Patent Trial and Appeal Board's Final Written Decision
(January 12, 2017)

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

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

I. INTRODUCTION

Petitioner, Repro-Med Systems, Inc. ("RMS" or "Petitioner"), 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 Corporation ("EMED" or "Patent Owner"), filed a Preliminary Response (Paper 8, "Prelim. Resp.") to the Petition. We instituted trial on all challenged claims. Paper 9, 46 ("Dec. on Inst.")

After institution of trial, Patent Owner filed a Patent Owner Response ("PO Resp.") to the Petition. Paper 28.[1] Petitioner filed a Reply ("Reply") to the Patent Owner Response. Paper 31. Patent Owner filed a contingent Motion to Amend Claims ("Motion to Amend"). Paper 27.[2] Petitioner filed an Opposition to the Motion to Amend (Paper 32) and Patent Owner filed a Reply to that Opposition (Paper 36[3]). We authorized Petitioner to file a paper (Paper 40) identifying material in Patent Owner's Reply to the Opposition to the Motion to Amend that allegedly exceeds the proper scope of a reply. Paper 38, 3.

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[1] Patent Owner originally filed its response to the Petition as Paper 24. We subsequently instructed Patent Owner to file Paper 28 as a replacement response that complies with our word count limitations. *See* Paper 26, 3. This Final Written Decision's citations to the Patent Owner Response are citations to Paper 28.

[2] Patent Owner originally filed its Motion to Amend in Paper 25. We subsequently instructed Patent Owner to file Paper 27 as a replacement motion to correct certain procedural issues. *See* Paper 26, 2.

[3] Patent Owner originally filed its reply as Paper 34. We ordered Paper 34 expunged for exceeding the page limit for such a reply and further ordered a compliant paper (Paper 36) be filed. Paper 38, 4.

Petitioner relies on the Declaration testimony of Dr. David O. Kazmer ("Dr. Kazmer") in support of its Petition (Ex. 1002). Patent Owner relies on the Declaration testimony of Mr. Ron Stoker (Exs. 2003, 2007) ("Mr. Stoker") in support of its Patent Owner Response and Motion to Amend.

Both parties filed Motions to Exclude Evidence (Papers 42, 49), Oppositions to those motions (Papers 53, 55), and Replies to the respective oppositions (Papers 56, 58).

Oral hearing was conducted on November 22, 2016. The record contains a transcript of the hearing. Paper 64 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6. This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Petitioner has shown by a preponderance of the evidence that (a) claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by JP H9-66106 to Harada (Ex. 1003,[4] "Harada"); (b) claims 1, 5, and 7 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,944,731 to Cole (Ex. 1005, "Cole"); (c) claims 1, 7, and 8 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,147,319 to Ishikawa (Ex. 1006, "Ishikawa"); (d) claims 2, 3, and 4 are unpatentable under 35 U.S.C. § 103(a) over Harada and U.S. Patent No. 6,911,020 B2 to Raines (Ex. 1009, "Raines"); (e) claim 5 is unpatentable under 35 U.S.C.

[4] Exhibit 1003 includes both the original Japanese version of Harada and a certified English translation.

§ 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 are unpatentable under 35 U.S.C. § 103(a) over Harada and U.S. Patent No. 6,500,155 B2 to Sasso (Ex. 1010, "Sasso"); and (h) claim 8 is unpatentable under 35 U.S.C. § 103(a) over Harada and Ishikawa. Petitioner has not shown by a preponderance of the evidence that claim 9 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Ishikawa or that claim 9 is unpatentable under 35 U.S.C. § 103(a) over Harada and Ishikawa.

We deny Patent Owner's Motion to Amend. Further, we dismiss Patent Owner's Motion to Exclude Evidence and we grant-in-part, deny-in- part, and deny as moot-in-part Petitioner's Motion to Exclude Evidence.

A. Related Matters

The '476 patent is the subject of a district court proceeding 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, Paper 5, 2. 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. The '703 patent is subject to a district court proceeding 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. Pet. 2, Paper 5, 2.

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.

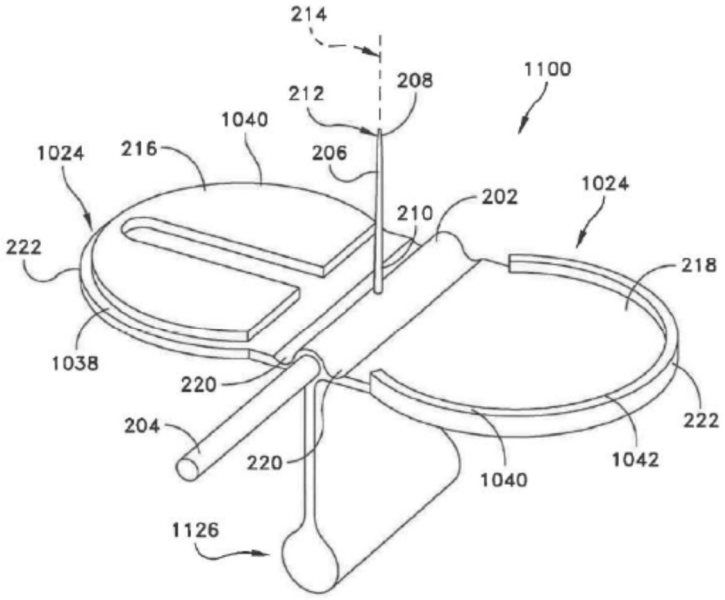

FIGURE 11

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. Device 1000, depicted in Figure 10 of the '476 patent is identical to device 1100, except that device 1000 does not include handle 1126. *See id.*, Fig. 10.

C. Illustrative Claims

Claim 1 is the sole independent claim of the '476 patent 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

We instituted *inter partes* review on grounds of unpatentability for claims 1–10 of the '476 patent that rely on the following references:

Cole	US 4,499,731	July 31, 1990	Ex. 1005
Ishikawa	US 5,147,319	Sept. 15, 1992	Ex. 1006
Sasso	US 6,500,155 B2	Dec. 31, 2002	Ex. 1010
Raines	US 6,911,020 B2	June 28, 2005	Ex. 1009
Harada	JP H9-66106	Mar. 11, 2011	Ex. 1003

E. Grounds of Unpatentability

We instituted *inter partes* review on the following grounds of unpatentability for the challenged claims of the '476 patent.[5]

No.	References	Basis	Claims Challenged
1.	Harada	§ 102(b)	1
2.	Cole	§ 102(b)	1, 5, and 7
3.	Ishikawa	§ 102(b)	1 and 7-9
4.	Harada and Raines	§ 103(a)	2, 3, and 4
5.	Harada and Cole	§ 103(a)	5
6.	Harada	§ 103(a)	6 and 7
7.	Harada and Sasso	§ 103(a)	8 and 10
8.	Harada and Ishikawa	§ 103(a)	8 and 9

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent, such as the '476 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 Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (concluding

[5] The Decision on Institution considered 27 separate grounds. *See* Dec. on Inst. 6–8.

that 37 C.F.R. § 42.100(b) "represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office"). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). 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. Level of Ordinary Skill in the Art

RMS's expert, Dr. Kazmer, contends that the level of ordinary skill of the '476 patent is "a degreed Chemical, Mechanical, or Plastics engineer with three years of experience directly related to plastics product design and injection molding" or, alternatively, "a non-degreed practitioner with ten years of experience directly related to plastics product design and injection molding." Ex. 1002 ¶ 21. EMED counters that the level of ordinary skill is "a degreed BioMedical, Chemical, Mechanical, or Plastics engineer with 3-5 years [of] experience designing medical products including medical products with a sharps protection device or alternatively a professional with 5-7 years [of] experience designing medical products, including medical products with a sharps protection device." PO Resp. 6 (citing Ex. 2003

¶ 22).[6] At oral argument, EMED clarified that the "experience designing medical products including medical products with a sharps protection device" merely required some of the experience in product design must concern sharps. See Tr. 36:13–6 ("[O]ne of skill in the art necessarily wouldn't need three to five years specifically working in sharps technology, but they would have to have at least some experience.").

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*). We find that the prior art is primarily directed to medical devices with sharp needles. *See, e.g.*, Exs. 1003–1010. We find, however, that the '476 patent expressly states that the invention may be applied to other devices with needles. *See* Ex. 1001, 4:57–61. We also find that the invention lacks complexity and the alleged innovative aspect of the '476 patent is its

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[6] In his Declaration supporting EMED's Motion to Amend, Mr. Stoker provides a different level of ordinary skill in the art—"a degreed BioMedical, Chemical, Mechanical, or Plastics engineer with five years of experience directly related to needle product design, particularly concentrating on the safety aspects of needle design" or, alternatively, "a non-degreed practitioner with ten years of experience directly related to the safety aspects of needle design." Ex. 2007 ¶ 44.

mechanical fastener. *See, e.g.*, Pet. 8 (indicating that the claims of the '476 patent were allowed after claim 1 was amended to include certain features of the mechanical fastener); Reply 3 ("The invention described in the '476 patent is an alleged improvement that involves a design that includes wings with a lip/mating portion mechanical fastener."). This lack of complexity and emphasis on a mechanical fastener supports a broader experience base for a person having ordinary skill in the art than advocated for by EMED.

Based on these underlying factual findings and EMED's and RMS's definitions, we determine that the level of ordinary skill in the art is a hybrid of the two proposed definitions. We agree with EMED that a degreed artisan would have had a degree in Biomedical, Chemical, Mechanical, or Plastics engineer with at least 3 years of experience. We further determine, however, that this skilled artisan's experience would have been in product design in general, with at least some of that experience directed to medical products. Although protecting a user from a sharp tip of a medical needle is an intended use of the claimed invention, we determine that protecting a user from the sharp point of a needle would be a hazard that would have been understood by an artisan of ordinary skill, even if that artisan did not have specific experience with medical sharps. For example, the '476 patent envisions a broader application of its invention beyond medical sharps.[7] We further

[7] Even though our factual findings support a broader definition of the level of ordinary skill in the art of the '476 patent, we note that both Dr. Kazmer and Mr. Stoker have at least some experience with medical sharps. *See, e.g.*, Exhibit 2004, 29:15–30:22, 31:1–25, 32:1–11, 34:14–25, and 44:20–

determine that a non-degreed artisan would have had at least 10 years of experience in product design, including at least some of that experience being in medical product design. In this regard, we agree with both Dr. Kazmer and Mr. Stoker. *See* Ex. 1002 ¶ 22; Ex. 2007 ¶ 44.

2. "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. For the Decision on Institution, we determined that the term "rigid" means "[u]nable to bend or be forced out of shape, not flexible" and the term "semi-rigid" means "[s]tiff and solid, but not inflexible." Dec. on Inst. 10. 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 refined the constructions, determining that none of soft, gel, cloth, and non-woven cloth materials alone is "rigid" or "semi-rigid," and that "semi-rigid" may include "PVC and polypropylene." Dec. on Inst. at 10–11; *see* Ex. 1001, 7:21–32; 11:18–20.

EMED contends that these terms "do not need to be construed as they would be understood without construction by one of ordinary skill in the art." PO Resp. 8. EMED adds, however, that our constructions

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45:18 (including testimony regarding Dr. Kazmer's experience with medical products and, specifically, syringes); Ex. 2003 ¶ 8 (providing Mr. Stoker's "extensive experience" with medical sharps).

are "consistent with the ['476] patent's written description and the plain language of the claims" and that our refinement "is proper." *Id.*

RMS does not address our construction of "semi-rigid" but contends that our construction of the term "rigid" "would render the device described and claimed in the '476 patent inoperable." Reply 12. RMS argues that, in the embodiment of Figure 11, for example, inner region 220 of each wing must be bent so that the wings may be closed to cover the medical needle and that a wing made of rigid material in accordance with our construction would not be capable of bending. *Id.* As a consequence, RMS proposes that we construe the term "rigid" to mean "resistant to bending or being forced out of shape, less flexible than a semi-rigid material." *Id.*

We discern no reason to alter our constructions of the terms "rigid" and "semi-rigid." We are not persuaded that our construction of the term "rigid" would render the device disclosed and claimed in the '476 patent inoperable. First, the only claim that recites the term "rigid" is claim 4, which requires "the pair of wings [to be] formed of rigid material." Ex. 1001, 14:28–29. We are not convinced that this claim language requires the entire wing, including inner region 220, to be rigid, and RMS offers no explanation as to why we should construe claim 4 as such. Second, even if claim 4 was so construed, the recited device would still be operable, as a person having ordinary skill in the art would understand that a different hinge structure could be employed. *See, e.g.*, Ex. 1004, Figs. 1–4 (providing protective wings that rotate about a central body portion of the needle safety enclosure). That is, the device of claim 4 is not limited

to the embodiments disclosed in the specification, such as the embodiment of Figure 11. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description,… a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

After considering anew the underlying bases for the above constructions, as informed by the parties' assertions, we maintain our above constructions of "rigid" and "semi-rigid," as set forth in the Decision on Institution.

3. "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 (emphases added). In our Decision on Institution, we determined that the term "perimeter" is entitled to its ordinary and customary meaning: "[t]he outermost parts or boundary of an area or object." Dec. on Inst. 11. This construction is consistent with the Specification's use of that term. *See, e.g.*, Ex. 1001, 6:19–24, Fig. 11 (including perimeter 1040).

EMED contends that this term "does not need to be construed as the term would be understood without construction by one of ordinary skill in the art." PO Resp. 9. EMED adds that our construction is "consistent with the ['476] patent's written description

and the plain language of the claims" but "is more commonly used in lay language than many terms the courts have declined to construe." *Id.* RMS does not address this construction. *See* Reply 3–12 (providing Petitioner's claim construction analysis).

After considering anew the underlying bases for the above construction, as informed by the parties' assertions, we discern no reason to alter the construction of the term "perimeter" applied in our Decision on Institution.

4. "in attachment to"

Claim 1 requires "the inner region of each wing [to be] in attachment to the central body portion." Ex. 1001, 13:40–41. In our Decision on Institution, we determined that the term "'in attachment to' [ ] encompasses configurations [of the device of claim 1] where wings are attached, directly or indirectly, to the central body portion of the device," rejecting EMED's proposed construction limiting the term to direct attachment only. Dec. on Inst. 12.

In its Patent Owner Response, EMED repeats its contention first made in its Preliminary Response that the term "in attachment to" should be construed to mean "directly attached to." PO Resp. 9–12. Specifically, EMED contends that the Specification of the '476 patent implicitly defines the term to mean direct attachment. EMED argues that throughout the '476 patent, "in attachment to" describes direct attachment between two components and further in each embodiment of the '476 patent, the inner region of the wing is directly attached to the central body. *Id.* at 10–11.

RMS replies that the construction in our Decision on Institution is proper under the broadest reasonable construction standard. Reply 4. RMS argues that EMED's proposed construction improperly reads into the term "in attachment to" a limitation from the Specification. *Id.* at 5. We agree.

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, unless the patentee acted as its own lexicographer or disavowed certain claim scope. *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016). "The standards for finding lexicography and disavowal are '*exacting*.'" *Id.* (emphasis added). "To act as a lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' and 'clearly express an intent to redefine the term.'" *Id.* Disavowal (or disclaimer) requires that the patentee make it clear, either in the Specification or in the prosecution history, "that the invention does not include a particular feature." *Id.* "While such disavowal can occur either explicitly or implicitly, *it must be clear and unmistakable*." *Id.* (emphasis added). "Absent a clear disavowal or contrary definition in the [S]pecification or the prosecution history, the [claim] is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

First, EMED does not identify any portion of the Specification that clearly sets forth a definition of the term "in attachment to" that limits the meaning of that term to direct attachment only. We find that all of EMED's identifications are to exemplary

embodiments only. "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). EMED fails to direct us to any disclosure that *clearly* expresses an intent to limit the term "in attachment to" to direct attachment. Similarly, "[i]t is . . . not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the [S]pecification into claims; we do not redefine words. Only the patentee can do that." *Thorner*, 669 F.3d at 1366. The '476 patent does not redefine "in attachment to" as far as we can discern.

Second, EMED does not persuasively identify in the record, in either the Specification or the prosecution history, any clear and unmistakable disavowal or disclaimer of claim scope where the inner region of a wing is *indirectly* attached to a central body. Instead, EMED attempts to improperly read into the term "in attachment to" a limitation from a single exemplary embodiment disclosed in the Specification depicting direct attachment of the inner region of the wing with the central body portion.

As we indicated in our Decision on Institution, the ordinary and customary meaning of the term "in attachment to" encompasses both direct and indirect attachment. *See* Dec. on Inst. 12; *see e.g.*, *Southco, Inc. v. Fivetech Tech. Inc.*, 611 F. App'x 681, 686 (Fed. Cir.), *cert. denied*, 136 S. Ct. 587 (2015) ("Southco is correct that the ordinary meaning of 'attached'

includes both direct and indirect attachment.").[8] We are not persuaded by EMED's arguments that the Specification necessitates that we depart from this construction.

5. "to allow"

Claim 1 requires "the wings in the open position [to 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). In our Decision on Institution, we construed the term "to allow" to mean "to permit." Dec. on Inst. 12–13. EMED contends that the term "to allow" "does not need to be construed as the term would be understood without construction by one of ordinary skill in the art" but that our "construction is consistent with the ['476] patent's written description and the plain language of the claims." PO Resp. 14. RMS argues that EMED "tries to have its cake and eat it too by appearing to express no disagreement with the construction contained in the Decision [on Institution], yet arguing that" the term "to permit placement" would be understood by a person having ordinary skill in the art to require the wings be folded back to permit the needle to be inserted into a

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[8] We recognize that in *Southco, Inc.*, the Federal Circuit agreed with the lower court that the term "attached" was limited to direct attachment in that case. *See Southco, Inc.*, 611 F. App'x at 686. In that case, however, certain language in the claim itself made it clear that "attached" was limited to direct attachment. *Id.* We determine that claim 1 of the '476 patent does not include language that would limit "in attachment to" to direct attachment.

treatment site. Reply 7; *see also* PO Resp. 31 ("One of skill in the art would understand permitting placement to mean that the wings could be folded back to permit insertion of the needle."). To be clear, EMED's position is that the two wings are folded back so that they touch each other and can be grasped between the user's thumb and index finger. *See* Tr. 48:1–8, 55:1–13; *see also* Ex. 2003 ¶ 94 ("One of ordinary skill in the art would understand that the term 'wing' is a term of art that refers to structures that . . . can be folded behind and grasped together with the fingers of a user . . . to allow placing the medical needle into the treatment site.").

EMED relies solely on the Declaration of its expert, Mr. Stoker, to support its contention that an artisan of ordinary skill would understand the claim limitation "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" to require the wings to be folded back to permit inserting the needle. *See* PO Resp. 31 (citing Ex. 2003, Decl. of Ron Stoker, ¶ 78). Mr. Stoker merely provides the same statement as that appearing in the Patent Owner Response—"[o]ne of skill in the art would understand permitting placement to mean that the wings could be folded back to permit insertion of the needle"—without providing any basis for his opinion. *See* Ex. 2003 ¶ 78. Accordingly, we give little weight to this testimony. *See In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed.Cir.2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."); *see also* 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.").

At oral argument, EMED further argued that the recitation of "wings" in claim 1 informs a person having ordinary skill in the pertinent art that the wings are to fold back against each other to allow a user to insert the medical needle into a treatment site. *See* Tr. 43:21–47:25. EMED contends that an artisan of ordinary skill would understand that the recited wings are the wings illustrated in Exhibits 2034, 2052, 2053, 2064, and 2069. *Id.* at. 43:21–44:2. EMED argues that such artisan would have this understanding because the claims of the '476 patent are directed to the embodiments of Figures 10 and 11 of the '476 patent *only* and those figures depict the same type of winged needle as illustrated in the identified exhibits. *Id.* at. 44:22– 47:25. With respect to the identified exhibits, these exhibits identify exemplary winged subcutaneous and Huber needles, where the wings are folded and grasped and the needle is inserted into a treatment site. *See* Exs. 2034, 2052, 2053, 2064, and 2069.

The '476 patent is clear that "[t]he devices described herein include, *but are not limited to*, subcutaneous needles and Huber needles." Ex. 1001, 4:57–58 (emphasis added). Further, Mr. Stoker declared that "'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." Ex. 2003 ¶ 94. Exhibits 2034, 2053, and 2069, however, depict wings that are folded in a 90-degree orientation from the needle, not opposite the needle. *See* Ex. 2034, 8; Ex. 2053, 5; Ex.

2069, 1. This distinction cuts against Mr. Stoker's testimony.

As RMS argues, the language of claim 1 merely requires that the wings be oriented in an open position that exposes the needle to allow or permit placing the needle at a treatment site. *See* Reply 8. Nothing in the language of the claim requires the wings to be folded back to enable this placement. Also, EMED fails to identify any suitable evidence, other than Mr. Stoker's Declaration, that supports its proposed construction.[9]

Further, EMED's claim construction position is contrary to the express disclosures in the '476 patent. For example, the embodiment depicted in Figure 11 of the '476 patent shows a device for protecting a user from a medical needle where the device's two wings 216, 218 are opened and oriented at 90 degree angles from medical needle 206, such that the needle is exposed. *See* Ex. 1001, Fig. 11. In this configuration, a user could use handle 1126 to place the needle at a treatment site to deliver medicinal fluid without folding back wings 216, 218. *See id.*; *see also* Tr. 55:14– 57:18. EMED's counsel recognizes that the wings do not have to be pulled back to allow placement of the needle to a treatment site in the embodiment of Figure 11:

[9] EMED does rely on Ex. 2034 in support of a similar position with respect to its Motion to Amend. We address this evidence when we analyze the motion.

JUDGE COCKS: So the horizontal configuration of the wings in Figure 11, for instance, that's an arrangement of the wings that allows placement into a patient.

MR. RAMEY: Okay. Yes, I understand your point now. Sorry. Yes, that does allow placement, and the handle aids with that placement.

Tr. 57:1–7.

Further, the '476 patent characterizes the orientation of the wings in Figure 1, which depicts a prior art winged needle similar to that depicted in Figure 10, except for the mechanical fastener, as positioned to allow placement of needle 104 into a patient. Ex. 1001, 1:41–45; *see* Tr. 76:20–25. As seen in Figure 1, the wings are in an approximately 90-degree orientation from needle 104; that is, the wings are not folded back so that they can be pinched by the fingers of the user. *See* Ex. 1001, Fig. 1.

Although the claimed invention of the '476 patent is depicted only in Figures 10 and 11 of the '476 patent, we are not persuaded that the claims are *limited* to those depicted embodiments. The Specification makes clear that Figures 10 and 11 merely are exemplary embodiments of the invention. *See, e.g.*, Ex. 1001, 6:43–45 ("A device 1100 (FIG. 11) provides an exemplary embodiment of handle 1126 extending from central body portion 202."). As we stated from the outset, "limitations are not to be read into the claims from the [S]pecification." *In re Van Geuns*, 988 F.2d at 1184.

Accordingly, we determine that the claim limitation of claim 1 reciting "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" does not require the wings to be folded back to allow or permit placement.

6. "therebetween"

Claim 1 requires "the pair of wings disposed in opposition to one another with the medical needle positioned therebetween" and "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." Ex. 1001, 13:43–14:1, 14:9–14. In our Decision on Institution, we construed the term "therebetween" as "between the closed pair of wings." Dec. on Inst. 13 (adopting EMED's proposed construction); *see* Prelim. Resp. 10 (substituting the phrase "between the pair of wings" for the term "therebetween"). We determined 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, that is, in a closed position. *See* Dec. on Inst. 13.

EMED contends that the construction should be "between" as the phrase "the closed pair of wings" renders other words of the claim superfluous. PO Resp. 14–15. RMS takes no position.

We agree with EMED to the extent that the word "closed" is not necessary. We do not agree, however, that the phrase "the pair of wings" is superfluous, as it defines the "there" in the term "therebetween." Accordingly, we modify our construction of "therebetween" to mean "between the pair of wings."

7. "lip"

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" and requires "the mating portion and the lip [to be] configured to align the at least one wing relative to the at least one other wing in the closed position." Ex. 1001, 14:15–21. In our Decision on Institution, we determined that "lip" should be afforded its ordinary and customary meaning—"a rounded, raised, or extended piece along an edge." Dec. on Inst. 14. We determined that this construction is consistent with the Specification's use of that term. *See, e.g.*, Ex. 1001, 6:22–27, Fig. 11 (depicting lip 1042).

EMED contends that our construction should be further limited to exclude a flap. PO Resp. 15. To support this position, EMED substituted the word "flap" into sentences provided in a dictionary to illustrate the use of the word "lip" to demonstrate that the word "flap" provides nonsensical results. *Id.* at 16–17. In reply, RMS argues that EMED's position with respect to excluding a "flap" is "untenable" and fails to focus on the claims. We agree with RMS. Just because the word "flap" may not be substituted into sentences

appearing in a dictionary that use the word "lip," that does not exclude the structure of a flap from being encompassed by the recited "lip" of claim 1.

EMED further contends that the use of the term "lip" in the Specification of the '476 patent implicitly defines the term "lip" to exclude a flap. PO Resp. 17–18, 19–21. EMED argues the embodiments of Figures 10 and 11 in the '476 patent—the embodiments with a "lip" as a component of the mechanical fastener—show a structure that does not extend past the wing. *Id.* at 19–20. From this argument, we interpret EMED's proposed modification of our construction to exclude those structures that are a rounded, raised, or extended piece along an edge of the wing but that also extend beyond the wing.

We are not persuaded by EMED's arguments that the '476 patent implicitly defines the term "lip" to exclude a flap—a component of a mechanical fastener that extends beyond a wing. EMED's position attempts to improperly read into the "lip" limitation of claim 1 an embodiment from the Specification, as we discern no clear intent to define "lip" in a way to limit it to the embodiments of Figures 10 and 11. As we stated above in connection with our analysis of "in attachment to," "[i]t is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Thorner*, 669 F.3d at 1365.

EMED also relies on its expert, Mr. Stoker, to support its refinement of our construction to exclude a flap from the meaning of the term "lip." PO Resp. 18

(citing Ex. 2003 ¶ 92). This reliance is misplaced. Mr. Stoker's testimony is directed to why an artisan of ordinary skill would not consider the specific flap structure in Cole to be the recited "lip" of claim 1, not that the understanding of the term "lip" by a person of ordinary skill in the art would exclude a flap.

EMED also proposes that we further modify our construction of the term "lip" such that the size of the lip is limited to about 70 percent of the thickness of a wing. PO Resp. 19. EMED argues that the structure must have a maximum size. *Id.* In support of its proposed 70 percent value, EMED relies on testimony from RMS's expert, Dr. Kazmer, to support the position that the recited "lip" would have a maximum size and that the maximum size would be 70 percent of the thickness of the wing. *Id.* at 18– 19 (citing Ex. 2004, 170:3–20, 174:2–16). In reply, RMS contends Dr. Kazmer's testimony was that a lip could have a variety of lengths or widths, as what matters is that the lip functions as designed. Reply 11.

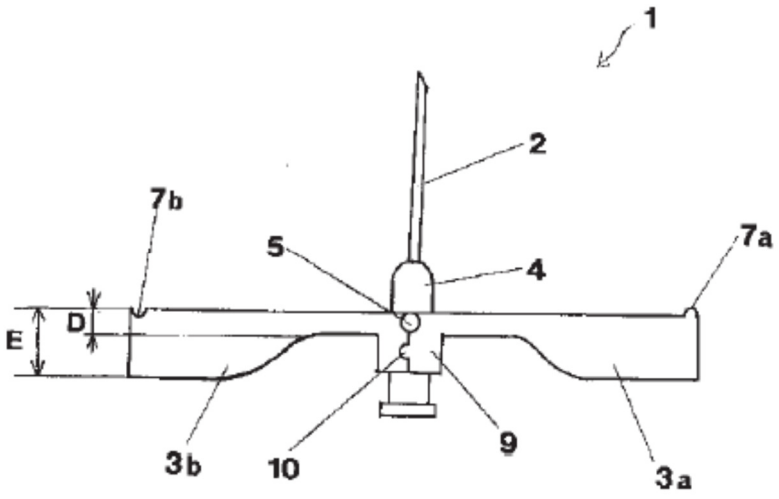
We are not persuaded that our construction of the term "lip" should be limited to a structure that is no more than 70 percent of the thickness of the wing. EMED's sole basis for the 70 percent value is testimony of Dr. Kazmer concerning the approximate size of the lip in the embodiments of Figures 10 and 11 of the '476 patent. *See* Ex. 2004, 174:2–17. We do not understand Dr. Kazmer to have testified that the term "lip" as used in claim 1 would be limited in size to 70 percent of the thickness of a wing, but instead appeared to have mentioned in passing that 70 percent was possible for a particular lip size.

Accordingly, after considering the underlying bases for the above construction anew, and in light of the parties' assertions, we discern no reason to alter the construction of the term "lip" applied in our Decision on Institution—"a rounded, raised, or extended piece along an edge."

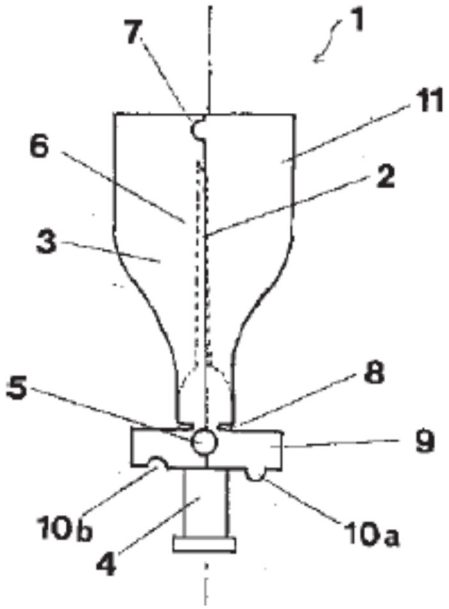
B. Overview of the Prior Art

1. Harada

Harada is directed to a device that prevents accidental contact with an injection needle. Ex. 1003, Abstract.[10] Figures 1 and 2 of Harada are reproduced below.



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



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 of Harada are reproduced below.

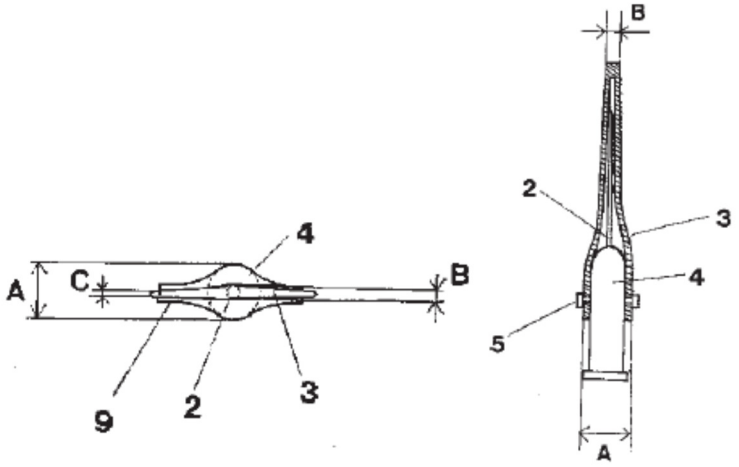


Figure 3 provides a top view of the embodiment of Figure 2. Ex. 1003, Brief Descriptions of the Drawings. Figure 4 provides a cross- sectional view of the embodiment of Figure 2. *Id.*

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.*

2. 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.

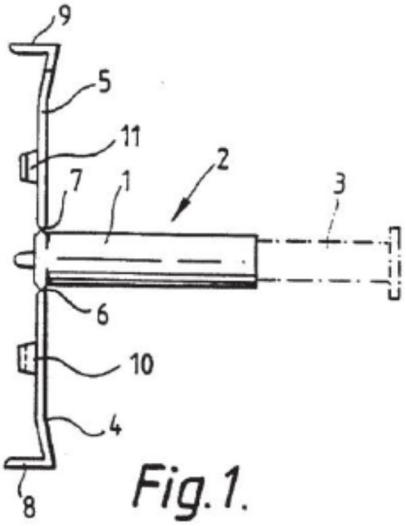


Fig. 1.

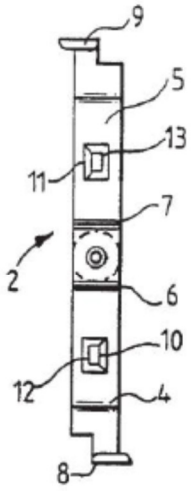


Fig. 2.

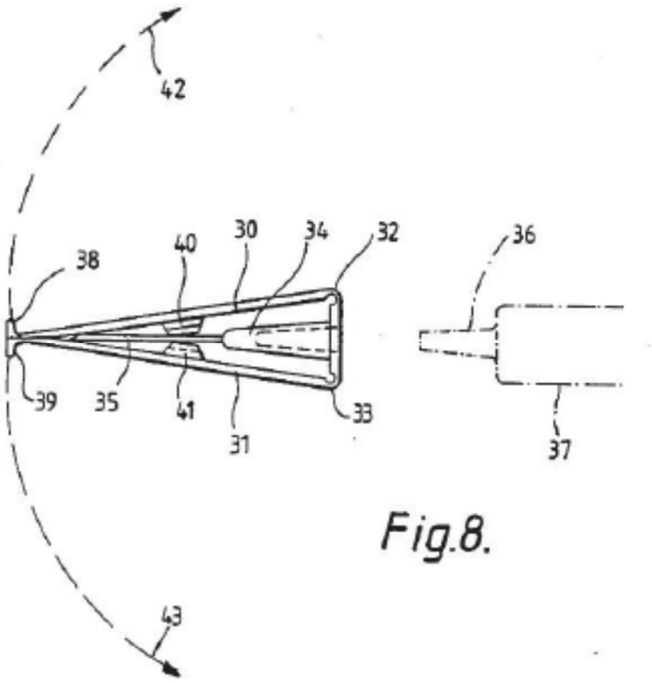


Fig.8.

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).

3. 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* PO Resp. 42; Ex. 1011, 114–26 (providing first office action), 164–72 (providing second office action). Ishikawa's Figures 1 and 2 are reproduced below.

FIG.1

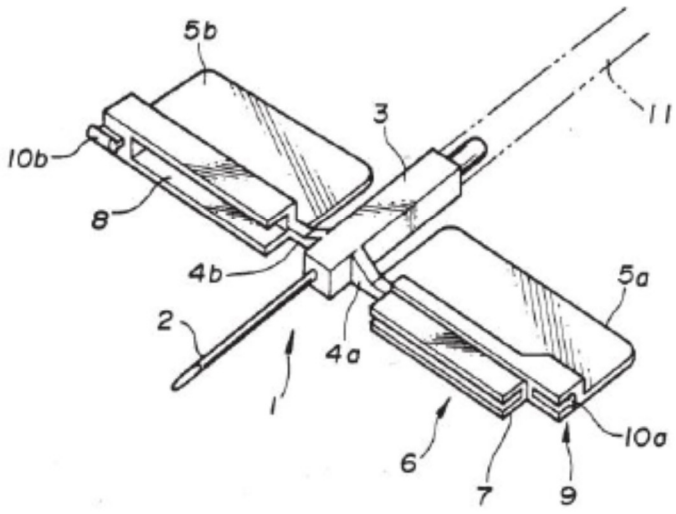


FIG. 2

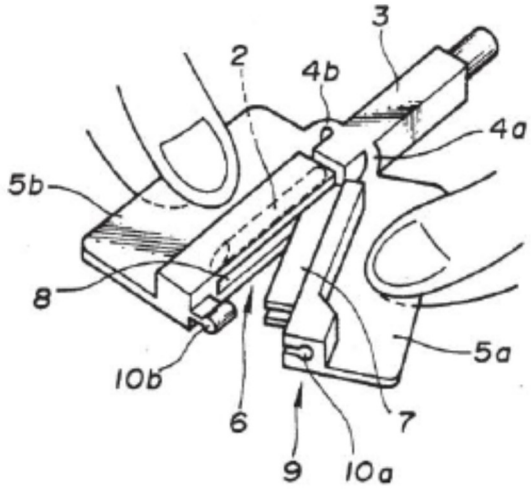


Figure 1 provides a perspective of an embodiment of Ishikawa's winged needle, and Figure 2 depicts the embodiment of Figure 1, during the process of covering the needle. Ex. 1006, 1:56–59. Ishikawa's winged needle 1 includes needle 2 attached at one end to base 3 and wings 5a, 5b attached to base 3 through 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 (ditched projection 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.

4. Raines

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

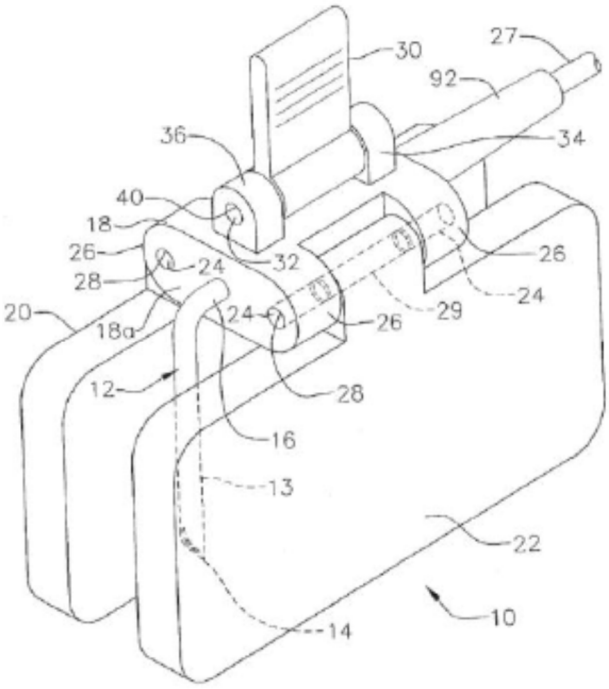


Figure 1 provides a perspective view of Raines's needle safety device. As seen in Figure 1, Raines's device includes wings 20, 22, which fold around needle 12 to prevent a user from being injured by the needle, and third wing 30. Ex. 1009, 3:18–25, 4:12–14. Third wing 30 serves as a handle. *See, e.g.*,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

5. 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:

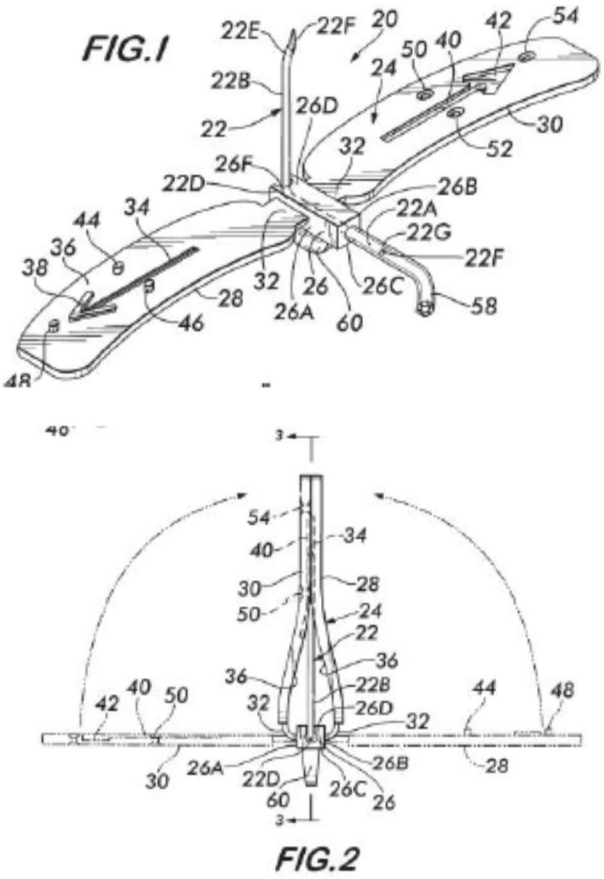


Figure 1 provides an isomeric view of Sasso's needle safety device in an open position, and Figure 2 depicts the same embodiment in a closed position. Ex. 1010, 3:34–41. As seen in Figure 1, Sasso's mechanical fastener includes posts 44, 46, 48 that mate with apertures 50, 52, 54.

C. Instituted Grounds of Unpatentability

We instituted trial on eight grounds of unpatentability covering claims 1–10 of the '476 patent: 1) claim 1 under 35 U.S.C. § 102(b) as

anticipated by Harada; 2) claims 1, 5, and 7 under 35 U.S.C. § 102(b) as anticipated by Cole; 3) claims 1 and 7–9 under 35 U.S.C. § 102(b) as anticipated by Ishikawa; 4) claims 2–4 under 35 U.S.C. § 103(a) over Harada and Raines; 5) claim 5 under 35 U.S.C. § 103(a) over Harada and Cole; 6) claims 6 and 7 under 35 U.S.C. § 103(a) over Harada; 7) claims 8 and 10 under 35 U.S.C. § 103(a) over Harada and Sasso; and 8) claims 8 and 9 under 35 U.S.C. § 103(a) over Harada and Ishikawa. Dec. on Inst. 46–47. We address each of these grounds in turn, below.

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

RMS contends that Harada anticipates independent claim 1. Pet. 10– 11, 15–23. 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)).

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 of claim 1, including being selectively positionable to allow placing the needle into a treatment site. *Id.* at 18 (citing the open position depicted in Figure 1 and the closed position depicted in Figure 2); *see also* Ex. 1003, 8 (describing that, when the injection needle is used, needle cover 3 is opened and wings 3a and 3b are secured, in the open position, to the patient), Fig. 1 (providing "a front view illustrating the state of the present invention at the time of use").

RMS indicates that the inner region of wings 3a and 3b are "in attachment to" needle hub 4. Pet. 18; *see also* Ex. 1003, Figure 1 (depicting the inner region of wings 3a and 3b connected to hub 4 at junction portion 5). RMS contends that junction portion 5 is an integral portion of each wing 3a and 3b, that is, each wing and junction portion are the same unitary structure. Reply 15. As such, RMS argues that junction portion 5 of each wing directly attaches to Harada's central body—needle hub 4. *Id.*; *see also* Tr. 24:10–16 ("[T]he written description clearly describes the junction portion as being part of the wing. And I think that's clearly illustrated.…So that portion of the wing is what's connected through the rivet to the central body portion 4 in Harada.").

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 female means 7b as the mating portion. *Id.* at 20. RMS emphasizes that "Harada explicitly describes the lip and mating portion [(stopping means 7a and female means 7b)] as

being disposed "***on a tip end portion***" of the wings." Reply 18 (emphasis in original).

EMED contends that Harada's wings do not allow placement of the medical needle at a treatment site. PO Resp. 31. EMED argues that "[o]ne of [ordinary] skill in the art would understand permitting placement to mean that the wings could be folded back to permit insertion of the needle." *Id.* That is, EMED argues that the claim limitation reciting "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" would be understood by an artisan of ordinary skill to require the wings to be folded back against each other to place the medical needle at the treatment site. As we discussed above in connection with our claim construction of the phrase "to allow," EMED's position improperly attempts to narrow claim 1. The broadest reasonable construction of the term "to allow" merely requires that the wings, in their open position, expose the medical needle such that it may be inserted in a treatment site. As is clear from Harada, its wings 3a, 3b open to expose a medical needle, which is then inserted into a treatment site:

> When the injection needle is used, the needle cover 3 can be divided easily by opening the needle cover 3 from the tip end side. The two divided wings 3a and 3b … are able to pivot in a range wherein the angle formed by both of the wings 3a and 3b is between 0 and 180° … and the two wings 3a and 3b that extend to both sides of the needle base are secured to the body of the

> patient through tape or through an adhesive plaster, or the like …

Ex. 1003, 8.[11]

EMED argues that the inner region of each of Harada's wings is not "in attachment to" the central body portion. PO Resp. 33. EMED argues that the wings are attached to a junction portion, not the central body portion. *Id.* EMED explains that Dr. Kazmer testified that Harada's wings are attached to the junction portion 5, which is a rivet. *Id.* (citing Ex. 2004, 217:20–218:1). RMS replies that claim 1 does not require direct attachment, as EMED alleges, and that, even if direct attachment were required, junction portion 5 is a portion of the wing, in direct attachment to the central body portion—needle base 4. Reply 15. That is, junction portion 5 is a *portion* of the wing, based on the use of the word "portion." *Id.*; *see also* Tr. 23:5–15 ("It's a portion. It's a portion of the overall wing. And so, therefore, there's nothing that would prevent one from reading that portion to be an inner region of the wing. It's closest to the central body portion or hub 4 of Harada.")

We find that Harada's wings are at least indirectly attached to needle hub 4, through junction

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[11] RMS further argues that Harada contemplates that, in an alternative embodiment, its wings can be folded at an angle greater than 180 degrees. Reply 14. We need not reach this issue, as we determine that claim 1 does not require the wings to be folded back beyond 180 degrees to allow placement of the medical needle at the treatment site.

portion 5, thus satisfying the requirement of claim 1 that the wings be "in attachment to" the central body portion. We are not persuaded, however, that junction portion 5 is a part of wings 3a, 3b; rather we find that junction portion 5 is a rivet holding the wings to the central body portion such that the wings may pivot on that rivet. *See, e.g.*, Ex. 1003, Figs. 1, 3, and 4 (identifying the rivet as element 5); *id.* at 8 ("As illustrated in FIG. 1, FIG. 2, and FIG. 4, in the junction portion 5, the wings 3a and 3b are connected to the needle base 4 through a rivet or the like, but are not secured rigidly, but rather can move over a prescribed range."); Ex. 2004, 217:20–218:1 (providing testimony from RMS's expert that junction portion 5 is the rivet).

Further, we find that attaching wings 3a, 3b to hub 4 through a rivet (junction portion 5) constitutes a direct attachment of the wings to the central body portion. *See* Ex. 1003, Figs. 1, 3, and 4. By analogy, if one were to stack two 2x4s of similar length together and drive a nail through both boards so that the boards may pivot about the nail, the 2x4s would be directly attached to one another *by the nail*. Here, wings 3a, 3b are directly attached to hub *4 by junction portion (rivet) 5.*

EMED also contends that Harada's wings "are not spaced apart from one another in the open position" because the bases of the wings are adjacent to one another. PO Resp. 33–34. EMED argues that each pair of wings disclosed in the '476 patent is spaced apart when open. *Id.* at 33. EMED further argues that a person having ordinary skill in the art would understand that the term "spaced apart" means

that the wings do not touch—apparently at any point. *Id.* (citing Ex. 2003 ¶ 84). In reply, RMS contends that EMED's position relies on an unsupported construction of the term "spaced apart." Reply 16. RMS argues that EMED's construction reads the term "spaced apart" in a vacuum and ignores the remainder of the claim element of which it is a part. *Id.*[12]

"[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 v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[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 the complete trial record, that the Specification limits the structure in this way. *See, e.g., In re Trans Tex. Holdings Corp.*, 498 F.3d 1290, 1298–99 (Fed. Cir. 2007) (refusing to See, e.g., *In re Trans Tex. 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). Claim 1 requires that

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[12] In its Reply, RMS provides an additional argument that Harada discloses an alternative embodiment with a pivoting preventing means on the injection needle, rather than on the wings, such that when the wings are opened, they would contact the pivoting preventing means and not each other. Reply 17. We do not address this position, as the Petition did not assert that this alternative embodiment anticipates claim 1.

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).

Further, we give little weight to Mr. Stoker's testimony on this issues. Mr. Stoker declares that "[o]ne of skill in the art would understand 'spaced apart' to mean not touching" without providing any basis for this assertion and without explaining that "not touching" means that the wings do not touch at any point. *See* Ex. 2003 ¶ 84.

Accordingly, for the reasons discussed above, we find that Harada's wings 3a and 3b are selectively positionable from an open position to a closed position, and that 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. We also find that wings 3a and 3b, in the closed position, cover the medical needle to protect against accidental needle stick injury from the medical needle. *See* Pet. 18, *see also* Ex. 1003, Fig. 2 (depicting wings 3a and 3b covering needle 2).

Next, EMED contends that Harada discloses an injection needle and "[o]ne of ordinary skill in the art would understand that an injection needle is a specific type of needle used for infusion." PO Resp. 31. EMED

argues that "[a]n injection needle is composed of at least two parts, the needle and the needle base" and claim 1 requires "'the medical needle having … [ ] a second *end distal from the central body portion*.'" *Id.* at 31–32 (emphasis in original). EMED continues that "[t]he '476 patent discloses and claims devices separate from the needle, while Harada discloses an injection needle with a needle cover." *Id.* In reply to EMED's apparent argument that Harada's needle 2 and hub 4 are a single structure, RMS argues that Harada discloses needle 2 and needle base 4 as separate components. Reply 14.

We are persuaded that Harada discloses the recited medical needle (needle 2) and central body portion (needle base or hub 4). We agree with RMS that Harada identifies needle 2 and needle base 4 as separate components and EMED fails to provide persuasive evidence to the contrary. Further, even if EMED is correct, Harada's needle 2/needle base 4 would still satisfy the language of claim 1. Claim 1 requires "[a] device … comprising: a central body portion; [and] [a] 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." *See* Ex. 1001, 13:33–38. We find that needle base 4 constitutes a central body portion of Harada's device and that Harada's needle 2 has a sharp tip at an end distal from needle base 4. *See* Ex. 1003, Fig. 1 (showing the tip of needle 2 at the end opposite of needle base 4). Nothing in claim 1 precludes the needle and central body portion from being a unitary structure. EMED's argument improperly imports limitations from the Specification of the '476 patent instead of being directed to the language of claim 1.

Finally, EMED argues that Harada's male locking means 7a does not include a lip nor does it extend along the perimeter, basing its arguments on RMS's expert's testimony and EMED's own expert's testimony. PO Resp. 34. Specifically, EMED cites Dr. Kazmer's deposition testimony at 169:1– 10, 173:12–17, and 174:2–177:1 and Mr. Stoker's Declaration at paragraphs 85 and 86. *Id.* at 35–35. Similarly, EMED contends that female means 7b is not along the perimeter. *Id.*

In reply, RMS contends that EMED takes Dr. Kazmer's testimony out of context. Reply 17. RMS also argues that EMED's contention that Harada's male locking means 7a and female means 7b are not along a perimeter is erroneous. *Id.*

Based on the complete trial record, we are not persuaded by EMED's argument and we find that Harada's male locking means 7a and female means 7b correspond to the recited lip and mating portions, and that male locking means 7a and female means 7b extend along a perimeter of wings 3a and 3b as required by claim 1. As Harada expressly discloses, male stopping means 7a is positioned at the tip of wing 3a (that is, the edge or outermost part of the wing) and extends from that tip or edge. *See* Ex. 1003, Figs. 1 and 2; *see also id.* at 9 ("[I]t is convenient to provide first engaging means 7, which can separate or engage, on the tip end portion of the needle cover 3, that is, the tip end portion for securing the two wings 3a and 3b, as illustrated in FIG. 1."); Section II.A, *supra* (construing the terms "perimeter" and "lip"). Female means 7b is similarly positioned at the tip 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.* Although Harada's Figures 1 and 2 show that female means 7b includes a depression for receiving male means 7a and this *depression* is slightly removed from the absolute edge of wing 3b, the absolute edge of wing 3b forms one of the walls of the depression, such that female means 7b is located at the tip or edge of wing 3b.

EMED's reliance on Dr. Kazmer's testimony to support its argument is misplaced. The cited testimony is directed to Dr. Kazmer's definition of a lip and discussion of the relative sizing of a lip. We can discern nothing in this testimony to indicate that Harada's male means 7a would not correspond to the recited lip; nor has EMED adequately explained the significance of this testimony.

Further, we give little weight to Mr. Stoker's testimony relied on by EMED. Mr. Stoker declares that "Harada's snap protrusion is not a lip; nor does it extend along a perimeter. Further, Harada's female locking means is not along a perimeter of the other wing." Ex. 2003 ¶ 85. Mr. Stoker's sole basis for these statements is that Harada's figures do not show means 7a and 7b along the perimeter without providing any further explanation. "Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." 37 C.F.R. § 42.65(a).

On the complete record before us, we conclude that RMS has demonstrated, by a preponderance of the evidence, that Harada anticipates claim 1. In addition to findings we make above in connection with our analysis of claim 1 as anticipated by Harada, we

also adopt as our findings RMS's positions as to how Harada discloses each of the claim limitations of claim 1. *See* Pet. 10–11, 15–23.

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

RMS contends that the embodiment of Cole's Figure 8 anticipates claims 1, 5, and 7. Pet. 14, 25. We address these three claims below.

a. 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, with needle 35 having a sharp tip extending away from (that is, distal from) hub 34. Pet. 16–17. During use, syringe 37 would contain medicinal fluid that would be delivered to a patient by way of a plunger. *See* Pet. 18; Ex. 1005, 3:41–51. In this way, tube-shaped syringe 37 corresponds to the recited delivery tube.

EMED argues that "any needle associated with Cole is not in fluid communication with a delivery tube, as required in element 1(c) of [c]laim 1 of the '476 patent, but rather a syringe." PO Resp. 37. EMED continues that "Figure 8 of Cole discloses a detachable hub including a needle that is then attached to a syringe. Therefore, the embodiment of Figure 8 also fails to disclose a needle in fluid communication with a delivery tube." *Id.*

We are not persuaded by EMED's arguments. To the extent EMED argues that syringe 37 is a

syringe, not a delivery tube, we find that syringe 37 is tube-shaped and is used to deliver medicinal fluid—a delivery tube. To the extent that EMED argues that, because hub 34 is detachable, needle 35 is not in fluid communication with syringe 37 when detached, we determine that claim 1 is not so limited as to require continuous, that is, at all times, fluid communication between the recited needle and delivery tube. EMED does not direct us to any language in the claim to support such a limited reading and, indeed, does not offer any construction of claim 1 that would so limit the claim. We find that, when hub 34 is attached to syringe 37, the first end of needle 35 (that is, the end attached to hub 34) is in fluid communication with syringe 37. *See* Ex. 1005, Fig. 8 (depicted, using a dashed line, how stub outlet 36 of syringe 37 interfaces with hub 34 such that the first end of needle 35 is in fluid communication, through hub 34 and stub 36, with syringe 37).

EMED also argues that hub 34 is a cap for syringe 37 and not a central body portion, without further explaining this position. PO Resp. 38. We are not persuaded by this conclusory contention, as EMED fails to explain why hub 34, which is central to arms 30, 31 and connects to a delivery tube, is not a central body portion. We find that the recited central body portion encompasses Cole's hub 34.

RMS identifies arms 30, 31 as corresponding to the recited wings, contending that the arms are selectively positionable such that, as the arms pivot towards the side of the syringe (that is, as they move from a closed to an opened position), they expose needle 35 and allow the needle to be placed into a treatment site. Pet. 18–19. RMS provides that, in a

closed position, arms 30, 31 cover needle 35 to protect a user from an accidental needle stick. *Id.* Further, arms 30, 31 have an inner region that is directly attached to hub 34 and an outer region that extends away from hub 34. *See* Ex. 1005, Fig. 8 (depicting wings 30, 31 directly attached to hub 34 at pivot portions 32, 33). Pivot portions 32, 33 allow arms 30, 31 to pivot from a fully closed position (closed over needle 35) to a fully open position where the arms are alongside syringe 37. *See* Pet. 18–19; Ex. 1005, 4:19–21.

EMED contends that Cole's arms 30, 31 are not wings. PO Resp. 38. EMED argues 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." *Id.* (citing Ex. 1001, 2:2–11). EMED continues that "[o]ne of ordinary skill in the art would understand that the term 'wing' is a term of art that refers to structures that are capable of use for handling a medical needle." *Id.* EMED contends that "'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. When grasped behind, 'wings' provide increased stability for placing the medical needle." *Id.*

EMED further argues that, "[c]ontrary to the 'wings' of [c]laim 1 of the '476 patent, the arms of Cole are not disclosed for use in placing the medical needle into the patient or for removing a medical needle from a patient." *Id.* at 39. EMED continues that "'arms' would be understood to be larger or longer than 'wings.'" *Id.* EMED also argues that Cole expressly

discloses that its arms are used to assist in using the plunger of a syringe and not for allowing placement of a medical needle at a treatment site. PO Resp. 40.

In reply, RMS argues that claim 1 does not require the functionality argued by EMED. Reply 20. RMS further contends that, even if this functionality were implicit in claim 1, then Cole's arms 30, 31 perform this function. *Id.* (referencing Ex. 1005, Fig. 4, 3:47–51). RMS explains that Cole's arms 30, 31 "can likewise be folded behind and grasped together with the fingers of the user." *Id.*

We are persuaded that a person having ordinary skill in the art would understand that the recited wings of claim 1 encompass Cole's arms 30, 31, and are not persuaded by EMED's argument otherwise. EMED fails to provide any persuasive evidence that an artisan of ordinary skill would understand the term "wings" to *require* that the structures must be capable of folding back to aid in placing the needle into a treatment site. *See*, *e.g.*, PO Resp. 38 (offering attorney argument but providing no citations to evidence in support of the arguments). As we discussed above in connection with our analysis of the construction of the term "to allow," a construction requiring the wings to fold back to place the medical needle in the treatment site is not supported by the evidence of record and, with respect to at least the embodiment of Figure 11, which includes a handle, is inconsistent with the disclosure of the '476 patent.

We are also not persuaded by EMED's argument that a person having ordinary skill in the art would understand that "arms" are larger or longer than "wings." EMED offers no persuasive evidence to

support this position. Mr. Stoker does declare that "'arms' would be [ ] understood to be larger or longer than 'wings,'" but provides no support for this statement. *See* Ex. 2002 ¶ 94. Accordingly, we afford the statement very little weight. *See* 37 C.F.R. § 42.65(a).

Further, we are persuaded by the evidence of record that Cole's arms 30, 31 fold back to expose the medical needle and allow placement of the needle into the treatment site. As RMS argues and Cole expressly discloses, arms 30, 31 fold back against the syringe, with the user's index and middle fingers resting on flaps 8, 9 to aid in delivering the medicinal fluid from the syringe. *See* Reply 20; Ex. 1005, Fig. 4, 3:44–51 ("[I]n FIG. 4 the flaps have been disengaged from their position in FIG. 3 and have been [pivoted] round in the direction of arrows 18, 19 so that the arms lie alongside the cylinder body of the hypodermic syringe 2, at which position the flaps 8, 9 can be used as grips for the first and second finger whilst the thumb is applied to the head of the plunger 3 for the injection of a fluid via the needle into a patient."). That is, contrary to EMED's argument, Cole discloses that its arms are used for placing the needle at the treatment site. We are also not persuaded that there is a distinction between aiding in using syringe 37's plunger and aiding in the stable placing of the needle at a treatment site to deliver medicinal fluid, as EMED argues. As such, we find that Cole's arms 30, 31 correspond to the recited wings of claim 1 even under EMED's implied construction of "wings."

RMS identifies flaps 38, 39 and the adjacent notches as corresponding to the recited mechanical fastener. Pet. 20–21. Cole discloses that "[p]rotection

of the tip of the needle 35 prior to use is by means of flaps 38, 39 corresponding to those of the embodiment of FIGS. 1 to 7 [that is, flaps 8, 9]." Ex. 1005, 4:22–24. Cole further discloses that "flaps 8, 9 of the arms are capable of mutual engagement upon forward folding of the arms, and" Figure 3 depicts "flaps 8, 9 of the two arms interengaged to protect the needle 10 of the syringe prior to use." *Id.* at 3:32–37.

EMED contends that Cole's flaps 38, 39 do not correspond to the recited mechanical fastener of claim 1. PO Resp. 40. With respect to the "lip" structure recited in claim 1, EMED argues that "[o]ne of ordinary skill in the art would understand that lips and flaps are different structures, as shown in the illustrations above." PO Resp. 42. EMED further contends that Cole does not disclose a corresponding mating portion for the flaps. *Id.* EMED argues that flaps 8, 9 (and flaps 38, 39) and the notched section of Cole's arms cannot correspond to the recited lip and mating portion because RMS's expert, Dr. Kazmer, stated that the lip and mating portion are held together by "a press fit." *Id.* (citing Ex. 2004, 179:23–180:20). RMS replies that claim 1 does not require the lip and mating portion to be joined by a press fit and that Dr. Kazmer did not testify as such. Reply 21.

We agree with RMS that claim 1 does not require the recited lip and mating portion to be joined by a press fit. EMED does not offer an express construction of the recited mechanical fastener that would require the lip and mating portion to press fit together, and we discern no language in claim 1 to support such a requirement. Further, we find that Dr. Kazmer's testimony does not clearly define the claim term "mating portion" of claim 1 as requiring the

recited mating portion to provide a press fit with the recited lip. Dr. Kazmer's testimony speculates as to how lip 1042 and recessed portion 1038 would interact to maintain the device of Figure 10 of the '476 patent closed. EMED does not rely on any other evidence, including testimony from its own expert, regarding the meaning of the term "mating portion."

EMED also appears to argue that Cole's flaps are not lips because their sizes are not about 70 percent of the thickness of the arms. *See* PO Resp. 41 (quoting Dr. Kazmer's testimony estimating the size of the lip in the disclosed embodiment of the '476 patent, without providing any further argument). As we discussed above in connection with the construction of the term "lip," the proper construction of that term is not limited to a structure sized to about 70 percent of the thickness of the wing, as proposed by EMED. Accordingly, this argument does not persuade us that Cole's flaps 38, 39 do not correspond to the recited lip of the mechanical fastener.

EMED further argues the following as to why it believes that a person having ordinary skill in the art would not consider Cole's flaps to be lips:

> This is especially true in the needle protection arts where care is taken to keep a user from contacting a sharp end of a needle and therefore closure devices such as flaps are not preferred because a user may be required to fold over the flap when attaching as described in Cole.

PO Resp. 37 (citing Ex. 2003 ¶¶ 92, 97–98).

As we discussed above in connection with our claim construction analysis of the claim term "lip," the broadest reasonable interpretation of the term lip would not exclude a flap. Further, we do not credit Mr. Stoker's testimony. Mr. Stoker declares that Cole's flaps must be folded over when the arms are closed. *See* Ex. 2003 ¶ 92. We discern no such characterization in Cole, nor does Mr. Stoker identify any citation to Cole in support of this characterization. We find that Cole's flaps are not folded over to secure the arms closed. As seen clearly in Cole's Figures 3 and 8,flaps 8, 9 and flaps 38, 39 maintain their near 90-degree relationship with the arms when the arms are closed, indicating that the flaps are not folded over.

Instead:

> flaps 8, 9 of the arms are capable of mutual engagement upon forward folding of the arms, and in FIG. 3 the syringe cylinder body 1, with needle 16 attached at a hub 17, is shown with the flaps 8, 9 of the two arms interengaged to protect the needle 10 of the syringe prior to use. Protection is enhanced by a slight elbow 14, 15 adjacent the needle tip, in each arm, to lay the outer portions of arms parallel to each other.

Ex. 1005, 3:32–40. That is, the slight bend at elbows 14, 15 causes flaps 8, 9 to be slightly angled down to facilitate engagement of the arms—flaps 8, 9 are not folded over to secure closed Cole's arms.

Based on the complete record before us, we determine that RMS has demonstrated, by a

preponderance of the evidence, that Cole anticipates claim 1. In addition to findings we make above in connection with our analysis of claim 1 as anticipated by Cole, we also adopt as our findings RMS's positions as to how Cole discloses each of the claim limitations of claim 1. *See* Pet. 13–14, 15–23.

b. 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,[13] are rectangular in shape. *Id.*

With respect to claim 7, EMED argues that Cole does not disclose rectangular wings, as the end of each wing adjacent to the flaps includes a cutout. PO Resp. 42. In reply, RMS contends that the overall shape of each of Cole's arms is rectangular, despite the small, cut-out portions. Reply 21.

[13] 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.

We agree with RMS and find that Cole's arms are rectangular in shape as recited in claim 7. We reproduce Cole's Figure 2, below.

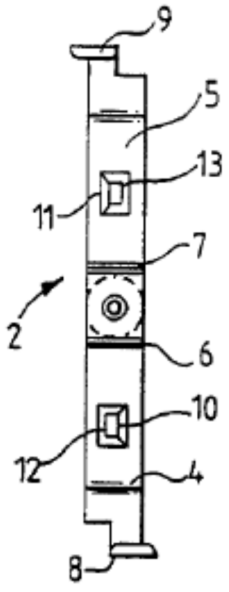

Fig.2.

Figure 2 depicts an end elevation of the hypodermic syringe of Cole's Figure 1. Ex. 1005, 2:64–68. As seen in the depiction, side arms 4, 5 (which, as discussed above, are arranged the same as arms 30, 31) are generally rectangular. Although we agree with EMED that each of the rectangles is missing a corner adjacent to flaps 8, 9, the arms are still "rectangular in shape." That is, our interpretation of claim 7 is not limited to wings that form perfect rectangles. We base this interpretation on the language of claim 7, which recites that the "wings each have a rectangular shape," instead of reciting, more restrictively, that each wing forms a rectangle. Our

interpretation is also consistent with the Specification. For example, the embodiment depicted in Figure 7 shows a rectangular wing with a small cutout adjacent to inner region 220. *See* Ex. 1001, Fig. 7; see also id. at 3:55–56 ("FIG. 7 illustrates a safety device with a mechanical fastener having a rectangular shape.").

We conclude that RMS has shown, by a preponderance of the evidence, that Cole anticipates claims 5 and 7. In addition to findings we make above in connection with our analysis of claims 5 and 7 as anticipated by Cole, we also adopt as our findings RMS's positions as to how Cole discloses each of the claim limitations of claims 5 and 7. *See* Pet. 25.

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

RMS asserts that Ishikawa anticipates claims 1 and 7–9. Pet. 14–15, 25, 26. We address each of these claims below.

a. Analysis of 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. Id. at 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 open and closed positions. Id. at 19. As such, wings 5a, 5b, in the open position, permits placement of the medical needle at a treatment site. *See* Ex. 1006, Figs. 1, 2.

RMS identifies coupling means 9 as the recited mechanical fastener, with female part 10a (the recited mating portion) and male part 10b (the recited lip) located at the tip of each wing—that is, located at the perimeter of each wing. Pet. 20–21, 22. To better illustrate RMS's anticipation positions with respect to Ishikawa and to aid in understanding EMED's contentions, Ishikawa's Figures 1 and 2 are reproduced below.

FIG.1

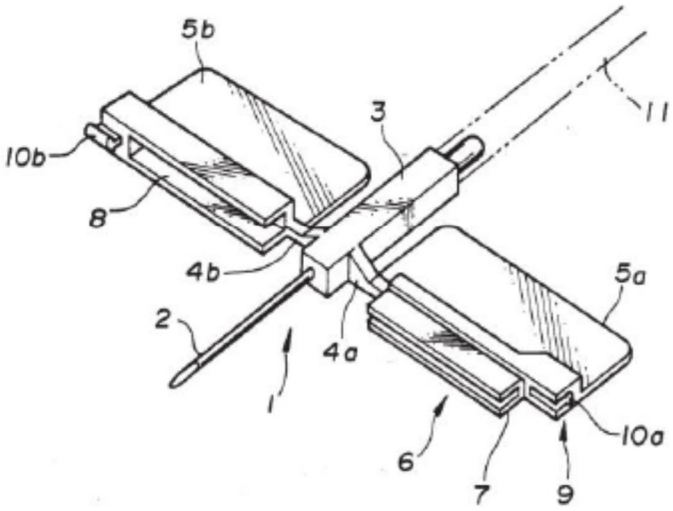

FIG. 2

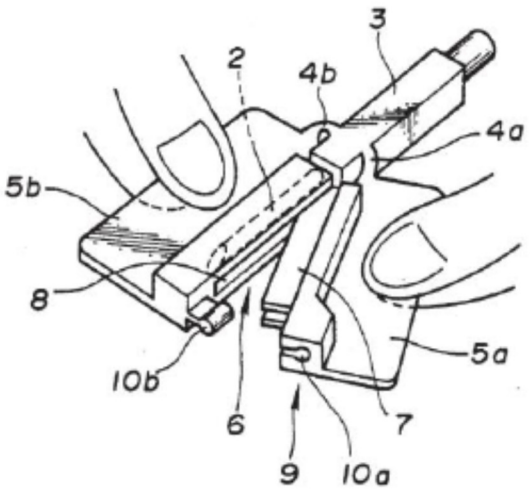

Figure 1 provides a perspective of an embodiment of Ishikawa's winged needle, and Figure 2 depicts the embodiment of Figure 1, during the process of covering the needle. Ex. 1006, 1:56–59. RMS contends that the entire structures attached to either side of base 3, with the exception of coupling means 9 (including female part 10a and male part 10b), correspond to the recited wings of claim 1. RMS's position is that arms 4a, 4b, and sheath 6 (consisting of ditched projection 7 and lipped section 8) form part of the wings. *See* Reply 22–24.

EMED contends that sheath 6 and arms 4a, 4b are not part of Ishikawa's wing structure. PO Resp. 45–46. Specifically, EMED argues that Ishikawa's wings 5a, 5b do not cover needle 2 as required by claim 1, but instead, sheath 6 covers the needle when Ishikawa's wings are closed. *Id.* at 45. EMED also contends that arms 4a, 4b connect wings 5a, 5b with

body 3, such that the wings are not directly attached to body 3. EMED argues that "[o]ne of skill in the art would understand the inner portion of the wings in Ishikawa to be the edge that is parallel to the central body when the wings are open" and, as such, the inner portion of the wings are not "inattachment to" Ishikawa's central body portion. PO Resp. 46 (citing Mr. Stoker's Decl., Ex. 2003 ¶106).

In reply, RMS argues that sheath 6, with ditched projection 7 and lipped section 8, are part of the same unitary structure as wings 5a, 5b. Reply 22–23. That is, RMS is of the view that these structures are part of the wing. RMS also argues that wings 5a, 5b are in attachment to body 3, as the term "in attachment to" would encompass indirect attachment. *Id.* at 23. RMS further argues that arms 4a, 4b are part of the wings and, as such, Ishikawa's wings are directly attached to body 3. *Id.* RMS explains that arms 4a, 4b are hinges that operate just like inner regions 220 included in the embodiments in the '476 patent. *Id.* at 23–24. As such, arms 4a, 4b correspond to the recited inner region of each wing.

We are not persuaded by EMED's arguments that RMS's positions with respect to how Ishikawa discloses the recited pair of wings are deficient. We find that sheath 6 is an integral part of wings 5a, 5b and, as such, Ishikawa's pair of wings in the closed position covers needle 2. *See* Ex. 1006, Figs. 2 and 3 (depicting needle 2 within lipped section 8 as wings 5a, 5b are folded from the open to the closed position and the final closed position of the wings, with needle 2 completely covered). We also find that wings 5a, 5b are at least indirectly attached to body 3. As we determined above, in connection with our claim

construction analysis of the claim term "in attachment to," claim 1 is broad enough to encompass indirect attachment.

We also agree with RMS that arms 4a, 4b correspond to the recited inner region of the wings and, as such, are part of the wings. Because arms 4a, 4b are part of Ishikawa's wings, we find that these wings are directly attached to body 3. We base our interpretation that the recited "inner region" of the wing encompasses arms 4a, 4b based on the language of claim 1 and on the '476 patent's use of the term. Claim 1 recites that the inner region of a wing is the region closest to the central body portion and is the point of attachment of the entire wing with the central body portion. Ishikawa's arms 4a, 4b satisfy this claim language. The rest of claim 1 and the other claims do not provide us with any additional understanding of what is meant by the inner region of the wings.

The '476 patent depicts embodiments of the inventive device in Figures 2 to 13. In many of these embodiments, inner region 220 connects the outer region of a wing to the central body portion, and the inner region has a length of the side adjacent to the central body portion that is shorter than the parallel side of the wing. *See* Ex. 1001, Figs. 2–9. All of these embodiments use the same reference numerals for the inner regions of the wing (item 220), the outer region of the wings (222), and the wings themselves (216, 218). *See id.*, *see also id.* at 5:4–7 ("A pair of wings 216, 218 have an inner region 220 and an outer region 222. Inner region 220 of each one of the pair of wings 216, 218 may be provided in attachment to central body portion 202."); 37 C.F.R. § 1.84(p)(4) ("The same

part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts."). Accordingly, the '476 patent contemplates an inner region of a wing that is shorter in the dimension adjacent to the central body portion than of the parallel side of the outer region of the wing. Arms 4a, 4b have this structure. Further, as evident by the disclosure of the '476 patent, in order for wings 216, 218 to fold into a closed position covering at least part of medical needle 206, inner region 220 acts as a living hinge. *See* Ex. 1001, Figs. 2–13; *see also* Ex. 1008 22:18–25:5 (providing Mr. Stoker's explanation of how the wings of the embodiment of Figure 10 of the '476 patent folds). Arms 4a, 4b also act as living hinges, upon which Ishikawa's wings fold to cover needle 2. *See* Ex. 1006, Fig. 2.

We do not credit Mr. Stoker's Declaration testimony with respect to the inner region of Ishikawa's wings. Mr. Stoker testifies that "[o]ne of skill in the art would understand the inner portion of the wings in Ishikawa to be the edge that is parallel to the central body when the wings are open" and that "[a]rms 4a and 4b are separate structures from the wings." Ex. 2003 ¶ 106. Mr. Stoker fails to provide any basis for this statement and, as a consequence, we afford this testimony little weight.

EMED also argues that "coupling means 10b is not on the perimeter but exterior to the wing and built at the tip is far different than built along the perimeter." PO Resp. 47 (citing Mr. Stoker's Decl., Ex. 2003 ¶ 107). In support of this position, Mr. Stoker declares that:

> One of skill in the art would understand that neither sheath 6, lipped portion 8, female part of coupling means 10a, nor male part of coupling means 10b extend along at least a portion of a perimeter of at least one wing for at least the reason that the coupling means 10b is not on the perimeter but exterior to the wing.

Ex. 2003 ¶ 107.

In response, RMS contends that sheath 6 is part of Ishikawa's wings and forms the perimeter of the wing and that elements 10a and 10b are disposed on that perimeter.

We agree with RMS that Ishikawa's female part 10a and male part 10b of coupling means 9 are disposed on the perimeter of Ishikawa's wings. As we discussed above, we find that sheath 6 is part of Ishikawa's wings. Further, as Ishikawa expressly discloses, female part 10a and male part 10b of coupling means 9 are disposed at the tip of the meeting edges of heath 6, and, as such, are located on the perimeter of Ishikawa's wings. *See* Ex. 1006, 2:29–32, Figs. 1, 2. EMED fails to explain adequately how male part 10b is not on the perimeter of Ishikawa's wing 5b or how a tip of a wing is different from a perimeter of a wing, or at least in a manner sufficient to disturb our above findings. Similarly, Mr. Stoker fails to provide sufficient basis to support his opinion.

On the complete record before us, we conclude that RMS has shown, by a preponderance of the

evidence, that Ishikawa anticipates claim 1. In addition to findings we make above in connection with our analysis of claim 1 as anticipated by Ishikawa, we also adopt as our findings RMS's positions as to how Ishikawa discloses each of the claim limitations of claim 1. *See* Pet. 14–23.

b. Analysis of dependent claims 7 and 8

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 [to 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.

RMS contends that Ishikawa's wings have a rectangular shape, referencing Figure 1. Pet. 25; *see also* Ex. 1006, Fig. 1 (depicting wings 5a and 5b, including ditched projection 7 and lipped section 8, as having a rectangular shape). With respect to claim 8, RMS contends that ditched projection 7 of Ishikawa's sheath 6 houses medical needle 2 and lipped section 8 houses ditched projection 7, such that Ishikawa's wings are formed with a groove on at least one of the pair of wings that houses at least a portion of the medical needle when Ishikawa's wings are in a closed position. *Id.* at 25–26; *see also* Ex. 1006, Figs. 2, 4 (depicting needle 2 in ditched projection 7, which is within lipped section 8 when wings 5a, 5b are closed around needle 2). EMED does not directly contest these contentions. *See* PO Resp. 48 (addressing claim 9 only).

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that Ishikawa anticipates claims 7 and 8. In addition to findings we make above in connection with our analysis of claims 7 and 8 as anticipated by Ishikawa, we also adopt as our findings RMS's positions as to how Ishikawa discloses each of the claim limitations of claims 7 and 8. *See* Pet. 25–26.

c. Analysis of dependent claim 9

Claim 9 depends from claim 8 and further recites "wherein the groove [recited in claim 8] is formed in a single one of the pair of wings." Ex. 1001, 14:40–41. As RMS explains, "[c]laim 9 differs from Claim 8 in that the groove for the needle is on only one wing." Pet. 26. RMS contends that Ishikawa "has the groove in only one wing for housing the needle. That entire groove assembly is then inserted into the depression in the second wing." *Id.* (citing Ex. 1006, 2:19–23). Column 2, lines 19 to 23 of Ishikawa discloses that "[w]hen the wings 5a, 5b meet . . ., the ditched projection 7 makes a three-sided cover for the needle, and the lipped section 8 embraces the ditched projection 7 to cover the needle on all four sides." Ishikawa continues, "sheath 6 doubly covers [ ] needle 2 as shown in" Figure 4. Ex. 1006, 2:23–24.

EMED argues that "[o]ne of skill in the art would understand that if ditched [projection] 7 is a groove, lipped section 8 with sheath 6 also qualifies as a groove. Therefore, there is not a groove on a single one of the pair of wings." PO Resp. 56. EMED does not provide an express construction for the limitation of claim 9. Its argument, however, implicitly interprets claim 9 to limit the device to a single groove

for housing at least a portion of the medical needle formed on one wing only.

RMS replies that lipped section 8 is the groove recited in claim 9. Reply 24. Lipped section 8 houses ditched projection 7, which forms a pair of projection within lipped section 8, such that lipped section 8 is the groove formed in a single wing. *Id.* RMS further argues that "even if one did construe [ditched projection 7] of Ishikawa's [sheath 6 as] defining an additional groove, the requirements of claim 9 are still satisfied by the arrangement described in Ishikawa." *Id.* at 25. RMS does not further explain this position, but at least implies that the proper construction of claim 9 would encompass a groove on wing 5a and a separate groove on wing 5b.

We agree with EMED that RMS has failed to prove, by a preponderance of the evidence, that Ishikawa anticipates claim 9. We interpret the claim limitation "wherein the groove is formed in a single one of the pair of wings" as requiring a groove for housing at least a portion of the medical needle in only one of the two wings that constitute the recited pair of wings—that is, in a single one of the wings. This interpretation is consistent with the plain language of claim 9. The phrase "single one of the pair of wings" means one of the two wings making up the pair. This interpretation is also consistent with the Specification of the '476 patent. Figures 10 and 11 depict a groove—groove 1044—in wing 216. *See* Ex. 1001, Figs. 10, 11, 6:36–38. Wing 218 does not include a groove, but instead, forms the fourth side of the enclosure of the needle when the wings are in a closed position. *See* Ex. 1001, Figs. 10, 11. The '476 patent further discloses that "[i]n one embodiment, groove 1044 *may*

be formed in a single one of the wings 216, 218. In another embodiment, *groove may be formed in both of the wings* 216, 218." *Id.* at 6:40–42 (emphasis added). That is, the '476 patent expressly distinguishes an embodiment with a groove formed in a single one of the pair of wings from an embodiment with grooves in each wing.

We find that Ishikawa discloses grooves for housing at least a portion of the medical needle in each of the wings. Wing 5a includes ditched projection 7 as a groove and wing 5b includes lipped section 8 as a groove. As illustrated in Ishikawa's Figure 4, when the wings are in a closed position, ditched projection 7 houses medical needle 2, encompassing the needle on three sides. Lipped section 8 forms the fourth side of the needle enclosure *and further encompasses* the two side walls (which RMS characterizes as the two projections) of ditched projection 7. In this way, both structures (ditched projection 7 and lipped section 8) serve as grooves for housing the needle. Ishikawa expressly discloses this double cover configuration and indicates the advantage of such a configuration. *See* Ex. 1006, 2:24–28. As Ishikawa explains (and illustrates in Figure 5), if a force external to wings 5a, 5b causes a bending at the meeting edges of sheath 9, the dual covering configuration will still house the needle. *Id.* This express disclosure of a dual covering configuration supports our finding that both ditched projection 7 and lipped section 8 form grooves for housing medical needle 2. As ditched projection 7 is formed in wing 5a and lipped section 8 is formed in wing 5b, Ishikawa does not disclose a groove being formed in a single one of the pair of wings as required by claim 9.

Accordingly, for the reasons discussed above, we determine that RMS has not demonstrated, by a preponderance of the evidence, that Ishikawa anticipates claim 9.

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

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. 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." *Id.* at 14:24–26. Claim 4 depends from claim 1 and further recites "wherein the pair of wings are formed of rigid material." *Id.* at 14:27–28. RMS contends that Harada, in combination with Raines, renders obvious the subject matter of claims 2, 3, and 4. Pet. 35–37.

> Section 103(a) [of 35 U.S.C.] forbids issuance of a patent 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."

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. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze these factual determinations, along with the reasons for combining Harada and Raines, below.[14]

As discussed above in connection with our analysis of Harada and claim 1, we find that Harada discloses each and every claim limitation of claim 1. RMS contends that Raines "discloses a handle that extends from the central body portion of a winged needle protection device" as recited in claim 2. Pet. 35 (citing Ex. 1009, Fig. 1, 4:43–44). With respect to claim 3, RMS contends that Raines's handle extends away from the central body portion in a direction opposite the second end of the needle. *Id.* at 36; *see* Ex. 1009, Fig. 1. As seen in Raines's Figure 1, third wing 30 extends from the central body portion of Raines's device 10. As Raines discloses, third wing 30 is used to pick up safety needle assembly 10 as first and second wings 20, 22 are positioned to shield needle 12. Ex. 1009, 4:43–47. RMS reasons that it would have been obvious to modify Harada's device with a handle as taught by Raines "because all of the

[14] We analyze the level of ordinary skill in the art in Section II.A.1, supra. Also, EMED does not present any evidence of secondary considerations in response to RMS's obviousness assertions. Accordingly, as we have no evidence of secondary considerations to weigh in our ultimate determination of obviousness, our analysis applies the other three *Graham* factors.

references teach very similar winged needle protection devices for the same purpose." Pet. 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.

With respect to claim 4, RMS contends that Raines discloses that its wings are preferably formed of a rigid material, such as polycarbonate. See Pet. 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, RMS asserts that an artisan of ordinary skill would have had reason to modify the wings of Harada 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 Harada fails to disclose each of the elements of claim 1 and that Raines does not cure this deficiency, such that the combination cannot render obvious claims 2, 3, and 4. PO Resp. 49–51. As we discussed above, we find that Harada anticipates claim 1.

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that the combination of Harada and Raines renders obvious claims 2–4. In addition to findings we

make above, we also adopt as our findings RMS's positions as to how Harada in combination with Raines discloses the subject matter of claims 2–4. We further adopt as our own the reasons for combining Harada and Raines as presented above. *See* Pet. 32–34, 35–37, 42–50.

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

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 Harada, combined with Cole, renders claim 5 obvious. Pet. 37–38. We analyze the factual determinations underlying the obviousness analysis, along with the reasons for combining Harada and Cole, below.

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 concludes that it would have been obvious to make Harada's wings out of semi-rigid material as taught by Cole. Pet. 38. 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; *see also* Harada ¶ 7 ("As illustrated in FIG. 2, the

injection needle 1 with securing wings according to the present invention is made from a sheet-shaped needle cover 3 of a flexible material").

EMED argues that Harada fails to disclose each of the elements of claim 1 and that Cole does not cure this deficiency, such that the combination cannot render obvious claim 5. PO Resp. 51. As we discussed above, we find that Harada anticipates claim 1.

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that the combination of Harada and Cole renders obvious claim 5. In addition to findings we make above, we also adopt as our findings RMS's positions as to how Harada in combination with Cole discloses the subject matter of claim 5. We further adopt as our own the reasons for combining Harada and Cole as presented above. *See* Pet. 37–38, 42–48, 50.

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

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. Claim 7 depends from claim 1 and further recites "wherein the pair of wings each have a rectangular shape." *Id.* at 14:34–35. 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)). Similarly, RMS contends that Harada alone as a matter of design choice renders claim 7 obvious. Pet. 39–40. We

analyze the factual determinations underlying this obviousness analysis, below.

RMS's reasoning in support of its obviousness determination is based on a finding by the Examiner during prosecution of the application that matured into the '476 patent that 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." Pet. 39, *see also id.* at 40 ("[W]here an applicant does not 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." (citing *Dailey*)).

With respect to claim 6, EMED responds that "[o]ne of skill in the art would understand that the substantially circular shape solves a problem by at least maximizing the perimeter for engagement of the lip and mating portion of the embodiments disclosed in Figures 10 and 11 of the '476 patent." PO Resp. 52 (citing Ex. 2003 ¶ 115). With respect to claim 7, EMED argues that "[o]ne of skill in the art would understand that the rectangular shape solves a problem by a least simplifying production techniques." *Id.* (citing Ex. 2003 ¶ 116). In paragraphs 115 and 116 of his Declaration, Mr. Stoker identifies, *verbatim*, these same alleged problems solved by the circular and rectangular wing shapes recited in claims 6 and 7, without providing any additional bases for these opinions. RMS argues that the '476 patent's Specification does not support EMED's assertion of how the circular and rectangular shapes solve certain problems. Reply 25–26.

To the extent that RMS argues that the evidence that the rectangular or circular wing shapes solve certain problems must be from the Specification, we do not agree. *See In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995) ("We have found no cases supporting the position that a patent applicant's evidence and/or arguments traversing a § 103 rejection [based on design choice] must be contained within the specification."). We conclude, however, when viewing the totality of the evidence, that the subject matter of claims 6 and 7 would have been obvious over Harada alone, as the recited rectangular and circular shapes are a matter of design choice. Our factual findings supporting this conclusion are discussed below.

We find that the specific geometric shape of the wing, such as a circular shaped wing or a rectangular shaped wing, does not solve any specific problem or present an unexpected results. *See 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"). EMED fails to provide persuasive evidence: (1) that maximizing the perimeter for engagement of the lip and mating portion of the embodiments disclosed in Figures 10 and 11 of the '476 patent, and (2) that simplifying production techniques are recognized problems, or at least sufficient to overcome a finding of design choice. The only evidence that EMED identifies is the unsupported statements of Mr. Stoker. As Mr. Stoker does not provide any basis for these statements, we afford them little weight. Instead, to the contrary, we credit the prosecution history evidence where the examiner that examined

the application that matured into the '476 patent found that a person having ordinary skill in the art would have found the wing shape a matter of design choice, which the applicant did not traverse. *See Ex.* 1011, 119, 146–50.

Further, as to maximizing the perimeter for engagement of the lip and mating portion, we discern that square wings of roughly the same size as wings 216, 218 disclosed in Figures 10 and 11 of the '476 patent would have a greater perimeter length.[15] EMED fails to explain adequately why a circular shape would be chosen to maximize the perimeter length.

Still further, the '476 patent depicts wings that are circular, elliptical, rectangular, and trapezoidal without explaining any reason for the wings' shapes. *See* Ex. 1001, Figs. 2–13; 6:4–8 ("Wings 216, 218 may have various shapes. For example, device 600 has wings 216, 218 with a circular shape (FIG. 6.) Device 700 has wings 216, 218 with a rectangular shape (FIG. 7.) Device 800 has wings 216, 218 with an elliptical shape (FIG. 8)."). The Specification also states that "[t]he pair of wings 216, 218 of device 1000 may be provided in various shapes including, but not limited to, circular shapes and rectangular shapes." *Id.* at 6:32–34. These disclosures support a finding that the wings' shape is merely a design choice. That is, this disclosure in the Specification indicates that a person having ordinary skill in the art would have understood, at the time of the invention, that the

[15] The perimeter "d" is equal to π x d, or approximately 3.14d. A square with a side length of "d" has a perimeter length of 4 x d, or 4d, which is greater than 3.14d.

wings may be formed in a variety of geometric shapes and that these shapes are interchangeable without providing any specific functionality tied to their geometric shape.

Further, we credit Dr. Kazmer's testimony, cited in the Petition, regarding wing shape as an obvious design choice. *See* Pet. 39, 40. As Dr. Kazmer declares, an artisan or ordinary skill would have recognized that using a circular or rectangular shape for the wings would be, in part, an aesthetic choice with no functional advantage. Ex. 1002 ¶¶ 196, 201. "Aesthetic design choices using differing geometric shapes is accomplished with relative ease in injection molding and would be recognized as a common choice for product designers." *Id.* at ¶ 196.

Accordingly, we agree with RMS that a person having ordinary skill in the art would have found it obvious to form Harada's wings in either a circular shape or rectangular shape. An artisan of ordinary skill would have understood, at the time of the invention, that (1) the wings would be a certain geometric shape; (2) the geometric shape of the wings is interchangeable, as the shape does not solve any particular problem, and (3) circular and rectangular wings are two possible choices for wing shapes that could be predictably implemented using injection molding. *See e.g., KSR Int'l Co.*, 550 U.S. at 417 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."); *id.* at 418 ("[A]nalysis [of whether the subject matter of a claim would have been obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for [we] can take account of *the inferences and creative steps that a*

person of ordinary skill in the art would employ.") (emphasis added).

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that Harada alone renders obvious claims 6 and 7. In addition to findings we make above, we also adopt as our findings RMS's positions as to how Harada renders claims 6 and 7 obvious. *See* Pet. 38–40, 42–48.

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

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. Claim 10 depends from claim 8 and further recites "further comprising a handle extending from the central body portion." *Id.* at 14:42–43. We analyze the factual determinations underlying RMS's obviousness analysis with respect to claim 8 and 10, along with the reasons for combining Harada and Sasso, below.

With respect to claim 8, RMS contends that "Harada … combined with … Sasso" renders claim 8 obvious. Pet. 40. As seen in Sasso's Figures 2 and 3, at least a portion of needle 22 is contained within grooves 34, 40. RMS explains that Sasso discloses the recited "groove configured to house the needle" when Sasso's wings are in a closed position. *Id.*; *see* Ex. 1001, 4:57–5:12; *see also id.* at 5:13–17 ("As can be seen in FIG. 2 when the two wings 28 and 30 are

flexed to their closed orientation their slots 34 and 40 respectively form an enclosed channel in which the sharpened free end 22F and contiguous portion of the distal end portion 22B of the needle is located and confined"). RMS's expert explains that modifying Harada with Sasso's groove would have been obvious to a person having ordinary skill in the art to "provide [ ] a secure and enclosed compartment for the needle." Ex. 1002 ¶ 214.

With respect to claim 10, RMS contends that Sasso discloses a handle extending from the central body portion of a needle safety device. Pet. 35 (addressing dependent claim 2, which recites the same claim limitation as claim 10). As seen in the embodiment depicted in Sasso's Figures 1–3, device 20 includes handle 60. *See also* Ex. 1010, 5:66–6:3 ("[A] short flange 60 is provided upstanding from the top wall 26C of the central hub 26 to serve as a portion that can be grasped between the user's fingers to hold the device 20 and facilitate its mounting and dismounting with respect to the patient."). RMS reasons that it would have been obvious to modify Harada's device with a handle as taught by Sasso "because all of the references teach very similar winged needle protection devices for the same purpose." Pet. 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 Harada fails to disclose each of the elements of claim 1 and that Sasso does not cure this deficiency, such that the combination cannot render obvious claims 8 and 10. PO Resp. 53–

54, 56–57. As we discussed above, we find that Harada anticipates claim 1.

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that the combination of Harada and Sasso renders obvious claims 8 and 10. In addition to findings we make above, we also adopt as our findings RMS's positions as to how Harada in combination with Sasso discloses the subject matter of claims 8 and 10. We further adopt as our own the reasons for combining Harada and Sasso as presented above. *See* Pet. 40–48, 51–52.

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

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. Claim 9 depends from claim 8and further recites "wherein the groove is formed in a single one of the pair of wings." Ex. 1001, 14:40–41. RMS contends that the combination of Harada and Ishikawa renders claim 8 obvious. Pet. 40. RMS further contends that Harada, as modified by Ishikawa as asserted for claim 8, renders claim 9 obvious. *Id.* at 41. We analyze the factual determinations underlying RMS's obviousness analysis with respect to claim 8 and 9, along with the reasons for combining Harada and Ishikawa, below.

RMS contends that Ishikawa discloses the recited groove of claim 8. Pet. 40 (referencing

Ishikawa's Figures 1 and 2, 2:16–23); *see also* Section II.C.3.b, *supra* (addressing how Ishikawa anticipates claim 8). As discussed above in connection with our analysis of Ishikawa anticipating claim 8, we find that Ishikawa discloses the subject matter of claim 8.

RMS further contends that "Ishikawa, as shown in the discussion of the anticipation of [c]laim [9], houses the needle in a single groove in the closed position." Pet. 41. As discussed above in connection with our analysis of Ishikawa anticipating claim 9, we find that Ishikawa fails to disclose the subject matter of claim 9. That is, we find that Ishikawa has grooves formed in both of its wings, not just a single one of its wings. RMS fails to adequately explain why a person having ordinary skill in the art would modify Ishikawa's dual groove system when combining its teachings with Harada to arrive at the subject matter of claim 9.

With respect to claim 8, RMS's expert explains that modifying Harada with Ishikawa's teaching of a groove would have been obvious to a person having ordinary skill in the art to "provide[ ] a secure and enclosed compartment for the needle." Ex. 1002 ¶ 214.

With respect to claim 8, EMED argues that Harada fails to disclose each of the elements of claim 1 and that Ishikawa does not cure this deficiency, such that the combination cannot render obvious claim 8. PO Resp. 54–55. As we discussed above, we find that Harada anticipates claim 1.

On the complete record before us, we conclude that RMS has shown, by a preponderance of the evidence, that the combination of Harada and

Ishikawa renders obvious claim 8. In addition to findings we make above, we also adopt as our findings RMS's positions as to how Harada in combination with Ishikawa discloses the subject matter of claim 8. We further adopt as our own the reasons for combining Harada and Ishikawa as presented above for claim 8. See Pet. 40–41, 42–48, 50. We further conclude that RMS has not proven, by a preponderance of the evidence, that the combination of Harada and Ishikawa renders obvious claim 9.

D. *Pending Motions*

1. Patent Owner's Motion to Amend

EMED filed a contingent Motion to Amend the claims of the '476 patent. Paper 27, 1 ("Motion to Amend"). EMED moves to replace claim 1 with substitute claim 11 "in the event that the original claims of the '476 patent are found unpatentable." *Id.* We interpret this request to be if we find any of the claims unpatentable, then we should cancel the unpatentable claims and substitute in the corresponding new claim. As we conclude that claims 1–8 and 10 are unpatentable, we address EMED's motion.

EMED has the burden of proving patentability of a proposed substitute claim. *See Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2016) ("[T]he Board permissibly interpreted [37 C.F.R. § 42.20(c)] as imposing the burden of proving patentability of a proposed substitute claim on the movant: the patent owner."). Specifically, EMED has the burden of proving that the substitute claim is patentably distinct over the prior art of record in the

proceeding. *See Microsoft Corp. v. Proxyconn, Inc.,* 789 F.3d 1292, 1307–08 (Fed. Cir. 2015); *MasterImage 3D, Inc. v. RealD Inc.*, Case IPR2015–00040 (PTAB July 15, 2015) (Paper 42) (precedential); *Idle Free Systems, Inc. v. Bergstrom, Inc.,* Case IPR2012–00027 (PTAB June 11, 2013) (Paper 26) (informative); but see *In re Aqua Products*, No.2015–1177, 2016 WL 4375651, at *1 (Fed. Cir. Aug. 12, 2016) (granting rehearing *en banc* to address burdens of persuasion and production regarding motions to amend under 35 U.S.C. § 316(d) and vacating *In re Aqua Products*, 823 F.3d 1369 (Fed. Cir. 2016)).

a. New Claim 11 and its Support in the Specification

EMED proposes to substitute new independent claim 11 for claim 1.

New claim 11 recites:

> 11. 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 direct 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~~ and are configured for 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.

Motion to Amend 5–7.

As can be seen from the marked-up version of claim 11 above, EMED makes two amendments: EMED (1) adds the word "direct" to the phrase "in attachment to" to further limit the claim to wings that are in direct attachment to the central body portion; and (2) replaces the term "to allow" with the term "and are configured for." EMED does not offer an express claim construction associated with either of these amendments.[16]

EMED asserts that the claim amendments are supported by the Specification. Motion to Amend 8–9. As to the first amendment, EMED contends that Figures 10 and 11; the Abstract; column 1, line 55 to column 2, line 39; and column 5, lines 5–7 support the "in direct attachment to" subject matter. *Id.* at 8. RMS does not dispute this contention and we agree with EMED that the Specification supports the subject matter requiring the inner region of the wing be in direct attachment to the central body portion.

As to the second amendment, EMED contends that Figures 10 and 11; the Abstract; column 1, line 55 to column 2, line 39; and column 5, lines 9– 15 support the "and are configured for" subject matter.

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[16] In his Declaration supporting EMED's Motion to Amend, Mr. Stoker declares that the claim terms of substitute claim 11 are entitled to their plain and ordinary meaning. See Ex. 2007, 27, 28, 29–31, 32, 33, 35.

Motion to Amend 9. EMED does not further explain this support; nor does Mr. Stoker, who merely states that he found these aspects of the '476 patent "useful for construing" the amended claim limitation reciting "the pair of wings being selectively … to protect against accidental needle stick injury from the medical needle" and including the amended phrase "and configured for placement." *See* Ex. 2007, 31–32.[17]

RMS contends in its Opposition to EMED's Motion to Amend that the second amendment—replacing "to allow" with "and configured for"—is not supported by the written description. Paper 32, 22 ("Opp. Motion to Amend"). RMS argues that "none of these cited portions of the '476 patent disclosure adequately support this new limitation." *Id.* RMS explains that:

> There is nothing in the disclosure of the '476 patent that evidences that the inventor had possession of the notion that the wings *per se* were "configured for" placing a medical needle into a patient, much less that the wings are configured to be "*folded back* to allow placement."

Id. at 22–23.

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[17] Ex. 2007, which contains Mr. Stoker's Declaration in support of EMED's Motion to Amend, erroneously numbers its paragraphs—it numbers paragraphs 1–74 sequentially, then begins the numbering again at paragraph 53. To avoid confusion, we cite to a page number of Ex. 2007 rather than a paragraph number.

In reply, EMED contends that "[o]ne of skill in the art would be aware of *what* position the wings must take to allow placement of the needle into a patient." Paper 36, 7 ("PO Reply"). EMED argues that "[t]he National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) 2006 Guidelines indicates the position of the wings and manner of holding the wings to give an injection." *Id.* at 7.

EMED also argues that the Motion to Amend included a construction for the term "and are configured for"—"a pair of wings being selectively positionable from a first position to a second position, the first position for placing the medical [ ] needle into a patient and delivering a medicinal fluid to a second position." PO Reply 9–10 (citing its Motion to Amend at 11– 14). The Motion to Amend, however, refers to the disclosure that serves as the basis for this "construction" as support for the amendment, *not* as the meaning of the term. Also, this construction conflicts with how EMED evaluates the claim limitation with respect to the prior art. Accordingly, we address EMED's implicit construction and this *post hoc* construction, below.

"[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1353–54 (Fed. Cir. 2010) (*en banc*) (quoting *Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 920 (Fed. Cir. 2004)). To satisfy the written description requirement, the focus is not just on whether the

claims are supported by the specification, but whether one of ordinary skill in the art reasonably would conclude from the original disclosure that the inventor had possession of the claimed invention. *See*, *e.g.*, *Ariad Pharm.*, 598 F.3d at 1351. The parties' dispute centers on the scope of claim 11, which turns on the interpretation of the phrase "are configured for."

As we noted above, EMED does not provide an express construction for the phrase "are configured for" in its Motion to Amend, but implicitly construes this phrase to mean that the wings are folded back together (that is, pinched between the thumb and index finger) to place the needle in the treatment site. *See*, e.g., Motion to Amend 16 ("The wings in Harada cannot be folded back to allow placement. Therefore, they are not configured for placement of the needle into a treatment site."); *id.* ("The wings in Ishikawa cannot be held back together to allow placement of the medical needle."). As EMED's counsel explained at oral argument, "to one of ordinary skill in the art, configured for placement means that the wings are capable of being folded back and used for insertion into the vascular body." Tr. 74:22–25; *see also id.* at 55:1–13 (confirming EMED's position that wings "configured to allow placement" are used by "fold[ing the wings] all the way back against each other, and . . . pinch[ing] them between the thumb and forefinger").

RMS contends that the recitation "wings … configured for placement of the medical needle into the treatment site" should be construed under 35 U.S.C. § 112, paragraph 6—that is, as a means-plus-function claim limitation. Paper 32, 20–21 (Opp. Mot. To Amend"). RMS argues that the claim limitation lacks sufficient structure because "[t]here is an

insufficient nexus between the structure of a 'wing' and the recited function of placement of the medical needle into the treatment site" such that construing the term as a means-plus-function element is warranted. *Id.* at 21.

As an initial matter, we do not agree with RMS that the disputed claim term should be construed as a means-plus-function limitation. In construing claim terms, we determine whether to apply analysis under § 112, paragraph 6, by determining "whether the words of the claim are understood by persons of ordinary skill in the art to have sufficiently definite meaning as the name for structure." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). Use of the word "means" gives rise to a rebuttable presumption that such means-plus-function analysis should apply and absence of the word "means" gives rise to the opposite rebuttable presumption. *Id.* "When a claim term lacks the word 'means,' the presumption can be overcome and § 112, para[graph] 6 will apply if he challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Williamson*, 792 F.3d at 1348. Here, we determine that the claim term recites sufficiently definite structure—a wing—such that the presumption that § 112, paragraph 6 does not apply is not overcome.

We determine, however, that EMED's implicit construction is improper. As a reminder, we rejected this same implicit construction for the term "to allow." *See* Section II.A.5, *supra*. We determine that EMED's construction is not supported by the '476 patent's intrinsic record or any persuasive extrinsic evidence.

We also note that EMED had the opportunity to amend claim 1 to explicitly require the wings to be folded back against each other and grasped to insert the needle at the treatment site and chose not to make such an amendment.

As mentioned above, in its Reply, EMED contends that the phrase "and configured for" should be construed to mean "a pair of wings being selectively positionable from a first position to a second position, the first position for placing the medical [ ] needle into a patient and delivering a medicinal fluid to a second position." PO Reply 9. We determine that this construction fails to add any understanding to the claim term; provides extra language that is not needed; and does not make logical sense. First, the words "a pair of wings being selectively positionable from a first position to a second position" already appear in amended claim 11, albeit in a slightly different form—"the pair of wings being selectively positionable from an open position to a closed position." All this proposed construction does is define "open position" as a "first position." Second, the proposed construction states that the wings are placed into a "first position" for placing the medical [ ] needle into a patient and delivering a medicinal fluid. Claim 11, however, already states that the open position is for placement of the medical needle to a treatment site to deliver medicinal fluid. Third, the proposed construction states that, in the first position, medicinal fluid is delivered *to a second position*. This aspect of the construction makes no logical sense—the second position is a position of the wings, not a position to which medicinal fluid is delivered, such as a treatment site. For these three reasons, we reject this construction.

Instead, we construe the phrase "and configured for" to mean "and arranged in a certain configuration for" performing the recited function—its ordinary and customary meaning in light of the Specification.[18] We discern no reason why the phrase "and configured for" should be construed to require the wings to be folded back together to place the needle at the treatment site. We find nothing in the Specification to require that this arranged configuration must be such that the wings are capable of being folded back and used for inserting the needle into the treatment site. As we previously discussed, the '476 patent discloses other wing configurations (where the wings are at a 180-degree orientation from one another and a 90- degree orientation from the needle) for placement of the needle at a treatment site. *See* Ex. 1001, Figs. 1, 11, 1:41–45. Further, EMED does not identify anything in the prosecution history that would cause us to depart from this ordinary and customary meaning.

Further, EMED's own expert declares that the amended claim term "the pair of wings being selectively ... to protect against accidental needle stick injury from the medical needle" and including the amended phrase "and configured for placement"

[18] RMS further contends that EMED's second amendment results in a claim limitation that is indefinite. Opp. Motion to Amend 23–25. RMS argues that "the specification of the '476 patent fails to provide any guidance whatsoever as to the metes and bounds of this newly added term.... The specification does not offer any guidance as to what position the wings must take in order to allow placement of the medical needle into a treatment site." Id. at 23. In light of our construction, we find RMS's argument unpersuasive.

should be afforded its plain and ordinary meaning because the phrase "does not have a technical meaning that would be understood by one of ordinary skill in the art." *See* Ex. 2007, 32. As to its reliance on the NKF KDOQI 2006 Guidelines, EMED presents no evidence or explanation as to why the device of claim 1 should be limited to the application that falls within these guidelines.[19]

With this understanding of the claim limitation at issue, we do not agree with RMS that EMED's second amendment lacks written description support. We find that the '476 patent adequately supports a device with wings that are arranged in a certain configuration for placement of the medical needle at a treatment site. For example, wings open in the orientation depicted in Figure 11 are arranged in a configuration for placement of the medical needle at a treatment site as required by new claim 11.

b. New Claim 11 and the Prior Art of Record

EMED contends that the prior art of record does not teach the amended claim elements of substitute claim 11. Motion to Amend 15. In its Motion to Amend, EMED enumerates the prior art of record and identifies one or more claim elements of substitute claim 11 that are not present in that prior art reference. *See id.* at 15–23. To be clear, for certain of the references, EMED identifies elements from

[19] We also observe that the winged needle depicted in NKF KDOQI 2006 Guidelines at Figure 1B is different from those depicted in the '476 patent— the wings in the Guidelines fold in a direction 90-degrees from the needle while the needles depicted in the '476 patent would fold 180-degrees from the needle.

claim 11 other than the amended elements that are not present in the prior art reference. *See, e.g., id.* at 17 ("Rosato is missing other elements of Claim [11], including but not limited to 'a lip, do[ ] not extend along a perimeter, and do[ ] not include a mating portion that is along a perimeter of the other wing.'") (alteration in original). Effectively, EMED concludes that no reference of record anticipates substitute claim 11.

RMS first argues that not all of the prior art of record was addressed in the Motion to Amend. Opp. Motion to Amend 3. Specifically, RMS identifies the Hayes and Ono references, which appear on the face of a related patent.[20] EMED did not address these references in its Motion to Amend, but addressed the references in its PO Reply, contending that neither Hayes nor Ono anticipate or render obvious substitute claim 11. PO Reply 2–4.

RMS next argues that we should deny EMED's Motion to Amend because it fails to address obviousness and simply addresses each prior art reference of record individually. Opp. Motion to Amend. 7. RMS further notes that EMED's expert also does not present any obviousness analysis in his Declaration in support of the Motion to Amend, merely providing a conclusory statement that "[i]n my opinion, claims 1-10 would not have been obvious to a person of ordinary skill in the art at the time of the invention [in] light of the prior art"—a statement not relied on by EMED in its Motion to Amend. *Id.* (citing

[20] "Hayes" refers to U.S. Patent No. 5,693,022, Exhibit 1020 and "Ono" refers to U.S. Patent 7,291,135 B2, Exhibit 1021. The related patent is U.S. Patent No. 9,308,322 B2, Exhibit 1019.

Ex. 2007 ¶ 103 (page 48)). RMS does not include an obviousness analysis of its own in its Opposition. RMS further argues that certain prior art references of record do disclose both of the amended claim elements of substitute claim 11. *See id.* at 8–16 (addressing Harada, Ishikawa, Cole, and Sasso).

In reply, EMED argues that, in light of the Federal Circuit's decision in *Veritas*,[21] EMED has met its burden in demonstrating that substitute claim 11 is patentable over the prior art of record. PO Reply 2. EMED further argues that it addressed obviousness by stating that substitute claim 11 is patentably distinct over the prior art of record. *Id.* at 4. EMED then addresses RMS's assertions with respect to Harada, Ishikawa, Cole, and Sasso. *Id.* at 4–9.

We find that certain prior art references of record anticipate substitute claim 11. For example, each of Harada, Cole, and Ishikawa anticipates claim 11. As discussed above in our analysis of claims 1–10 of the '476 patent over the prior art, we find that Harada, Cole, and Ishikawa anticipate original claim 1. *See* Sections III.C.1–II.C.3, *supra*. We further find that each of these references discloses wings in direct attachment to a central body portion.

With respect to Harada, we find that attaching wings 3a, 3b to hub 4 through junction portion (rivet) 5 constitutes a direct attachment of the wings to the central body portion. *See Ex.* 1003, Figs. 1, 3, and 4. Wings 3a, 3b are directly attached to hub 4 by junction

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[21] *Veritas Techs, LLC v. Veeam Software Corp.*, 835 F.3d 1406 (Fed. Cir. 2016).

portion (rivet) 5, such that the wings may pivot. With respect to Cole, wings 30, 31 are directly attached to hub 34 at pivot portions 32, 33. *See* Ex. 1005, Fig. 8

With respect to Ishikawa, we find that arms 4a, 4b correspond to the recited inner region of the wings 5a, 5b and, as such, are part of the wings. *See* Ex. 1006, Figs. 1, 2, 6. Because arms 4a, 4b are part of Ishikawa's wings, we find that these wings are directly attached to body 3. *See id.* We base our interpretation that the recited "inner region" of the Wingen compasses arms 4a, 4b on the language of the claims and on the '476 patent's use of the term. Substitute claim 11 recites that the inner region of a wing is the region closest to the central body portion and is the point of attachment of the entire wing with the central body portion. Ishikawa's arms 4a, 4b satisfy this claim language. The rest of claim 11 and the other claims do not provide us with any additional understanding of what is meant by the inner region of the wings. Further, the '476 patent contemplates an inner region of a wing that is shorter in the dimension adjacent to the central body portion than the length of the parallel side of the outer region of the wing. *See* Ex. 1001, Figs. 2–9 (depicting inner region 220 connecting the outer region of a wing to the central body portion and the inner region having a length of the side adjacent to the central body portion that is shorter than the parallel side of the wing). Arms 4a, 4b of Ishikawa have this structure. Further, as evidenced by the disclosure of the '476 patent, in order for wings 216, 218 to fold into a closed position covering at least part of medical needle 206, inner region 220 acts as a living hinge. *See* Ex. 1001, Figs. 2– 13; *see also* Ex. 1008 22:18–25:5 (providing Mr. Stoker's explanation of how the wings of the

embodiment of Figure 10 of the '476 patent folds). Arms 4a, 4b also act as a living hinge, upon which Ishikawa's wings fold to cover needle 2. *See* Ex. 1006, Fig. 2.

We also find that Harada, Cole, and Ishikawa disclose a pair of wings that are configured for placement of the medical needle into a treatment site and delivery of a medicinal fluid as required by substitute claim 11. As expressly disclosed in Harada, we find that wings 3a, 3b can be arranged in a configuration for placing a medical needle at a treatment site. *See* Ex. 1003, 8 (describing that, when the injection needle is used, needle cover 3 is opened and wings 3a and 3b are secured, in the open position, to the patient), Fig. 1 (providing "a front view illustrating the state of the present invention at the time of use").

With respect to Cole, we find that Cole's arms 30, 31 fold back to expose the medical needle and allow placement of the needle into the treatment site. Cole expressly discloses that arms 30, 31 fold back against the syringe, with the user's index and middle fingers resting on flaps 8, 9, to aid in delivering the medicinal fluid from the syringe. *See* Ex. 1005, Fig. 4, 3:44–51 ("[I]n FIG. 4 the flaps have been disengaged from their position in FIG. 3 and have been [pivoted] round in the direction of arrows 18, 19 so that the arms lie alongside the cylinder body of the hypodermic syringe 2, at which position the flaps 8, 9 can be used as grips for the first and second finger whilst the thumb is applied to the head of the plunger 3 for the injection of a fluid via the needle into a patient."). Indeed, Cole's arms 30, 31 fold all the back against syringe 37 for placement of the needle at the treatment site.

With respect to Ishikawa, we find that wings 5a, 5b, in the open position, are arranged in a configuration for placement of the medical needle at a treatment site. *See* Ex. 1006, Figs. 1, 2, 6. Further, Ishikawa expressly discloses that the device of Figure 6 (which includes engaging means 12 but is otherwise the same as the embodiment of Figure 1) is arranged such that its wings may be folded up against each other to place the needle at the treatment site. *See* Ex. 1006, Fig. 6, 2:47–53 ("The engaging means 12 reinforces the rigidity of the unit, particularly when the wings 5a, 5b are folded up like a sandwich along the base 3. Thus the user can securely hold the needle by grasping the sandwiched wings when applying the needle 2 to a patient.").

Further, EMED's reliance on *Veritas* to support its assertion that it met its burden for a Motion to Amend is inapposite. In *Veritas*, the patent owner asserted that the amended claim limitations were not found in any of the prior art systems of record. *Veritas Techs. LLC*, 835 F.3d at 1414–15. That is, the patent owner effectively asserted that no single reference could anticipate the substitute claim nor could any combination of references render the claims obvious—any possible combination of the prior art of record would be missing the amended claim limitations. That situation is not the case here, as each amended claim element is found in multiple prior art references.[22] Given our findings with respect to

[22] In addition to Harada, Cole, and Ishikawa, discussed above, at least Sasso, Rosata (Ex. 1004), Nicoletti (Ex. 1007), and Keaton (Ex. 1008) disclose direct attachment of the wings to a central body portion. Figure 1 of the '476 patent, admitted prior art, discloses a device with wings identical to those of Figures 10 and

anticipation, however, we need not look to obviousness.

For the reasons above, EMED's Motion to Amend is *denied.*

2. *Petitioner RMS's Motion to Exclude Evidence*

RMS moves to exclude Exhibit 2005, Exhibits 2003 and 2007 (Mr. Stoker's Declarations), and portions of Exhibit 2004 (Dr. Kazmer's deposition). We take each of these in turn.

a. Exhibit 2005

RMS argues that Exhibit 2005, a "Decision Prior Art Chart," is cited in Mr. Stoker's first Declaration (Exhibit 2003). Pet. Mot. Excl. 2. RMS indicates that the authorship was not identified until RMS objected to the exhibit, whereupon EMED admitted that Exhibit 2005 was prepared by counsel. *Id.* RMS argues that "[i]t is still unclear whether the contents of the chart constitute the opinions of Mr. Stoker, argument of counsel, or both." *Id.* RMS continues that, if Exhibit 2005 is part of Mr. Stoker's Declaration, then it should be incorporated a part of the Declaration and subject to the attestation of the Declaration. *Id.* Otherwise, it should be part of the Patent Owner Response and subject to the word count limit. *Id.*

11, such that they are capable of being folded all the way back and grasped by a user. Exhibits 2029 and 2030 also depict needles with wings that fold back and are grasped by the user to insert the treatment needle. Other references disclose wings that are arranged in a configuration for placing a needle at a treatment site, such as Rosata, Keaton, Raines, and Sasso.

EMED responds that Mr. Stoker directed counsel to compile Exhibit 2005 using Mr. Stoker's opinions. PO Opp. Mot. Excl. 1. RMS replies that Exhibit 2005 does not meet the requirements of 37 C.F.R. § 42.53(a) as it is not submitted in the form of an affidavit. Pet. Reply Opp. Mot. Excl. 1.

We agree with RMS that Exhibit 2005 needed to be part of Mr. Stoker's Declaration and subject to the attestation regarding perjury. As it was not properly included in his Declaration, we grant RMS's motion to exclude it as evidence. We take this opportunity to state that our final written decision with respect to the patentability of claims 1–10 does not, in any part, rely on Exhibit 2005.

b. Exhibits 2003 and 2007

RMS moves to exclude under Federal Rule of Evidence (FRE) 702 Mr. Stoker's Declarations. Pet. Mot. Excl. 3. RMS argues that Mr. Stoker lacks the requisite scientific, technical, or other specialized knowledge to help the Board understand the evidence or make factual findings. *Id.* at 4. RMS also argues that Mr. Stoker's educational background does not provide an adequate foundation for his opinions and that his experience is devoted to non-technical endeavors. *Id.* at 4–5. RMS further argues that Mr. Stoker's testimony is not the product of reliable principles. *Id.* at 6.

EMED responds that Mr. Stoker has authored a number of articles and presentations on sharps protection. PO Opp. Mot. Excl. 2. EMED further argues that Mr. Stoker's education and experience

supports Mr. Stoker as an expert. *Id.* at 3. EMED also argues that Mr. Stoker's Declarations identify the principles that underlie his opinions and that Mr. Stoker's opinions are consistent with these principles and the specific facts relevant to those opinions. *Id.* at 4–8.

We deny RMS's motion to exclude Exhibits 2003 and 2007. We find that Mr. Stoker has a sufficient educational foundation and sufficient experience in sharps protection to help the Board understand the evidence or make factual findings in this proceeding. Further, to the extent that RMS identifies specific deficiencies in the methods and principles supporting Mr. Stoker's opinions, we find that such matters go to the probative weight of his testimony, as opposed to its admissibility. We note that the policy considerations for excluding expert testimony, such as those implemented by the gatekeeping framework established by the Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579 (1993), are less compelling in bench proceedings such as *inter partes* reviews than in jury trials because, unlike a lay jury, the Board by statutory definition has competent scientific ability (35 U.S.C. § 6) and has significant experience in evaluating expert testimony. Accordingly, the danger of prejudice in this proceeding is considerably lower than in a conventional district court trial.

c. Portions of Exhibit 2004

RMS seeks to exclude certain testimony from Dr. Kazmer's deposition because the testimony was the subject of valid and uncured objections to form or the cross-examination questioning exceeded the scope

of Mr. Kazmer's direct testimony. Pet. Mot. Excl. 9; *see also id.* at 10–14 (listing specific sections of testimony and providing reasons to exclude the testimony). EMED refutes each one of MS's specific objections. PO Opp. Mot. Excl. 10–15.

We deny RMS's motion to exclude portions of Exhibit 2004 as moot, because we do not rely on any of the cited testimony in rendering our final written decision with respect to the patentability of claims 1–10.

3. *Patent Owner EMED's Motion to Exclude Evidence*

EMED moves to exclude Dr. Kazmer's Declaration, Ex. 1002. Paper 42 ("PO Mot. Excl."). A motion to exclude evidence preserves objections made during trial. 37 C.F.R. § 42.64(c). As we previously reminded EMED, our rules require that "[a]ny objection to evidence submitted during a preliminary proceeding must be filed within ten business days of the institution of the trial." 37 C.F.R. § 42.64(b)(1); *see* Paper 26, 2. We also reminded EMED that "[t]o the extent that an objection was not timely made, the motion [to exclude evidence] must provide why the objection requirements of rule 42.64 should be waived. Paper 26, 2.

EMED objected to Dr. Kazmer's Declaration no earlier than May 13, 2016. Paper 29, 1 ("Patent Owner EMED Technologies Corporation's Objection to Purported Expert David Kazmer, Ph.D."). We instituted trial on February 19, 2016—almost three months prior to the objection. As RMS notes, EMED's motion to exclude does not explain why we should waive the timing requirements of Rule 42.64. Paper

53, 2 ("Pet. Opp. Mot. Excl."). In reply, EMED contends that "Petitioner is not prejudiced by Patent Owner's [untimely] objection to the Declaration of Kazmer as he had a full opportunity to supplement his Declaration during the deposition." Paper 56, 2 ("PO Reply Mot. Excl.").

We dismiss EMED's motion as untimely. EMED fails to explain adequately why we should waive the timing requirement of Rule 42.64. We do not see how Petitioner was not prejudiced by the delay in the objection. Specifically, we do not see how RMS could have cured any objection to Dr. Kazmer's qualifications at a deposition taken on April 26, 2016, when the objection was not made until May 13, 2016.

III. CONCLUSION

For the foregoing reasons, Petitioner has demonstrated by a preponderance of the evidence that claims 1–8 and 10 of the '476 patent are unpatentable. Petitioner has not demonstrated by a preponderance of the evidence that claim 9 of the '476 patent is unpatentable.

We deny EMED's motion to amend. We grant-n-part, deny-in-part, and deny as moot-in-part RMS's motion to exclude evidence and dismiss EMED's motion to exclude evidence.

IV. ORDERS

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

ORDERED that claim 1 of the '476 patent is held to be *unpatentable* under 35 U.S.C. § 102(b) as anticipated by Harada;

FURTHER ORDERED that claims 1, 5, and 7 of the '476 patent are held to be *unpatentable* under 35 U.S.C. § 102(b) as anticipated by Cole;

FURTHER ORDERED that claims 1, 7, and 8 of the '476 patent are held to be *unpatentable* under 35 U.S.C. § 102(b) as anticipated by Ishikawa;

FURTHER ORDERED that claims 2, 3, and 4 of the '476 patent are held to be *unpatentable* under 35 U.S.C. § 103(a) over Harada and Raines;

FURTHER ORDERED that claim 5 of the '476 patent is held to be *unpatentable* under 35 U.S.C. § 103(a) over Harada and Cole;

FURTHER ORDERED that claims 6 and 7 of the '476 patent are held to be *unpatentable* under 35 U.S.C. § 103(a) over Harada;

FURTHER ORDERED that claims 8 and 10 of the '476 patent are held to be *unpatentable* under 35 U.S.C. § 103(a) over Harada and Sasso;

FURTHER ORDERED that claim 8 of the '476 patent is held to be *unpatentable* under 35 U.S.C. § 103(a) over Harada and Ishikawa;

FURTHER ORDERED that claim 9 of the '476 patent is <u>not</u> held to be unpatentable based on any ground presented in the Petition underlying this proceeding;

FURTHER ORDERED that EMED's Motion to Amend is *denied*;

FURTHER ORDERED that EMED's Motion to Exclude is *dismissed*;

FURTHER ORDERED that RMS's Motion to Exclude is *granted-in-part, denied-in-part, and denied as moot-in-part*; and

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

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