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571-272-7822

Paper No. 8
Entered: November 2, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REPRO-MED SYSTEMS, INC.,
Petitioner,

v.

EMED TECHNOLOGIES CORPORATION,
Patent Owner.

Case IPR2018-00981
Patent 9,808,576 B2

Before JOSIAH C. COCKS, MICHAEL W. KIM, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

DECISION DENYING INSTITUTION
35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner, Repro-Med Systems, Inc. ("RMS"), filed a Petition ("Pet.") requesting *inter partes* review of claims 1–3 (the "Challenged Claims") of U.S. Patent No. 9,808,576 B2 (Ex. 1001, the "'576 patent"). Pet. 1. Patent Owner, EMED Technologies Corp. ("EMED"), filed a Preliminary Response ("Prelim. Resp.") to the Petition. Paper 7. We have jurisdiction under 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4(a) (permitting the Board to institute trial on behalf of the Director).

To institute an *inter partes* review, we must determine whether the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we determine that RMS has not established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. So we do not institute an *inter partes* review.

A. Related Matters

The '576 patent is the subject of an infringement suit in the U.S. District Court for the Eastern District of Texas, in a case styled: *EMED Tech. Corp. v. Repro-Med Sys., Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:17-cv- 00728-JRG (E.D. Tex.). Pet. 6; Paper 6, 2.

The ’576 patent is related to U.S. Patent Nos. 8,500,703 (the “’703 patent”) and 8,961,476 (the “’476 patent”), both of which are the subject of two additional patent infringement suits: *Repro-Med Sys., Inc. d/b/a/ RMS Medical Product v. EMED Tech. Corp.*, Case No. 2:13-cv-1957- TLN-CKD (E.D. Cal.) (involving the ’703 patent) and *EMED Tech. Corp. v. Repro-Med Sys., Inc. d/b/a/ RMS Medical Products*, Case No. 2:15-cv-1167 (E.D. Tex.) (involving the ’476 patent). Pet. 5; Paper 6, 2. The ’703 patent is the subject of an *ex parte* reexamination. Pet. 5; *see also* Ex. 1008 (providing certain file history for the reexamination, Control No. 90/013,585). Certain claims of the ’476 patent were found unpatentable in IPR2015-01920 and that decision is currently on appeal. Pet. 5–6; Paper 6, 2.

B. The ’576 Patent

The ’576 patent, titled “Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle,” issued November 7, 2017, with claims 1–3. Ex. 1001, (54), (45), 14:19–61. The claims of the ’576 patent are directed to a device for protecting a user from the sharp tip of a medical needle. *Id.* at 1:22–24, 14:19–61.

A colorized version of Figure 11 of the ’576 patent, taken from the Petition and reproduced below, depicts an embodiment of the apparatus.

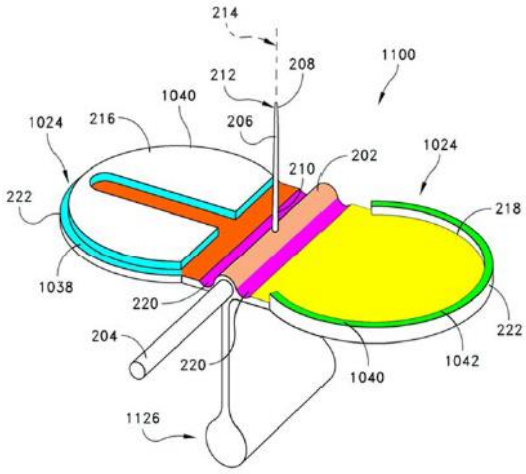


FIGURE 11

Pet. 16. Figure 11 depicts "a safety device with a mechanical fastener having a lip and a recessed portion configured to engage for attachment with one another, and with a groove sized to house the medical needle" and "further includ[ing] a handle." Ex. 1001, 4:1–6. Figure 10 depicts device 1000, which is identical to device 1100 except for handle 1126. *Compare id.* at Fig. 10 *with id.* at Fig. 11. Device 1100 includes wings 216, 218 attached to central body portion 202. *Id.* at 5:6–16, 6:29–39, 7:25–27. Medical needle 206 has sharp tip 212 and is in fluid communication with central body 202 and delivery tube 204. *Id.* at 5:8–12. Significant to our analysis, medical needle 206 is depicted perpendicular to delivery tube 204. *See id.* at Figs. 10, 11.

Wings 216, 218 include inner region 220, which attaches the wings to central body portion 202. Ex. 1001, 5:15–18. Mechanical fastener 1024 includes recessed portion 1038 adjacent to perimeter 1040 of one wing and lip 1042 extending from perimeter 1040 of the

other wing. *Id.* at 6:29–34. Lip 1042 and recessed portion 1038 are configured to engage with one another to attach the wings together along perimeter 1040. *Id.* at 6:34–37. Device 1100 includes groove 1044 (not labeled in Figure 11) in wing 216 sized to house needle 206 when the wings are in a closed position, such that when wings 216, 218 close, needle 206 is positioned between the wings within the groove. *Id.* at 7:16–19.

C. Challenged Claims

Of the Challenged Claims, claim 1 is the sole independent claim. Ex. 1001, 14:19–61. Claim 1 is reproduced below.

> 1. A device for protecting a user from a sharp tip of a winged medical needle, the device comprising:
>
> a central body portion;
>
> a winged medical needle located in the central body portion; the winged medical needle having a first end in fluid connection with a delivery tube, and a second end distal from the central body portion including the sharp tip; *wherein the winged medical needle is substantially perpendicular to the delivery tube*,
>
> a pair of wings, each wing of the pair of wings having an inner region and an outer region, the inner region of each wing in attachment to the central body portion, the outer region of each wing extending away from the central body portion, and the pair of wings being selectively positionable from an open position to a closed position, where the wings in an open position are spaced apart from each other to expose the medical needle to allow placement of the medical needle into a treatment site and delivery of a medicinal fluid; and
>
> wherein the wings in the closed position cover the medical needle to protect against accidental needle stick injury from the medical needle;

> a mechanical fastener disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together in the closed position with the medical needle positioned therebetween to protect against accidental needle stick injury from the sharp tip of the medical needle;
>
> the mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align the at least one wing relative to the at least one other wing in the closed position.

Ex. 1001, 14:19–51 (emphasis added).

D. The Applied References

RMS's asserted grounds of unpatentability for the Challenged Claims rely on the following references:

Harada	JP H9-66106	Mar. 11, 1997	Ex. 1012[1]
Cole	US 4,944,731	July 31, 1990	Ex. 1013
Ishakawa	US 5,147,319	Sept. 15, 1992	Ex. 1014
Norelli	US 4,820,277	Apr. 11, 1989	Ex. 1015
Keaton	US 2008/0177234 A1	July 24, 2008	Ex. 1016
Raines	US 6,911,020 B2	June 28, 2005	Ex. 1017
Sasso	US 6,500,155 B2	Dec. 31, 2002	Ex. 1018

[1] Ex. 1012 includes the original Japanese version of Harada as well as an English translation.

RMS also relies on the declaration testimony of Dr. George Yanulis. *See* Ex. 1010. EMED relies on the declaration testimony of Mr. Ron Stoker. *See* Ex. 2001.

E. Asserted Grounds of Unpatentability

The Petition asserts four grounds of unpatentability under 35 U.S.C. § 102(b) that claims 1 and 2 are anticipated by Harada, Norelli, Ishikawa, and Cole. Pet. 9. The Petitioner also asserts the following:

> Claims 1–3 are obvious in view of ***Harada*** combined with any of ***Norelli***, ***Ishikawa***, ***Cole***, ***Sasso***, and/or ***Raines***.
>
> Claims 1–3 are obvious in view of ***Cole*** combined with any of ***Norelli***, ***Ishikawa***, ***Harada***, ***Sasso***, and/or ***Raines***.
>
> Claims 1–3 are obvious in view of ***Ishikawa*** combined with any of ***Norelli***, ***Harada***, ***Cole***, ***Sasso***, and/or ***Raines***.
>
> Claims 1–3 are obvious in view of ***Norelli*** combined with any of ***Harada***, ***Ishikawa***, ***Cole***, ***Sasso***, and/or ***Raines***.
>
> Claim 1 is obvious in view of ***Harada***, ***Norelli***, ***Ishikawa***, ***Cole***, ***Sasso***, ***Raines,*** and/or ***Keaton*** whether alone or in various combination.

Id. These five assertions result in 119 separate grounds.[2] We address these catch-all assertions below, in Section II.C.2.a.

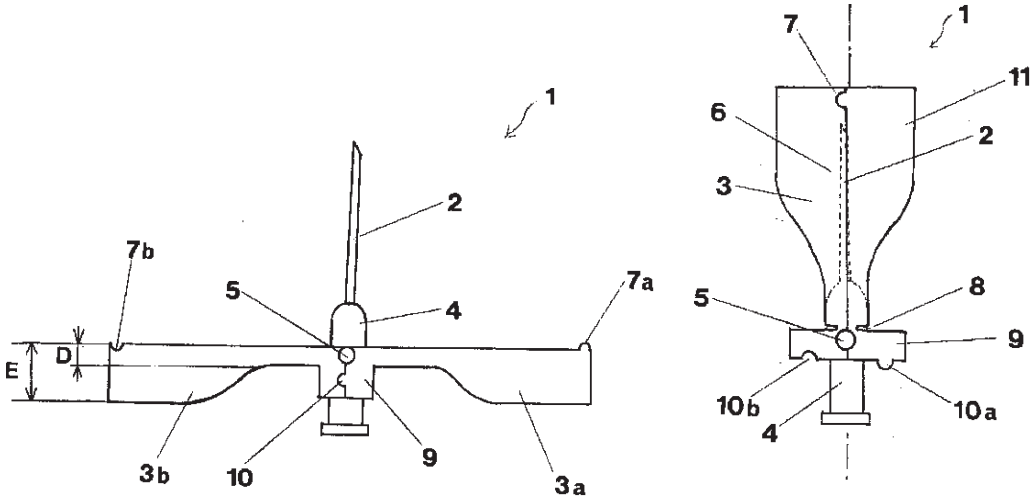
[2] Our calculation assumes that "Harada combined with Cole," for example, is the same ground as "Cole combined with Harada." Otherwise, RMS asserts 187 obviousness grounds.

F. Overview of the Applied References

The Petition relies on seven prior art references in its asserted grounds of unpatentability—Harada, Cole, Ishakawa, Norelli, Keaton, Raines, and Sasso. We briefly discuss these references below.

1. Harada

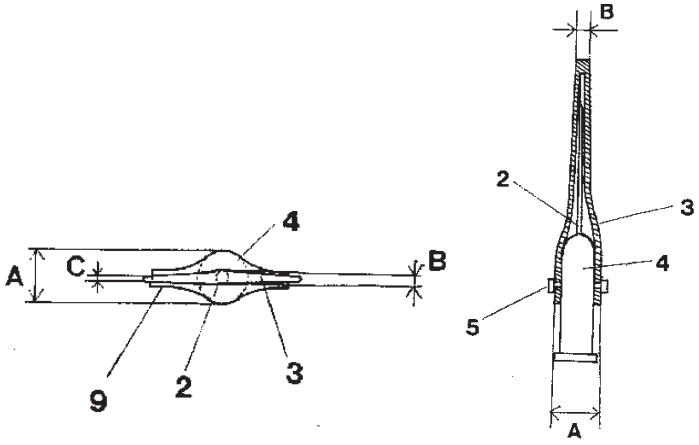
Harada, titled "Injection Needle with Needle Cover that is a Securing Wing," published March 11, 1997. Ex. 1012, 6, (54), (43). Harada is directed to a device that prevents accidental contact with an injection needle. *Id.*, Abstract.[3] Figures 1 and 2 of Harada are reproduced below.



Id. at 13. Harada's Figure 1, shown above on the left, illustrates a front view of the device when the medical needle is in use. Ex. 1012 ¶ 7. Figure 2, above at right, depicts a front view of the device before

[3] Our references to Harada are to the English translation provided with Exhibit 1012.

or after use of the medical needle. *Id.* Figures 3 and 4 of Harada are reproduced below.



Id. Figure 3 provides a top view of the embodiment of Figure 2. *Id.*, Brief Descriptions of the Drawings. Figure 4 provides a cross-sectional view of the embodiment of Figure 2. *Id.*

Harada's device includes medical needle shaft 2 and needle base 4. Ex. 1012 ¶ 7. Needle cover 3, which includes wings 3a and 3b, connects to and pivots on needle base 4 at junction portion 5. *Id.* "[N]eedle cover 3 is made from a thin sheet of a flexible material, and is formed from, for example, a vinyl chloride resin, polyethylene, polypropylene, an ethylene vinyl acetate copolymer, or the like." *Id.*

Needle cover 3 includes first engaging means 7 located at the tip end of needle cover 3 for securing wings 3a, 3b. Ex. 1012 ¶ 11. Engaging means 7 includes male stopping means 7a on wing 3a and female means 7b on wing 3b. *Id.*

2. Cole

Cole, titled "Needle Protection," issued July 31, 1990. Ex. 1013, (54), (45). Cole discloses a device for protecting a user from a sharp point after a medical device, such as a needle, is used. *Id.*, 1:5–16. Cole's Figures 1, 2, and 8 are reproduced below.

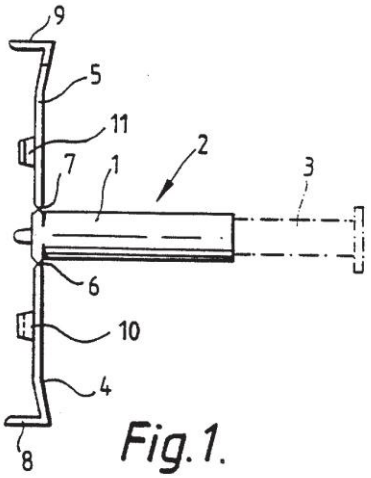


Fig.1.

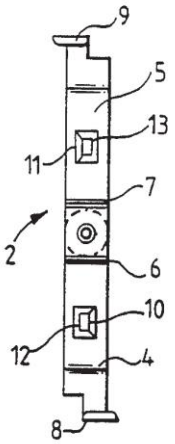


Fig.2.

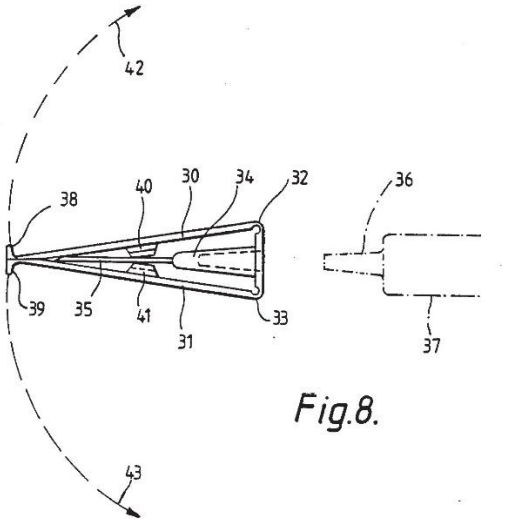


Fig.8.

Figure 1 depicts a side view of a hypodermic needle showing the protector attachment, and Figure 2 depicts an end view of the same

embodiment. *Id.* at 2:64–68. Figure 8 depicts an alternative arrangement for attaching the protector. *Id.* at 3:14–15.

Figure 8 depicts needle 35 attached to detachable hub 34, which is mounted on stub outlet 36 of syringe 37. Ex. 1013, 4:13–18. Protector arms 30, 31 are mounted to detachable hub 34 through pivot portions 32, 33. *Id.* at 4:15–16. Protector arms 30, 31 pivot such that their ends adjacent to flaps 38, 39 trace arcs 42, 43. *See id.* at Fig. 8.

Flaps 38, 39 operate in the same way as flaps 8, 9 to protect the tip of the needle prior to use. Ex. 1013, 4:22–25. When the arms fold forward, the flaps mutually engage the arms. *Id.* at 3:32–37; *see also id.* at Fig. 3 (depicting engaged flaps).

3. Ishikawa

Ishikawa, titled "Winged Needle," issued September 15, 1992. Ex. 1014, (54), (45). Ishikawa is directed to a winged needle that safely exposes and covers the needle. *Id.*, Abstract. Ishikawa's Figures 1 and 2 are reproduced below.

FIG.1

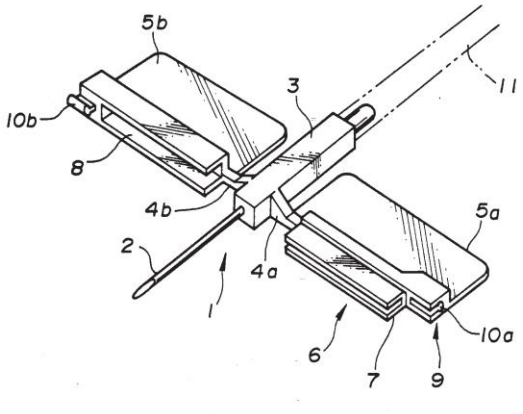


FIG.2

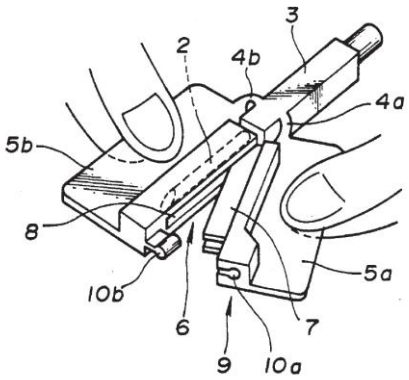


Figure 1 provides a perspective of an embodiment of Ishikawa's winged needle, and Figure 2 depicts the embodiment of Figure 1, during the process of covering the needle. *Id.* at 1:56–59. Ishikawa's winged needle 1 includes needle 2 attached at one end to base 3 and wings 5a, 5b attached to base 3 through arms 4a, 4b. *Id.* at 2:6–9. These components are made from an elastomeric material, such as synthetic rubber. *Id.* at 2:9–11. Base 3 is attached to flexible tube 11. *Id.* at 2:34–35.

Wings 5a, 5b fold as depicted in Figure 2, with needle 2 covered by lipped section 8 and ditch projection 7 (ditch projection 7 and lipped section 8 form sheath portion 6). Ex. 1014, 2:14–19. When closed, needle 2 is enclosed in ditch projection 7, with lipped section 8 covering ditch projection 7. *See id.*, Fig. 4. When the wings close, female part 10a engages male part 10b to make up coupling means 9 and interlock to keep the wings in a closed position. *Id.* at 2:29–33.

4. Norelli

Norelli, titled "Safety Cover for Syringe Needles," issued April 11, 1989. Ex. 1015, (54) (45). Norelli is directed to "protective devices for covering a needle on a syringe." *Id.* at 1:6–7. We reproduce RMS's colorized versions of Norelli's Figures 4 and 5, below:

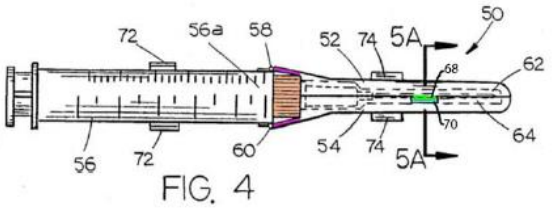


FIG. 4

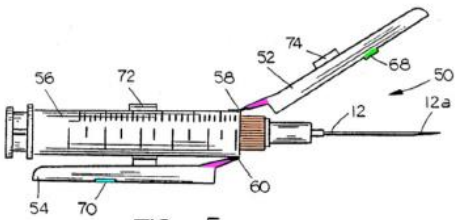


FIG. 5

Pet. 28. Figure 4 depicts "an elevational view of a syringe with the safety cover of [Norelli's] invention thereon, the safety cover in a secured, closed condition." Ex. 1015, 3:23–25. Figure 5 depicts "an elevational view of a syringe with one jaw of [Norelli's] invention being moved into a closed position." *Id.* at 3:26–28.

Device 50 includes jaws 52, 54, which move to completely encase needle 12. Ex. 1015, 4:54–58. Each jaw 52, 54 is connected to syringe barrel 56 by hinges 58, 60, respectively. *Id.* at 4:58–60. Jaws 52, 54 are each a single piece of flexible, resilient plastic material that bends at hinges 58, 60, such as the type of plastic used for constructing a conventional syringe barrel. *Id.* at 4:64–5:2.

Each jaw 52, 54 includes longitudinal grooves 62, 64 respectively, which form aperture 66 that encases needle 12. Ex. 1015, 5:8–11. Locking clips 68 are mounted on jaw 52 to cooperate with receiving sockets 70 in jaw 54, to positively secure jaws 52, 54 together to encase needle 12. *Id.* at 5:12–16. Syringe barrel 56

includes clips 72, which interfaces with clips 74 to hold jaws 52, 54 adjacent the syringe barrel until released. *Id.* at 5:17–20.

5. Keaton

Keaton, titled "Safety Subcutaneous Infusion Set," published July 24, 2008. Ex. 1016, (54) (43). Keaton is directed "to a subcutaneous infusion set with a winged anchor in which the wings fold over the needle/catheter and latch in place to protect it after use." *Id.* ¶ 3. We reproduce Keaton's Figure 1, below:

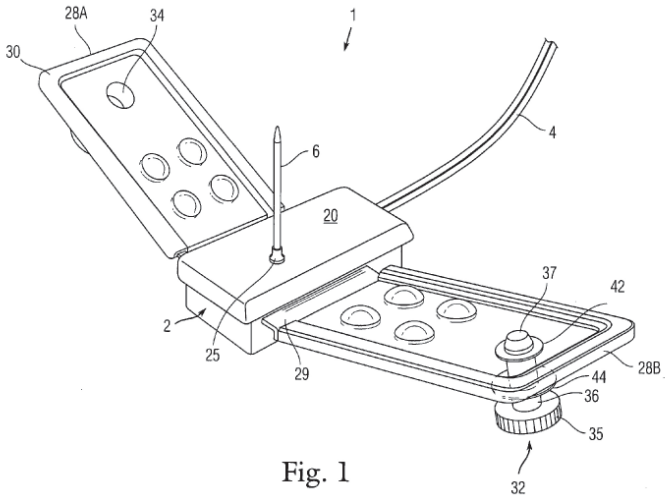


Fig. 1

Figure 1 depicts "a bottom perspective view of the infusion set 1 with winged anchor 2." *Id.* ¶ 14. Wings 28A, 28B are integrally joined to body 20 at hinges 29. *Id.* ¶ 20. Wings 28A, 28B fold inward to releasably latch together to fully enclose catheter 6. *Id.* ¶ 21. Detent post 32 of wings 28B is press-inserted into receiving aperture 34 on wing 28A and locked into place by depressing detent post 32 forcing locking tip 37 into receiving aperture 34. *Id.*

6. Raines

Raines, titled "Huber Needle with Folding Safety Wings," issued June 28, 2005. Ex. 1017, (54) (45). Raines discloses a needle safety device with wings. *Id.*, 1:14–18. Figure 1 of Raines is reproduced below.

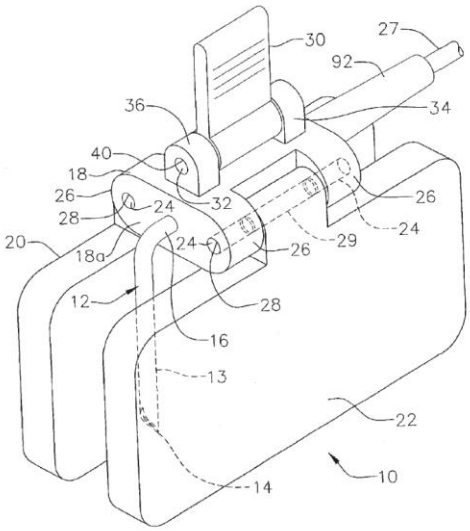


Figure 1 provides a perspective view of Raines's needle safety device. As seen in Figure 1, Raines's device includes wings 20, 22, which fold around needle 12 to prevent a user from being injured by the needle, and third wing 30. *Id.* at 3:18–25, 4:12–14. Third wing 30 serves as a handle. *See, e.g., id.* at 6:29–31 ("[T]he safety needle assembly 10 may be pulled away from the patient by holding the third wing 30 between the thumb and forefinger of one hand."). Raines discloses that wings 20, 22 preferably are made "of molded plastic material, such as polymethylmethacylate, polycarbonate, and ABS (acrylonitrile-butadiene-styrene-terpolymer)." *Id.* at 4:48–50.

7. Sasso

Sasso, titled "Safety Angled Indwelling Needle and a Protective Shield for a Safety Angled Indwelling Needle," issued December 31, 2002. Ex. 1018, (54) (45). Sasso is directed to a needle safety device. *Id.*, Abstract. Sasso's Figures 1 and 2 are reproduced below:

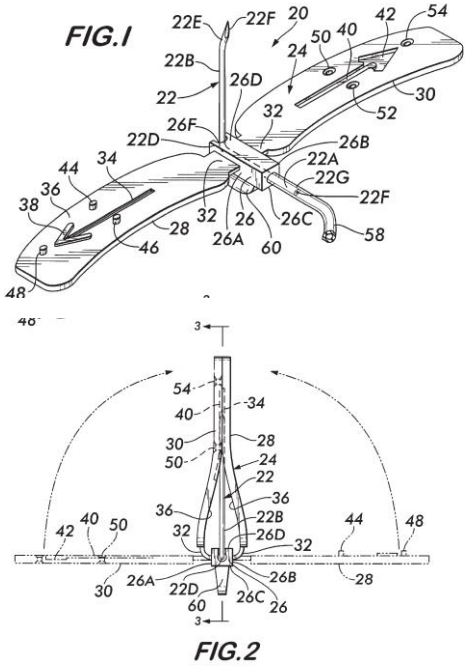


Figure 1 provides an isometric view of Sasso's needle safety device in an open position, and Figure 2 depicts the same embodiment in a closed position. *Id.* at 3:34–41. As seen in Sasso's Figure 1, Sasso's mechanical fastener includes posts 44, 46, 48 that mate with apertures 50, 52, 54. Also as seen in Figure 1, distal end portion 22B is perpendicular to proximal end portion 22A.

Hinges 32 connect wings 28, 30 to hub 26. Ex. 1018, 4:50–53. As seen in Sasso's Figure 2, wings 28, 30 flex from an open position to a closed position, covering needle 22. Also, "the plastic forming

the wings is preferably somewhat flexible, thereby enabling the wings to flex or bend readily at their hinges." *Id.* at 4:54–56.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). RMS does not offer an express definition of the level of ordinary skill in the art in the Petition. RMS's declarant, Dr. Yanulis, defines the level of ordinary skill as:

> an individual . . . who has degrees in both Chemistry and Biomedical Engineering, with at least three years of experience related to plastics product design, injection molding, and the safe use of medical sharps in both a research and clinical setting. Additionally, I believe that a non-degreed practitioner with at least 10 years of experience could also be considered as one of ordinary skill in the art.

Ex. 1010 ¶ 19. Dr. Yanulis adds that "I believe that the PTAB's findings regarding 'level of ordinary skill in the art,' as set forth in the '476 IPR Decision [Ex. 1003], are reasonable and accurate." *Id.*

EMED defines the level of ordinary skill in the art as "a degreed BioMedical, Chemical, Mechanical, or Plastics engineer with three years of experience of product design in general with at least some of that experience in medical products or a non[-]degreed artisan with ten years of experience of product design in general with at least

some of that experience in medical products." Prelim. Resp. 6–7 (referencing Ex. 2001 ¶ 4). As noted by Mr. Stoker, this definition is the same as that found in the Final Written Decision for *inter partes* proceeding IPR2015-01920, involving the related '476 patent. *See* Ex. 2001 ¶ 4; Ex. 1003, 9–11.

We note that Dr. Yanulis's definition differs from the definition in IPR2015-01920, yet he declares that the definition in that proceeding is "reasonable and accurate." *See* Ex. 1010 ¶ 19. For the purposes of this decision only, we adopt EMED's definition of the level of ordinary skill in the art, which is the same as the Board reached in IPR2015-01920.

We note that our patentability and claim construction analyses presented below would reach the same findings and determinations under either EMED's or Dr. Yanulis's definition of the level of ordinary skill in the art.

B. Claim Construction

The claim construction standard to be employed in an *inter partes* review is set to change. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42). At the time of the filing of the Petition in this proceeding, however, the applicable claim construction standard was set forth in 37 C.F.R. § 42.100(b), which provides that "[a] claim in an unexpired patent . . . 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); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). Accordingly, in this *inter partes* review, claim terms are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

1. The Parties' Proposed Constructions

RMS provides express constructions for the terms "lip," "perimeter," "mechanical fastener," and "in attachment to." Pet. 19–21. EMED provides an express construction of "winged medical needle." Prelim. Resp. 8. EMED adopts the constructions for the terms "in attachment to," "to allow," "therebetween," "lip," and "perimeter" from IPR2015-01920. *See id.* 11–16. EMED does not provide a construction for the term "mechanical fastener." *Id.* As will be apparent from our analysis below, we need not construe expressly any of these terms. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*,

200 F.3d 795, 803 (Fed. Cir. 1999) (construing *explicitly* only those claim terms in controversy and only to the extent necessary to resolve the controversy).

2. "wherein the winged medical needle is substantially perpendicular to the delivery tube"

The parties' implicit constructions of one claim term—"wherein the winged medical needle is substantially perpendicular to the delivery tube"—requires us to address this term. RMS contends that the proper scope of this claim term encompasses a structure where the delivery tube is flexible, and where some orientation at some point along the flexible tube may be perpendicular to the device's needle. *See, e.g.*, Pet. 24 (addressing the "substantially perpendicular" limitation and Harada); 27 (addressing Ishikawa and stating that "[a]s delivery tube 11 is specifically stated to be flexible, the needle 2 may be substantially perpendicular to the delivery tube 2.").

EMED responds that "[t]he needle of Harada is not perpendicular to the delivery tube shown below are Fig. 1 of Harada and Fig. 10 of the '576 patent." Prelim. Resp. 24; *see also id.* at 28 (addressing Ishikawa). EMED provides no further explanation of its position, other than presenting images of Harada and Ishikawa next to Figure 10 of the '576 patent. We interpret EMED's position to be that the proper scope of "wherein the winged medical needle is substantially perpendicular to the delivery tube" would not encompass a structure with a flexible delivery tube, where the tubing may flex so

that it is oriented perpendicular to the medical needle. In general, and for the reasons set forth below, we agree with Patent Owner.

As indicated above, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. We start with the language of the claims. *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) ("[T]he context in which a term is used in the [claim at issue] can be highly instructive."). The claim language provides the specific relationship between the medical needle, central body portion, and delivery tube:

> a central body portion; [and]
> a winged medical needle located in the central body portion; the winged medical needle having a first end in fluid connection with a delivery tube, and a second end distal from the central body portion including the sharp tip; *wherein the winged medical needle is substantially perpendicular to the delivery tube*.

Ex. 1001, 14:21–27 (emphasis added). The express language specifies that the medical needle is located in the central body, and that the non-sharp-tipped end of the needle is in fluid connection with the delivery tube and in the central body portion (with the sharp end distal from the central body portion).

The Specification discloses embodiments with the central body portion of the safety device in fluid communication with a delivery tube. *See* 5:6–8 (describing Fig. 2), Figs. 2–13, 37–39 (depicting central body 202 and delivery tube 204); *see also* 9:3–4 ("Device 1700 includes a central body portion 1702 in fluid connection with a

delivery tube 1704."), Figs. 17–21 (depicting central body portion 1702 and delivery tube 1704). In each of these configurations, the delivery tube extends along roughly the same centerline as the central body portion. *See, e.g.*, *id.* at Fig. 10 (showing delivery tube 204 connected to central body portion 204 and extending along the centerline of central body portion 204). Also in each of these configurations, the medical needle extends perpendicularly from the central body portion (and the delivery tube). *See, e.g.*, *id.* at Fig. 10 (showing needle 206 oriented substantially perpendicular to central body portion 202 and delivery tube 204).

We do not discern anything in the prosecution history that illuminates the meaning of "wherein the winged medical needle is substantially perpendicular to the delivery tube" over what is in the Specification. *See, e.g.*, Ex. 1007, 240–42 (finding that Sasso discloses a medical needle oriented substantially perpendicular to its device's delivery tube).

We determine that the broadest reasonable construction of the term "wherein the winged medical needle is substantially perpendicular to the delivery tube" does not encompass a structure where the "substantially perpendicular" orientation between the medical needle and the delivery tube is achieved at *any* location along a length of flexible tubing. Instead, we construe the term to require the perpendicular orientation to be judged where the delivery tube connects to the device.

We base this construction on the plain language of the claims and the descriptions in the Specification. Again, every embodiment disclosed in the Specification includes a delivery tube oriented perpendicularly to the device's medical needle at a point where the tube connects with the needle-protecting device. Also, the language of the claim dictates a relationship between the central body portion, delivery tube, and medical needle. *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 (Fed. Cir. 2017) ("Moreover, 'the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning' of terms in a claim.") (internal citation omitted). Here, we determine that the context of the claim term dictates that the recited orientation between the delivery tube and medical needle is at the point where the delivery tube establishes fluid communication with the medical needle, that is, where the delivery tube connects to the device. Again, every embodiment of the '576 patent discloses a delivery tube that connects to a central body portion to establish fluid communication with the medical needle (and, at that connection, the tube is perpendicular to the medical needle).

We understand that "it is 'not enough that the only embodiments, or all of the embodiments, contain a particular limitation' to limit claims beyond their plain meaning." *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1359 (Fed. Cir. 2016) (internal citation omitted). Here, we are not reading a limitation into the claims. Instead, we are determining the spatial requirement

implicit in the claim limitation—that the "substantially perpendicular" language is measured where the delivery tube connects to the device. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prod., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) ("Even under the broadest reasonable interpretation, the Board's construction 'cannot be divorced from the specification and the record evidence.'").

In summary, we construe the term "wherein the winged medical needle is substantially perpendicular to the delivery tube" to require the "substantially perpendicular" limitation to be judged at the point where the delivery tube connects with the device.

C. Asserted Grounds of Unpatentability

RMS asserts grounds of unpatentability based on anticipation and obviousness. *See* Pet. 9. A "prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc*., 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

A patent claim is unpatentable as obvious when "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." 35 U.S.C. § 103(a);[4] *see 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 ordinary skill in the art; and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We address these underlying factual issues in our obviousness analyses below.[5]

1. The Anticipation Grounds

a. Harada and claims 1 and 2.

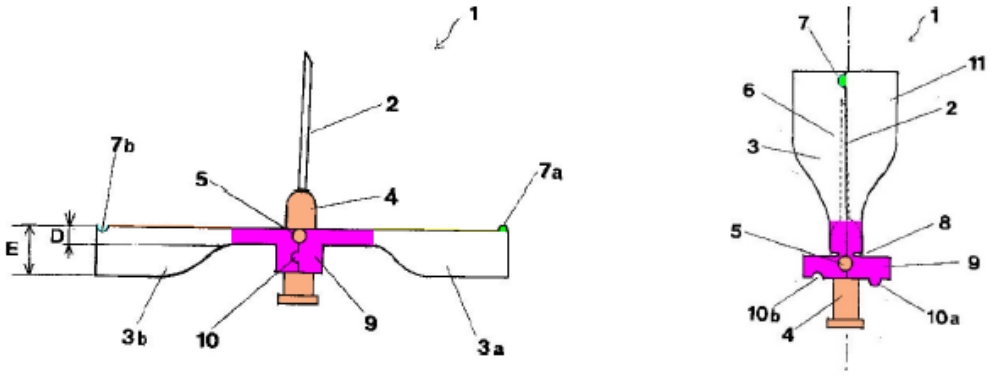
Claim 1 recites, in relevant part:

> a winged medical needle located in the central body portion; the winged medical needle having a first end in fluid connection with a delivery tube, and a second end distal from the central body portion including the sharp tip; *wherein the winged medical needle is substantially perpendicular to the delivery tube*.

[4] Subsection (a) of 35 U.S.C. § 103 was revised when § 4(c) of the America Invents Act (AIA), Pub.L. No. 112–29, took effect on September 16, 2012. Because the application that matured into the '576 patent claims priority to an application filed before that date, we refer to the pre-AIA version of § 103. *See* Ex. 1001, 1:8–17.

[5] We address the level of ordinary skill in the art in Section II.A., above. EMED does not present any evidence concerning secondary considerations at this stage of the proceeding. RMS indicates that it is not aware of any secondary considerations relevant to the obviousness analysis. Pet. 42–43.

Ex. 1001, 14:21–27 (emphasis added) (the "substantially perpendicular" limitation). RMS contends that Harada anticipates claims 1 and 2, including the "substantially perpendicular" limitation of claim 1. Pet. 22–24, 34. We reproduce RMS's annotated versions of Harada's Figures 1 and 2, below:



Id. at 22. These annotated figures show Harada's winged needle with the wings in the open and closed positions, with certain components allegedly corresponding to recited claim limitations colorized. See Ex. 1012, Brief Description of the Drawings. With respect to the "substantially perpendicular" limitation, RMS contends that Harada discloses that "when it is necessary to hold the injection needle *or infusion tubing* against the body, such as during an infusion, the wings can be used as securing means, enabling securing to be carried out simply and reliably even over, for example, an infusion over an extended period of time." *Id.* at 24 (referencing Ex. 1012 ¶ 15). RMS adds that "[i]t is reasonable for broad interpretation to understand that the needle of ***Harada*** may be substantially perpendicular to the delivery tube—the needle disposed through the skin, the tubing

disposed against the skin." *Id.* EMED disputes this contention, without further argument. Prelim. Resp. 24–25.

We determine that RMS fails to make the requisite showing that Harada discloses the "substantially perpendicular" limitation of claim 1. First, RMS fails to explain adequately what constitutes the alleged delivery tube and how the delivery tube connects to Harada's injection needle. RMS merely quotes a passage from Harada that indicates, during an infusion, that Harada's wings may be used to secure the device to a patient's body. RMS appears to imply that, in securing Harada's device, with associated infusion tubing, to a patient, the infusion tubing (the apparent "delivery tube") "may be" substantially perpendicular to the needle. RMS fails to provide any support or explanation as to the orientation of these components or how they meet the limitations of claim 1. This lack of explanation fails to satisfy RMS's burden.

Second, as discussed above, we construe the "substantially perpendicular" limitation of claim 1 to be judged at the point where the delivery tube connects with the device. To the extent that RMS contends that, at some point along the length of the infusion tubing, the tubing may become oriented perpendicular to the medical needle, this contention does not meet the limitations of the claim. Instead, we interpret Harada as disclosing that an infusion tube would connect to needle base 4 opposite the tip of needle shaft 2. *See* Ex. 1012, Fig. 1, ¶ 15 (disclosing that the device may be used with infusion tubing and illustrating a device where the apparent only place to connect the

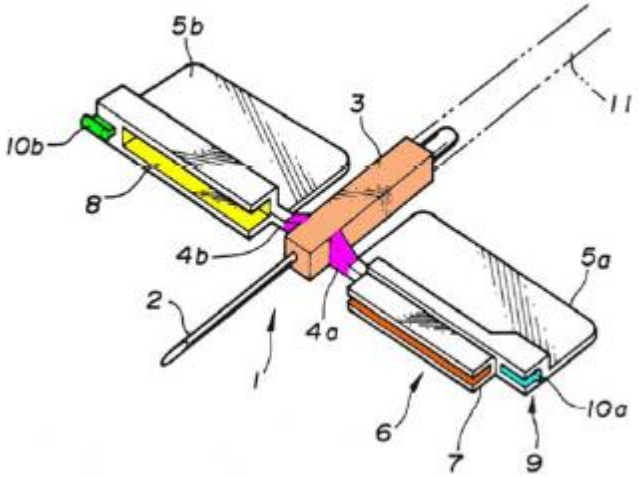
tubing is the end of needle base 4 opposite the needle). In this position, the delivery tube would not be perpendicular to the medical needle as determined at the point where the tubing connects with needle base 4.

For the reasons above, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Harada. Also, because claim 2 depends from claim 1, we determine that RMS fails to demonstrate a reasonable likelihood that claim 2 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Harada.

b. Ishikawa and claims 1 and 2.

RMS contends that Ishikawa anticipates claims 1 and 2, including the "substantially perpendicular" limitation of claim 1. Pet. 24–27, 34. We reproduce RMS's annotated version of Ishikawa's Figure 1, below.

FIG.1



Id. at 25. The colorized figure highlights certain features of Ishakawa's winged needle allegedly corresponding to claim element structures. With respect to the "substantially perpendicular" limitation, RMS contends that "***Ishikawa*** . . . teaches a flexible delivery tube **11**. As delivery tube **11** is specifically stated to be flexible, the needle **2** may be substantially perpendicular to the delivery tube **2** [*sic*]." *Id.* at 27. EMED disputes this contention, without further argument. Prelim. Resp. 28.

Similar to our determination with respect to Harada, we determine that RMS fails to make the requisite showing that Ishikawa discloses the "substantially perpendicular" limitation of claim 1. RMS fails to explain adequately how "needle 2 may be substantially perpendicular to the delivery tube." Again, to the extent that RMS contends that delivery tube 11 *may* flex at some point along its length so that it is perpendicular to needle 2, this contention does not explain how the tube meets the "substantially perpendicular" limitation of claim 1 as we have construed it. We interpret Ishikawa to disclose that flexible tube 11 connects with base 3 at a point opposite needle 2. *See* Ex. 1014, Fig. 1, 2:34–35. As shown in Ishikawa's Figure 1, flexible tube 11 is not perpendicular to needle 2, but instead extends roughly along the same centerline. *See id.* at Fig. 1.

For the reasons above, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Ishikawa. Also, because claim 2 depends from claim 1, we determine

that RMS fails to demonstrate a reasonable likelihood that claim 2 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Ishikawa.

c. Norelli and claims 1 and 2.

RMS contends that Norelli anticipates claims 1 and 2, including the "substantially perpendicular" limitation of claim 1. Pet. 27–30, 34. We reproduce RMS's annotated version of Norelli's Figure 5, below.

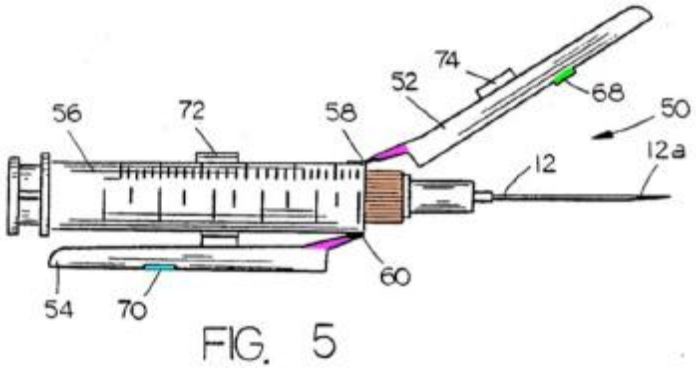


FIG. 5

Pet. 28. The annotated figure shows Norelli's device 50, with certain components allegedly corresponding to recited claim limitations colorized. With respect to the "substantially perpendicular" limitation of claim 1, RMS contends that "[a]s syringes are known to have curved delivery tubes that provide fluid delivery at a perpendicular angle to the barrel of the syringe, under broad interpretation of the claim elements the needle **2** may be substantially perpendicular to the delivery tube **2**." Pet. 30. EMED disputes this contention without further argument. Prelim. Resp. 31.

We determine that RMS fails to make the requisite showing that Norelli discloses the "substantially perpendicular" limitation of claim 1. RMS fails to provide any support for its contention that

"syringes are known to have curved delivery tubes," or that these "curved delivery tubes" would be perpendicular to needle 12. Dr. Yanulis declares that he is "well aware that syringes are known to have curved delivery tubes that provide fluid delivery at a perpendicular angle to the barrel of the syringe." Ex. 1010 ¶ 70. Dr. Yanulis, however, fails to provide any support, including the underlying facts or data on which he relies, for his opinion and, so, we give this opinion little evidentiary weight. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").[6]

Based on our review of Norelli, we determine that Norelli fails to disclose a delivery tube that is substantially perpendicular to its medical needle. The only configuration disclosed in Norelli is one of an injection syringe having a barrel that is oriented along the same centerline as its needle. *See, e.g.*, Figs. 4–8, 10, 12, 16 (depicting straight syringes).

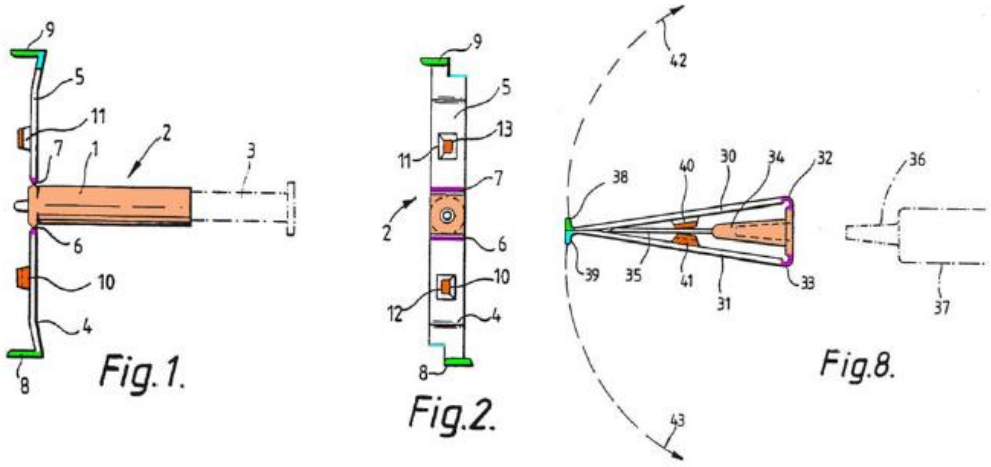
For the reasons above, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by

[6] EMED argues that we should give Dr. Yanulis's testimony no weight, in part because Dr. Yanulis is not an expert in sharps protection. *See* Prelim. Resp. 17–20. As is evident from our definition of the level of ordinary skill in the art, such expertise is not needed. Also, we determine, on the current record, that Dr. Yanulis has the requisite education and background to provide testimony that, if adequately supported, could be given probative weight.

Norelli. Also, because claim 2 depends from claim 1, we determine that RMS fails to demonstrate a reasonable likelihood that claim 2 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Norelli.

d. Cole and claims 1 and 2.

RMS contends that Cole anticipates claims 1 and 2, including the "substantially perpendicular" limitation of claim 1. Pet. 30–34. We reproduce RMS's annotated versions of Cole's Figures 1, 2, and 8, below.



Pet. 31. These annotated figures show Cole's device 2, with certain components allegedly corresponding to recited claim limitations colorized. With respect to the "substantially perpendicular" limitation of claim 1, RMS contends that "as stub outlets are known to be curved to provide fluid delivery at a perpendicular angle to the barrel of the syringe, the needle **35** may be substantially perpendicular to the delivery tube **36**." *Id.* at 33. RMS continues that:

> ***Cole*** specifically states that the invention relates to needle protection after the use of "*stylettes, catheters and similar surgical or medical devices* having, integrally or as an

> attachment, a sharp ended point for piercing or injecting . . . ." ([Ex. 1013], Col. 1, 6-11 (emphasis added).) Stylettes, catheters, and other medical devices as listed by ***Cole*** are well understood in the art to include flexible tubes with a needle, and as such the needle when disposed into the tissue of a patient may be perpendicular to the delivery tube.

Id. EMED disputes these contentions without further argument. *See* Prelim. Resp. 26.

Dr. Yanulis provides the identical language we quote above and adds "[i]t is my opinion that because the delivery tube is flexible it is entirely reasonable to understand that the needle disposed into the tissue of a patient may be perpendicular to at least some portion of the delivery tube." Ex. 1010 ¶ 80. Again, Dr. Yanulis fails to provide any support for his opinion that stylettes, catheters, and other medical devices are *well understood* to be flexible and, more significantly, why flexible tubes result in a needle disposed in a patient "may be perpendicular to the delivery tube," so we afford this opinion little weight.

We determine that RMS fails to make the requisite showing that Cole discloses the "substantially perpendicular" limitation of claim 1. Once again, RMS fails to explain adequately how Cole's disclosure that its safety cover may be used with stylettes, catheters, and other medical devices and that these components are flexible results in a device that satisfies the "substantially perpendicular" claim limitation of claim 1, as we have construed that claim term.

Based on our review of Cole, we determine that Cole fails to disclose a delivery tube that is substantially perpendicular to its medical needle. The only configuration disclosed in Cole is one of an injection syringe having a barrel that is oriented along the same centerline as its needle. *See, e.g.*, Figs. 1–6, 8 (depicting straight syringes).

For the reasons above, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Cole. Also, because claim 2 depends from claim 1, we determine that RMS fails to demonstrate a reasonable likelihood that claim 2 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Cole.

2. The Obviousness Grounds

a. Catch-all Grounds.

Section 312(a)(3) of 35 U.S.C. requires a petition to "identif[y], in writing and *with particularity*, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." (Emphasis added). For the reasons that follow, we are not satisfied that the Petition provides adequate explanation or is appropriately precise and specific in articulating the basis of the proposed grounds to warrant institution of an *inter partes* review on these grounds.

As we indicated above, RMS alleges at least *119 grounds* for which claims 1, 2, or 3 are obvious.[7] RMS fails to specify, with particularity, how each of these 119 grounds renders the claims obvious, including how teachings from one or more references are combined to arrive at the subject matter of claims 1–3 and why a person having ordinary skill in the art would have had reason to combine the teachings. *See* Pet. 35–43 (providing RMS's obviousness assertions); *see also KSR Int'l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position, the proponent should provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

First, with respect to Harada, Ishikawa, Norelli, and Cole, RMS states that, "[t]o the extent that a contention of anticipation is more properly characterized as a contention of obviousness, then [RMS]

[7] The U.S. Supreme Court, in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), held that an *inter partes* review must institute on all challenged claims or no challenged claims. The Patent Office has further determined that, if instituting an *inter partes* review, the Board must institute on all challenged claims *and all grounds*. *See* U.S. Patent and Trademark Office, Guidance on the impact of *SAS* on AIA trial proceedings, available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (Apr. 26, 2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) ("Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*."). So, in this proceeding, if trial were instituted, we would need to evaluate each of the 119 grounds.

asserts such contention." Pet. 35. RMS repeats, from its anticipation contentions with respect to Norelli and Cole, that syringes with curved outlet tubes were well known and a matter of operator choice. *Id.* With respect to Harada, RMS repeats that Harada discloses that an infusion tube may be held against the body when using Harada's winged needle. *Id.* To the extent that RMS argues that these disclosures render the "substantially perpendicular" limitation of claim 1 obvious, the presentation in the Petition is lacking. Indeed, the Petition fails to even link these statements to a specific obviousness contention. Instead, RMS leaves it to the Board to connect the dots, which we decline to do.

Second, RMS contends, in a single sentence, that "the orientation of the delivery tube as perpendicular to the needle is an obvious design choice." Pet. 36. Again, this catch-all contention fails to specify, with particularity, the obviousness contention. Indeed, this contention fails to explain adequately what RMS means by an orientation of the delivery tube as perpendicular to the needle, for example, where that orientation is achieved. Also, this single sentence fails to satisfy the legal requirements of demonstrating why a claim limitation would have been obvious as a matter of design choice—it fails to provide a reason for making the design choice and fails to provide evidence that the claimed orientation fails to solve a specific problem. *See Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016) (non-precedential) ("Merely stating that a particular placement of an element is a design choice does not

make it obvious. The [proponent] must offer a reason for why a person of ordinary skill in the art would have made the specific design choice."); *In re Kuhle,* 526 F.2d 553, 555 (CCPA 1975) (concluding that the use of a claimed feature solves no stated problem and presents no unexpected result and "would be an obvious matter of design choice within the skill of the art").

Third, RMS states that "***Sasso***, ***Raines***, and ***Keaton*** all teach central body portions clearly depicting needles perpendicular to delivery tubes within the device structure," but fails to explain further the significance of this statement. *See* Pet. 36.

For the reasons above, we determine that RMS's catch-all approach fails to satisfy the requirements of 35 U.S.C. § 312(a)(3), which is unfair to EMED, as EMED must "shoot into the dark" in responding to these contentions. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2154 (2016) (Alito, L., concurring in part and dissenting in part) ("Section 312(a)(3)'s particularity requirement is designed, at least in part, to ensure that a patent owner has sufficient notice of the challenge against which it must defend. Once inter partes review is instituted, the patent owner's response—its opening brief, essentially—is filed as an opposition to the challenger's petition. Thus, if a petition fails to state its challenge with particularity—or if the Patent Office institutes review on claims or grounds not raised in the petition—the patent owner is forced to shoot into the dark. The potential for unfairness is obvious.").

b. Sasso, Raines, and Keaton.

Although we determined above that the Petition's catch-all obviousness positions are deficient, we attempt to address our understanding of certain of RMS's obviousness contentions with respect to Sasso, Raines, and Keaton on the merits as best we can. *See* Pet. 36–42.

i. Sasso

Claim 1 recites, in relevant part:

> a mechanical fastener disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together in the closed position with the medical needle positioned therebetween to protect against accidental needle stick injury from the sharp tip of the medical needle;
>
> the mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align the at least one wing relative to the at least one other wing in the closed position

Ex. 1001, 14:40–51 (the "mechanical fastener" limitation). RMS contends that Sasso discloses the subject matter of claim 1, including the "substantially perpendicular" limitation, but recognizes that Sasso does not disclose the "mechanical fastener" limitation. *See* Pet. 36–38. RMS adds that "[a]s noted above, a mechanical fastener consisting of a lip and a mating portion along at least a portion of the perimeter of the wings was and is clearly taught by ***Harada***, ***Cole***, ***Ishikawa***, and ***Norelli***." *Id.* at 38. RMS provides no further

explanation or argument. *See id.* Indeed, RMS does not even expressly contend that combining the teachings of a mechanical fastener in any of these four references with Sasso teaching of its needle protection device would render claim 1 obvious. *See id.*

RMS makes a blanket statement, at the beginning of its obviousness assertions, that:

> All the claimed elements were explicitly disclosed in the cited references; one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would be nothing more than predictable results to one of ordinary skill in the art.

Id. at 36. RMS also provides the blanket assertion that "[b]ecause these references are all addressed to the identical problem and employ nearly identical solutions, a person of ordinary skill in the art would have a clear motive to combine the teachings of the references." *Id.* at 35.

RMS additionally relies on Dr. Yanulis's testimony to support its obviousness positions. *See* Pet. 42 (referencing Ex. 1010 ¶¶ 84–113 without further explanation: "Dr. Yanulis concurs in the above rationale for invalidating the '576 Patent on grounds of obviousness."). With respect to Sasso, Dr. Yanulis declares that "[i]t is my opinion that ***Sasso***, in combination with ***Harada***, ***Cole***, ***Ishikawa***, and/or ***Norelli***, provides all of the elements of Claim 1, thus rendering Claim 1 obvious." Ex. 1010 ¶ 92.

We determine that RMS fails to satisfy its burden of showing a reasonable likelihood of prevailing on its obviousness position with

respect to Sasso. First, RMS's contentions merely demonstrate that Sasso in combination with Harada, Cole, Ishikawa, or Norelli disclose all of the limitations of claim 1. Although we do not disagree with this contention, this contention alone is insufficient to support a conclusion of obviousness. As the Supreme Court made clear, "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 Int'l Co.*, 550 U.S. at 418. RMS fails to explain adequately that it would have been obvious to modify Sasso with the teachings of one or more other references or the knowledge of a person having ordinary skill in the art to arrive at the claimed invention or why the modification would have been made. Indeed, RMS fails to even expressly specify what modification it proposes. Instead, RMS merely states that Harada, Cole, Ishikawa, or Norelli discloses a mechanical fastener and leaves it to the Board to infer a position from this statement, an invitation we decline.

Second, RMS's blanket statements do not provide the missing piece for its obviousness assertions. As to the first statement—that all of the elements were known and a person having ordinary skill in the art *could* have combined the elements with predictable results—the statement fails to provide a reason as to why an artisan of ordinary skill *would* have made the modification. *See* Pet. 36; *see also 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.") (emphasis omitted).[8] As to the second statement—that all of the references address the same problem—this statement is merely a recognition that all of the cited references are analogous art, a prerequisite for any reference used in an obviousness contention. *See* Pet. 35; *see also In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) ("References within the statutory terms of 35 U.S.C. § 102 qualify as prior art for an obviousness determination only when analogous to the claimed invention."). That recognition, without more, does not provide an adequate basis to reach a conclusion of obviousness.

RMS's reliance on Dr. Yanulis's testimony fares no better. First, merely stating that Dr. Yanulis concurs with RMS's obviousness positions as support, and citing to thirty paragraphs in Dr. Yanulis's Declaration, amounts to improper incorporation by reference of his testimony. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document."). Second, even if we consider Dr. Yanulis's testimony, it also fails to adequately support RMS's obviousness

[8] We recognize that in certain cases, such as the *simple* substitution of one known element for another or the mere application of a known technique to a piece of prior art *ready for improvement*, an express motivation to combine references may not be necessary under the Supreme Court's flexible analysis. *See KSR Int'l Co.*, 550 U.S. at 417. RMS fails, however, to characterize its obviousness position as falling under these categories of modifications, nor do we read RMS's position as advocating a simple substitution or applying a known technique to a reference ready for improvement.

position. Dr. Yanulis merely states in conclusory fashion that Sasso combined with Harada, Cole, Ishikawa, *and/or* Norelli provide all of the elements of claim 1, which is insufficient to support an obviousness contention. *See* Ex. 1010 ¶ 92.

For the reasons above, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 103(a) over Sasso alone or in combination with Harada, Cole, Ishikawa, or Norelli. Also, because claims 2 and 3 depend from claim 1, we determine that RMS fails to demonstrate a reasonable likelihood that claims 2 and 3 are unpatentable under 35 U.S.C. § 103(a) over Sasso in combination with Harada, Cole, Ishikawa, or Norelli.

ii. Raines and Keaton

RMS's obviousness positions based on Raines or Keaton suffer from the same deficiencies we identify above with respect to Sasso. *See* Pet. 39–42. We note that, in contrast to its description of its obviousness position with respect to Sasso, RMS at least states "***Raines***, in combination with ***Harada***, ***Cole***, ***Ishikawa***, ***Norelli***, and/or ***Sasso***, provides all of the elements of Claim 1, thus rendering Claim 1 obvious" and "***Keaton*** discloses a different mechanical fastener, however a mechanical fastener consisting of a lip and a mating portion along at least a portion of the perimeter of the wings was and is clearly taught by ***Harada***, ***Cole***, ***Ishikawa***, and ***Norelli***, thus rendering Claim 1 obvious." Pet. 40, 42. These conclusory statements, however, are insufficient to support an obviousness

contention, as they merely state that claim 1 is obvious because all of the elements were known in the art, but without providing any reason why a person having ordinary skill in the art would have modified Raines or Keaton to arrive at the claimed invention.

For the reasons above, including those made in connection with our analysis of RMS's Sasso obviousness position, on the limited record before us, we determine that RMS fails to demonstrate a reasonable likelihood that claim 1 is unpatentable under 35 U.S.C. § 103(a) over Raines or Keaton, alone or in combination with Harada, Cole, Ishikawa, or Norelli. Also, because claims 2 and 3 depend from claim 1, we determine that RMS fails to demonstrate a reasonable likelihood that claims 2 and 3 are unpatentable under 35 U.S.C. § 103(a) over Raines or Keaton in combination with Harada, Cole, Ishikawa, or Norelli.

3. EMED's Duty of Candor

Rule 1.56 specifies that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability" of a claim. 37 C.F.R. § 1.56(a). As the rule indicates, "[t]he public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability." *Id.*

RMS asks us to cancel the claims of the '576 patent because EMED allegedly failed to satisfy its duty of candor under 37 C.F.R. § 1.56. Pet. 46. Specifically, RMS contends that EMED failed to disclose our decision in IPR2015-01920 involving the '476 patent, which is related to the '576 patent. *See id.*

We agree with RMS that a Final Written Decision in an *inter partes* review represents the type of information that could be material to the prosecution of a patent application related to the patent involved in the *inter partes* review proceeding, such that it should be disclosed under 37 C.F.R. § 1.56's duty of candor requirement. RMS, however, does not explain from where we derive the authority to cancel claims of a patent based on an allegation that the claims were procured through a patent owner's failure to satisfy its duty of candor. In an *inter partes* review, the Director is authorized "to cancel as unpatentable 1 or more claims of a patent *only on a ground that could be raised under section 102 or 103* and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b) (emphasis added).

Accordingly, we deny RMS's request to cancel the claims of the '576 patent based on its allegations related to EMED's duty of candor.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, including its supporting testimonial evidence, and

Preliminary Response, we determine that RMS has not established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. Accordingly, we do not institute an *inter partes* review.

IV. ORDER

After due consideration of the record before us, it is:

ORDERED that the Petition is *denied* as to all challenges and no trial is instituted.

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