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Paper No. 9
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B. BRAUN MELSUNGEN AG,
Patent Owner.

Case IPR2017-01590
Patent 9,370,641 B2

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

DANIELS, *Administrative Patent Judge.*

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

I. INTRODUCTION

A. Background

Becton, Dickinson and Company ("Petitioner") filed a Petition requesting *inter partes* review of claims 15, 17, 18, 20, and 22 of U.S. Patent No. 9,370,641 B2 ("the '641 patent"). Paper 3, ("Pet."). B. Braun Melsungen AG ("Patent Owner") filed a Preliminary Response contending that the Petition should be denied as to all challenged claims. Paper 7, ("Prelim. Resp.").

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

B. Additional Proceedings

Petitioner represents that the '641 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1. Petitioner represents that petitions for *inter partes* review were also filed challenging related patents US. Patent Nos.: 8,337,463;

8,333,735; 8,540,728; 9,149,626; 8,597,249; 8,460,247; and 8,328,762. *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

C. The '641 Patent (Ex. 1001)

The '641 patent, titled "Catheter Assembly and Components Thereof," discloses catheter assemblies having "a tip protector, a valve, a valve opener, and . . . a needle wiper." Ex. 1001, [54], [57]. The '641 discusses the need to prevent accidental needle sticks following withdrawal of the needle from a patient's vein, and to minimize the risk of dangerous blood-borne pathogens. *Id.* at 1:38–47. The '641 patent discusses a desire to cover needles immediately following use, and to provide a valve to minimize blood exposure following successful catheterization. *See id.* at 1:57–67.

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

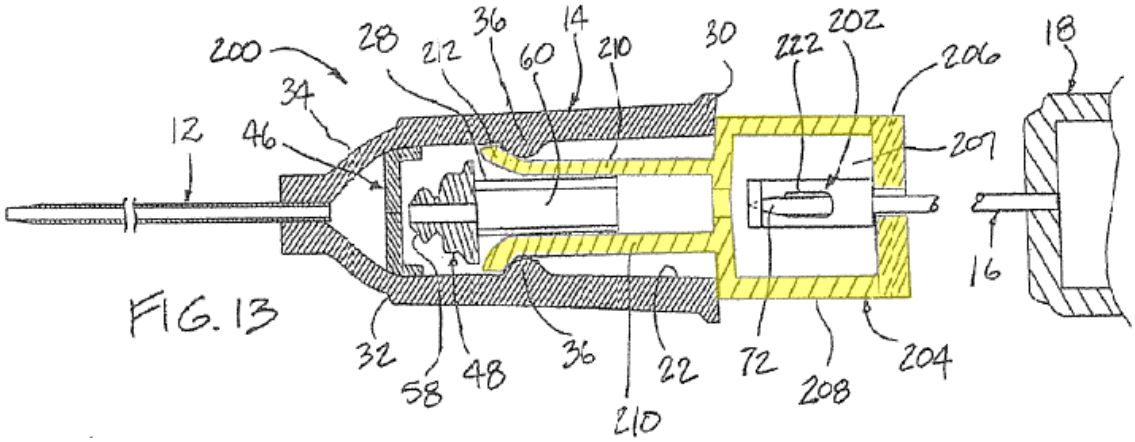


FIG. 13

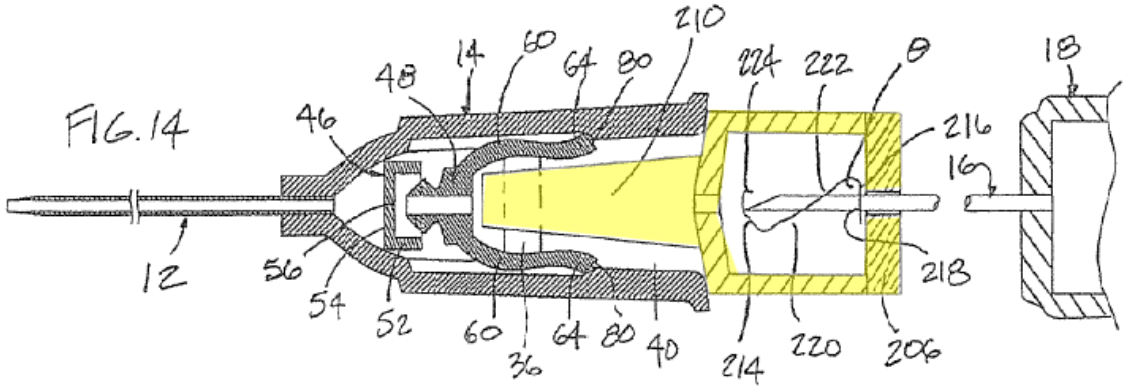


FIG. 14

We have annotated Figures 13 and 14, above, which depict a particular embodiment of Patent Owner's catheter assembly with a *third housing* 204 shown in yellow, positioned between the catheter and needle hub. *Id.* at 4:41–44. Figure 14 "is a cross-sectional side view" of Figure 13's catheter assembly "taken along an orthogonal plane." *Id.* at 4:45–46. In particular, Figures 13 and 14 depict catheter assembly 200, including catheter tube 12, catheter hub 14, needle 16 with needle tip 72, needle hub 18, third housing 204, hemostatic valve 46, and valve opener 48. *Id.* at 11:13–20. Valve opener 48 comprises a pair of legs 60 positioned in corresponding channels 28. *Id.* at 11:10–12. In this particular embodiment, third housing 204 is provided to "accomodat[e] the tip protector." *See id.* at 11:20–24. Housing

204 incorporates a pair of arms 210, each of which comprises a hook 212. *Id.* at 11:41–42. The two hooks 212 are configured to engage two bumps 36 to retain third housing 204 to catheter hub 14 in a "ready to use position," and are preferably flexible to provide a gripping force against bumps 36. *Id.* at 11:44–46. During use, needle 16 extends through valve 46 and through catheter tube 12, and upon withdrawal of needle 16 from catheter tube 12 and valve 46, valve 46 closes to prevent an outflow of blood. *See id.* at 7:13–16.

Following a successful catheterization, needle 16 is retracted away from catheter tube 12, and in the rightward direction as shown in Figures 13 and 14. *Id.* at 11:53–56. As needle tip 72 moves to the right of distal wall 214 of tip protector 202, tip protector 202 engages needle 16 and further movement of needle 16 causes tip protector 202 to pull on rear plate 206 of third housing 204, which then disengages hooks 212 from bumps 36. *Id.* at 11:56–61. At completion of the process, needle 16 is covered by *both* tip protector 202 and third housing 204 to minimize the risk of injury from needle tip 72. *Id.* at 11:56–61.

D. Illustrative Claim

Of the challenged claims, claim 15 is independent. Each of dependent claims 17, 18, 20, and 22 depend directly from independent claim 15. Claim 15 illustrates the claimed subject matter and is reproduced below:

15. A safety catheter assembly comprising:

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

> a needle hub having a needle with a needle tip attached to the needle hub and projecting distally of the needle hub and into the catheter tube with the needle tip extending out the distal opening of the catheter tube;
>
> a valve for limiting fluid flow and a valve opener in cooperative arrangement therewith positioned in the interior cavity of the catheter hub;
>
> *a safety device for covering the needle tip comprising a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub*; and
>
> wherein the valve opener comprises two proximally extending legs having a gap therebetween, the two proximally extending legs being sized and shaped to be pushed distally towards the valve to transfer a force imparted by a male Luer to the valve.

Ex. 1001, 13:55–14:8 (emphasis added).

E. The Alleged Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable on the following specific grounds.[1]

References	**Basis**	**Claims Challenged**
Woehr[2] and Callaway[3]	§ 103	15, 17, 18, 20, and 22
Woehr, and Villa[4]	§ 103	15, 17, 18, 20, and 22

[1] Petitioner supports its challenge with the Declaration of Jack Griffis, III, (Ex. 1002), and in its Preliminary Response, Patent Owner relies upon the Declaration of Richard Meyst (Ex. 2001). *See infra*.
[2] (Exs. 1003, 1005) PCT WO 2004/004819 A1, published Jan. 15, 2004.
[3] (Ex. 1004) US 2006/0178635 A1, published Aug. 10, 2006.
[4] (Ex. 1006) US 2004/0225260 A1, published Nov. 11, 2004.

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

At the outset, Patent Owner argues that we should deny institution because Petitioner has failed to provide a compliant affidavit attesting to the accuracy of the English translation (Ex. 1005), of the original German language publication Woehr (Ex. 1003). Prelim. Resp. 18; *see also id.* at 18–22 (arguing Woehr should not be considered as evidence).

"When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an *affidavit* attesting to the accuracy of the translation must be filed with the document." 37 C.F.R. § 42.63 (emphasis added). Pursuant to 37 C.F.R. § 42.2, an "[a]ffidavit means affidavit *or* declaration under § 1.68 of this chapter." (emphasis added). Patent Owner's contentions seem to misplace the requirements for a "declaration" (under § 1.68) onto a sworn affidavit. These are distinct documents. For example, the requirements of 28 U.S. Code § 1746 are for "Unsworn declarations." If a document is sworn, under oath, before an appropriate official, such as a qualified notary public, the additional requirements of § 1746 would seemingly not apply. *See also* 37 C.F.R. § 1.68 ("Declaration *in lieu of oath*"). It appears to us that the translation of Woehr (Ex. 1005) was sworn testimony before a notary public, and as such, qualifies 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. *See, e.g.*, N.Y. Comp. Codes R. & Regs. tit. 19, Part 182 § 135 (2017) ("Every notary public duly qualified is hereby authorized and empowered within and throughout the State to administer

oaths and affirmations, to take affidavits."). 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'")).

II. CLAIM CONSTRUCTION

A. Legal Standard

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). 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. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'"). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Safety Device

Independent claim 15 and dependent claim 20 each recite a "safety device." Ex. 1001, 14:1, 25. Petitioner contends the term "safety device" invokes 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Pet. 10–16. 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 12 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc)) and further contends that "the modifier 'safety' does not impart any structure to the term 'device'" (*id.*)). Petitioner's argument is supported by the declaration of Mr. Griffis, who testifies that "[t]he phrase 'safety device' is not defined in any technical dictionaries or engineering handbooks, nor is it used in common parlance or by persons of skill in the pertinent art to designate structure." *Id.* at 12–13 (citing Ex. 1002 ¶¶ 54–56) (citations omitted).

Patent Owner disagrees that the safety device limitation should be construed in means-plus-function format. Prelim. Resp. 6–14. Patent Owner argues that the claim does not use the word "means" and "there is a rebuttable presumption that §112, ¶ 6 does not apply." *Id.* at 6. Patent Owner contends that "safety device" is expressly defined in independent claim 15 as "a safety device for covering the needle tip comprising ***a tip protector housing*** having ***a housing section positioned proximally*** of a proximal end of a proximal end of the catheter hub." *Id.* at 7 (citing Ex. 1001, 14:1–3. Patent Owner points out further that dependent claim 20 recites further that "the safety device 'comprises a resilient portion made from a metal material [i.e., a tip protector] and the tip protector housing surrounding the resilient portion.'" *Id.* (citing Ex. 1001, 14:24–27). Patent

Owner asserts that the functional and structural recitations further describing the "safety device" in the claims, along with the rest of the written description, are sufficient to maintain the presumption that § 112 ¶ 6 does not apply. *Id.* (citing Ex. 2001 ¶¶ 30–36; *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 safety device limitation should be construed as a means-plus-function term. Because the term "means" is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. For instance, we are not persuaded by Mr. Griffis's testimony that there is insufficient structure recited in the claims merely because claim 15 recites the safety device "comprising a tip protector housing," and dependent claim 20 adds more structural elements, such as a metal "resilient portion." *See* Ex. 1002 ¶ 62. Rather, as pointed out by Patent Owner, we determine that the safety device "comprising a tip protector housing having a housing section" describes sufficient physical structure, and the related verb predicate, "positioned proximally of a proximal end of the catheter hub" provides relative physical relationships between the claimed structural elements so as to be reasonably understood by one of ordinary skill in the art to accomplish the goals to cover and protect a needle tip. *See* Prelim. Resp. 11, *see also Williamson, LLC*, 792 F.3d at 1349 (explaining that the presumption is overcome when "the claim term fails to 'recite sufficiently

definite structure' or else recites 'function without reciting sufficient structure for performing that function.'").

Based on the record before us, the term "safety device" should not be construed under §112 ¶ 6. Instead, we agree with Patent Owner that the term "safety device" means a device for preventing accidental needle sticks by protecting the needle tip. *See* Prelim. Resp. 13–14.

III. ANALYSIS

A. 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, 17–8 (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).

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

Patent Owner relies upon the declaration of Richard 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 '641 patent, the types of problems and solutions described in the '641 patent and applied prior art, and the testimony of Mr. Griffis and Mr. Meyst, we determine that a POSITA would include a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical

degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. 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).

C. Petitioner's Citations to Sutton (Ex. 1014)

We address at the outset Petitioner's references to Sutton (Ex. 1014) and Patent Owner's objection that such references to Sutton makes the Petition unclear and defective. *See* Pet. 8, 25, 40; *see also* Prelim. Resp. 23.

The Petition refers at several points to Sutton as disclosing that "a 'shroud' that 'substantially encloses the needle guard' provides the benefit of 'reduc[ing] the likelihood of inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub.'" Pet. 40 (citing Ex. 1014 ¶ 11). The Petition, citing to Mr. Griffis's testimony, explains that Sutton is an example of what was known to those of skill in the art, namely, that "[i]t was known that hubs or housing structures for the tip protector provided additional security for the tip protector so the tip protector can better prevent accidental needle sticks." *See, e.g.*, *id.* (citing Ex. 1002 ¶ 114).

We agree with Patent Owner that the Petition does not include Sutton in any ground. We do not, however, find the reference to Sutton particularly unclear. According to Mr. Griffis's testimony, Sutton, like Villa and Callaway, apparently shows that "[c]atheters having three (or additional) hubs or housing structures were well known as of 2006." Ex. 1002 ¶ 114. We understand that Mr. Griffis relies on Sutton as evidence to bolster his testimony that one of skill in the art would have understood that such housing structures "provide[] the benefit of 'reduc[ing] the likelihood of

inadvertently activating the needle guard or pulling the needle guard loose from the catheter hub.'" *Id.* (quoting Ex 1014 ¶ 11).

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

D. Alleged Obviousness over Woehr (Exs. 1003, 1005)[5] and Callaway (Ex. 1004)

Petitioner contends that claims 15, 17, 18, 20, and 22 are unpatentable over Woehr and Callaway. Pet. 3, 17–37.

1. Woehr (Ex. 1005)

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

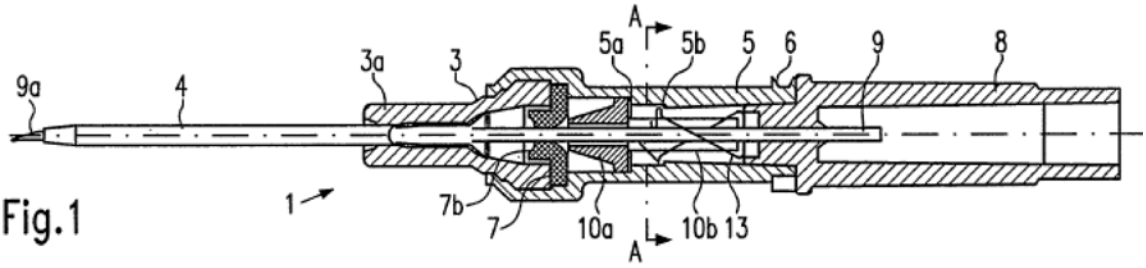


Fig.1

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

[5] Unless otherwise stated, we refer in this Decision to the certified English translation version of Woehr, Ex. 1005.

elements 10a, 10b) is arranged in hub element 5 between needle hub 8 and valve disk 7. *Id.*

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

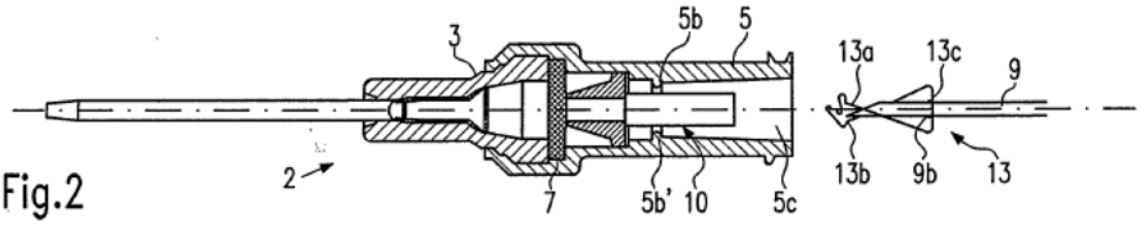


Fig.2

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

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

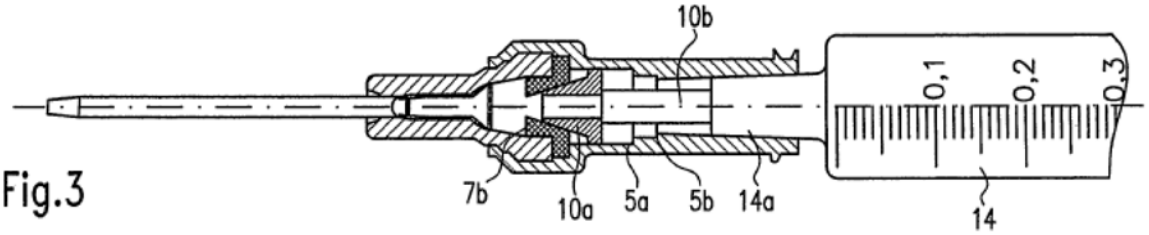
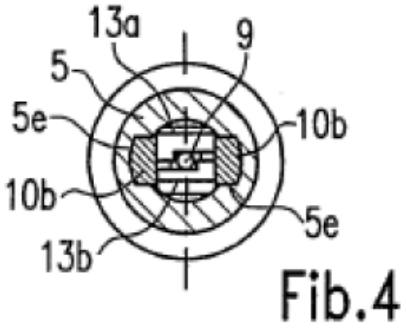


Fig.3

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

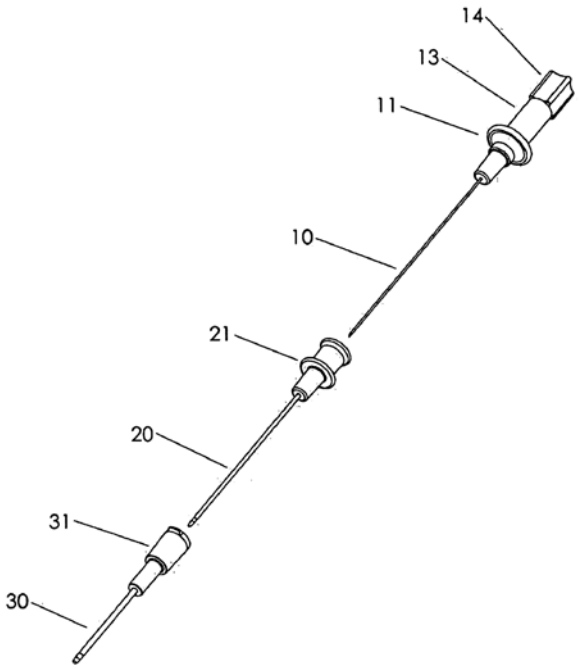
To better illustrate valve actuating element 10 and its arrangement within hub 5, we reproduce Woehr's Figure 4, below:



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.*

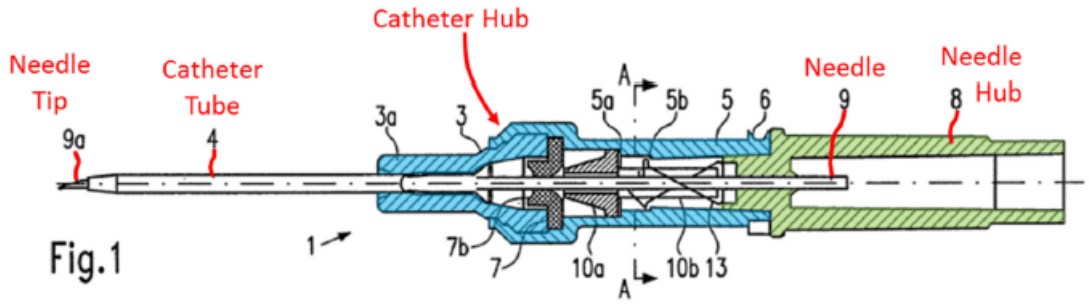
Callaway further discloses:

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

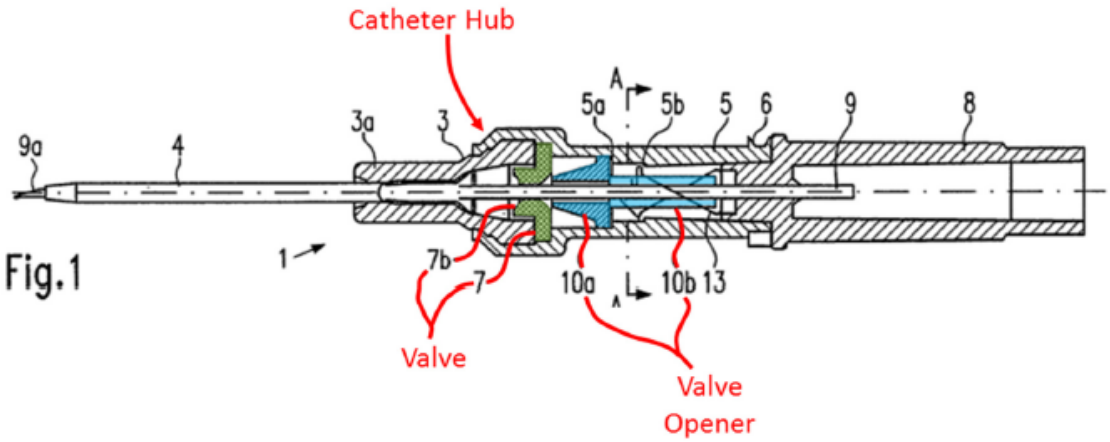
Id. ¶ 61 (emphasis added).

3. Analysis – Claims 15, 17, 18, 20, and 22

Petitioner argues that Woehr teaches every aspect of the claimed catheter insertion assembly except for "a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub," as recited in independent claim 15. *See* Pet. 19–29. For example, Petitioner asserts that Woehr discloses a safety catheter assembly having a catheter hub and catheter tube, a needle hub and a needle projecting through the catheter hub and tube, as well as a valve and valve opener as recited in claim 15. *Id.* at 19–23. These elements Petitioner contends, are illustrated in different annotated versions of Woehr's Figure 1, reproduced below.



Petitioner's annotated version of Woehr's Figure 1, above, depicts the needle hub in green and catheter hub in blue. Pet. 22.



Another annotated version of Woehr's Figure 1, above, as provided in the Petition, depicts the valve in green and valve opener in blue. *Id.* at 23.

For the missing safety device and housing limitation, Petitioner contends that "Callaway discloses an embodiment where a needle safety device in the form of a spring clip is placed in the middle hub." *Id.* at 18 (citing Ex. 1004, 0061; Ex. 1002 ¶ 72). Petitioner argues that a middle hub, i.e., tip protector hub structure 21 as that disclosed by Callaway, was a familiar structure to catheter design engineers that simply performed "known functions with predictable results and there is no unexpected result on which to base the patentability of the claims." *Id.* (citing Ex. 1002 ¶ 75). Petitioner reasons that a person of ordinary skill in the art would have understood that Callaway's tip protector housing would "also prevent unintended contact with the tip protector itself and/or contact with any fluids remaining on the needle after it is removed." *Id.* at 28 (citing Ex. 1002 ¶¶ 90–91).

Patent Owner makes essentially three arguments in rebuttal: (1) that the proposed combination requires a change in principle of operation of each of Callaway's and Woehr's devices thereby, (2) rendering each device inoperable for its intended purpose, and that, (3) the combination relies on improper hindsight. Prelim. Resp. 24, 26–37. Patent Owner's first argument that Callaway's inner hub 21 includes an inseparable catheter is not persuasive because it 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).

More specifically, Patent Owner contends that Callaway's principle of operation "requires two nested catheter hubs," both "inseparably" connected to respective different diameter catheters. Prelim. Resp. 26. What Petitioner relies upon from Callaway, however, is the specific teaching of a third needle protective housing 21, notwithstanding the "inseparable" catheter 20. *See* Pet. 25 ("Callaway discloses a tip protector housing (e.g., element 21) having a housing section positioned proximally of a proximal end of the catheter hub (e.g., element 31)"). Although Callaway does disclose the use of a smaller diameter "inner" catheter 21 to guide a larger diameter "outer" catheter 30 and that these catheters are attached to respective nested hubs 21 and 31, Petitioner is not incorporating all aspects of Callaway's structure and function into its obviousness analysis. *See KSR*, 550 U.S. at 420 ("any need or problem known in the field . . . and addressed by the patent can provide a reason for combining the elements in the manner claimed"). This argument is misplaced as it is error to "hold[] that courts and patent examiners should look only to the problem the patentee was trying to solve." *Id*. Moreover, Patent Owner's second argument, i.e., that Callaway would be inoperable for its intended purpose, does not show substantive error in Petitioner's reasoning and evidence that needle hub 21 would work as asserted regardless of catheter 20, where "Callaway teaches that 'clip and hub (21) protect users from the sharp tip of the needle (10).'" Pet. 27 (citing Ex. 1004 ¶ 61; Ex. 1002 ¶ 88).

Turning to Woehr, Patent Owner's first argument is not persuasive because 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, and to Patent owner's second argument, given our finding above with respect to the teachings of Callaway as discussed above, we are not persuaded that adding a third hub to protect the needle tip would render Woehr inoperable for its intended purpose of preventing blood discharge from the catheter.

In view of our analysis above, we disagree with the assertion that Petitioner's combination of Woehr and Callaway is based on impermissible hindsight. Prelim. Resp. 35–37. In the present case, Petitioner's reasoning does not rely only on knowledge gleaned from the '641 patent's disclosure. *See In re McLaughlin*, 443 F.2d 1392, 1313–14 (CCPA 1971) ("Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and *does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper" (emphasis added)). As pointed out by Petitioner, Callaway expressly teaches the use of its "third hub" 21 in conjunction with a protective needle clip for the purpose of protecting users from the sharp needle tip. Pet. 25 (citing 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 supported by 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 and Callaway, and Petitioner's showing that the proposed combination satisfies the limitations recited in independent claim 15.

The Petition sets forth how the combination of Woehr and Callaway satisfies the limitations of dependent claims 17, 18, 20, and 22. *See* Pet. 30–37 (incorporating by reference analysis presented under Woehr and Callaway). Patent Owner does not specifically respond to Petitioner's challenge of these claims. *See generally* Prelim. Resp. With regard to these dependent claims 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 17, 18, 20, and 22 are unpatentable over Woehr and Callaway.

E. Alleged Obviousness over Woehr (Exs. 1003, 1005) and Villa (Ex. 1006)

Petitioner contends that claims 15, 17, 18, 20, and 22 are unpatentable over Woehr and Villa. Pet. 3, 37–45.

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:

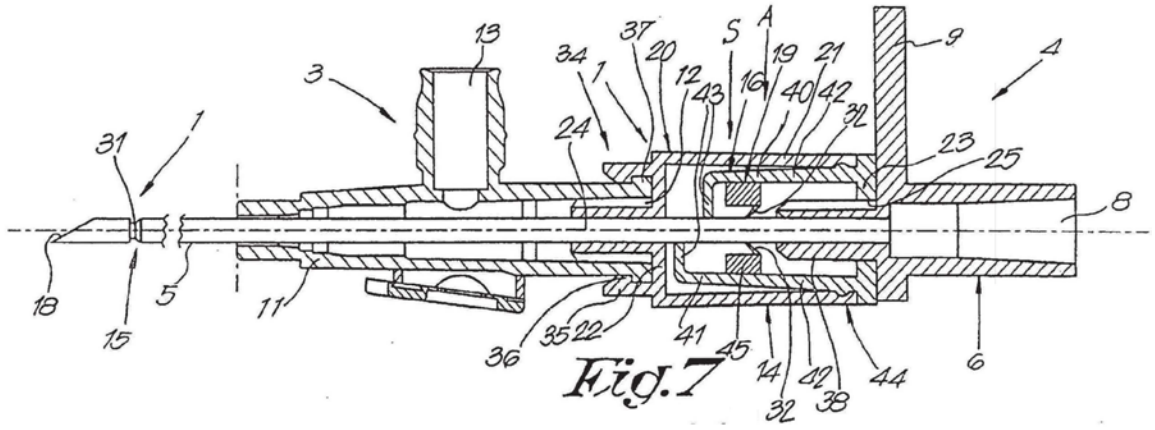
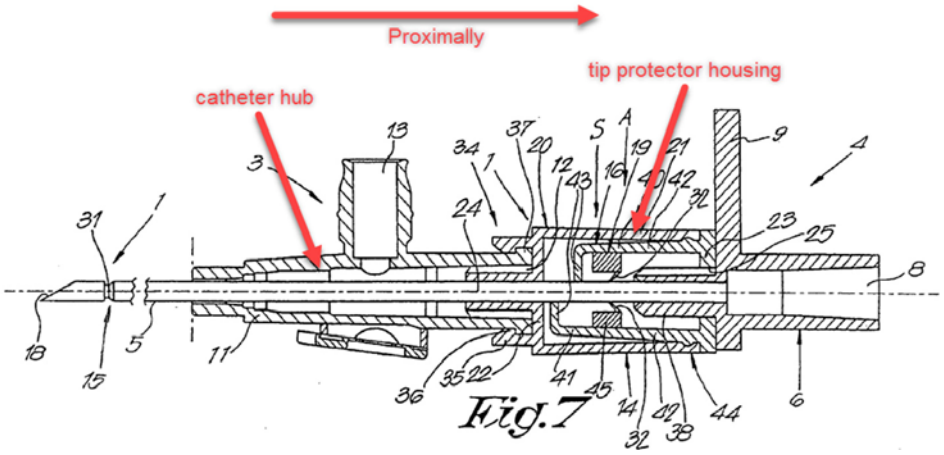


Figure 7 depicts a cross-sectional view of a cannula needle assembly with Villa's protective device. *See id.* ¶¶ 32, 38, 66. In particular, Figure 7 depicts protective device 1 with protective means 14, which slidably fits onto needle 5. *Id.* ¶ 45. Protective means 14 comprises safety means 16 and blocking means 19, which are preferably incorporated in housing 20, and which have openings 24, 25 for needle 5. *See id.* ¶¶ 46, 47. Housing 20 may include coupling means 34 at end wall 22, which allows for a releasable connection with the catheter hub. *Id.* ¶ 53. During passage from the non-operative state to the operative state, needle 5 slides through scraping means 33 to dry needle 5 from liquids that are adhered to needle 5, and the liquids are retained in hollow body 20. *Id.* ¶ 63. Although hollow body 20 is not completely closed, the fluids retained in housing 20 by scraping means 33 "are practically completely held inside," even if needle 5 "were to undergo shocks or vibrations." *Id.*

2. Analysis – Claims 15, 17, 18, 10, and 22

As with the prior ground based on Woehr and Callaway, Petitioner asserts that Woehr discloses a "safety catheter assembly" comprising the claimed "catheter hub," "needle hub," "needle," "valve," and "safety device." *See* Pet. 37–39 (incorporating by reference analysis based on Woehr and Callaway).

In addressing the claimed "safety device," Petitioner cites, *inter alia*, to their 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 "safety device" i.e. tip protector housing 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 41 (citing Ex. 1006 ¶¶ 1, 2, 47).

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 housing "because the Villa housing for the

protective means presents a number of advantages over the Woehr spring clip alone." *Id.* at 42. An advantage, Petitioner asserts, is to "'considerably reduce[] the risk of contact with a patient's bod[ily] fluids or drugs on the needle.'" *See id.* (citing Ex. 1002 ¶ 117; Ex. 1006 ¶¶ 15, 80).

Patent Owner argues that the proposed combination changes the principle of operation of each of these references and results in inoperability. *See* Prelim. Resp. 38. In particular, Patent Owner presents the following three arguments:

(1) Patent Owner argues that 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 40–43);

(2) Patent Owner argues that Petitioner's combination would render Villa's housing 20 inoperable and unsatisfactory for its intended purpose (*id.* at 43–48);

(3) Patent Owner argues that the proposed combination would render Woehr's device inoperable and unsuitable for its intended purpose (*id.* at 49–52).

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.

On the record at this stage in the proceeding, 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 and Callaway, Patent Owner's argument is premised

on the physical combinability, or un-combinability as it were, 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 housing, as taught by Villa, and to place Woehr's needle guard element 13 into the housing for the purpose of 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 needle sticks. *See* Pet. 40; Ex. 1002 ¶ 114.

Also, we are not persuaded that Petitioner's proposed combination would compromise Villa's housing 20 such that it would be inoperable and unsatisfactory for its intended purpose (Prelim. Resp. 44–48), 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 housing, as taught by Villa. *See* Pet. 42. Patent Owner's argument is also unpersuasive as it appears, again, to be premised on the physical combinability of Woehr's and Villa's specific structures. *Nievelt*, 482 F.2d at 968.

Turning to Patent Owner's third argument, 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. 50 ("there is nothing in Villa's housing (20) to hold Woehr's needle guard (13) in place"); *see also id.* at 51 ("[a]dding Villa's housing to Woehr's catheter hub would cause Woehr's actuator (10) to be pushed distally, activating Woehr's valve (7), never allowing the valve to close upon removal of the needle"). As explained above, "[c]ombining the teachings of references does not involve an ability to combine their specific structures." *Nievelt*, 482 F.2d at 968.

At this stage of the proceeding, we credit Mr. Griffis's testimony that "[a] person of ordinary skill in the art would have been motivated to modify the Woehr . . . because the Villa housing for the protective means presents a number of advantages over the Woehr spring clip alone." Ex. 1002 ¶ 117. We are also persuaded at this stage of the proceeding by Petitioner's asserted reasons for combining Woehr and Villa, and Petitioner's showing that the proposed combination satisfies the limitations recited in independent claim 15.

The Petition sets forth also how the combination of Woehr and Villa satisfies the limitations of dependent claims 17, 18, 20, and 22. *See* Pet. 43–45 (incorporating by reference analysis presented under Woehr and Callaway). Patent Owner does not specifically respond to Petitioner's challenge of these claims. *See generally* Prelim. Resp. With respect to these dependent claims 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 17, 18, 20, and 22 are unpatentable over Woehr and Villa.

F. Secondary Considerations

Patent Owner asserts that in the event trial is instituted it will present secondary consideration evidence of the commercial success, long-felt need, copying, and failure by others. Prelim. Resp. 52. In the event that Patent Owner provides such evidence during trial, we agree with the general proposition that evidence of secondary considerations of non-obviousness, when present, must always be considered en route to a determination of obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538—39 (Fed. Cir. 1983).

IV. SUMMARY

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail on at least one alleged ground of unpatentability with respect to each of claims 15, 17, 18, 20, and 22 of the ’641 patent.

The Board has not made a final determination on the patentability of any challenged claims.

V. ORDER

For the reasons given, it is

ORDERED that *inter partes* review of the ’641 patent is hereby instituted as to claims 15, 17, 18, 20, and 22 on the following grounds.

1. Claims 15, 17, 18, 20, and 22 as obvious over Woehr and Callaway; and
2. Claims 15, 17, 18, 20, and 22 as obvious over Woehr and Villa;

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

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

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