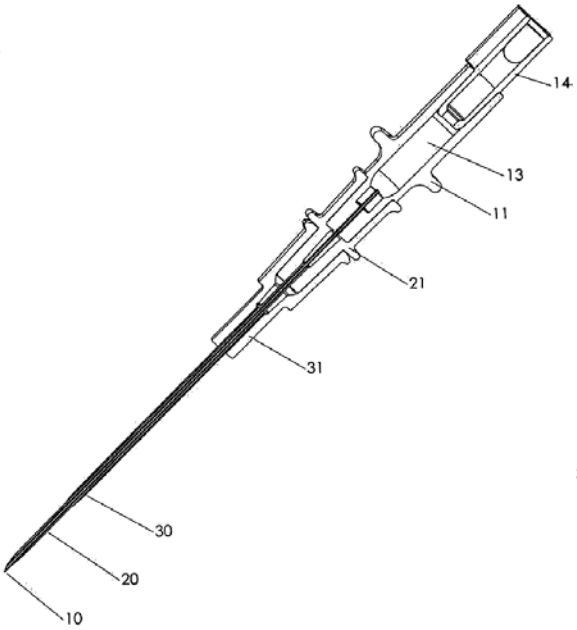


Figure 3

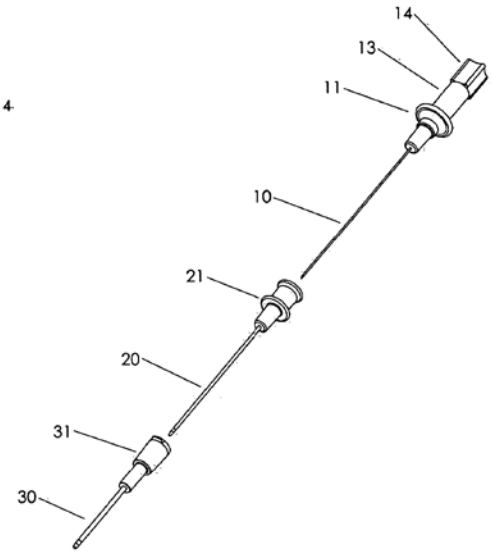


Figure 5

According to Petitioner, Figures 3 and 5 depict Callaway's "third hub" 21 that "is located at least in part in the first hub" 31. *Id.* at 26. Petitioner asserts that Callaway "explains that a needle safety device in the form of a metal clip can be placed into" third hub 21 (*id.* at 27) and that Callaway teaches that its "third hub, together with the metal clip, 'protect users from the sharp needle tip'" (*id.* at 28). *See also* Ex. 1004 ¶ 61 ("The clip and hub (21) protect users from the sharp tip of the needle (10).").

In combining Woehr with Callaway, Petitioner reasons that a person having ordinary skill in the art would have found it obvious to modify Woehr by adding a third hub to "prevent unintended contact with the tip protector itself and/or contact with any fluids remaining on the needle after it is removed, *based on the known technique disclosed in Callaway to improve a similar catheter insertion device*." Pet. 29 (emphasis added).

In addressing the claimed "arm extends distally of a third hub and is located at least in part in the first hub in a ready position," Petitioner relies on Sutton. *Id.* at 50–53. In particular, Petitioner submits annotated versions of Sutton's Figures 6A and 3C (*id.* at 52), which we reproduce below:

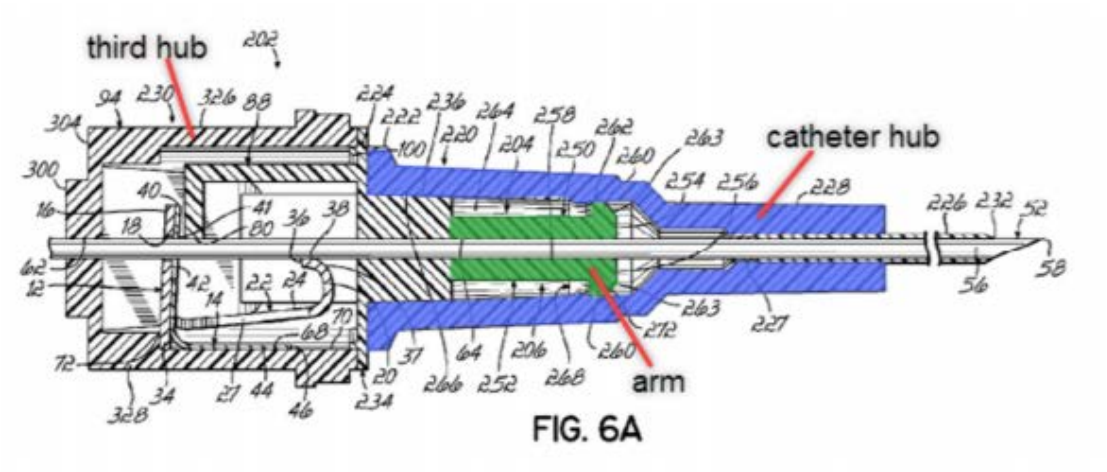


FIG. 6A

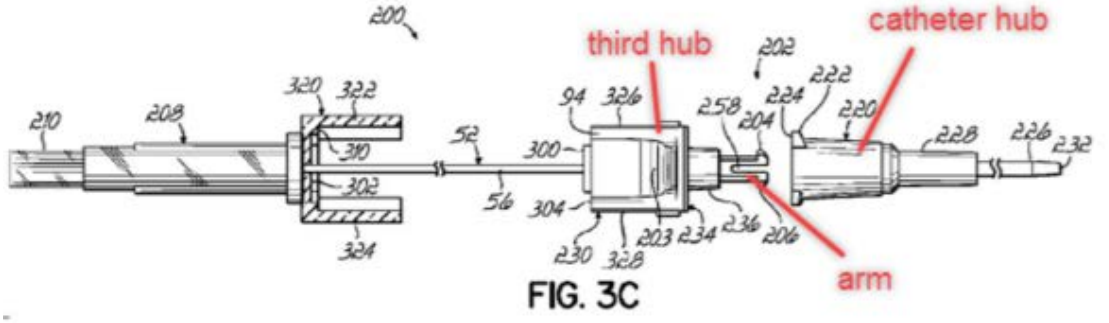


FIG. 3C

According to Petitioner, annotated Figures 6A and 3C depict Sutton's arms 204, 206, 250, and 252 that extend distally from "third hub" 230 and are located at least in part of a catheter hub, or "first hub" 220, in a ready position. *Id.* at 51. Sutton discloses that "needle guard duckbills 204, 206 and catheter hub rib 268 cooperate to define a duckbill release mechanism." Ex. 1009 ¶ 47.

In combining Sutton with Woehr and Callaway, Petitioner reasons that it would have been obvious to modify Callaway's "third hub" 21 "so that it has an arm extending distally into a catheter hub as disclosed in Sutton." *Id.* at 52. Petitioner cites to the declaration of Mr. Griffis, who testifies that Sutton's "*arms present a number of advantages over the Callaway third hub alone*." *Id.* (citing Ex. 1002 ¶ 171) (emphasis added). Petitioner cites to Sutton's disclosure that "some needle guards are intended to be used with catheter assemblies" and for those "needle guards, *it is advantageous to have a portion of the needle guard hold to the catheter hub while the needle projects out of the catheter tube*, but to thereafter allow for ready removal of the needle guard upon withdrawal of the needle to the tip-protected position." *Id.* at 53 (citing Ex. 1009 ¶ 5) (emphasis added). Petitioner reasons that

> Sutton discloses that its "needle guard duckbills 204, 206 and catheter hub rib 268 cooperate to define a duckbill release mechanism." (Ex. 1009, Sutton at [0047]). *Callaway notes that its three hubs "fit together with slight friction which prevents unintentional separation."* (Ex. 1004, Callaway at [0055]). *Thus, a POSA would have been motivated to add arms to the third hub in Callaway, including arms as disclosed in Sutton to accomplish the predictable result of preventing unintentional separation of the third hub and the second hub*.

Id. (citing Ex. 1002 ¶ 172) (emphases added). Petitioner further reasons that

> Further, a POSA would have had a reasonable expectation of success of modifying Callaway in view of Sutton because Sutton discloses that "the duckbill release mechanism of the present invention is not limited in use to such active elements, but may be used with other clip designs and even non-clip-based needle

> guards such as those including housings that served as a needle guard."

Id. (quoting Ex. 1009 ¶ 47; citing Ex. 1002 ¶ 172).

5. Patent Owner's Arguments

In its Response, Patent Owner presents numerous arguments in contesting Petitioner's challenge under Woehr, Callaway, and Sutton. PO Resp. 5–42, 55–63. In particular, Patent Owner argues that "Petitioner mischaracterizes (or misunderstands) Callaway" and that a POSITA would not have modified Woehr to add Callaway's "third hub," as Petitioner proposes (*see id.* at 5, 30). Specifically, Patent Owner contends that "Petitioner's entire motivation to combine argument appears to be premised on Callaway's disclosure of '[t]he clip and hub (21) protect users from the sharp tip of the needle (10),'" yet, "Petitioner never evaluated what this sentence actually means." *Id.* at 33. Patent Owner seeks to prove "that the Callaway hub (21) provides no needle protection in the spring clip version, and (b) the sentence cited by Petitioner and Mr. Griffis does not support its motivation to combine statements." *Id.*

Patent Owner further argues that Petitioner fails to provide adequate reasoning for further adding Sutton's "arms." *See id.* at 56 ("This is not a reason at all.").

For the reasons discussed below, Patent Owner's arguments are persuasive.

6. Analysis

a) Callaway does not teach Woehr-630's spring clip retained in hub 21 after the needle is withdrawn

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) interpret 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.E.2.

Petitioner proposes to "combine the catheter insertion device of Woehr with a third hub . . . that houses a metal clip form of needle protection *such as the third hub disclosed in Callaway*." Pet. 28 (emphasis added); *see also id.* at 50 (incorporating by reference the analysis of Woehr and Callaway in presenting its challenge under Woehr, Callaway, and Sutton). 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 third hub, together with the metal clip, 'protect users from the sharp needle tip.'*" *Id.* at 28 (quoting Ex. 1004 ¶ 61) (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.* (citing Ex. 1002 ¶¶ 96–99) (emphasis added)) and that a POSITA "would have found it obvious to improve Woehr by adding protective elements, such as a third hub to also prevent unintended contact with the tip

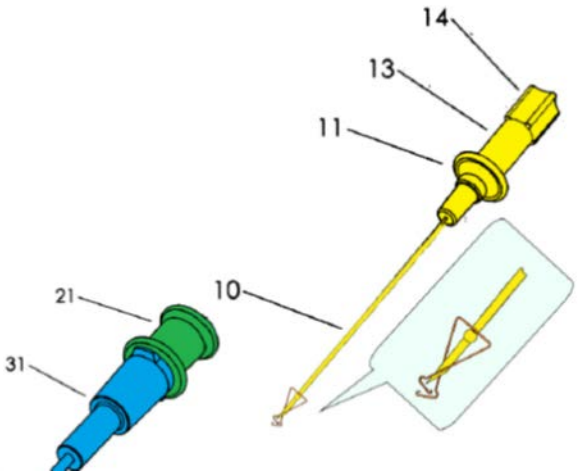
protector itself and/or contact with any fluids remaining on the needle *after it is removed, based on the known technique disclosed in Callaway* to improve a similar catheter insertion device." *Id.* at 29 (citing Ex. 1005, 1) (emphasis added).

Notably, Petitioner's reasoning relies on *Callaway specifically teaching* that its "third hub, together with the metal clip, 'protect users from the sharp 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.* at 28 (emphasis added).

At first impression, 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 ¶ 99 (citing Ex. 1004 ¶ 76). This disclosure and testimony support Petitioner's argument.

We must be 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 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. 12 (citing Ex. 1004 ¶¶ 53, 77) (emphasis added). Below, we reproduce an annotated figure (Callaway's Figure 5) that Patent Owner's expert, Mr. Meyst, provides (Ex. 2028 ¶ 71):



In referencing the above annotated figure, 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 other words, the annotated figure depicts the spring clip as being removed from catheter hub 21 once the clip covers the tip of the needle, and hub 21 itself does not provide additional protection from the needle tip.

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. 29 ("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."). We credit Mr. Meyst's testimony 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 had 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 with Mr. Meyst, and find that his interpretation 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 much different safety device and hub 21 of the Critikon embodiment.

As discussed above (*see supra* Part II.E.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 mentioned in only the "one version," and not the "preferred version," which Petitioner specifically relies on. *See* Ex. 1004 ¶ 61; *see also* Pet. Reply 7 ("It is the 'preferred version' of the catheter assembly which 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. 17 ("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.E.2.), nor does Petitioner rely on Callaway's Critikon embodiment; rather, Petitioner instead relies 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 7 (citing Ex. 1004 ¶ 84). Sutton'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. 27; *id.* at n.8 (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 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. *See, e.g.*, *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004) ("[W]e are mindful of the repeated warnings of the Supreme Court and this court as to the danger of hindsight bias."). 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 (emphasis added, emphasis omitted). 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. 12 ("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. 28), Callaway would have had no reason to disclose *replacing* hubs with a needle safety device, as it does in paragraph 77.

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.E.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 structure that hub 21 could retain the Woehr-630 safety clip after the needle is withdrawn weighs against Petitioner.

Further, we have considered Mr. Griffis's testimony that "it would have been a matter of *routine design* to ensure that the spring clip remains in the inner catheter hub" (Ex. 1064 ¶ 32 (emphasis added)), 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). As such, this new argument is improper.

Second, even if Petitioner's "routine design" argument was presented in the Petition, which it was not, we would not find it persuasive. As

discussed above, Callaway and Woehr disclose distinctive catheter devices (*supra* Parts II.E.1 and II.E.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 "third 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. 35), which does not integrate Woehr-630's safety clip (Ex. 1004 ¶ 62), and which Petitioner does not rely on (*see* Pet. 26–27).

Accordingly, because Petitioner fails to demonstrate by a preponderance of the evidence that Callaway teaches Woehr-630's spring clip retained in hub 21 after the needle is withdrawn, Petitioner has not shown that claims 12, 13, 20–23, and 29 are unpatentable over Woehr, Callaway, and Sutton.

b) Adding Sutton's "Arms"

In addition to the above deficiencies in Petitioner's proposed combination of Woehr and Callaway, we are also unpersuaded that a POSITA would have further modified the references to add Sutton's arms.

The issue before us is whether Petitioner's reason for modifying Woehr and Callaway to include Sutton's "arms" is articulately reasoned with some rational underpinning. *KSR*, 550 U.S. at 418. We determine that it is not.

As discussed above (*see supra* Part II.E.4), Petitioner reasons that it would have been obvious to modify Callaway's "third hub" 21 "so that it has an arm extending distally into a catheter hub as disclosed in Sutton." Pet. 52. Petitioner cites to Sutton's disclosure that "some needle guards are intended to be used with catheter assemblies" and for those "needle guards, *it is advantageous to have a portion of the needle guard hold to the catheter hub while the needle projects out of the catheter tube*, but to thereafter allow for ready removal of the needle guard upon withdrawal of the needle to the tip-protected position." *Id.* at 53 (citing Ex. 1009 ¶ 5) (emphasis added). Petitioner further explains that

> Sutton discloses that its "needle guard duckbills 204, 206 and catheter hub rib 268 cooperate to define a duckbill release mechanism." (Ex. 1009, Sutton at [0047]). *Callaway notes that its three hubs "fit together with slight friction which prevents unintentional separation."* (Ex. 1004, Callaway at [0055]). *Thus, a POSA would have been motivated to add arms to the third hub in Callaway, including arms as disclosed in Sutton to accomplish the predictable result of preventing unintentional separation of the third hub and the second hub*.

Id. (citing Ex. 1002 ¶ 172) (emphases added).

Although Petitioner asserts that Sutton's "arms present a number of advantages over the Callaway third hub alone" (Pet. 52 (citing Ex. ¶ 171)), upon reviewing the Petition and Mr. Griffis's cited testimony, we find no stated "advantages." *See* Ex. ¶ 171.

Mr. Griffis testifies that "Sutton discloses that 'some needle guards are intended to be used with catheter assemblies' and for those 'needle guards, *it is advantageous* to have a portion of the needle guard hold to the catheter hub while the needle projects out of the catheter tube, but to thereafter allow for ready removal of the needle guard upon withdrawal of the needle to the tip-protected position.'" *Id.* ¶ 172 (emphasis added). As discussed below, however, Callaway's hubs are already held together to prevent unintentional separation, and we see no "advantage" in using Sutton's "arms" here.

Importantly, Petitioner acknowledges that Callaway discloses that its three hubs "fit together with slight friction which prevents unintentional separation," but nevertheless reasons that a POSITA "would have been motivated to add arms to the third hub in Callaway, including arms as disclosed in Sutton[,] to accomplish the predictable result of preventing unintentional separation of the third hub and the second hub." Pet. 53. Indeed, Callaway discloses that its "hubs fit together with slight friction which *prevents unintentional separation*." Ex. 1004 ¶ 55 (emphasis added). Because Callaway's hubs already fit together to prevent unintentional separation, there is no reason to add Sutton's arms to "prevent[] unintentional separation," as Petitioner argues. Pet. 53.

Only after Patent Owner persuasively raised this argument in its Patent Owner Response (*see* PO Resp. 56–63) did Petitioner provide some reason for modifying Woehr and Callaway. In particular, in its Reply, Petitioner argued that a POSITA "would have recognized that *the frictional fit in Callaway is less secure and could lead to premature separation* of the catheter and third hubs" and that a POSITA "would therefore have found it obvious to use the Sutton arms instead of the connections disclosed in Callaway" (Pet. Reply 25 (citing Ex. 1064 ¶ 67)). Petitioner also argues, for the first time in its Reply, that "substituting the Sutton arms for the connections in Callaway . . . is a simple design choice." Pet. Reply 26 (citing Ex. 1064 ¶ 68).

Petitioner's attempt to modify its original reason for combining Sutton with Woehr and Callaway is not persuasive for at least two reasons.

First, and as also persuasively argued by Patent Owner (PO Sur-Reply 3–4), Petitioner's argument is not responsive to Patent Owner's Response because it does not dispute Patent Owner's argument that Callaway already discloses a technique for preventing unintentional separation (*see* PO Resp. 56–63), and instead *presents a new reason* for why a POSITA would have replaced Callaway's frictional fit, namely, because Callaway's frictional fit is less secure and would lead to premature separation and such a substitution is a simple design choice (Pet. Reply 25–26).

"Unlike district court litigation—where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material—the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute."

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1369 (Fed. Cir. 2016). As participants in an adjudication under the Administrative Procedure Act, parties in an *inter partes* review must be given notice of the "matters of fact and law asserted," and the opportunity to meaningfully respond. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015). For this reason, petitioners may not assert, and we may not base our final decision on, late-arising factual assertions or theories. *See Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016). While it may be permissible in some cases for a petitioner to "merely expand on a previously argued rationale" (*Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018)), we cannot rely on "an entirely new rationale to explain why one of skill in the art would have been motivated to combine" the prior art. *Intelligent Bio-Systems*, 821 F.3d at 1370.

In the present case, we find nothing in the Petition (Pet. 50–53) or Mr. Griffis's original declaration (Ex. 1002) that supports Petitioner's new argument that Callaway's frictional fit is prone to premature separation or that such a substitution is a simple design choice. We, therefore, apply 37 C.F.R. § 42.23(b) and decline to consider this new theory.

Second, even if Petitioner had argued that Callaway's frictional fit would lead to premature separation and that the modification was a simple design choice in its Petition, which it did not, we would still find Petitioner's argument unpersuasive as lacking sufficient rational underpinnings. Callaway explicitly discloses that "[t]he hubs fit together with slight friction which *prevents* unintentional separation." Ex. 1004 ¶ 55 (emphasis added).

Although Mr. Griffis testifies in his supplemental (not original) declaration that "[t]he Callaway frictional fit connection is less secure than the arms connection taught in Sutton, so *the hubs in Callaway could prematurely separate*," Mr. Griffis does not cite to any evidence to support his assertion that Callaway's frictional fit could prematurely separate. *See* Ex. 1064 ¶ 67. "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."). Rather, Callaway explicitly discloses that its frictional fit "prevents unintentional separation" (Ex. 1004 ¶ 55), and Mr. Griffis's conclusory assertion that Callaway's fit is prone to premature separation directly contradicts the evidence of record, namely, Callaway.

For the foregoing reasons, we are not persuaded that a POSITA would have modified Woehr and Callaway to include Sutton's "arms," as Petitioner proposes, and Petitioner has not shown that claims 12, 13, 20–23, and 29 are unpatentable over Woehr, Callaway, and Sutton.

c) Summary

After considering the evidence and arguments of both parties, and for the two distinct reasons set forth above, we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that claims 12, 13, 20–23, and 29 of the '247 patent are unpatentable over Woehr, Callaway, and Sutton.

F. Woehr, Callaway, Sutton, and Nakajima

Petitioner contends that claim 22 is unpatentable over Woehr, Callaway, Sutton, and Nakajima. Pet. 66. Claim 22 depends indirectly from claim 12 (Ex. 1001, 14:23–29) and Petitioner relies on the same unsupportable findings and reasoning discussed in connection with its Woehr, Callaway, and Sutton challenge. *See* Pet. 66.

After considering the evidence and arguments of both parties, and for the two distinct reasons discussed above (*supra* Part II.E.6), we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that claim 22 of the '247 patent is unpatentable over Woehr, Callaway, Sutton, and Nakajima.

G. Woehr, Villa, and Sutton

Petitioner also contends that claims 12, 13, 20–23, and 29 are unpatentable over Woehr, Villa, and Sutton. Pet. 3, 57. As distinguished from the challenge based on Woehr, Callaway, and Sutton, however, Petitioner relies on *Villa* for addressing the claimed third hub. *See id.* at 40–44 (setting forth its challenge based on Woehr and Villa); *see also id.* at 58 (referencing its analysis from the Woehr and Villa challenge in presenting its challenge under Woehr, Villa, and Sutton).

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:

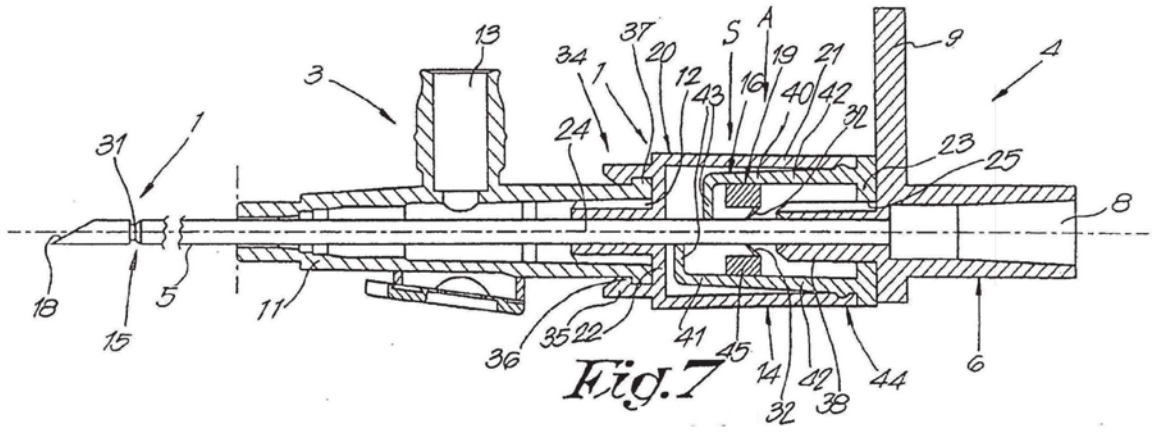


Fig.7

Figure 7 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 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.*

Most relevant to our Decision, however, is Villa's disclosure in its paragraph 53, which states:

> 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*

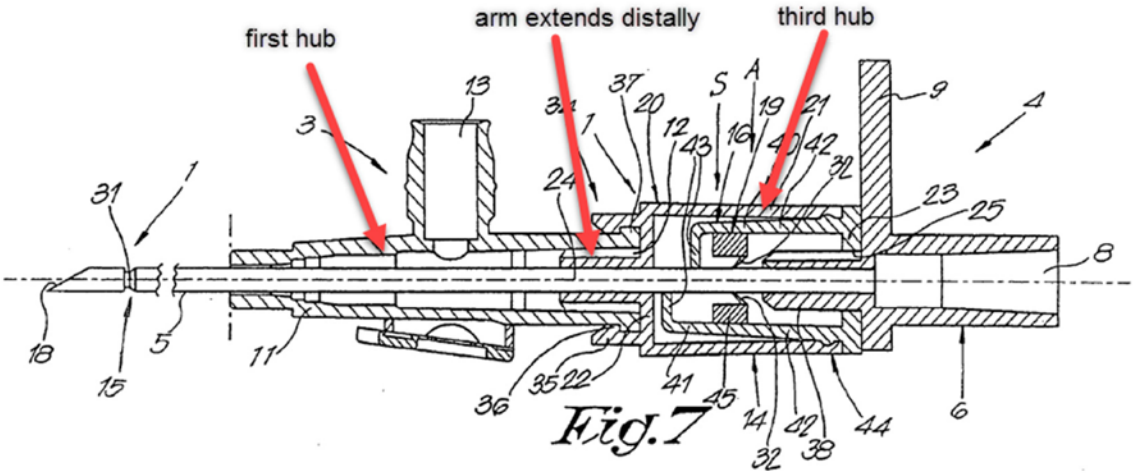
> *connection*. To this end, in the represented embodiment, said couple means **34** comprise a number of elastically bendable fins **35**, having locking portions **36** which can cooperate with a collar **37** at the rear edge of the rear portion of the cannula **3**.

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 "first hub," "second hub," "needle," "valve," "valve actuating element," and "needle protective device." *See* Pet. 57–58 (incorporating by reference analysis based on Woehr and Callaway).

In addressing the claimed "third hub," Petitioner 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 depicts Villa's "third hub" 20. *Id.* at 41. 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 42 (citing Ex. 1006 ¶¶ 1, 2, 47).

In combining Woehr with Villa, Petitioner reasons that a person having ordinary skill in the art would have found it obvious to modify Woehr by moving its spring clip into a third hub "based on the specific teaching in Villa that a housing for the protective means presents a number of advantages over the Woehr spring clip alone." *Id.* at 43. Petitioner further reasons that doing so would considerably reduce the risk of contact with a patient's bodily fluids or drugs on the needle, and would further prevent accidental pricking with the needle. *See id.* (citing Ex. 1006 ¶¶ 15, 80).

In addressing the claimed "arm extends distally of a third hub and is located at least in part in the first hub in a ready position," Petitioner relies on Sutton. *Id.* at 58–60. In particular, and as discussed above with regards to the ground based on Woehr, Callaway, and Sutton, Petitioner submits that Sutton discloses an "arm" that extends distally from a "third hub." *Id.* at 58 (citing Ex. 1009, Figs. 3, 4, 6, 9, ¶¶ 39–47; Ex. 1002 ¶ 195). As with the prior ground, Petitioner reasons that it would have been obvious to modify Villa's "third hub" "so that it has an arm extending distally into a catheter hub as disclosed in Sutton" (*id.* at 58) and that Sutton's "arms present a number of advantages over the Villa third hub alone" (*id.* at 59 (citing Ex. 1002 ¶ 196)).

3. Patent Owner's Argument

Patent Owner argues, *inter alia*, that the Petitioner presents insufficient reasoning for further modifying Woehr and Villa to include Sutton's "arms." *See* PO Resp. 56–63. We agree.

4. Analysis

As discussed similarly above (*see supra* Part II.E.6.b), the issue before us is whether a POSITA would have modified Woehr and Villa to include Sutton's "arms."

Petitioner reasons that

> A POSA would have been motivated to modify the third hub of Villa to add arms extending distally into a catheter hub based on the knowledge and motivations in the art as well as the specific teaching in Sutton that *third hub arms present a number of advantages over the Villa third hub alone*. (Ex. 1002; Decl. ¶196).
>
> Sutton discloses that "some needle guards are intended to be used with catheter assemblies" and for those "needle guards, it is advantageous to have a portion of the needle guard hold to the catheter hub while the needle projects out of the catheter tube, but to thereafter allow for ready removal of the needle guard upon withdrawal of the needle to the tip-protected position." (Ex. 1009, Sutton at [0005]). Sutton discloses that its "needle guard duckbills 204, 206 and catheter hub rib 268 cooperate to define a duckbill release mechanism." (Ex. 1009, Sutton at [0047]). Villa discloses that its "housing 20, is carried out as an extension piece, which can be coupled to the catheter hub. To this end, the housing is provided with coupling means 34 at the end wall 22, allowing a releasable connection with said catheter hub, preferably by means of a snap connection." (Ex. 1006, Villa at [0053]; Ex. 1002, Decl. ¶197).

> Thus, a POSA would have been motivated to add arms to the third hub in Villa, including the arms disclosed in Sutton, to accomplish the predictable result of *preventing unintentional separation of the third hub and the second hub*. Further, a POSA would have had a reasonable expectation of success of modifying Villa in view of Sutton because Sutton discloses that "the duckbill release mechanism of the present invention is not limited in use to such active elements, but may be used with other clip designs and even non-clip-based needle guards such as those including housings that served as a needle guard." (Ex. 1009, Sutton at [0047] Ex. 1002, Decl. ¶198).

Pet. 59–60 (emphases added).

Upon careful review of Petitioner's purported reasons for adding Sutton's "arms," we find none that persuades us. Although Petitioner and its expert state that Sutton's "arms present a number of advantages," the only identified advantage is that "it is 'advantageous' for those needle guards to hold onto the hub, as well as allow for ready removal of the needle guard when the needle is withdrawn." *Id.* at 59. Petitioner then concludes that a POSITA would have been motivated to add Sutton's "arms" "to accomplish the predictable result of preventing unintentional separation of the third hub and the second hub." *Id.* Villa's structure, however, already prevents unintentional separation.

In particular, Villa explicitly discloses that its "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. Accordingly, we are not persuaded

that a POSITA would have modified Villa to add Sutton's "arms" to prevent unintentional separation of the hubs. *See* Pet. 59.

Only after Patent Owner persuasively raised this argument in its Patent Owner Response (*see* PO Resp. 56–63) did Petitioner provide some reason for modifying Woehr and Villa. In particular, in its reply, Petitioner argued for the first time that a POSITA "would have understood the snap connection in Villa could require a lot of manipulation to separate from the catheter hub, which could harm the patient" and that a POSITA "would therefore have found it obvious to use the Sutton arms instead of the connections disclosed in . . . Villa" (Pet. Reply 25 (citing Ex. 1064 ¶ 67)). Petitioner also argues, for the first time in its reply, that "substituting the Sutton arms for the connections in . . . Villa is a simple design choice." Pet. Reply 26 (citing Ex. 1064 ¶ 68).

Petitioner's attempt to modify its original reason for combining Sutton with Woehr and Villa is not persuasive for at least two reasons.

First, and as also persuasively argued by Patent Owner (PO Sur-Reply 4–5), Petitioner's argument is not responsive to Patent Owner's Response because it does not dispute Patent Owner's argument that Villa already discloses a technique for preventing unintentional separation (*see* PO Resp. 56–63), and instead *presents a new reason* for why a POSITA would replace Villa's snap fit, namely, because manipulating Villa's snap fit can somehow harm the patient and that such a substitution is a simple design choice (Pet. Reply 25–

26). We determine that this is significant departure from the reasoning provided in the Petition.

As discussed above, "the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute." *Intelligent Bio-Sys.*, 821 F.3d at 1369. Petitioners may not assert, and we may not base our decision on, late-arising factual assertions or theories (*see Dell Inc.*, 818 F.3d at 1301), and we cannot rely on "an entirely new rationale to explain why one of skill in the art would have been motivated to combine" the prior art (*Intelligent Bio-Systems*, 821 F.3d at 1370).

In the present case, we find nothing in the Petition (Pet. 58–60) or Mr. Griffis's original declaration (Ex. 1002) that supports Petitioner's new argument that manipulating Villa's snap fit may harm the patient or that such a substitution is a simple design choice.

Second, even if Petitioner had argued that manipulating Villa's snap fit could harm the patient and that the modification was a simple design choice in its Petition, which it did not, we would still find Petitioner's argument unpersuasive as lacking sufficient rational underpinnings. Villa explicitly discloses that "[t]he 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 in his supplemental (not original) declaration that "[t]he snap connection in Villa may require *undesirable manipulation* to separate the third hub from the catheter

hub, which can cause harm to the patient and lead to phlebitis or inflammation of a patient's vein," Mr. Griffis does not cite to any evidence to support his assertion that Villa's snap fit itself requires undesirable manipulation. *See* Ex. 1064 ¶ 67 (citing Ex. 1066, 354) (emphasis added). Specifically, 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. 1066, 354. Although Exhibit 1066 supports a finding that using smaller cannulas and medical technicians with increased expertise reduces the risk for mechanical phlebitis, the 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 their hubs. *See supra* Parts II.E.3, II.G.1.

As discussed above, "[e]xpert 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.

H. Woehr, Villa, Sutton, Nakajima

Petitioner further contends that claim 22 is unpatentable over Woehr, Villa, Sutton, and Nakajima. Pet. 66. Claim 22 depends indirectly from claim 12 (Ex. 1001, 14:23–29) and Petitioner relies on the same unsupportable findings and reasoning discussed in connection with its Woehr, Villa, and Sutton challenge. *See* Pet. 67.

After considering the evidence and arguments of both parties, and for the reasons discussed above (*supra* Part II.G.4), we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that claim 22 of the '247 patent is unpatentable over Woehr, Villa, Sutton, and Nakajima.

III. PATENT OWNER'S MOTION TO AMEND

Patent Owner filed a Motion to Amend. Paper 23. Importantly for our analysis, Patent Owner filed its motion as a "*Contingent* Motion to Amend." *Id.* (emphasis added). Patent Owner argues that in the event the Board finds original claims 12, 13, 20–23, and 29 unpatentable, Patent Owner requests the Board to replace certain challenged claims with new

claims as well as to amend the dependency of other claims to the new substitute claims 31 and 33. *Id.* at 1.

Patent Owner filed an even number of requests to substitute claims with newly added claims, making the motion truly contingent. A proposed substitute claim will be considered only if the original patent claim it seeks to replace is determined unpatentable or is otherwise cancelled.

As discussed above, Petitioner has not demonstrated by a preponderance of the evidence that any of the challenged claims are unpatentable. Accordingly, we need not reach Patent Owner's Contingent Motion to Amend, and the motion is *dismissed* as moot.

IV. CONCLUSION

In consideration of the foregoing, it is hereby:

ORDERED that claims 12, 13, 20–23, and 29 of the '247 patent have not been shown to be unpatentable based on Woehr, Callaway, and Sutton;

FURTHER ORDERED that claims 12, 13, 20–23, and 29 of the '247 patent have not been shown to be unpatentable based on Woehr, Villa, and Sutton;

FURTHER ORDERED that claim 22 of the '247 patent has not been shown to be unpatentable based on Woehr, Callaway, Sutton, and Nakajima;

FURTHER ORDERED that claim 22 of the '247 patent has not been shown to be unpatentable based on Woehr, Villa, Sutton, and Nakajima;

FURTHER ORDERED that Patent Owner's Motion to Amend (Paper 23) is dismissed as moot; 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.

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