UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

B.BRAUN MELSUNGEN AG,
Patent Owner of
U.S. Patent No. 8,328,762 to Woehr et al.

IPR Trial No. IPR2017-01586

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 83) in IPR2017-01586 (Exhibit A), and all prior and interlocutory rulings related thereto or subsumed therein.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner further indicates that the issues on appeal include, but are not limited to, whether the Patent Trial and Appeal Board erred in its claim construction of the term "needle protective device" as recited in U.S. Patent No. 8,328,762; 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 18 and 22 of U.S. Patent No. 8,328,762 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 Petitioner had not established by a preponderance of the evidence that claim 25 of U.S. Patent No. 8,328,762 is unpatentable under 35 U.S.C. § 103 over the combinations of Woehr and Tauschinski and/or Van Heugten and Lynn; whether the Patent Trial and Appeal Board erred in denying Petitioner's Motion to

Exclude; 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 703738752 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. 83
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 IPR2017-01586
Patent 8,328,762 B2

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

DANIELS, *Administrative Patent Judge.*

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

I. INTRODUCTION

Becton, Dickinson and Company ("Petitioner" or "Becton, Dickinson") filed a Petition (Paper 3, "Pet.") requesting *inter partes* review of claims 18, 22, and 25 of U.S. Patent No. 8,328,762 B2 ("the '762 patent"). Pet. 1. We issued a Decision to Institute an *inter partes* review of the challenged claims of the '762 patent under all grounds. Paper 8, 30 ("Decision to Institute").

After institution of trial, B. Braun Melsungen AG ("Patent Owner" or "B. Braun") filed a Patent Owner Response (Paper 21, "PO Resp."), and a Supplemental Response (Paper 44, PO Supp. Resp.), to which Petitioner replied (Paper 47, "Pet. Reply"). We authorized via an email of August 21, 2018, and Patent Owner timely filed, a Sur-Reply (Paper 59, "PO Sur-Reply") to Petitioner's Reply.

Patent Owner filed a Motion to Exclude Evidence (Paper 57, "PO Mot. Exclude"), Petitioner filed an Opposition (Paper 64, "Pet. Opp."), and Patent Owner a Reply to the Opposition (Paper 67, "PO Reply Opp."). Petitioner likewise filed a Motion to Exclude Evidence (Paper 56, "Pet. Mot. Exclude"), Patent Owner filed an Opposition (Paper 63, "PO. Opp."), and Petitioner a Reply to the Opposition (Paper 66, "Pet. Reply Opp.").

Oral argument was conducted on September 26, 2018, and the transcript of the hearing has been entered as Paper 82.

We have jurisdiction under 35 U.S.C. § 318(a). After considering the evidence and arguments of both parties, and for the reasons set forth below, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 18 and 22 of the '762 patent are unpatentable. Petitioner has not

shown by preponderance of the evidence that claim 25 of the ’762 patent is unpatentable.

A. Additional Proceedings

Petitioner represents that the ’762 patent is at issue in *B. Braun Melsungen AG et al. v. Becton, Dickinson & Co. et al.*, No. 1:16-cv-00411 (D. Del.). Pet. 1. Petitioner also represents that petitions for *inter partes* review were also filed challenging related patents US. Patent Nos.: 8,337,463; 8,333,735; 8,540,728; 9,149,626; 8,597,249; 8,460,247; and

9,370,641. *Id.* Below is a chart that associates the *inter partes* reviews with each patent:

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

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

B. The '762 Patent (Ex. 1001)

The '762 patent, titled "Catheter Insertion Device," purports to prevent "an outflow of blood from the catheter . . . after removal of the hollow needle with [a] needle guard element." Ex. 1001, 1:31–33. Figure 1 of the '762 patent's catheter insertion device is reproduced below:

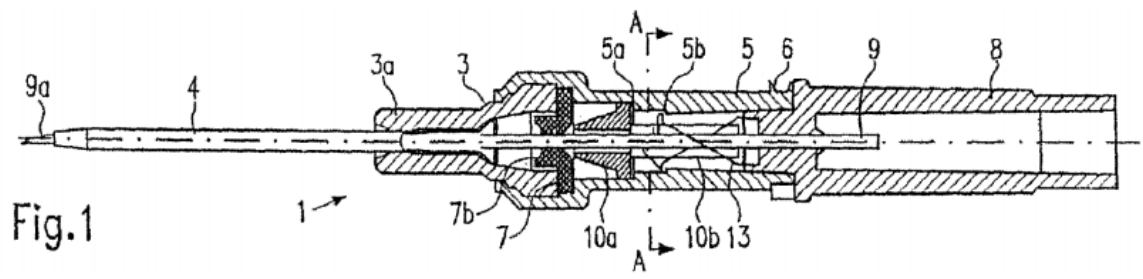


Fig.1

According to the ’762 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 passes through valve disc 7 and extends through catheter 4. Ex. 1001, 2:8–9, 18–20. Between needle hub 8 and valve disc 7 is valve actuating element 10, which has a truncated cone-shaped section 10a, which serves to open valve disc 7. *Id.* at 2:20–24. Also shown is needle guard element 13 in the form of a spring clip. *Id.* at 2:27–29. 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 2:31–39.

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

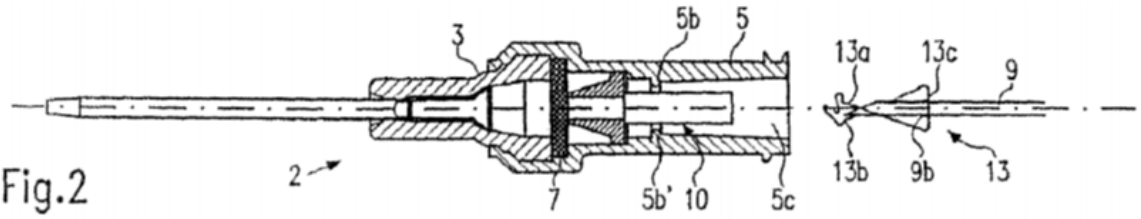


Fig.2

Figure 2 of the ’762 patent, above, depicts the catheter insertion device with needle 9 removed from catheter hub 2. Ex. 1001, 1:55–56, 2:31–39. As shown, when needle guard element/spring clip 13 is removed from the catheter hub along with needle 9, the spring clip’s spring arms 13a, 13b cover the needle’s tip. *Id.* at 2:31–39. Figure 2 depicts also 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 2:39–42.

C. Illustrative Claim

Of the challenged claims, claim 18 is independent. Each of dependent claims 22 and 25 depend directly from independent claim 18. Claim 18 illustrates the claimed subject matter and is reproduced below:

> 18. A method of manufacturing a catheter insertion device comprising:
>
> forming a catheter hub comprising a body comprising an interior cavity with an opening at a proximal end and attaching a catheter tube thereto;
>
> positioning a valve in sealing communication with the interior cavity of the catheter hub for regulating fluid flow through the interior cavity;
>
> positioning a valve actuating element in mechanical communication with the valve for detecting the valve to permit fluid flow through the interior cavity of the catheter hub;
>
> positioning a needle protective device at least partially inside the interior cavity of the catheter hub such that the needle protective device is in-line with the catheter hub and the valve actuating element;
>
> positioning a needle hub having a needle attached thereto proximally of the catheter hub so that the needle projects through the catheter hub and the catheter tube; and
>
> wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub.

Ex. 1001, 6:15–36 (emphasis added).

D. The Alleged Grounds of Unpatentability

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

References	**Basis**	**Claims Challenged**
Woehr[2] and Tauschinski[3]	§ 103	18, 22, and 25
Van Heugten[4]	§ 103	18 and 22
Van Heugten and Lynn[5]	§ 103	25
Van Heugten and Tauschinski	§ 103	22

II. CLAIM CONSTRUCTION

A. Legal Standard

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2016). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Under that standard, claim terms are generally given their ordinary and customary meaning as would be understood by one of ordinary

[1] Petitioner supports its challenge with the Declaration of Jack Griffis, III, (Ex. 1002), and, in its Preliminary Response, Patent Owner relies upon the Declaration of Richard Meyst (Ex. 2001). *See infra*.
[2] (Ex. 1004) US 6,117,108, issued Sept. 12, 2000.
[3] (Ex. 1005) US 4,387,879, issued June 14, 1983.
[4] (Ex. 1006) US 5,053,014, issued Oct. 1, 1991.
[5] (Ex. 1010) WO 01/12249 A1, pub. Feb. 2, 2001.

skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'"). Only terms 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).

B. Needle Protective Device

In our Decision to Institute, we determined that the only term that required construction for purposes of that decision was "needle protective device," and that this term did *not* invoke 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Paper 8, 6–9. Petitioner disagrees, pointing out that the District Court in the related litigation construed "needle protective device" as a means-plus-function term. Pet. Reply 1–2 (citing Ex. 2001, 20–23).

Given that there is a discrepancy between the District Court's construction and the Board's, we note that, on October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial And Appeal Board, 83 Fed. Reg. 51,340 (Nov. 13, 2018). This rule change, however, applies to petitions filed after November 13, 2018, and therefore does not apply to this proceeding. *Id*.

As discussed below, we are not persuaded to deviate from our initial determination that "needle protective device" is not a means-plus-function

limitation, and we maintain our construction that "needle protective device" means a device configured to prevent unintended needle sticks.

Independent claim 18 and dependent claim 25 each recite a "needle protective device." Ex. 1001, 6:27–30, 54–57. Petitioner contends the needle protective device invokes 35 U.S.C. § 112 ¶ 6 such that it should be construed as a means-plus-function limitation. Pet. 6–9; Pet. Reply 1–2. 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.'" Pet. 9 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc). Petitioner further contends that "the modifier 'needle protective' does not impart any structure to the term 'device.'" *Id.* at 10. Petitioner's argument is supported by the declaration of Mr. Griffis, who testifies that "[t]he term 'needle protective device' is not a term used in common parlance or by persons of skill in the pertinent art to designate structure, nor has it achieved recognition as a noun denoting structure." *Id.* (citing Ex. 1002 ¶ 44).

Patent Owner disputes that the needle protective device limitation should be construed in means-plus-function format. Prelim. Resp. 5–18; PO Sur-Reply 3. Patent Owner argues that "[t]he claim language following 'needle protective device' . . . indicates the term is structural." Prelim. Resp. 17. Patent Owner notes that independent claim 18 imposes certain structural constraints on the needle protective device, such as "that the 'needle protective device' be positioned 'at least partially inside the interior cavity of the catheter hub such that the needle protective device is in-line with the catheter hub and the valve actuating element.'" *Id.* Patent Owner points out

that the dependent claims recite additional structure, such as "the 'needle protective device' comprise 'a *guard section* for blocking the needle tip'" (claim 21), and "the 'needle protective device comprises two arms extending distally of *a proximal wall*'" (claim 24). *Id.* (emphasis omitted) (citing Ex. 2001 ¶¶ 60–62; *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")).

We agree that the term "device" can be a nonce word like "means." *See Williamson*, 792 F.3d at 1350. Claims 18 and 25 do not, however, simply recite "device," but recite a "needle protective device at least partially inside the interior cavity of the catheter hub . . . [and] in-line with the catheter hub and the valve actuating element." Ex. 1001, 6:15–36, 6:43–45. Based on the entirety of the record, we are not convinced that "needle protective device" 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. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002) (explaining that "a claim term that does not use 'means' will trigger the rebuttable presumption that § 112 ¶ 6 does not apply"). Petitioner has not overcome that presumption. *See Williamson*, 792 F.3d at 1349 (noting that "[w]hen a claim term lacks the word 'means,' the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting

sufficient structure for performing that function.'"). We consider the relevant language of independent claim 18:

> positioning a needle protective device at least partially inside the interior cavity of the catheter hub such that the needle protective device is in-line with the catheter hub and the valve actuating element.

Ex. 1001, 6:27–30. Claim 18, as noted by Patent Owner in its Preliminary Response, specifies a structural relationship between the needle protective device, the catheter hub, and the valve actuating element. Prelim. Resp. 17. Although we understand that the "needle protective device" has a function, i.e. protecting the needle, it is also explicitly structurally linked to other elements in the claim. From this recitation, in the context of an intravenous ("IV") catheter, the claim imposes an express physical relationship between the recited catheter elements. Claim 25 recites:

> The method of claim 18, wherein the needle protective device comprises a resilient portion made from a metallic material for moving the needle protective device from a ready position to a protective position.

Id. at 6:54–57. Claim 25 describes both structural and functional aspects of the needle protective device; specifically, a metallic "resilient portion" (structure), which moves the needle protective device (function) between ready and protective positions (structure).

Importantly, 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 '762 patent).[6] The testimony by Mr. Meyst is persuasive evidence that one of ordinary skill in the art would have understood "needle protective device" as a structure, perhaps somewhat ambiguous as to a specific type, but a structure nonetheless, and not simply a functional recitation. *See Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998) (concluding that the term "detector" did not necessitate application of 35 U.S.C. § 112 ¶ 6, and stating that "even though the term 'detector' does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures known as 'detectors'"). Mr. Meyst also points to various prior art references that describe "needle guards" and "protective device for a needle," which, according to Mr. Meyst, a person of ordinary skill in the art would have understood as "structure in connection with IV catheters that protects the operator from unintended needlesticks." Ex. 2001 ¶¶ 55–56 (citing Exs. 2016, 2017).

Petitioner's declarant, Mr. Griffis, disagrees, stating that "'needle protective device' is a functional term that does not connote sufficiently definite structure to those of ordinary skill in the art," and it "is not a term used in common parlance or by persons of skill in the pertinent art to designate structure." Ex. 1002 ¶¶ 42–44. Mr. Griffis's testimony is, overall,

[6] Ex. 2014, U.S. RE38,996 E, which indicates on its cover page as having been assigned to Petitioner, explains that "[n]eedle guards are of three types which either hide the withdrawn needle within the needle carrying hub, require replacement of a separate needle guard or include a sliding shield which can be positioned distally over the used needle. Some of these types of guards lock to secure the guard in the needle protecting position thereby preventing injury." Ex. 2014, 1:39–45.

somewhat contradictory. For example, Mr. Griffis explains that similar descriptive terms used in journals and medical publications such as, e.g., "needlestick prevention devices . . . are used idiosyncratically by particular authors to discuss specific components or medical devices as a whole." *Id.* ¶ 46 (citing Exs. 1021–24). Thus, it may be that there is not one particular term that describes all types of needle protection devices, but Mr. Griffis's testimony is consistent in certain respects with Mr. Meyst's—i.e., that a person of skill in the art would, in context, have recognized 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." *Compare* Ex. 1002 ¶ 46, *with* Ex. 2001 ¶ 56.

As noted above, per *Williamson*, the lack of the term "means" gives rise to a rebuttable presumption that the claims are not construed under 35 U.S.C. § 112 ¶ 6. *Williamson*, 792 F.3d at 1349. Petitioner has not overcome that presumption—that is, Petitioner has not demonstrated that the term "needle protective device" recites function without reciting sufficient structure for performing that function. *See id.*

Based on the entirety of the record in this proceeding, we conclude the term "needle protective device" should not be construed under §112 ¶ 6. Instead, we agree with Patent Owner that the term "needle protective device" would have been understood by a person of ordinary skill in the art to mean a device configured to prevent unintended needle sticks. *See* Prelim. Resp. 18.

III. ANALYSIS

A. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–8 (1966).

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

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

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

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

B. Level of Ordinary Skill in the Art

In our Decision to Institute, we determined the level of ordinary skill in the pertinent art at the time of the invention. Paper 8, 9–10.

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

Accordingly, and as explained in our Decision to Institute, we determine that a POSITA would be either a medical practitioner (e.g., a nurse or doctor) having at least some experience with vascular catheter devices, or a person with a technical degree (e.g., associate's degree in engineering or physics) and having at least some experience with vascular catheter devices. Paper 8, 9–10.

C. Whether Claims 18 and 22 are Obvious over Van Heugten

Petitioner contends that claims 18 and 22 are unpatentable over Van Heugten. Pet. 30–41; Pet. Reply 1–2. We note at the outset that Patent

Owner's main opposition to this ground lies largely upon secondary considerations. *See generally*, PO Resp. As discussed below, considering the complete record developed during trial including the secondary considerations addressed further below, we find Petitioner's arguments and evidence with respect to Van Heugten and claims 18 and 22 persuasive.

1. Van Heugten (Ex. 1003)

Van Heugten is a U.S. Patent titled "Catheter with Controlled Valve." Ex. 1003, [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:

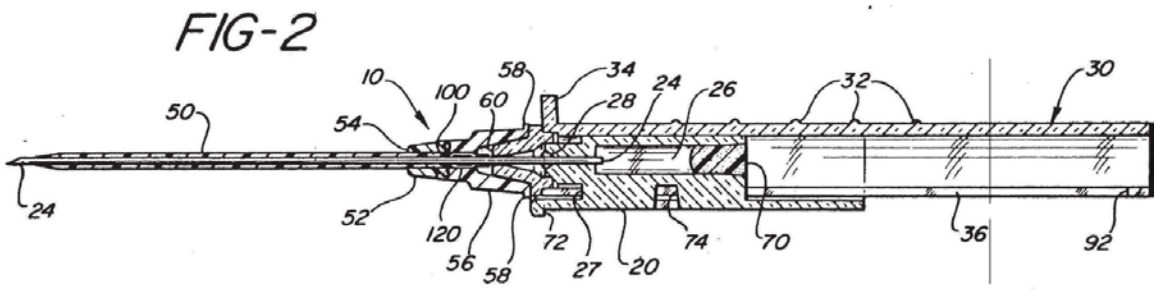
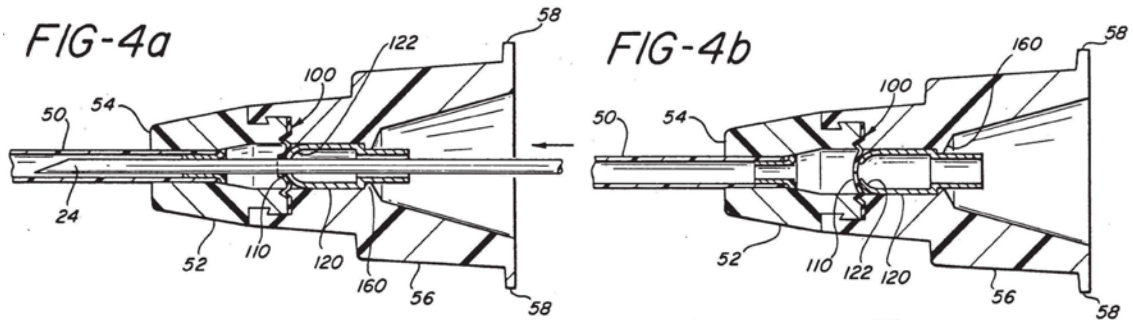


Figure 2 depicts a cross-sectional view of Van Heugten's catheter assembly 10. *Id.* at 2:9–10, 19–21. In particular, Figure 2 illustrates catheter assembly 10 with catheter tube 50 and needle 24, which needle guard 30 covers upon retraction of needle 24 to prevent inadvertent needle injury to the user or others. *See id.* at 2:36–39, 3:34–58.

Van Heugten explains how once needle 24 and catheter tube 50 are inserted initially into a patient's blood vessel, needle guard 30 is manually pushed via tab 34 and projections 32 to advance catheter tube 50 into a patient's blood vessel. *Id.* at 3:26–34. Van Heugten describes that, simultaneous with this manual pushing action, needle hub 20 and needle 24

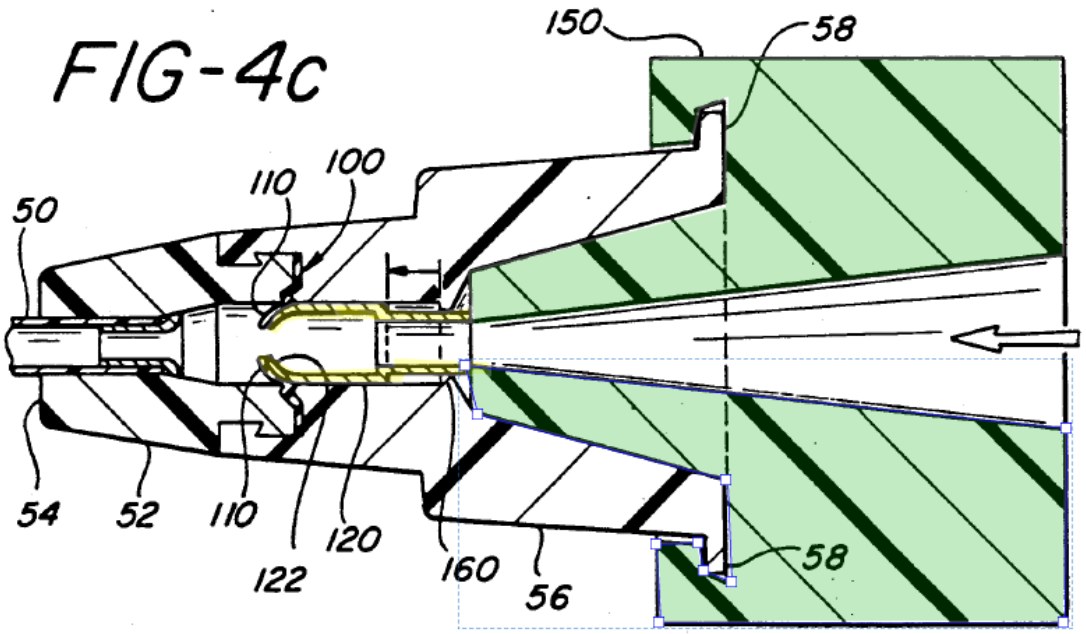
are retracted in an opposite direction so that needle 24 is withdrawn from blood vessel and catheter tube 50, and then finally safely locked into needle guard 30 so that injury is prevented. *Id.* at 3:34–58.

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 show membrane assembly 100 comprising a one-directional valve membrane 110. *Id.* at 3:59–64. In this embodiment, 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 110 closes" (*id.* at 4:6–9). Van Heugten also describes embodiments where the sealed valve membrane 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.

Figure 4c, reproduced below and annotated by the Board, illustrates membrane opener 120, highlighted in yellow, following retraction of needle 24 into needle cover 30, being contacted by luer assembly 150, highlighted in green.



Annotated Figure 4c, above, shows how luer assembly 150 attaches to catheter hub 52 and influences membrane opener 120 to open valve membrane 110. According to Van Heugten, this permits "intravenous fluids [to be] connected with the catheter 50 so that they may be diffused into the body." *Id.* at 4:40–42.

2. Petitioner's Challenge to Claims 18 and 22

Petitioner maintains that Van Heugten teaches a "catheter insertion device" that meets all the method and step limitations of claims 18 and 22, including forming catheter hub 52 and attaching catheter tube 50. Pet. 31 (citing Ex. 1003, 2: 6–15, 45–55, Fig. 3). According to Petitioner, Van Heugten discloses also positioning valve member 100, 110, and a valve actuating element 120 within catheter hub 52. *Id.* at 32–35 (citing Ex. 1003, 1:62–2:4, 3:59–4:3, 4:6–36, 43–49, Figs. 3, 4a–4c; Ex. 1002 ¶¶ 95–96). Petitioner argues that Van Heugten discloses aligning needle guard 30 in-

line with the catheter hub and illustrates needle guard tip 60 positioned "partially inside" catheter hub 52. *Id.* at 37. Needle hub 20 carrying needle 24, Petitioner contends, is located proximally of catheter hub 52 and extends through catheter hub 52 and tube 50. *Id.* at 37–38. Petitioner asserts that Van Heugten's valve member 110 closes and remains inside catheter hub 52 when the needle is withdrawn from the catheter tube and hub to prevent blood leakage. *Id.* at 38–39 (citing Ex. 1003, 1:60–2:4, 2:19–23, 2:36–40, 2:56–62, 3:59–4:3, 4:6–30, Figs. 1, 2, 3, 4a–4b; 1002 ¶¶ 100–102).

For claim 22, Petitioner argues that Van Heugten's "opener 120 is generally cylindrical in shape and contains nose-shaped opening means 122" and is essentially "truncated cone-shaped," as called for in claim 22. *Id.* at 39–40 (citing Ex. 1003, 1:62–2:4, 4:31–36, 4:43–49, Fig. 4c; Ex. 1002 ¶¶ 103–105).

3. Analysis

Patent Owner does not substantively dispute that the elements asserted by Petitioner are encompassed by Van Heugten. *See generally* PO Resp. With the complete record of the proceeding now before us, our analysis of Van Heugten as set forth in our Decision to Institute, in comparison to claims 18 and 22, has not changed. *See* Dec. Inst. 28–32. We determine, upon a review of the full record, that the scope and content of Van Heugten is consistent with Petitioner's analysis discussed above. Accordingly, we are persuaded that Van Heugten teaches all the elements recited in claims 18 and 22.

Based upon a review of the final record of all factors of the obviousness analysis, including the evidence of objective indicia of nonobviousness discussed in detail below, we are persuaded that Petitioner

has shown a by a preponderance of the evidence that claims 18 and 22 would have been obvious in view of Van Heugten.

D. Whether claim 25 is Obvious over Van Heugten and Lynn

Claim 25 recites:

> The method of claim 18, wherein the needle protective device comprises a resilient portion made from a metallic material for moving the needle protective device from a ready position to a protected position.

Ex. 1001, 6:54–57.

Petitioner contends that claim 25 is unpatentable over the combination of Van Heugten and Lynn because Lynn discloses a resilient metal spring device for retracting the needle into a protective receptacle. Pet. 41–45.

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 automatic spring actuator to retract the needle. PO Resp. 21–46. Patent Owner asserts further, that to the extent the devices *could* be combined, Petitioner has failed to adequately support the combination of Van Heugten and Lynn with sufficient facts, evidence and reasoning. *Id.*

1. Lynn (Ex. 1010)

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. 1010, 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.

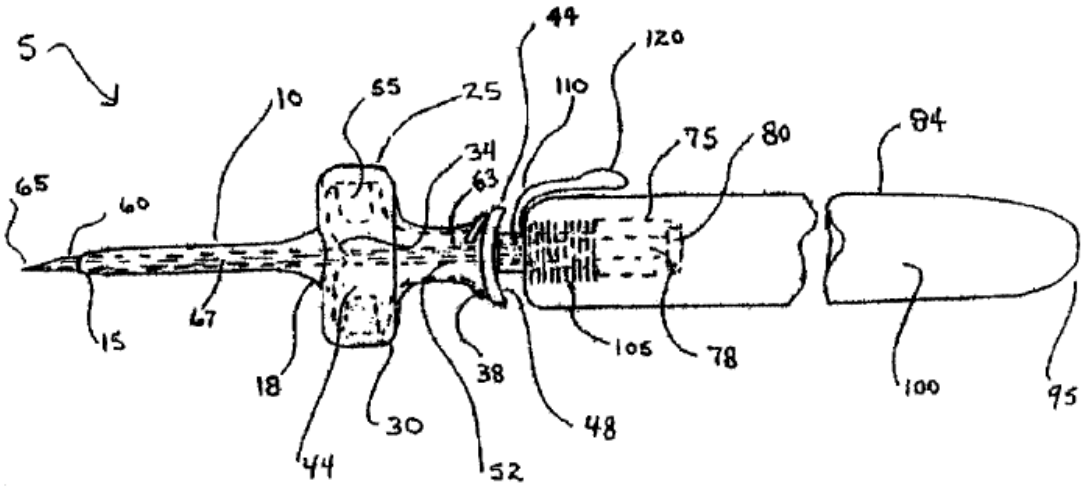


Figure 1 from Lynn, above, depicts vascular access system 5 including a needle protective device (needle receptacle 84) for receiving spring biased needle 60. Ex. 1010, 7:11–28. According to Lynn, when a user depresses button 120, "finger pressure against the button 120 causes the retainer 110 to shift 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.* at 7:15–26.

2. Petitioner's Challenge to claim 25

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. Pet. 42 (citing Ex. 1002 ¶ 121). Petitioner asserts that the benefits of automating the retraction function were known in the art, as discussed for example by Cuppy (Ex. 1011), 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 44 (citing Ex. 1011, 2:52–58).

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, Abst., Fig. 2). Relying on Mr. Griffis, Petitioner argues that one of ordinary skill in the art would understand Van Huegten and Lynn to be a "combination of known elements to function for their intended result. A [person of ordinary skill in the art] would have understood that there are a finite number of ways to provide needle protective device configured in this way, and would have found this to be a predictable solution." *Id.* at 45 (citing Ex. 1002 ¶ 120).

3. Patent Owner's Argument

Patent Owner contends that Petitioner's arguments that Van Heugten can be readily modified and automated, and that there are a finite number of ways to provide needle protection, are not supported by sufficient evidence. PO Resp. 21–22. 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 "what its proposed combination is, e.g., whether it is proposing to (a) replace components of Van Heugten with components of Lynn, (b) add components from Lynn to Van Heugten, or (c) something else." *Id.* at 27–28.

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 29–30 (citing Ex. 2029 ¶¶ 68–70). Patent Owner's declarant, Mr. Meyst, testifies that a person of ordinary skill in the art would not simply add an automated spring operated needle retraction device to Van Heugten's manual catheter insertion/needle protective function because "a POSITA would have understood that automating the manual catheter insertion process required in Van Heugten would harm a patient by jamming a catheter improperly and with too much force into a vein." Ex. 2029 ¶ 70.

4. 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 is automated." Pet. 42. In both devices, Petitioner argues, "accidental needle pricks are prevented by similarly encasing the needle tip in a needle protective device." *Id.* (citing Ex. 1010, 7:15–28, 8:9–13, Fig. 1; Ex. 1002 ¶¶ 116–122). 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. 1002 ¶¶ 117–119. Mr. Griffis also testifies persuasively that automation of needle retraction was known in the art to ensure full retraction of a needle. *See id.* ¶ 121 (citing Ex. 1011, 2:52–62; Ex. 1012, 57(6):572-7, Abst.).

Petitioner and Mr. Griffis's arguments and testimony present a general summary of Van Heugten and Lynn's components and function of retracting the needle into a protective hub. *See, e.g.*, Pet. 42 ("Van Heugten prevents accidental needle sticks when the user of the device applies a linear force to encase the needle tip within the needle protective device."). 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. *Id.* Although this end result is similar for both prior art references, both devices accomplish the task in very different ways and with different structure. 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* would they have been combined.

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 or cause the motion that's described in claim 25 of the '762 patent.

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 Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007) ("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").

A Finite Set of Choices

Petitioner attempts to buttress its arguments for obviousness of claim 25 by arguing that "A POSA would have understood that there are a finite number of ways to provide needle protective device configured in this way." Pet. 45 (citing Ex. 1002 ¶ 120). Mr. Griffis reiterates this position in his testimony stating that use of Lynn's resilient retraction mechanism "amounted to nothing more than selecting a configuration of a needle protective device within a catheter insertion device from among a finite set of choices." Ex. 1002 ¶ 121.

Where it can be shown that there are a finite number of solutions to a problem, then the Board will weigh that evidence in its obviousness analysis. *See KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known

options within his or her technical grasp."). If a sufficient showing can be made as to a dearth of alternatives, then the purported invention is likely obvious to one of ordinary skill in the art. *See id.* ("If [pursuing known options] leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.").

Petitioner and its declarant, however, are complicit in their failure to provide any evidence to support this conclusion beyond the statement that Lynn's needle protective device is one of a "finite set of choices." *Compare* Pet. 45, *with* Ex. 1002 ¶ 121. Petitioner has not provided evidence or reasoning to suggest that the possible approaches to solve the problem are "known and finite" or that one of ordinary skill had "good reason to pursue the known options within his or her technical grasp." *See Takeda Chem. Indus. v. Alphapharm Pty.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (discussing the requirements of an "obvious to try" -type obviousness rejection).

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.'" Pet. 44 (citing Ex. 1011, 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 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 and Mr. Meyst assert that automating Van Heugten's retraction of the needle, which occurs simultaneously and in concert with manual advancement of the catheter "would replace a user's careful insertion of the catheter into a vein with an automated and uncontrolled springing of the catheter into the vein," potentially causing injury and kinking of the catheter tube. PO Resp. 33 (citing Ex. 2029 ¶¶ 76, 81). Whether or not this would truly be the result of a combination that could have been accomplished by a person of ordinary skill in the art exercising ordinary creativity, we need not decide here. Patent Owner's argument, however, 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 25 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 25 is obvious over Van Heugten and Lynn.

E. Whether claim 25 is Obvious over Woehr (Ex. 1004) and Tauschinski (Ex. 1005)

Petitioner contends that claims 18, 22, and 25 are unpatentable over Woehr and Tauschinski. Pet. 3, 10–40. Because we have determined that claims 18 and 22 are unpatentable over Van Heugten, we address only Petitioner's challenge to claim 25.

1. Woehr (Ex. 1004)

Woehr is a U.S. Patent titled "Spring Clip Safety IV Catheter" and discloses a "catheter in which the needle tip is automatically covered after needle withdrawal to prevent the health-care worker from making accidental contact with the needle tip." Ex. 1004, [54], 1:8–11. Figure 1A illustrating Woehr's catheter is reproduced below:

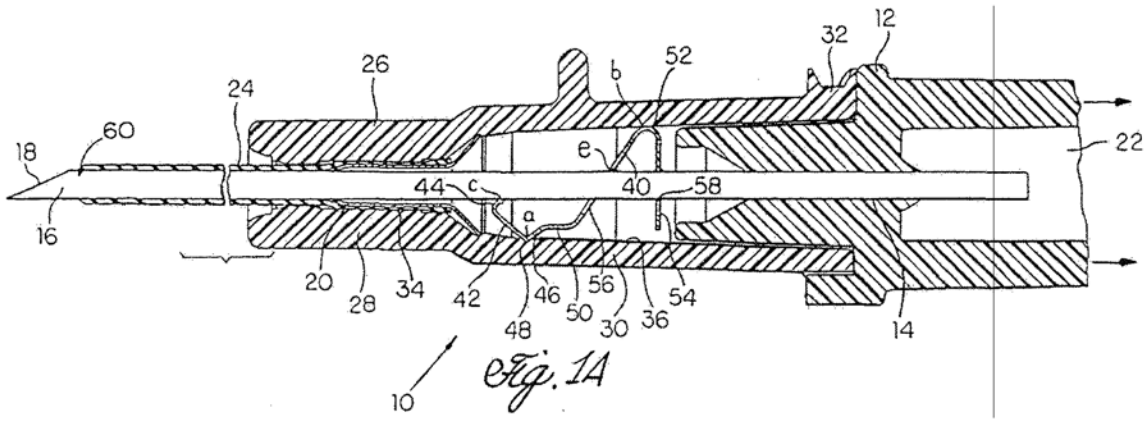
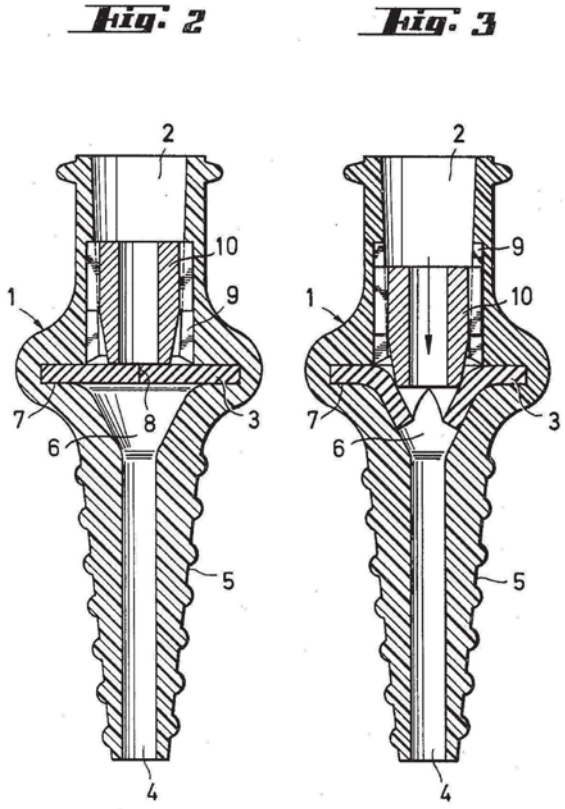


Fig. 1A

Woehr describes Figure 1A as depicting catheter 10 including needle hub 12, needle 16 with needle tip 18, catheter hub 26, and needle guard 40 in the form of a unitary spring clip. *Id.* at 4:8–28, 50–51. Functionally speaking, as needle 16 is withdrawn from a patient, needle guard 40 "automatically snaps into a retracted position" to block needle tip 18 to prevent accidental contact to the health care practitioner. *Id.* at 4:43–49.

2. *Tauschinski (Ex. 1005)*

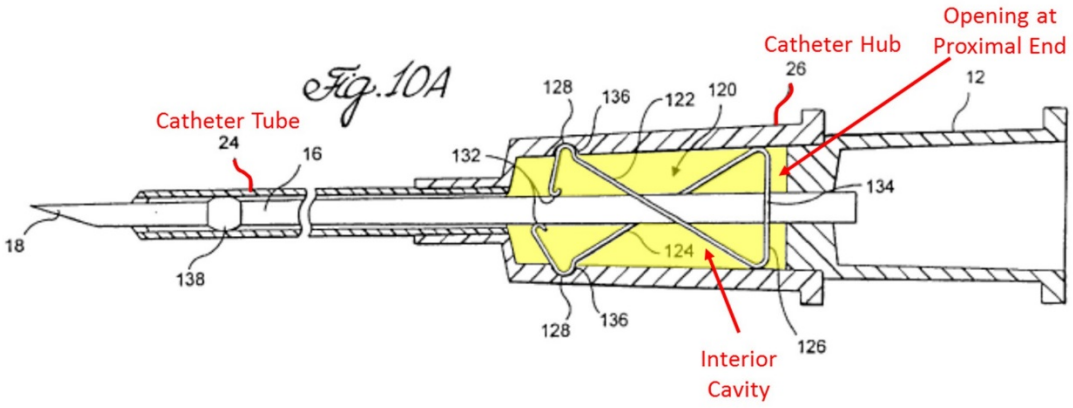
Tauschinski is a U.S. Patent titled "Self-Sealing Connector for Use with Plastic Cannulas and Vessel Catheters" and discloses a connector that will close automatically when a corresponding catheter is pulled from the connector, thereby "prevent[ing] an emergence of blood or an ingress of air" through the connector. *See* Ex. 1005, [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.

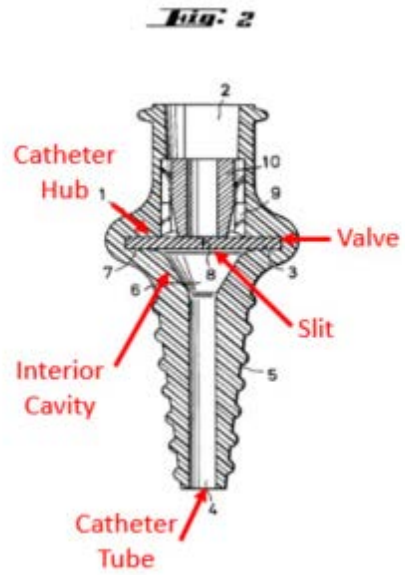
3. *Petitioner's Challenge to Claim 25*

In challenging claim 25, Petitioner submits that Woehr discloses a "catheter insertion device" comprising a "catheter hub," "needle," and "needle protective device." *See* Pet. 14–15, 21–24 (challenging independent claim 18). To illustrate, Petitioner submits an annotated version of Woehr's Figure 10A, which we reproduce below:



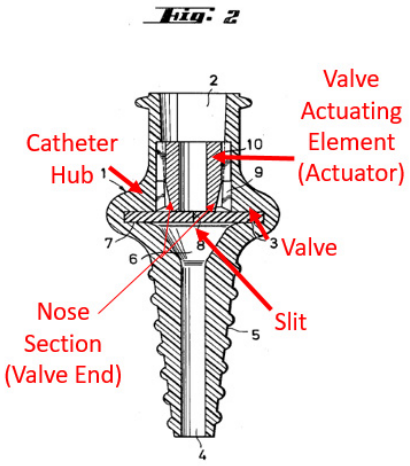
According to Petitioner, and referring to annotated Figure 10A, Woehr discloses the claimed "catheter hub" and "body," "interior cavity," (highlighted element 120) including the step of "positioning a needle protective device at least partially inside the interior cavity" (element 120). *Id.*

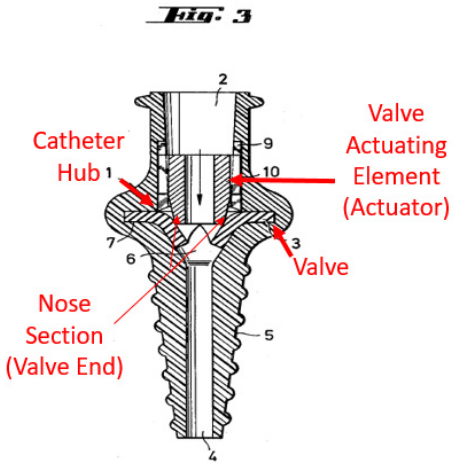
Addressing the claimed step of "positioning a valve," Petitioner relies on Tauschinski and reasons that it would have been obvious to modify Woehr to include Tauschinski's valve in the catheter hub. *See id.* at 15–18 (citations omitted). In relying on Tauschinski, Petitioner submits an annotated version of Tauschinski's Figure 2 (*id.* at 16), which we reproduce below:



Petitioner asserts that Tauschinski discloses valve 3 with slit 8 configured to obstruct fluid flow through catheter hub 1. *Id.* at 15–16 (citing Ex. 1005, 3:14–19). Petitioner reasons that it would have been obvious to modify Woehr "by adding protective elements, such as a valve to prevent the emergence of blood," as disclosed by Tauschinski. *Id.* at 17 (citing Ex. 1002 ¶¶ 63–68).

To address the claimed step of "positioning a valve actuating element" Petitioner submits additional annotated versions of Tauschinski's Figures 2 and 3, which we reproduce below:





According to Petitioner, and as shown in the above Figures 2 and 3, Tauschinski allegedly discloses valve actuating element 10 slidingly disposed in catheter hub 1, and configured to actuate valve 3 to open slit 8. *Id.* at 19 (citing Ex. 1005, 3:20–36).

With respect to "positioning a needle hub," Petitioner argues that Woehr discloses a needle hub 12 and needle attached to the catheter hub so that "the needle projects through the catheter hub and the catheter tube" as called for in claim 18. *Id.* at 24–25. Further, Petitioner contends that with a valve such as disclosed by Tauschinski combined with Woehr's catheter insertion hub, the valve would logically, and predictably, have to remain in the catheter hub after removal of the needle "to prevent fluid flow through the device and out of the proximal end of the catheter." *Id.* at 26–27 (citing Ex. 1002 ¶ 82).

In summary, Petitioner reasons that

> It would have been apparent to a POSA that such a valve could be introduced into the catheter insertion device of Woehr '108 without compromising the function of the instrument, while at the same time, providing a readily implementable solution to the

> well-recognized problem of mitigating blood outflow from a catheter insertion device.

Id. at 17.

4. Patent Owner's Argument

Patent Owner argues that Petitioner has not supported the combination of Woehr and Tauchinski with proper evidentiary underpinnings. PO Supp. Resp. 4–11. Patent Owner argues, specifically, that Petitioner's declarant, Mr. Griffis, fails to provide objective evidence to support his testimony, and is, therefore, unsupported and conclusory testimony. *Id.* at 4–7. For example, Patent Owner points out that Mr. Griffis states "'[t]he device in Woehr '108 *could* be improved by adding protective elements.'" *Id.* at 7 (citing Ex. 1002 ¶ 65). In addition, according to Patent Owner, the evidence shows that a person of ordinary skill in the art would not have combined Woehr and Tauschinski because of significant design challenges. *Id.* at 11–22.

Patent Owner contends that ISO standards and design tolerances in IV catheter devices significantly constrain the space available to accommodate a valve, actuator, and safety needle spring guard. *Id.* at 14 (citing Ex.1026, ISO 594-2; Ex. 2020, ISO 594-1). Patent Owner argues that "in Woehr-108 and Tauschinski, the same distal part of the interior wall has two incompatible features: an **annular bump or groove** in Woehr-108 to engage and retain the needle protective device, and **axial grooves** in Tauschinski to engage a slidable actuator." *Id.* at 16. Mr. Meyst supports Patent Owner's position explaining that, "a [person of ordinary skill in the art] would understand that combining Woehr '108 and Tauschinski would require the

accommodation of two incompatible features in the same location." Ex. 2001 ¶ 68.

5. Whether Petitioner has provided sufficient rational underpinning to support the combination of Woehr and Tauchinski

Petitioner argues that its reasoning and evidence is sufficient to show that a person of ordinary skill in the art would have known the benefits of blood control, and that "accommodate[ing] both a valve and actuator mechanism and a needle protective device would have been a routine modification, in that it simply calls for modifying the size of the catheter hub or actuator to accommodate the additional components." Pet. Reply 41 (citing Ex. 1036 ¶¶ 38–42).

Petitioner's declarant, Mr. Griffis, arguably provides a reason to combine Woehr and Tauschinski, that is— preventing blood leakage from Woehr's catheter and needle tip protection assembly would be a safety improvement. *See* Ex. 1002 ¶ 65 ("One would understand that the device in Woehr '108 could be improved by adding protective elements, such as a valve to prevent the emergence of blood."). Mr. Griffis relies on a third reference, Van Heugten (discussed above), as evidence to support his reasoning that one of ordinary skill could have added Tauschinski's actuator and valve to Woehr "so as to reduce the risk of transmitting blood-borne diseases to medical personnel." *Id.* ¶ 66 (citing Ex. 1003, 1:15–18). Mr. Griffis testifies also that a person of ordinary skill in the art would have found it predictable to improve Woehr with Tauchinski's actuator and valve because "there are a limited number of ways to position the valve in the catheter hub, and doing so is a known arrangement." *Id.* ¶ 67.

From a structural design and compatibility standpoint, Mr. Griffis states that it would have been "a matter of routine design to make a space in the catheter hub of Woehr '108 to accommodate the valve and valve actuator of Tauschinski." *Id.* ¶ 71. Mr. Griffis states that even under the universal standard of ISO 594-2 (1998) "[a]s shown in Tauschinski, [] there was sufficient space in a catheter hub to incorporate a valve and an actuator." *Id.* ¶ 78.

Patent Owner's declarant, Mr. Meyst, does not dispute that Woehr discloses a "needle guard element," or that Tauschinski teaches a valve and an "axially slidable actuator." Ex. 2001 ¶¶ 65–71. Mr. Meyst testifies, on the other hand, that although these were known elements of separate devices, "[c]ombining these two incompatible features would be a significant design challenge for a [person of ordinary skill in the art]." *Id.* ¶ 70. Specifically, Mr. Meyst explains that the "annular bump or groove" on the inside surface of the catheter hub that engages and retains Woehr's needle protective device is incompatible with the axial grooves disclosed by Tauschinski which guide the slidable actuator. *Id.* According to Mr. Meyst, space is very constrained within the catheter hub which would have created significant design challenges for one of ordinary skill in the art to add a valve and slidable actuator to Woehr's structure. *Id.* ¶ 71. Mr. Meyst testifies that in light of the strict design tolerances proscribed by ISO 594-1 (1986) for a catheter hub, the combination of a valve and slidable actuator with Woehr's needle protective device, "would require the accommodation of two incompatible features in the same location." *Id.* ¶ 68. Mr. MeystMeyst points out that both Woehr's bump or groove, and Tauschinski's axial guide grooves are incompatible because they are

similarly located in the "distal part of the interior wall of the catheter hub." *Id.* ¶¶ 69–70.

Mr. Griffis responds, explaining that the structural accommodation of Woehr with Tauschinski's valve could have been accomplished by a person of ordinary skill in the art, ostensibly by enlarging the length or width of the catheter hub. Ex. 1036 ¶ 40. Petitioner argues that this "would have been a routine modification, in that it simply calls for modifying the size of the catheter hub or actuator to accommodate the additional components." Pet Reply 41 (citing Ex. 1036 ¶¶ 38–42).

We agree with Patent Owner, however, that it is not enough to argue that the combination of elements was possible. PO Sur-Reply 20. Evidentiary underpinnings require more than the elements are simply found in the prior art. *See Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) ("obviousness 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 to insert Tauschinski's connector valve and actuator into a catheter hub with Woehr's needle guard. *See* Ex. 1002 ¶ 76 (Mr. Griffis states that the valve, actuator and needle protective device is "a predictable variation of known concepts, which, when combined, would yield [a] predictable [] result."), *see also* Ex. 1036 ¶ 35 ("A [person of ordinary skill in the art] would have known how to incorporate a valve and valve actuator as described in Tauschinski in a catheter hub."). We find Petitioner's arguments to consist mainly of

uncorroborated conclusions. For example, even if the catheter hub were lengthened to permit Tauschinski's connector valve and sliding actuator to be positioned axially distal of Woehr's needle guard, Mr. Griffis provides no detail as to how the actuator would function, e.g., be motivated to open and close the valve, with Woehr's needle guard now positioned between the needle hub and the valve actuator. We know from the '762 patent, that one way to do this could be to employ plunger sections 10b, as shown in Figures 1–4 of the '762 patent. Ex. 1001, 2:47–54. Petitioner has not, however, explained this critical structural and functional aspect of the asserted combination. Besides which, any reliance on the '762 patent would be the epitome of hindsight.

We are not persuaded that simply because blood control and needle stick prevention were known concerns in the medical field, and that such components existed independently in prior art references, that it was simply a matter of routine that they could be incorporated into the same catheter hub. *See* Ex. 1002 ¶ 78 (Mr. Griffis states that "it would have been a matter of routine design to accommodate a valve and a valve actuator alongside a spring clip within the space in the catheter hub of Woehr '108."). Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). Mr. Griffis's declaration does not provide persuasive facts, data, or analysis to support the stated opinion. Without such testimony, we are not persuaded that the mere existence of the elements, and the allegation that such a combination could be effected, is sufficient to support a finding of obviousness. *See* Ex. 1002 ¶ 75; *see also* Ex. 2062, 27:9–15 (Petitioner's employee stated that one reason for not commercializing such a device was

that "[t]here were some functional issues that were seen as very negative by clinicians so that they -- it was doubtful that they would accept the technology, the functionality of the valve.").

We are also not swayed by Petitioner's argument that there are a finite number of ways in which this could be accomplished. *See* Pet. 27; *see also* Ex. 1002 ¶ 67. Neither Petitioner, nor its declarant, has provided evidence or reasoning to suggest that the possible approaches to solve the problem are "known and finite" or that one of ordinary skill had "good reason to pursue the known options within his or her technical grasp." *See Takeda Chem. Indus. v. Alphapharm Pty.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (discussing the requirements of an "obvious to try" -type obviousness rejection).

With respect to Petitioner's reference to Van Heugten, illustrating that a valve can be implemented with a catheter and needle protective device, this does not show persuasively why one of skill in the art would combine Woehr and Tauschinski. The simple fact that Woehr could be modified does not satisfy the requirements for a finding of obviousness. *In re Laskowski*, 871 F.2d 115, 117 (Fed. Cir. 1989); *In re Mills*, 916 F.2d 680,682 (Fed. Cir. 1990). 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 valve and slidable actuator to adequately support a finding of obviousness.

Having considered the evidence in the complete record established during trial, including the evidence of secondary considerations discussed below, we are not persuaded that Petitioner has shown by a preponderance of the evidence that claim 25 is obvious over Woehr and Tauschinski.

F. Objective Evidence of Non-Obviousness

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 '762 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 '762 patent in trying to satisfy this need, leading to the development of its Insyte Autoguard BC product ("IAG-BC") product. PO Resp. 68–70. Patent Owner alleges that both Petitioner and Patent Owner developed and introduced products embodying the invention of the '762 patent, which have both been commercially successful,

and that the objective evidence demonstrates that Petitioner had earlier failed to develop such a product." *Id.* at 68.

Analysis of evidence of secondary considerations begins with an evaluation of a causal relationship, or nexus, 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. PO Resp. 46–80. Petitioner responds, also addressing each of these factors. *See* Pet. Reply 14–25. Below, we address each of these secondary consideration factors in turn, first, determining whether Patent Owner has established that certain commercial products embody the claimed invention giving rise to a presumption of nexus.

1. Nexus of Patent Owner's IS3 product

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 Resp. 48–54, claim chart; Ex. 2029 ¶¶ 110–123; *see also* Exs. 2107 (describing the IS3 as covered by the '762 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 18 and 25. PO Resp.. 48–54, claim chart. Patent Owner supports its analysis with testimony from Mr. Meyst, who states that "[i]t is my opinion that Patent Owner's method of manufacturing its Introcan Safety 3 ("IS3") product meets all of the elements of, and, therefore, is covered by at least claims 18 and 25 of the '762 patent." Ex. 2029 ¶ 110.

Petitioner does not expressly dispute that Patent Owner's IS3 product is covered by the '762 patent, but argues that Patent Owner "offered no explanation or evidence that IS3 is *coextensive* with the claimed invention." Pet. Reply 16 (citing *Demaco*, 851 F.2d at 1392). Specifically, Petitioner argues that Patent Owner has failed to analyze whether the commercial success of the IS3 was due to the '762 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 claims 18 and 25 together describe a method of manufacturing essentially a complete catheter IV insertion device, including that the needle protective device "comprises a resilient portion made from a metal material." Ex. 1001, 6:15–36, 55–56. The claimed invention is not merely a component of the IS3 product, but

reasonably describes manufacture of a complete catheter insertion device, essentially soup to nuts, including *inter alia*, forming 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.[7] 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. *See* PO Resp. 48–54. 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 18 and 25. *See, e.g.*, Ex. 2029 ¶¶ 112–123. 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 '762 patent are not reasonably coextensive with the IS3 product.

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 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

[7] Claims 18 and 22 do not specifically claim the visually apparent "wings" which appear to extend on either side of the IS3 catheter hub. *See* 2029 ¶¶ 124–125 (Mr. Meyst explains that "[t]he Introcan Safety, [] comes either with or without wings.").

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).

2. Nexus of Petitioner's IAG-BC product

Similarly, the evidence provided by Patent Owner regarding Petitioner's IAG-BC product is also sufficient. PO Resp. 54–63 (citing Ex. 2029 ¶¶ 86–109; Ex. 2035; Ex. 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, 22, and 25. PO Reply. 54–60, claim chart. Patent Owner supports its claim chart analysis with testimony from Mr. Meyst, who states that "[i]t is my opinion that Petitioner's method of manufacturing its IAG-BC product meets all of the elements of claims 18, 22, and 25 of the '762 patent." Ex. 2029 ¶ 86.

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 17. Petitioner argues that Patent Owner and Mr. Meyst's analyses are "cursory" and that Mr. Meyst did not analyze the order in which the IAG-BC product is manufactured. *Id.* Petitioner's argument regarding the order of the methods steps is not persuasive because, on their face, the method claims do not require a certain order, nor have we

interpreted the claims as restricted to any order. *See Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one."). In addition, we do not agree that Patent Owner's analysis of the IAG-BC product in comparison to the claims is "cursory." The claim chart showing the IAG-BC product in comparison to claims 18, 22, and 25 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. 54–63. 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 18, 22, and 25. *See* Ex. 2029 ¶¶ 86–109. Further, although the "needle protective device" limitation is certainly disputed, our interpretation suggests that the IAG-BC may have such a device.

Petitioner also argues that Mr. Meyst did not "understand the claim term 'in-line,'" and thus has no basis to make a comparison. Pet. Reply 18 (citing Ex. 1033, 91:11–13). We disagree that this deposition testimony undermines Mr. Meyst's comparison. The attorney's questions, and Mr. Meyst's answers, discuss whether the term "in-line" means that the elements are not only sequential, but can also be arranged "side-by-side" and "inside each other." *See* Ex. 1033 86:4–91:13. Mr. Meyst's answer—that he hadn't considered this question of the elements being side-by-side one another, does not contradict his testimony that "in line" elements are sequential.

Overall, Mr. Meyst was clear that "in-line" at least means sequential and "next to each other":

> Q. And is the catheter hub in Figure 1 in line with the spring clip, Element 13?
>
> A. The catheter hub is in line. These are lined up together, the catheter hub extends a little bit beyond the spring clip. So it's in line.
>
> Q. Earlier you said that in line means that they are sequential, and one after another, as opposed to side by side.
> Do you remember saying that?
>
> A. Meaning that they are – they are not just next to each other. That they are lined up.

Id. at 90:16–91:5.

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 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, n. 4. Our analyses and resulting determinations, of course, relate solely to patentability of claims, 18, 22, and 25 of the '762 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 that 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 relies 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.

3. Long-Felt 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. 68–70 (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]

By way of example, testimony from Mark Crawford, an employee of Petitioner, states [redacted]

[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 Petitioner [redacted]

For example, Mr. Crawford also indicated that [redacted]

[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] *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.

4. 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) (emphases added).

Patent Owner contends that both its IS3 product and Petitioner's IAG-BC product embody the claimed features of claims 18, 22, and 25 of the '762 patent. PO Resp. 48 (citing Ex. 2107; Ex. 2029 ¶¶110–123). Patent Owner's evidence of copying rests mainly [redacted] Specifically, Patent Owner alleges, "Petitioner, by copying the features disclosed in the '325 application and claimed in the '762 patent, successfully developed a straight catheter combining needle stick protection with blood control technology." *Id.* at 75. 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 compelling 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. 74 (citing Ex. 2063, 40:7–10). 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. 51, 57. 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 noninfringement 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").

We have reviewed Patent Owner's evidence (PO Resp. 71–73) establishing that [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 '762 patent) over alternative designs. *Id.* at 73. Thus, according to Patent Owner, Petitioner incorporated into the IAG-BC the same blood

control features disclosed in the ’325 application. *Id.* at 74 (citing Ex. 2029 ¶¶ 91–93, 101–104).

Petitioner argues that there cannot be copying because the IAG-BC is not covered by the claims of the ’762 patent, and because Petitioner has not produced “*any* evidence” of efforts to replicate a specific product. Pet. Reply 23–24. 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. 1033, 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.* at 24; Ex. 1036 ¶ 47. 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,” Petitioner argues that catheters with valves, valve actuators, and needle protection were known in the art long before the priority date of the ’762 patent. Pet. Reply 24–25 (citing Ex. 1003, 3:62–64, 4:6–19, 4:43–49, Figs. 2, 4c; Ex. 1028, 7:29–8:1, Fig. 15; Ex. 1085; Ex. 1086; Ex. 1088; Ex. 1094, 1:20–21, 5:21–23, 6:14–43, 6:67–7:14, Fig. 19). Petitioner also contends that its specific valve and valve actuator design are materially distinct from the designs in the ’762 patent and its priority documents and are covered by its own patents. *Id.* (citing Ex.1036 ¶¶ 47–48). Further, Petitioner notes that several of its patents were issued over the ’762 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.* Thus, according to Petitioner, Patent Owner's copying evidence is nothing more than ordinary competitive behavior. *Id.*

Based on the complete record before us, Patent Owner presents no persuasive 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. Indeed, 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, to the extent that Patent Owner relies essentially on IAG-BC's alleged infringement of the '762 patent to establish copying, 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. 71) 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 '762 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 '762 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.

5. 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 '762 patent and Petitioner defines the market broadly to encompass both blood control flow and nonblood control products. *Compare* PO Resp. 75–78, *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 decrease sales for the other. *See* Pet. Reply 19, n.6 [redacted] Ex. 2101 ¶ 11; Ex. 1035 ¶ 22. Ms. Stamm testifies for Petitioner that [redacted] The record before us establishes that safety IV catheter products with or without the blood control technology directly compete in the same market. *See* Ex. 1035 ¶ 36 [redacted] Thus, for example, we do not find persuasive [redacted]

[redacted]." PO Resp. 75–76. [redacted]

Considering just the relevant market, [redacted] PO Resp. 76. [redacted] *Id.* at 77.

Patent Owner contends that both the IAG-BC and IS3 are successful from a revenue perspective. *Id.* [redacted]. *Id.* Patent Owner also relies [redacted].

Patent Owner also argues that the IAG-BC and IS3 have received praise. *Id.* at 79. For example, Patent Owner relies [redacted]

[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 14–21. [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).

Petitioner presents evidence, which we find persuasive, that neither the IS3 nor the IAG-BC product 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] *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]

[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 that [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. Petitioner has also presented persuasive evidence that [redacted]. Ex. 1035 ¶ 40. IAG and IAG BC also both have active needle protection with a push button shielding technique that allows clinicians more control over the process. *Id.* ¶ 41. [redacted] Patent Owner and Mr. Napper do not persuasively address these features 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 '762 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]

[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 '762 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.

G. Conclusion as to Claims 18, 22, and 25

Petitioner has presented a strong case of obviousness of claims 18 and 22 based on Van Heugten. As discussed above, Patent Owner has established a minimal 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 and some evidence of praise in the form of customer surveys, 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. Patent Owner also has also presented some evidence of praise in the form of customer surveys. Thus, we weigh the factor of commercial success and industry praise only slightly favorable toward Patent Owner.

We weigh the totality of the evidence of secondary considerations together with our other strong findings of obviousness based on Van Heugten. Based on the foregoing, after consideration of all of the *Graham* factors on the full record before us, we are persuaded that Petitioner has established by a preponderance of evidence that claims 18 and 22 would have been obvious over Van Heugten as the marginal weight of secondary considerations does not overcome the strong evidence of obviousness over Van Heugten. These secondary considerations add minimally in the totality of our determinations and the weight we accord to our findings of nonobviousness of claim 25.

H. Motions to Exclude

Both Patent Owner and Petitioner filed Motions to Exclude certain evidence, and timely opposed each other's motions. *See* Papers 56, 58, 62, 64.

Patent Owner's Motion to Exclude

Patent Owner moves to exclude Exhibits 1083–1086, 1088–1095, 1097, 1098, 1102, and portions of Exhibit 1036. Our determinations do not rely upon Exhibits 1085, 1086, 1088, 1090, 1093, 1097, 1098, 1102,

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.[8] 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, 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. Pet. Opp. Mot. Exclude 7–8. 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. 4.

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

[8] 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.

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, 68 (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. 68 (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 that Petitioner relies upon, *because* it is from the same line of questioning and the same deposition relied upon by Patent Owner, is highly probative of the issue of long-felt need in this proceeding. Patent Owner essentially asks us to apply a double standard here, however, 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." Pet. Opp. 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.

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]. 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. 3–4.

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]

[redacted]. Ex. 1091; Ex 1092.

Patent Owner's Motion to Exclude Exhibits 1090 and 1091 is DENIED.

Exhibits 1094 and 1095

Exhibit 1094 is US Patent No. 5,954,698, and Exhibit 1095 is U.S. Patent No. 5, 501,675. 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 '762 patent. *See, e.g.*, Pet. Reply 13; Ex. 1036 ¶ 19. 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 purported objective indicia of nonobviousness set forth in Patent Owner's Response. Pet. Opp. Mot. Exclude, 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 '762 patent. PO Mot. Exclude 6 (citing Ex. 1036). 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, are generally used to reinforce Petitioner's explanation of the background knowledge in the art, i.e., that IV devices including both needlestick protection and blood control were known in the art. *See* Pet. Reply 11–14. 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 the context of secondary considerations, for example to rebut assertions of long-felt need, and in direct response to arguments raised in Patent Owner's secondary considerations. *Compare* PO Response 63 (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 13 (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.").

In any event, these exhibits are referred to in our Decision only with respect to our analysis of secondary considerations and the general knowledge of one of ordinary skill in the art. Accordingly, we give them little weight and only to the extent that they are essentially cumulative to Van Heugten in consideration of long-felt need.

Patent Owner's Motion to Exclude Exhibits 1094 and 1095 is DENIED.

Exhibit 1036

Patent Owner argues that paragraphs 14–24, 27–29, 31–34, 36, 43, and 49, 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.

Petitioner's Motion to Exclude

Petitioner seeks to exclude a host of Patent Owners evidence relating to objective indica of nonobviousness as either, irrelevant under FRE 402 and 403, or as unauthenticated under FRE 901. *See* Pet. Mot. Exclude, 1. Without excluding this evidence, we have determined that Petitioner has demonstrated the unpatentability of challenged claims 18 and 22. Thus, the motion to exclude is moot as to our determination for these claims.

As to claim 25, 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 claim 25. For these reasons, Petitioner's motion to exclude is DENIED.

IV. SUMMARY

For the reasons expressed above, we determine that Petitioner has established by a preponderance of the evidence that claims 18 and 22 are unpatentable over Van Heugten and that claim 25 is not unpatentable over Van Heugten and Lynn, or Woehr and Tauschinski.

V. ORDER

In view of the foregoing, it is hereby:

ORDERED that claims 18 and 22 of the '762 patent have been determined to be unpatentable in this *inter partes* review, and that claim 25 has not been determined to be unpatentable;

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

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

FURTHER ORDERED that this is a Final Written Decision under 35 U.S.C. § 318(a) and that parties to the proceeding seeking judicial review of the decision under 35 U.S.C. § 319 must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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