

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*.

DECISION

Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Becton, Dickinson and Company (“Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting *inter partes* review of claims 12, 13, 20–23, and 29 of U.S. Patent No. 8,460,247 B2 (“the ’247 patent”). Pet. 1. B. Braun Melsungen AG (“Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”) in response to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 1.

We have authority to determine whether to institute a trial under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). An *inter partes* review may be instituted only if “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

We are persuaded there is a reasonable likelihood that Petitioner would prevail in showing that the challenged claims are unpatentable. Pursuant to 35 U.S.C. § 314, we institute an *inter partes* review as to claims 12, 13, 20–23, and 29 of the ’247 patent.

A. *Related Proceedings*

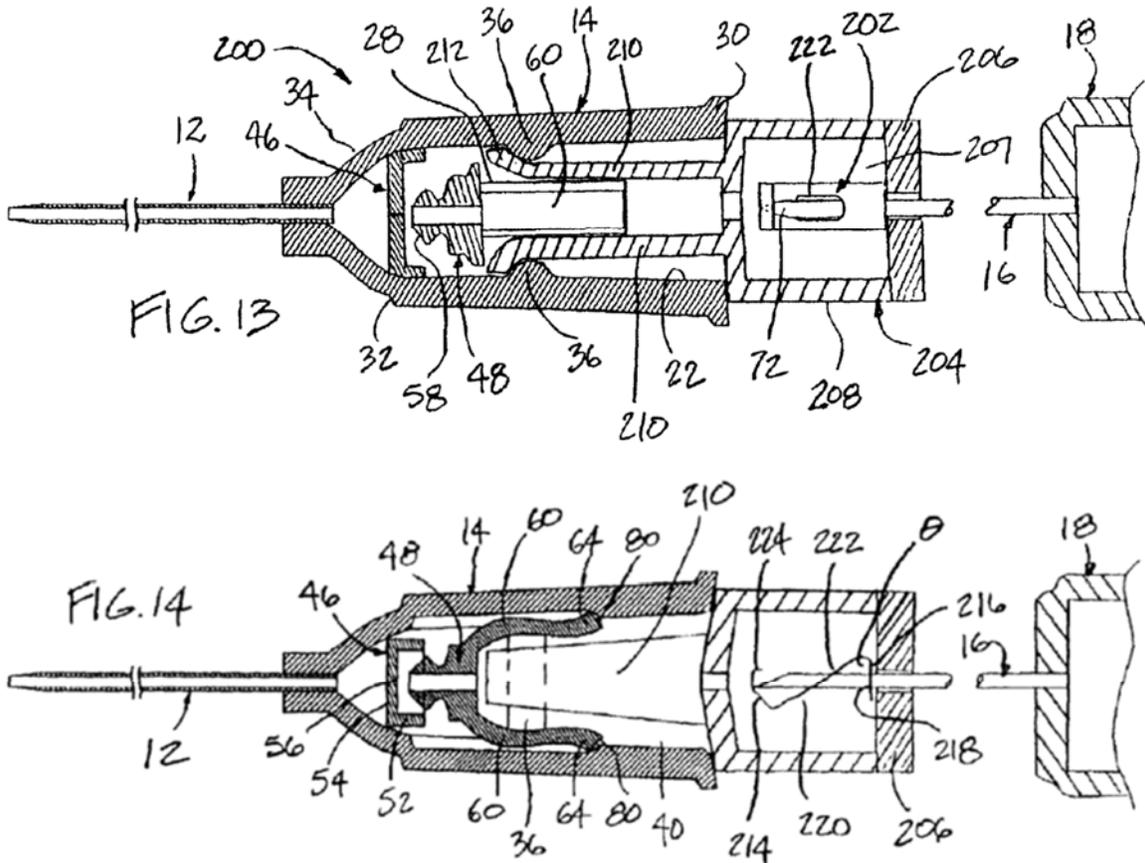
Petitioner represents that the ’247 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1–2. Petitioner also represents that petitions for *inter partes* review were filed challenging related patents US. Patent Nos.: 8,328,762; 8,337,463; 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

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 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 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:



Figures 13 and 14 depict a particular embodiment of Patent Owner’s catheter assembly with a *third housing* positioned between the catheter and needle hub. *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 47, 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 “accomodat[e] the tip protector.” *See id.* at 11:16–19. Third housing 204 incorporates a pair of arms 210, each of which comprises a 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. Claim 12 is illustrative of the subject matter at issue and is reproduced 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 slidably 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

With respect to the German language publication Woehr (Ex. 1003), Patent Owner argues that we should deny institution because Petitioner has failed to provide a compliant affidavit attesting to the accuracy of its translation, namely, that of Exhibit 1005. Prelim. Resp. 22; *see also id.* at 22–25 (arguing Woehr should not be considered as evidence).

“When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an *affidavit* attesting to the accuracy of the translation must be filed with the document.” 37 C.F.R. § 42.63 (emphasis added). Pursuant to 37 C.F.R. § 42.2, an “[a]ffidavit means affidavit *or* declaration under § 1.68 of this chapter.” (emphasis added). Patent Owner’s contentions seem to place the requirements for a “declaration” (under § 1.68) onto a sworn affidavit. These are distinct documents. For example, the requirements of 28 U.S. Code § 1746 are for “Unsworn declarations.” If a document is

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

sworn, the additional requirements of § 1746 would seemingly not apply. It appears to us that the translation of Woehr (Ex. 1005) was sworn testimony before a notary public, and as such, would qualify as an affidavit – sworn testimony under oath. *See* Ex. 1005, final page (stating “*Sworn* to before me this August 9, 2016”) (emphasis added). Every state provides for a variety of officials, civil servants, and others with special status to give oaths, with notaries public being the most common. Based on the record before us, Petitioner’s translation (Ex. 1005) is a compliant affidavit because it was administered as a sworn affidavit before a notary public pursuant to the laws of the State of New York. *See Berry v. United States*, 86 Fed. Cl. 750, 754, n.10 (2009) (quoting “Black’s Law Dictionary 62 (8th ed.2004) (defining ‘affidavit’ as ‘[a] voluntary declaration of facts written down and sworn to by the declarant before an officer authorized to administer oaths, such as a notary public’”).

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 12, 13, 20–23, 29 of the ’247 patent are unpatentable under the following grounds:

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

Pet. 3.

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

II. ANALYSIS

A. *Claim Construction*

As a first step in our analysis, we determine the meaning of the claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear.” 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach). Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

We determine that the only terms that that require construction for purposes of this Decision are: (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). Ex. 1001, 13:34–14:59.

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. Petitioner acknowledges that a presumption exists that the limitation is not in means-plus-function format, yet Petitioner contends that the “use of the word ‘device’ in the claims does not impart any structure and is tantamount to using the word ‘means’” (*id.* at 13 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc))) and 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).

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 id.* at 5–17. Patent Owner contends that “[t]he claim language following ‘needle protective device’ . . . indicates the term is structural.” *Id.* at 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 “how [the needle protective device] cooperates with the needle, and that it has a wall and an arm and/or a resilient portion” (claim 20). *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”)).

Based on the record before us, we are not convinced that the needle protective device limitation should be construed as a means-plus-function term. Because the term “means” is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. Rather, as pointed out by Patent Owner, we determine that the needle protective device limitation recites sufficient structure. *See Williamson, LLC*, 792 F.3d 1349 (explaining that the presumption is overcome when “the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’”). Further, Mr. Meyst explains how a person of ordinary skill in the art “would recognize that the claimed ‘needle protective device’ refers to the class of structures included in safety IV catheters that prevent unintended needle-sticks by covering (*i.e.*, protecting or guarding) the needle tip.” Ex. 2001 ¶ 56 (citing Ex. 2014, which is cited in the ’735 patent). We find Mr. Meyst’s testimony persuasive as to this issue.

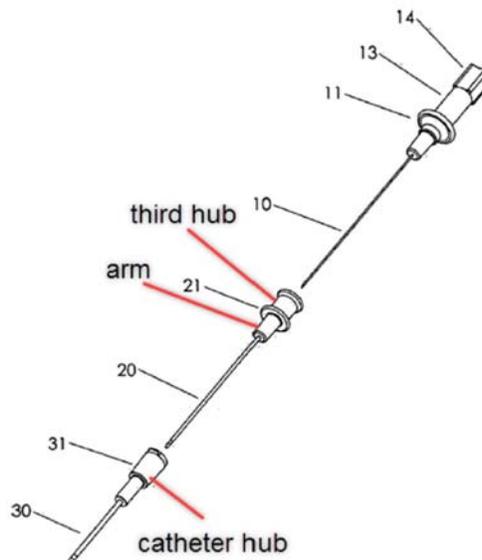
Based on the record before us, the term “needle protective device” should not be construed under § 112 ¶ 6. Instead, we agree with Patent

Owner that the term “needle protective device” means *a device configured to prevent unintended needle sticks*. See Prelim. Resp. 17.

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) and Whether Prior Art Discloses this Structure

In challenging the claims based on Woehr and Callaway (*see* Pet. 26) and Woehr and Villa (*see id.* at 41–42), 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 (*see id.* at 26, 41–42). Because the parties address the scope of the claim term “arm” in reference to the prior art, we likewise consider the construction of this term in reference to the arguments made by the parties.

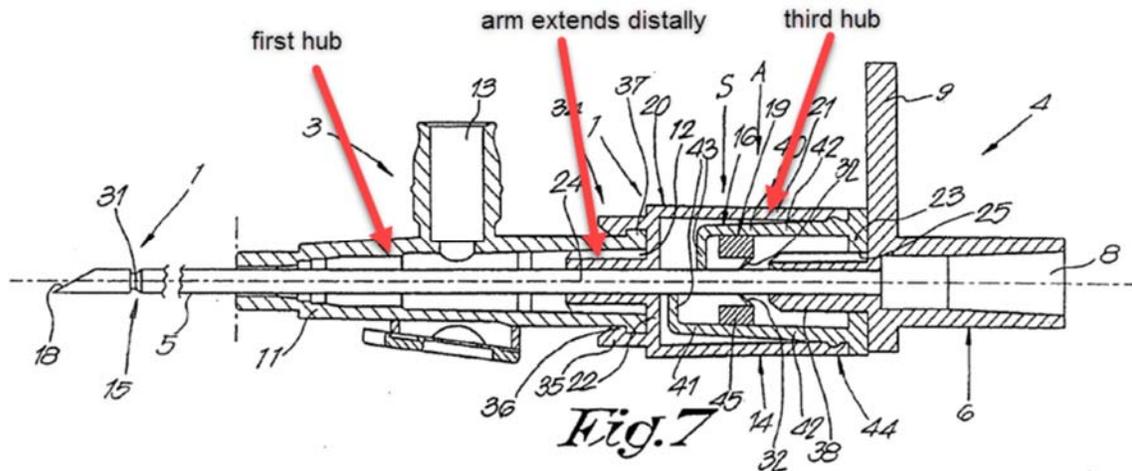
To illustrate Petitioner’s finding with respect to Callaway, Petitioner submits an annotated version of Callaway’s Figure 5 (*id.* at 27), which we reproduce, below:



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 relies on Villa for disclosing 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”).

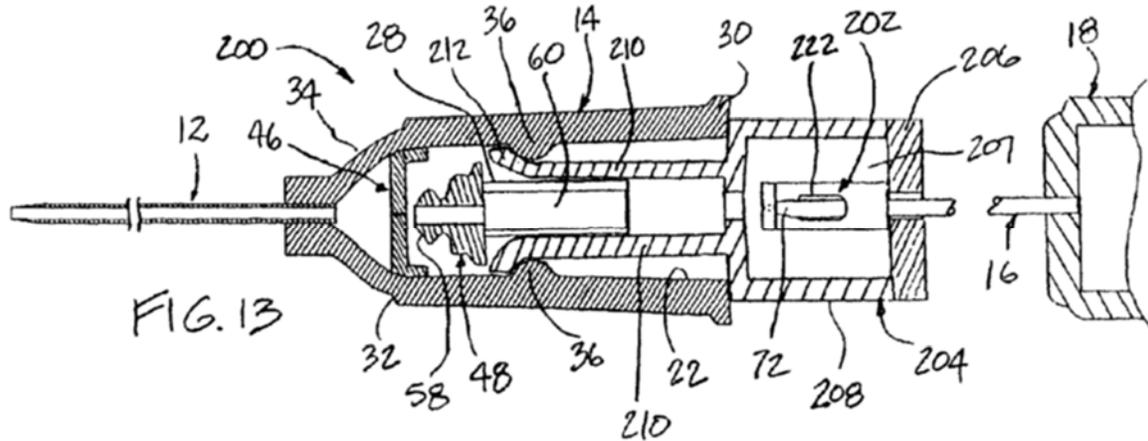
Patent Owner, on the other hand, contends that Callaway’s distal section of hub 21 and Villa’s walls 22 “noses” cannot reasonably be construed as the claimed “arm.” See Prelim. Resp. 55, 62. Patent Owner argues that the Specification depicts the “arms” as being elongated. See *id.* at 56–57 (“*Arms 210 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, to determine how the claim term is used throughout the '247 patent. 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:



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, and the Specification, we conclude that the claimed limitation, “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 requires the arm to be a flexible, elongate structure that extends from the claimed “third hub,” such as, for example, Figure 13’s elongate arms 210 that extend distally from “third hub” 204. 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 finding 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)).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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

C. Level of Ordinary Skill in the Art

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

Petitioner relies upon the declaration of Mr. Griffis (Ex. 1002) and contends that a person of ordinary skill in the art (“POSITA”) would have been either “a medical practitioner with experience using vascular access devices and with training, experience and/or familiarity applying principles

of engineering to the design, development, and/or testing of vascular access devices,” or “an engineer having at least a bachelor of science degree and with several years of experience in the design, development, and/or testing of vascular access devices and their clinical use; a higher level of education could reduce the number of years of experience required.” Pet. 10 (citing Ex. 1002 ¶¶ 28–30).

Patent Owner, on the other hand, relies upon the declaration of Mr. Meyst (Ex. 2001) and contends that a POSITA would have had “at least an associate’s degree in engineering or Physics or the equivalent, and at least five years of experience with IV catheters. Alternatively, more education, such as a Bachelor of Science degree, could reduce the number of years of experience to at least two years of experience.” Prelim. Resp. 2 (citing Ex. 2001 ¶¶ 26–28).

Based on our review of the ’247 patent, the types of problems and solutions described in the ’247 patent and applied prior art, and the testimony of Mr. Griffis and Mr. Meyst, we determine that a POSITA would be either a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical degree (e.g., associate’s degree in engineering or physics) and having at least some experience with vascular catheter devices. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Woehr and Callaway

Petitioner contends that claims 12, 13, 20–23, and 29 are unpatentable over Woehr and Callaway. Pet. 3. In challenging these claims based on

Woehr and Callaway alone, Petitioner relies on Callaway's hub 21 has having an "arm" that extends distally thereof. *See id* at 25–27. As discussed above, however, Petitioner's interpretation of "arm" is unreasonably broad and we disagree with Petitioner's assertion that Callaway's "third hub" 21 has an "arm" that extends distally therefrom, as required by the claims. *See supra* Section II.A.2.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Woehr and Callaway alone render obvious claims 12, 13, 20–23, and 29.

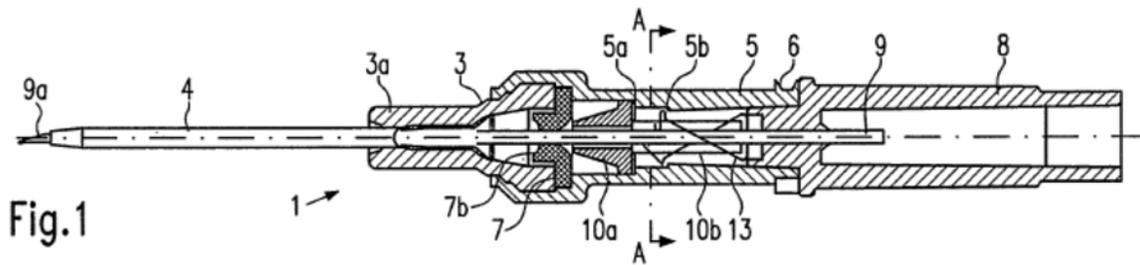
E. Woehr, Callaway, and Sutton

Petitioner contends that claims 12, 13, 20–23, and 29 are unpatentable over Woehr, Callaway, and Sutton. Pet. 3. Unlike Petitioner's challenge based on Woehr and Callaway alone, Petitioner relies on Sutton for teaching the claimed "arm." *See id.* at 50–53.

1. Woehr (Exs. 1003, 1005)²

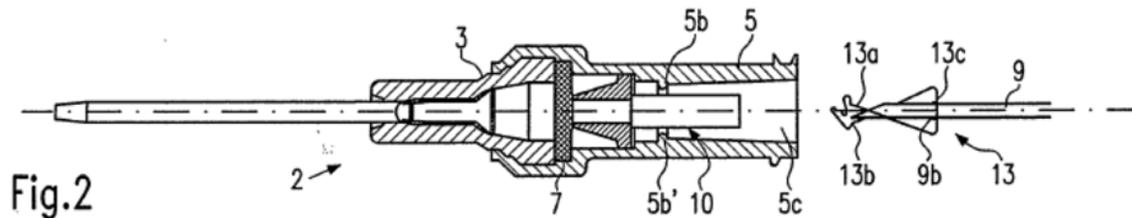
Woehr is a PCT Patent Publication titled "Catheter Insertion Device." Ex. 1005, [54]. To illustrate an embodiment of Woehr's device, we reproduce Figure 1, below:

² *See supra* n. 1.



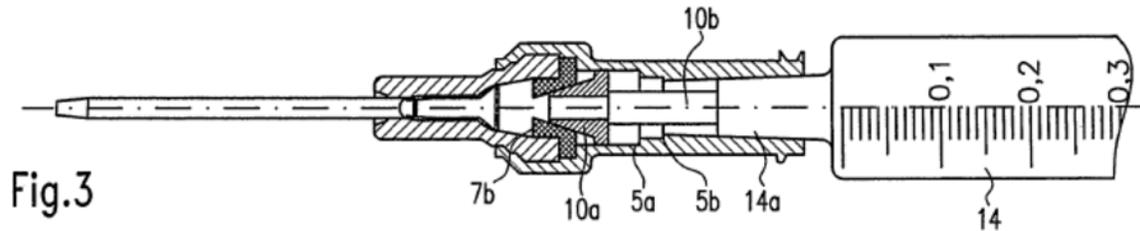
Woehr describes Figure 1 as depicting its catheter insertion device 1 in a ready-to-use position. *Id.* at 1, 2. Device 1 comprises distal hub 3, catheter 4, hub element 5, and a check valve in the form of valve disk 7. *Id.* at 2. In the ready-to-use position, needle hub 8 is inserted into hub element 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:



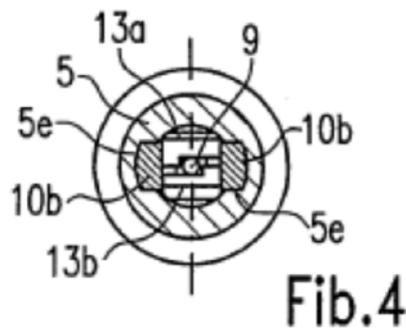
Woehr describes Figure 2 as depicting hollow needle 9 withdrawn from catheter insertion device 1. *Id.* at 1. During needle 9 withdrawal, spring clip 13 is drawn out of hub 5 along with needle 9, and spring arms 13a and 13b of spring clip 13 "lie around . . . and completely cover and block" needle point 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:



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

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

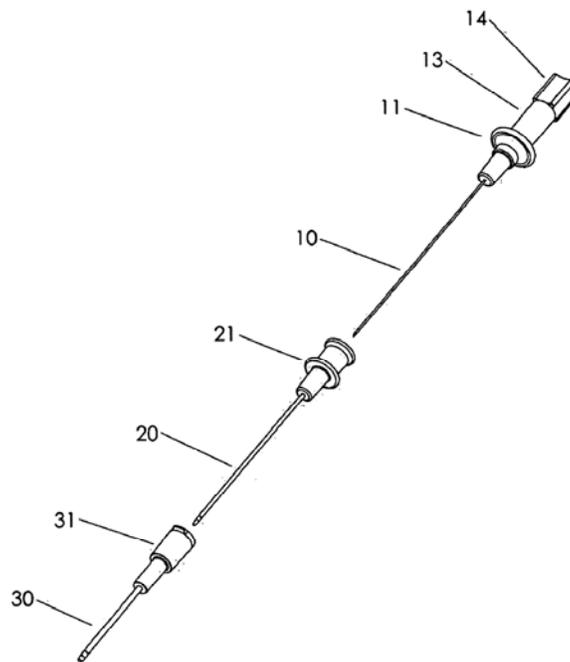


Woehr describes Figure 4 as depicting a side view along line A-A of Figure 1. *Id.* at 1. In particular, Figure 4 depicts two plungers 10b of valve actuating element 10 as being guided in longitudinal grooves 5e of hub element 5, such that plungers 10b form a contact surface for neck section 14a of injection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

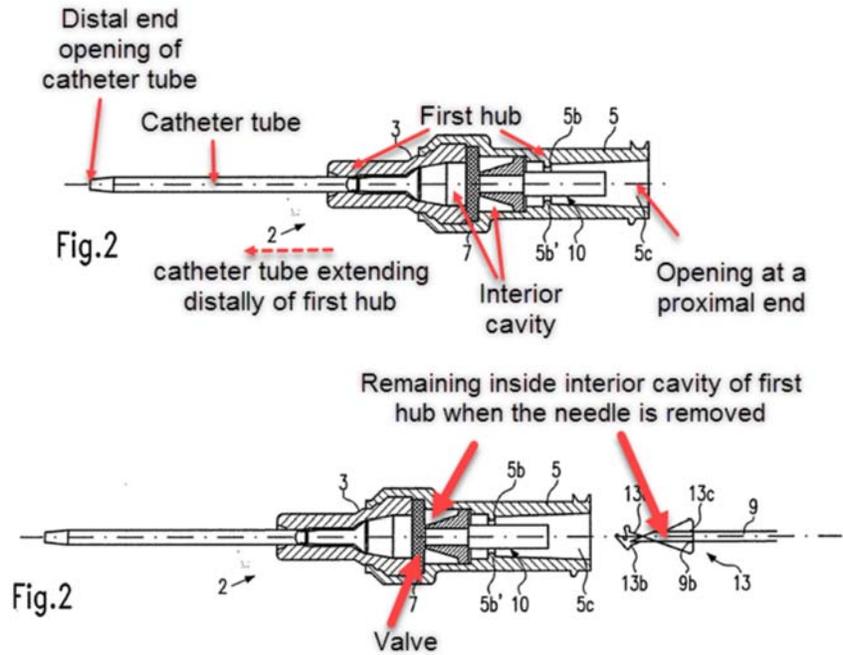
2. *Callaway (Ex. 1004)*

Callaway is a U.S. Patent Publication titled “Easy Entry Catheters.” Ex. 1004, [54]. To illustrate a particular embodiment of Callaway’s catheter, we reproduce Figure 5, below:



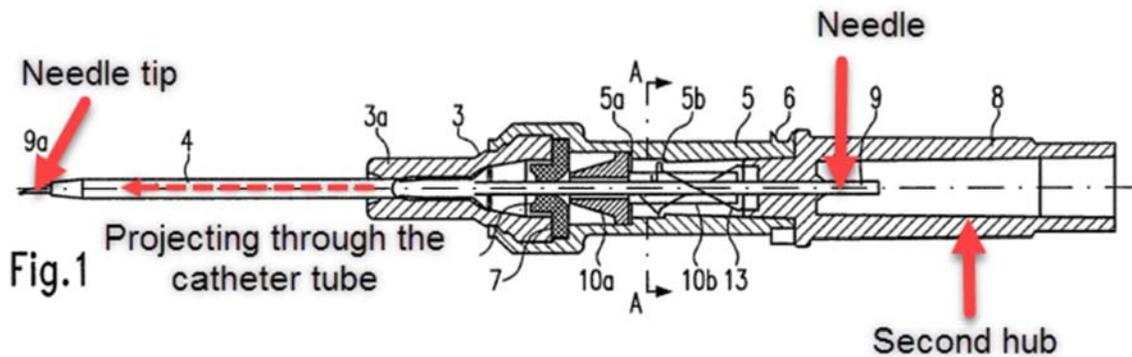
Callaway describes Figure 5 as depicting its catheter insertion device “with the three major parts disassembled from each other” and “separated along their common axis.” *Id.* ¶¶ 37, 57. In particular, Figure 5 depicts needle 10, proximal hub 11, and flash chamber 13 on the right, and with outer catheter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

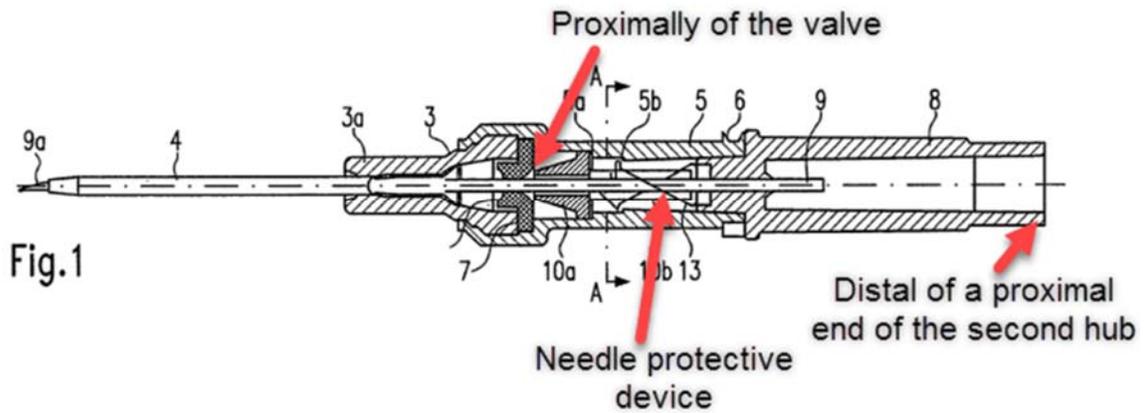
Callaway further discloses:



According to Petitioner, annotated Figure 2 depicts 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.

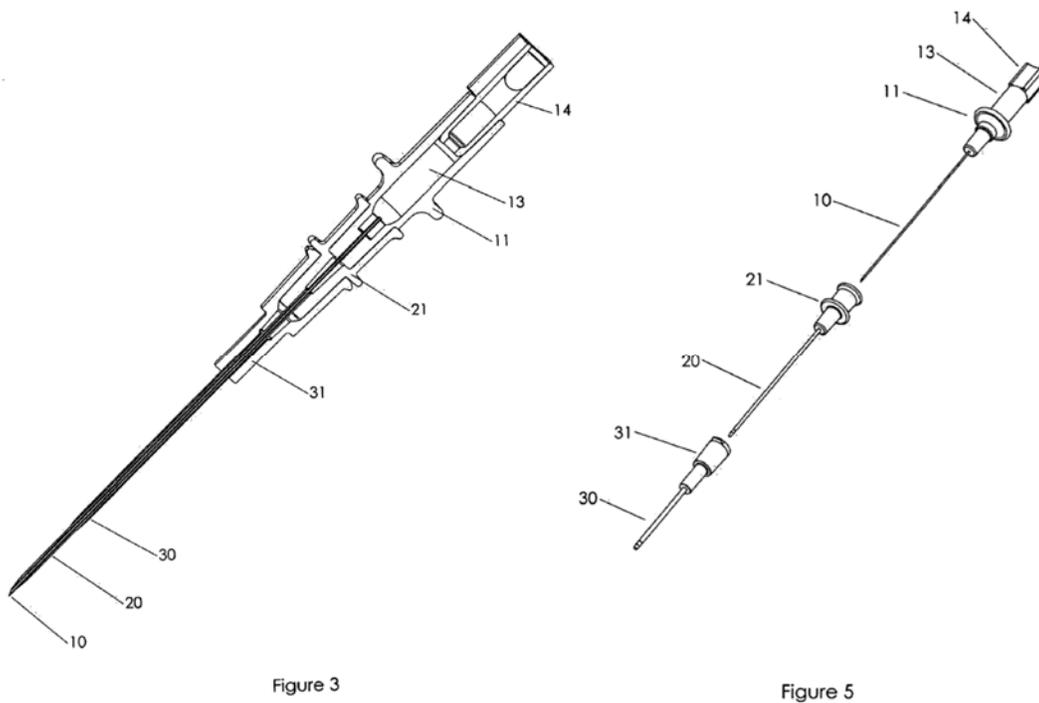
Petitioner also submits two annotated versions of Woehr’s Figure 1 (*id.* at 19, 25), copies of which we reproduce below:





According to Petitioner, and as shown above in the annotated versions of Woehr's Figure 1, Woehr discloses its safety catheter assembly as also comprising the claimed "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:



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.

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:

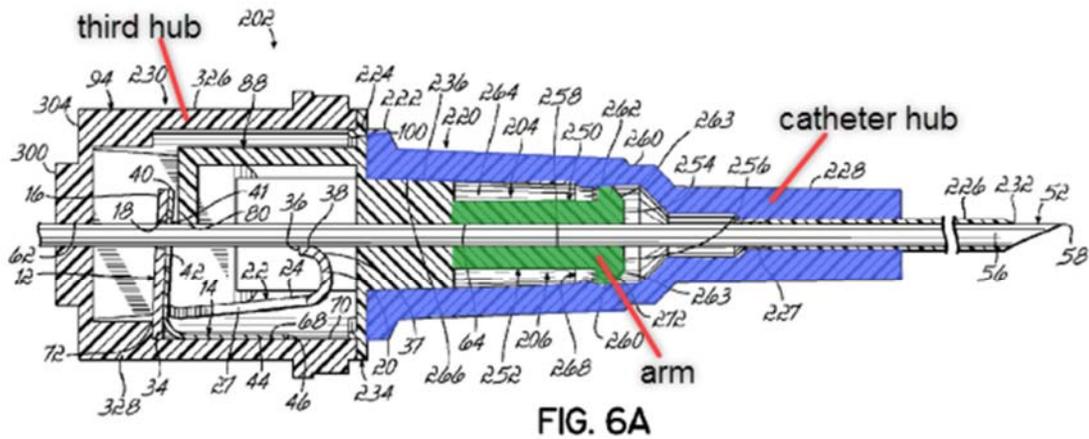


FIG. 6A

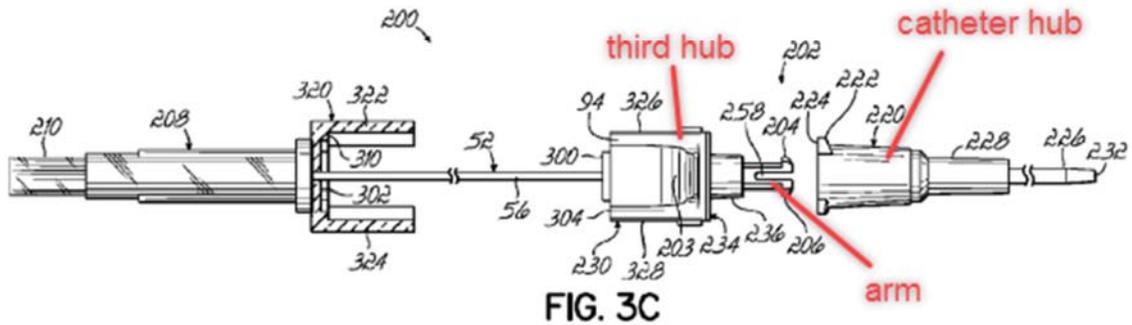


FIG. 3C

According to Petitioner, annotated Figures 6A and 3C depict Sutton's arms 204, 206, 250, 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).

5. *Patent Owner's Argument*

Patent Owner presents numerous arguments in contesting Petitioner's challenge. Prelim. Resp. 26–39. In particular, Patent Owner first argues that modifying Woehr's two-hub device to include a third hub, as disclosed by Callaway, would render Woehr inoperable for its intended purpose. *Id.* at 26–37. Patent Owner also argues that Petitioner's reason for combining Woehr with Callaway is based on improper hindsight reconstruction. *Id.* at 37–39.

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

6. *Analysis (independent claims 12 and 23)*

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

Callaway, for the purpose of further preventing unintended contact with Woehr's needle and any fluids remaining on the needle after removal. *See* Pet. 28–29.

Furthermore, Patent Owner's argument is based on the assertion that Callaway's principle of operation "requires two nested catheter hubs." Prelim. Resp. 29. We are not persuaded that Woehr's principle of operation requires two hubs. Rather, we find that Woehr's principle of operation is to provide a needle protecting element that prevents blood from discharging from the catheter after removal of a hollow needle. *See, e.g.*, Ex. 1005, 1 ("The underlying object of the invention is to design a catheter insertion device of the type indicated at the beginning such that a blood discharge from the catheter after removing the hollow needle is prevented by the needle protecting element"). At this stage of the proceeding, we are not persuaded that adding a third hub would render Woehr inoperable for its intended purpose of preventing blood discharge from the catheter.

Patent Owner also argues that Callaway's "third hub" 21 is physically inseparable from its catheter 20, and that the proposed combination would render *Callaway's device inoperable* and unsuitable for its intended purpose. Prelim. Resp. 32–33. Here, Patent Owner's argument is based on a misapplication of Petitioner's challenge. Petitioner does not propose to modify Callaway's device to remove its catheter, but instead proposes to modify Woehr's device to include a third hub that itself does not include Woehr's inseparable catheter. *See* Pet. 28–29. Accordingly, Patent Owner's argument is not responsive to Petitioner's ground of unpatentability.

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

on impermissible hindsight. Prelim. Resp. 37–39. In the present case, Petitioner’s reasoning does not rely only on knowledge gleaned from the ’247 patent’s disclosure. *See In re McLaughlin*, 443 F.2d 1392 1313–1314 (CCPA 1971) (“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and *does not include knowledge gleaned only from applicant’s disclosure*, such a reconstruction is proper” (emphasis added)). As pointed out by Petitioner, Callaway expressly teaches the use of its “third hub” 21 in conjunction with a protective needle clip for the purpose of protecting users from the sharp needle tip. Pet. 28 (citing Ex. 1004 ¶ 61); Ex. 1004 ¶ 61 (“The clip and hub (21) protect users from the sharp tip of the needle (10).”). Accordingly, Petitioner’s reasoning for modifying Woehr to add a third hub to “prevent unintended contact with the tip protector itself and/or contact with any fluids remaining on the needle after it is removed” is explicitly taught by Callaway and is articulately reasoned with some rational underpinning. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*, 550 U.S. at 418) (“rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

For the foregoing reasons, we are persuaded at this stage of the proceeding by Petitioner’s asserted reasons for combining Woehr, Callaway, and Sutton and Petitioner’s showing that the proposed combination satisfies the limitations recited in independent claims 12 and 23.

7. *Dependent Claims 13, 20–22, and 29*

The Petition sets forth how the combination of Woehr, Callaway, and Sutton satisfies the limitations of dependent claims 13, 20–22, and 29. *See* Pet. 54, 56 (incorporating by reference analysis presented under Woehr and Callaway); *see also id.* at 29–32, 38 (challenging claims 13, 20–22, and 29 based on Woehr and Callaway). Patent Owner does not specifically respond to Petitioner’s challenge of these claims. *See generally* Prelim. Resp.

We have considered the Petition, its underlying supporting evidence, and the Patent Owner Preliminary Response. On this record, we are persuaded that Petitioner has shown that it has a reasonable likelihood of prevailing in its assertion that claims 13, 20–22, and 29 are unpatentable over Woehr, Callaway, and Sutton.

F. Woehr and Villa

Petitioner contends that claims 12, 13, 20–23, and 29 are unpatentable over Woehr and Villa. Pet. 3. In challenging these claims based on Woehr and Villa *alone*, Petitioner relies on Villa’s “third hub” 20 as having an “arm,” namely element 22, that extends distally from “third hub” 20. *See* Pet. 41. As discussed above, however, Petitioner’s interpretation of “arm” is unreasonably broad and we disagree with Petitioner’s assertion that Villa’s element 22 can be construed as an “arm” that extends distally from “third hub” 20, as required by the claims. *See supra* Section II.A.2.

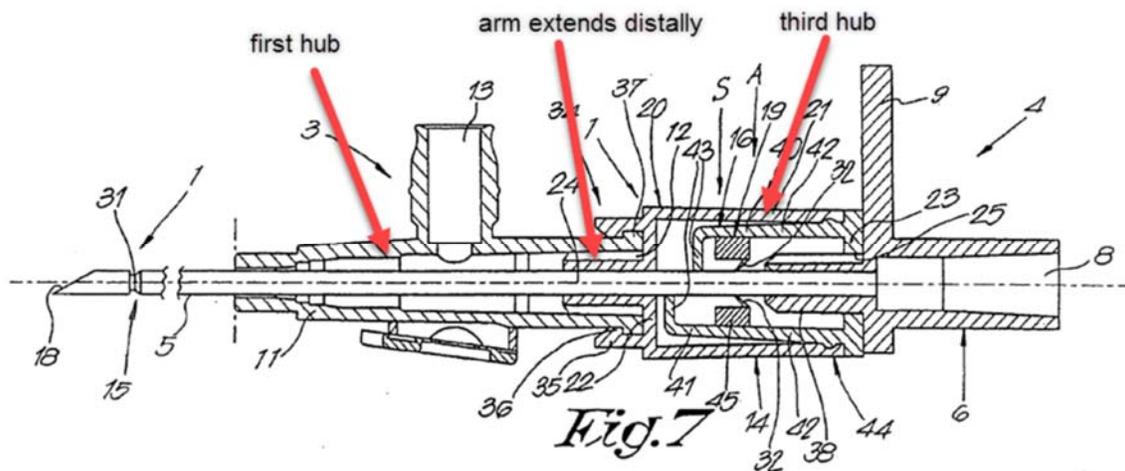
Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Woehr and Villa *alone* render obvious claims 12, 13, 20–23, and 29.

completely closed, the fluids retained in housing 20 by scraping means 33 “are practically completely held inside,” even if needle 5 “were to undergo shocks or vibrations.” *Id.*

2. *Petitioner’s Challenge (independent claims 12, 23)*

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 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 that the proposed combination changes the principle of operation of each of these references and results in inoperability. *See* Prelim. Resp. 39–53. In particular, Patent Owner presents the following three arguments:

(1) Patent Owner argues that the Petitioner provides inadequate explanation as to how Woehr's needle guard element 13 is moved into Villa's housing without disrupting the housing's essential features (*id.* at 41–44);

(2) Patent Owner argues that Petitioner's combination would render Villa's housing 20 inoperable and unsatisfactory for its intended purpose (*id.* at 44–49);

(3) Patent Owner argues that the proposed combination would render Woehr's device inoperable and unsuitable for its intended purpose (*id.* at 50–53).

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

4. *Analysis (independent claims 12 and 23)*

With regards to Patent Owner's argument (1), at this stage, we are persuaded that Petitioner provides sufficient explanation as to how to move Woehr's needle guard element 13 into Villa's housing 20. As discussed above with the prior ground based on Woehr, Callaway, and Sutton, Patent Owner's argument appears to be premised on the physical combinability of Woehr with Villa. However, "it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *Sneed*, 710 F.2d at 1550. Rather, the relevant inquiry is whether the claimed subject matter would have been obvious to those of ordinary skill in the art in light of the *combined teachings* of those references. *See Keller*, 642 F.2d at 425; *see also In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) ("Combining the *teachings* of references does not involve an ability to combine their specific structures."). Based on the record before us, and as

Mr. Griffis testifies, we are persuaded that a person having ordinary skill in the art would have modified Woehr to include a third hub, as taught by Villa, and to place Woehr's needle guard element 13 into the third hub for the purpose further reducing the risk of contact with a patient's bodily fluids (or drugs) on Woehr's needle, and that the proposed modification would further prevent accidental pricking with the needle. *See* Pet. 43; Ex. 1002 ¶ 141.

With regards to Patent Owner's argument (2), we find it to be unresponsive to Petitioner's proposed combination. In particular, we are not persuaded that Petitioner's proposed combination would render Villa's housing 20 inoperable and unsatisfactory for its intended purpose (Prelim. Resp. 44), as Petitioner does not propose to modify Villa's housing—as Patent Owner's argument presumes—but rather proposes to modify Woehr by adding a third hub, as taught by Villa. *See* Pet. 43. Patent Owner's argument is also unpersuasive as it appears to be premised on the physical combinability of Woehr's and Villa's specific structures. *Nievelt*, 482 F.2d at 968.

In response to Patent Owner's third argument, at this stage of the proceeding, we find it unpersuasive. As discussed above, Patent Owner's argument focuses overly on the physical combinability of Villa's particular structure (Villa's housing 20) and Woehr's particular structure (Woehr's needle guard 13), overlooking the general teachings of Villa. *See, e.g.*, Prelim. Resp. 51 (“there is nothing in Villa's housing (20) to hold Woehr's needle guard (13) in place”); *see also, e.g., id.* at 52 (“[a]dding Villa's housing to Woehr's catheter hub would cause Woehr's actuator (10) to be pushed distally, activating Woehr's valve (7), never allowing the valve to

close upon removal of the needle”). As explained above, “[c]ombining the teachings of references does not involve an ability to combine their specific structures.” *Nievelt*, 482 F.2d at 968.

At this stage of the proceeding, we credit Mr. Griffis’ testimony that “a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching of Woehr with those of Villa.” Ex. 1002 ¶ 143. We are also persuaded at this stage of the proceeding by Petitioner’s asserted reasons for combining Woehr, Villa, and Sutton and Petitioner’s showing that the proposed combination satisfies the limitations recited in independent claims 12 and 23.

5. *Dependent Claims 13, 20–22, and 29*

The Petition sets forth how the combination of Woehr, Villa, and Sutton satisfies the limitations of dependent claims 13, 20–22, and 29. *See* Pet. 60–61, 63 (incorporating by reference analysis presented under Woehr and Callaway); *see also id.* at 29–32, 38 (challenging claims 13, 20–22, and 29 based on Woehr and Callaway). Patent Owner does not specifically respond to Petitioner’s challenge of these claims. *See generally* Prelim. Resp.

We have considered the Petition, its underlying supporting evidence, and the Patent Owner Preliminary Response. On this record, we are persuaded that Petitioner has shown that it has a reasonable likelihood of prevailing in its assertion that claims 13, 20–22, and 29 are unpatentable over Woehr, Callaway, and Sutton.

H. Woehr, Callaway, and Nakajima

Petitioner contends that dependent claim 22 is unpatentable over Woehr, Callaway, and Nakajima. Pet. 63. In challenging claim 22 based on Woehr, Callaway, and Nakajima alone, and without Sutton, Petitioner relies on Callaway's hub 21 has having an "arm" that extends distally thereof. *See id.* (incorporating by reference prior analysis based on Woehr and Callaway). As discussed above, however, Petitioner's interpretation of "arm" is unreasonably broad and we disagree with Petitioner's assertion that Callaway's "third hub" 21 has an "arm" that extends distally therefrom, as required by the claims. *See supra* Section II.A.2.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Woehr, Callaway, and Nakajima alone render obvious claim 22.

I. Woehr, Villa, and Nakajima

Petitioner contends that dependent claim 22 is unpatentable over Woehr, Villa, and Nakajima. Pet. 66. In challenging claim 22 based on Woehr, Villa, and Nakajima alone, and without Sutton, Petitioner relies on Villa's "third hub" 20 as has having an "arm," namely element 22, that extends distally from "third hub" 20. *See id.* (incorporating by reference prior analysis based on Woehr and Villa, alone). As discussed above, however, Petitioner's interpretation of "arm" is unreasonably broad and we disagree with Petitioner's assertion that Villa's element 22 can be construed as an "arm" that extends distally from "third hub" 20, as required by the claims. *See supra* Section II.A.2.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Woehr, Callaway, and Nakajima alone render obvious claim 22.

J. Woehr, Callaway, Sutton, Nakajima

Claim 22 depends indirectly from claim 12, and further recites “wherein the valve actuating element remains engaged to the valve to open the slit for fluid flow through the first hub.” Ex. 1001, 14:27–29. Petitioner presents this additional challenge of claim 22 if Patent Owner argues, and we conclude, that the claim is interpreted to mean that “the valve actuating element causes the valve slit to remain open after the male implement is withdrawn from the catheter hub.” Pet. 65; *id.* at 63–64 (citing Ex. 1002 ¶ 217).

Based on this particular interpretation, Petitioner asserts that it would have been obvious to further modify Woehr’s valve actuating element so that it keeps its valve open after the luer connector is removed, in light of Nakajima’s teachings, “to obtain predictable results of allowing fluid flow through the catheter hub.” *See id.* at 64–65 (citing in part Ex. 1007 ¶¶ 14, 38; Ex. 1002 ¶¶ 219–222).

Patent Owner does not propose a particular interpretation of this claim and does not specifically respond to Petitioner’s challenge of claim 22. *See generally* Prelim. Resp.

We have considered the Petition, its underlying supporting evidence, and the Patent Owner Preliminary Response. On this record, we are persuaded that Petitioner has shown that it has a reasonable likelihood of

prevailing in its assertion that claim 22 is unpatentable over Woehr, Callaway, Sutton, and Nakajima.

K. Woehr, Villa, Sutton, Nakajima

As with the prior ground based on Woehr, Callaway, Sutton, and Nakajima, Petitioner presents this additional challenge of claim 22 if Patent Owner argues, and we conclude, that the claim is interpreted to mean that “the valve actuating element causes the valve slit to remain open after the mail implement is withdrawn from the catheter hub.” Pet. 67; *id.* at 63–64 (citing Ex. 1002 ¶ 217).

Patent Owner does not propose a particular interpretation of this claim and does not specifically respond to Petitioner’s challenge of claim 22. *See generally* Prelim. Resp.

We have considered the Petition, its underlying supporting evidence, and the Patent Owner Preliminary Response. On this record, we are persuaded that Petitioner has shown that it has a reasonable likelihood of prevailing in its assertion that claim 22 is unpatentable over Woehr, Villa, Sutton, and Nakajima.

III. CONCLUSION

For the foregoing reasons, upon review of Petitioner’s analysis and supporting evidence, we conclude that Petitioner has demonstrated a reasonable likelihood that it will prevail with regards to its challenge of: claims 12, 13, 20–23, and 29 based on Woehr, Callaway, and Sutton; claims 12, 13, 20–23, and 29 based on Woehr, Villa, and Sutton; claim 22 based on Woehr, Callaway, Sutton, and Nakajima; and claim 22 based on Woehr,

Villa, Sutton, and Nakajima. Pet. 3. We further conclude that Petitioner has not demonstrated a reasonable likelihood that it will prevail with regards to its challenge of: claims 12, 13, 20–23, and 29 based on Woehr and Callaway; claims 12, 13, 20–23, and 29 based on Woehr and Villa; its challenge of claim 22 based on Woehr, Callaway, and Nakajima; and its challenge of claim 22 based on Woehr, Villa, and Nakajima. *Id.*

At this stage of the proceeding, although we exercise our discretion and institute review, we remind the parties that we have not yet made a final determination as to the patentability of any challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 12, 13, 20–23, and 29 of the '247 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Callaway, and Sutton;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 12, 13, 20–23, and 29 of the '247 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Villa, and Sutton;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claim 22 of the '247 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Callaway, Sutton, and Nakajima;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claim 22 of the '247 patent as unpatentable under 35 U.S.C. § 103 over Woehr, Villa, Sutton, and Nakajima;

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

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FURTHER ORDERED that the trial is limited to the grounds identified above.

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