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Paper No. 9
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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 IPR2015-01920
Patent 8,961,476 B2

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

MAYBERRY, *Administrative Patent Judge*.

DECISION

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

I. INTRODUCTION

Petitioner, Repro-Med Systems, Inc. ("RMS"), filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–10 of U.S. Patent No. 8,961,476 B2 (the "'476 patent"). Patent Owner, EMED Technologies, Corp. ("EMED"), filed a Preliminary Response (Paper 8, "Prelim. Resp.") to the Petition. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that 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 and the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that RMS will prevail in challenging claims 1–10 of the '476 patent. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to those claims.

Our preliminary factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Maters

According to the Petition, the '476 patent is the subject of litigation in *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical*

Products, No. 2:15-cv-01167 (E.D. Tex.). Pet. 2.[1] The application that matured into the '476 patent is a continuation of application No. 13/931,218, filed on June 28, 2013, which is a division of application No. 12/187,256, filed on Aug. 6, 2008, which matured into US 8,500,703 (the "'703 patent"). Ex. 1001, 1:7–12. According to the Petition, the '703 patent is subject to litigation in *Repro-Med Systems, Inc. d/b/a RMS Medical Products v. EMED Tech. Corp.*, No. 2:13-cv-1957-TLN-CKD (E.D. Cal.) and is also the subject of *ex parte* reexamination No. 90/013585.

B. The '476 Patent

The '476 patent, titled "Sharps Protector Device for Protecting a User from a Sharp Tip of a Medical Needle," issued February 24, 2015. The claims of the '476 patent are directed to a device for protecting a user from the sharp tip of a medical needle. Ex. 1001, 1:23–25. Specifically, the claims are to a device with a pair of wings attached to a central body and a mechanical fastener configured to attach the wings together to position the needle between the wings. *Id.*, Abstract.

Figure 11, reproduced below, depicts an embodiment of the apparatus.

[1] The parties are reminded of their continuing obligation to update their mandatory notices within 21 days of any change of the information listed in 37 C.F.R. § 42.8(b) stated in an earlier paper, including, *inter alia*, changes in related matters. 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

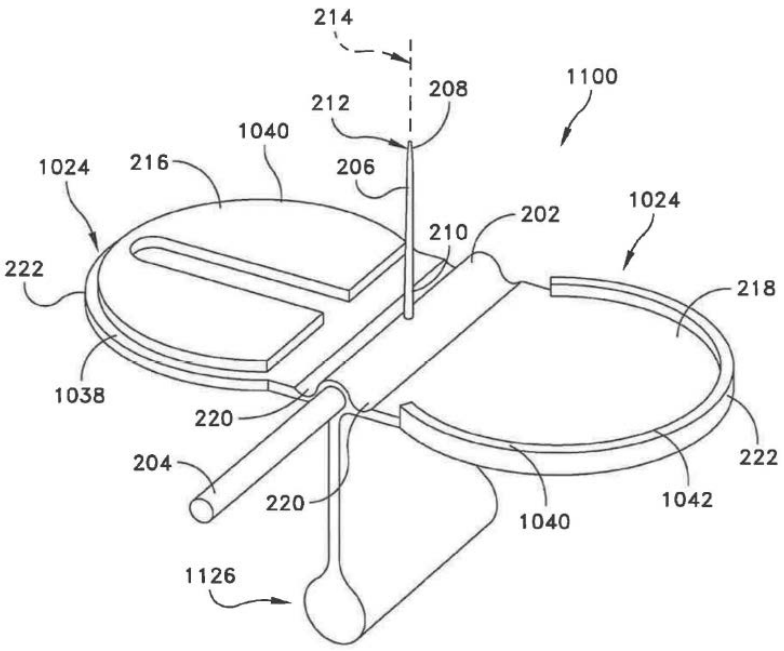


FIGURE 11

Figure 11 illustrates a safety device in an open position with a mechanical fastener having a lip and a recessed portion configured to engage one another, a groove to house a medical needle, and a handle. Ex. 1001, 3:62–67. Device 1100 includes wings 216, 218 attached to central body portion 202. *Id.* at 4:62–64, 5:4–5, 6:43–45. Medical needle 206 has sharp tip 212 and is in fluid communication with central body 202 and delivery tube 204. *Id.* at 4:64–5:1.

Wings 216, 218 include inner region 220, which attaches the wings to central body portion 202. Ex. 1001, 5:4–7. 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 6:19–24. Lip 1042 and recessed portion 1038 are configured to engage with one another to attach the wings together along perimeter 1040. *Id.* at 6:24–27. 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 6:35–38. The wings may be made of a rigid or semi-rigid material and may be circular, as shown in Figure 11, rectangular, or another shape. *Id.* at 6:30–34.

Device 1100 includes handle 1126, which extends from central body portion 202 in opposition to needle 206. Ex. 1001, 6:44–48.

C. Illustrative Claims

Claim 1 is the sole independent claim and is reproduced below.

> 1. A device for protecting a user from a sharp tip of a medical needle, the device comprising:
>
> a central body portion;
>
> the 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;
>
> 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, the pair of wings disposed in opposition to one another with the medical needle positioned therebetween, and
>
> the pair of wings being selectively positionable from an open position to a closed position, where the wings in the 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 with the medical needle positioned therebetween so as to protect against accidental needle stick injury from the sharp tip of the medical needle;

> the mechanical fastener including 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, 13:33–14:21.

D. The Prior Art

RMS's asserted grounds of unpatentability for the challenged claims of the '476 patent rely on the following references:

Cole	US 4,944,731	July 31, 1990	Ex. 1005
Ishikawa	US 5,147,319	Sept. 15, 1992	Ex. 1006
Nicoletti	US 5,279,588	Jan. 18, 1994	Ex. 1007
Rosato	US 5,951,522	Sept. 14, 1999	Ex. 1004
Sasso	US 6,500,155 B2	Dec. 31, 2002	Ex. 1010
Raines	US 6,911,020 B2	June 28, 2005	Ex. 1009
Keaton	US 2008/0177234 A1	July 24, 2008[2]	Ex. 1008
Harada	JP H9-66106	Mar. 11, 1997	Ex. 1003

E. Asserted Grounds of Unpatentability

RMS asserts the follow grounds of unpatentability for the challenged claims of the '476 patent.

No.	References	Basis	Claims Challenged
1.	Harada	§ 102(b)	1

[2] Keaton was filed Nov. 21, 2007, making it prior art under 35 U.S.C. § 102(e). *See* Pet. 31.

No.	References	Basis	Claims Challenged
2.	Rosato	§ 102(b)	1–3 and 5
3.	Cole	§ 102(b)	1, 5, and 7
4.	Ishikawa	§ 102(b)	1 and 7–9
5.	Sasso and Harada, Rosato, Cole, Ishikawa, or Nicoletti	§ 103(a)	1, 6, and 7
6.	Harada and Sasso, Raines, or Rosato	§ 103(a)	2, 3, 5, and 10
7.	Cole and Sasso, Raines, or Rosato	§ 103(a)	2, 3, 4, and 10
8.	Ishikawa and Sasso, Raines, or Rosato	§ 103(a)	2, 3, 5, and 10
9.	Harada and Raines	§ 103(a)	4
10.	Rosato and Raines	§ 103(a)	4
11.	Ishikawa and Raines	§ 103(a)	4
12.	Harada, Sasso, and Raines	§ 103(a)	4
13.	Rosato, Sasso, and Raines	§ 103(a)	4
14.	Cole, Sasso, and Raines	§ 103(a)	4
15.	Ishikawa, Sasso and Raines	§ 103(a)	4
16.	Harada and Cole	§ 103(a)	5
17.	Ishikawa and Cole	§ 103(a)	5
18.	Harada, Sasso, and Cole	§ 103(a)	5
19.	Ishikawa, Sasso, and Cole	§ 103(a)	5
20.	Harada, Sasso, and Rosato	§ 103(a)	5
21.	Ishikawa, Sasso, and Rosato	§ 103(a)	5
22.	Harada	§ 103(a)	6 and 7
23.	Harada and Raines, Keaton, or Sasso	§ 103(a)	7

No.	References	Basis	Claims Challenged
24.	Sasso and (Harada, Rosato, Cole, Ishikawa, or Nicoletti) and (Raines or Keaton)	§ 103(a)	7
25.	Harada and Sasso or Ishikawa	§ 103(a)	8
26.	Sasso and (Harada, Rosato, Cole, or Nicoletti) and Ishikawa	§ 103(a)	8 and 9
27.	Harada and Ishikawa	§ 103(a)	9

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent 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); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA."), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 72016 WL 205946 (U.S. Jan. 15, 2016) (No. 15-446). 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.") (citation omitted).

1. "rigid" and "semi-rigid"

Claim 4 requires that the pair of wings be formed of a rigid material. Ex. 1001, 14:27–28. Similarly, claim 5 requires the pair of wings be formed of a semi-rigid material. *Id.* at 14:29–30. RMS contends that "the term 'rigid material' is a relative term which means a material that will hold its shape and has resistance to bending to some degree. The term 'semi-rigid material' is also a relative term that means a material which will hold its shape but is flexible to some degree." Pet. 9 (citing Ex. 1002 ¶ 128).[3] EMED counters that these terms do not need construction and should be given their ordinary and customary meanings, without offering what those meanings are or indicating whether RMS's construction comports with the plain and ordinary meanings of the terms. Prelim. Resp. 11 ("The plain and ordinary meaning of the terms of [c]la[i]m[s] 2–10 are appropriate for construction and therefore no construction beyond the words of the claims is necessary.").

We determine that RMS's constructions are imprecise such that they do not provide any useful meaning of the terms. The use of the phrase "to some degree," without any guidance on determining the "degree" results in constructions where a "rigid" material may be more flexible than a "semi-rigid" material. For example, a material that resists bending to a small degree would be readily flexible and a material that is flexible to a small degree may have very little flexibility.

[3] This reference appears to be a typographical error and paragraph 129 should have been cited.

We agree with EMED that the terms "rigid" and "semi-rigid" should be afforded their ordinary and customary meanings and turn to a general purpose dictionary for those meanings. Although the Federal Circuit cautions that "'a general-usage dictionary cannot overcome art-specific evidence of the meaning' of a claim term," "[d]ictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322 (Fed. Cir. 2005) (en banc) (citation omitted); *see also* Trivascular, Inc. v. Samuels, 2016 WL 463539, at *4 (Fed. Cir. Feb. 5, 2016) ("We find the Board's reliance on the dictionary definition of ridge when considered in the context of the written description and plain language of the claims was proper.").

Accordingly, we determine, for the purposes of this Decision, that the term "rigid" means "[u]nable to bend or be forced out of shape, not flexible." *See, e.g.*, OXFORD ONLINE DICTIONARY, available at www.oxforddictionaries.com/us/definition/american_english/rigid (last visited Jan. 25, 2016) (Ex. 3001). The term "semi-rigid" means "[s]tiff and solid, but not inflexible." *See, e.g.*, OXFORD ONLINE DICTIONARY, available at www.oxforddictionaries.com/us/definition/american_english/semi-rigid (last visited Jan. 25, 2016) (Ex. 3002). These constructions are consistent with the Specification's use of those terms. *See, e.g.*, Ex. 1001, 7:21–32, 11:18–20.

Furthermore, based on the Specification, we further refine the constructions as follows. For example, the Specification differentiates between "a rigid material, a semi-rigid material, a soft material, a gel

material, a cloth material, and a non-woven cloth material." Ex. 1001, 7:21–32. Accordingly, we determine that none of soft, gel, cloth, and non-woven cloth materials alone is "rigid" or "semi-rigid." In another example, the Specification provides the following examples of "semi-rigid plastics": PVC and polypropylene. Ex. 1001, 11:18–20. Accordingly, we determine that "semi-rigid" may include "PVC and polypropylene."

2. "perimeter"

Claim 1 recites "the mechanical fastener including 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." Ex. 1001, 14:15–18 (emphasis added). RMS contends that the term "perimeter" should be afforded its plain and ordinary meaning—"the boundary of a closed plane or figure." Pet. 9 (referencing Merriam Webster's online dictionary and Ex. 1002 ¶ 54). EMED agrees that the term should be afforded its ordinary and customary meaning, but does not offer a meaning. Prelim. Resp. 11.

For the purposes of this Decision, we agree with the parties that the term "perimeter" is entitled to its ordinary and customary meaning. For this Decision, we determine that the ordinary and customary meaning is "[t]he outermost parts or boundary of an area or object." *See, e.g.*, OXFORD ONLINE DICTIONARY, available at www.oxforddictionaries.com/us/definition/american_english/perimeter (last visited Jan. 25, 2016) (Ex. 3003).[4] This construction is consistent with the

[4] We recognize that our construction is very similar to RMS's construction. We do not adopt RMS's construction at this time as the construction is more applicable to the narrower use of the term in geometry.

Specification's use of that term. *See, e.g.*, Ex. 1001, 6:19–24, Fig. 11 (perimeter 1040).

3. "in attachment to"

Claim 1 requires "the inner region of each wing [be] in attachment to the central body portion." Ex. 1001, 13:40–41. EMED provides that the term "in attachment to" should be construed to mean "directly attached to." Prelim. Resp. 9. EMED contends that "[o]ne of ordinary skill in the art would understand that the use of the phrase 'in attachment' means 'directly attached to' and not attached through another structure." *Id.* fn. 15. RMS does not offer a construction for this term.

Based on the record before us, we are not persuaded that EMED's construction is correct. EMED provides no additional arguments or citations to the current record, such as the Specification or prosecution history for the '476 patent, to support limiting the construction of this term to require direct attachment. Furthermore, we are also unable to ascertain any disclosure in the Specification that supports EMED's construction. For the purposes of this Decision, we determine that the term "in attachment to" is not so limited and encompasses configurations where wings are attached, directly or indirectly, to the central body portion of the device.

4. "to allow"

Claim 1 requires "the wings in the open position [be] 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." Ex. 1001, 14:3–6 (emphasis added). EMED contends that the term "to allow" should be construed to mean "configured for." Prelim. Resp. 10. EMED states that "[o]ne of ordinary skill in the art would understand the

term 'allow' to mean, based on the support in the specification, 'configured for.'" *Id.* fn. 19. EMED does not identify any specific disclosures in the Specification (or elsewhere in the record) that support this construction. RMS does not offer a construction of this term.

Based on the record before us, we are not persuaded that EMED's construction is correct as EMED's construction unduly narrows the meaning of the term. The phrase "configured to" may be interpreted to require the wings to be designed for placement of the medical needle at a treatment site. The term "allow" is broader than that—the wings need merely permit the medical needle to be placed at the treatment site. *See, e.g.*, OXFORD ONLINE DICTIONARY, available at www.oxforddictionaries.com/us/definition/american_english/allow (last visited Jan. 25, 2016) (Ex. 3004). This construction is consistent with the Specification's use of that term. *See, e.g.*, Ex. 1001, 1:41–43, 7:62–65, 8:49–54, 9:63–64, 11:22–25, 12:43–46.

5. "therebetween"

Claim 1 requires "a mechanical fastener . . . configured to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect against accidental needle stick injury from the sharp tip of the medical needle." EMED contends that the term "therebetween" should be construed to mean "between the closed pair of wings." Prelim. Resp. 10 fn. 21 (citing Ex. 1001, 6:19–29). RMS does not provide a construction of this term.

For the purposes of this Decision, we agree with and adopt EMED's construction. We determine that the plain meaning of claim 1 provides that

the medical needle is positioned between the pair of wings when the wings are attached together by the mechanical fastener.

6. "lip"

Neither party offers a construction of the term "lip." As seen below, our analysis turns, in part, on the meaning of this term, so we provide a construction here. For the purposes of this Decision, based on our review of the current record, we determine that "lip" should be afforded its ordinary and customary meaning—"[a] rounded, raised, or extended piece along an edge." *See, e.g.*, OXFORD ONLINE DICTIONARY, available at www.oxforddictionaries.com/us/definition/american_english/lip (last visited Jan. 26, 2016) (Ex. 3005). This construction is consistent with the Specification's use of that term. *See, e.g.*, Ex. 1001, 6:22–27, Fig. 11 (lip 1042).

B. Asserted Grounds of Unpatentability

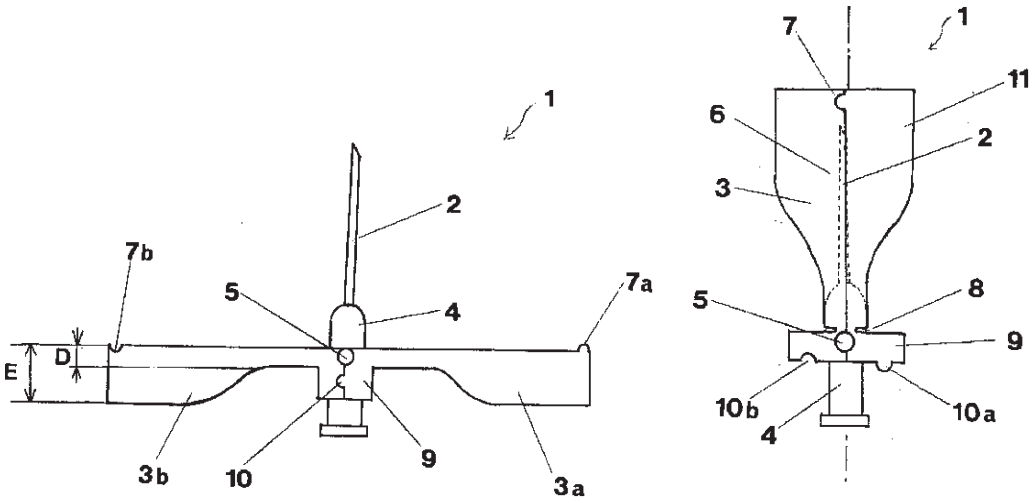
RMS asserts that claims of the '476 patent are unpatentable under 35 U.S.C. § 102(b), 35 U.S.C. § 103(a), or both. Pet. 5–6. RMS analyzes the identified claims against the identified references, an analysis supported by Dr. Kazmer's declaration. *See* Pet. 10–52; Ex. 1002. EMED's Preliminary Response presents detailed arguments countering positions taken in the Petition. *See* Prelim. Resp. 13–42.

We recognize that EMED has not yet had an opportunity to offer countervailing testimony to Dr. Kazmer's testimony. Our findings and determinations provided below are based on the limited record before us at this stage of the proceedings.

1. Claim 1 under 35 U.S.C. § 102(b) by Harada

a. Overview of Harada

Harada is directed to a device that prevents accidental contact with an injection needle. Ex. 1003, Abstract.[5] Figures 1 and 2 of Harada are reproduced below.



Harada's Figure 1, shown above on the left, illustrates a front view of the device when the medical needle is in use. Ex. 1003 ¶ 7. Figure 2, above at right, depicts a front view of the device before or after use of the medical needle. *Id.* Figures 3 and 4 are reproduced below.

[5] Our references to Harada are to the English translation provided with Exhibit 1003.

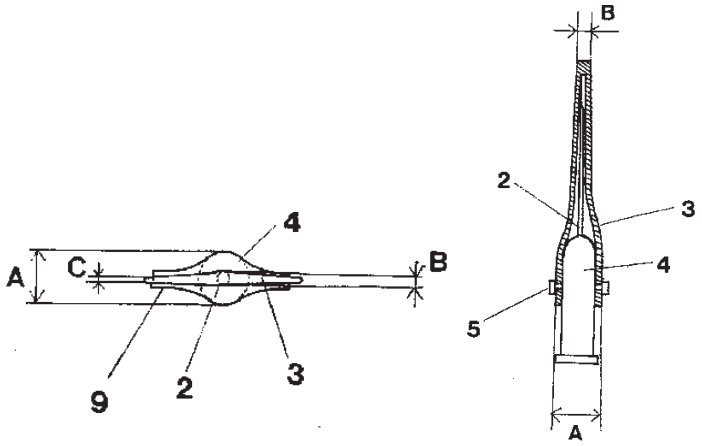


Figure 3 provides a top view of the embodiment of Figure 2. Ex. 1003, Brief Descriptions of the Drawings. Figure 4 provides a cross-sectional view of the embodiment of Figure 2. *Id.*

Harada's device includes medical needle 2 and needle base 4. Ex. 1003 ¶ 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. 1007 ¶ 11. Engaging means 7 includes male stopping means 7a on wing 3a and female means 7b on wing 3b. *Id.*

b. Analysis of claim 1

RMS contends that Harada discloses each and every claim limitation of independent claim 1. Specifically, RMS identifies Harada's needle base 4 as corresponding to the recited central body and medical needle 2 as corresponding to the recited needle, with medical needle 2 including a sharp tip at one end and in fluid communication with needle base 4, as required by

independent claim 1. Pet. 16–17. RMS further contends that wings 3a and 3b satisfy the requirements of the recited pair of wings, including being selectively positionable to allow placing the needle into a treatment site. *Id.* at 18.

Finally, RMS contends that engaging means 7 corresponds to the mechanical fastener of claim 1. Pet. 19. RMS identifies male stopping means 7a as corresponding to the recited lip structure of the mechanical fastener and the female means 7b as the mating portion. *Id.* at 20.

EMED argues that Harada does not anticipate claim 1. First, EMED contends that Harada's wings do not allow placement of the medical needle at a treatment site. Prelim. Resp. 15–16. This argument apparently stems from EMED's proposed construction of "to allow" to mean "configured for." EMED argues that Harada's wings are designed for increasing the surface area by which the needle structure is secured with tape to a patient, and thus not configured to place the needle at a treatment site. *Id.* As discussed above in our claim construction analysis, we determine, based on the current record, that EMED's proffered construction is too narrow. We agree with RMS that Harada's wings permit medical needle 2 to be placed at a treatment site.

Next, EMED argues that Harada's needle is an injection needle composed of two parts—the needle and a needle base. Prelim. Resp. 16. EMED contends that this structure does not have a central body portion as required by claim 1 and that RMS erroneously identifies the needle as the central body portion. *Id.* As EMED explains, claim 1 requires the recited needle to have an end distal from the central body portion and, by identifying the needle as the central body portion, RMS's position requires

the needle to be distal from itself. *Id.* at 17. EMED further argues that Harada does not have wings that are in attachment to a central body portion because Harada does not have a central body portion. *Id.*

Based on the record before us, we are not persuaded by EMED's argument that RMS's position is deficient. We recognize that claim 1 recites both a central body portion and a medical needle. RMS identifies needle base 4 and medical needle 2, respectively, as corresponding to these elements. *See* Pet. 16–17. Medical needle 2 includes a first end that is in fluid communication with needle base 4. *See* Ex. 1003, Fig. 1. Medical needle 2 also includes a second end with a sharp tip distal from the needle base 4. *See id.* Wings 3a and 3b are attached to needle base 4 at point 5. *See id.*

Next, EMED argues that Harada's wings "are not spaced apart from one another in the open position" because the base of each wing are adjacent to one another. Prelim. Resp. 18. EMED contends that each pair of wings disclosed in the '476 patent are spaced apart when open.

Based on the record before us, we are not persuaded by EMED's argument that RMS's position is deficient. Claim 1 recites, in relevant part, "where the wings in the 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." Ex. 1001, 14:2–6. EMED's argument is that this phrase should be construed to require that every part of one wing be spaced apart from every part of the other wing and supports this position by contending that every embodiment of the '476 patent is depicted as such. We determine that EMED's argument seeks to improperly narrow the claim.

"[I]t is the claims, not the written description, which define the scope of the patent right." *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) (citation omitted); *see also Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). Although the specification consistently depicts wings that, in the open position, are not adjacent to one another at any point, we are unpersuaded, on this record, that the Specification *limits* the structure in this way. *See, e.g.*, *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1298–99 (Fed. Cir. 2007) (refusing to limit the meaning of a claim term, under a broadest reasonable construction rubric, despite the fact that every embodiment in the specification was so limited). The claim requires that the wings be spaced apart *to expose the medical needle* and *allow the needle to be placed at a treatment site*. In Harada's device, the wings open such that the ends of each wing distal from needle base 4 are spaced apart to expose needle 2 and permit needle 2 to be placed at a treatment site. *See, e.g.*, Ex. 1003, Fig. 1 (depicting Harada's device with open wings); *cf. id.* Fig. 2 (depicting Harada's device with closed wings where the wings are adjacent to one another).

Finally, EMED argues that Harada's male locking means 7a does not include a lip nor does it extend along the perimeter. Prelim. Resp. 18. Similarly, EMED contends that female means 7b is not along the perimeter. *Id.* EMED fails to further explain these positions. Based on the record before us, we are not persuaded by EMED's argument that RMS's position is deficient. Male stopping means 7a appears to be positioned at the edge (or outermost part) of wing 3a and extend from that edge. *See* Ex. 1003, Figs. 1

and 2; *see also* Section II.A, *supra* (construing the terms "perimeter" and "lip"). Female means 7b appears to be positioned at the edge (or outermost part) of wing 3b and includes a recess that mates with the extension of stopping means 7a to lock the wings in a closed position. *See id.*; *see also* Ex. 1011, 147–50 (distinguishing the prior art cited by the Examiner because the lip and mating portion of US 7,569,044 B2 ("Triplett") locked the wings in an *open* position).

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that Harada anticipates claim 1. We are not persuaded, at this time, that EMED's arguments show deficiencies in the proposed ground of unpatentability applied to this claim.

2. Claims 1–3 and 5 under 35 U.S.C. § 102(b) by Rosato

a. Overview of Rosato

Rosato is directed to a needle safety enclosure. Ex. 1004, Abstract. Rosato was in front of the Examiner during prosecution of the application that matured into the '476 patent, but did not form the basis of a rejection. *See* Prelim. Resp. 18–19; Ex. 1011, 114–26 (providing first office action), 164–72 (providing second office action). Rosato's Figures 1 and 3 are reproduced below.

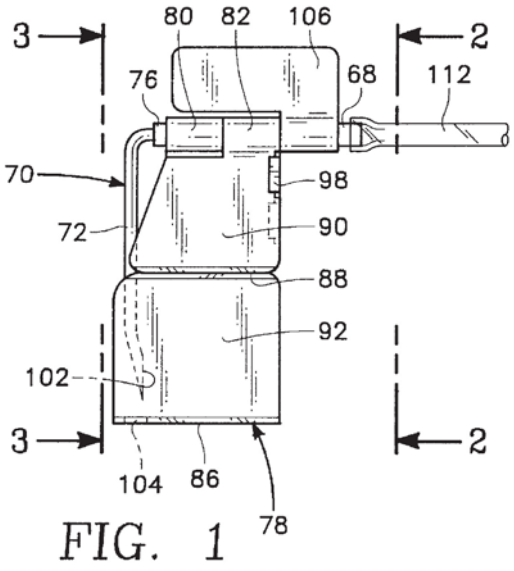


FIG. 1

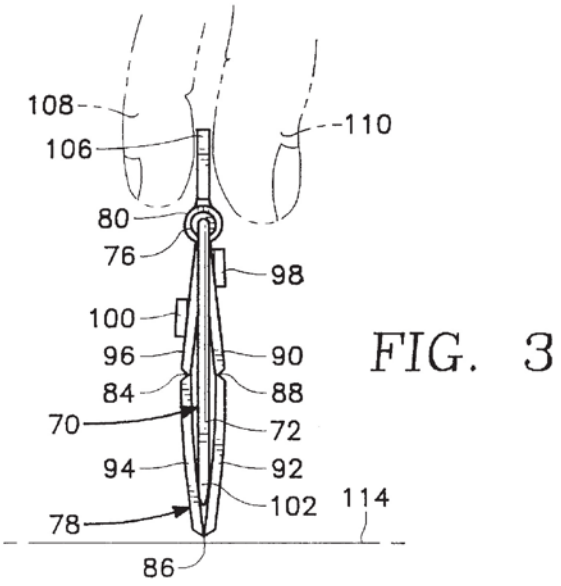


FIG. 3

Figure 1 depicts a side elevation of an embodiment of Rosato's needle safety device. Figure 3 provides a front view of the same embodiment. Rosato's needle safety device includes needle 70, with sharpened point 72 distal from where needle 70 meets stop sleeve 76. Ex. 1004, 4:15–46. Flexible tube 112, which carries fluid, is connected to aft end 68. *Id.* at 4:59–61.

Aft end 68 is conducted through short tubes 80, 82, which attach and pivotally mount wing assembly 78 to aft end 68. Ex. 1004, 4:21–25. Wing assembly 78 includes four panels 90, 92, 94, 96 with three parallel fold lines 84, 86, 88 separating the panels. *Id.* at 4:25–33. Handle fin 106 is also pivotally mounted on aft end 68. *Id.* at 4:52–53.

Panel 96 includes locking tab 98 and panel 90 includes locking tab 100. Ex. 1004, 4:36–38. When Rosato's device is positioned as shown in Figures 1 and 3, locking tab 98, which includes an inward protrusion, overrides the edge of panel 90 to lock the wings in place to encase sharpened point 102 within the wing assembly. *Id.* at 4:38–47. Locking tab 100 works in the same way. *See id.*

b. Analysis of claims 1, 2, 3, and 5

RMS identifies locking tabs 98 and 100 as corresponding to the recited mechanical fastener of claim 1. Pet. 19–20. The locking tabs include an inward protrusion that RMS contends corresponds to the recited mating portion, with the edge of the wing allegedly forming the lip. *Id.* at 21.

EMED argues that Rosato's locking tabs do "not include a lip, do[] not extend along a perimeter, and do[] not include a mating portion that is along a perimeter of the other wing." Prelim. Resp. 22. We agree. Our construction of the term "lip" requires a structure that is more than just an edge—it requires a structure that is raised or otherwise extends from an edge. *See* Section II.A.6, *supra*. RMS fails to explain how an edge of Rosato's wing corresponds to the recited lip.

On the record before us, we conclude that RMS has not shown a reasonable likelihood of prevailing in its assertion that Rosato anticipates claim 1. Further, as claims 2, 3, and 5 depend, directly or indirectly, from claim 1, we conclude that RMS has not shown a reasonable likelihood of prevailing in its assertion that Rosato anticipates claims 2, 3, and 5 as well.

3. Claims 1, 5, and 7 under 35 U.S.C. § 102(b) by Cole

a. Overview of Cole

Cole discloses a device for protecting a user from a sharp point after a medical device, such as a needle, is used. Ex. 1005, 1:5–16. Cole's Figures 1, 2, and 8 are reproduced below.

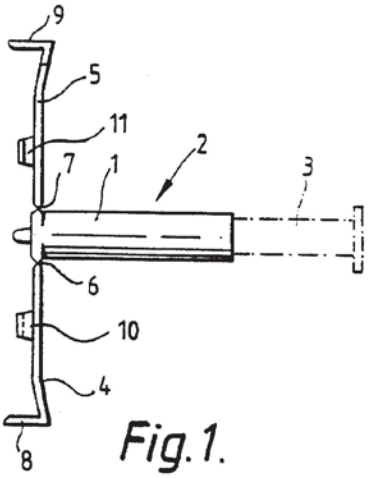


Fig.1.

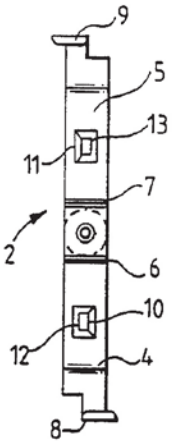


Fig.2.

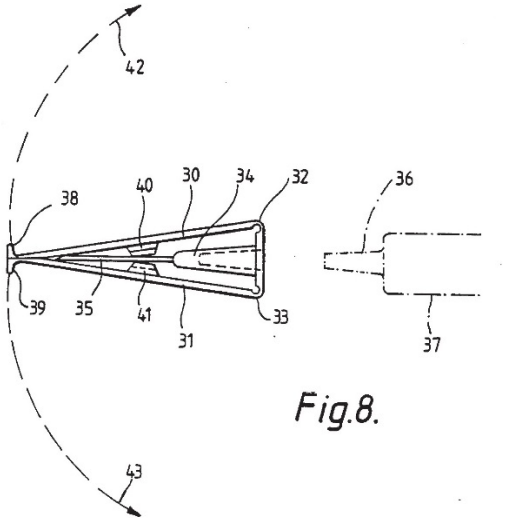


Fig.8.

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. Ex. 1005, 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. 1005, 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.

Flaps 38, 39 operate in the same way as flaps 8, 9 to protect the tip of the needle prior to use. Ex. 1005, 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).

b. Analysis of claim 1

RMS contends that the embodiment of Cole's Figure 8 anticipates claim 1. RMS identifies detachable hub 34 as corresponding to the recited central body, with needle 35 in fluid communication with syringe 37 through hub 34 and a sharp tip extending away from hub 34. Pet. 16–17.

RMS identifies arms 30, 31 as corresponding to the recited wings, contending that as the arms pivot towards the side of the syringe, they allow the needle to be placed into a treatment site. Pet. 18–19.

RMS identifies flaps 38, 39 as corresponding to the recited mechanical fastener. Pet. 20. RMS fails to specifically identify the recited lip and mating portion—apparently contending that the mutual protruding flaps (lips) at the edge of the wings engage the corresponding recesses (mating portions) on the edge of the wings adjacent to the flaps. *See id.* at 21.

EMED argues that Cole's needle is not in fluid communications with a delivery tube as required by claim 1. Prelim. Resp. 25. EMED contends that Cole's syringe is not a delivery tube. *Id.* Based on the record before us, we are not persuaded by EMED's argument that RMS's position is deficient. Neither EMED nor RMS offer a construction for the term "delivery tube." We are persuaded on the record that Cole's syringe is tube-shaped and

delivers fluid to a patient. *See* Ex. 1005, 3:19–20, 3:41–51. Needle 35 is in fluid communication with syringe 37 through hub 34.

EMED next argues that hub 34 cannot correspond properly to the recited central body portion. Prelim. Resp. 25. However, EMED fails to explain why detachable hub 34, which attaches to syringe 37, needle 35, and arms 30, 31 and is positioned centrally, is not a central body portion.

EMED further argues that arms 30, 31 are not wings, contending that "[o]ne of ordinary skill in the art would understand 'arms' to be very different than 'wings' because, as discussed in the '476 patent, wings are capable of use for placing the medical needle into the patient." Prelim. Resp. 26. EMED continues that an artisan of ordinary skill would understand that wings "are capable of use for handling a medical needle." *Id.* As EMED explains, "'wings' can be folded behind and grasped together with the fingers of a user, opposite a medical needle, to allow placing the medical needle into the treatment site" to provide stability when placing the needle at the treatment site and protect the user from the sharp needle point. *Id.* In contrast, EMED contends that Cole's arms are not used to place the needle at the treatment site, but instead are used to assist in operating a plunger. *Id.* at 27. EMED further contends that arms are longer than wings. *Id.*

Based on the record before us, we are not persuaded by EMED's argument that RMS's position is deficient, as EMED argues limitations that are not recited in claim 1. Claim 1 merely requires that the wings permit placement of the medical needle in a treatment site, not that the wings provide stability during that operation. By opening arms 30, 31, needle 35 is

exposed and can be placed at a treatment site. Also, claim 1 does not limit the length of the wings in any way.

Finally, EMS argues that Cole fails to disclose the mechanical fastener of claim 1. Prelim. Resp. 28. Specifically, EMED argues that the recited lip of claim 1's mechanical fastener and flaps 38, 39 are different structures and that Cole's flaps 38, 39 do not include mating portions. As noted above in our analysis of Harada and claim 1, we construe the term lip, under a broadest reasonable interpretation, to mean "a rounded, raised, or extended piece along an edge." *See* Section II.A.6, *supra*. Based on the record before us, we find that flaps 38, 39 include an extended piece along the edge of arms 30, 31 and that the notches adjacent to each flap that receive the other arm's flap constitutes a mating portion. Both the flaps and notches are along the perimeter—the outermost part or boundary—of arms 30, 31. *See* Section II.A.2, *supra*.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that Cole anticipates claim 1. We are not persuaded, at this time, that EMED's arguments show deficiencies in the proposed ground of unpatentability applied to this claim.

c. Analysis of dependent claims 5 and 7

Claim 5 depends from claim 1 and further requires "the pair of wings [to be] formed of semi-rigid material." Ex. 1001, 14:30–31. Claim 7 also depends from claim 1 and further requires "the pair of wings each [to] have a rectangular shape." *Id.* at 14:34–35.

With respect to claim 5, RMS contends that Cole discloses that its arms are flexible and made of a plastic material. Pet. 25; *see also* Ex. 1002 ¶ 190 (discussing Cole and stating that "a molded plastic capable of

providing needle protection while providing easy disengagement of flaps but with slight elbows in the arms would need to be both moderately rigid and moderately flexible, and thus be 'semi-rigid'"). As to claim 7, RMS contends that Cole's arms, as depicted in Figure 2,[6] are rectangular in shape. *Id.* EMED contends that Cole fails to disclose the subject matter of claims 5 and 7, but does not provide further explanation. Prelim. Resp. 28.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that Cole anticipates claims 5 and 7. As construed above, semi-rigid materials include at least some plastics and Figure 2 depicts rectangular arms.

4. Claims 1 and 7–9 under 35 U.S.C. § 102(b) by Ishikawa

a. Overview of Ishikawa

Ishikawa is directed to a winged needle that safely exposes and covers the needle. Ex. 1006, Abstract. Ishikawa was in front of the Examiner during prosecution of the application that matured into the Ishikawa patent, but did not form the basis of a rejection. *See* Prelim. Resp. 28; Ex. 1011, 114–26 (providing first office action), 164–72 (providing second office action). Ishikawa's Figures 1 and 2 are reproduced below.

[6] We note that Cole discloses that arms 30, 31 of the embodiment of Figure 8 are similar to arms 4, 5 depicted in Figures 1–7, except for arms 30, 31 interfacing with hub 34.

FIG.1

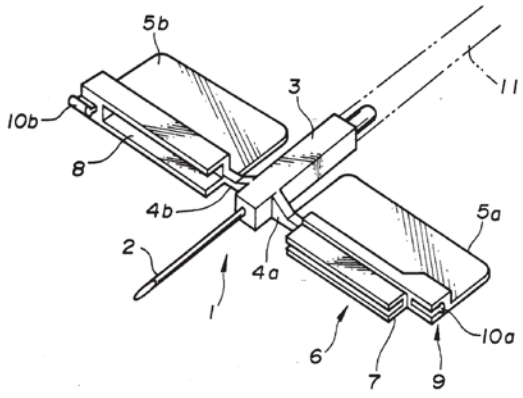


FIG.2

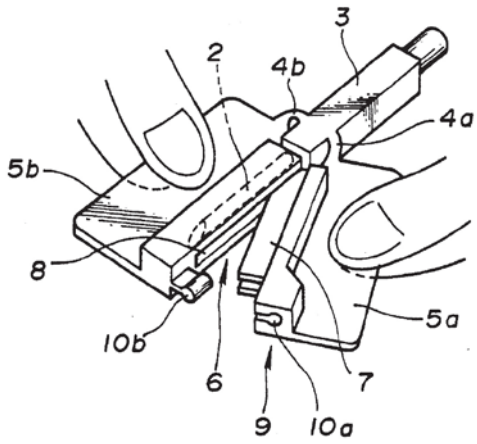


Figure 1 provides a perspective of an embodiment of Ishikawa's winged needle, and Figure 2 depicts the embodiment of Figure 1, during the process of covering the needle. Ex. 1006, 1:56–59. Ishikawa's winged needle 1 includes a needle 2 attached at one end to base 3 and wings 5a, 5b attached to base 3 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 (ditched portion 7 and lipped section 8 form sheath portion 6). Ex. 1006, 2:14–19. When closed, needle 2 is enclosed in ditch projection 7, with lipped section 8 covering ditch projection 7. *See* Ex. 1006, 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.

b. Analysis of claim 1

RMS asserts that Ishikawa anticipates claim 1. RMS contends that needle 2 corresponds to the recited medical needle and base 3 corresponds to

the recited central portion, with needle 2 in fluid communication with flexible tube 11 through base 3. Pet. 17. RMS further contends that wings 5a, 5b correspond to the pair of wings of claim 1, with arms 4a, 4b working like hinges to allow the wings to move between opened and closed positions. *Id.* at 19.

RMS identifies coupling means 9 as the recited mechanical fastener, with female part 10a and male part 10b located at the tip of each wing. Pet. 20. Presumably, male part 10b corresponds to the lip and female part 10a corresponds to the mating portion of the recited mechanical fastener.

EMED contends that Ishikawa's wings do not cover the needle—instead, sheath 6 covers the needle. Prelim. Resp. 31. That is, sheath 6 is not part of wings 5a, 5b. Based on the record before us at this point in the proceeding, we are not persuaded by EMED's argument that RMS's position is deficient. Based on our reading of Ishikawa, ditch protection 7 and lipped section 8 are formed on the edge of wings 5a, 5b and, as such, may be considered part of the wings.

Similarly, EMED contends that "[i]n Ishikawa, the needle is positioned in a sheath attached to the edges of the wings and not the broad side of the wing as claimed in Claim 1 of the '476 patent." Prelim. Resp. 31. EMED argues that Ishikawa's wings, in a closed position, do not cover the needle. *Id.* at 31–32. Again, we are not persuaded at this time that sheath 6 is not part of Ishikawa's wings.

EMED also contends that Ishikawa's wings are not attached to the central body portion (base 3), but instead arms 4a, b are attached to the central body portion. Prelim. Resp. 32. This contention appears to be based on EMED's proposed construction of "in attachment to," which EMED

argues should require direct attachment. *See id.* at 9. As discussed above in our claim construction analysis, we determine, at this point in the proceeding that "in attachment to" does not require direct attachment.

EMED also contends that Ishikawa's coupling means does not include a lip or mating portion extending along a perimeter of the wings. Prelim. Resp. 32. However, we are unpersuaded that Ishikawa's coupling means being positioned at the tip (or outermost part) of the wings cannot be considered as extending along the perimeter.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that Ishikawa anticipates claim 1. We are not persuaded, at this time, that EMED's arguments show deficiencies in the proposed ground of unpatentability applied to this claim.

c. Analysis of dependent claims 7–9

Claim 7 depends from claim 1 and further requires "the pair of wings each [to] have a rectangular shape." Ex. 1001, 14:34–35. Claim 8 depends from claim 1 and further requires "at least one of the pair of wings [be] formed with a groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position." *Id.* at 14:36–39. Claim 9 depends from claim 8 and further recited "the groove [be] formed in a single one of the pair of wings." *Id.* at 14:40–41.

RMS contends that Ishikawa's wings have a rectangular shape, referencing Figure 1. Pet. 25. As to claims 8 and 9, RMS also contends that ditched projection 7 of Ishikawa's sheath 6 houses medical needle 3 and lipped section 8 houses ditched portion 7, such that Ishikawa's wings have a groove on a single one of the pair of wings for housing the needle. *Id.* at 25–26. EMED does not directly contest this position. *See* Prelim. Resp. 32.

On the record before us based on the parties' arguments and our independent review of the evidence at this stage of the proceeding, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that Ishikawa anticipates claims 7–9.

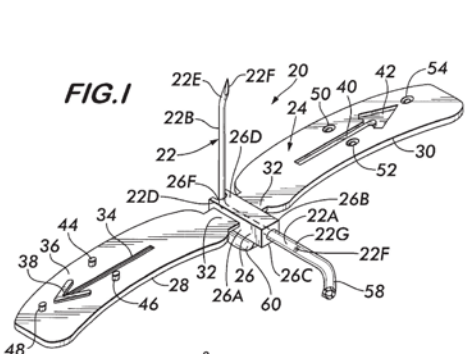
5. Claims 1, 6, and 7 under 35 U.S.C. § 103(a) over Sasso and Harada, Rosato, Cole, Ishikawa, or Nicoletti

a. Overview of Sasso

Sasso is directed to a needle safety device. Ex. 1010, Abstract. Sasso was in front of the Examiner and served as the basis of an obviousness rejection, in view of US 7,569,044 B2 to Triplett (not of record in this proceeding), during prosecution of the application that matured into the '476 patent. During prosecution, the Examiner found that Sasso and Triplett did not teach or render obvious

> the mechanical fastener including 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. 1011, 170–71. Sasso's Figures 1 and 2 are reproduced below:



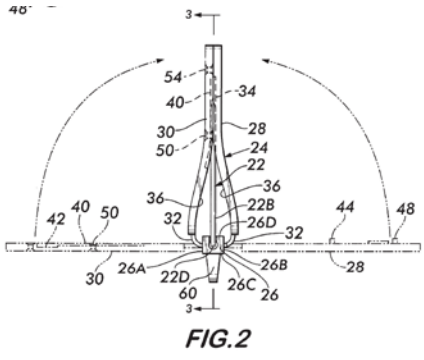


Figure 1 provides an isomeric view of Sasso's needle safety device in an open position and Figure 2 depicts the same embodiment in a closed

position. Ex. 1010, 3:34–41. As seen in Figure 1, Sasso's mechanical fastener includes posts 44, 46, 48 that mate with apertures 50, 52, 54,

b. Overview of Nicoletti

Nicoletti is directed to a device that protects a user from accidental needle punctures from a butterfly needle. Ex. 1007, Abstract. RMS relies on Nicoletti for disclosing a mechanical fastener with a lip and mating portion. *See* Pet. 34–35. The fastener is depicted in Nicoletti's Figure 26, reproduced below.

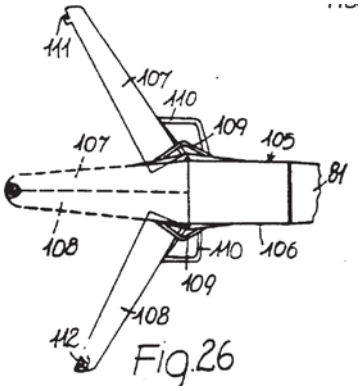


Figure 26 depicts an embodiment of Nicoletti's protection device. Ex. 1007, 2:30–31, 35–37. Tooth 111 and recess 112 provide a "snap-together engagement" to engage and retain the two half-shells 107, 108. *Id.* at 6:12–16.

c. Analysis of claim 1

RMS contends that the Examiner found that Sasso discloses each and every claim element of claim 1, except a mechanical fastener with a lip and mating portion extending along a perimeter as recited in claim 1. Pet. 34. RMS further contends that "it would have been obvious to a person of ordinary skill in the art to combine the lip and mating portion fastening

mechanism used on Harada, Rosato,[7] Cole, Ishikawa, or Nicoletti with the needle protection device disclosed in Sasso." *Id.* at 34–35. RMS provides no reason to modify Sasso other than stating "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," which RMS provides for all of its obviousness positions. *Id.* at 42; *see also* Ex. 1002 ¶ 156 (providing that it would have been obvious to combine the references as they are all directed to "molded plastic winged devices for needle safety"—essentially that all of the references are in the same field of endeavor).

On the record before us, we conclude that RMS has failed to show a reasonable likelihood of prevailing in its assertion that Sasso, in combination with any one of Harada, Rosato, Cole, Ishikawa, or Nicoletti, renders claim 1 obvious. We recognize that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). RMS fails to articulate why an artisan of ordinary skill would replace Sasso's posts and apertures for one of the locking mechanisms of Harada, Rosato, Cole, Ishikawa, or Nicoletti (or move the posts and apertures to the perimeter of the wings as taught by these references) other than providing

[7] As discussed above in connection with our analysis of whether Rosato anticipates claim 1, we conclude the Petition has failed to show that Rosato's mechanical fastener includes a lip.

reasoning that all of the references are in the same field of endeavor and further providing a global reason in support of all of its obviousness contentions that such a substitution involve known features and would yield predictable results. Such reasoning is insufficient by itself to constitute the requisite rational underpinning in this case. *See, e.g.*, *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."); *see also KSR*, 550 U.S. at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art").

Further, on the record before us, we conclude that RMS has failed to show a reasonable likelihood of prevailing in its assertion that Sasso, in combination with any one of Harada, Rosato, Cole, Ishikawa, or Nicoletti renders claims 6 and 7, which depend from claim 1, obvious for the reason provided above.

6. Claims 2–10 under 35 U.S.C. § 103(a)

a. Overview of Raines

Raines discloses a needle safety device with wings. Ex. 1009, 1:14–18. Figure 1 of Raines is reproduced below.

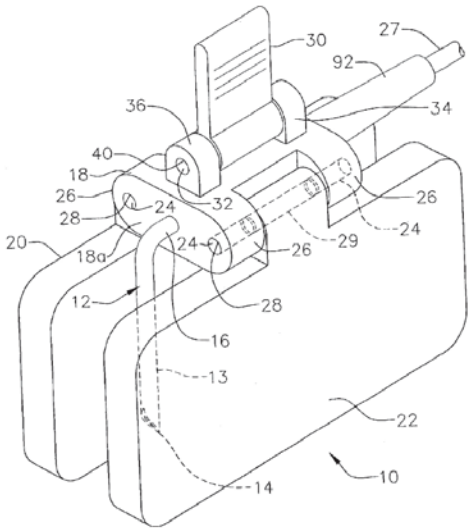


Figure 1 provides a perspective view of Raines's needle safety device. As seen in Figure 1, Raines's device includes wings 20, 22, which fold around needle 12 to prevent a user from being injured by the needle and third wing 30. Ex. 1009, 3:18–25, 4:12–14. Third wing 30 serves as a handle. *See, e.g.*, *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."); *see also* Prelim. Resp. 35 ("Raines further discloses a third wing that can be used as a handle."). 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.

b. Analysis of dependent claim 2

Claim 2 depends from claim 1 and requires the device to "further compris[e] a handle extending from the central body portion." Ex. 1001, 14:22–23. RMS contends that each of Harada, Cole, or Ishikawa could be combined with any of Sasso, Raines, or Rosato to render the subject matter of claim 2 obvious. Pet. 35–36. As RMS explains, Raines, Rosato, and

Sasso each disclose a handle extending from the central body portion of a needle safety device. *Id.* at 35. RMS states that it would have been obvious to modify Harada, Cole, or Ishikawa to include a handle extending from the central body portions of their needle safety devices as taught by Raines, Rosato, and Sasso "because all of the references teach very similar winged needle protection devices for the same purpose." *Id.* at 35–36. Dr. Kazmer adds that the proposed combinations render claim 2 obvious because "a handle facilitates safe handling of the device and improved needle safety." Ex. 1002 ¶ 163.

EMED argues that Raines fails to disclose the elements of claim 1 nor does it cure the deficiencies in RMS's positions regarding claim 1. Prelim. Resp. 35–36. However, RMS relies on Harada, Cole, or Ishikawa for disclosing the subject matter of claim 1. Further, as discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada, Cole, or Ishikawa anticipating claim 1 deficient.

On the record before us, including Dr. Kazmer's added rationale, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 2 is obvious. RMS treats the proposed combinations as interchangeable—it fails to identify any one combination as preferable over others. Accordingly, we exercise our discretion to go forward with the representative combination of Harada and Raines only for claim 2 and not the other eight possible combinations proposed by RMS. *See* 35 U.S.C. § 314(a).

c. Analysis of dependent claim 3

Claim 3 depends from claim 2 and further recites "wherein the handle extends away from the central body portion in opposition to a direction of the second end of the medical needle." Ex. 1001, 14:25–27. RMS contends that each of Harada, Cole, or Ishikawa would have been combined with any of Sasso, Raines, or Rosato to render the subject matter of claim 3 obvious. Pet. 36. RMS asserts that "[e]ach of the handles disclosed in Raines, Rosato, and Sasso extends away from the central body portion in opposition to a direction of the second end of the medical needle" as required by claim 3 and further relies on the reasoning provided for claim 2. *Id.*

EMED argues that the proposed combinations fail to disclose the mechanical fastener of claim 1. Prelim. Resp. 36. As discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada, Cole, and Ishikawa anticipating claim 1 deficient as to the mechanical fastener recitation.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 3 is obvious. RMS treats the proposed combinations as interchangeable. Accordingly, we exercise our discretion to go forward with the representative combination of Harada and Raines only for claim 3 and not the other eight possible combinations proposed by RMS. *See* 35 U.S.C. § 314(a).

d. Analysis of dependent claim 4

Claim 4 depends from claim 1 and further recites "wherein the pair of wings are formed of rigid material." Ex. 1001, 14:28–29. RMS contends that each of Harada, Cole, and Ishikawa, in combination with Raines,

renders the subject matter of claim 4 obvious. Pet. 36.[8] RMS asserts that Raines discloses that its wings are preferably formed of a rigid material, such as polycarbonate. *See id.* at 36–37; *see also* Ex. 1002 ¶ 183 (declaring that one of ordinary skill in the art would understand that the disclosed materials in Raines include rigid plastic materials). Dr. Kazmer declares that the proposed combinations would have been obvious "because the devices disclosed are all molded plastic winged devices designed for needle safety." Ex. 1002 ¶ 185. Further, Raines discloses that a *preferred* material for molded plastic is a rigid plastic material. Ex. 1009, 4:48–51. That is, an artisan of ordinary skill would have reason to modify the wings of Harada, Cole, and Ishikawa based on Raines's express teaching that a rigid material is a preferred material for wings in a molded plastic needle protection device.

EMED argues that the proposed combinations fail to disclose the mechanical fastener of claim 1 and Raines fails to cure the deficiencies. Prelim. Resp. 37. As discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada, Cole, and Ishikawa anticipating claim 1 deficient as to the mechanical fastener recitation.

[8] RMS asserts that Rosato and Raines renders claim 4 obvious as well. RMS fails to explain how Raines cures the deficiency we find in RMS's position that Rosato anticipates claim 1. Similarly, RMS fails to explain how the addition of Raines cures the deficiency we identified in RMS's position that claim 1 is obvious over Sasso and Harada, Rosato, Cole, or Ishikawa. Accordingly, RMS fails to show a reasonable likelihood of prevailing in its assertion that claim 4 is obvious over these combinations.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 4 is obvious. RMS treats the proposed combinations as interchangeable. Accordingly, we exercise our discretion to go forward with the representative combination of Harada and Raines only for claim 4 and not the other possible combinations proposed by RMS. *See* 35 U.S.C. § 314(a).

d. Analysis of dependent claim 5

Claim 5 depends from claim 1 and further recites "wherein the pair of wings are formed of semi-rigid material." Ex. 1001, 14:30–31. RMS contends that each of Harada or Ishikawa combined with either Cole or Rosato render claim 5 obvious. Pet. 37–38. RMS contends that Cole discloses that its arms are made of flexible plastic material and further contends that one of ordinary skill in the art would understand that the plastic as characterized in Cole is semi-rigid. *Id.* at 37; *see also* Ex. 1002 ¶ 190 ("[A] molded plastic capable of providing needle protection while providing easy disengagement of flaps but with slight elbows in the arms would need to be both moderately rigid and moderately flexible, and thus be 'semi-rigid.'").

RMS contends that Rosato discloses that fold lines 84, 86, 88 between the wing panels act as living hinges if the wings are made of plastic. Pet. 37. RMS further contends that an artisan of ordinary skill would understand that, to act as a living hinge, the plastic material must be semi-rigid. *Id.* at 37–38; *see* Ex. 1002 ¶ 189. RMS concludes that it would have been obvious to make Harada or Ishikawa's wings out of semi-rigid material as taught by Cole or Rosato. Dr. Kazmer declares that "[o]ne of ordinary skill in the art would be motivated to use a semi-rigid material especially for wings

described as requiring flexibility or requiring the use of a living hinge." Ex. 1002, ¶ 191.

EMED argues that the proposed combinations fail to disclose the mechanical fastener of claim 1 and Cole or Rosato fail to cure the deficiencies. Prelim. Resp. 37–38. As discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada and Ishikawa anticipating claim 1 deficient as to the mechanical fastener recitation.

On the record before us, we conclude that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 5 would have been obvious. Again, RMS treats the proposed combinations as interchangeable. Accordingly, we exercise our discretion to go forward with the representative combination of Harada and Cole only for claim 5 and not the other possible combinations proposed by RMS. *See* 35 U.S.C. § 314(a).

e. Analysis of dependent claim 6

Claim 6 depends from claim 1 and further recites "wherein the pair of wings each have a substantially circular shape." Ex. 1001, 14:32–33. RMS contends that it would be a matter of obvious design choice to shape Harada's wings to be substantially circular. Pet. 38–39 (citing *In re Dailey*, 357 F.2d 669 (CCPA 1966)).[9] RMS's reasoning is based on a finding by the Examiner during prosecution of the application that matured into the '476

[9] RMS further contends that claim 6 is a matter of obvious design choice over Sasso and Harada, Rosato, Cole, or Ishikawa. Pet. 38–39. As discussed above, we find RMS's position as to these combinations of references applied to claim 1 deficient. Accordingly, RMS fails to show a reasonable likelihood of prevailing in its assertion that claim 6 is obvious over these combinations.

patent—EMED's Specification does "not disclose[ ] that the particular wing shape claimed provided any advantage, was used for a particular purpose, or solved a stated problem, and that wing shape was thus an obvious design choice." *Id.* at 39.

EMED argues that the prior art fails to disclose the mechanical fastener of claim 1. Prelim. Resp. 38–39. As discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada anticipating claim 1 deficient as to the mechanical fastener recitation.

Based on the record before us, we agree with RMS that the Specification fails to disclose that a circular shape solves a stated problem or provides an unexpected result. *See* Ex. 1001, 6:32–34; *cf. In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (concluding that the use of 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") (citation omitted). Accordingly, on this record, we determine that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 6 is obvious over Harada as a matter of obvious design choice.

f. Analysis of dependent claim 7

i. Overview of Keaton

Keaton discloses a butterfly infusion set that includes two wings that fold closed to protect a user from the sharp end of a catheter needle. Ex. 1008, Abstract. RMS relies on Keaton for disclosing rectangular wings. Pet. 39. Keaton's Figure 1, reproduced below, depicts the rectangular wings.

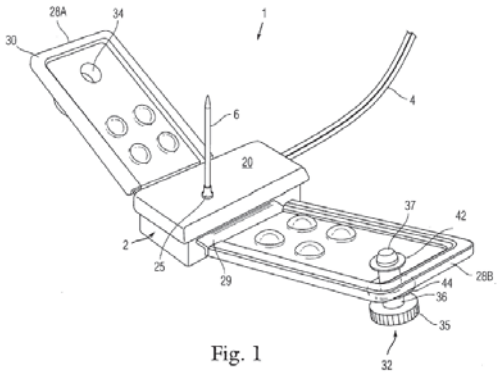


Fig. 1

Figure 1 is a bottom perspective view of Keaton's infusion set. Ex. 1008 ¶ 14.

ii. Analysis

Claim 7 depends from claim 1 and further recites "wherein the pair of wings each have a rectangular shape." Ex. 1001, 14:34–35. RMS contends that "Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti) in view of Raines, Keaton, Sasso, or" alone as a matter of design choice renders claim 7 obvious. Pet. 39 (emphasis omitted).[10] RMS notes that Raines, Keaton, and Sasso each teach rectangular wings. *Id.* RMS further contends that it would have been a mere matter of design choice to modify Harada to have rectangular shaped wings, again basing the reasoning on the fact that the Specification fails to "disclose that a particular shape claimed provides any advantage, is used for a particular purpose, or solves a stated problem, the disclosed shape is considered an obvious design choice." *Id.* at 40; *see* Ex. 1002 ¶ 201.

[10] As discussed above, we found RMS's position regarding Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti as applied to claim 1 deficient. Accordingly, RMS fails to show a reasonable likelihood of prevailing in its assertion that claim 7 is obvious over these combinations.

EMED argues that the prior art fails to disclose the mechanical fastener of claim 1. Prelim. Resp. 39–40. As discussed above in connection with our analysis of RMS's anticipation grounds, based on the record before us, we do not find RMS's positions as to Harada anticipating claim 1 deficient as to the mechanical fastener recitation.

Based on the record before us, we agree with RMS that the Specification fails to disclose that a rectangular shape solves a stated problem or provides unexpected result. *See* Ex. 1001, 6:32–34; *see also In re Kuhle*, 526 F.2d at 555 ("Use of such a means of electrical connection in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill of the art"). The fact that Raines, Keaton, and Sasso disclose needle safety devices with rectangular wings further supports that the rectangular shape would have been a design choice option.

Accordingly, based on the record before us, we determine that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 7 is obvious over Harada as a matter of obvious design choice. As RMS treats the proposed combinations as interchangeable, we exercise our discretion to go forward with this representative combination only and not any of the other three combinations. *See* 35 U.S.C. § 314(a).

g. Analysis of dependent claim 8

Claim 8 depends from claim 1 and further recites "wherein at least one of the pair of wings is formed with a groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position." Ex. 1001, 14:36–39. RMS contends that "Harada . . . combined with either of Sasso or Ishikawa" renders claim 8 obvious. Pet. 40

(emphasis omitted).[11] RMS explains that Sasso discloses the recited "groove configured to house the needle" when Sasso's wings are in a closed position. *Id.* RMS also contends that Ishikawa discloses the recited groove. *Id.*; *see also* Section II.B.4.c, *supra* (providing an analysis of Ishikawa and claim 8).

RMS's expert explains reasons why modifying Harada with Sasso's or Ishikawa's groove would have been obvious to one of ordinary skill in the art to "provide[ ] a secure and enclosed compartment for the needle." Ex. 1002 ¶ 214.

Again, EMED does not dispute RMS's position with respect to claim 8, other than to contend that the cited references fail to disclose the mechanical fastener of claim 1—a contention we find unpersuasive on the record before us. Prelim. Resp. 40.

Based on the limited record before us, we determine with RMS's position that Harada, as modified by the teachings of Sasso or Ishikawa, discloses the recited subject matter and further that RMS has provided a reason, with rational underpinning, for making the modification.

Accordingly, we determine that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 8 is obvious over (1) Harada and Sasso, and (2) Harada and Ishikawa.

[11] RMS further contends that claim 8 is obvious over Sasso and (Harada, Rosato, Cole, or Ishikawa) in view of Ishikawa. Pet. 40. As discussed above, we found RMS's position as to these combinations of references applied to claim 1 deficient. Accordingly, RMS fails to show a reasonable likelihood of prevailing in its assertion that claim 8 is obvious over these combinations.

h. Analysis of dependent claim 9

Claim 9 depends from claim 8 and further recites "wherein the groove is formed in a single one of the pair of wings." Ex. 1001, 14:40–41. RMS contends that Harada, as modified by Ishikawa as asserted for claim 8, renders claim 9 obvious. Pet. 41. As RMS explains in its position that Ishikawa anticipates claim 9, ditched projection 7 of Ishikawa's sheath 6 houses medical needle 3 and lipped section 8 houses ditched portion 7, such that Ishikawa's wings have a groove on a single one of the pair of wings for housing the needle. *Id.* at 25–26.

EMED does not dispute RMS's position with respect to claim 9, other than to contend that the cited references fail to disclose the mechanical fastener of claim 1—a contention we find unpersuasive on the record before us. Prelim. Resp. 41.

Accordingly, for the reasons stated above with respect to our obviousness analysis of claim 8 and our anticipation analysis of Ishikawa with respect to claim 9, we determine that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 9 is obvious over Harada and Ishikawa.

i. Analysis of dependent claim 10

Claim 10 depends from claim 8 and further recites "further comprising a handle extending from the central body portion." Ex. 1001, 14:42–43. RMS asserts that the combination of Harada and Sasso would render claim 10 obvious for the reasons explained in RMS's obviousness contentions with respect to claims 2 and 8. Pet. 41–42. Again, EMED does not dispute RMS's position with respect to claim 10, other than to contend that the cited references fail to disclose the mechanical fastener of claim 1—

a contention we find unpersuasive on the record before us. *See* Prelim. Resp. 42.

Accordingly, for the reasons stated above with respect to our obviousness analysis of claims 2 and 8, we determine that RMS has shown a reasonable likelihood of prevailing in its assertion that claim 10 is obvious over Harada and Sasso.[12]

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that RMS would prevail in showing that claims 1–10 of the '476 patent are unpatentable. We have not made a final determination with respect to the patentability of those claims or the construction of any claim term.

IV. ORDERS

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

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–10 of the '476 patent on the following grounds:

[12] We cannot discern from the Petition if RMS further contends that the combination of Harada, Ishikawa, and Sasso renders claim 10 obvious or if Harada and Ishikawa in combination with Raines or Rosato renders claim 10 obvious. To the extent that RMS asserts these grounds, we exercise our discretion to go forward with the representative combination of Harada and Sasso only. *See* 35 U.S.C. § 314(a).

A. Claim 1 as unpatentable under 35 U.S.C. § 102(b) as anticipated by Harada;

B. Claims 1, 5, and 7 as unpatentable under 35 U.S.C. § 102(b) as anticipated by Cole;

C. Claims 1 and 7–9 as unpatentable under 35 U.S.C. § 102(b) as anticipated by Ishikawa;

D. Claims 2, 3, and 4 as unpatentable under 35 U.S.C. § 103(a) over Harada and Raines;

E. Claim 5 as unpatentable under 35 U.S.C. § 103(a) over Harada and Cole;

F. Claims 6 and 7 are unpatentable under 35 U.S.C. § 103(a) over Harada.

G. Claims 8 and 10 as unpatentable under 35 U.S.C. § 103(a) over Harada and Sasso; and

H. Claims 8 and 9 are unpatentable under 35 U.S.C. § 103(a) over Harada and Ishikawa.

FURTHER ORDERED that no other ground of unpatentability other than those specified above is authorized for *inter partes* review; and

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

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