UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B.BRAUN MELSUNGEN AG,
Patent Owner of
U.S. Patent No. 9,149,626 to Woehr et al.

IPR Trial No. IPR2017-01587

PETITIONER'S NOTICE OF APPEAL

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

Pursuant to 35 U.S.C. §§ 141-44 and 319, and 37 C.F.R. § 90.2-90.3, notice is hereby given that Petitioner Becton, Dickinson and Company appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered December 12, 2018 (Paper 93) in IPR2017-01587 (Exhibit A), and all prior and interlocutory rulings related thereto or subsumed therein.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner further indicates that the issues on appeal include, but are not limited to, whether the Patent Trial and Appeal Board erred in its claim construction of the term "needle protective device" as recited in U.S. Patent No. 9,149,626 and/or in Patent Owner's proposed substitute claims; whether the Patent Trial and Appeal Board erred in declining to address and/or determining that Petitioner has not shown by a preponderance of the evidence that claims 11 and 21 of U.S. Patent No. 9,149,626 are unpatentable under 35 U.S.C. § 103 over the combination of Woehr and Tauschinski; whether the Patent Trial and Appeal Board erred in determining that Patent Owner's proposed substitute claims meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a

preponderance of the evidence that proposed substitute claim 21 of U.S. Patent No. 9,149,626 is unpatentable under 35 U.S.C. § 103 over the combinations of Van Heugten and Lynn and/or Kuracina and Tauschinski; whether the Patent Trial and Appeal Board erred in determining that Petitioner has not shown by a preponderance of the evidence that proposed substitute claim 21 of U.S. Patent No. 9,149,626 fails to satisfy the written description requirement of 35 U.S.C. § 112; whether the Patent Trial and Appeal Board erred in denying Petitioner's Motion to Exclude; whether the Patent Trial and Appeal Board erred in granting Owner's Motion to Amend to substitute claim 21 for claim 11, and amend claims 12-20 to depend from claim 21; and any finding or determination supporting or related to those issues, as well as all other issues decided adversely to Petitioner in the Final Written Decision and any prior and interlocutory orders, decisions, rulings, and opinions.

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

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

Dated: February 8, 2019

Respectfully submitted,

/Heather M. Petruzzi/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 90.2(a)(1) and 104.2(a), I hereby certify that, in addition to being filed electronically through the Patent Trial and Appeal Board's End to End (PTAB E2E), a true and correct original version of the foregoing PETITIONER'S NOTICE OF APPEAL is being filed by Express Mail (Express Mail Label EK 703738749 US) on this 8th day of February 2019, with the Director of the United States Patent and Trademark Office, at the following address:

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

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

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

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EXHIBIT A

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Paper No. 93
Entered: December 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B. BRAUN MELSUNGEN AG,
Patent Owner.

Case IPR2017-01587
Patent 9,149,626 B2

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

KINDER, *Administrative Patent Judge.*

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

ORDER ON MOTION TO AMEND
35 U.S.C. § 316(d) and 37 C.F.R. § 42.121

I. INTRODUCTION

Becton, Dickinson and Company ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting *inter partes* review of claims 11 and 20 of U.S. Patent No. 9,149,626 B2 ("the '626 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.

Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we issued a Decision to Institute an *inter partes* review of claims 11 and 20 of the '626 patent, but not under all challenged grounds. Paper 8, 7, 50 ("Dec.").

Patent Owner subsequently filed a Patent Owner Response (Paper 21; Paper 22 (publicly available redacted version), "PO Resp.") and Petitioner filed a Reply (Paper 51; Paper 52 (publicly available redacted version), "Pet. Reply"). Patent Owner also filed a Sur-Reply (Paper 69; Paper 70 (publicly available redacted version), "PO Sur-Reply")

Patent Owner also filed a Contingent Motion to Amend (Paper 23, "Amend Mot."), to which Petitioner opposed (Paper 53, "Amend Opp."), which Patent Owner replied (Paper 61; Paper 62 (publicly available redacted version), "Reply to Opp.").

Patent Owner filed a Motion to Exclude Paper 68; Paper 67 (publicly available redacted version)) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 76; Paper 74 (publicly available redacted version)), and Patent Owner filed a Reply (Paper 77).

Petitioner also filed a Motion to Exclude (Paper 66), to which Patent Owner filed an Opposition (Paper 72; Paper 73 (publicly available redacted version)) and Petitioner filed a Reply (Paper 83).

A combined oral hearing with Case IPR2017-01586 was held September 26, 2018, and a transcript of the hearing is included in the record (Paper 92; Paper 91(publicly available redacted version), "Tr.").

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348, 1359–60 (2018). On April 26, 2018, the Office issued Guidance on the Impact of *SAS* on AIA Trial Proceedings, which states that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial. Subsequently, on May 7, 2018, we issued an Order modifying the Decision on Institution "to institute on all of the grounds presented in the Petition." Paper 31, 1.

Pursuant to our authorization (Paper 42), the parties thereafter filed a "Joint Motion to Limit the Proceeding" (Paper 46), requesting that we limit the proceeding to a subset of the instituted grounds in the Petition, as identified in the motion. Paper 46, 1–2. On June 14, 2018, we issued a Decision (Paper 48), accepting the Parties' joint proposal to limit the proceeding "to those claims and grounds as set forth in Paper 46, 1–2." Paper 48, 2. The "Asserted Grounds" section below reflects the claims and grounds agreed upon by the parties and addressed in our Decision to Limit the Proceeding.

Based on the addition of grounds to the proceeding, we authorized additional briefing. Paper 35. On June 13, 2018, Patent Owner filed a Supplemental Response. Paper 47 ("Supp. Resp."). Petitioner's Reply was filed after Patent Owner's Supplemental Response and Petitioner was given additional pages. *See* Papers 51–52.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 11 and 20 are unpatentable. Additionally, we address the Parties' motions to exclude as set forth below.

Additionally, we grant Patent Owner's Contingent Motion to Amend. In particular, we grant Patent Owner's proposed request to substitute claim 21 for claim 11 and thereafter change the dependency of claims 12–20 to depend from claim 21.

A. Related Proceedings

The parties represent that the '626 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1; Paper 6, 4. Petitioner also represents that petitions for *inter partes* review were also filed challenging related patents US. Patent Nos.: 8,328,762; 8,333,735; 8,337,463; 8,540,728; 8,597,249; 8,460,247; and 9,370,641. *Id.* The following chart associates each *inter partes* review with its corresponding patent:

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

B. The '626 Patent (Ex. 1001)

The '626 patent, titled "Catheter Insertion Device," states that an intended goal is to prevent "an outflow of blood from the catheter . . . after removal of the hollow needle with [a] needle guard element." Ex. 1001, [54], 1:20–23.

An embodiment of the '626 patent's catheter insertion device is illustrated in Figure 1 of the '626 patent, as depicted below:

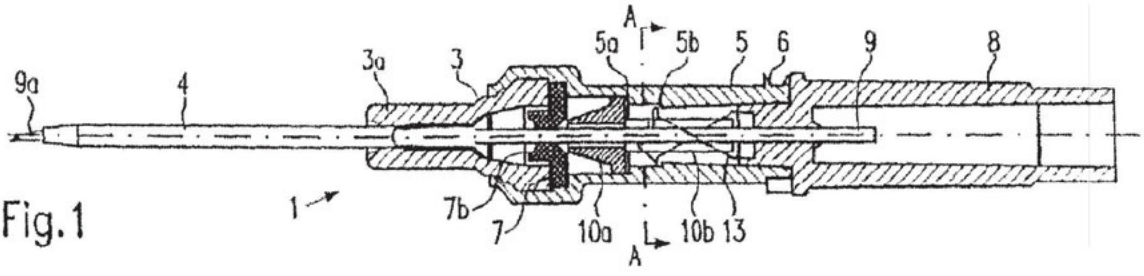


Fig.1

Figure 1 shows a longitudinal section through a catheter insertion device in the ready position. According to the '626 patent, Figure 1 depicts catheter insertion device 1 with catheter 4, needle hub 8, to which hollow needle 9 is fixed and which needle 9 extends through valve disc 7. Ex. 1001, 2:6–9. Between needle hub 8 and valve disc 7 is valve actuating element 10 (depicted as 10a, 10b), which has a truncated cone-shaped section 10a, which serves to open valve disc 7. *Id.* at 2:9–14. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:15–37. Needle guard element 13 serves to cover needle tip 9a upon withdrawal of needle 9 from the catheter hub, thereby "completely protecting and blocking it," as shown in Figure 2. *See id.* at 2:21–29.

To illustrate the removal of needle 9 from catheter hub 2, we reproduce Figure 2, below:

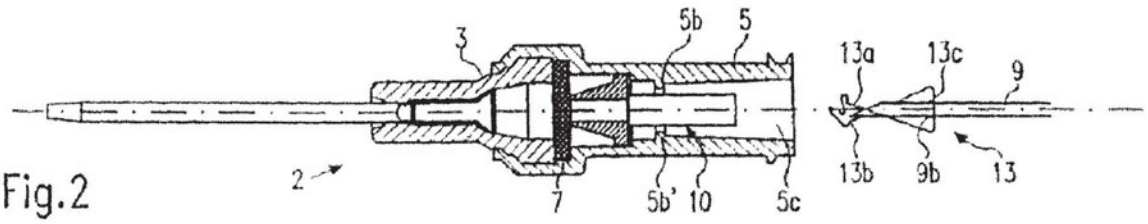


Fig.2

Figure 2 depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:44–45, 2:21–29. As shown above, needle guard element or spring clip 13 is removed from the catheter hub along with needle 9, causing the spring clip's spring arms 13a, 13b to cover the needle's tip. *Id.* at 2:26–29. Figure 2 also depicts valve disc 7—which is elastic—as closing the through-hole from which needle 9 is removed to prevent blood flow from exiting the catheter. *Id.* at 2:30–32.

As depicted in Figure 6 below, valve disc 7 may be provided with three slits 7a that extend radially from the middle over section X.

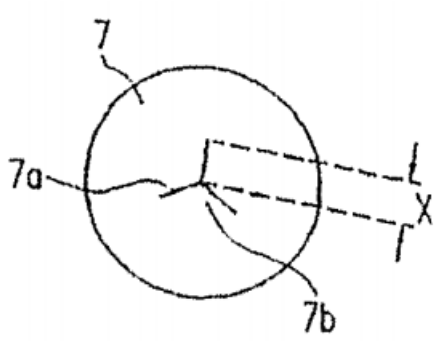


Fig. 6

Figure 6 shows a view of valve disc 7 with slits 7a. *Id.* at 1:44–45. Slits 7a help form elastic flaps 7b, which can be expanded by the insertion of the hollow needle. *Id.* at 2:32–36.

C. Challenged Claims

Claim 11 is independent and claim 20 depends from claim 11. *Id.* at 5:46–6:21, 6:45–48. Each claim is reproduced below:

> 11. A catheter insertion device comprising:
>
> a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached to a distal end;
>
> a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube in a ready position and comprises a needle tip;
>
> a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow and comprises a wall surface comprising a slit; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;
>
> a valve actuating element slidingly disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open

> the slit and a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon; and
>
> a needle protective device spaced from the needle tip in the ready position and movable relative to the needle tip, at least in part distally of the needle tip to prevent unintended needle sticks.
>
> 20. The catheter insertion device of claim 11, wherein the catheter hub further comprises a shoulder in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element.

Id.

D. References Relied Upon

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

Name	Reference	Ex. No.
Woehr	US 6,117,108, issued Sept. 12, 2000	Ex. 1003
Tauschinski	US 4,387,879, issued June 14, 1983	Ex. 1004
Arnett	US 5,817,069, issued Oct. 6, 1998	Ex. 1005
Van Heugten	US 5,053,014, issued Oct. 1, 1991	Ex. 1006

E. Alleged Grounds of Unpatentability

Pursuant to our Decision to Institute (Paper 7) and our Decision (Paper 48) on the parties' Joint Motion to Limit Proceeding (Paper 46), the following challenges to the patentability of the '626 patent are before us for consideration:

References	Basis	Claim(s)
Woehr and Tauschinski[1]	§ 103(a)	11 and 20
Van Heugten	§ 103(a)	11 and 20

Pet. 3.

Petitioner also relies on the declaration testimony of Jack Griffis, III (Exs. 1002, 1036) in support of its Petition. Petitioner also relies on the Rebuttal Declaration of Laura B. Stamm (Ex. 1035).

Patent Owner relies on the declaration testimony of Richard Meyst (Exs. 2001, 2029) in support of its 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) (2016); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the

[1] Based on our determination below that claims 11 and 20 are unpatentable as obvious based on Van Heugten, we decline to address this ground based on Woehr and Tauschinski as unnecessary to the ultimate decision. Further, our related IPR2017-01586, decided concurrently, addresses the rationale to combine Woehr and Tauschinski. In that decision, we determined that Petitioner has not provided the necessary evidentiary underpinnings to explain why one of ordinary skill in the art would have looked to improve Woehr's catheter hub with the addition of Tauschinski's connector valve and slidable actuator to adequately support a finding of obviousness.

use of the broadest reasonable interpretation approach).[2] Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms that 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). Based on the final record before us, we determine it necessary to construe the term "needle protective device."

Needle Protective Device

Independent claim 11 requires "[a] catheter insertion device comprising . . . a needle protective device spaced from the needle tip in the ready position and movable relative to the needle tip, at least in part distally of the needle tip to prevent unintended needle sticks." Ex. 1001, 6:18–21. Petitioner contends the term needle protective device invokes 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Pet. 7–10. 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 8 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc). Petitioner further contends that "the modifier 'needle protective' does not

[2] The USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. 83 Fed. Reg. 51,340 (Nov. 13, 2018). This rule change applies to petitions filed after November 13, 2018, however, and does not apply to this proceeding. *Id*.

impart any structure to the term 'device.'" *Id.* at 9. 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 9 (quoting Ex. 1002 ¶ 44).

In our Decision to Institute, we determined that this term should not be construed as a means-plus-function term, and that the term means "a device configured to prevent unintended needle sticks." Dec. 10; *see also* Ex. 2001 ¶¶ 29–62. Patent Owner contends, "[t]he record before the Board with respect to this term has not changed, and the Board's prior construction remains correct for the reasons addressed in the POPR and Decision." PO Resp. 3.

Our Decision to Institute was based upon arguments and evidence presented by Patent Owner in its Preliminary Response. For example, Patent Owner argued that "[t]he claim language following 'needle protective device' . . . indicates the term is structural." Prelim. Resp. 16. Patent Owner noted that "[c]laim 11 requires that the 'needle protective device' be physically 'spaced from the needle tip in a ready position and movable relative to the needle tip to a protective position, at least in part, distally of the needle tip.'" *Id.* Patent Owner also quoted claim 15, which requires that the "needle protective device comprises a proximal wall and two arms that converge to a single point," and the language of claim 19, which requires that the "'needle protective device comprises an arm that is located, at least in part, in the' first hub or catheter hub." *Id.* According to Patent Owner, because this language provides definition to "the location of the 'needle

protective device,' how it cooperates with the needle, and structural requirements such as a wall and arm(s), a POSITA would understand it to be structural." *Id.* at 16–17 (citing Ex. 2001 ¶¶ 61–62; *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")).

In Reply, Petitioner notes that district court determined that the term "needle protective device" is a means-plus-function term because the term does not recite sufficiently definite structure for performing the function of preventing unintended needle sticks. Pet. Reply 1 (citing Ex. 2002, 20–23). We have considered the district determination. For the reasons set forth below we maintain our initial determination.

Based on the final record before us, we are not convinced that the needle protective device limitation should be construed as a means-plus-function term. Because the term "means" is not used, there is a presumption that the limitation is not subject to § 112 ¶ 6, and Petitioner has not overcome this presumption. Rather, as pointed out by Patent Owner, we determine that the needle protective device limitation and the claims as a whole recite sufficient structure. *See Williamson*, 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.'").

The claims do not simply recite a "needle protective device," without more, but explicitly require that the "needle protective device be physically spaced from the needle tip in a ready position and movable relative to the

needle tip to a protective position, at least in part, distally of the needle tip. Ex. 1001, Claim 11. Claim 15 also requires that the "needle protective device comprises a proximal wall and two arms that converge to a single point," and claim 19 sets forth definite structure for the needle protective device in the form of "an arm that is located, at least in part, in the first hub or catheter hub." *Id.* Petitioner fails to address the several structural limitations of these claims in its proposed claim construction, instead focusing only on the three words "needle protective device." *See* Pet. 7–10. Moreover, Petitioner's proposed interpretation would seemingly render superfluous several of these other claimed structural features.

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 guarding (*i.e.*, protecting) the needle tip." Ex. 2001 ¶ 52 (citing Ex. 2014, which is cited in the '626 patent). Mr. Griffis argues to the contrary that "[t]he term 'needle protective device' is not consistently or commonly used or defined in journal articles or other publications circulated to those in the field," and "a person of ordinary skill would not have understood the term 'needle protective device' to define any particular structure or class of structures." Ex. 1002 ¶¶ 46, 47. Mr. Meyst counters that the term "'needle protective device'/'needle guard element' is a well-known class of structures." Ex. 2001 ¶ 53. Mr. Meyst also relies on several patents that teach of known members of the class of needle protective devices and also describe these devices in structural terms. *Id.* ¶¶ 54, 55. Based on the final record, we find Mr. Meyst's testimony more persuasive as to this issue. Specifically, that a person of skill in the art would, in context,

recognize a descriptive term such as "needle protective device" as a component, or "structure in connection with IV catheters that protects the operator from unintended needlesticks." Ex. 2001 ¶¶ 56–59.

Based on the final record before us, Petitioner has not overcome the presumption that 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*.

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. 6–7 (citing Ex. 1002 ¶¶ 30).

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

Based on our review of the '626 patent, the types of problems and solutions described in the '626 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. Obviousness of Claims 11 and 20 over Van Heugten

Petitioner contends that claims 11 and 20 are unpatentable over Van Heugten. Pet. 3. Patent Owner does not dispute that Van Heugten discloses all but one of the limitations in claims 11 and 20—that Van Heugten's valve has a slit as required by claim 11. *See* PO Resp. 8–31. For the reason set forth below, and based on the final record before us, including evidence related to objective indicia of nonobviousness, Petitioner has shown by a preponderance of the evidence that claims 11 and 20 would have been obvious in view of Van Heugten. Below, we first provide an overview of Van Heugten, then address the differences between Van Heugten and claims 11 and 20. Next, we address the objective evidence of nonobviousness (secondary considerations), and finally, we provide an analysis of how we have weighed all the *Graham* factors to reach our ultimate determination.

1. Van Heugten (Ex. 1006)

Van Heugten is a U.S. Patent titled "Catheter with Controlled Valve." Ex. 1006, [54]. Van Heugten discloses a "catheter hub assembly . . . wherein the assembly contains a membrane useful in preventing backflow of blood." *Id.* at [57]. To illustrate Van Heugten's catheter assembly, we reproduce Figure 2, below:

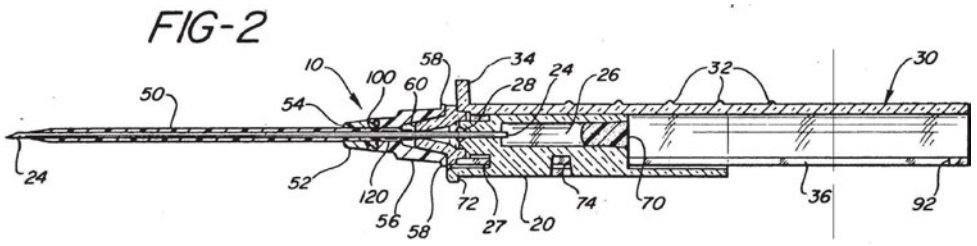
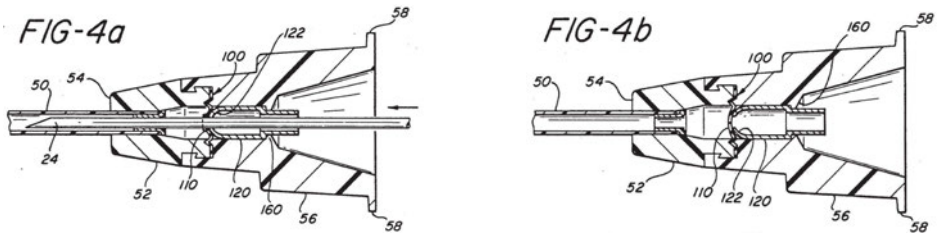


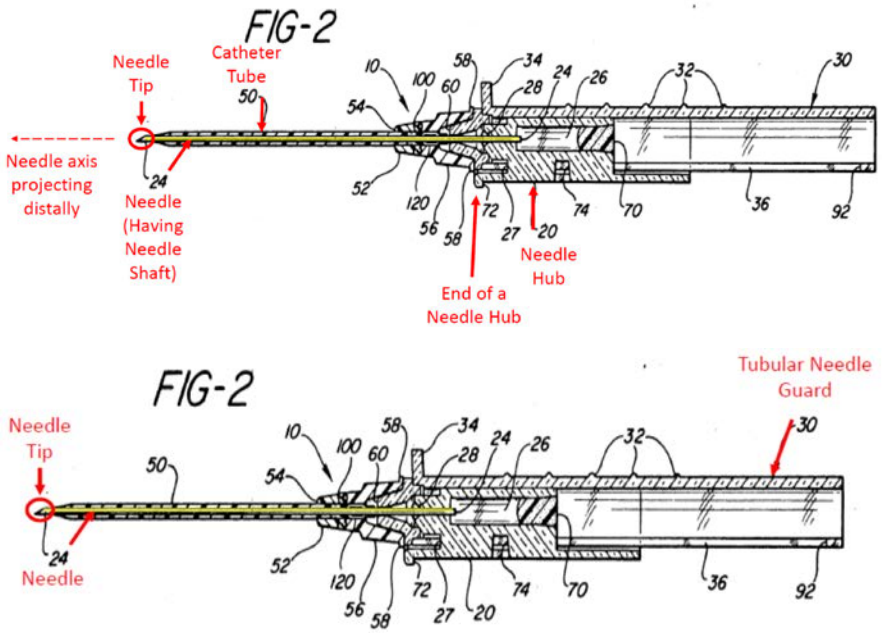
Figure 2 depicts a cross-sectional view of Van Heugten's catheter assembly 10. *Id.* at 2:6–10, 19–21. In particular, Figure 2 illustrates catheter assembly 10 with catheter 50 and needle 24, which needle guard 30 covers upon retraction of needle 24 to prevent inadvertent needle injury to the user or others. *See id.* at 2:36–39, 3:34–58. Catheter assembly 10 also includes valve membrane 110, which is illustrated in Figures 4a and 4b, which we also reproduce, below:



As disclosed in Van Heugten, Figures 4a and 4b further show membrane assembly 100 comprising a one-directional valve membrane 110. *Id.* at 3:59–64. Figure 4a (above-left) depicts membrane 110 as being "punctured" by needle 24 (*id.* at 3:59–4:3), while Figure 4b (above-right) depicts needle 24 removed, where upon "removal from the catheter hub 52, the valve membrane closes" (*id.* at 4:6–9). Valve member 110 is "generally configured as a 'duck bill' valve or a valve of similar configuration and smoothly allows removal of . . . needle 24[, so that upon] removal of the needle 24 from the catheter 50, the valve membrane unidirectionally closes so that blood will not flow into flash chamber 26." *Id.* at 4:23–30.

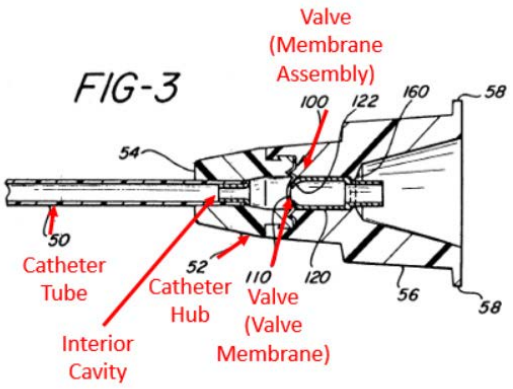
2. Petitioner's Challenge to Claims 11 and 20

Petitioner asserts that Van Heugten discloses a "catheter assembly" comprising the claimed "catheter, a catheter hub, a needle, a needle hub, a septum, an actuator, and tubular needle protection." Pet. 33–43. In support of these findings, Petitioner submits annotated versions of Van Heugten's Figure 2 (*id.* at 40, 46), which we reproduce, below:



Annotated versions of Figure 2 of Van Heugten show a cross-sectional view of the catheter assembly. According to Petitioner, and as shown above, Figure 2 depicts Van Heugten's "catheter hub" 52, "needle" 24, and "needle protective device" 30. *Id.* at 34, 35, 41.

Petitioner also submits an annotated version of Van Heugten's Figure 3 (*id.* at 39), which we also reproduce, below:



According to Petitioner, and as shown in Figure 3, Van Heugten also discloses the claimed "valve" 100, 110. *See* Pet. 36–38 ("a POSA would have understood Van Heugten to disclose the valve membrane 110 having a slit") (citing Ex. 1002 ¶¶ 97–99).

Petitioner argues that Van Heugten's valve membrane can be configured in multiple ways, and at least three of these embodiments meet the "valve . . . comprises a wall surface comprising a slit" limitation required by claim 11. Ex. 1001, 6:5–8; Pet. 36–38 (citing Ex. 1002 ¶ 99). First, Petitioner argues that in one configuration "the valve is originally sealed," but "upon insertion of a needle, the valve is punctured." Pet. 37 (citing Ex. 1006, 3:64–4:3). As explained by Mr. Griffis, "[w]hen the needle in Van Heugten punctures the valve during assembly, a POSA would have understood that the puncture creates a slit in the valve." Ex. 1036 ¶ 30.

Second, Petitioner notes that Van Heugten states specifically that the valve can be configured as a duck-bill valve and such a valve has a slit. *Id.* at 38. Petitioner relies on Van Heugten's disclosure:

> Also, even though valve membrane 110 is inserted into the catheter assembly 10, the valve membrane 110 is configured so that there is no frictional drag on needle 24 during its retraction

> from the catheter 50. This is so because valve membrane 110 is generally configured as a "duck-bill" valve or a valve of similar configuration and smoothly allows removal of the needle 24 from the catheter.

Ex. 1006, 19–27. Petitioner then argues that when "the valve is configured as a 'duck-bill' valve or a valve of similar configuration," a person of ordinary skill in the art would understand such a configuration to have a slit." Pet. 38 (citing Ex. 1006, 4:23–27). Petitioner further argues in Reply, that "Van Heugten's reference to a duck-bill valve simply indicates that the valve can be a commonly understood duck-bill valve." Pet. Reply 6. Mr. Griffis explains that "[t]here is a common understanding of the structure of duck-bill valves, and they have slits," such that a person of ordinary skill in the art "would understand the reference in Van Heugten to refer to the commonly understood device." Ex. 1036 ¶ 35. Petitioner then notes that claim 4 of Van Heugten expressly recites a duck-bill valve without any mention of the shape of the valve. Pet. Reply 8.

In response to Patent Owner's contentions that duck-bill valves may not have a slit, Petitioner offers additional evidence in Reply to demonstrate that a duck-bill valves are known to have a slit. Pet. Reply 8. For example, Petitioner cites to patents that describe a duck-bill valve as having "an outlet slit 59 defining a pair of resilient sealing lips" (Ex. 1105, 1:20–26), or that have "a slitted opening or lips which are arranged in a converging relationship," (Ex. 1120, 1:112–27). Mr. Griffis further testifies that "a POSA would have understood that duck-bill valves have a commonly understood configuration, which includes a slit opening." Ex. 1036 ¶ 36.

Third, Petitioner also contends that Van Heugten's valve membrane may have multiple slits whereas "Van Heugten explains the desirability of applying the valve principle of U.S. Patent No. 3,585,996 ('Reynolds') to a catheter assembly." *Id.* (citing Ex. 1006, 1:28–32, 1:47–57). Specifically, Van Heugthen states: "It would be desirable to apply the valve principle of the '996 patent [Reynolds] to a catheter assembly to enable the catheter to automatically open when an insertion needle is passed through the catheter, then automatically close when the needle is withdrawn from the catheter, then automatically open when a tubing set is connected to the catheter." Ex. 1006, 1:47–53. Petitioner and Mr. Griffis then rely on Figure 5 of Reynolds, which depicts a valve element having slits in the form of a "Y," similar to that of Figure 6 of the '626 patent.

Figure 5 of Reynolds depicts "Y" shaped slit valve 27. Mr. Griffis explains that

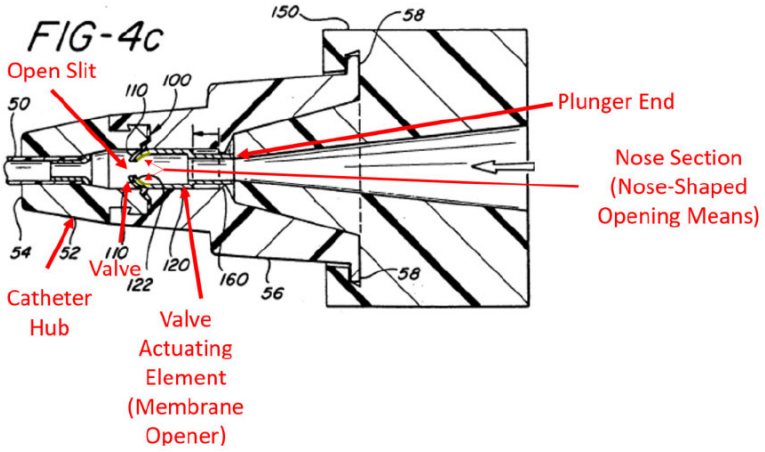
> Reynolds also discloses a valve (e.g., element 26) having slits in the form of a "Y" (e.g., element 27). (Ex. 1007, Reynolds at 2:56-60 ("Seated against that shoulder 25 is a selfsealing disc valve 26 made of a relatively thick piece of rubber or equivalent material provided with several fine slits 27 which may satisfactorily be arranged in the form of a "Y" as seen best in FIG. 5."); Fig. 5.).

Ex. 1002 ¶ 99.

In addressing the claimed "valve actuating element," Petitioner relies on Van Heugten for teaching

> a valve actuating element (e.g., element 120) slidingly disposed in the catheter hub (e.g., element 52) to actuate the valve (e.g., elements 100, 110), the valve actuating element comprising a nose section having a tapered end (e.g., element 122) for pushing the valve to open the slit and a plunger end (e.g., proximal end of element 120 extending past element 160) extending proximally of the nose section (e.g., element 122)[.]

Id. at 39. Petitioner also submits an annotated version of Van Heugten's Figure 4c (*id.* at 40), which we reproduce, below:



According to Petitioner, Figure 4c depicts "valve actuating element" 120 comprising a nose section with a tapered end 122. *Id.* at 43–44 (citing Ex. 1006, 4:31–36, 4:43–49). Further, according to Petitioner, the plunger end transfers a distally directed force to the nose section to push the valve to open the slit when pressed upon. *Id.*

Petitioner identifies the claimed needle protective device of claim 11 as being taught by Van Heugten's disclosure of tubular needle guard 30 spaced from the needle tip (e.g., end of element 24) in the ready position and movable relative to the needle tip, at least in part distally of the needle tip to

prevent unintended needle sticks. Pet. 40–41 (citing Ex. 1002 ¶¶ 104–105). Patent Owner has not challenged Petitioner's contention that Van Heugten's tubular needle guard teaches the needle protective device limitation. *See generally* PO Resp.

As for claim 20, Petitioner contends that "Van Heug[]ten renders obvious 'the catheter hub further comprises a shoulder in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element.'" Pet. 42. Petitioner contends that "Van Heug[]ten discloses the catheter hub further comprises a shoulder (e.g., shoulder near narrowing portion of the membrane opener shown as element 160) in the interior cavity of the catheter hub, the shoulder being a stop for the valve actuating element (e.g., element 120)." *Id.* Petitioner relies on collar mechanism 160 attached to catheter hub 52 as acting "as a stop for membrane opener 120 because it interacts with the projection on the membrane opener 120." *Id.* at 42 (citing Ex. 1002, ¶¶ 106–109).

3. Patent Owner's Argument

Patent Owner argues that Van Heugten does not disclose a valve with a slit. PO Resp. 9. Specifically, Patent Owner argues that "Van Heugten's thin membrane 100 does not have a slit." *Id.* Patent Owner relies on Van Heugten's disclosure of "'one-directional valve membrane (110)' that is 'originally sealed' before the needle 24 is inserted in the catheter 50, and is 'punctured' upon insertion of the needle into the catheter assembly." *Id.* Patent Owner's theory is that because the valve is "sealed" and then later punctured, the valve cannot have a slit.

Patent Owner argues that the disclosure of a duck-bill valve is also insufficient because this valve must also be sealed. *Id.* at 15. Patent Owner

argues that "Van Heugten emphasizes the benefits of using an 'originally sealed' sealed thin membrane placed on a membrane assembly in a 'duck-bill' configuration, where the thin membrane is 'punctured' by a needle during assembly." *Id.* Patent Owner contends that a duck-bill valve refers to a one-way valve that prevents backflow and the reference to a duck-bill valve relates only to how the valve is configured to ensure there is no frictional drag on the needle. *Id.* at 16–18. Patent Owner argues that

> These statements from Van Heugten inform a POSITA that Van Heugten is distinguishing over prior art slit valves, such as those disclosed by Reynolds. A POSITA knows that the slit valves of Reynolds would have frictional drag – the thick nature of the Reynolds slit valve increases the amount of friction when a needle is removed, which is why Van Heugten emphasizes the fact that its membrane places "no frictional drag on the needle 24 during its retraction from the catheter."

Id. at 17–18. Patent Owner further elaborates that "the elastic flaps of a slit valve, such as Reynolds, purposefully exert pressure downward in order to create a seal, causing the frictional drag Van Heugten seeks to prevent in its catheter assembly." *Id.* at 18 (citing Ex. 2029 ¶¶ 46–50). Because Van Heugten states that its valve may be configured as a duck-bill valve or a valve of similar configuration and because Reynolds valve is not a duck-bill valve or a valve of similar configuration, Patent Owner contends that Van Heugten is distinguishing its valve member from the Reynolds slit valve. *Id.*

Patent Owner also argues that "reading Van Heugten as a whole, a POSITA would know that Van Heugten's referral to 'duck-bill' is simply a reference to the valve membrane's orientation." *Id.* at 21. This is so, according to Patent Owner, because Figure 3 depicts a distally convex shaped valve member. *Id.* at 22. Thus, Patent Owner argues that

> a POSITA would know that Van Heugten's reference to 'duck-bill' in the phrase 'because valve membrane 110 is generally configured as a "duck bill" valve or a valve of similar configuration' is an indication of the valve membrane's configuration (i.e., its distally convex shape) and is not a reference to or a disclosure of a valve with slits.

Id. Patent Owner, again relying on the embodiment of Figure 3, contends that Van Heugten's membrane cannot be a slit valve because it is too thin and "requires a rigid housing to hold it in place." *Id.* at 23 (citing Ex. 2029 ¶ 55).

Patent Owner also argues that Van Heugten does not incorporate Reynolds, and its slit valve, by reference. *Id.* at 24. Patent Owner reads the statement '[i]t would be desirable to apply the valve principle of the '996 patent" from Van Heugten as not incorporating the slit valve of Reynolds, but instead, applying the backflow stoppage and valve actuator principles of Reynolds to Van Heugten's new catheter assembly that utilizes an originally sealed and then punctured thin valve membrane. *Id.* at 25–31.

4. Scope and Content of the Prior Art and Differences Between the Claimed Subject Matter and the Prior Art

i. Uncontested Limitations

We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 9, 6; *see also* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted."); *In re NuVasive, Inc.*, 842 F.3d 1376, 1379–82 (Fed. Cir. 2016) (holding patent owner waived an argument addressed in the preliminary response by not raising the same argument in the patent owner response). Additionally, the Board's Patent

Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

With the complete trial record before us, we note that we have reviewed arguments and evidence advanced by Petitioner to support its unpatentability contentions where Patent Owner chose not to address certain limitations in its Patent Owner Response. In this regard, the record now contains persuasive arguments and evidence presented by Petitioner, many of which are unrebutted, regarding the manner in which the asserted prior art teaches corresponding limitations of claims 11 and 20 against which that prior art is asserted. Based on the preponderance of the evidence before us, we conclude that Van Heugten teaches all uncontested limitations of claims 11 and 20.

ii. "A Valve . . . Comprises a Wall Surface Comprising a Slit"

The issue before us is whether Van Heugten teaches a valve with a slit. Petitioner has sufficiently shown, based on the final record, that Van Heugten teaches a valve with a slit. Claim 11 requires "a valve . . . comprises a wall surface comprising a slit" and later "the valve to open the slit." Ex. 1001, 6:8, 6:14.

Although Petitioner presents three plausible theories as to why Van Heugten teaches a slit valve, we are convinced that Van Heugten's statement that its valve membrane "is generally configured as a 'duck-bill' valve or a valve of similar configuration" teaches use of a valve with a slit in at least one embodiment. Ex. 1006, 4:19–29.

The record before us establishes that a "duck-bill" valve is a known valve in the art that will have two lips coming together to form a slit. We find most persuasive Mr. Griffis's testimony that "[t]here is a common understanding of the structure of duck-bill valves, and they have slits," such that a person of ordinary skill in the art "would understand the reference in Van Heugten to refer to the commonly understood device." Ex. 1036 ¶ 35. Although Patent Owner's expert, Mr. Meyst, contends that "disclosure of a 'duck-bill' valve does not inherently disclose a slit valve to a POSITA," the final record before us convinces us that reference to a duck-bill valve is to a valve with a slit. Ex. 2001 ¶ 82; Ex. 2029 ¶¶ 51–52. Mr. Griffis provides persuasive testimony, supported by numerous examples, that "duck-bill valves have a slit to allow fluid to flow through the valve," and as such, "a POSA would have understood that duck-bill valves have a commonly understood configuration, which includes a slit opening." Ex. 1036 ¶¶ 35–36 (citing Exs. 1105; 1015; 1120, 1:12–27 ("Duckbill valves . . . usually consist of a slitted opening or lips which are arranged in a converging relationship"); 1121).

The record before us also establishes that Van Heugten specifically discloses use of a duck-bill valve, which would have a slit, in at least one embodiment of its invention. The Specification is clear, "valve member 110 is generally configured as a 'duck-bill' valve or a valve of similar configuration." Ex. 1006, 4:23–25. We likewise find persuasive Mr. Meyst's testimony that a person of ordinary skill in the art would immediately recognize that reference to a duck-bill valve, regardless of whether also referring to shape, is referencing a configuration of the Van Heugten valve that has a slit. Ex. 1036 ¶ 37. Further, claim 1 of Van

Heugten requires "a valve and valve opener assembly" but claim 4 further narrows the invention by specifically requiring "said valve comprising a duck-bill valve." Ex. 1006, 5:12, 5:28–29. Claim 4 does not suggest that only the "shape" of a duck-bill valve is being used in the invention, but instead a duck-bill valve as would be understood to a person of ordinary skill in the art. Such a valve would have a slit as we determined above.

Patent Owner's arguments focus on one embodiment of Van Heugten that has a sealed valve with a convex dome shape as depicted in Figure 3. Such a configuration, according to Patent Owner, does not depict a duck-bill valve with a slit. *See* Ex. 2029 ¶ 52. Further, even if a duck-bill valve is used, Patent Owner contends that this means only a convex shape but such an embodiment would still have a sealed valve membrane. *See id.* For example, Patent Owner contends that "Van Heugten's duck bill is made of an originally-sealed membrane that must be punctured by a needle," and would thus not be a slit. PO Sur-reply 4–5. Patent Owner quotes Van Heugten and argues "that Van Heugten's duck bill valve comprises a thin membrane requiring a needle puncture—not a slit." *Id.* at 6.

Mr. Meyst contends that Van Heugten's reference to "duck-bill" refers to the "convex shape" of the valve rather than referring to the commonly understood valve configuration discussed above. We find more persuasive Mr. Griffis testimony that convex shaped valves have a commonly understood name (dome valve), as well as a commonly understood structure and configuration and, like duck-bill valves and other valves through which fluid flows, would include an opening such as a slit. *See* Ex. 1036 ¶ 37.

Reading Van Heugten as a whole, the invention contemplates some embodiments wherein the valve assembly is configured as a duck-bill valve with a slit, and other embodiments as depicted in Figures 3 and 4, having a dome valve assembly that could, but may not necessarily, be a duck-bill valve. Ex. 1006, Figs. 3 and 4a–c, 1:47–57, 4:23–29, 5:12–29; *see also* Tr. 29:9–31:21. For example, claim 1 of Van Heugten requires "a valve and valve opener assembly," but dependent claim 4 further limits the invention by requiring "said valve comprising a duck-bill valve." Ex. 1006, 5:12–13, 28–29. Accordingly, Van Heugten teaches that its valve assembly could be configured as a duck-bill valve, as set forth in both the specification and in claim 4 of Van Heugten. Ex. 1006, 4:19–29, 5:28–29. We also note that if "duck-bill" referred only to the valve's shape and configuration, as Patent Owner contends, then the phrase "or a valve of similar configuration" would be meaningless. *See id.* Likewise, claim 4, which specifically requires a duck-bill valve, makes no mention of requiring just a duck-bill shape.

Although Petitioner also presents a plausible theory that Van Heugten's reference to applying the valve principles, and thus slit valve, of Reynolds to Van Heugten's catheter assembly also teaches a valve with a slit, we need not reach this issue. Van Heugten's use of a duck-bill valve teaches use of a valve with a slit. Having now considered the evidence in the complete record established during trial, we are persuaded that, based on this record, Petitioner has demonstrated by a preponderance of the evidence that the configuration of the Van Heugten valve "as a 'duck-bill' valve" would inform a POSA that the valve of Van Heugten has a slit as required by claim 11.

Van Heugten teaches every limitation of claims 11 and 20. Below, we consider the objective evidence of nonobviousness presented by Patent Owner and then weigh the totality of the *Graham* factors in making a final determination of obviousness.

5. Objective Evidence of Non-Obviousness

In cases such as this, the objective indicia of nonobviousness should be closely considered because "[a] determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered." *Apple v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citations omitted). "This requirement is in recognition of the fact that each of the *Graham* factors helps inform the ultimate obviousness determination." *Id.* The Federal Circuit has recognized that:

> Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art.

Id. at 1052–53 (*quoting Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983)).

Patent Owner contends the objective evidence demonstrates that, at the time of the invention of the '626 patent, there was a long-felt and unsolved need for a straight IV catheter insertion product having both a device for needle stick protection and blood control technology, and also that Petitioner copied the invention of the '626 patent in trying to satisfy this

need, leading to the development of Petitioner's Insyte Autoguard BC product ("IAG-BC") product. PO Resp. 49. Patent Owner alleges that both Petitioner and Patent Owner developed and introduced products embodying the invention of the '626 patent, which have both been commercially successful, and the objective evidence demonstrates that others had failed to develop such a product." *Id.*

For evidence of secondary considerations to be considered, a causal relationship, or nexus, must be shown between the evidence and the claimed invention. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005); *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (there must be "a nexus between the evidence and the merits of the claimed invention"). For example, with respect to commercial success, the evidence must show that the commercial success came from the merits of the invention and not from external factors. "[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (internal quotation marks omitted).

Patent Owner's analysis addresses nexus, long felt but unsolved need, failure of others, copying, commercial success and industry praise. Below, we address each in turn, but we first determine whether Patent Owner has established that certain commercial products embody the claimed invention giving rise to a presumption to nexus.

i. Commercial Products Embody the Claimed Invention

Patent Owner's evidence of nexus shows that the claimed invention reads on the product sold, specifically, Patent Owner's Introcan Safety 3

("IS3") product. PO Response 33–49, claim chart; Ex. 2029 ¶¶ 89–104; *see also* Exs. 2107 (describing the IS3 as covered by the '626 and eight other patents); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016) ("[T]here is a presumption of nexus . . . when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed.'"); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

Patent Owner presents photographs of its IS3 product in a claim chart, comparing the complete IS3 product and components, such as catheter tube, catheter hub, valve, valve actuating element, needle and needle protective device, to each limitation of claims 11 and 20. PO Response 34–41, claim chart. Patent Owner supports its analysis with testimony from Mr. Meyst, who opines that the IS3 product meets all of the elements of, and, therefore, is covered by at least claims 11 and 20 of the '626 patent." Ex. 2029 ¶¶ 89–104.

Petitioner does not expressly dispute that Patent Owner's IS3 product is covered by the '626 patent, but argues that Patent Owner "offered no explanation or evidence that IS3 is *coextensive* with the claimed invention." Pet. Reply 17. Specifically, Petitioner argues that Patent Owner has failed to analyze whether the commercial success of the IS3 was due to the '626 patent, or any of the other eight listed patents, which Patent Owner indicates as covering the IS3 product. *See* Ex. 2017. Petitioner's argument is unpersuasive because the claimed invention is not merely a component of the IS3 product, but reasonably describes a complete catheter insertion device, essentially soup to nuts, including *inter alia*, a catheter hub, catheter tube, needle hub, needle, needle protective device, valve, and valve actuator,

as well as the structural and functional relationships of each element. Here, it is quite easy to look at the pictures in evidence and compare them to the claims; the claims are to a particular structure, and that structure is shown plainly in the pictures in the claim charts. Moreover, our review of the claim charts presented by Patent Owner is consistent with the description by Mr. Meyst, that the IS3 structural elements appearing in the claim chart photographs, match the elements of claims 11 and 20. *See, e.g.*, Ex. 2029 ¶¶ 89–104. Although the claims may not describe every single detail of the IS3 product, such as the wings, Petitioner presents no credible evidence that the challenged claims of the '626 patent are not reasonably coextensive with the IS3 product.

Patent Owner's evidence regarding nexus indicates that there will be a strong correlation between any evidence in this case highlighting the merits of the commercial IS3 product and the merits of the claimed invention. In other words, we will consider evidence of long felt-need, failure of others, copying, as well as the success and praise of the IS3 product, as direct evidence of long felt-need, failure of others, copying and the success of the claimed invention. *See Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d 281, 306 (Fed. Cir. 1985) (holding that the weight attributed to the secondary evidence is proportional to its nexus to the merits of the invention, implying that a weak nexus requires some discount factor to the evidence, but a strong nexus does not).

Similarly, the evidence provided by Patent Owner regarding Petitioner's IAG-BC product is also sufficient. PO Resp. 41–49 (citing Ex. 2029 ¶¶ 72–88; Ex. 2035; Exs. 2052–53; Ex. 2083; Ex. 2093). Patent Owner argues that we should also find nexus for Petitioner's IAG-BC

product as Petitioner's product embodies the claimed invention and thus objective evidence relating to IAG-BC product should also be considered.

Patent Owner presents photographs of the IAG-BC product in a claim chart, comparing the entire IAG-BC product and components, such as catheter tube, catheter hub, valve, valve actuating element, needle and needle protective device, to each limitation of claims 18 and 25. PO Resp. 41–49, claim chart. Patent Owner supports its claim chart analysis with testimony from Mr. Meyst, who opines that the IAG-BC product meets all of the elements of claims 11 and 20 of the '626 patent. Ex. 2029 ¶¶ 72–88.

Petitioner argues that Patent Owners' declaratory and comparative evidence fails to show nexus "because it has not shown that IAG BC is covered by the claims even under the Board's interpretation of 'needle protective device.'" Pet. Reply 18. Petitioner argues that Patent Owner and Mr. Meyst's analyses are "cursory" because "Braun cites only a cursory comparison of the patent claims to the IS3 and IAG BC products." *Id.* We do not agree that Patent Owner's analysis of the IAG-BC product in comparison to the claims is "cursory." The claim charts showing the IAG-BC product in comparison to claims 11 and 20 is clear and complete in that it compares the product as a whole, and its substantive components, directly to each claim limitation. It is quite easy to look at the pictures in evidence and compare them to the claims; the claims are to a particular structure, and that structure is shown plainly in the pictures in the claim charts. *See* PO Resp. 41–49. Moreover, our review of the claim charts presented by Patent Owner is consistent with the description by Mr. Meyst that the IAG-BC structural elements shown in the claims chart photographs match the elements of claims 11 and 20. *See* Ex. 2029 ¶¶ 72–88. Further, although the

"needle protective device" limitation is certainly disputed, our interpretation suggests that the IAG-BC may have such a device.

Patent Owner's evidence regarding nexus indicates that there will be a correlation between any evidence in this case highlighting the merits of the commercial IAG-BC product and the merits of the claimed invention. In other words, we will consider evidence of long-felt need and failure by others, along with copying and the success and praise of the IAG-BC product as direct evidence of the long-felt need, failure of others, copying and success and praise of the claimed invention.

We also address Petitioner's concern that our nexus and copying analysis could be perceived as an improper attempt to obtain an infringement opinion from the Board. Pet. Reply, 15–16, n.5. Our analyses and resulting determinations, of course, relate solely to patentability of claims of the '626 patent. *See* 35 U.S.C. § 311(b) (scope of IPRs are limited to the patentability); 35 U.S.C. § 318(a) (PTAB issues "final written decision[s] with respect to the patentability"). Besides the fact that our claim construction here was undertaken under the broadest reasonable interpretation, different from the standard applied by the District Court, our nexus analysis relied upon evidence presented by Patent Owner and Petitioner in this IPR proceeding. To the extent there has been a finding of non-infringement by the District Court and some of the evidence relating to secondary considerations may overlap with evidence in the district court litigation, this does not conflate the separate issues of patentability and infringement. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374, (2018) (Acknowledging that district courts and the Board can reach different outcomes, Justice Thomas noted that "[p]atents

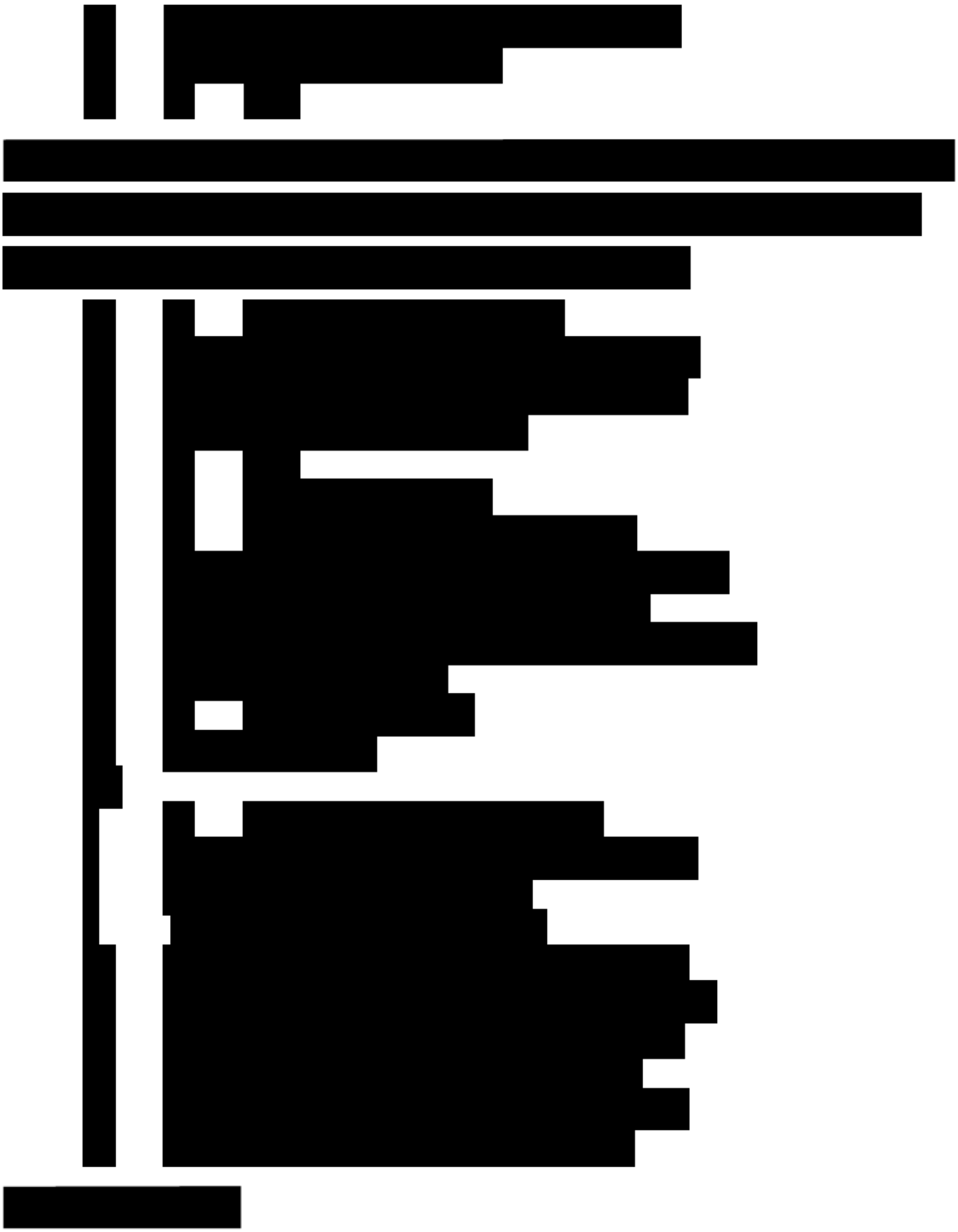
thus remain 'subject to [the Board's] authority' to cancel outside of an Article III court.") (citation omitted).

We turn next to the evidence of long-felt need and failure of others.

ii. Satisfaction of a Long-felt but Unsolved Need and Failure of Others

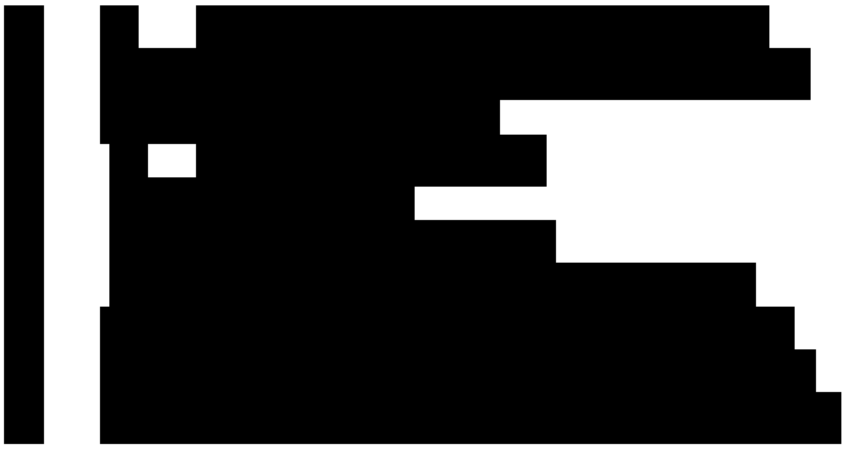
Patent Owner presents a variety of evidence, mainly testimonial and product and marketing development documents from Petitioner, indicating that there existed a level of interest in the industry for a catheter with both needle stick protection and blood control. PO Resp. 53–56 (citing Ex. 2062, 29:14–30:14, 48:5–10, 127:6–128:3; Ex. 2063, 41:6-11, 47:21–48:3, 74:1–7, 169:13–170:6, 173:4–13; Ex. 2039, BBDE0317607). [redacted] *Id.*

By way of example, testimony from Mark Crawford, an employee of Petitioner, states [redacted]. For example, during a deposition in 2017, Mr. Crawford stated [redacted]



Petitioner, on the other hand, argues that there was not a long-felt unmet need in the marketplace for a straight catheter combining needlestick protection with blood control,

[redacted] Petitioner points to testimony, for example, by Mr. Chad Adams, an employee of Petitioner, who stated during a deposition that [redacted]



[redacted] Petitioner also provides evidence in the form of a [redacted]

The evidence shows, overall, that [redacted] For example, Mr. Crawford also indicated that [redacted]

Considering the evidence as a whole, there is little confirmation that a long-felt need was driving actual market demand for a straight catheter with combined needlestick and blood control features. [redacted]

[redacted]. *Compare* Ex. 1091, *with* Ex. 1092. We are also not persuaded that there existed a significant market and long-felt need for the product based on [redacted]

Accordingly, we give this factor some, but not strong, weight towards non-obviousness.

iii. Copying

"[C]opying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner contends that both its IS3 product and Petitioner's IAG-BC product embody the claimed features of claim 11 of the '626 patent. PO Resp. 41. Patent Owner's evidence of copying rests [redacted] Specifically, Patent Owner alleges, "Petitioner, by copying the features disclosed in the '325 application and

claimed in the '626 patent, successfully developed a straight catheter combining needle stick protection with blood control technology." *Id.* at 61. Below, we consider the parties' evidence and arguments related to copying and the impact on the obviousness analysis, but first we summarize our view of this evidence.

What is lacking in Patent Owner's case is evidence of efforts to replicate a specific product. Indeed, such evidence may be difficult to produce for two reasons. First, Petitioner's IAG-BC product was released onto the market in July 2011 before Patent Owner's IS3 product was released in 2012. PO Resp. 60 (citing Ex. 2063, 40:7–10), 50. Second, Patent Owner's IS3 product uses a distinctive "spring clip that automatically covers the needle tip after removing the needle from the catheter" as the claimed needle protective device, and Petitioner's IAG-BC uses "the activation button, the spring, the safety barrel, and the needle hub which together act to prevent unintended needle sticks." PO Resp. 47–49, 39, 40. These mechanisms are notably different, even if both may broadly be considered needle protective devices. The parties recognized this distinction by agreeing to a stipulated finding of noninfringment based on the district court's claim construction for needle protective device as being limited to a spring clip (as found in the IS3) to prevent unintended needle sticks. Ex. 2002, 20–23; Ex. 1038 (Order staying trial pending appeal of the term "needle protective device"). Patent Owner has thus not established copying of its IS3 product for these two reasons.

We have reviewed Patent Owner's evidence (PO Resp. 56–58) establishing that [redacted]

[redacted] Patent Owner alleges that this [redacted] resulted in Petitioner using the valve and valve actuator features disclosed in the ’325 application (and eventually claimed in the ’626 patent) over alternative designs. *Id.* at 59. Thus, according to Patent Owner, Petitioner incorporated into the IAG-BC the same blood control features disclosed in the ’325 application. *Id.* at 60 (citing Ex. 2029 ¶¶ 80–85).

Petitioner argues that there cannot be copying because the IAG-BC is not covered by the claims of the ’626 patent, and because Petitioner has not produced any evidence of efforts to replicate a specific product. Pet. Reply 24. Petitioner argues that Patent Owner has failed to identify any internal company documents or other internal company evidence that would suggest Petitioner copied Patent Owner’s patented device. *Id.* Petitioner also points out that Patent Owner has not provided any expert testimony to support is assertion of copying. *Id.* (citing Ex. 1029, 6:12–15).

The claimed invention captures needle safety features, and Petitioner contends that the needle safety features of the IAG-BC are actually identical to the needle safety features in the original IAG product, which was launched in the 1990s. *Id.*; Ex. 1036 ¶ 118. To counter Patent Owner’s

argument that copying is supported by the fact that the patent and the IAG-BC each include a "valve and valve actuator" (PO Resp. 57), Petitioner argues that catheters with valves, valve actuators, and needle protection were known in the art long before the priority date of the '626 patent. Pet. Reply 25 (citing Exs. 1006, 1094, 1005, 1088). Petitioner also contends that its specific valve and valve actuator design are materially distinct from the designs in the '626 patent and its priority documents and are covered by its own patents. *Id.* (citing Ex.1036 ¶¶ 118–119). Further, Petitioner notes that several of its patents were issued over the '626 patent family and/or patents naming Kevin Woehr as an inventor. *Id.* (citing Exs. 1095, 1096).

Petitioner argues that [redacted] does not give rise to evidence of copying because [redacted] Patent Owner cites evidence that [redacted] but Petitioner contends that this evidence is still insufficient because proof of copying requires more than mere evidence of efforts to provide a competing product or evidence of a product having the same features. *Id.* at 26. Thus, according to Petitioner, Patent Owner's copying evidence is nothing more than ordinary competitive behavior. *Id.*

Based on the final record before us, Patent Owner presents unpersuasive evidence of copying. Accordingly, this factor does not weigh in favor of an ultimate determination of nonobviousness. Patent Owner does not present direct evidence that Petitioner attempted to copy a product. Indeeed, as noted above Petitioner's IAG-BC release predated Patent

Owner's IS3 release. Typically, copying in the context of secondary considerations considers efforts to replicate a product. No such evidence is presented here. Further, Patent Owner relies essentially on IAG-BC's infringement of the '626 patent to establish copying, but the district court has entered the parties' stipulation to non-infringement based on the claim construction of "needle protective device" as being limited to a spring clip. *See* Ex. 1038.

Even if we were to presume infringement of the IAG-BC could be found and was relevant to copying, Patent Owner's evidence of copying is still marginal. Patent Owner relies on certain claimed features being copied in the IAG-BC product. For example, Patent Owner relies on the IAG-BC as including a "valve and valve actuator" (PO Resp. 57) as evidence of copying, but this argument is weakened because Van Heugten also teaches catheters with valves, valve actuators, and needle protection elements, proving that these features were known in the art before the priority date of the '626 patent. *See* Ex. 1006 (as discussed above). Considering the record as a whole, Patent Owner's evidence of copying does not persuade us that Petitioner copied Patent Owner's IS3 or the claimed features of the '626 patent. At best, the testimony and related expert analysis show a weak case of copying, made weaker by the failure to adequately address the "needle protective device" limitation. Thus, even presuming infringement, we give no weight to the factor of copying as it relates to nonobviousness.

iv. Commercial Success and Industry Praise

"When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed

that the commercial success is due to the patented invention." *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). However, "if the feature that creates the commercial success was known in the prior art, the success is not pertinent." *Ormco Corp.*, 463 F.3d at 1311–12; *see also J.T. Eaton*, 106 F.3d at 1571 ("[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art"). To be pertinent to the issue of nonobviousness, the commercial success of products falling within the claims of the patent must flow from the functions and advantages disclosed or inherent in the description in the specification. The commercial success must arise from the benefits of the claimed invention and not from factors such as advertising and marketing.

We first find it necessary to establish the relevant market. *See J.T. Eaton & Co.*, 106 F.3d at 1571 ("usually shown by significant sales in a relevant market"). The parties disagree as to the relevant market – Patent Owner defines the market narrowly to encompass only non-integrated safety catheters with blood control technology that would infringe the '626 patent and Petitioner defines the market broadly to encompass both blood control flow and nonblood control products. *Compare* PO Resp. 62, *with* Pet. Reply 19. Petitioner has the strongest position because the products, with or without blood control, compete directly with one another and increased sales of one will presumably decrease sales for the other. *See* Pet. Reply 19, n.7

[redacted] Ex. 2101 ¶ 22; Ex. 1035 ¶ 22. Ms. Stamm testifies for Petitioner that [redacted]

The record before us establishes that products with or without the blood control technology directly compete in the same market. *See* Ex. 1035 ¶ 36 Thus, for example, we do not find persuasive PO Resp. 62.

Considering just the relevant market, PO Resp. 62. *Id.* *Id.* at 62–63.

Patent Owner contends that both the IAG-BC and IS3 are successful from a revenue perspective. *Id.* at 63.

[redacted] *Id.* Patent Owner also relies [redacted]

Patent Owner also argues that the IAG-BC and IS3 have received praise. *Id.* at 65. For example, Patent Owner relies [redacted] Patent Owner cites to [redacted] Patent Owner also notes that the IS3 has won several industry awards since its launch, including a Red Dot award and a German Design Award in 2016. *Id.* (citing Ex. 2086, 37:5–18). Patent Owner does not provide any criteria or basis for these awards, giving us no basis to weigh them in our analysis.

[redacted] Pet. Reply 15–21. [redacted]

[redacted]. *Id.* at 19 (citing Ex.1035 ¶¶ 14, 17–22; Ex. 2103, Napper Schedule 8.2, 2). [redacted] *Id.* at 20. [redacted] *Id.* (citing Ex. 1035 ¶¶ 23–26). [redacted] *Id.*

Petitioner presents evidence, which we find somewhat persuasive, that neither the IS3 nor the IAG-BC has been commercially successful when viewed in relation to the relevant market, that is, in comparison to other safety IV catheter products that compete with the IS3 and IAG BC. *Id.* at 19. [redacted] *Id.* Petitioner argues that [redacted] More specifically, Petitioner argues that [redacted]

[redacted]

Id. (citing Ex. 1035 ¶ 34).

Petitioner also makes a persuasive argument that [redacted] Petitioner notes that neither Patent Owner nor Mr. Napper analyzed [redacted] Petitioner argues that [redacted]

The evidence before us shows that [redacted] Ms. Stamm explains that Instaflash refers to the technology

that allows blood to flow between the needle and the catheter (also called "flashback"), which signals to clinicians that the catheter is in the vein. Ex. 1035 ¶ 39. The Instaflash technology is designed to improve first-stick proficiency by confirming immediately vessel entry at the point of insertion. *Id.* Ms. Stamm points to evidence showing [redacted] which directly relates to the Instaflash technology and ease of use. [redacted] Mr. Napper did not address this feature of IAG-BC in his declarations and confirmed at his deposition that he did not consider the impact of the feature or its marketing on the sales of IAG-BC. *See* Ex. 1058, 148–150.

Petitioner's safety catheters are made of Vialon, a proprietary material that has unique softening properties. Ex. 1035 ¶ 40; Ex. 1074, 381:1–20, 383:13–385:5. Petitioner has also presented persuasive evidence that [redacted] IAG and IAG-BC also both have active needle protection with a push button shielding technique that allows clinicians more control over the process. Ex. 1035 ¶ 41. [redacted] *Id.* Patent Owner and Mr. Napper do not persuasively address these feature that have also contributed to the success of the IAG products.

Petitioner persuasively argues that the features set forth above [redacted] and that these features are not claimed or required by the '626 patent. Pet. Reply 18–19. Petitioner also shows [redacted]

Based on the evidence presented by both parties, both the IS3 and IAG-BC products have enjoyed some commercial success in the relevant market. [redacted] Petitioner establishes that [redacted] Patent Owner has not persuasively addressed these other features in the IAG-BC. Further, we do not find persuasive Patent Owner's evidence of praise persuasive because Mr. Napper cites no documents evidencing any praise for IS3, and the documents he cites relating to IAG-BC only generally discuss blood control features rather than the invention claimed in the '626 patent.

At best, commercial success and industry praise weigh marginally in Patent Owner's favor for the obviousness analysis. [redacted] Although Patent Owner has presented

evidence to demonstrate the unique characteristics of the claimed invention may have marginally impacted sales, Petitioner has countered that evidence with persuasive evidence showing that other product features and commercial factors unrelated to the patented subject matter have also contributed to sales and success. We therefore weigh the factor of commercial success and industry praise only marginally favorable toward Patent Owner.

6. Conclusion as to Claims 11 and 20.

Petitioner has presented a strong case of obviousness of claims 11 and 20 based on Van Heugten. As noted above, the only limitation in contention is the slit valve, which is taught by Van Heugten. Patent Owner has established a minimum level of objective indicia of nonobviousness related to long felt need and failure of others. Patent Owner has not shown persuasively that Petitioner made efforts to replicate a specific product. Patent Owner has presented some evidence of commercial success, but as noted above Petitioner has countered that evidence with persuasive evidence showing that other product features and commercial factors unrelated to the patented subject matter have also contributed to demand and sales, thus, we weigh the factor of commercial success only slightly favorable toward Patent Owner. Patent Owner also has also presented some evidence of praise in the form of customer surveys.

We weigh the totality of the evidence of secondary considerations with our findings against Petitioner's strong case of obviousness based on Van Heugten. Based on the foregoing, after consideration of all of the *Graham* factors and the full record before us, we are persuaded that

Petitioner has established, by a preponderance of evidence, that claims 11 and 20 would have been obvious over Van Heugten.

III. MOTIONS TO EXCLUDE

A. Petitioner's Motion to Exclude

Petitioner seeks to exclude a host of Patent Owners evidence relating to objective indica of nonobviousness or to claim scope as either, irrelevant under FRE 402 and 403, or as unauthenticated under FRE 901. *See* Paper 66, Pet. Mot. Exclude, 1. Without excluding this evidence, we have determined that Petitioner has demonstrated the unpatentability of challenged claims 11 and 20. Thus, the motion to exclude is moot as to our determination for these claims.

Much of the evidence sought to be excluded relates to the testimony and opinion of Patent Owner's declarant, Mr. Meyst. *See id.*, 4–5. This evidence, such as the photographs of the ProtectIV Plus Safety IV catheter device, is evidence that an expert would reasonably rely upon in forming an opinion as to factors of obviousness. *See* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."). Even if there is a question of admissibility as to certain evidence, Mr. Meyst's reliance on this evidence was reasonable. Further, Petitioner's arguments go mainly to the weight to be accorded the evidence in our consideration of secondary considerations. We are capable of determining and assigning appropriate weight to the evidence. We have given some weight to Mr. Meyst's testimony and certain of the objected to evidence, particularly as it relates to secondary considerations in this proceeding. Were we to discount the evidence to which Petitioner objects, we would still determine that the totality of the evidence weighs in favor of nonobviousness for substitute claim 21, as

discussed below. For these reasons, Petitioner's motion to exclude is DENIED.

B. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Exhibits 1083–1086, 1088–1095, 1097, 1098, 1102, 1105–1107, 1111, 1114, 1120, 1121, 1122, 1124, and 1125, as well as portions of Exhibit 1036. *See* Paper 66. Our determinations do not rely upon Exhibits 1085, 1086, 1088, 1090, 1093, 1097, 1098, 1102, 1106, 1107, 1111, 1114, 1122, and 1124 therefore, Patent Owner's motion to exclude these exhibits is DENIED as moot.

We discuss the remaining exhibits challenged in Patent Owner's motion, below.

Exhibits 1083 and 1084

Exhibits 1083 and 1084 are deposition transcripts of Petitioner's employees Mark Crawford and Chad Adams, respectively.[3] The videotaped depositions were taken by Patent Owner's counsel in the related district court lawsuit. *See* Ex. 1083, 1; Ex. 1084, 1. Patent Owner argues that we should exclude certain deposition testimony addressing the reason Becton, Dickinson did not earlier commercialize a prototype straight catheter with combined needlestick prevention and blood control structure and function, because it is hearsay, and not covered by any exception to the rule against hearsay. PO Mot. Exclude, 3–4. Petitioner counters that this deposition testimony is simply personal knowledge of the declarants and is covered by the residual exception to hearsay under FRE 807. Paper 74, Pet. Opp. Mot.

[3] Patent Owner's Exhibit 2062 is the same videotaped deposition transcript of Mr. Mark Crawford as Petitioner's Exhibit 1083 that Patent Owner moves to exclude here.

Exclude 6–9. Patent Owner responds, arguing that Petitioner has failed to show that FRE 807 applies "because Petitioner made no showing that there was no other more probative evidence concerning what was known to a POSITA as of 2002." PO Reply Opp. 3.

We agree with Petitioner's analysis and reliance on FRE 807, specifically, that both Mr. Crawford and Mr. Adams's testimony is a credible recollection of probative material facts from their personal knowledge and experience as employees of Becton, Dickinson—employees who worked directly on the subject matter and development of the products relevant to Patent Owner's assertions of objective indicia of nonobviousness in this IPR. *See* PO Response, 54 (citing Ex. 2062, 29:14–30:14, 127:6–128:3); *see also* Ex. 1083, 25:6–27:23; Ex. 1084, 307:4-22. With respect to Patent Owner's contention that Petitioner has not made the requisite showing under FRE 807(a)(3), we do not agree that because such evidence is corroborative of other evidence, that it is not "more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts."

As noted in our Decision, above, Patent Owner relies upon parts of Mr. Crawford's testimony from this same deposition testimony. *See* PO Resp. 54 (citing Ex. 2062, 29:14–30:14, 127:6–128:3). Yet Patent Owner is attempting to exclude related parts of Mr. Crawford's testimony *from the same* deposition, and *from the same* line of questioning upon which it relies. *See* Ex. 1083, 25:6–30:14. Mr. Crawford's testimony, which Petitioner relies upon, is highly probative of the issue of long-felt need in this proceeding, *because* it is from the same line of questioning and the same deposition relied upon by Patent Owner. Patent Owner essentially asks us to

apply a double standard here, but, what's good for the goose is also good for the gander. All of the declarant's pertinent testimony in these exhibits is relevant and highly probative with respect to the same questions regarding long-felt need, failure of others, commercialization and other facts of objective indicia of nonobvious which the Board must analyze.

Further, as noted by Petitioner, "[Patent Owner] has provided no explanation as to why the facts in these exhibits relied on by [Petitioner] are any more or less trustworthy than those upon which [Patent Owner] relies." *Id.* at 9. All of the testimony by Mr. Crawford and Mr. Adams, as referenced by both parties to this IPR, serves the purpose of the Board determining the trustworthiness and accuracy of the evidence of long-felt need and failure of others as a whole. Patent Owner makes no credible argument as to why certain of Mr. Crawford's testimony is admissible, and other testimony is not.

Further, to the extent these exhibits were inadmissible hearsay, they are properly relied upon as the foundation of expert testimony pursuant to FRE 703.

Patent Owner's motion to exclude Exhibits 1083 and 1084 is DENIED.

Exhibits 1091 and 1092

Exhibit 1091 is a Becton, Dickinson internal email, written by Mr. Curtis Bloch, [redacted]

[redacted] Patent Owner argues that these exhibits are hearsay and not subject to FRE 803(3) "because they are not statements of a "then-existing mental, emotional or physical condition." PO PO Reply Opp., 4, *see also* PO Mot Ex. 4–5.

We agree with Petitioner that these exhibits fall within FRE 803(3), because both documents are "[a] statement of the declarant's then-existing state of mind (such as motive, intent, or plan)." Each of these documents relates explicitly the state of mind of each respective declarant, namely [redacted] Ex. 1091; Ex 1092.

Patent Owner's motion to exclude Exhibits 1090 and 1091 is DENIED.

Exhibits 1094, 1095, 1105, 1120, 1121

Exhibit 1094 is US Patent No. 5,954,698, and Exhibit 1095 is U.S. Patent No. 5, 501,675. Exhibit 1105 is US Patent No. 4,524,805. Exhibit 1120 is U.S. Patent No. 4,948,092. Exhibit 1121 is U.S. Patent No. 4,332,249. Petitioner offered these exhibits in its Reply as examples of safety IV catheters having both needle protection and blood control features apparently known in the art before the priority date of the '626 patent and for the proposition that duck-bill valves have a slit. *See, e.g.*, Pet. Reply 9, 13, 14, 25; Ex. 1036 ¶¶ 21, 24, 25, 27, 31, 35–38, 81, 86, 87, 115, 119. Patent Owner argues that these references "are not properly before the Board because they were not timely raised." PO Mot. Exclude 6. Petitioner explains that these references are not improper as they were submitted in response to Patent Owner's arguments in Response related to purported

objective indicia of nonobviousness and position that a duck-bill valve does not include a slot. Pet. Opp. Mot. Exclude, 13–14.

As the Board has explained, a motion to exclude is properly related to the admissibility of evidence (e.g., authenticity or hearsay). *See Bloomberg Inc. v. Markets-Alert Pty Ltd.*, CBM2013-00005, slip op. at 5 (PTAB Nov. 15, 2013) (Paper 56). Patent Owner's argument here is directed, on the other hand, to the question of whether this evidence was timely submitted in and is an alleged new argument made by Petitioner regarding prior art to the claimed subject matter in the '626 patent. Essentially, Patent Owner contends that these exhibits are improper supplemental information intended to support an argument on the merits. Such evidence may only be filed if a § 123 motion is both authorized and granted. *Handi Quilter, Inc. and Tacony Corp. v. Bernina International AG*, Case IPR2013-00364, slip op. at 2-3 (PTAB June 12, 2014) (Paper 30).

These exhibits, which Petitioner uses solely in its reply to Patent Owner's evidence of secondary considerations, or to counter Patent Owner's argument that a generally know duck-bill valve would not have a slit, are generally used to reinforce Petitioner's explanation of the background knowledge in the art, i.e., either that IV devices including both needlestick protection and blood control were known in the art or the very definition of a duck-bill valve is a valve with a slip. A motion to exclude, however, is not the appropriate vehicle for making such a challenge. Here, we find that Petitioner's use of these exhibits occurred only in appropriately responding to arguments made in the Patent Owner Response, such as in the context of secondary considerations or to respond to how a person of ordinary skill in the art would understand Van Heugten's disclosed duck-bill valve.

Compare PO Response 49 (Patent Owner argues that "there was a long-felt and unsolved need for a straight IV catheter insertion product having both a device for needle stick protection and blood control technology."), *with* Pet. Reply 12 (Petitioner responded that "[s]traight" catheters were known long before 2002, including in catheters that prevent needlesticks, have blood control, and that combine both features."); *compare also* PO Resp. 21 ("referral to 'duck-bill' is simply a reference to the valve membrane's orientation"), *with* Pet. Reply 7 ("Van Heugten's reference to a duck-bill valve simply indicates that the valve can be a commonly understood duck-bill valve.").

Patent Owner's motion to exclude Exhibits 1094, 1095, 1105, 1120, and 1121 is DENIED.

Exhibit 1036

Patent Owner argues that paragraphs 18–25, 35-37, 39–41, and 43, of Mr. Griffis's testimony in his supplemental declaration (Ex. 1036) should be excluded because they are essentially improper supplemental information and "relied on to support arguments that are not properly before the Board in this proceeding and are thus irrelevant." PO Mot. Exclude 2. Similar to our discussion, above, a motion to exclude is not the appropriate vehicle for challenging alleged improper supplemental information. In any event, we do not rely on any of these paragraphs in our Decision. Patent Owner's motion to exclude these portions of Exhibit 1036 is DENIED as moot.

IV. PATENT OWNER'S CONTINGENT MOTION TO AMEND

As discussed above, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 11 and 20 are unpatentable. As we find claims 11 and 20 to be unpatentable, we address Patent Owner's Contingent Motion to Amend. Paper 23, "Amend Mot." The Motion seeks to replace unpatentable claim 11 with substitute claim 21 and thereafter change the dependency of claims 12–20 to depend from substitute claim 21. As discussed below, we grant the Motion to Amend

A. Analysis of the 37 C.F.R. § 42.121 Requirements

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). The Board must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc). However, Patent Owner's proposed substitute claims must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *See* "Guidance on Motions to Amend in view of *Aqua Products*" (Nov. 21, 2017) (https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf) (last accessed Dec. 5, 2018) ("Guidance"). Accordingly, Patent Owner must demonstrate: (1) the amendment responds to a ground of unpatentability involved in the trial; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment proposes a reasonable number of

substitute claims; and (4) the proposed claims are supported in the original disclosure. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

For reasons set forth below, we determine Patent Owner has met the above-discussed requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. Patent Owner seeks to add a substitute claim to replace challenged claim 11, found unpatentable, and the substitute claim adds limitations that narrow the scope of the original claim it replaces. *See* Amend Mot. 3–17, Claim Appendix, 1–3. Patent Owner also identifies disclosures in the originally-filed priority application that support proposed substitute claim 21. Amend Mot. 3–17 (citing the priority German Patent Application No. DE 20210394.3, filed July 4, 2002 (Exs. 2048, 2049)). Based on the citations provided in the motion and for the additional reasons discussed below, we find sufficient written description support for Patent Owner's proposed substitute claim 21. Patent Owner recognizes that once original claim 11 is replaced, claims 12–20, which depend therefrom, will depend from a nonexistent claim, so Patent Owner seeks to change the dependency of claims 12–20 to depend from claim 21. Because Patent Owner's proposal is narrowly focused and does not add or change any limitation (apart from the new limitation in base claim 21) to claims 12–20, we find Patent Owner's proposed amendment to these dependent claims acceptable. Moreover, Patent Owner proposes a narrowing limitation in proposed substitute claim 21 in direct response to the grounds of unpatentability involved in this trial. Therefore, Patent Owner has satisfied the requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. Accordingly, we now focus on the patentability of proposed substitute claim 21.

B. Analysis of the Patentability of Proposed Claim 21

As discussed above, Patent Owner does not have the burden of persuasion with respect to the patentability of the substitute claims presented in its Motion to Amend. *See Aqua Prods.*, 872 F.3d at 1327; Guidance 2. For the reasons explained below, considering the record before us, we determine that Petitioner has not shown by a preponderance of the evidence that proposed substitute claim 21 is unpatentable.

As a replacement for independent claim 11, Patent Owner proposes claim 21. Amend Mot. 1. Proposed substitute claim 21, with amendments indicated by underlining, is shown below:

> 21. A catheter insertion device comprising:
>
> a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached to a distal end;
>
> a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube in a ready position and comprises a needle tip;
>
> a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow and comprises a wall surface comprising a slit; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub
>
> a valve actuating element slidingly disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit and a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon;

> a needle protective device spaced from the needle tip in the ready position and movable relative to the needle tip, at least in part distally of the needle tip to prevent unintended needle sticks, wherein the needle protective device comprises a resilient portion made from a metallic material for moving the needle protective device from the ready position to a protected position.

Id. at Claim App., 1. Relevant to the analysis of patentability over the prior art, proposed substitute claim 21 affirmatively requires that the needle protective device "comprises a resilient portion made from a metallic material." To the extent that needle protective device may have been considered a means-plus-function limitation before, this amendment provides additional structure that takes this claim limitation outside the realm of § 112, ¶ 6.

1. Analysis of the Patentability of Proposed Substitute Claim 21 Over the Cited Prior Art

Patent Owner makes an initial showing that "Van Heugten does not disclose, teach or suggest a needle protective device that comprises a resilient portion made from a metallic material for moving the needle protective device from the ready position to a protected position in connection with the other claimed features of claim 11." Amend Mot. 4. Patent Owner argues that because Van Heugten requires a tubular needle guard made of transparent or translucent polymeric materials to allow the practitioner to view blood flashback upon proper insertion of the needle in a vessel, it would not have taught the amended claim requirement. *Id.* at 19. Based on Patent Owner's showing, and based on Petitioner not directly challenging whether Van Heugten alone teaches the amended limitation, we find Patent Owner's showing as to Van Heugten alone persuasive.

Petitioner asserts that claim 21 would have been obvious under 35 U.S.C. § 103 over Van Heugten and Lynn[4] (Amend Opp. 5–11) as well as over the combination of Kuracina[5] and Tauschinski (*id.* at 11–24). We address each of these contentions in turn below.

At the outset, we note that neither party has specifically addressed secondary considerations as they relate to amended claim 21. Patent Owner has not established whether IS3 or IAG-BC is covered by the new amended claim. Thus, although we have considered secondary considerations to the extent possible (such as long felt need), these factors do not influence our decision as to substitute claim 21.

i. Van Heugten and Lynn

Petitioner asserts that claim 21 would have been obvious under 35 U.S.C. § 103 over Van Heugten and Lynn. Amend Opp. 5–11. As addressed in detail above, Van Heugten teaches each limitation of claim 11. Petitioner relies on the combination of Van Heugten and Lynn to address the newly added claim 21 limitation. Specifically, Petitioner argues that "Lynn discloses the only limitation of substituted claim 21 not shown or suggested by Van Heugten: 'wherein the needle protective device comprises a resilient portion made from a metallic material for moving the needle protective device from the ready position to a protected position.'" Amend Opp. 7.

[4] International Patent Application PCT/US00/40638 to Lynn, "Luer Receiving Vascular Access System," published as WO/01/12249 on Feb. 22, 2001 (Ex. 1109, "Lynn").
[5] U.S. Patent No. 6,001,080 was issued on December 14, 1999 (Ex. 2009, "Kuracina").

Patent Owner disputes Petitioner's contention, arguing that a person of ordinary skill in the art would not have looked to replace Van Heugten's manually retracted needle with Lynn's automated spring/trigger to retract the needle. Reply to Opp. 7–8. Patent Owner asserts further that, to the extent the devices could be combined, the combination of Van Heugten and Lynn would require a complete redesign of the Van Heugten catheter and Petitioner has failed to adequately support the combination of Van Heugten and Lynn with sufficient facts, evidence and reasoning. *Id.*

Below we provide an overview of Lynn (Van Heugten is discussed in detail above), examine the parties' arguments, and then provide our reasoning why we do not agree with Petitioner's contentions that claim 21 would have been obvious over Van Heugten and Lynn.

a) Lynn (Ex. 1009)

Lynn discloses vascular access system 5 including needle hub 75 supporting needle 60 "within a needle receptacle 84, which includes an enclosed proximal end 95 and defines a receptacle chamber 100 for receiving the retracted needle." Ex. 1009, 7:16–18. Lynn teaches a retraction spring mechanism for retracting needle 60 into receptacle chamber 100 to protect from inadvertent needle sticks. *Id.* at 2:16–20, 7:18–26. The sole Figure from Lynn is reproduced below.

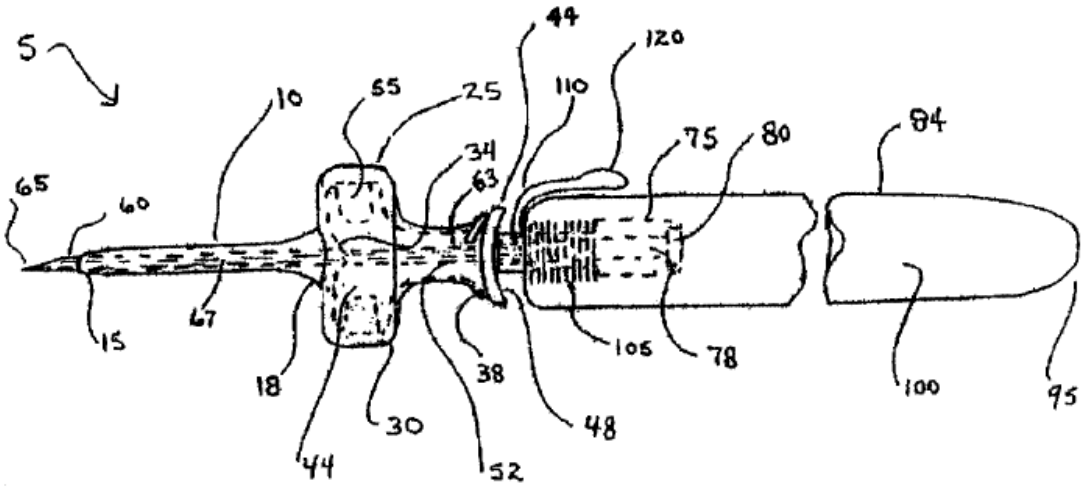


Figure 1 of Lynn, above, depicts vascular access system 5 including a needle protective device (needle receptacle 84) for receiving spring biased needle 60. *Id.* at 7:11–28. According to Lynn, when a user depresses button 120, "finger pressure against the button 120 causes the retainer 110 to shift in position, releasing the hub 75 from its retained position thereby allowing the spring 105 to actively retract the needle 60 back into the receptacle chamber 100." *Id.*

b) Petitioner's Argument

Petitioner argues that "[a] POSA would understand that the needle protective device of Van Heugten could be readily modified to operate according to an automated spring/trigger-based needle retraction mechanism rather than relying on the user to manually withdraw and lock the needle guard and housing together." Amend Opp. 9. ("[I]t would have been obvious to design a device where the manual catheter insertion would be followed by automated retraction of the needle into the needle receptacle as taught in Lynn."). Thus, Petitioner argues that it would be a simple matter of automation for a person of ordinary skill in the art to replace the manual

force for retracting the needle in Van Heugten with Lynn's automatic needle retraction spring mechanism. *Id.* Petitioner asserts that the benefits of automating the retraction function were known in the art, as discussed for example by Cuppy (Ex. 1112), which explains that a danger with manual retraction is that "people forget to fully retract the needle into the locked position allowing the needle to slip out of safety tube and again risking a needle stick or puncture of [] the disposal receptacle." *Id.* at 9–10 (citing Ex. 1112, 2:52–58).

Although Petitioner acknowledges that "the automatic needle retraction of Lynn to Van Heugten would change the operation of Van Heugten so that the catheter is manually advanced before the needle is retracted," Petitioner argues that "the disclosure in Lynn itself and the prior art teaches a POSA how that device would operate." *Id.* at 10. According to Petitioner, the Lynn device was commercialized as the "Autoguard system," that was "widely available prior to 2002." *Id.* at 45 (citing Ex. 1012, 57(6):572-7, Abstract, Fig. 2). Relying on Mr. Griffis, Petitioner argues that one of ordinary skill in the art "would have modified the catheter assembly of Van Huegten to automate the needle retraction as in Lynn to prevent accidental needle sticks, which would provide a known safety advantages by combining known elements to function for their intended result." *Id.* at 11 (citing Ex. 1036 ¶¶ 77–88).

c) Patent Owner's Argument

Patent Owner contends that Petitioner's arguments that Van Heugten can be readily modified and automated are not supported by sufficient evidence. Reply to Opp. 7–8. Patent Owner argues also that Petitioner has

failed to explain how and why a person of ordinary skill in the art would have combined Van Heugten and Lynn, and to the extent spring retraction was known in the art, and that the references could be combined, Petitioner has not explained with particularity and rational underpinnings the need "to automate the 'liner force' of Van Heugten with the automated/spring trigger of Lynn." *Id.* at 7.

Patent Owner argues that a person of ordinary skill in the art would not have readily altered Van Heugten's manually operated needle protective device, which simultaneously advances the catheter tube in a blood vessel while also retracting the needle into its protective cover. *Id.* at 7–8. As explained by Patent Owner, "[t]his is because Van Heugten's catheter assembly involves a manual sliding of a catheter into a vein (a process that cannot be automated) during which the needle is simultaneously withdrawn into the needle guard." *Id.* Patent Owner contends that "[t]he linear force required to move the 'sheath' in Van Heugten cannot be automated because that same linear force also moves the catheter into the vein; automating that process would potentially harm a patient by jamming a catheter improperly and with too much force into a vein." *Id.* at 8. Further, Patent Owner argues that as recognized by Mr. Griffis, "the combination of Van Heugten and Lynn would require a complete redesign of the Van Heugten catheter." *Id.* (citing Ex. 1036 ¶ 87).

d) Discussion

Automation and Evidentiary Underpinnings

Petitioner argues that the same safety principle, prevention of accidental needle sticks as taught in Van Heugten, is "disclosed in Lynn,"

"but the retraction of the needle is automated." Amend Opp. 8. In both devices, Petitioner argues, "accidental needle pricks are prevented by encasing the needle tip in a needle protective device, but the motion in Lynn is derived from an automated spring/trigger system." *Id*. Mr. Griffis's testimony confirms that both devices do indeed encase the needle in needle receptacle 84 (Lynn) and needle guard 30 (Van Heugten). Ex.1036 ¶¶ 58, 80–82, 84–88. Mr. Griffis also testifies persuasively that automation of needle retraction was known in the art to ensure full retraction of a needle. *See id.*

Petitioner's and Mr. Griffis's arguments and testimony present a general summary of Van Heugten's and Lynn's components and function of retracting the needle into a protective hub. This summary, however, emphasizes the end result, i.e., retention of the needle in a guard or receptacle and the benefit of preventing needle sticks. Although this end result is similar for both prior art references, both devices accomplish the task in very different ways and with different structures. What is not apparent from Petitioner's challenge and the associated evidence is *how* one of ordinary skill in the art would have combined the references and *why* one would have combined them.

Neither Petitioner, nor Mr. Griffis, provides persuasive testimony or technical description of any structural element or functional construct, apart from the end result, detailing how an automatic spring loaded needle retraction device would work with Van Heugten. Petitioner provides no explanation as to how the manual advancing of the catheter tube and simultaneous cooperative needle retraction, which occurs in Van Huegten, would be accomplished technically with a metal resilient member

influencing the needle and needle hub. Moreover, during his deposition, Mr. Griffis either could not, or would not, explain how the combination would have been accomplished. *See* Ex. 2030, 57:2–60:4.

> Q. Did you provide an opinion as to what the button 120 does in Lynn?
> A. No. When I used the teachings of Lynn in combination with Van Heugten, the idea was to show that Lynn -- a person of ordinary skill in the art, like the disclosure in Lynn, would show that resilient metallic retraction springs were known and that they could be used to essentially cause the activation . . .

Id. at 58:12–21. Mr. Griffis also stated during his deposition that "I limited my analysis to the fact that Lynn incorporates this resilient metallic retraction spring." *Id.* at 59:3–5.

We are not persuaded that Petitioner has provided the necessary evidentiary underpinnings to support the combination of Lynn and Van Heugten. The mere allegation that the combination could have yielded a predictable result is insufficient to show the predictability of adding a metal resilient member from Lynn to Van Heugten's simultaneous catheter advancement and needle retraction operation. *See KSR*, 550 U.S. at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

Reason to Combine Van Heugten and Lynn

Petitioner's articulated reason to combine Lynn's automated spring needle retraction device is that there was a known problem in the art, namely that needle protective devices that require the user to manually position the

needle with a housing suffer from the disadvantage that "people forget to fully retract the needle into the locked position, allowing the needle to slip out of safety tube and again risking a needle stick or puncture of [] the disposal receptacle." Amend Opp. 10 (citing Ex. 1012, 2:52–58). At first pass, this seems logical—automated retraction would remove occurrences of uncompleted manual needle retraction into a needle guard. This reason, however, is not advanced based on any specificity and analysis of the combined references themselves. Petitioner has skipped over the details and any analysis of the prior art and improperly concluded that a person of skill in the art would have automated Van Heugten, as in Lynn, to solve this noted problem. *See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) ("Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.").

Relying on the premise that automation is better than manual retraction does not explain why one of ordinary skill in the art would have been motivated to automate Van Heugten with Lynn's automatic spring retraction mechanism. For example, Patent Owner asserts that "[t]he linear force required to move the 'sheath' in Van Heugten cannot be automated because that same linear force also moves the catheter into the vein; automating that process would potentially harm a patient by jamming a catheter improperly and with too much force into a vein. Reply to Opp. 8 (citing Ex. 1029, 133:20–137:1, 141:19–143:1, 144:15–146:2). Patent Owner's argument emphasizes that automation is not always better, and, highlights the absence of an adequate explanation as to why a person of skill in the art would have combined Van Heugten and Lynn, even though the

references appear, individually, to disclose all the elements of the claimed invention. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.").

Patent Owner's position on claim 21 is persuasive—that simply finding the requisite elements in the prior art, without sufficient explanation and credible testimony as to the motivations to modify and combine the prior art does not provide the necessary articulated reasoning and sufficient evidentiary underpinnings to support a finding of obviousness. We are not persuaded that Petitioner has shown by a preponderance of the evidence that claim 21 is obvious over Van Huegten and Lynn.

ii. Kuracina and Tauschinski

Petitioner asserts that claim 21 would have been obvious under 35 U.S.C. § 103 over Kuracina and Tauschinski. Amend Opp. 11–24. Petitioner contends that Kuracina teaches "a safety IV catheter with a metallic resilient portion for moving a needle protective device over a needle tip to prevent needle sticks." *Id.* at 12. Petitioner contends that "Tauschinski describes a well-known valve and valve actuator that are used with catheters to prevent the emergence of blood." *Id.* Petitioner provides analysis, supported by the testimony of Mr. Griffis, as to how the combination of prior art teaches each limitation in claim 21. *Id*. at 12–23

Patent Owner disputes Petitioner's contention "because there is no motivation to combine Kuracina and Tauchinski and because a POSA would

not have a reasonable expectation of success in combining the references in the manner suggested by Petitioner." Reply to Opp. 8–9.

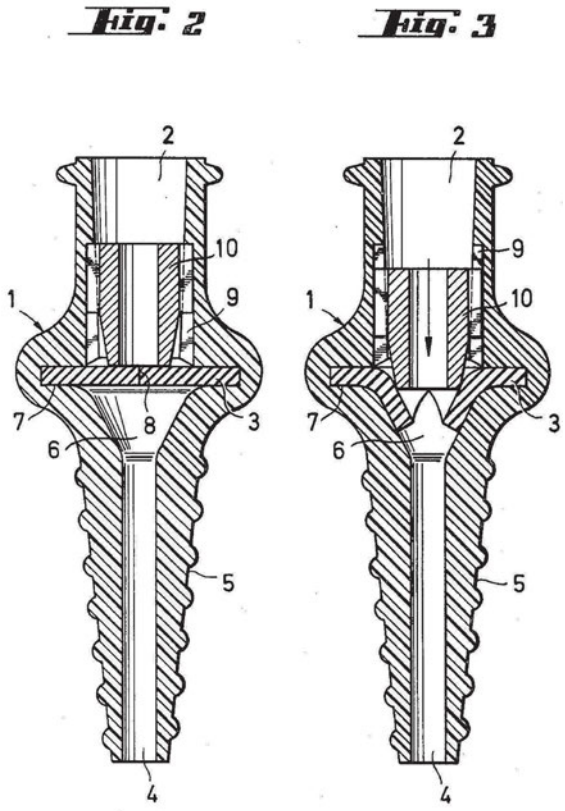
Below we provide an overview of Kuracina and Tauchinski, examine the parties' arguments, and then provide our reasoning why we do not agree with Petitioner's contentions that claim 21 would have been obvious over Kuracina and Tauchinski.

a. Kuracina

Kuracina, titled "Intravenous Catheter Assembly," discloses a needle tip protective device including a needle guard in one embodiment that is slidably mounted on a hypodermic needle having a needle at the distal end of the needle. Ex. 2009, [54], [57]. "The needle guard contains a movable needle trap that is biased against or toward the hypodermic needle." *Id.*, [57]. "The needle trap [will] advance over the tip of the needle, entrapping the needle tips as the needle guard is urged forward near the sharpened distal end of the hypodermic needle." *Id.* Notably, Kuracina has 128 figures depicting numerous distinct embodiments.

b. Tauschinski (Ex. 1004)

Tauschinski is a U.S. Patent titled "Self-Sealing Connector for Use with Plastic Cannulas and Vessel Catheters" and discloses a connector that will close automatically when a corresponding catheter is pulled from the connector, thereby "prevent[ing] an emergence of blood or an ingress of air" through the connector. *See* Ex. 1004, [54], 2:7–29. To illustrate the disclosed connector, we reproduce Tauschinski's Figures 2 and 3, below:



Tauschinski's Figures 2 and 3 depict a connector with a slit sealing disc. *See id.* at 2:62–68. In particular, these figures depict member 10 slidable within hollow-conical portion 2 and disc 3 provided with central slit 8. *See id.* at 3:17–25. Figure 2 depicts disc 3 as closed, with Figure 3 depicting member 10 advanced downward and within slit 8 of disc 3 to open the slit. *See id.* at 3:29–36.

Tauschinski discloses valve actuating element 10 slidingly disposed in catheter hub 1, and that actuating element 10 slides within the catheter hub to open slit 8 in the valve. Ex. 1005, 3:21–36. Tauschinski's valve is intended to allow a catheter to be inserted through the valve element 10 and, when the catheter is removed, "the closed connector is intended to prevent

an emergence of blood or an ingress of air through the fitting." *Id.* at 2:17–19.

c. Petitioner's Argument

Petitioner relies on Kuracina as teaching the claimed catheter insertion device, catheter hub, and needle limitations. *See* Amend Opp. 13–14. Petitioner relies on Kuracina in view of Tauschinski as teaching "a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow and comprises a wall surface comprising a slit; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub." *Id.* at 14 (citing Ex. 1036 ¶¶ 98–102). Petitioner alleges that "Tauschinski discloses a valve (e.g., element 3) positioned inside the interior cavity of the catheter hub (e.g., element 1) and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow." *Id.* at 14–15. Petitioner further contends that "[i]t would have been obvious for a POSA to combine the catheter insertion device of Kuracina with the valve in Tauschinski," because "[a] POSA would have been motivated to modify Kuracina based on Tauschinski's teaching that its valve prevents the emergence of blood." *Id*. at 16 (citing Ex.2009, 2:44–47, 3:3–4). Thus, according to Petitioner, "[a] POSA would have found it obvious to improve Kuracina by adding fluid protective elements, such as a valve, to prevent the emergence of blood from the catheter once inserted in a patient, based on the known technique in Tauschinski." *Id.*

Petitioner further argues that "[a] POSA would place the valve of Tauschinski inside Kuracina's catheter hub," and that "[a] POSA would know how to fit the Tauschinski valve inside a catheter hub by placing the

valve in a groove inside the catheter hub as taught by Tauschinski." *Id.* (citing Ex.1036 ¶¶ 100–102). As support for how Tauschinski's connector valve could be fit inside a catheter hub, Petitioner argues that "[a] POSA would know how to fit the Tauschinski valve inside a catheter hub by placing the valve in a groove inside the catheter hub as taught by Tauschinski." *Id.* Petitioner basis this combinability argument on Tauschinski's disclosure of a "peripheral annular radial groove" (Ex.1004, 3:14–18, 3:43–46) and Kuracina's purported lack of disclosure of "particular properties or characteristics of its catheter hub and in fact discloses that the inside of a catheter hub can contain an 'inner channel, recess, slot or undercut' as necessary to incorporate design features of catheter insertion devices" (Ex. 2009, 35:9–12). Amend Opp. 17. Finally, Petitioner argues that "[a] POSA would follow the teaching of Tauschinski and know how to make equivalent changes to a catheter hub in Kuracina to incorporate a valve." *Id.*

d. Patent Owner's Argument

Patent Owner contends that "Kuracina does not contemplate the use of a valve or valve actuator in connection with the claimed needle guard in any of the disclosed embodiments." Reply to Opp. 9. Patent Owner notes that

> Petitioner's alleged motivation to combine the blood control of Tauschinski with Kuracina in 2002 (Opposition at 16) is undermined by Petitioner's own assertion that "the market did not desire such a product," i.e., a product with needlestick prevention and blood control, in 2002, and that the desire to add blood control only began in "2007 and later" (Paper No. 52 at 22-23).

Id.

Patent Owner points out that Petitioner's contention "that adding a slit valve and valve actuator to Kuracina 'would have been an uncomplicated design choice' and 'routine design optimization,'" is contradicted by Petitioner's position in related proceedings "that claims directed to a valve with 'air flow gaps . . . for ensuring sufficient air flow' were not enabled as of 2006—let alone the 2002 priority date of the '626 patent—and that adding 'air flow gaps' to a valve 'required excessive, undue experimentation.'" Reply to Opp. 9. (citing Ex. 2127, IPR2017-01590, Paper 34 at 10–14). "In particular, Petitioner relied on the Stout declaration, [redacted] (citing Petitioner arguments at Amend Opp. 19–20). Patent Owner faults Petitioner's reversal because "the proposed combination includes a needle guard that is not contemplated in connection with an actuator/valve assembly," and

> Petitioner provides no explanation as to how to complete the proposed combination and provides no analysis of how the needle guard of Fig. 42A of Kuracina (which includes the needle guard assembly 22, the tether 24 and the needle tip guard 41) could function in connection with a valve actuator in a catheter hub.

Reply to Opp. 10.

Patent Owner further questions Petitioner's reliance on Kuracina for the proposition that the inside of the catheter hub can contain an inner channel, recess, slot or undercut for the purpose of holding a valve in place,

because the cited portion of Kuracina further explains that the "inner channel, recess, slot or undercut 32 [in the catheter hub is] for being releaseably held by said movable arm 45 and said projection [of the needle guard]" as depicted in Kuracina's Figure 104 below, as annotated by Patent Owner. *Id.* at 10–11 (emphasis omitted) (citing Ex. 2009, 34:58–35:14 (discussing Fig. 104)).

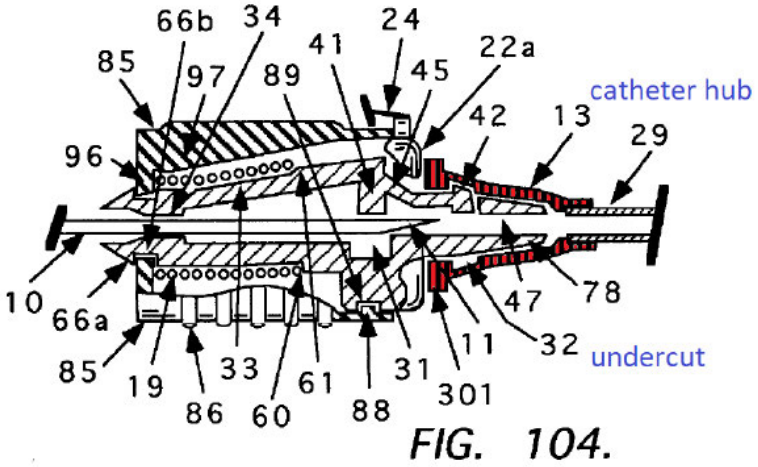


FIG. 104.

Patent Owner's annotated Figure 104 (Reply to Opp. 11) show a catheter with highlighted inner channel, recess, slot or undercut 32 and catheter hub 13. Patent Owner notes that Petitioner "does not address any of the Kuracina embodiments that combine the claimed needle trap with a catheter hub, *see, e.g.*, Figs. 61-63, 103-105, 118, each of which show that the needle trap is specifically designed to attach to (and fill) the interior of the catheter hub (Ex. 2009 at 19:42-20:62, 33:52-35:36, 38:9-34)." Reply to Opp. 11. Thus, according to Patent Owner, "Petitioner has not shown that a POSA would have a reasonable expectation of success in combining the valve and actuator of Tauschinski with Kuracina." *Id.*

Patent Owner further argues that "Petitioner's assertion that Tauschinski discloses a catheter hub is undeniably false," because

"Tauschinski is a connector for connecting to a catheter—not a catheter hub as the Opposition incorrectly asserts." *Id.* at 12. Patent Owner relies on the Mr. Griffis's cross-examination admission that Tauschinski is a connector that may be used with a catheter hub. *Id.* (citing Ex. 2122, 37:4–38:8). Patent Owner then argues that "Petitioner's use of 'hub' when referring to Tauschinski is incorrect and controverts the plain facts." *Id.* Based on Tauschinski being a connector and not a catheter hub, Patent Owner argues that "[a]bsent hindsight there is no reason for a POSA to take the valve/actuator assembly of the Tauschinski ***connector***, and completely redesign the Kuracina ***catheter hub***, as vaguely proposed by Petitioner." *Id.* Patent Owner argues that "Petitioner's unexplained combination cannot carry their burden to show that there is a 'reasonable expectation of success' of adding the valve/actuator to Kuracina." *Id.*

e. Discussion

We first note that both Kuracina and Tauschinski were cited references[6] on the issued '626 patent. Ex. 1001, [56]. Based on the record before us, Petitioner has not established by a preponderance of the evidence that claim 21 would have been obvious over Kuracina in view of Tauschinski. Petitioner has not persuasively established that Kuracina

[6] Petitioner separately argues that Patent Owner failed its duty of candor under 37 C.F.R. § 42.11 by failing to disclose a litigation expert report and Petitioner's litigation invalidity contentions. Amend Opp. 24. We find these arguments unavailing. Petitioner argues certain references are material, yet, Petitioner did not rely on them either in its Petition or its Opposition to the Motion to Amend as part of this adversarial proceeding. These references were also identified by Petitioner during this proceeding, thus placing them before us prior to this Final Decision. *See* Ex. 1100 (invalidity contentions filed July 16, 2018).

contemplates the use of a valve or valve actuator in connection with the claimed needle guard in the embodiments relied upon. Further, Petitioner has not persuasively shown that Tauschinski's connector was designed for use in a catheter hub, or more importantly, that it could be integrated into the hub of Kuracina.

Petitioner's contention that Kuracina can contain an "inner channel, recess, slot or undercut" as necessary to incorporate Tauschinski's connector is not supported by the record before us. *See* Amend Opp. 17 (Ex. 2009, 35:9–12). This is so because Kuracina explains that inner channel, recess, slot or undercut 32 in the catheter hub is releaseably held by movable arm 45 and the projection of the needle guard as shown in Figure 104. Ex. 2009, 34:58–35:14 ("[N]eedle guard 22a having a male section 78 for removably attaching . . . catheter hub 13, said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said male section 78 after insertion of the catheter 29 into a patient. Said catheter hub 13 having at least one flange 301 and an inner channel, recess, slot or undercut 32 *for being releasably held by said movable arm 45 and said projection 42*.") (emphasis added). Petitioner's reliance on Kuracina's undercut 32 as providing structure to incorporate a connector ignores the relationship of movable arm 45 and projection 42 with undercut 32. Petitioner's proposed integration would negatively impact how movable arm 45 and projection 42 releasably retain catheter hub 13 and Petitioner ignores these problems by simply not explaining how this integration could occur.

We agree with Patent Owner that it is not enough to argue that the combination of elements was possible. Evidentiary underpinnings require more than that the elements are simply found in the prior art. *See Unigene*

Labs., Inc. v. Apotex, Inc., 655 F.3d 1352, 1360 (Fed. Cir. 2011) ("[O]bviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention."). Neither Petitioner, nor Mr. Griffis, explains with any technical sufficiency how and why a person of skill in the art would have found it routine or a basic design modification to insert Tauschinski's valve and actuator into a Kuracina's catheter hub with a needle guard.

Regarding Petitioner's arguments directed to the needle guard of Figure 42A (which includes needle guard assembly 22, tether 24 and needle tip guard 41) and Figure 26 of Kuracina, Petitioner has also not persuasively shown how this structure could function in connection with a valve actuator in a catheter hub. *See* Amend Opp. 14–20. Further, other Kuracina embodiments combine the needle trap with a catheter hub and these embodiments show that the needle trap is specifically designed to attach and fill the interior of the catheter hub making Petitioner's proposed design modifications impractical for those embodiments. *See* Ex. 2009, Figs. 61–63, 103–105, 118, 19:42–20:62, 33:52–35:36, 38:9–34.

Even if the catheter hub were redesigned to permit Tauschinski's valve and sliding actuator to be positioned axially distal of Kuracina's needle guard, Mr. Griffis does not persuasively establish how the actuator would function, e.g., be operated to open and close the valve, with Kuracina's needle guard now positioned between the needle hub and the valve actuator. Petitioner has not persuasively explained this structural and functional aspect of the asserted combination. Besides which, any reliance on the '626 patent would be the epitome of hindsight. Based on the totality

of the evidence before us, Petitioner has not shown that a POSA would have a reasonable expectation of success in combining the valve and actuator of Tauschinski with Kuracina.

2. Analysis of Proposed Claim 21 for Compliance with 35 U.S.C. § 112, ¶ 1

Petitioner asserts that proposed substitute claim 21 does not satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1. Amend Opp. 1–4. According to Petitioner, none of Patent Owner's specific citations to the specification of the '626 patent provide adequate written description support for the amended claim requirement that "wherein the needle protective device comprises a resilient *portion* made from a metallic material." *Id.* at 1 (emphasis added). More specifically, Petitioner argues that the specification supports needle protective devices only that are entirely made from one material, but not those having only a *portion* made from one material. *Id.* As to all other limitations not contested by Petitioner, we have reviewed and agree with Patent Owner's showing as to how each is supported by the original specification and thus, complies with both the written description requirement and the prohibition against adding new matter. *See* Amend Mot. 6–17.

Petitioner argues that Patent Owner's support in the priority applications, including German Priority application (Ex. 2049) for this limitation refers only to a spring clip, shown in Figures 1, 2, 4, 5, 7d, 8, 9a, and 10 of the German Priority application (Ex. 2049). *Id.* at 2. According to Petitioner, the spring clip is made of one material with spring arms that overlap and provide a physical barrier in front of the needle tip when the needle is withdrawn from the catheter hub. *Id.* Further, Petitioner contends

that the spring clip in the '626 patent is shown as a single material, with the spring arms 13a and 13b extending from rear wall 13c by a fold. *Id.* "The specification," according to Petitioner, "does not disclose structures that have only a portion that is resilient and metallic – the entire device is metallic or plastic." *Id.* at 3–4. Thus, Petitioner alleges that there is "no evidence or explanation from Mr. Meyst to explain how a spring clip made entirely from resilient metal conveys to a POSA that the needle protective device can have a portion that is resilient and metal, and a portion that is not." *Id.* at 4.

Patent Owner argues it identifies adequate support in the Motion to Amend for "the needle protective device comprises a resilient *portion* made from a metallic material" limitation. Reply to Opp. 1 (citing Motion to Amend 11–12). More specifically, Patent Owner quotes portions of the priority German application that identify spring clip 13 as having identified "outer areas of the spring arms 13a, 13b" that "snap in at the shoulder 5b under elastic deformation." *Id.* (quoting Ex. 2049, 5, 7 (English translation for German Patent Application No. DE 20210394.3 (Ex. 2048)); Ex. 2003 ¶ 18 (emphasis added). Further, another portion of the original specification identifies rear wall portions of the spring clip. *Id.* at 2.

Patent Owner also points out that Petitioner argues in related IPR proceedings that the Woehr patent applications (sharing the same specification)[7] disclose a safety device (e.g., element 13) for covering the

[7] Woehr, WO Publication No. 2004/004819, is the PCT application from which the present application claims priority. Mr. Griffis agrees that the specification of the present patent application and the German priority application (Ex. 2049) are substantially the same. *See* Ex. 1036, 35 n.5.

needle tip comprises a resilient portion made from a metal material. *Id.* at 3. Patent Owner contends that these arguments amount to an admission that the parent German application discloses a safety device for covering the needle tip, which may comprise a resilient portion made from a metal material. *Id.* (citing Ex. 2123, 33 (further citing exhibits and expert report for IPR2017-1590)).

To satisfy the written description requirement, the disclosure must reasonably convey to ordinarily skilled artisans that the inventors possessed the claimed invention as of the filing date. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* (alteration in original) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

> [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Id. "[T]he hallmark of written description is disclosure." *Id.* "This inquiry . . . is a question of fact," which "var[ies] depending on the context" and "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* (citations omitted). Demonstrating adequate written description "requires a precise definition" of the invention. *Id.* at 1350. However, the claimed invention

need not be recited *in haec verba* in the original specification in order to satisfy the written description requirement. *Id*. at 1352.

Petitioner's arguments do not persuade us that the original specification lacks sufficient written description support for the amended claim language. The sections cited by Patent Owner demonstrate that the inventors possessed the claimed invention as of the filing date. For example, the '626 patent, including its earliest priority application, discusses a needle protective device in the form of a spring clip that is further comprised of distinct resilient portions. The specification describes "outer areas of the spring arms 13a, 13b" that "snap in at the shoulder 5b under elastic deformation. Ex. 2049 at 5, 7; Ex. 2003 ¶ 18. Thus, the specification shows the inventors contemplated a spring clip with distinct portions. Based on the above and the evidence cited by Patent Owner, we agree that the priority application discloses a needle protective device (e.g., a "spring clip 13") comprising a resilient portion made of metal (e.g., "spring arms").

We are also persuaded by Petitioner's, and its expert's, arguments in a related proceeding that the Woehr German patent application (sharing the same specification) discloses a safety device (e.g., element 13) for covering the needle tip, which comprises a resilient portion made from a metal material. Ex. 2123, 33. As Mr. Griffis testifies in the IPR2017-01590 proceeding, "Woehr [WO 2004/004819] discloses a safety device (e.g., element 13) for covering the needle tip comprises a resilient portion made from a metal material." IPR2017-01590, Ex. 1002 ¶ 100. Accordingly, we do not find Petitioner's contradictory arguments in this proceeding persuasive.

Therefore, we determine, based on the final record before us, that Petitioner has not shown, by a preponderance of the evidence, that proposed substitute claim 21 is unpatentable for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1.[8]

C. Conclusion on Motion Amend

Amended claim 21 is responsive to a ground of unpatentability in the trial, the amendment does not constitute new matter, there is written description support for the claim, and Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 21 is unpatentable as obvious. Accordingly, we grant Patent Owner's Motion to Amend to substitute claim 21 for original claim 11. We also authorize the amendment of claims 12–20 to reflect the change of dependency from claim 11 to claim 21.

V. SUMMARY

For the foregoing reasons, we conclude that Petitioner has demonstrated by a preponderance of the evidence the unpatentability of claims 11 and 20 of the '626 patent. Specifically, Petitioner has demonstrated by a preponderance of the evidence that claims 11 and 20 would have been obvious under 35 U.S.C. § 103 over Van Heugten.

Petitioner's Motion to Exclude is denied.

Patent Owner's Motion to Exclude is denied.

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[8] Our determination is the same regardless of whether or not Patent Owner has the burden to establish the proposed amendment does not "introduce new matter." *See* 35 U.S.C. § 316(d)(3). Proposed substitute claim 21 has sufficient written description support in the original parent application of the '626 patent, and does not introduce new matter.

We grant Patent Owner's Motion to Amend to replace claim 11 with substitute claim 21 and to amend claims 12–20 to depend from claim 21.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 11 and 20 are unpatentable over Van Heugten;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *denied*.

FURTHER ORDERED that Petitioner's Motion to Exclude is *denied*.

FURTHER ORDERED that Patent Owner's Motion to Amend substitute claim 21 for claim 11, and amend claims 12–20 to depend from claim 21, is *granted*; and

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

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