UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REPRO-MED SYSTEMS, INC.,
Petitioner

v.

EMED TECHNOLOGIES CORPORATION,
Patent Owner

Case: IPR2018-00981

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,808,576

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PETITIONER'S EXHIBIT LIST

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Exhibit 1003	Final Written Decision in *Repro-Med Systems, Inc. v. EMED Tech. Corp.*, Case IPR2015-01920, Patent 8,961,476 B2 (Jan. 12, 2017)
Exhibit 1004	Judgment in *EMED Technologies Corp. v. Repro-Med Systems, Inc.*, No. 2017-1547 (Fed. Cir. April 3, 2018)
Exhibit 1005	Declaration of William P. Ramey, III, *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:17-cv- 00728-JRG, Doc. 29-3 (E.D. Tex. Feb. 26, 2018)
Exhibit 1006	EMED Technologies Corporation's Motion for Preliminary Injunction, *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:17-cv- 00728-JRG, Doc. 29 (E.D. Tex. Feb. 26, 2018)
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Exhibit 1016	U.S. Publication No. 2008/0177234 A1 to Keaton et al.
Exhibit 1017	U.S. Patent No. 6,911,020 B2 to Raines
Exhibit 1018	U.S. Patent No. 6,500,155 to Sasso

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

Repro-Med Systems, Inc. ("RMS") petitions for an *inter partes* review of U.S. Patent No. 9,808,576 (the "'576 Patent"), a copy of which is attached as Exhibit 1001, titled "Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle," which is assigned to EMED Technologies Corporation ("EMED").

Petitioner seeks the cancellation of (1) Claims 1 and 2 of the '576 Patent on the grounds of anticipation under 35 U.S.C. § 102, (2) Claims 1-3 of the '576 Patent on the grounds of obviousness under § 103, and (3) Claims 1-3 of the '576 Patent on the grounds of violation of the duties of candor, good faith, and disclosure owed by EMED and its representatives to the U.S. Patent and Trademark Office ("USPTO") during the examination and issuance of the '576 Patent, under 37 C.F.R. § 1.56(a). Cancellation of Claim 1 of the '576 Patent is further supported by the PTAB's earlier invalidation, on grounds of anticipation and obviousness, of the patentably indistinct Claim 1 of EMED's U.S. Patent No. 8,961,476 (the "'476 Patent") (copy attached as Exh. 1002), in *Repro-Med Systems, Inc. v. EMED Tech. Corp.*, Case IPR2015-01920, Patent 8,961,476 B2 (the "'476 IPR Case") (Final Written Decision, Jan. 12, 2017) (copy attached as Exh. 1003) (the "'476 IPR Decision"), affirmed by the U.S. Court of Appeals for the Federal Circuit in *EMED*

Technologies Corp. v. Repro-Med Systems, Inc., No. 2017-1547 (Fed. Cir. April 3, 2018) (copy attached as Exh. 1004) (the "'476 Federal Circuit Judgment").

The '576 Patent claims a device for protecting against accidental medical needle stick injuries. The device consists of two wings that fold over the needle and fasten together. The prior art teaches numerous examples of such "winged needle" devices, and discloses every element of the claims. Despite this prior art, the examiner allowed EMED's claims because of amendments to 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. The examiner thus allowed EMED's claims based on its contentions that the amendments supposedly distinguished its claims from specific prior art references.

However, in allowing EMED's claims, the examiner never saw—and, therefore, never considered—the USPTO's prior decisions (or nearly all of the prior art underlying those decisions) invalidating EMED's substantially similar claims under two patentably indistinct patents. The congruence between EMED's earlier invalidated patents and the '576 Patent is inescapable, after EMED's counsel stated under penalty of perjury that (a) the determinative amendments to the '576 Patent's claims were made to overcome the prior art cited in the '476 IPR Case, in which the substantially similar claims of EMED's '476 Patent were

invalidated, and (b) the '576 Patent claimed priority through the patent family of both invalidated patents. (*See* Declaration of William P. Ramey, III (copy attached as Exh. 1005), ¶ 10, *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:17-cv- 00728-JRG (E.D. Tex.) (the "'576 Infringement Case").) EMED has also contended that the '576 Patent, the '476 Patent, and the '703 Patent, were all "related" and were "co-pending applications." (*See* EMED's Motion for Preliminary Injunction in the '576 Infringement Case, p. 2, attached as Exh. 1006.)

The file wrapper of Application 15/443,919 (the "File Wrapper") (copy attached as Exh. 1007), which matured into the '576 Patent, contains no reference to the '476 IPR Decision. Neither does the File Wrapper contain any reference to the USPTO's final action on Ex Parte Reexamination Application No. 90013585, dated July 19, 2017 (copy attached as Exh. 1008) (the "'703 Ex Parte Final Rejection"), invalidating EMED's U.S. Patent No. 8,500,703 (the "'703 Patent") (copy attached as Exh. 1009). What the File Wrapper *does* show is that, during prosecution of the '576 Patent, the examiner determined that the '703 Patent was sufficiently duplicative of the '576 Patent to require EMED to file a terminal disclaimer for the '703 Patent before the '576 Patent could issue, which EMED filed on September 12, 2017. Although the '703 Ex Parte Final Rejection occurred over two months before EMED filed its terminal disclaimer regarding the '703

Patent, and over three months before the '576 Patent was issued, the examiner was never informed of, and therefore could not consider, the invalidation of EMED's similar patent.

Here, as with its other extinct patents, EMED cannot overcome the invalidating effect of the prior art. The same elements at issue in the '476 Patent are substantially at issue in the '576 Patent, and the prior art teaches precisely such a standard mechanical fastening device on the wings of needle protection devices. As shown below in detail, RMS is more than reasonably likely to prevail on the asserted grounds with respect to Claims 1-3 of the '576 patent.

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 RMS, the real-party-in-interest.

B. Related Matters

The '576 Patent is but one of an intertwined family of EMED's related applications and patents, as shown in the following table:

App No	Filed	Status	Patent No.	Issue Date	Related to
61/130,880	6/2/08	Dead			
12/187,256	*8/6/08*	*Patented*	*8,500,703*	*8/6/13*	*Claims Priority to 61/130,880*
13/931,226	6/23/13	Patented	9,308,322	4/12/16	CIP from 12/187,256
15/090,040	4/4/16	Pending			Divisional of 13/931,226
15/443,919	**2/27/17**	**Patented**	**9,808,576**	**11/7/17**	**Continuation of 15/090,040 - Current Matter**
15/718,470	9/28/17	Pending			Continuation of 15/443,919
90/013,585	*9/15/15*	*Pending* ***(Re Exam)***			*Ex Parte Re-Examination of 12/187,256 - (Final Rejection of all claims - Appeal Brief Filed 01/25/2018 with Petition for Revival)*
13/931,218	6/28/13	Patented	9,226,773	1/5/16	Divisional of 12/187,256
14/080,434	11/14/13	Abandoned			Continuation of 13/931,218
14/221,803	*3/21/14*	*Patented* ***(IPR)***	*8,961,476*	*2/24/15*	*Continuation of 13/931,218; invalidated (except for Claim 9) by PTAB in Case IPR2015-01920; PTAB decision affirmed by Fed. Cir.*

The continuing grandparent patent to the '476 Patent, the '703 Patent, has been asserted in 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 the '703 Ex Parte Final Rejection. EMED filed a petition for revival and an appeal brief regarding the '703 Ex Parte Final Rejection on January 25, 2018.

The '476 Patent is related to the '703 Patent by way of divisional application 13/931,218. The '476 Patent has been asserted in 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.). That matter was stayed upon the filing of the '476 IPR Case, which resulted in the '476 IPR Decision on January 12, 2017 holding all claims of the '476 Patent invalid save for dependent Claim 9. As stated earlier, EMED's appeal to the Federal Circuit of the '476 IPR Decision resulted in a complete affirmance of that decision to invalidate all relevant claims of the '476

Patent in the '476 Federal Circuit Judgment. On April 18, 2018, EMED filed a petition for rehearing *en banc* with the U.S. Court of Appeals for the Federal Circuit regarding the '476 Federal Circuit Judgment.

As stated earlier, EMED has sued RMS for infringement of the '576 Patent in *EMED Tech. Corp. v. Repro-Med Systems, Inc. d/b/a RMS Medical Products*, Civ. Action No. 2:17-cv- 00728-JRG (E.D. Tex.).

C. Notice of Lead and Backup Counsel; Service Information

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Backup Counsel:	James G. Sawtelle (motion for *pro hac vice* admission pending) Sherman & Howard L.L.C. 633 17th Street, Suite 3000 Denver, CO 80202 Tel: (303) 297-2900 Facsimile: (303) 298-0940
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Please address all correspondence to Lead Counsel at the address shown above. Petitioner also consents to electronic service by email at: dan@robertsiplegal.com or jsawtelle@shermanhoward.com.

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

Petitioner certifies that the '576 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging Claims 1-3 of the '576 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 and Appeal Board End to End System. No excess claim fees are required.

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

Petitioner requests that Claims 1-3 of the '576 Patent be canceled on the grounds of unpatentability under 35 U.S.C. §§ 102 and 103, in light of the identified prior art patents and the attached Declaration of George Yanulis ("Yanulis Declaration") (Exh. 1010 hereto). Petitioner further requests that Claims 1-3 of the '576 Patent be canceled or invalidated due to EMED's and its attorneys' violation of their duties to the USPTO of candor, good faith, and disclosure, under 37 C.F.R. § 1.56(a). A copy of each reference cited by Petitioner in support of its request for an invalidity determination 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. A chart identifying where specifically in each item of prior art each element of each asserted claim is found, is attached hereto as Exh. 1011.

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 Exh. 1012;

2. U.S. Patent No. 4,944,731 to Cole, titled "Needle Protection" (hereinafter referred to as "***Cole***"), attached hereto as Exh. 1013;

3. U.S. Patent No. 5,147,319 to Ishikawa et al., titled "Winged Needle" (hereinafter referred to as "***Ishikawa***"), attached hereto as Exh. 1014;

4. U.S. Patent No. 4,820,277 to Norelli, titled "Safety Cover For Syringe Needles" (hereinafter referred to as "***Norelli***"), attached hereto as Exh. 1015;

5. U.S. Publication No. 2008/0177234 A1 to Keaton et al., titled "Safety Subcutaneous Infusion Set" (hereinafter referred to as "***Keaton***"), attached hereto as Exh. 1016;

6. 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 Exh. 1017; and

7. 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 1018.

Summary of Claims Anticipated Under § 102(b)

Claims 1 and 2 are anticipated by ***Harada***.

Claims 1 and 2 are anticipated by ***Norelli***.

Claims 1 and 2 are anticipated by ***Ishikawa***.

Claims 1 and 2 are anticipated by ***Cole***.

Summary of Claims Rendered Obvious Under § 103(a)

Claims 1-3 are obvious in view of ***Harada*** combined with any of ***Norelli***, ***Ishikawa***, ***Cole***, ***Sasso***, and/or ***Raines***.

Claims 1-3 are obvious in view of ***Cole*** combined with any of ***Norelli***, ***Ishikawa***, ***Harada***, ***Sasso***, and/or ***Raines***.

Claims 1-3 are obvious in view of ***Ishikawa*** combined with any of ***Norelli***, ***Harada***, ***Cole***, ***Sasso***, and/or ***Raines***.

Claims 1-3 are obvious in view of ***Norelli*** combined with any of ***Harada***, ***Ishikawa***, ***Cole***, ***Sasso***, and/or ***Raines***.

Claim 1 is obvious in view of ***Harada***, ***Norelli***, ***Ishikawa***, ***Cole***, ***Sasso***, ***Raines,*** and/or ***Keaton*** whether alone or in various combination.

VI. THE ’576 PATENT

A. Claims and Prosecution History of the ‘576 Patent Provide Substantial Grounds for Invalidity.

The ‘576 Patent issued on November 7, 2017, based on application 15/443,919 filed on February 27, 2017, and claims priority to provisional

application 61/130,880 filed on March 21, 2014 (*see* table above). More specifically, the '576 Patent claims priority as a continuation of 14/090,040, which is a division of 13/931,226 (Patent 9,308,322), which is a Continuation in Part of 12/187,256 (the '703 Patent), which claimed the benefit of provisional 61/130,880. Note that the filing date of the application for the '576 Patent occurred after the '476 IPR Decision was entered on January 12, 2017 and before EMED's filing of its appeal from the '476 IPR Decision. The File Wrapper for the '576 Patent is attached as Exh. 1007 hereto, and citations thereto are specified by date, event, and page number therein. There is no disclosure or analysis of the '476 IPR Decision in the File Wrapper.

In an office action dated July 3, 2017 for 15/443,919, the examiner issued a rejection for nonstatutory double patenting: "Claims 1-3 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 11 of U.S. Patent No. 8,500,703 [the '703 Patent]. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claim 1 are to be found in claim 11 (as it encompasses claims 2 and 1)." (Office Action, dated July 3, 2017, pp. 5-7; Exh. 1007, pp. 68-70.)

As noted above, the '703 Patent is the subject of an ex parte reexamination request, Reexamination Application No. 90013585, which resulted in the '703 Ex

Parte Final Rejection on July 19, 2017, of all Claims 1-12 of the '703 Patent. (*See* Exh. 1008 hereto.)

Although aware of the '703 Ex Parte Final Rejection, EMED's counsel filed a terminal disclaimer with respect to the '703 Patent (Exh. 1007, p. 44) on September 12, 2017, but as the File Wrapper indicates, took no action to inform the examiner of this action by the USPTO.

Claim 1 is the only independent claim, and claims a device for protecting a user from the sharp tip of a winged 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 *consisting of* 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." (Emphasis added.)

As demonstrated by a comparison between Claim 1 of the '576 Patent and Claim 1 of the '476 Patent (*see* comparison at Yanulis Decl., ¶ 35, Exh. 1010 hereto), which was found unpatentable by both the PTAB (*see* Exh. 1003 hereto) and the Federal Circuit (*see* Exh. 1004 hereto), the most apparent change appears to regard the mechanical fastener: the '476 Patent having stated "the mechanical

fastener *including* a lip…" while the present '576 Patent now states "the mechanical fastener *consisting of* a lip…." (Emphasis added.)

It is well established that in the art of claim drafting the transitional term "including" is synonymous with "comprising" and is a term used to introduce the bare minimum of the essential elements, but it does not preclude more—it is open ended and does not exclude additional unrecited elements.

In contrast to the open-ended nature of "including," the narrowing option is "consisting of," which is understood to mean that these are the elements, and they are the only elements. It is closed-ended.

More simply stated, Claim 1 of the '576 Patent falls under the broad language of the '476 Patent and fixates on the "lip" while failing to overcome the prior art that the PTAB reasoned was sufficient to invalidate the '476 Patent. It is generally recognized that invalidity of a broader range or scope necessarily results in the invalidity of a narrower subset of that range or scope. *See Clear Value Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

Dr. Yanulis noted this narrowing substitution of terms and found that the use of "including" in Claim 1 of the '576 Patent provided no meaningful differentiation from the language of Claim 1 of the invalidated '476 Patent. (Yanulis Decl., ¶ 18, Exh. 1010.) Moreover, the '576 Patent claim falls under the broader language of the '476 Patent, but this narrowing of focus to fixate upon the

"lip" does not in any way undo the application of the prior art which both the PTAB and the Federal Circuit found to render Claim 1 of the '476 Patent unpatentable. More to the point, it appears that EMED is attempting to recast an issue that has already been decided—the unpatentability of at least Claim 1. Thus, Dr. Yanulis has concluded that EMED has done nothing more than focus on an element that was already understood to exist in the prior art, as the PTAB held and the Federal Circuit agreed. (*Id*.)

With regard to the further superficial and immaterial changes to Claim 1 of the '576 Patent, Dr. Yanulis has pointed out that the addition of "winged" to the description of the medical needle in the first line is of no significance, as the prior art listed above (***Harada***, ***Sasso***, ***Ishikawa***, ***Cole***, ***Norelli***, ***Raines***, and ***Keaton***) all clearly involve winged needles. (*See id*. at ¶ 36.)

Furthermore, the fourth line—"a winged medical needle located in the central body portion"—is indefinite for it is apparently recursive: The preamble notes that the device is a winged medical needle comprising, etc., then properly introduced "a central body portion" and then recursively asserts that the winged medical needle which has a central body portion has a winged medical needle located in the central body portion. Dr. Yanulis, who is a former assistant patent examiner, states that he would have rejected the claim under 35 U.S.C. §112(b) as being indefinite for failing to particularly point out and distinctly claim the subject

matter which the inventor regards as the invention. (*Id*. at ¶ 37.) He concluded that this statement did not provide any meaningful differentiation from the language of Claim 1 in the '476 Patent. (*Id*.)

Continuing with the purported new language of Claim 1 of the '576 Patent, Dr. Yanulis has shown that, because the delivery tube is understood to connect the needle disposed in the tissue of a person or animal to a fluid reservoir, it is entirely reasonable to understand that this delivery tube is flexible. (*Id*. at ¶ 38.) As such, it is entirely reasonable that the needle may be perpendicular to some portion of that delivery tube. (*Id*.) Thus, the amendment in Claim 1 to note the needle being substantially perpendicular to the delivery tube likewise does not provide any meaningful differentiation from the language of Claim 1 in the '476 Patent. (*Id*.)

Furthermore, the amendment to remove "the" and add "an open position…" in the third clause of Claim 1 introduced an antecedent basis uncertainty, as "an open position" was previously stated; consequently, it is now unclear whether the claim is referring to the original instance of an open position or some other instance of "an" open position. (*See id*. at ¶ 39.) As Dr. Yanulis points out, this statement not only fails to provide any meaningful differentiation from the language of Claim 1 in the '476 Patent but makes the claim more indefinite. (*Id*.)

Finally, the addition of "in the closed position" in the 19th line of Claim 1 was obviously implied by stating that the medical needle would be disposed

therebetween. (*Id*. at ¶ 40.) Neither does this statement provide any meaningful differentiation from the language of Claim 1 in the '476 Patent. (*Id*.)

All of the above points justify Dr. Yanulis's conclusions that Claim 1 of the '576 Patent is substantially indistinct from Claim 1 of the '476 Patent, and that any changes in language are insignificant and insufficient to overcome the invalidity determinations in the '476 IPR Decision, the '476 Federal Circuit Judgment, and the '703 Ex Parte Final Rejection. (*Id*. at ¶ 42.)

Figure 11, reproduced below with color emphasis, has evolved as the general illustration for comparison and discussion with respect to the present proceedings and depicts an embodiment of the apparatus. The striking similarity between the '576 Patent and the invalidated '476 and '703 Patents is due in no small part to EMED's recycling of *identical* core specification text and *identical* figures to illustrate the embodiment of the patented devices in the '476 Patent (*see* Exh. 1002, pp. 1, 12, 13); the '703 Patent (*see* Exh. 1009, pp. 1, 11, 12); and the '576 Patent (*see* Exh. 1001, pp. 1, 12, 13). This coloration is not intended to be exclusively definitive for the annotated elements, but is offered to assist in further identifying and relating similar structures.

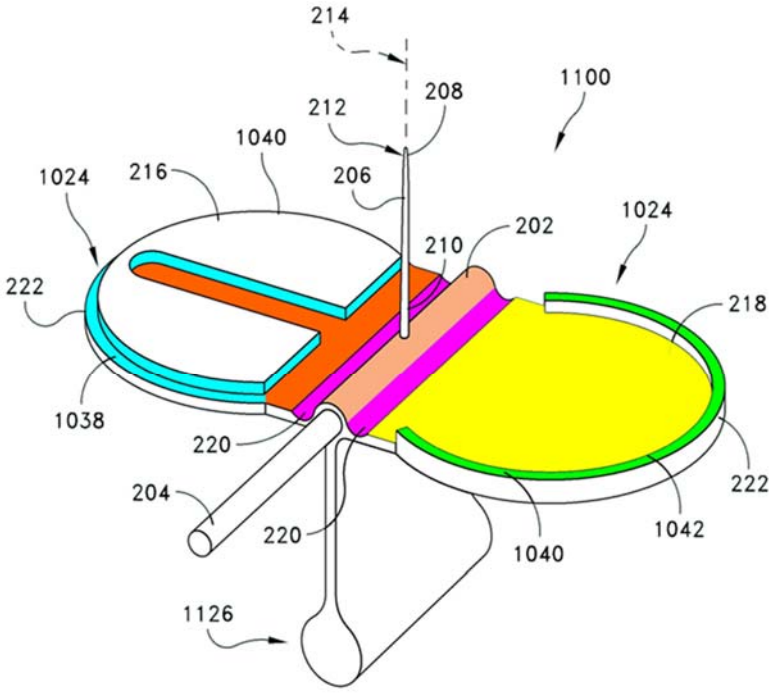


FIGURE 11

Device **1100** has wings **216**, **218**, which include an inner region **220** (purple), and which attach to central body portion **202** (brown). Medical needle **206** has a sharp tip **212** and is in fluid communication with central body **202** and delivery tube **204**. The mechanical fastener **1024** includes a recessed portion **1038** (outer light blue) adjacent to the perimeter of one wing, and a lip **1042** (green) extending from the perimeter **1040** of the other wing. Lip **1042** and recessed portion **1038** are configured to engage with one another to attach the wings together. Wing **216** has a central groove, un-numbered (orange). Wing **218** is shown to have a large central area (yellow) partially bounded by the lip **1042**. With respect to the lip **1042**, it may be appreciated that the yellow central area is a recessed area. It may be appreciated that in this open position, the yellow area of

wing **218** and the light blue and orange areas of wing **216** are generally in the same plane.

Described as groove **1044** in the specification, but un-numbered in Figure 11, the orange groove **1044** may be sized for housing medical needle **206**. It is respectfully noted that groove **1044** is perceived as such due to a narrow width with respect to long length, the rising sidewall thereby defining the apparent groove shown in orange. However, it is respectfully noted that the lip **1042** defining the yellow inner central area is akin to the groove, though differing in overall width, but still presenting a central recessed area sized to receive the needle **206**.

As such, when device **1100** is closed, it will be appreciated that the needle **206** lies within the unnumbered groove of wing **216**, but also within the central yellow area of wing **218**. Moreover, when device **1100** is closed, needle **206** is very likely disposed equally between the respective orange and yellow surfaces of wings **216** and **218**.

This type of safety device for needles is and was well known in the prior art, and there are many examples of the use of wings that fold over the needle to protect against accidental punctures. During the prosecution of the '576 Patent, EMED's attorney filed (*see* Exh. 1007, pp. 141-143) copies of IDS statements from 12/187,256 (the '703 Patent), 13/931,226 (now U.S. Patent No. 9,308,322),

and 15/090,040—this last (Exh. 1007, pp. 128-140) being an uncertified IDS statement listing twenty-five patents and applications, including those noted above (***Harada***, ***Ishikawa***, ***Cole***, ***Sasso***, ***Raines***) but without indication as to their significance to the '576 Patent, the '476 IPR Case, or the Ex Parte Reexamination of the '703 Patent. Although the File Wrapper section of July 3, 2017 demonstrates that some of these spurious IDS statements show an added statement of "All References Considered Except Where Lined Through," others do not, and this statement is justifiably questionable given the significance accorded to many of these references in the '476 IPR Decision and the '703 Ex Parte Final Rejection. Conspicuously absent in the File Wrapper is an IDS statement specifically titled for 15/443,919. (*See* Exh. 1007, pp. 79, 82, 86, 91, 94, 101, 106, 116, 119, 123, 128.) In the File Wrapper, ***Norelli***, which was relied upon in the '703 Ex-Parte Final Rejection, does not appear in *any* of the IDS documents submitted in the File Wrapper for the '576 Patent.

During the prosecution of the '576 Patent, the claims were initially rejected by the examiner under §103(a) as being obvious over ***Sasso*** in view of ***Kashmirian*** (2010/0010451). The examiner held that ***Sasso*** disclosed all of the elements of Claim 1 except for the lip portion extending along at least a portion of a perimeter of at least one wing of the pair of wings. But the examiner found that

Kashmirian did disclose such a lip. (Exh. 1007, July 3, 2017 Office Action, pp. 64-73 (emphasis added).)

The applicant, EMED, then amended Claim 1 to recite "a *winged* medical needle…" and "the *winged* medical needle…" (July 7, 2017 Response, Exh. 1007, pp. 52) (emphasis in original). EMED also argued that ***Kashmirian*** did not disclose a mechanical fastener, including a lip, with the needle positioned therebetween to protect against a needle stick. After EMED filed a terminal disclaimer relative to the '703 Patent on September 12, 2017, a notice of allowance issued on September 28, 2017.

B. Claim Construction

The terms in Claims 1-3 are to be given their broadest reasonable interpretations as understood by one of ordinary skill in the art and consistent with the disclosure. 37 C.F.R. §42.1000(b).

"**Lip.**" Claim 1 recites "the mechanical fastener consisting of a *lip* extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings" and 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." (Emphasis added.) The '576 Patent provides no special meaning for the term "lip." Dictionary.com defines the term "lip" as a projecting edge on a container or

other hollow object: the lip of a pitcher; a liplike part or structure; an edge or rim; the edge of an opening or cavity. Merriam-webster.com defines the term "lip" as the edge of a hollow vessel or cavity; a projecting edge. These definitions are consistent with the ordinary and customary meaning of a "lip." Moreover, the term "lip" is reasonably understood as an edge, or portion of an edge, or a projecting part of an edge according to its plain meaning, such that the term "mechanical fastener consisting of a lip" is given its plain and ordinary meaning of an edge or portion thereof or some projecting structure at an edge that is a functional component of a mechanical fastener, or, as the PTAB found and the Federal Circuit affirmed, "a rounded, raised, or extended piece along an edge." (*See* Exh. 1003, p. 25.)

"**Perimeter.**" As noted in the discussion of "lip" above, Claim 1 relies on "perimeter," but the term 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. The PTAB construed this term similarly to mean "the outermost parts or boundary of an area or object." (*See* Exh. 1003, p. 13.)

"**Mechanical fastener.**" Again, Claim 1 notes a "mechanical fastener," which is not expressly defined in the specification. Given its ordinary meaning and the broadest reasonable construction, the term "mechanical fastener" refers to

elements or mechanisms which join or connect a first member to a second member, and the element could be a portion of one of the members or a separate element. The term would have been understood and appreciated by those skilled in the art to exclude chemical fasteners such as adhesives.

"**In attachment to.**" Claim 1 requires the "the inner region of each wing [to be] in attachment to the central body portion." The PTAB held, and the Federal Circuit affirmed, with respect to the identical language in Claim 1 of the '476 Patent, that the term "in attachment to" will "encompass[ ] configurations of the device of claim 1 where wings are attached, directly or indirectly, to the central body portion of the device." (Exh. 1003, p. 14.) The PTAB emphasized that "the ordinary and customary meaning of the term 'in attachment to' encompasses both direct and indirect attachment." (*Id*., at p. 16.)

VII. EXPLANATION OF HOW THE CLAIMS ARE RENDERED UNPATENTABLE

A. Specification of Anticipating References.

The examiner recognized that all the limitations of the '576 Patent claims were disclosed in the art in similar devices that had the same purpose, but allowed the claims on the distinction that the '576 Patent required a mechanical fastener that consisted of 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. It is again noted that this basis appears to differ

only by the terms "consisting of" in place of "including" presented in the '476 Patent, which was invalidated in relevant part by both the PTAB and the Federal Circuit in view of ***Harada***, ***Ishikawa***, ***Cole***, ***Raines,*** and ***Sasso***—but only ***Sasso*** was apparently actually considered and discussed by the examiner.

Harada—JP Appl. Pub. No. JPH 09-6616(a) to Harada et al. (Exh. 1012). As the File Wrapper makes clear, ***Harada***, titled "Injection Needle with Needle Cover Used as Fixed Wing," was presented in an IDS, but was never discussed on the record and did not form the basis of a rejection. The findings of its relevance to the substantially similar '476 Patent in the '476 IPR Decision are absent from the present record of the '576 Patent.

Figs. 1 and 2 of ***Harada*** are reproduced below with corresponding color annotations correlating to the '576 Patent:

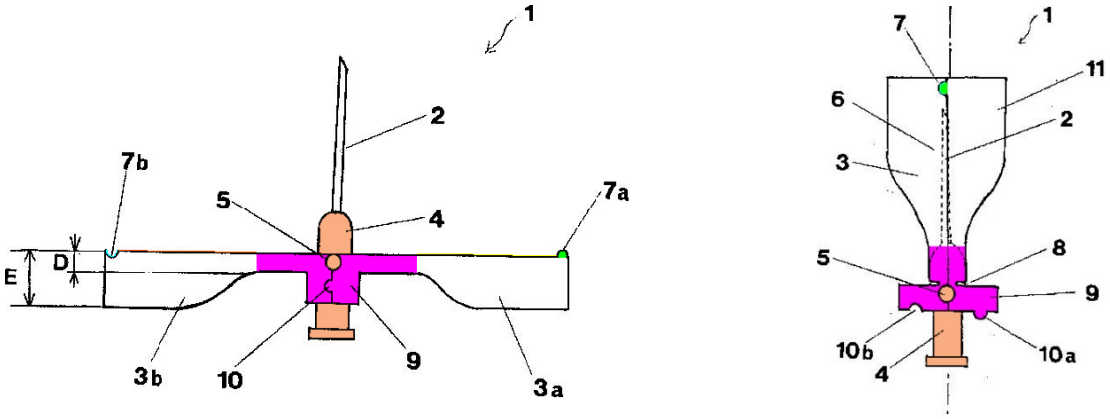


Figure 1, shown on the left, illustrates a front side view of injection needle with needle cover **1** when the medical needle **2** is in use. (Exh. 1012, ¶ 7.) Figure

2, shown on the right, illustrates a front side view of needle with needle cover **1** before or after use of the medical needle **2**. (*Id.*)

The needle cover **1** includes first engaging means **7** located at the tip end of needle cover **3** for securing wings **3a** and **3b**. (*Id.*, ¶ 11.) A mechanical fastener, *e.g.*, engaging means **7**, includes a male engaging means **7a** (green) on wing **3a** and female engaging means **7b** (blue) shown on wing **3b**. (*Id.*) Wings **3a** and **3b** are attached to the central body of the needle base **4** (brown). (*Id.*, ¶ 7.)

Harada clearly teaches a pair of wings **3a**, **3b** having an inner region and an outer region, the inner region of each wing **3a**, **3b**, in attachment to the central body portion **4**, the outer region of each wing **3a**, **3b**, extending away from the central body portion **4**, the pair of wings **3a**, **3b** disposed in opposition to one another with the medical needle **2** positioned therebetween in the central body portion **4**, and the pair of wings **3a**, **3b**, being selectively positionable from an open option to a closed position, where the wings **3a**, **3b**, in an open position are spaced apart from each other to expose the medical needle **2** to allow placement of the medical needle **2** into a treatment site and delivery of a medical fluid; and wherein the wings **3a**, **3b**, in the closed position cover the medical needle **2** to protect against accidental needle stick injury from the medical needle **2**.

A mechanical fastener **7** is disposed on at least one of the pair of wings, the mechanical fastener **7** configured to selectively attach the pair of wings **3a**, **3b**,

together in a closed position with the medical needle **2** positioned therebetween so as to protect the user from the sharp tip of the medical needle **2**.

Moreover, the mechanical fastener **7** includes a lip **7a** (green), extending along at least a portion of the perimeter of at least one of the wings **3a** and a mating portion **7b** (blue), along the perimeter of at least the other one of the wings **3b**. As can be ascertained from the drawing figures, the wings **3a** and **3b**, have surfaces which meet when the wings are in the position shown in Figure **2**, and these surfaces of each wing will define a perimeter. The lip **7a** is "extending along at least a portion of the perimeter" of wing **3a**, and the mating portion **3b** is "along a perimeter" of wing **3b**, as broadly recited in Claim 1.

Harada also notes, "when it is necessary to hold the injection needle *or infusion tubing* against the body, such as during an infusion, the wings can be used as securing means, enabling securing to be carried out simply and reliably even over, for example, an infusion over an extended period of time." (*Id.* at ¶ 15 (emphasis added).) It is reasonable for broad interpretation to understand that the needle of ***Harada*** may be substantially perpendicular to the delivery tube—the needle disposed through the skin, the tubing disposed against the skin.

Ishikawa—U.S. Patent No. 5,147,319 (Exh. 1014). As with ***Harada***, ***Ishikawa*** appears innocuously in an IDS, but was never discussed on the record and did not form the basis of a rejection. The findings of its relevance to the

substantially similar ‘476 Patent in the ‘476 IPR Decision are absent from the present record of the ‘576 Patent.

Figures 1, 2, and 4 of ***Ishikawa*** are reproduced below with corresponding color annotation correlating to the ‘567 Patent:

FIG.1

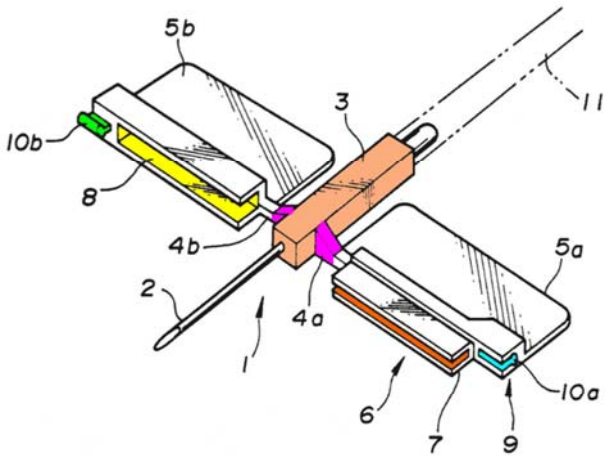


FIG.2

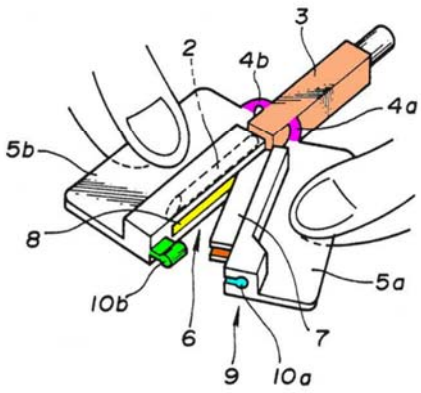


FIG.4

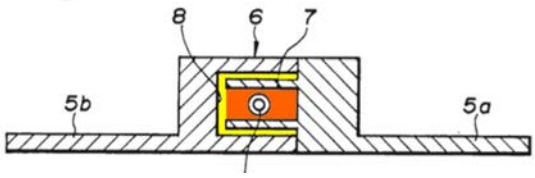


Figure 1 depicts a perspective view of an embodiment of the winged needle in an open state, and Figure 2 depicts the embodiment of Figure 1 during the process of covering the needle. (Exh. 1014 at 1:56-59.) Figure 4 provides a cut-through view further showing the relative arrangement of the wings about the needle.

Ishikawa’s winged needle **1** includes needle **2** attached at one end to base **3** (central body portion) 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 2:34-35.) 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**). (*Id*. at 2:14–19.) When closed, needle **2** is enclosed in ditch projection **7**, with lipped section **8** covering ditch projection **7**. (*Id*. at 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.)

Moreover, ***Ishikawa*** presents a pair of wings **5a**, **5b**, having an inner region and an outer region, the inner regions of each one of the pair of wings **5a**, **5b**, in attachment to the central body portion **3**, the outer region of each one of the pair of wings **5a**, **5b**, extending away from the central body portion **3**, the pair of wings **5a**, **5b**, disposed in opposition to one another with the medical needle **2** positioned therebetween, and the pair of wings **5a**, **5b**, being selectively positionable from an open position to a closed position, where the wings **5a**, **5b**, in an open position are spaced apart from each other to expose the medical needle **2** to allow placement of the medical needle **2** into a treatment site, the wings **5a**, **5b**, in a closed position covering the medical needle **2** to protect against accidental needle stick injury from the medical needle **2**.

Ishikawa presents a mechanical fastener **9** disposed on at least one of the pair of wings **5a**, **5b**, and configured to selectively attach the pair of wings **5a**, **5b**, together in a closed position with the medical needle **2** positioned therebetween to protect against accidental needle stick from the medical needle **2**. The wings **5a**, **5b**, include perimeters, such as the surfaces which meet when the wings **5a**, **5b** are in the position shown in Figs. 3 and 4. The mechanical fastener **9** including a lip **10b** extending along at least a portion of the perimeter of at least one of the wings **5b**, and mating portion **10a** along a perimeter of at least the other one of the wings **5a**.

The mating portion **10a** and the lip **10b** are configured to engage with one another to selectively attach the pair of wings **5a**, **5b**, together with the medical needle **2** positioned therebetween to protect against accidental needle stick injury. ***Ishikawa*** further teaches a flexible delivery tube **11**. As delivery tube **11** is specifically stated to be flexible, the needle **2** may be substantially perpendicular to the delivery tube **2**.

Norelli—U.S. Patent No. 4,802, 277 (Exh. 1015). ***Norelli*** was not before the examiner during the prosecution of the '576 Patent, but it was clearly known to EMED as it was cited and relied upon in the Ex Parte Reexamination proceeding for the '703 Patent, as noted above. (*See* Exh. 1008, pp. 12-14.) Figures 4, 5, and

5A of ***Norelli*** are reproduced below with corresponding color annotation correlating to the '576 Patent.

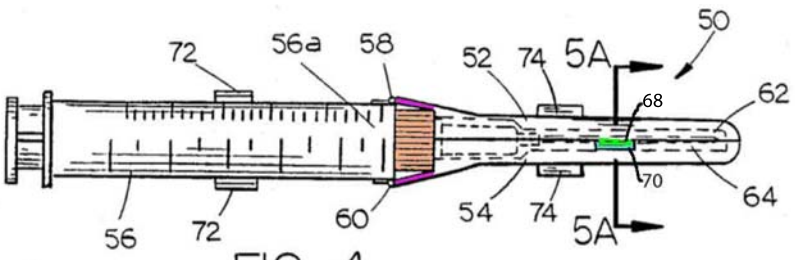


FIG. 4

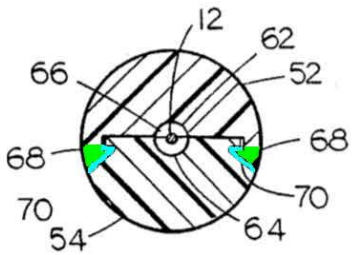


FIG 5A

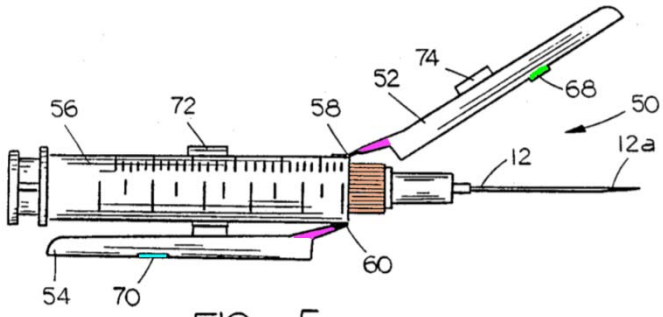


FIG. 5

Norelli discloses a device **50** for protecting a user from a sharp tip of a medical needle **12**, the device comprising a central body portion **78** in fluid connection with a delivery tube **10**. The ***Norelli*** device further comprises a pair of wings (jaws **52**, **54**) with each wing having an inner region **58**, **60**, in attachment to the central body portion **78**, and outer region extending away from the central body portion. The pair of wings **52**, **54**, are selectively positionable from an open position to a closed position, where the wings **52**, **54**, in an open position are spaced apart from each other to expose the medical needle extending from the central body portion **78** to allow placement of the medical needle into a treatment

site. In a closed position, the wings **52**, **54**, cover the medical needle to protect against accidental needle stick injury from the medical needle **12**.

The wings **52**, **54**, are configured with structures which define a perimeter or perimeters such as the edges between the semi-circular outer surfaces and the flat surfaces of each wing **52**, **54**. A mechanical fastener is disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together in the closed position with the medical needle **12** positioned therebetween.

Norelli states, "As shown in Figs. 4 and 5A, each jaw **52** and **54** is a generally solid semi-cylinder having a longitudinal groove **62** and **64** respectively which cooperate to form a tubular aperture **66** which will encase needle **12**. A pair of projecting locking clips **68** are diametrically opposed and mounted on jaw **52** to cooperate with receiving sockets **70** in jaw **54**, as shown in the drawings. Clips **68** and sockets **70** allow the jaws **52** and **54** to be positively secured together to encase needle **12**." (Exh. 1015 at 5:8-16.)

Moreover, a mechanical fastener is disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings **52**, **54**, together in the closed position with the medical needle positioned therebetween to protect against accidental needle stick injury from the medical needle **12**. The mechanical fastener consisting of a lip **68** extending along at least

a portion of the perimeter of at least one of the wings **52**, and a mating portion **70** along a perimeter of at least the other one of the wings **54**, and the mating portion **70** and the lip **68** configured to align the at least one wing relative to the at least one other wing in the closed position.

As syringes are known to have curved delivery tubes that provide fluid delivery at a perpendicular angle to the barrel of the syringe, under broad interpretation of the claim elements the needle **2** may be substantially perpendicular to the delivery tube **2**.

Cole—U.S. Patent No. 4,944,731 (Exh. 1013). As with ***Harada*** and ***Ishikawa, Cole*** appears innocuously in an IDS, but was never discussed and did not form the basis of a rejection. The findings of its relevance to the substantially similar '476 Patent in the '476 IPR Decision are absent from the present record of the '576 Patent.

Cole discloses a device for protecting a user from a sharp point after a medical device such as a needle is used. (*Id*., pp. 26-28.) "This invention relates to needle protection, and more particularly, although not exclusive, relates to the protection after use, of hypodermic syringe needles, *stylettes, catheters and similar surgical or medical devices* having, integrally or as an attachment, a sharp ended point for piercing or injecting…." (*Id*., Col. 1, 6-11 (emphasis added).)

Figures 1, 2, and 8 of ***Cole*** are reproduced below with corresponding color annotations correlating to the '567 Patent.

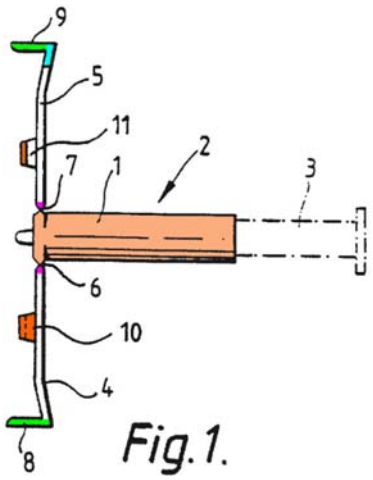


Fig.1.

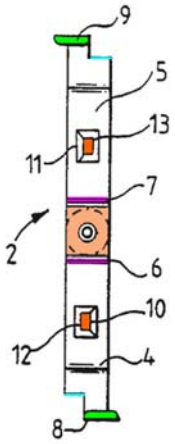


Fig.2.

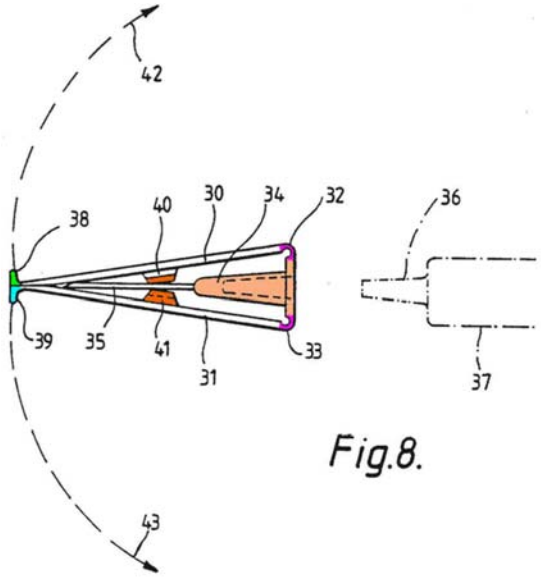


Fig.8.

More specifically, Figures 1 and 2 depict side and end views illustrating protector arms **4** and **5** (aka wings) deployed. In Figure 8, where the protector is removable from the syringe, protector arms **30** and **31** (aka wings) operate in the same fashion as in Figures 1 and 2. With respect to Figures 1 and 2, arms **4** and **5** connect to the body **2** at the needle end via thin portions providing pivoting lines **6** and **7**. (*Id.*, Cols. 3, 19-24.) Similarly, in Figure 8, arms **30** and **31** are mounted via thin pivot portions **32**, **33**, on detachable hub **34** (central body), carrying a needle **35** (the medical needle 35 located in the central body portion **34**), the hub being mounted on a stub outlet **36** from a syringe body **37**. (*Id.*, Cols. 4, 13-18.)

Moreover, ***Cole*** presents a pair of wings **4**, **5** (Figures 1 and 2) (**30**, **31**, in Figure 8), having an inner region and an outer region, the inner regions of each one of the pair of wings **4**, **5**, in attachment to the central body portion **2**, the outer region of each one of the pair of wings **4**, **5**, extending away from the central body portion **2**, the pair of wings **4**, **5**, disposed in opposition to one another with the medical needle **2** positioned therebetween, and the pair of wings **5a**, **5b**, being selectively positionable from an open position to a closed position, where the wings **5a**, **5b**, in an open position are spaced apart from each other to expose the medical needle **2** to allow placement of the medical needle **35** into a treatment site, the wings **4**, **5**, in a closed position covering the medical needle **35** to protect against accidental needle stick injury from the medical needle **2**.

Cole presents a mechanical fastener disposed on at least one of the pair of wings **4**, **5** (Figures 1 and 2) (**30, 31**, in Figure 8), and configured to selectively attach the pair of wings **4**, **5**, together in a closed position with the medical needle **35** positioned therebetween to protect against accidental needle stick from the medical needle **35**. The wings **4**, **5**, include perimeters, such as the surfaces which meet when the wings **4**, **5**, are in the position shown in Fig. 8. The mechanical fastener includes a lip **8** (green) on wing **4** and lip **9** (green) on wing **5** extending along at least a portion of the perimeter of at least one of the wings, and a mating

portion un-numbered (blue) along a perimeter of at least the other one of the wings.

The mating portions and the lips are configured to engage with one another to selectively attach the pair of wings **4**, **5**, together with the medical needle **35** positioned therebetween to protect against accidental needle stick injury.

As ***Cole*** further teaches the device mounted on a stub outlet **36** of a syringe **37**, and as stub outlets are known to be curved to provide fluid delivery at a perpendicular angle to the barrel of the syringe, the needle **35** may be substantially perpendicular to the delivery tube **36**. And as noted above, ***Cole*** specifically states that the invention relates to needle protection after the use of "*stylettes, catheters and similar surgical or medical devices* having, integrally or as an attachment, a sharp ended point for piercing or injecting …." (*Id*., Col. 1, 6-11 (emphasis added).) Stylettes, catheters, and other medical devices as listed by ***Cole*** are well understood in the art to include flexible tubes with a needle, and as such the needle when disposed into the tissue of a patient may be perpendicular to the delivery tube.

Moreover, ***Harada*** and ***Ishikawa*** specifically disclose that the needle and the delivery tube can be in different orientations, and their broad interpretations reasonably extend to perpendicular orientations.

With ***Norelli*** and ***Cole***, these references speak to attachment to a syringe, but again broad interpretation permits the reasonable interpretation of all types of syringes—including those with an angled output tube. And ***Cole*** specifically notes the application of the invention to stylettes, catheters, and similar medical devices that comprise a flexible delivery tube and a sharp needle.

Harada, ***Ishikawa***, ***Norelli***, and ***Cole*** therefore anticipate all of the elements of Claim 1 of the '576 Patent.

As to Claim 2, "wherein each wing of the pair of wings is capable of extending generally planarly away from the central body portion, the pair of wings disposed in opposition to one another with the medical needle positioned therebetween," there is nothing in the specification to clarify the intended meaning of "planarly away." However, it is visually plain to see that a similar arrangement of the wings shown in Fig. 11 of the '576 Patent is shown in ***Harada*** Fig. 1, ***Ishikawa*** Fig. 1, ***Norelli*** Fig. 16, and ***Cole*** Figs. 1 and 2.

Dr. Yanulis concurs in the above rationale for invalidating the '576 Patent on grounds of anticipation. (*See* Yanulis Decl., ¶¶ 46-83, Exh. 1010 hereto.)

B. Obviousness

1. Specification of References Establishing Obviousness

The references cited above and additional references support an obviousness rejection of each Claim 1-3 of the '576 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 review of each reference—***Harada***, ***Ishikawa***, ***Norelli***, and ***Cole***—as stated above for anticipation is incorporated herein for a contention of determination of obviousness. To the extent that a contention of anticipation is more properly characterized as a contention of obviousness, then RMS asserts such contention, and similarly if a contention of obviousness is more properly characterized as a contention of anticipation, the same applies.

As noted above, ***Norelli*** and ***Cole*** both teach attachment of the device for protecting a user from a sharp tip of a medical needle to a syringe. Although illustrated as straight outlet tubes, syringes with curved outlet tubes are well known and a matter of operator choice for a given application. ***Harada*** does not show the intended delivery tube, but does state that "when it is necessary to hold the injection needle *or infusion tubing* against the body, such as during an infusion, the wings can be used as securing means, enabling securing to be carried out simply and reliably even over, for example, an infusion over an extended period of time." (Exh. 1012 at ¶ 15 (emphasis added).)

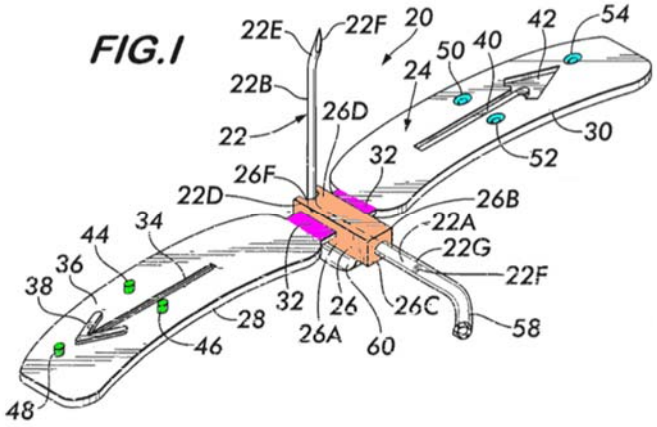
Moreover, the orientation of the delivery tube as perpendicular to the needle is an obvious design choice.

Sasso, ***Raines***, and ***Keaton*** all teach central body portions clearly depicting needles perpendicular to delivery tubes within the device structure.

The dependent claims of the ’576 Patent add only limitations that are obvious design choices or elements known in the art for use on the same devices. The dependent claims further note that the pair of wings are capable of extending generally planarly away from the central body (Claim 2), and the wings provide a handle (Claim 3).

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

Sasso—U.S. Patent No. 6,500,155 (Exh. 1018). ***Sasso*** discloses a needle safety device. (*Id*.) Figures 1 and 2 of ***Sasso*** are reproduced below with corresponding color annotation correlating to the ‘576 Patent:



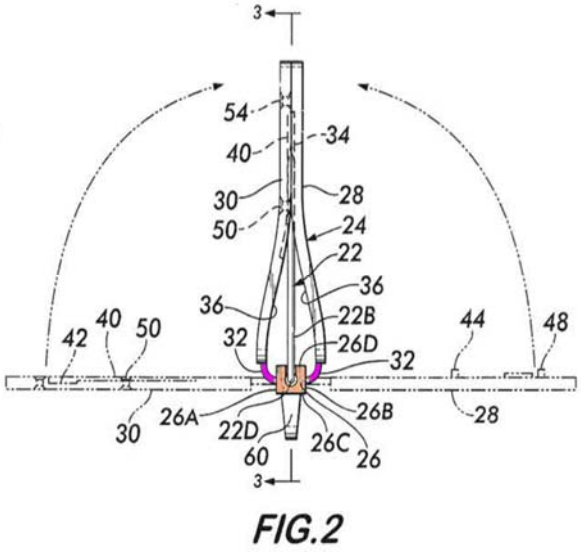


FIG.2

Sasso teaches a shield **24** is provided by a pair of wings, **28** and **30**, which project outward from hub **26** and bend at their hinges **32**. (*Id.* at 4:15-29, 50-56.) ***Sasso's*** mechanical fastener includes posts **44**, **46**, and **48** that mate with apertures **50**, **52**, and **54**. (*Id*. at 5:24-48.)

As noted above, ***Sasso*** has been considered by the examiner during the original examination of the '576 Patent. Indeed, ***Sasso*** was also considered by the PTAB in the '476 IPR Decision invalidating the '476 Patent. In both proceedings, ***Sasso*** was viewed as teaching all of the claim elements except for a lip extending along at least a portion of the perimeter of at least one of the wings, which engaged a mating portion along the perimeter of the other wing when the wings are in the closed position.

Additionally, ***Sasso*** presents a central body portion **26**, and a needle **22** in the central body portion **26** and substantially perpendicular to the delivery tube **58**. ***Sasso*** further presents a pair of wings **28** and **30** having an inner region and an

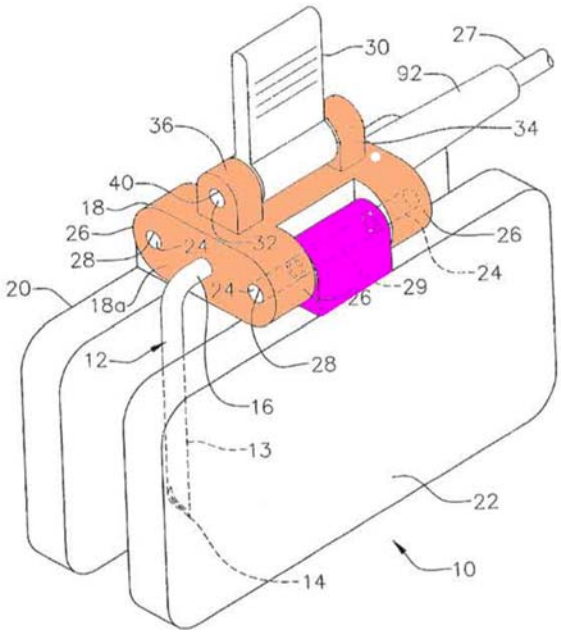
outer region, the inner regions of each one of the pair of wings **28**, **30**, in attachment to the central body portion **26**, the outer region of each one of the pair of wings **28**, **30**, extending away from the central body portion **26**, the pair of wings **28**, **30**, disposed in opposition to one another with the medical needle **22** positioned therebetween, and the pair of wings **28**, **30**, being selectively positionable from an open position to a closed position, where the wings **28**, **30**, in an open position are spaced apart from each other to expose the medical needle **22** to allow placement of the medical needle **22** into a treatment site, the wings **28**, **30**, in a closed position covering the medical needle **22** to protect against accidental needle stick injury from the medical needle **22**.

As noted above, a mechanical fastener consisting of a lip and a mating portion along at least a portion of the perimeter of the wings was and is clearly taught by ***Harada***, ***Cole***, ***Ishikawa***, and ***Norelli***.

In addition to the obviousness of Claim 1 when combined with ***Harada***, ***Cole***, ***Ishikawa***, and/or ***Norelli***, when the wings **28**, **30**, of ***Sasso*** are open, the needle is positioned therebetween—rendering Claim 2 obvious.

The wings **28**, **30**, of ***Sasso*** may also be bent back to serve as a handle—thereby rendering Claim 3 obvious. As previously noted in the '476 IPR Decision, ***Sasso*** actually has a handle **60**, though there is no apparent reason that the wings **28**, **30** cannot be bent back about the handle **60** to augment the grasping ability.

Raines—U.S. Patent No. 6,911,020 (Exh. 1017). ***Raines*** appears innocuously in an IDS, but was never discussed on the record and did not form the basis of a rejection. ***Raines*** discloses a needle safety device with wings: "The present invention relates generally to hypodermic needles and relates more practically to a 90^0 Huber needle having a pair of safety wings which fold around the needle so as to mitigate the likelihood of an inadvertent needle stick." Exh. 1017 at 1:14-18 discloses a winged needle that safely exposes and covers the needle. Figure 1 of ***Raines*** is reproduced below with corresponding color annotations correlating to the '576 Patent.



As shown, 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** located in the central body portion **18** to prevent a user from

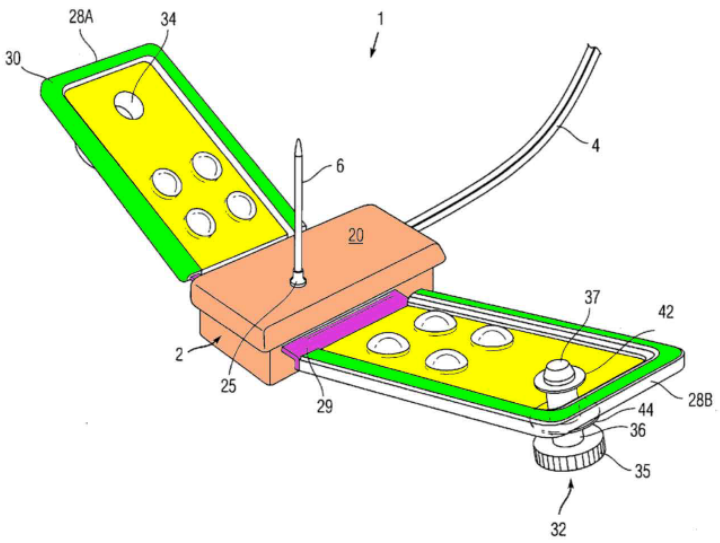
being injured by the needle, and third wing **30**. (*Id.* at 3:18–25, 4:12–14.) Third wing **30** serves as a handle. (*See, e.g.*, *id.* at 6:29–31 ("[T]he safety needle assembly **10** may be pulled away from the patient by holding the third wing **30** between the thumb and forefinger of one hand.").) ***Raines*** also depicts the 90^0 Huber needle **12** being substantially perpendicular to the delivery tube **27**, the needle **12** being protectively enclosed by the wings **20**, **22**.

Raines, in combination with ***Harada***, ***Cole***, ***Ishikawa***, ***Norelli***, and/or ***Sasso***, provides all of the elements of Claim 1, thus rendering Claim 1 obvious.

As shown in Figures 3 and 4, when the wings **20**, **22**, of ***Raines*** are open, the needle **12** is positioned therebetween—rendering Claim 2 obvious.

The wings **20**, **22**, of ***Raines*** may also be bent back to serve as a handle—rendering Claim 3 obvious.

Keaton—U.S. Publication No. 2008/0177234 (Exh. 1016). ***Keaton*** discloses a "Safety Subcutaneous Infusion Set." As with most of the above cited references, ***Keaton*** appears innocuously in an IDS, but was never discussed on the record and did not form the basis of a rejection. Figure 1 of ***Keaton*** is reproduced below with corresponding color annotations correlating to the '567 Patent.



Keaton teaches a winged medical needle for protecting a user from a sharp tip of a needle, having a central body portion **20**, a needle **6** located in the central body portion **20**, having a first end in fluid connection with a delivery tube **4**, and a second end distal from the central body portion **20** including the sharp tip. This needle **6** is also substantially perpendicular to the delivery tube **4**.

The ***Keaton*** device further has a pair of wings **28A** and **28B**, having an inner region and an outer region, the inner regions of each one of the pair of wings **28A**, **28B**, in attachment to the central body portion **30**, the outer region of each one of the pair of wings **28A**, **28B**, extending away from the central body portion **20**, the pair of wings **28A**, **28B**, disposed in opposition to one another with the medical needle **6** positioned therebetween, and the pair of wings **28A**, **28B**, being selectively positionable from an open position to a closed position, where the wings **28A**, **28B**, in an open position are spaced apart from each other to expose

the medical needle **6** to allow placement of the medical needle **6** into a treatment site; and the wings **28A**, **28B**, in a closed position are covering the medical needle **6** to protect against accidental needle stick injury from the medical needle **6**.

As with ***Sasso*** noted above, ***Keaton*** discloses a different mechanical fastener, however a mechanical fastener consisting of a lip and a mating portion along at least a portion of the perimeter of the wings was and is clearly taught by ***Harada***, ***Cole***, ***Ishikawa***, and ***Norelli***, thus rendering Claim 1 obvious.

As shown in Figure 1 when the wings **28A**, **28B**, of ***Raines*** are open, the needle **12** is positioned therebetween—rendering Claim 2 obvious.

Keaton further states that the wings are made of pliant plastic, so they are clearly understood to be flexible, bending readily. There is no reason to presume that the wings of ***Keaton*** cannot be bent back to touch and be used as a handle, thus rendering Claim 3 obvious. Certainly ***Keaton*** may be combined with any or all of the references ***Harada***, ***Cole***, ***Ishikawa***, ***Norelli***, ***Sasso***, and/or ***Raines*** to render Claims 1-3 all obvious.

Dr. Yanulis concurs in the above rationale for invalidating the '576 Patent on grounds of obviousness. (*See* Yanulis Decl., ¶¶ 84-113, Exh. 1010 hereto.)

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) (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. VIOLATION OF DUTY OF CANDOR, GOOD FAITH, AND DISCLOSURE

It is axiomatic that the inventor, and every other individual who is substantively involved in the preparation or prosecution of a patent application, including the applicant's attorneys, owe duties of candor, good faith, and disclosure toward the USPTO in conjunction with a patent application. (*See, e.g.*, Manual of Patent Examining Procedure ("MPEP"), Ninth Ed., Rev. 08.2017, Last Revised Jan. 2018, § 2000.01.) Those duties are codified in 37 C.F.R. § 1.56, which provides in relevant part as follows:

> (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. . . [N]o patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.

As stated above, 37 C.F.R. § 1.56(c) provides that these duties of candor, disclosure, and good faith apply to, among others, the inventor and each attorney who prepares or prosecutes the application.

Furthermore, the duties set forth in § 1.56(a) require an applicant and its attorneys to bring to the attention of the examiner evaluating a patent application "all information known to that individual to be material to patentability." The concept of "materiality" is further clarified in 37 C.F.R. § 1.56(b):

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Under these standards, RMS will demonstrate, and Dr. Yanulis concurs, that EMED and its attorneys and agents violated their duties of candor, good faith, and disclosure to the USPTO in the prosecution of the '576 Patent. (*See* Yanulis Decl., ¶¶ 118-129, Exh. 1010 hereto.) As Dr. Yanulis has concluded, based on his experience, including his tenure as an assistant patent examiner, if EMED and its attorneys had complied with their duties under 37 C.F.R. § 1.56(a) and had

properly disclosed all material information to the examiner in conjunction with the prosecution of the '576 Patent, the '576 Patent would not have been issued. (*Id*. at ¶ 129.) Therefore, RMS requests that this Board rectify the misconduct of EMED and its attorneys and representatives by taking the action that a properly-informed examiner would have done earlier, and cancelling the '576 Patent.

EMED's chief executive officer, Paul Lambert, its attorney, William Ramey, and others representing EMED before the USPTO knowingly failed to inform the examiner that the PTAB held unpatentable all but one dependent claim of the '476 Patent in its January 12, 2017 '476 IPR Decision. The violation of their duties occurred "knowingly" because EMED and its counsel failed to disclose to the examiner for the '576 Patent material information that they indisputably knew at the time. (*See id*. at ¶ 118.) Ramey has stated under penalty of perjury in the '576 Infringement Case that the '576 Patent application "claimed priority through the patent family of the '476 patent and the '703 patent" and the claims of the '576 Patent "were drafted specifically to overcome the prior art cited in the [IPR Decision]." (Exh. 1005, ¶ 10.) EMED has also contended that the '576 Patent, the '476 Patent, and the '703 Patent, were all "related" and were "co-pending applications." (*See* EMED's Motion for Preliminary Injunction in the '576 Infringement Case, p. 2, Exh. 1006 hereto.) But the File Wrapper (Exh. 1007 hereto) of EMED's Application 15/443,919, which matured into the '576 Patent,

does not disclose any indication that the examiner was informed of the January 12, 2017 '476 IPR Decision by EMED or anyone else before the '576 Patent was issued nearly 10 months later on November 7, 2017.

Consequently, because the '476 IPR Decision was not included in the File Wrapper, EMED prevented the examiner from considering not only the broad invalidation of all relevant claims of the '476 Patent, but the relevant prior art, and specifically ***Cole***, ***Ishikawa***, ***Raines***, ***Sasso***, and ***Harada***, along with the PTAB's analysis of that prior art. In fact, the only common prior art reference between the '476 IPR Decision and the File Wrapper that the examiner apparently considered was ***Sasso***.

EMED and its attorneys also knowingly failed to inform the examiner that EMED's substantially similar and "related" '703 Patent had been invalidated. This, despite the fact that the examiner had required EMED to, and EMED did, file a terminal disclaimer regarding the '703 Patent as a condition of issuance of the '576 Patent to remove the issue of nonstatutory double patenting (*i.e.*, duplication) between the two patents. As a summary, on July 3, 2017, the examiner issued an office action notifying Ramey that "Claims 1-3 [of the '576 Patent application] are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 11 of U.S. Patent No. 8500703." ('576 Patent File Wrapper, p. 69, Exh. 1007.) The examiner stated, "A timely filed terminal disclaimer … may be

used to overcome an actual or provisional rejection based on nonstatutory double patenting …." (*Id.*)

At that same time, the '703 Patent was the subject of an ex parte reexamination application. On July 19, 2017, the ex parte reexamination proceeding concluded when the examiner issued a final office action, the '703 Ex Parte Final Rejection, that rejected all claims of EMED's '703 Patent. (Exh. 1007 hereto.) On September 12, 2017, nearly *two months* after the '703 Patent was invalidated under the '703 Ex Parte Final Rejection of all claims, Ramey filed a terminal disclaimer to overcome the '576 Patent examiner's double patenting rejection—without informing the examiner of the '703 Ex Parte Final Rejection of the '703 Patent. EMED's inventor, Lambert, and its attorney, Ramey, were certainly aware of the '703 Ex Parte Final Rejection of the '703 Patent, and the duplicative relationship between the '576 Patent and the '703 Patent, but they withheld from the examiner this material information.

Furthermore, EMED and its counsel were aware of the contents of the '703 Ex Parte Final Rejection, which cited ***Norelli*** as an anticipating reference for the '703 Patent sufficient to render it unpatentable. Despite this awareness, EMED's representatives failed to disclose ***Norelli*** to the examiner in conjunction with prosecution of the duplicative '576 Patent, as no reference to ***Norelli*** appears in the File Wrapper for the '576 Patent (*see* Exh. 1007).

Ramey also failed to meaningfully, fully, or accurately complete even a single IDS specifically for the 15/443,919 application, as shown by the File Wrapper for the '576 Patent. Those IDS's that were submitted were not drafted for the '576 Patent, do not contain any reference to that application, and do not contain any information whatsoever alerting the examiner to the relevance of the material submitted with the IDS's with regard to the '576 Patent. Instead, Ramey simply dumped into the file for the '576 Patent application, without any reference to the potential applicability to that application, photocopies of IDS's that he or others had drafted for other applications (*see* File Wrapper, pp. 79-143, Exh. 1007 hereto), including the application that matured into the later-invalidated '703 Patent (*see id*. at 91-93, 101-02, 104-115). EMED's and Ramey's submissions to the '576 Patent's examiner of IDS's relating to the '703 Patent application only highlights their violation of their duties in hiding from the same examiner the '703 Ex Parte Final Rejection that invalidated the '703 Patent. In essence, they are implicated by their own admissions of the relatedness of the two patents and proceedings.

As Dr. Yanulis opines, these actions by EMED and its counsel violate the standards of patent practice. (*See* Yanulis Decl., ¶ 124, Exh. 1010 hereto.) The MPEP provides at § 2004, "Care should be taken to see that prior art or other information cited in a specification or in an information disclosure statement is

properly described and that the information is not incorrectly or incompletely characterized."

The MPEP confirms that all individuals participating in the patent application process have a duty to disclose to the USPTO "all material information they are *aware* of regardless of the source or how they become aware of the information." (MPEP § 2001.06 (emphasis in original).) These individuals also have a duty to bring to the examiner's attention information as to other "copending United States applications which are material to patentability of the application in question." (*Id*. at § 2001.06(b).) This is true with respect to actions by an examiner involving material copending applications or patents, as occurred with both the '476 and the '703 Patents related to the '576 Patent: "For example, if a particular inventor has different applications pending in which similar subject matter but patentably indistinct claims are present that fact *must be disclosed* to the examiner of each of the involved applications. Similarly, the prior art references from one application *must be made of record* in another subsequent application if such prior art references are 'material to patentability' of the subsequent application." ((*Id*.) (emphasis added).)

The duty of disclosure is the same as to matters in litigation, such as the '476 IPR Case that led to the '476 IPR Decision holding unpatentable Claim 1 of that patent that is patentably indistinct from Claim 1 of the '576 Patent:

> Where the subject matter for which a patent is being sought is or has been involved in litigation and/or a trial proceeding, or the litigation and/or trial proceeding yields information material to currently pending applications, the existence of such litigation and any other material information arising therefrom *must be brought to the attention of the examiner* or other appropriate official at the U.S. Patent and Trademark Office. . . Where a patent for which reissue is being sought is, or has been, involved in litigation and/or trial proceeding which raised a question material to examination of the reissue application, such as the validity of the patent . . . the existence of such litigation and/or trial proceeding must be brought to the attention of the examiner by the applicant . . . .

(*Id*. at 2001.06(c) (emphasis added).) As Dr. Yanulis opines, it is self-evident that the materiality and necessity for disclosure of information going to the validity of the subject matter of a patent applies equally, if not more, to an application for initial issuance of a patent, such as the '576 Patent, than it does to a reissuance. (Yanulis Decl., ¶ 126, Exh. 1010 hereto.)

Dr. Yanulis further points out that the information regarding the '476 Patent and the '703 Patent, including the '476 IPR Decision, the '703 Ex Parte Final Rejection, the prior art cited in those decisions, and the faulty IDS's, that EMED and its counsel failed to disclose to, or concealed from, the examiner in conjunction with the '576 Patent application were certainly "material" to issuance of the '576 Patent. (*Id*. at ¶ 127.) That conclusion is apparent from the similarity

of the relevant devices and claims, as well as from EMED's statements (in its Motion for Preliminary Injunction in the '576 Infringement Case, p. 2, Exh. 1006 hereto) that the '576 Patent, the '476 Patent, and the '703 Patent, were all "related" and were "co-pending applications." That similarity and "relatedness" between these three patents is also exemplified by the fact that EMED used the identical figures to illustrate the embodiment of the patented devices in the '476 Patent (*see* Exh. 1002, pp. 1, 12, 13); the '703 Patent (*see* Exh. 1009, pp. 1, 11, 12); and the '576 Patent (*see* Exh. 1001, pp. 1, 12, 13).

For purposes of the duty of good faith, candor, and disclosure, the concept of "material" information, which must be disclosed, "embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." (MPEP § 2001.04 (emphasis in original).) The ultimate guide is, if there is any uncertainty, the information should be disclosed to the examiner: "In short, the question of relevancy in close cases should be left to the examiner and not the applicant." (*Id*. at § 2004.)

Dr. Yanulis has concluded that the information that EMED and its counsel failed to disclose to (or concealed from, in the case of the IDS's) the examiner in conjunction with issuance of the '576 Patent was material to the examiner's decision whether to issue that patent. (Yanulis Decl., ¶ 129, Exh. 1010 hereto.) He

further stated that, if he had been the examiner in that case, he certainly would have viewed that information as material to the decision whether to issue a patent on EMED's application. (*Id*.) He concluded that EMED's and its counsel's nondisclosure and concealment of material information from the examiner violated their duties of good faith, candor, and disclosure under 37 C.F.R. § 1.56. (*Id*.) If Dr. Yanulis had been the examiner evaluating issuance of EMED's application that matured into the '576 Patent, and if he had been given access to the information detailed above that EMED and its counsel improperly failed to disclose or concealed from the examiner, he would not have issued the '576 Patent. (*Id*.) Finally, he opined that a reasonable examiner would not have issued the '576 Patent if the examiner had been given proper and timely access, during the application process, to the information that EMED and its counsel failed to disclose or concealed from the examiner in violation of their duty of candor, good faith, and disclosure. (*Id*.) This Board should come to the same conclusion and invalidate the '576 Patent.

X. CONCLUSION

For the grounds specified above, *inter partes* review of Claims 1-3 of U.S. Patent No. 9,808,576 is respectfully requested.

DATED: May 4, 2018

By: 

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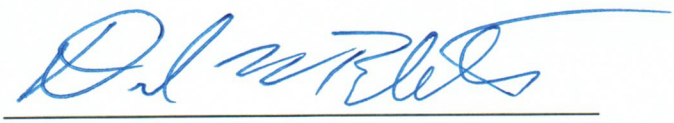
CERTIFICATE OF COMPLIANCE
WITH 37 C.F.R. §42.24(d)

The undersigned, counsel with the Law Office of Daniel W. Roberts, LLC, hereby certifies as follows as required by 37 C.F.R. §42.24(d): The foregoing document was created using 14-point Times New Roman proportional font, in accordance with 37 C.F.R. § 42.6(a)(2), and contains 11,898 words, not including material excluded under 37 C.F.R. 42.24(a)(1), in reliance on the word count of the word-processing system used to prepare the document.

Dated: May 4, 2018

By: 

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CERTIFICATE OF SERVICE

The undersigned, counsel with the law firm of Law Office of Daniel W. Roberts, LLC, hereby certifies that the following statements are true and correct under penalty of perjury, pursuant to 28 U.S.C. § 1746:

On May 4, 2018, the within PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,808,576 was served via Federal Express overnight mail upon the following party and/or attorney at the last known address indicated below:

William P. Ramey, III
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Attorneys for Patent Owner EMED TECHNOLOGIES CORPORATION

by depositing with Federal Express a true and correct copy of said papers, enclosed in a properly addressed, fully prepaid Federal Express envelope for overnight express delivery to the recipient addressed above.

Dated: May 4, 2018

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