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

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,961,476

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Patent Trial and Appeal Board
United States Patent and Trademark Office
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Submitted Electronically via the Patent Review Processing System

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PETITIONER'S EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION
Exhibit 1001	U.S. Patent No. 8,961,476
Exhibit 1002	Declaration of David O. Kazmer, P.E., Ph.D.
Exhibit 1003	Japanese Unexamined Patent Application Publication No. JPH 09-66106 (A) to Harada et al., with certified English Translation
Exhibit 1004	U.S. Patent No. 5,951,522 to Rosato and Stanek
Exhibit 1005	U.S. Patent No. 4,944,731 to Cole
Exhibit 1006	U.S. Patent No. 5,147,319 to Ishikawa et al.
Exhibit 1007	U.S. Patent No. 5,279,588 to Nicoletti
Exhibit 1008	U.S. Publication No. 2008/0177234 A1 to Keaton et al
Exhibit 1009	U.S. Patent No. 6,911,020 B2 to Raines
Exhibit 1010	U.S. Patent No. 6,500,155 to Sasso
Exhibit 1011	Prosecution History of U.S. Patent No. 8,961,476
Exhibit 1012	A copy of the Joint Claim Construction and Prehearing Statement in *Repro-Med Sys., Inc. (d/b/a RMS Med. Prod.) v. Emed Tech. Corp.*, Case No. 2:13-cv-1957-TLN-CKD (E.D. Cal.)
Exhibit 1013	U.S. Patent No. 3,648,400 to Wolfe
Exhibit 1014	U.S. Patent No. 4,280,636 to Lewis
Exhibit 1015	U.S. Patent No. 5,092,479 to Wells
Exhibit 1016	U.S. Patent No. 5,342,330 to Kane

I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED PURSUANT TO 37 C.F.R. § 42.22(A)

Repro-Med Systems, Inc. (doing business as RMS Medical Products) (hereafter referred to as "RMS" or "Petitioner") petitions for an *inter partes* review of U.S. Patent 8,961,476 (the "'476 Patent") titled "Sharps Protector Device for Protecting a User from the Sharp Tip of a Medical Needle," which is assigned to EMED Technologies Corporation.

Petitioner seeks the cancellation of Claims 1-10 of the '476 Patent on the grounds of (1) anticipation under 35 U.S.C. § 102, and (2) obviousness under § 103 as demonstrated herein.

The '476 Patent claims a device for protecting against accidental medical needlestick injuries. The device consists of two wings that fold over the needle and fasten together. The prior art taught numerous examples of such winged needle enclosures, and disclosed every element of the claims. The Examiner allowed the claims based on the assertion that the claims were distinguished from the prior art because of a limitation in the claims requiring that the wings include a mechanical fastener with a lip on a portion of the perimeter of one wing and a mating region on the other wing that aligned the wings when in a closed position. However, the prior art taught precisely such a standard mechanical fastening device on the wings of needle protection devices. As shown in detail herein, RMS

is reasonably likely to prevail on the asserted grounds with respect to the Claims 1-10 of the ’476 Patent.

A copy of the ’476 Patent is provided as Exhibit 1001.

II. MANDATORY NOTICES (37 C.F.R. § 42.8(b))

A. Real Parties In Interest

The petition for *inter partes* review is brought on behalf of Repro-Med Systems, Inc., the real-party-in-interest.

B. Related Matters

The ’476 Patent is asserted in a litigation styled *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:15-cv-01167 (E.D. Tex.). The complaint was filed on or about June 25, 2015, but has not yet been served.

The continuing grandparent patent to the ’476 Patent, U.S. Patent No. 8,500,703 (“the ’703 Patent”) has been asserted in a litigation styled *Repro-Med Systems, Inc. d/b/a RMS Medical Products v. EMED Tech. Corp.*, Case No. 2:13-cv-1957-TLN-CKD (E.D. Cal.). The ’703 Patent is also the subject of an *ex parte* reexamination request, with Reexamination Application No. 90013585.

C. Notice of Lead and Backup Counsel; Service Information

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III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner certifies that the '476 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging Claims 1-10 of the '476 Patent on the grounds identified herein.

IV. PAYMENT OF FEES (37 C.F.R. § 42.103)

The required fee is being paid through the Patent Review Processing System. No excess claim fees are required.

V. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))

Petitioner respectfully requests that claims 1-10 of the '476 Patent be canceled based on the grounds of unpatentability listed below under 35 U.S.C. §§ 102 and 103, in light of the following prior art patents and the Declaration of David O. Kazmer, P.E., Ph.D. ("Kazmer Declaration") (Exhibit 1002). A copy of each reference is filed herewith pursuant to 37 C.F.R. § 42.6(c), including a certified English translation of references that are not in the English language.

1. Japanese Unexamined Patent Appl. Pub. JPH0966106 to Harada et al., titled "Injection Needle with Needle Cover Used as Fixed Wing," with its certified English Translation (hereinafter referred to as "Harada"; citations to Harada refer to the English Translation), attached hereto as Exhibit 1003;
2. U.S. Patent No. 5,951,522 to Rosato et al., titled "Hypodermic Needle Safety Enclosure" (hereinafter referred to as "Rosato") attached hereto as Exhibit 1004;
3. U.S. Patent No. 4,944,731 to Cole, titled "Needle Protection" (hereinafter referred to as "Cole") attached hereto as Exhibit 1005;
4. U.S. Patent No. 5,147,319 to Ishikawa et al., titled "Winged Needle" (hereinafter referred to as "Ishikawa") attached hereto as Exhibit 1006;
5. U.S. Patent No. 5,279,588 to Nicoletti, titled "Device for Protecting Against Accidental Butterfly Needle Punctures" (hereinafter referred to as "Nicoletti") attached hereto as Exhibit 1007;
6. U.S. Publication No. 2008/0177234 A1 to Keaton et al., titled "Safety Subcutaneous Infusion Set" (hereinafter referred to as "Keaton") attached hereto as Exhibit 1008;
7. U.S. Patent No. 6,911,020 B2 to Raines, titled "Huber Needle with Folding Safety Wings" (hereinafter referred to as "Raines") attached hereto as Exhibit 1009; and

8. U.S. Patent No. 6,500,155 to Sasso, titled "Safety Angled Indwelling Needle and a Protective Shield for a Safety Angled Indwelling Needle" (hereinafter referred to as "Sasso") attached hereto as Exhibit 1010.

Claims Anticipated Under § 102(b)

- Claim 1 is anticipated by Harada.
- Claims 1, 2, 3, and 5 are anticipated by Rosato.
- Claims 1, 5, and 7 are anticipated by Cole.
- Claims 1, 7, 8, and 9 are anticipated by Ishikawa.

Claims 1-10 Rendered Obvious Under § 103(a)

- Claim 1 is obvious in view of Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti.
- Claim 2 is obvious in view of each of Harada, Cole, or Ishikawa combined with any of Sasso, Raines, or Rosato.
- Claim 3 is obvious in view of each of Harada, Cole, or Ishikawa combined with any of Sasso, Raines, or Rosato.
- Claim 4 is obvious in view of each of Harada, Rosato, Cole, or Ishikawa (or the foregoing in combination with Sasso) in combination with Raines.
- Claim 5 is obvious in view of each of Harada, or Ishikawa (or any of the foregoing combined with Sasso) combined with either Cole or Rosato.

- Claim 6 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti) in view of *In re Dailey*, 357 F.2d 669 (C.C.P.A. 1967).
- Claim 7 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti) in view of any of Raines, Keaton, Sasso, or *In re Dailey*, 357 F.2d 669 (C.C.P.A. 1967).
- Claim 8 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, or Nicoletti) combined with either of Sasso or Ishikawa.
- Claim 9 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, or Nicoletti) and Ishikawa.
- Claim 10 is obvious for the reasons stated with respect to Claims 2 and 8.

VI. THE ’476 PATENT

A. Claims and Prosecution History

The ’476 Patent issued on February 24, 2015, based on an application filed on March 21, 2014, claims priority to a provisional application filed on June 2, 2008. The ’476 Patent claims devices for protecting a user from a sharp tip of a medical needle. The Prosecution History of the ’476 Patent is attached as Exhibit 1011, and citations thereto are specified by date and event therein.

Claim 1 is the only independent claim, and claims a device for protecting a user from the sharp tip of a medical needle that comprises a needle with a fluid connection to a delivery tube, and a central body from which two wings extend and close to enfold the needle. The wings have a "mechanical fastener including a lip extending along at least a portion of a perimeter of at least one wing" and "a mating portion along a perimeter of at least one other wing" where "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."

The remaining dependent claims provide for a handle, wings made of rigid or semi-rigid material, circular or rectangular shaped wings, and a groove in one or both wings to house the needle.

Fig. 11 of the '476 Patent depicts an exemplary device in accordance with the claimed invention:

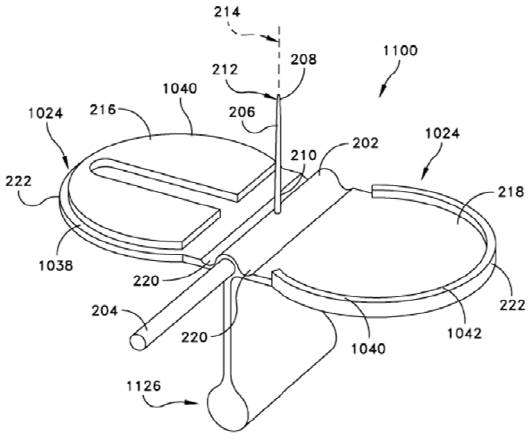


FIGURE 11

202	Central body portion
204	Delivery tube
206	Medical needle
216 and 218	Wings
1024	Mechanical fastener:
1038	Recessed portion
1042	Lip
1040	Perimeter
1126	Handle

This type of safety device for needles was well known in the prior art and there were many examples of the use of wings that fold over the needle to protect against accidental punctures. During the prosecution of the '476 Patent, the claims were initially rejected for double patenting and also for obviousness over U.S. patent 6,500,155 (Sasso) and 7,569,044 (Triplett). The Examiner held that Sasso disclosed all the elements of claim 1, except for the lip portion and the corresponding mating portion on the wings, but the Examiner found that Triplett disclosed wings protecting a needle with a lip and mating portion. (Exhibit 1011, July 16, 2014 Office Action at 4.)

The applicant then amended claims to recite, among other limitations: "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." (Exhibit 1011, July 31, 2014 Response, at 7) (emphasis in original). Applicant argued that Triplett did not teach or suggest the lips engaging in the "closed position," but only in the open position. After a terminal disclaimer was filed, a Notice of Allowance issued on December 22, 2014. (Exhibit 1011.)

B. Claim Construction

The terms in claims 1-10 are to be given their broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the disclosure. 37 C.F.R. § 42.100(b). [1]

The term "rigid material" that appears in Claim 4 and "semi-rigid material" that appears in Claim 5 are not defined in the patent specification, and no criteria are given for the meaning of rigid and semi-rigid. Giving the terms the broadest reasonable construction, the term "rigid material" is a relative term which means a material that will hold its shape and has resistance to bending to some degree. The term "semi-rigid material" is also a relative term that means a material which will hold its shape but is flexible to some degree. *See* Kazmer Declaration, ¶ 128.

The term "perimeter" is not expressly defined in the specification. Given its ordinary meaning and the broadest reasonable construction, the term "perimeter" refers to the boundary of a closed plane or figure." See Merriam-Webster.com; Kazmer Declaration ¶ 54. Accordingly, a lip is located on a portion of the perimeter of a wing if it is located at any location on a boundary of the wing.

[1] Petitioner encloses as Exhibit 1012 a copy of the Joint Claim Construction and Prehearing Statement regarding the parent '703 Patent that was filed by the parties in the litigation in the Eastern District of California. There has been no claim construction briefing or order.

VII. EXPLANATION OF HOW THE CLAIMS ARE RENDERED UNPATENTABLE

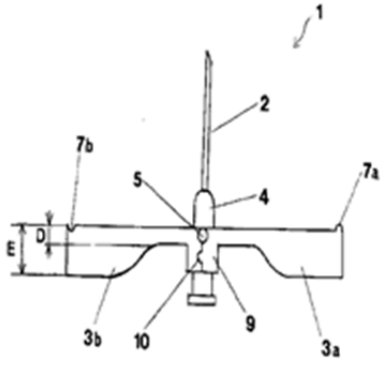
A. Anticipation

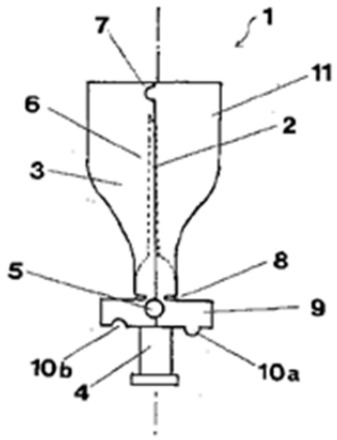
The Examiner recognized that all the limitations of the ’476 Patent claims were disclosed in the art in very similar devices that had the same purpose, but allowed the claims on the distinction that the ’476 Patent claims required a mechanical fastener that comprised a lip extending along at least a portion of the perimeter of the wings, and a corresponding mating portion on the other wing, configured to align the wings in the closed position. At least two prior art references which were not before the Examiner – Harada and Cole – have all the elements of the claim including a fastener comprising a lip and a mating portion on at least a portion of the perimeter of the wings that align the wings in the closed position.

1. Summary of the Anticipating References

- **JP Appl. Pub. No. JPH 09-66106 (A) to Harada et al. (Exhibit 1003)** (titled “Injection Needle with Needle Cover used as Fixed Wing”) was published on March 11, 1997, and is § 102(b) prior art. Harada was not before the Examiner during the prosecution of the ’476 Patent. By reference to Figs. 1 and 2 below, Harada discloses a needle hub (4) with a needle (2), and wings (3a and 3b). A coupling means (7) has a male part (a lip) (7a) on the perimeter of one wing, and a female part (mating part) (7b) on the other.

The lip and mating part (7a and 7b) can be locked together in the closed position. Thus, as will be further shown in the claim chart below, Harada discloses every feature of Claim 1 including the very feature that the Examiner believed was a distinction from the prior art – *i.e.*, a lip on the perimeter and a mating position to align the wings in the closed positon.





Needle	2
Needle hub	4
Wings 3b	3a and
Locking means	7
Male/female	7a/7b

- **U.S. Patent No. 5,951,522 to Rosato (Exhibit 1004)**, titled "Hypodermic Needle Safety Enclosure") issued on September 15, 1999, and is § 102(b) prior art. Rosato was not submitted in the prosecution until after the final office action and was not addressed by the Examiner's office actions during the prosecution of the '476 Patent. Rosato discloses the central body portion (horizontal shaft adjacent the aft end 68) between a pair of wings (90/92 and 94/96) (*see* Fig. 1, col. 4 ll. 13-15). The vertical shaft identified as a fore end 72 is in fluid connection with the tube 112 via one of its ends and the central body portion (horizontal shaft adjacent the aft end 68), (*see* Fig. 1).

The second end of the vertical shaft (fore end 72) extends away from the central body portion (horizontal shaft adjacent the aft end 68) to a sharp tip (102), and a line from the first end to the second end of the fore end 72 defines a longitudinal axis (*see* Fig. 1). Rosato also discloses a pair of generally rectangular wings (90/92 and 94/96) (each with inner and outer regions) attached to the horizontal shaft adjacent the aft end (68), the pair of wings disposed in opposition to one another with the fore end 72 positioned therebetween (*see* Figs. 1 and 2; col. 4 ll. 15-18), and the pair of wings being selectively positionable from a first position to a second position, the first position for placing the fore end 72 of the medical needle 70 into a patient and delivering a medicinal fluid, and the second position for removing the medical needle from the patient (*see* Fig. 1; *see also* col. 4 ll. 47-52 and col. 5 ll. 2-28); a handle (106); wings of rigid and semi-rigid materials (*e.g.*, plastic (col. 4 ll. 33-35); *see also* col. 6 ll. 7-12 discussing other embodiments of Rosato that disclose wing members made from molded semi-rigid plastic. Fixed at the edge of each wing is a locking tab (98/100) including an inward protrusion which overrides the edge of the other wing to lock the wings in a protective position over the tip of the needle (col. 4 ll. 36-47).

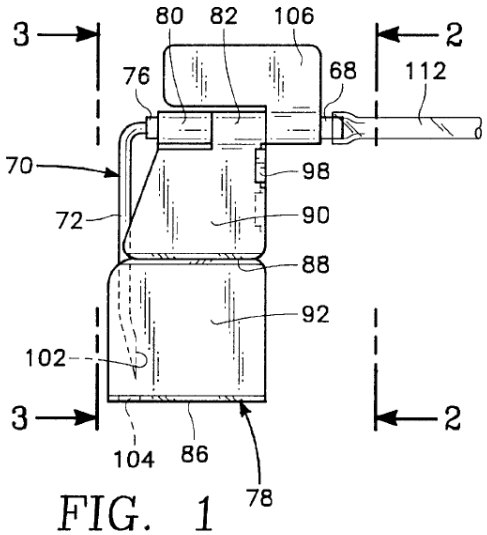


FIG. 1

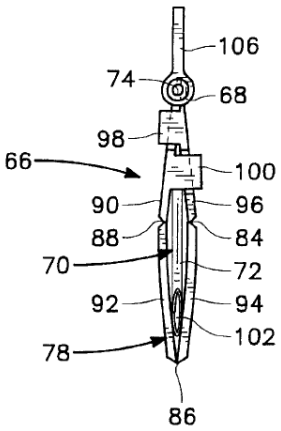
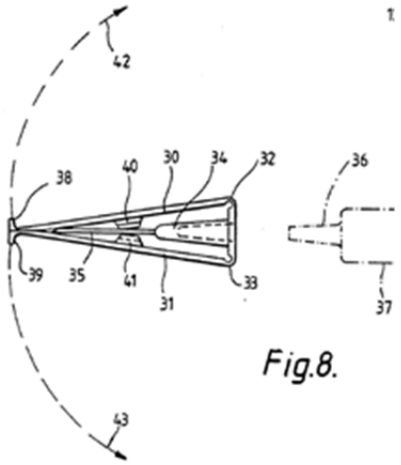
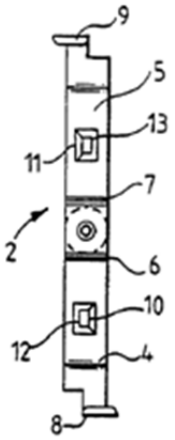


FIG. 2

Tube	112
Aft portion	68
Needle	70
Wings	90/92, 94/96
Handle fin	106
Locking tabs	98, 100

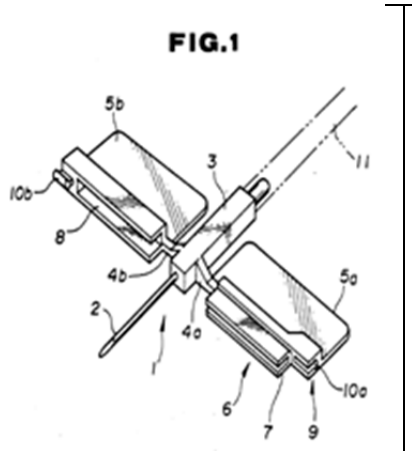
- **U.S. Patent No. 4,944,731 to Cole (Exhibit 1005)** issued on July 31, 1990, and is § 102(b) prior art. Cole was not before the Examiner in the prosecution of the '476 Patent. As indicated by its title ("Needle Protection"), Cole is directed to a needle protector (col. 1 ll. 8-9), which has two arms or wings (30 and 31), each wing having a flap (a lip) on a portion of the perimeter of the wing (38 and 39), which mates with an indented section of the perimeter of its opposite wing. (Col. 4 ll. 13-18.) The flaps interengage (and engage a recess along the portion of the perimeter of the other arm) when in the closed position. (col. 3 ll. 32-34). *See also*, *e.g.*, Figs. 8 and 2 that show in more detail the flap arrangement (with the corresponding recesses) and interconnection:

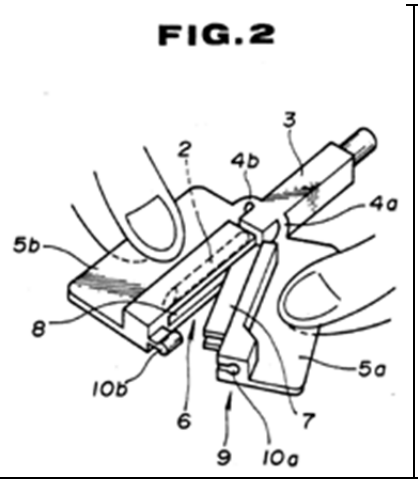
 Fig.8.	 Fig.2.	Arms 30 and 31 Thin pivot portions 32 and 33 Detachable hub 34 Needle 35 Stub outlet 36 Syringe body 37 Flaps (Fig. 8) 38 and 39 Flaps (Fig. 2) 8 and 9

Thus, Cole also discloses every limitation of Claim 1 including a lip and a mating portion on the perimeter of the wings that align the wings in the closed position.

- **U.S. Patent No. 5,147,319 to Ishikawa et al. (Exhibit 1006)** (titled "Winged Needle") issued on September 15, 1992, and is § 102(b) prior art. Ishikawa was not submitted in the prosecution until after the final office action and was not addressed by the Examiner during the prosecution of the '476 Patent. By reference to Figs. 1 and 2 below, Ishikawa discloses a base (3), connected to a flexible tube (11) on the one end, and to a needle (2) on the other, and with horizontally opened wings (5a and 5b) with arms (4a and 4b) working like hinges to meet over the needle. A coupling means has a protrusion (a lip) (10b) on the perimeter of one wing and a mating part (10a)

on the opposite wing which couple together with the wings aligned in the closed position. Therefore, Ishikawa also discloses every limitation of Claim 1, in particular the very feature that was argued to distinguish the claim from the prior art.





Tube	11
Base	3
Needle	2
Wings	5a, 5b
Coupling means	9
Female/male	10a, 10b

2. Detailed Anticipation Arguments

The following chart describes the detailed disclosures of Harada, Rosato, Cole, and Ishikawa, and demonstrates that each reference discloses every limitation of Claim 1 of the '476 Patent and accordingly supports the rejection of Claim 1 under § 102(b):

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
1a	A device for protecting a user from a sharp tip of a medical needle, the device comprising:	**Harada:** "[T]he object of the present invention is to . . . provide an injection needle with a needle cover that can be operated safely and easily to prevent accidental puncturing when removing or replacing the injection needle and

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		the needle cover and can prevent contact with blood fluids (other patient who may be infected)." (Harada, ¶ 0004). **Rosato:** "[T]his invention is directed to a safety enclosure for a hypodermic needle . . . ." (Rosato, col. 1 ll. 7-9.) **Cole:** "This invention relates to needle protection" (Cole, col. 1 l. 6). **Ishikawa:** "This invention is to eliminate the problems . . . by providing a winged needle with which a user can safely uncover the needle and replace it in a sheath." (Ishikawa, col. 1 ll. 32-34).
1b	a central body portion;	**Harada** discloses a needle hub 4 (Figs. 1 and 2) between wings 3a and 3b. (Harada, ¶¶ 0002 and 0015, indicating connection between the device, needle, and tubing). **Rosato** discloses the central body portion (horizontal shaft adjacent the aft end 68) between wings, 94/96 and 90/92. (Fig. 1; col. 4 ll. 13-15.) **Cole** discloses a central body portion (detachable hub 34) carrying a needle 35, the hub being mounted on a stub outlet 36 from a

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		syringe body 37 (tube). (Cole, Fig. 8, and col. 4 ll. 16-18. **Ishikawa** discloses a base 3 as a central body portion (Figs. 1 and 2, Ishikawa, col. 2 ll. 6-7).
1c	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;	**Harada** discloses a medical needle 2 with two ends (in Figs. 1 and 2), one end in fluid connection with the needle hub 4 and the delivery tube and the other extending to a sharp tip (*see*, *e.g.*, Figs. 1 and 2; *see also* ¶ 0006). **Rosato** discloses a vertical shaft identified as a fore end 72 of the needle (70) with two ends, the first in fluid connection with the delivery tube 112 via the central body portion (horizontal shaft adjacent the aft end 68) (*see* Fig. 1). The second end extends away from the central body portion to a sharp tip (102). (*See also* col. 4 ll. 10-61.) **Cole** discloses the needle 35 in fluid connection with the detachable hub 34 and the stub 36 and syringe 37, with the sharp tip extending away. (*See* Fig 8). **Ishikawa** discloses a needle 2 that is rooted in the base 3 and in fluid connection with the tube 11 via base 3). (Fig.1, Ishikawa at col. 2 ll. 6-7). The other end of the

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		needle is a sharp tip. (See Fig. 1).
1d	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;	**Harada** discloses a pair of wings (3a and 3b in Figs. 1 and 2) as claimed, with inner regions in attachment to the needle hub 4, and an outer region extending away from the hub, with the medical needle 2 positioned therebetween, and the wings selectively positionable for placing and removing the medical needle 2 (*e.g.*, open and closed positions in Figs. 1 and 2). (*See* ¶ 0007, discussing pivot positions of the wings. **Rosato** has pair of wings (wing assembly 78 with two wings, 94/96 and 90/92) being selectively "movable between a mounting position and a protective position" (col. 3 ll. 6-8), the mounting position for drug administration, and the protective position for needle removal and protection (*see* Figs. 1-4; *see also* col. 4 ll. 11-35, 47-52 and col. 5 ll. 1-28). **Cole** discloses protector arms 30, 31 mounted via thin pivot portions 32, 33, on a detachable hub 34. Fig. 8, Cole, col. 4 ll.15-16. "Pivoting of arms 30, 31 in the direction of arrows 42, 43 to lie alongside the body of the syringe 37 enables use of the syringe as in the arrangement of FIGS. 1 to 7.

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		Protection 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" (Figs. 2 and 8 for open/close positions; col. 4 ll. 19-24). **Ishikawa** discloses "horizontally opened wings 5a, 5b which, with arms 40, 4b, flank both sides of the base 3." (Fig. 1; col. 2 ll. 7-9). "The wings 5a, 5b can fold, arms 4a, 4b working like hinges, so as to meet each other along the needle 2 as shown in FIG. 2." (Col. 2 ll. 11-13; Figs. 1 and 2 for open and closed positions).
1e	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;	**Harada** discloses a mechanical fastener (locking means 7 in Fig. 2) disposed on the wings, configured to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect the user from the sharp tip of the medical needle. See, *e.g.*, Fig. 2 (closed and locked position); *see also* ¶ 0011). **Rosato** has a mechanical fastener configured to selectively attach the pair of wings together with the needle positioned between the wings. (*See* Fig. 2, items 98/100; col. 4 ll. 36-47 ("The locking tab 98 includes an inward protrusion (not shown) which is to override

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		the edge of the panel 90 when the first embodiment 66 is in the protective position . . . . At the same time, the locking panel 100 overrides the edge of the panel 96. Therefore, the locking tabs 98 and 100 function to lock and hold the wing assembly 78 in the protective position so as to keep the sharpened point 102 . . . of the hypodermic needle 70 encased between the panels 92 and 94 when in the protective position.").) **Cole** discloses flaps 38 and 39 (Fig. 8) (which correspond to flaps 8 and 9 in Fig. 2). "As can be appreciated from FIGS. 1 and 2 the flaps 8, 9 of the arms are capable of mutual engagement upon forward folding of the arms" (Fig. 8; col. 3 ll. 32-35). **Ishikawa** discloses a "coupling means 9 which is constituted of a female part 10a and a male part 10b built at the tip of each meeting edge respectively." (Figs. 1 and 2; col. 2 ll. 29-32).
1f	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	**Harada** discloses a mechanical fastener (locking mechanism 7 in Fig. 2) including a lip (male locking means 7a in Figs. 1 and 2) extending along at least a portion of the perimeter of at least one of the wings, and a mating portion (female locking means 7b in Figs.

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		1 and 2) along a perimeter of at least the other one of the wings; *see also* ¶ 0011 ("[A]fter use, there is the safety of being able to engage reliably when covering the injection needle after use."). **Rosato** has a mechanical fastener wherein the edge of the wing (a lip) mates with a locking tab (98/100) including an inward protrusion which overrides the edge of the other wing to lock the wings in a protective position over the tip of the needle (col. 4 ll. 36-47). **Cole** discloses flaps 38 and 39 (Fig. 8) (which correspond to flaps 8 and 9 in Fig. 2), which are capable of mutual engagement. (Fig. 8, col. 3 ll. 32-35; col. 4 ll.22-27). **Ishikawa** discloses a "coupling means 9 which is constituted of a female part 10a and a male part 10b built at the tip of each meeting edge respectively." (Figs. 1 and 2; col. 2 ll. 29-32).
1g	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.	**Harada** discloses that the mating portion (female locking means 7b in Figs. 1 and 2) and the lip (male locking means 7a in Figs. 1 and 2) are configured to align the wings in the closed position. See *e.g.*, Fig. 2 (closed and locked position; *see also* ¶ 11. [A]fter use, there is the

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		safety of being able to engage reliably when covering the injection needle after use."); *see also* ¶ 0006 ("When using the injection needle, the needle cover is divided into essentially equal halves along the axial direction of the injection needle, to expose the injection needle. The needle cover that has been divided in half is pivoted around the respective junction portions, to extend in both the left and right directions of the needle base, to be used as means for securing the injection needle, that is, to be used as wings. The wings are positioned, by pivoting preventing means that are provided in the needle cover or in the injection needle, at a position that is suitable for securing the wings (the injection needle). After the injection needle has been used, the wing parts are pivoted in the opposite direction from the time of use, to be rejoined in the state from prior to use of the injection needle, to thereby cover the injection needle."). **Rosato** discloses that the mating portion on the tabs (98, 100) lock with the edge of the wing to align one wing relative to the other in the closed position. *See* col. 4 ll. 36-47 ("The locking tab 98 includes an inward protrusion (not shown) which is to override the

Claim Identifier	Claim Limitation	Harada, Rosato, Cole, Ishikawa
		edge of the panel 90 when the first embodiment 66 is in the protective position . . . . At the same time, the locking panel 100 overrides the edge of the panel 96. Therefore, the locking tabs 98 and 100 function to lock and hold the wing assembly 78 in the protective position so as to keep the sharpened point 102 . . . of the hypodermic needle 70 encased between the panels 92 and 94 when in the protective position."). **Cole** discloses flaps 38 and 39 (Fig. 8) (which correspond to flaps 8 and 9 in Fig. 2). "As can be appreciated from FIGS. 1 and 2 the flaps 8, 9 of the arms are capable of mutual engagement upon forward folding of the arms" (Fig. 8; col. 3 ll. 32-35; col. 4 ll.22-27). **Ishikawa** discloses that "a user holds the wings 5a, 5b and folds the wings towards the needle 2 in order to form the sheath 6 to cover the needle, shown in FIG. 2, and couples the female and male parts 10a, 10b constituting the coupling means 9, to maintain the formation of the sheath or the bend of the arms, shown in FIG. 3." (Figs. 1 and 2; col. 2 ll. 28-46).

For each of the references identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 38-115 describes in detail the disclosures that teach the claimed limitations.

Claim 2 is anticipated by Rosato. Claim 2 is dependent on Claim 1 and requires that a handle extends from the central body portion. Rosato discloses every element of Claim 1 as shown above, and in addition discloses a handle that extends from the central body portion. *See* Rosato, Fig. 1, item 106 extending from the central body portion, and col. 4 ll. 52-53 ("Also pivotally mounted on the aft end 68 of the hypodermic needle 70 is a handle fin 106."). *See also* Kazmer Declaration at ¶¶ 116-118.

Claim 3 is anticipated by Rosato. Claim 3 is dependent on Claim 2 and requires in addition that the handle extend from the central body portion in a direction in opposition to the second end of the medical needle. As shown above, Rosato has every limitation of Claim 2, and in addition, the handle extends from the central body portion in a direction in opposition to the second end of the fore end 72. *See* Rosato, Fig. 1, item 106 extending from the central body portion (horizontal shaft adjacent the aft end 68), and col. 4 ll. 52-53 ("Also pivotally mounted on the aft end 68 of the hypodermic needle 70 is a handle fin 106."). *See also* Kazmer Declaration at ¶¶ 119-123.

Claim 5 is anticipated by both Cole and Rosato. Claim 5 is dependent on Claim 1 but requires that the wings be formed from semi-rigid material. As shown in the claim chart for Claim 1, both Cole and Rosato disclose every limitation of Claim 1. Cole further discloses that the wings or arms of the device can be disengaged "due to the flexibility of the plastics material concerned." (Col. 3 ll. 41-43). Similarly, Rosato further teaches that the embodiment 66 (that includes wings with "living hinges" as in Figs. 1-5) can be made of plastic (col. 4 ll. 33-35). The plastic capable of forming living hinges is semi-rigid.[2] *See also* Kazmer Declaration at ¶¶ 124-131.

Claim 7 is anticipated by each of Cole and Ishikawa. Claim 7 is dependent on Claim 1 and requires that the wings have a rectangular shape. Cole, in addition to having all the limitations of Claim 1, has wings that are rectangular in shape (*see* Figs. 2, 8). Similarly, Ishikawa, in addition to having all the limitations of Claim 1, has wings that are rectangular in shape (*see* Fig. 1). *See also* Kazmer Declaration at ¶¶ 132-139.

Claim 8 is anticipated by Ishikawa. Claim 8 depends from Claim 1 and requires in addition that at least one of the pair of wings has a groove to house the needle. Ishikawa contains every limitation of Claim 1 as shown in the above chart

[2] In a related embodiment that discloses wings, Rosato suggests semi-rigid plastics such as "polypropylene, polyethylene or polyurethane that is flexible enough to bend/flex when taped to the patient's skin but is rigid enough to allow removal of the needle from the implanted vascular port and the patient's skin. . ." Col. 6, ll. 7-12.

and also teaches a groove and states that the "sheath-portion consists of a ditched projection 7 [a groove formed in a single one of the wings for housing the needle] which is formed along one of the meeting edges of the wings 5a, 5b and of a lipped section 8 formed along the other meeting edge. When the wings 5a, 5b meet in this way, the ditched projection 7 makes a three-sided cover for the needle, and the lipped section 8 embraces the ditched projection 7 . . . ." (col. 2 ll. 16-23). Thus, only a groove in one of the wings (a ditched projection 7) houses the needle—the second groove (a lipped section 8) houses the ditched projection 7." *See also* Kazmer Declaration at ¶¶ 140-143.

Claim 9 is anticipated by Ishikawa. Claim 9 depends from Claim 8 that in turn depends from Claim 1. Claim 9 differs from Claim 8 in that the groove for the needle is on only one wing. Ishikawa, as shown in Figures 1 and 2 and the language quoted in the discussion of Claim 8, 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 (col. 2 ll. 19-23). *See also* Kazmer Declaration at ¶¶ 144-147.

B. Obviousness

1. Summary of the Additional References Establishing Obviousness

The following additional references support an obviousness rejection of each claim of the ’476 Patent.

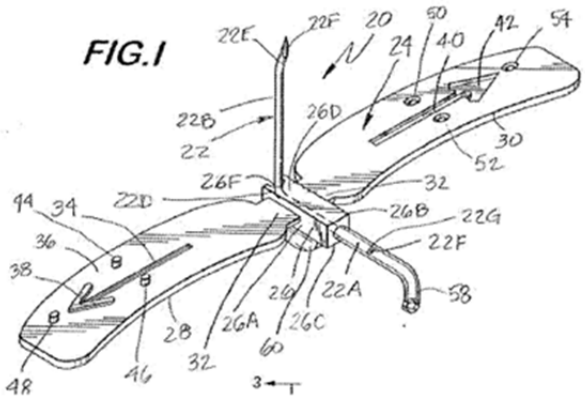
All the references cited below relate to needle protection devices comprising wings that fold around the needle to prevent needle stick injuries. Because these references are all addressed to the identical problem and employ nearly identical solutions, a person of ordinary skill in the art would have a clear motive to combine the teachings of the references.

The dependent claims of the ’476 Patent add only limitations that are obvious design choices or elements known in the art for use on the same devices. The dependent claims add circular or rectangular shape of the wings (Claims 6, and 7), inclusion of rigid or semi-rigid materials (Claims 4 and 5), a groove in one or both wings (Claims 8 and 9), and a handle (Claims 2, 3, and 10). All the claimed elements (other than the circular shape) were explicitly disclosed in the cited references, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would be nothing more than predictable results to one of ordinary skill in the art.

- **U.S. Patent No. 6,500,155 to Sasso (Exhibit 1010)**, titled “Safety angled indwelling needle and a protective shield for a safety angled indwelling needle” issued on December 31, 2002, and is prior art to the ’476 Patent.

Sasso discloses a device for protecting a user from a sharp tip of a medical needle, the device comprising: a central body portion (central hub 26); a medical needle (22) having a first end and a second end in opposition to one another, the first end in fluid connection with the central body portion and the delivery tube (58) (Fig. 1), and the second end of the needle extending away from the central body portion to a sharp tip (22 f, Fig. 1), and a line from the first end to the second end of the medical needle defining a longitudinal axis (Figs. 1 and 2); a pair of wings (28, 30) having an inner region (32) and an outer region (outer surface, Fig. 1), the inner region of each one of the pair of wings in attachment to the central body portion (col. 4 ll. 50-52), the outer region of each one of the pair of wings extending away from the central body portion (*see* Fig. 1), the pair of wings disposed in opposition to one another with the medical needle positioned therebetween (*see* Fig. 1), and the pair of wings being selectively positionable from a first position to a second position (col. 4 ll. 50-54), the first position for placing the medical needle into a patient and delivering a medicinal fluid, and the second position for removing the medical needle from the patient (*see* Figs. 1 and 2); and a mechanical fastener (44, 46, 48, with mating portions 50, 52, 54) disposed on at least one 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 a user from the sharp tip of the medical needle (col. 5 ll. 25-48). A short flange (60) can serve as a handle (*see* col. 5 l. 66-col.6-l. 2; *see also* Fig. 1). As explained in Section VI above, Sasso has been considered by the Examiner during the original examination of the patent, and was considered to teach all claim elements except for a lip extending along at least a portion of the perimeter of at least one of the wings, which engages a mating portion along the perimeter of the other wing when the wings are in the closed position.



Central hub	26
Tube	58
Needle	22
Wings	28/30
Handle	60
Mechanical fasteners	44, 46, 48
and mating portions	50, 52, 54

As noted in the anticipation section above, the limitation of a lip and a mating portion along at least a portion of the perimeter of the wings was taught by Harada, Rosato, Cole, and Ishikawa.

- **U.S. Patent No. 5,279,588 to Nicoletti et al. (Exhibit 1007)** (titled "Device for protecting against accidental butterfly needle punctures") issued on

January 18, 1994, and is § 102(b) prior art. Nicoletti was not before the Examiner during the prosecution of the '476 Patent. By reference to Fig. 26 below, Nicoletti discloses a tubular body (106) connected to a tube (which is connected to a needle), and half-shells (107 and 109) hinged to the tubular body (106) by rod-like elements (109 and 110). The half-shell wings are provided, at their tips, with means for mutual engagement and retention, *e.g.*, a tooth (a lip) (111) on one of the half-shells and an undercut recess (a mating portion) (112) on the other half-shelf for "mutual snap-together engagement in closed position." (Nicoletti, col. 6 ll. 12-16). Thus Nicoletti also teaches a mechanical fastener comprising a lip and a mating portion along at least a portion of the perimeter of the wings that align the wings in a closed position.

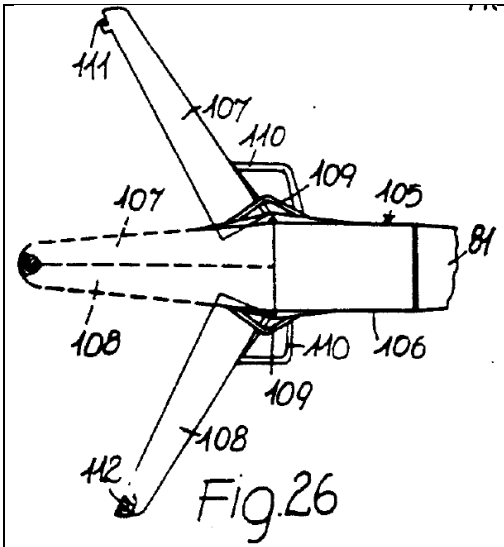


Fig.26

Tubular body	106
Half-shells	107 and 108
Rod-like elem. (hinges)	109 and 110
Tooth	111
Undercut recess	112

- **U.S. Publication No. 2008/0177234 A1 to Keaton et al. (Exhibit 1008)**, titled "Safety Subcutaneous Infusion Set" was published on July 24, 2008, filed on November 21, 2007, and is based on a provisional application filed on November 21, 2006. Keaton is 102(e) prior art because its filing date predates the earliest date of invention for the '476 Patent. Keaton was listed on the face of the '476 Patent. By reference to Fig. 1 below, Keaton discloses a device for protecting a user from a sharp tip of a needle, which includes central body portion (20) in fluid connection with a tube (4), a catheter (6), having a first end and a second end in opposition to one another, the first end in fluid connection with the central body portion (20) and the delivery tube (4) (*see* Fig. 1), and the second end extending away from the central body portion to a sharp tip, and a line from the first end to the second end of the medical needle defining a longitudinal axis (*see* Fig. 1), a pair of rectangular wings (28A and 28B) (each with inner and outer regions) attached to the body (20), the pair of rectangular wings disposed in opposition to one another with the medical needle positioned therebetween (*see* Fig. 1), and the 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, and the second position for removing the medical needle from the patient (*see* Fig. 1; *see also* ¶¶ 18-22),

a mechanical fastener with detent post (32) and a receiving aperture 34 (*see* Fig. 1), disposed on at least one of the pair of rectangular wings (28A and 28B), and configured to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect a user from the sharp tip of the medical needle (*see* ¶ 12).

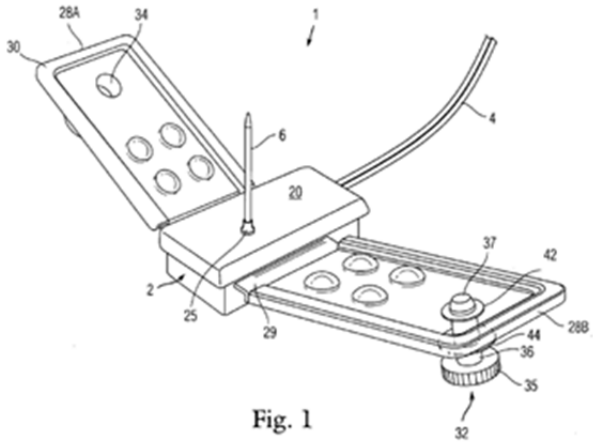
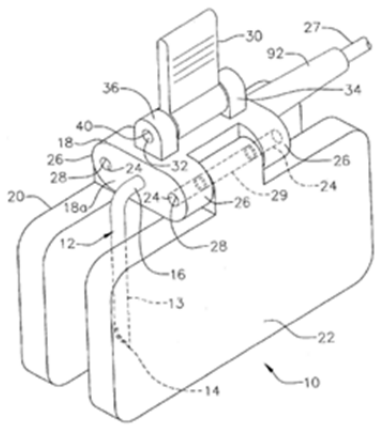
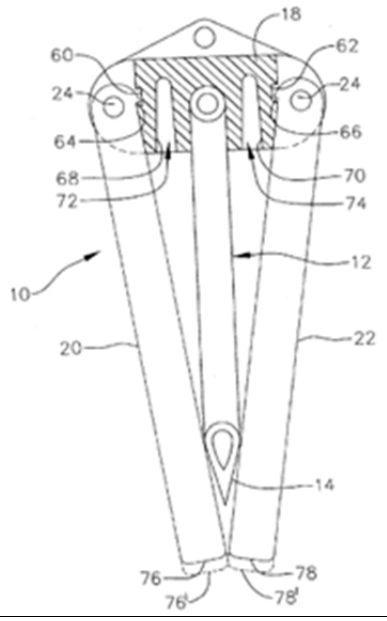


Fig. 1

Rectangular body	20
Catheter	6
Tube	4
Wings	28A and 28B
Detent post	32
Receiving aperture	34
Anchor	2

- **U.S. Patent No. 6,911,020 B2 to Raines (Exhibit 1009)**, titled "Huber Needle with Folding Safety Wings" issued on June 28, 2005, and is 102(b) prior art. Raines was not before the Examiner during the prosecution of the '476 Patent. It is directed to a safety needle assembly with a central body portion (hub 18) in fluid connection with a tube (27), a needle (12) with a sharp tip (14), having a first end and a second end in opposition to one another, the first end in fluid connection with the central body portion and the delivery tube (Fig. 1), and the second end extending away from the

central body portion to a sharp tip (14), and a line from the first end to the second end of the medical needle defining a longitudinal axis (Fig. 1), a pair of rectangular wings (20 and 22) (with an inner and outer regions) attached to the hub (18), the pair of rectangular wings disposed in opposition to one another with the medical needle positioned therebetween (Figs. 1 and 5), and the 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, and the second position for removing the medical needle from the patient (*see* Fig. 1, *see also* col. 2 ll. 17-21). A third rectangular wing (30) is used as a handle, col. 4 ll. 43-44 ("[w]hen the safety needle assembly 10 is picked up by the third Wing 30"). The wings are formed of rigid and semi-rigid materials (col. 4 ll. 48-51 ("the first Wing 20, the second Wing 22, and the third Wing 30 are preferably formed of molded plastic material, such as polymethylmethacylate [*sic*], polycarbonate, and ABS (acrylonitrile-butadiene-styrene-terpolymer")).

FIG.1  	FIG.5  	Needle 14 Tube 27 Hub 18 Wings 20 and 22 Third wing 30

2. Detailed Obviousness Arguments

Claim 1 is obvious in view of Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti. Sasso was cited by the Examiner in the original prosecution as disclosing all elements of Claim 1, other than the mating lips engaged in the closed position. *See* Section VII.A., *supra.* Sasso discloses each of limitations 1a through 1e. Each of Harada, Rosato, Cole, Ishikawa, and Nicoletti disclose mating lips engaged in the closed positon on a similar device designed to protect against accidental medical needle sticks. Even if the references described in the anticipation section above did not already anticipate Claim 1, it would have been obvious to a person of ordinary skill in the art to combine the lip and mating portion fastening mechanism used on Harada, Rosato, Cole, Ishikawa,

or Nicoletti with the needle protection device disclosed in Sasso. *See also* Kazmer Declaration at ¶¶ 148-156.

Claim 2 is obvious in view of each of Harada, Cole, or Ishikawa combined with any of Sasso, Raines, or Rosato. Claim 2 depends from Claim 1 and requires an additional handle that extends from the central body portion. As shown in the Claim 1 anticipation chart, Harada, Cole, and Ishikawa each disclose every limitation of Claim 1. Alternatively, each of those anticipating references discloses the element of a lip and mating portion that engage to align the wings in the closed position, and render Claim 1 obvious when combined with Sasso, which discloses all of the other limitation of Claim 1. Raines, Rosato, and Sasso each discloses a handle that extends from the central body portion of a winged needle protection device. (*See* Raines, Fig. 1, and col. 4 ll. 43-44 ("[w]hen the safety needle assembly is picked up by the third wing 30"); *see also* Rosato, Fig. 1, item 106 extending from the central body portion, and col. 4 ll. 52-53 ("Also pivotally mounted on the aft end 68 of the hypodermic needle 70 is a handle fin 106."); *see also* Sasso, Fig. 1, item 60 and col. 5 l. 65– col. 6 l. 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 . . . .").

It would be obvious to combine the safety needle device in Claim 1 of the '476 Patent with a handle as disclosed in Raines, Rosato, and Sasso, rendering

obvious Claim 2 of the ’476 Patent, because all of the references teach very similar winged needle protection devices for the same purpose. *See also* Kazmer Declaration at ¶¶ 157-163.

Claim 3 is obvious in view of each of Harada, Cole, or Ishikawa combined with any of Sasso, Raines, or Rosato. Claim 3 depends from Claim 2 and further requires that the handle “extends away from the central body portion in opposition to a direction of the second end of the medical needle.” Each of the handles disclosed in Raines, Rosato, and Sasso extends away from the central body portion in opposition to a direction of the second end of the medical needle. Accordingly, the same combination of references that renders Claim 2 obvious also renders Claim 3 obvious. *See also* Kazmer Declaration at ¶¶ 164-179.

Claim 4 is obvious in view of each of Harada, Rosato, Cole, or Ishikawa (or the foregoing in combination with Sasso) in combination with Raines. Claim 4 depends from Claim 1 and requires that the wings are made of a rigid material. Claim 1 is anticipated or obvious, as shown above, by each of Harada, Rosato, Cole, or Ishikawa, or the foregoing in combination with Sasso. Raines describes a needle protection device employing wings that enclose the needle. *See* Raines, Fig. 1. The wings are formed from rigid materials (col. 4 ll. 48-51 (“the first Wing 20, the second Wing 22, and the third Wing 30 are preferably formed of molded plastic material, such as polymethylmethacylate [*sic*], polycarbonate, and

ABS (acrylonitrile-butadiene-styrene-terpolymer")). Specifically, materials such as polycarbonate are a rigid plastic material. *See* Kazmer Declaration, at ¶ 185. It would be obvious to make a protective wing from such rigid materials. *See also* Kazmer Declaration at ¶¶ 180-185.

Claim 5 is obvious in view of each of Harada or Ishikawa (or any of the foregoing combined with Sasso) combined with either Cole or Rosato.

Claim 5 depends from Claim 1 and requires that wings include a semi-rigid material. As shown above, Claim 1 is anticipated or alternatively obvious from the combination of Sasso and either of the anticipating references Harada or Ishikawa. In addition, the Cole reference specifically refers to the wings as made of "flexible" plastic material (col. 3 ll. 41-43 states that the wings or arms of the device can be disengaged "due to the flexibility of the plastics material concerned," and col. 2 ll. 41-44 states that "the securement [of the arms] can be of a light nature and of easy disengagement attachability, so that the needle can be protected in this manner . . . whilst the needle is being carried, for example."). One of ordinary skill in the art would understand that a plastic with these characteristics would be semi-rigid (*see* Kazmer Declaration at ¶ 190).

Rosato at col. 4 ll. 28-35 describes the properties of the wings, explaining that "[t]he fold lines 84, 86, and 88 could comprise 'living hinges' if the . . . embodiment 66 is constructed of plastic." One of ordinary skill in the art reading

this language and viewing the provided embodiments would understand that a molded plastic capable of constituting a living hinge must be both moderately rigid and moderately flexible, and thus be "semi-rigid" as required by this claim language. One of ordinary skill would understand that Rosato expressly provides that the "pair of wings are formed of semi-rigid material." Rosato also discloses wing members 38 and 46 that may be made from a molded "semi-rigid" plastic such as polypropylene and polyethylene. Col. 6 ll. 7-11. See Kazmer Declaration, at ¶ 189.

Sasso discloses wings from molded biocompatible plastic (col. 4 l. 16), which can be "somewhat flexible." Col 4 ll. 54-55. Moreover, the Examiner rejected this claim in view of Sasso. (Exhibit 1011, July 16, 2014 Office action at 5 *See* Kazmer Declaration, at ¶ 189. Accordingly, it would have been obvious to make the wings of the claimed needle protection device with semi-rigid wings. *See* Kazmer Declaration, at ¶ 191.

For each of the combinations identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 186-191 describes in detail the disclosures that teach the claimed limitations.

Claim 6 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti) in view of *In re Dailey,* 357 F.2d 669 (C.C.P.A. 1967). Claim 6 of the '476 Patent claims a device

in accordance with Claim 1, "wherein the pair of wings each have a substantially circular shape." In the July 16, 2014 Office Action (*see* Exhibit 1011, Office Action, at 5), the examiner further explained that the Applicant had not disclosed that the particular wing shape claimed provided any advantage, was used for a particular purpose, or solved a stated problem, and that wing shape was thus an obvious design choice. *Id.* at 5-6. *See also In re Dailey,* 357 F.2d 669 (C.C.P.A. 1967) (holding that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant).

For each of the combinations identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 192-196 describes in detail the disclosures that teach the claimed limitations.

Claim 7 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, Ishikawa, or Nicoletti) in view of Raines, Keaton, Sasso, or *In re Dailey,* 357 F.2d 669 (C.C.P.A. 1967). Claim 7 depends from Claim 1 and requires wings with a rectangular shape. Each of Raines, Keaton, Rosato, and Sasso teaches wings of a rectangular shape. (*See* Raines, Figs. 1 and 2, items 20 and 22; *see also* Keaton, Fig. 1, items 28A and 28B; *see also* Rosato, Fig. 1, item 78; *see also* Sasso, Fig. 1, items 28 and 30.) It would

have been obvious to use a rectangular shape for the wings of the anticipated or obvious device of Claim 1. Further, where 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. *In re Dailey,* 357 F.2d 669 (C.C.P.A. 1967).

For each of the combinations identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 197-206 describes in detail the disclosures that teach the claimed limitations.

Claim 8 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, or Nicoletti) combined with either of Sasso or Ishikawa. Claim 8 depends from Claim 1 and requires that at least one wing have a groove configured to house the needle when the wings are in the closed position. Sasso illustrates a device with grooves configured to house the needle in the closed position (*see* Sasso, Fig. 2 and col. 5 ll. 13-19 ("[W]hen 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."). Ishikawa also includes a groove that houses the needle in the closed position (*see* Ishikawa, Figures 1 and 2, col. 2 ll. 16-23).

It would accordingly have been obvious to include a groove to house the needle in any of the devices described above which anticipate Claim 1 or render Claim 1 obvious in view of the teaching of grooves to house the needle in Sasso and Ishikawa.

For each of the combinations identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 207-214 describes in detail the disclosures that teach the claimed limitations.

Claim 9 is obvious in view of Harada (or alternatively Sasso combined with any of Harada, Rosato, Cole, or Nicoletti) and Ishikawa. Claim 9 depends from Claim 8 and provides that the groove to house the needle is in a single one of the wings. Ishikawa, as shown in the discussion of the anticipation of Claim 8, houses the needle in a single groove in the closed position.

For each of the combinations identified in this proposed ground for rejection, Kazmer Declaration at ¶¶ 215-219 describes in detail the disclosures that teach the claimed limitations.

Claim 10 is obvious for the reasons stated above with respect to Claims 2 and 8. Claim 10 depends on Claim 8 and requires a handle as described in Claim 2. It is thus a device with a groove to house the needle and a handle. Sasso in fact combines the groove and the handle as required by Claim 10. (*See* discussion of obviousness of Claims 2 and 8 above). It would have been obvious

to combine the handle in a grooved device for the same reasons as explained in connection with the obviousness and anticipation of Claim 2 and the obviousness of Claim 8. *See* Kazmer Declaration at ¶¶ 220-223.

In summary, all the claimed elements (other than the circular shape) were explicitly disclosed in the cited references, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would be nothing more than predictable results to one of ordinary skill in the art. The dependent claims of the '476 Patent are obvious design choices or disclosed in the prior art. A combination of the claimed elements would be obvious to try (including the circular shape of the wings) in light of the teachings of the cited references. The numerous references disclosing winged needles for protection against accidental needle sticks, and the widespread use of the same elements claimed in the '476 Patent claims support many more combinations of the above references establishing obviousness of all the claims, as we believe the Examiner will readily perceive from the following chart:

Claim Identifier	Claim Limitation	
1a	A device for protecting a user from a sharp tip of a medical needle, the device comprising:	**Harada** –at ¶¶ 0001 and 0004. **Rosato –** at col. 1 ll. 7-9. **Cole** –at col. 1 l. 6-16.

Claim Identifier	Claim Limitation	
		Ishikawa –at col. 1 ll. 31-33 and 51-53. **Sasso** –at col. 1 ll. 7-11. **Nicoletti** – at col. 1 ll. 28-30. **Keaton** – at ¶ 10. **Raines** – at col 1 ll. 14-18.
1b	a central body portion;	**Harada –** the "needle base 4" in Figs. 1 and 2; ¶¶ 0007 and 0014. **Rosato** – the horizontal shaft adjacent to "aft end 68" in Fig. 1 and extending at a 90-degree angle from the fore end 72 of the needle 70; *see also* col. 4 ll. 59-61. **Cole** – the "detachable hub 34" in Fig. 8, and col. 4 ll. 16-18. **Ishikawa** – the "base 3" in Figs. 1 and 2, and col. 2 ll. 6-10 and 34-35. **Sasso –** the "central hub 26" in Fig. 1, and col. 4 ll. 15-37. **Nicoletti** – the "tubular body 106" in Fig. 26, and col. 5 l. 60 – col. 6 l. 3. **Keaton** – the "body 20" in Fig. 1, and at ¶¶ 0019 and 0020. **Raines** – the "hub 18 with a tubing port 92" in Figs. 1 and 7-9, and col. 3, ll. 23-39 and col.5 ll. 45-52.

Claim Identifier	Claim Limitation	
1c	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;	**Harada –** the "needle shaft 2" with a sharp tip in Figs. 1 and 2 in connection with the infusion tubing via the needle base 4, ¶¶ 0002 and 0015. **Rosato –** the "fore end 72 of the needle 70" with a sharp tip 102 in Fig. 1 in fluid connection with the tubing 112 via the "aft portion 68 of the needle 70," col. 4 ll. 10-61. **Cole –** the "needle 35" with a sharp tip in fluid connection with a stub outlet 36 (delivery tube) of the syringe 37 via a detachable hub 34, *see* Fig 8; col. 4, ll. 16-18, 22-23, 28-30 and 31-33. **Ishikawa** – the "needle 2" with a sharp tip in Figs. 1 and 6 is rooted in the base 3, and in fluid connection with the delivery tube 11, col. 2 ll. 6-7, 34-35 and 65-67. **Sasso –** the "needle 22" has a sharp tip 22E and a proximal end 22A in fluid connection with a flexible tubing 58, *see* Fig. 1, and col. 3 l. 60 – col. 4 l. 8; col. 4 ll. 29-37 and col. 5 ll. 49-53. **Nicoletti** – the needle 70 with a sharp tip in fluid communication with the tube 72, col.6 ll. 15-30. **Keaton** – the "catheter 6" with a sharp tip in fluid connection with the tube 4 via the body 20. *See*

Claim Identifier	Claim Limitation	
		Fig. 1, and ¶ 0019. **Raines** – the "needle 12" with a sharp tip 14 in fluid connection with the tubing 27 via the hub 18. See Figs. 1 and 2, and col. 3, ll. 18-39.
1d	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;	**Harada --** the "wings" 3a and 3b connected to the needle base 4 through a rivet. *See* Figs. 1 and 2, ¶ 0007. **Rosato** – the "wings" 90/92 and 94/96 connected to the horizontal shaft adjacent to aft end 68 via short tube ends 80 and 82. *See* Fig. 1; col. 5 ll. 2-28 and col. 4 ll. 47-52. **Cole** – the "protector arms" 30 and 31 mounted via pivot portions 32 and 33 on the detachable hub 34. *See* Figs. 2 and 8, col. 4 ll. 15-16 and col. 4 ll. 19-24. **Ishikawa** – the "wings" 5a and 5b connected to the base 3 via the arms 4a and 4b. *See* Figs. 1-3, col. 2 ll. 6-13. **Sasso –** the "wings" 28 and 30 connected to the hub 26 at the sidewalls 26A and 26B. See Figs. 1 and 2, col. 4 ll. 16-27 and 38-42. **Nicoletti** – the "half-shells" 107 and 108 that are connected to the tubular portion 106 via the rod-like

Claim Identifier	Claim Limitation	
		elements 109 and 110. *See* Fig. 26, and col. 5, l. 59 – col. 6, l. 38. **Keaton** – the "wings" 28A and 28B integrally joined to the body 20 with the hinges 29. Fig. 1, ¶¶ 0020 and 0021. **Raines** – the "wings" 20 and 22 are hingedly or pivotally attached to the hub 18 via the pivot pins 24. Fig. 1 and col. 3, ll. 18-39 and col. 4, ll. 31-47.
1e	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;	**Harada** – the "engaging means 7" with the male means 7a and female means 7b, is disposed on the wings and attaches the wings together, with the needle between the wings. See Figs. 1 and 2; *see also* ¶ 0011). **Rosato** – the "locking tabs" 98 and 100 are disposed on the wings and attach the wings together, with the needle between the wings. Fig. 2, col. 4 ll. 36-47. **Cole** – the "flaps" 38 and 39 in Fig. 8 are disposed on the wings and attach the wings together, with the needle between the wings. *See* Fig. 8; col. 3 ll. 32-59 and col. 4, ll. 22-27. **Ishikawa** – the "coupling means 9" with the female and male parts 10a and 10b is disposed on the wings and attach the wings together, with the needle between

Claim Identifier	Claim Limitation	
		the wings. *See* Figs. 1-3, and col. 2 ll. 28-32 and 35-46. **Sasso –** the "posts" 44/46/48 and the "holes" 50/52/54 are disposed on the wings and attach the wings together, with the needle between the wings. *See* Fig. 1, and col. 5, ll. 24-48. **Keaton** – the "detent post 32" and the "receiving aperture 34" are disposed on the wings and attach the wings together, with the needle between the wings. *See* Fig. 1 and ¶ 0021.
1f	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	**Harada** – the "male means 7a" and the "female means 7b", Figs. 1 and 2; *see also* ¶ 0011. **Rosato** – the "locking tabs" 98 and 100 with inward protrusions engaging the sidewalls of the corresponding wings. Fig. 2, col. 4 ll. 36-47. **Cole** – the "flaps" 38 and 39 in Fig. 8 (engaging with each other, and with the corresponding cut-outs in the wings). *See* Fig. 8; col. 3 ll. 32-59 and col. 4 ll. 22-27. **Ishikawa** – the female and male parts 10a and 10b. *See* Figs. 1-3, and col. 2 ll. 28-32 and 35-46. **Nicoletti** – the "tooth 111" and the "undercut recess 112". See Fig.

Claim Identifier	Claim Limitation	
		26, and col. 6 ll. 4-16.
1g	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.	**Harada** – pivot at the junction portion 5, and male and female locking means 7a and 7b align the wings. *See* Figs. 1 and 2; and ¶¶ 6 and 11. *See also* Kazmer Declaration at ¶¶ 57-60. **Rosato** - the "locking tabs" 98 and 100 engaging the sidewalls of the corresponding wings. *See* Fig. 2, col. 4 ll. 36-47. *See also* Kazmer Declaration at ¶¶ 76-78. **Cole** – the "flaps" 38 and 39 in Fig. 8 (engaging with each other, and with the corresponding cut-outs in the wings). *See* Fig. 8; col. 3 ll. 32-59 and col. 4, ll. 22-27. *See also* Kazmer Declaration at ¶¶ 95-97. **Ishikawa** – the female and male parts 10a and 10b. *See* Figs. 1-3, and col. 2, ll. 28-46. *See also* Kazmer Declaration at ¶¶ 114-115. **Nicoletti** – the "tooth 111" and the "undercut recess 112". *See* Fig. 26, and col. 6 ll. 4-16.
2	The device in accordance with claim 1, further comprising a handle extending from the central body portion.	**Rosato** – the "handle fin 106" extends from the horizontal shaft adjacent to "aft end 68" which serves as the central body portion. *See* Fig. 1, and col. 4 ll. 52-53; *see also* Kazmer Declaration at ¶¶ 116-

Claim Identifier	Claim Limitation	
		118. **Sasso –** the "short flange 60" extends from the hub 26. *See* Fig. 2 and col. 5 l. 65 – col. 6 l. 3. **Raines** – the "third wing 30" extends from the hub 18. *See* Fig. 1 and col. 6 ll. 15-32.
3	The device in accordance with claim 2, wherein the handle extends away from the central body portion in opposition to a direction of the second end of the medical needle.	**Rosato** – the "handle fin 106" extends from the horizontal shaft adjacent to "aft end 68" which serves as the central body portion in opposition to a direction of the sharp tip 102. *See* Fig. 1, and col. 4 ll. 52-53; *see also* Kazmer Declaration at ¶¶ 119-123. **Sasso –** the "short flange 60" extends from the hub 26 in opposition to a direction of the sharp tip 22E. *See* Fig. 2 and col. 5 l. 65 – col. 6 l. 3. **Raines** – the "third wing 30" extends from the hub 18 in opposition to a direction of the non-coring tip 14. *See* Fig. 1 and col. 6 ll. 15-32.
4	The device in accordance with claim 1, wherein the pair of wings are formed of rigid material.	**Sasso –** The examiner already held that Sasso disclosed rigid and semi-rigid wings. *See* February 17, 2012 Office Action; *see also* col. 4, ll. 54-56. **Raines** – the wings are formed of molded plastic material. Col. 4 ll.

Claim Identifier	Claim Limitation	
		48-51.
5	The device in accordance with claim 1, wherein the pair of wings are formed of semi-rigid material.	**Rosato** – the semi-rigid materials for the wings disclosed at col. 6 ll. 7-11; also, wings constructed of plastic in which fold lines 84, 86, 88 are "living hinges" requires use of semi-rigid materials (*see* col. 4 ll. 33-35; *see also* Kazmer Declaration at ¶¶ 128-131. **Cole** – the semi-rigid materials for wings disclosed at col. 2 ll. 41-44 and col. 3 ll. 41-43; *see also* Kazmer Declaration at ¶¶ 124-127. **Sasso –** The examiner already held that Sasso disclosed rigid and semi-rigid wings. *See* February 17, 2012 Office Action; *see also* Col. 4 ll. 54-56. **Nicoletti** – the semi-rigid materials for the wings disclosed at col. 2 ll. 44-50.
6	The device in accordance with claim 1, wherein the pair of wings each have a substantially circular shape.	**Sasso –** The examiner already held that the circular shape would be an obvious design choice. *See* July 16, 2014 Office Action at 5.
7	The device in accordance with claim 1, wherein the pair of wings each have a rectangular shape.	**Rosato** – the generally rectangular "wings" 90/92 and 94/96. *See* Fig. 1; col. 5 ll. 2-28 and col. 4 ll. 47-52. **Cole** – the rectangular "protector arms" 30 and 31. *See* Figs. 1, 2 and 8, col. 4 ll. 15-16 and col. 4 ll.

Claim Identifier	Claim Limitation	
		19-24; *see also* Kazmer Declaration at ¶¶ 132-135. **Ishikawa** – the rectangular "wings" 5a and 5b. *See* Figs. 1-3, col. 2 ll. 6-13; *see also* Kazmer Declaration at ¶¶ 136-139. **Sasso –** the rectangular "wings" 28 and 30. See Figs. 1 and 2, col. 4 ll. 16-27 and 38-42. **Keaton** – the rectangular "wings" 28A and 28B. Fig. 1, ¶¶ 0020 and 0021. **Raines** – the rectangular "wings" 20 and 22. Fig. 1 and col. 3, ll. 18-39 and col. 4 ll. 31-47.
8	The device in accordance with claim 1, 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.	**Harada –** *See* Figs. 2-4. **Ishikawa** – the "ditched projection 7". *See* Figs 1-2, and col. 2 ll. 16-23; *see also* Kazmer Declaration at ¶¶ 140-143. **Sasso –** the "slots" 34 and 40. *See* Figs. 1-3, and col. 4 l. 57 – col. 5 l. 2.
9	The device in accordance with claim 8, wherein the groove is formed in a single one of the pair of wings.	**Ishikawa** – the "ditched projection 7". *See* Figs 1-2, and col. 2 ll. 16-23; *see also* Kazmer Declaration at ¶¶ 144-147. **Sasso** - *See* July 16, 2014 Office Action at 6.
10	The device in accordance	See the citations above in

Claim Identifier	Claim Limitation	
	with claim 8, further comprising a handle extending from the central body portion.	connection with claims 2 and 8.

VIII. SECONDARY CONSIDERATIONS

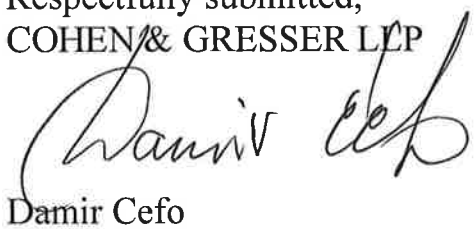
The Federal Circuit has held that secondary considerations, even where they exist, may not overcome a strong case of obviousness. *See Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (affirming this court's finding of obviousness based on the strong prima facie showing of obviousness despite "substantial evidence" of secondary considerations); *Asyst Techs., Inc. v. Emtrak, Inc*., 544 F.3d 1310, 1316 (Fed. Cir. 2008) ("Moreover, as we have often held, evidence of secondary considerations does not always overcome a strong prima facie showing of obviousness."); *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1372 (Fed. Cir. 2007) (finding that Pfizer's alleged unexpectedly superior results were insufficient to overcome a strong case of obviousness).

At the time of the filing of this Petition, Petitioner is not aware of the existence of any commercial success, long-felt need, licensing by competitors, failure of others, or unexpected results, and certainly none sufficient to overcome the *prima facie* showing of obviousness made herein.

IX. CONCLUSION

For the grounds specified above, *inter partes* review of Claims 1-10 of U.S. Patent No. 8,961,476 is respectfully requested.

Respectfully submitted,
COHEN & GRESSER LLP



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CERTIFICATE OF SERVICE

I the undersigned, counsel with the law firm of Cohen & Gresser, LLP, hereby certify that the following statements are true and correct under penalty of perjury, pursuant to 28 U.S.C. § 1746:

On September 17, 2015, the within PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,961,476 was served via first class mail upon the following party and/or attorney at the last known address indicated below:

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by depositing a true and correct copy of said papers, enclosed in a properly addressed, fully postpaid, first class mail envelope in an official depository under the exclusive care and custody of the United States Postal Service within the State of New York.

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