Paper No. ____
Filed: November 25, 2015

Filed on behalf of: Zimmer Surgical, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER SURGICAL, INC.
Petitioner

v.

STRYKER CORPORATION
Patent Owner

U.S. Patent No. 6,481,019

DECLARATION OF MICHAEL L. JONES

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I, Michael L. Jones, declare as follows:

I. INTRODUCTION

1. I have been retained by Zimmer Surgical, Inc. ("Petitioner") as an independent expert consultant in this proceeding before the United States Patent and Trademark Office regarding U.S. Patent No. 6,481,019 ("the '019 patent"), which I understand is labeled as Ex. 1001 in this proceeding. I have been asked to consider, among other things, whether certain references teach or suggest the features recited in claims 48, 56, and 125-129 of the '019 patent. My opinions are set forth below.

2. I am being compensated at my normal consulting rate for the time I spend on this matter. No part of my compensation is dependent on the outcome of this proceeding or any other proceeding involving the '019 patent. I have no other interest in this proceeding.

II. QUALIFICATIONS

3. I received a Bachelor of Science (B.S.) in Chemical Engineering from University of California, Berkley in May 1984, and a Masters of Science (M.S.) in Mechanics and Materials from California State University, Long Beach, in January 1995. My masters thesis project involved the design and development of a belt mounted powered air-purifying respirator.

4. I have more than 25 years of industrial experience designing, developing, studying, and/or testing medical devices. I was a Manufacturing Engineer at Mentor Corporation (1984-1985); a Process Engineer at Shiley (1985-1986); a Project Engineer at Baxter Healthcare (1986-1989), Survivair Inc. (1989-1991) and Laparomed Inc. (1991-1992); managed product development at Applied Medical Resources (1992-1994); and was a Senior Project Engineer at Micro Therapeutics, Inc. (1994-1997). I am presently a contract mechanical engineer with Design Development and Fabrication, Inc., and have been with this company since 1997. I am also presently a managing partner at Salt Creek Medical Device Development, a medical device incubator.

5. In my role as Project Engineer at Survivair Inc., I was responsible for the design and development of a half-mask air-purifying respirator and powered air-purifying respirator. While these systems were intended for use with industrial personal protection systems, the technology was similar to that for air filtration systems for surgical environments. Further, I have had personal experience with personal protection systems used in medical environments as a product engineer at various medical device companies.

6. I have over 36 issued patents to my name and several pending patent applications. A copy of my curriculum vitae is attached as Exhibit A.

III. SUMMARY OF OPINIONS

7. All of the opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this Declaration, I reviewed the documents mentioned in this declaration, including the '019 patent (Ex. 1001), the prosecution history file of the '019 patent (Ex. 1003), U.S. Patent No. 5,054,480 to Bare et al. ("*Bare*") (Ex. 1004), U.S. Patent No. 4,856,109 to Desy et al. ("*Desy*") (Ex. 1005), U.S. Patent No. 4,783,854 to Bjorklund et al. ("*Bjorklund*") (Ex. 1006), and U.S. Patent No. 3,787,113 to Shedrow et al. ("*Shedrow*") (Ex. 1007), while drawing on my experience designing medical devices including personal protection equipment or systems. My opinions are additionally guided by my appreciation of how a person of ordinary skill in the art would have understood the claims of the '019 patent at the time of the alleged invention, which I have been asked to assume is January 18, 2000. I understand that Stryker may allege an earlier date; this would not alter my opinions below.

8. Based on my experience and expertise, it is my opinion that certain references teach or suggest all the features recited in these claims.

IV. LEVEL OF ORDINARY SKILL IN THE ART

9. At the time of the alleged invention, in January 2000, a person of ordinary skill in the art would have had a background in engineering or similar

background, and at least two years of experience designing, developing, studying, and/or testing medical devices or personal protection equipment or personal protection systems generally. Alternatively, a person of ordinary skill in the art would have had a technical or medical background and at least two years of experience designing, developing, studying, testing and/or using personal protection equipment air filtration devices. More education can supplement relevant experience and vice versa.

10. In determining the level of ordinary skill, I have been asked to consider, for example, the types of problems encountered in the art, prior solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. Active workers in the field would have had at least an undergraduate or graduate degree in a relevant engineering specialty, as noted above. Depending on the level of education, it would have taken between 1-5 years for a person to become familiar with the problems encountered in the art and to become familiar with the prior and current solutions to those problems.

V. BACKGROUND OF THE '019 PATENT

11. The '019 patent is directed to protective gear systems such as an air filtration system 10 for filtering air and a helmet assembly 12 for use in the air filtration system 10. Ex. 1001 at 2:64-3:10, 5:41-52, Fig. 1. The air filtration

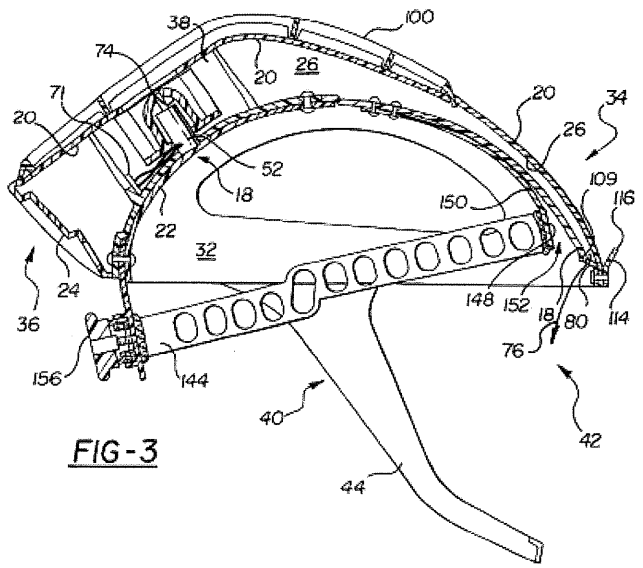


FIG-3

system 10 and helmet assembly 12 may be used in environments requiring the filtering of air between a head and body of a user and an external environment, such as may be required during a surgical procedure or in a clean room. *Id.* at 2:64-3:10.

12. The helmet assembly 12 includes an inner structural shell 18 and an outer structural shell 20. *Id.* at 5:53-61 Figs. 2, 3, 7, 9. The outer structural shell 20 extends from the inner structural shell 18 to define an air flow channel 26 between the inner and outer shells 18 and 20 for channeling air about the head of the user. *Id.* The helmet assembly 12 further includes a base section 32 and a facial section 40 extending from the base section 32 to define a facial opening 42. *Id.* at 6:13-16, 6:31-33.

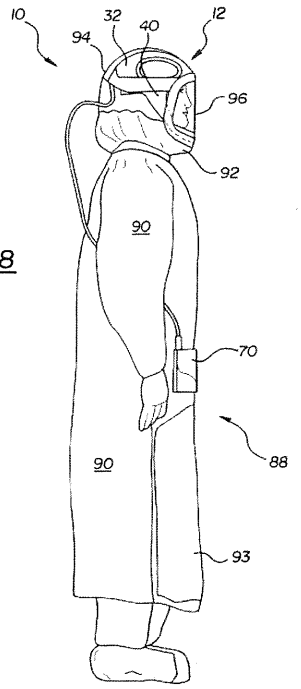


FIG-8

13. The air filtration system 10 includes a gown 88 having a body portion 90 and a head portion

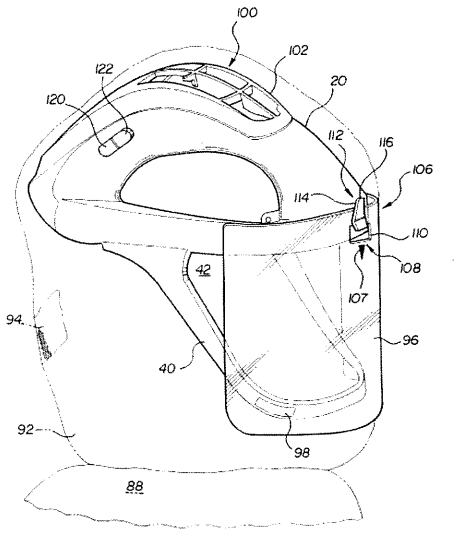
92. *Id.* at 9:17-21, Figs. 8, 9. The body portion 90 covers a portion of the body of the user and the head portion 92 covers the helmet assembly 12. *Id.* A face shield 96 is mounted to the head portion 92 (e.g., sewn into the head portion 92) to cover the facial opening 42, allowing the user to view through the head portion 92. *Id.* at 9:41-52.

14. The interior of the gown 88 is classified as non-sterile while the exterior is classified as sterile. *Id.* at 10:4-15 (describing the user putting on the air filtration system 10 and helmet assembly 12). According to the '019 patent, sterility can be compromised in the conventional protective gear systems if the user "repeatedly adjust[s] the face shield 96 in order to center the face shield 96." *Id.* at 10:16-17. Accordingly, the '019 patent discloses various components for allowing a user to center face shield 96 over the facial opening 42, which has the purported benefit of assisting the user in self-gowning while maintaining sterility. *Id.* at 10:1-12:2, Figs. 3, 9; *see also id.* at 3:64-4:18.

15. For example, as shown in Figures 3 and 9, a pair of first and second visual indicators 107 and 109 may be provided to center the face shield 96 over the facial opening 42. The face shield 96 may include a first visual indicator 107. *Id.* at 11:51-55. Similarly, the base section 32 of the helmet assembly 12 may include a second visual indicator 109 that may or may not be visible to a user in attaching a face shield 96 to the helmet assembly 12. *Id.* at 11:43-45, 11:51-62, 28:46-48,

Figs. 3, 9. The '019 patent discloses that because the second visual indicator 109 can be aligned with the first visual indicator 107, the '019 patent discloses means that allow for centering the face shield 96 over the facial opening 42, thereby assisting the user in self-gowning as the user maintains sterility. *Id.* at 11:63-12:2; *see also id.* at 12:3-10.

FIG-9



16. As also shown in Figure 9, the '019 patent discloses interlocking mounting mechanism 108 and a complementary mounting device 112 that may be provided to center the face shield 96 over the facial opening 42. Mounting mechanism 108 (e.g., aperture 110) is centered on the face shield. *Id.* at 10:28-30. The base section 32 of the helmet assembly 12 may include a corresponding mounting device 112 (e.g., mounting clip 114). *Id.* at 10:24-42, Fig. 9. Because the mounting mechanism 108 and mounting device 112 interlock, the '019 patent discloses means that allow for centering the face shield 96 over the facial opening 42 and assist the user in self-gowning as the user maintains sterility. *Id.* at 10:57-67; *see also id.* at 11:12-42. Further, the interlocked mounting device 112 and mounting mechanism 108 support the gown 88. *Id.* at 11:1-11; *see also id.* at 11:16-24.

VI. CLAIM CONSTRUCTION

17. I understand that in this proceeding, a claim receives the broadest reasonable construction in light of the specification of the patent in which it appears. I also understand that in these proceedings, any term that is not construed should be given its plain and ordinary meaning under the broadest reasonable construction. I have followed these principles in my analysis below.

A. "First Visual Indicator" and "Second Visual Indicator" (Claims 125-129)

18. Claims 125-129 recite the terms "first visual indicator" and "second visual indicator." I understand that Petitioner has taken the position that the first and second visual indicators should encompass mounting mechanisms. I also understand that a second visual indicator should encompass an indicator that is not in the user's field of view while the user is self-gowning. I agree that these constructions are consistent with the '019 patent's disclosure and have used them construction unless otherwise noted.

VII. OVERVIEW OF THE REFERENCES

19. In my opinion, the concepts claimed in the '019 patent were well-known at the time of the alleged invention.

A. *Bare*

20. *Bare* is directed to protective gear systems such as an air filtration system for filtering air and a headgear structure 100 for use in the air filtration system. Ex. 1004 at Abstract, 2:11-32, 2:56-59, Figs. 1-2. The air filtration system and helmet assembly 100 may be used in environments requiring the filtering of air between a head and body of a user and an external environment, such as may be required during a surgical procedure or in a clean room. *Id.* at 2:11-14; *see also id.* at 1:13-17.

21. A shroud 200 is provided as part of the air filtration system to "completely cover the [helmet] structure [100] and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions," as shown in Figure 1. *Id.* at 2:21-26, Fig. 1; *see also id.* at 5:38-50, Fig. 1. The shroud 200's material is made of a filtering medium and the shroud 200 also includes filter devices mounted within it so the air drawn into the shroud 200 from outside can be filtered. *Id.* at 6:1-12, 7:15-21, 8:9-27, 8:31-35, 8:46-55, 10:9-16. A transparent shield 201 is mounted to the shroud 200 and permits the user to view through a head portion of the

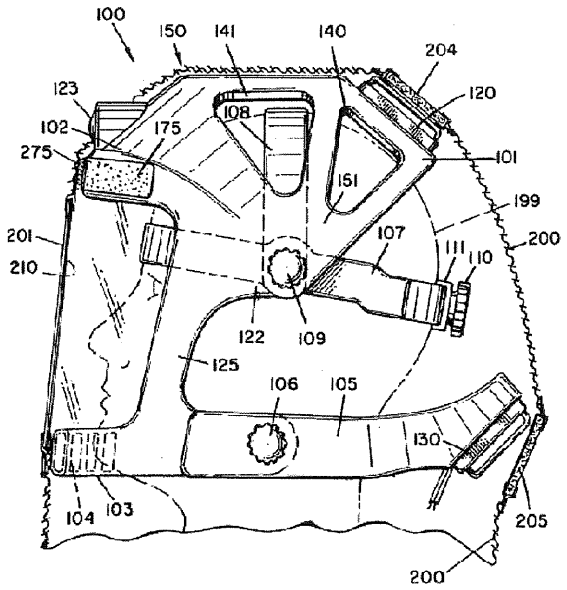


FIG. 1

shroud 200. In some embodiments, *Bare* discloses that transparent shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100. *Id.* at 6:50-68, Fig. 4.

22. *Bare* further discloses connection mechanisms 275 and 175 on the shroud 200 and headgear structure 100, respectively, for allowing a user to align the shroud 200 over the facial opening of the headgear structure 100 in a preferred orientation. *Id.* at 3:4-16. *Bare* teaches that those connection mechanisms can be "appropriate snaps, hook-and-loop fasteners, or the like." *Id.* at 5:38-40. As shown in Figure 1 above, connection mechanisms 175 and 275 allow for the shroud to be properly positioned over the headgear structure 100 and thereby support the transparent shield 201 (attached to the shroud 200) and the shroud 200, including any filtering devices mounted thereon. *See id.* at Fig. 1. Accordingly, the user may use connection mechanisms 175 and 275 to self-gown while maintaining sterility.

B. *Desy*

23. *Desy* is directed to protective headgear devices in environments where there is a risk of debris, chemicals, etc. coming into contact with a user's face. Ex. 1005 at 1:5-30. According to *Desy*, it is desirable to have an interchangeable face shield so that it can be replaced if it is exposed to undesirable material or otherwise rendered impractical for use. *Id.*

24. Therefore, *Desy* discloses the strategic placement of connection mechanisms to automatically align a faceshield with respect to a helmet, while also allowing for easy assembly and disassembly of the faceshield and helmet. *Id.* at 1:7-13, 3:8-32, 365-4:28.

25. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on a crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12 and support the face shield 16 on the headgear 14. *Id.* at 3:60-64, Figs. 1, 7, 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11).

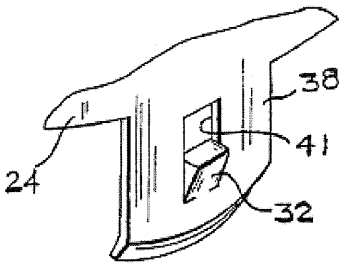


FIG. 7

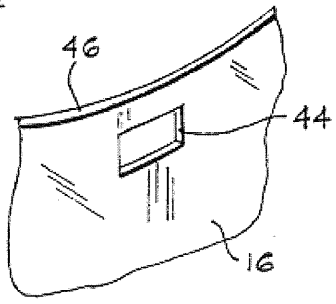


FIG. 7A

C. ***Bjorklund***

26. *Bjorklund* is directed to a surgical gown and method for gowning which allows for self-gowning while maintaining sterility. Ex. 1006 at Abstract, 1:4-35. *Bjorklund* discloses that shrouds are folded inside out such that the user can put on the garment without touching any of the outside sterile surfaces of the

garment to minimize contamination while putting on the shroud. *Id.* at 1:47-2:2, 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15 and 3:48-4:8 (describing the user putting on the garment without touching any of the outside sterile surfaces of the garment to minimize contamination), 3:19-27 (describing that the protective garment "can be put on in the same way as a dress"), 5:18-22, 5:36-6:3, 6:18-23.

D. *Shedrow*

27. *Shedrow* is directed to protective headgear devices in hazardous environments where there is a risk of debris, sparks, or other hazardous materials coming into contact with a user's face. Ex. 1007 at 1:5-16. *Shedrow* discloses the use of visual indicators to align a corrective lens attaching means 10 to a viewing glass G of a protective mask so that "the mask itself locates the eyeglasses with respect to the wearer's eyes." *See id.* at Abstract; *see also id.* at 2:32-37, 3:28-42, Figs. 1, 3, 4. *Shedrow* discloses that there is a

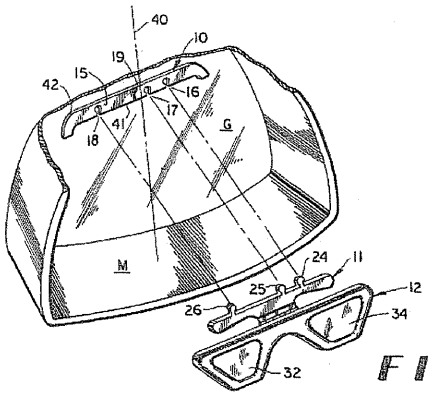


FIG 3

need to allow users to easily and properly align their lenses with a viewing glass. *See id.* at 3:49-58.

28. As shown in Figure 3, indicium 19 on attaching means 10 and vertical centerline 40 on viewing glass G of mask M allow a user to visually align attaching means 10 to glass G. *Id.* at 3:35-42 and Fig. 1. *Shedrow* discloses that indicium 19 is a visual mark on attaching means 10. *See, e.g., id.* at 2:44-52, Fig. 3. *Shedrow* also discloses that vertical centerline 40 is a visual mark on the viewing glass G of mask M. *See, e.g., id.* at 3:31-34, Fig. 3.

VIII. CERTAIN REFERENCES TEACH OR SUGGEST ALL OF THE CLAIMED FEATURES OF CLAIMS 48, 56, AND 125-129 THE '019 PATENT

29. In my opinion, *Bare* and *Desy* or *Bare* and *Desy* in combination with *Bjorklund* teach or suggest the features recited in claims 48, 56, and 125-129 of the '019 patent. Further, in my opinion, *Bare* and *Shedrow* or *Bare* and *Shedrow* in combination with *Bjorklund* teach or suggest the features recited in claims 125-129 of the '019 patent.

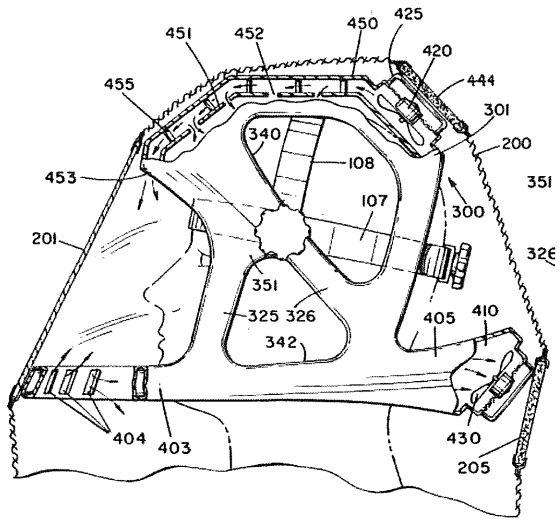
A. Ground 1: *Bare* and *Desy* Teach or Suggest All of the Features of Claims 48, 56, and 125-129

1. Overview of *Bare* and *Desy* and Reasons to Combine

30. As discussed above, *Bare* discloses that connection mechanism 275 is located on an inner surface of shroud 200 and mates with connection mechanism 175 placed under shroud 200 on the upper front portion 102 of headgear structure 100. Figure 1 depicts connection mechanism 275 located above transparent shield 201. As shown in Figure 4, transparent shield 201 may be modified to extend past the upper front portion of the headgear structure.

31. In my opinion, one of skill in the art would have known that modifying transparent shield 201 of Figure 1 to extend past the upper front portion 102 of headgear structure 100, as disclosed in Figure 4, would have been a simple redesign of *Bare's* system given the disclosure of *Bare*. When transparent shield 201 is modified in this way, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to locate connection mechanism 275 on transparent shield 201 to mate with connection mechanism 175 located on the upper front portion of the headgear structure. Since shield 201 is "sewn, taped,

FIG. 4



or otherwise secured" to shroud 200 in *Bare*, either shield 201 or shroud 200 can be mounted to the headgear structure 100 without affecting the function or the ease of assembly of the air filtration system in *Bare*. Ex. 1004 at 5:58-62.

32. *Bare* discloses that its connection mechanisms allow for easy attachment of shield 201 to headgear structure 100 and "operate[] to retain shroud 200 in the preferred orientation . . . ." Ex. 1004 at 3:11-12. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield, while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28.

33. In particular, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure.

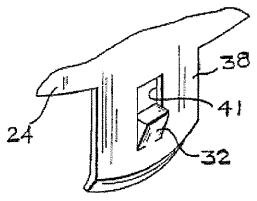


FIG. 7

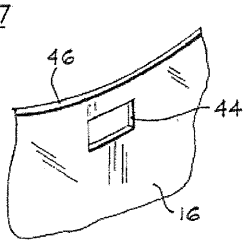


FIG. 7A

34. In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper front portion 102 of headgear structure 100, like the central detent 32 in *Desy*.

35. In my opinion, modifying *Bare* this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* and the results would have been predictable because such a modification to *Bare* would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Modifying *Bare* to centrally locate connection mechanism 275 on shield 200 in light of the teachings of *Desy* would have, in my opinion, been a common sense modification to *Bare's* placement of the connection mechanisms 175 and 275.

36. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip, or Velcro. Ex. 1004 at 3:7-11 (disclosing a

"suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . . , or the like"), 5:38-40 ("As noted, flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop fasteners, or the like."). As discussed above, *Desy* discloses different types of connection mechanisms, for instance a central detent 32 and corresponding rectangular opening 44, suitable for placement on the face shield itself. Ex. 1005 at 3:60-64, Figs. 1, 7, 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13, 6:16-21. Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17.

37. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent and rectangular opening of *Desy* to accomplish the same result of engaging and aligning shield 201 with headgear structure 100. As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. *Id.* at 2:5-17. Doing so, in my opinion, would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102

of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple redesign of *Bare's* system that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare*'s system.

2. Claim 125

38. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 125:

Claim Language	***Bare* and *Desy***
[125.a] A visual positioning system for assisting a single user in self-gowning as the user maintains sterility, said visual positioning system comprising:	*Bare* discloses a headgear structure with a shroud or hood draped over and attached to the structure for use in surgical settings. Ex. 1004 at Abstract, 2:11-26. *Bare* further discloses connection mechanisms 275 and 175 (i.e., visual positioning system) on a shroud 200 and headgear structure 100, respectively. As *Bare* explains, "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102. This mechanism

operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof. A complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175." *Id.* at 3:4-16; *see also id.* at 5:38-40 ("[t]the flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop fasteners, or the like.").

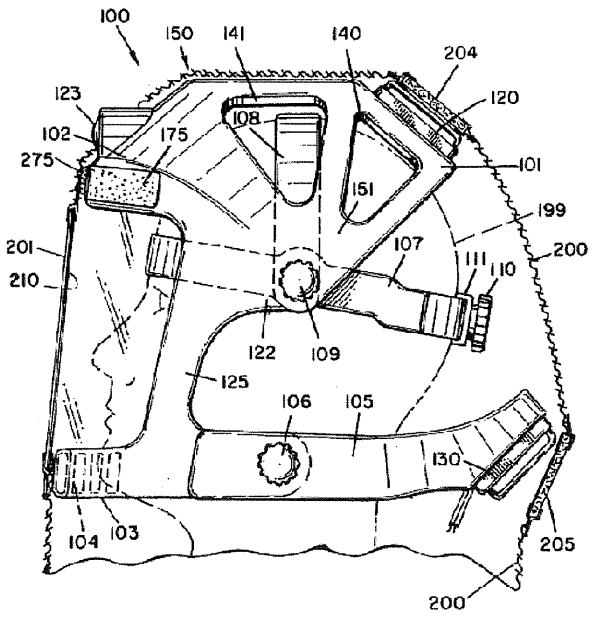


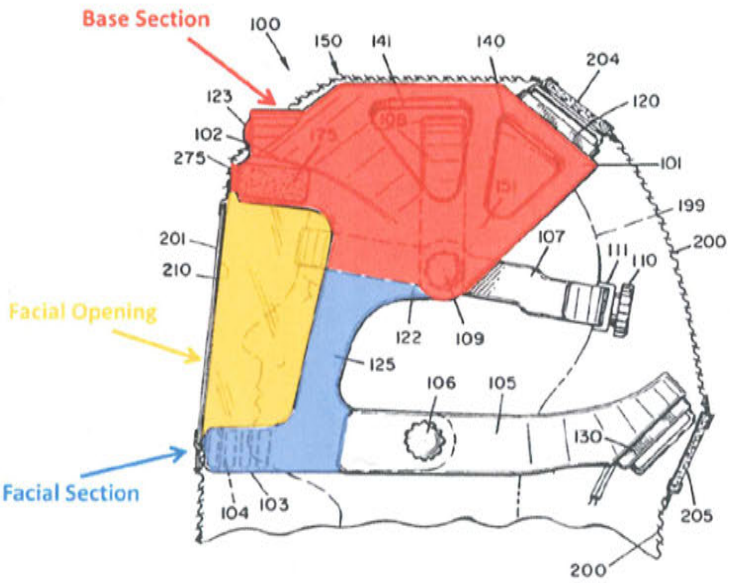
FIG. 1

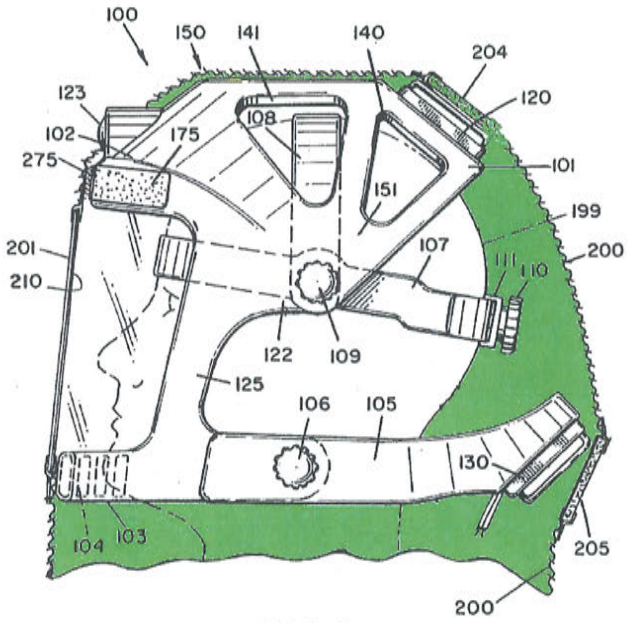
Id. at Fig. 1.

As shown in Figure 1 above, connection mechanisms 175 and 275 are visible and allow for the shroud to be properly positioned over the headgear structure 100. *See id.* at Fig. 1. Given *Bare's* disclosure that connection mechanisms

	175 and 275 are "snaps," a "tacky adhesive strip" or "a hook-and-loop material," in my opinion, a person of skill in the art at the time of the alleged invention would have understood connection mechanisms 175 and 275 to have been visible on shroud 200 and headgear structure 100, as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. In my opinion, a person of ordinary skill in the art would have also known to use "snaps," a "tacky adhesive strip" or "a hook-and-loop material" that would have been visible given that Velcro, for instance, is typically visible to a user. *Bare* further discloses that the "complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175," indicating that connection mechanism 275 would be visible to a wearer in self-gowning. *Id.* at 3:13-16. Indeed, in my opinion, a person of skill in the art at the time of the alleged invention would have understood that the placement of connection mechanism 275 where a wearer could easily access it and see it would assist a wearer in self-gowning. *Bare* also discloses that its shroud and headgear systems are intended "for use in surgical or 'clean room' situations." *Id.* at 1:17-18; *see also id.* at 2:11-14 ("A protective system which is worn by a surgeon during a surgical procedure, a

	technician during an assembly process, a worker during handling of toxic wastes, or the like.") *Bare* discloses a shroud 200 to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.
[125.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base	*Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1 (depicting headgear structure 100 mounted on the head 199 of a user). As shown in Figure 1 below, *Bare* discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section). *Id.* The headgear structure 100 further includes a lower front portion 103 and a strut 125 (i.e.,

section to define a facial opening;	collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58 ("The lower front portion 103 is joined to the upper (or cranial) portion 150 by a suitable strut 125. The front portion 103 is curved to form a support bar adjacent to the front bottom of the wearer's head in the region of the jaw. The lower front portion 103 is adapted to be spaced away from the wearer's face. In addition, the front portion 103 operates to maintain the shroud 200 spaced away from the wearer's face.").  FIG. 1 *Id.* at Fig. 1 (reproduced with annotations).
[125.c] a gown including a body portion for covering at least a portion of	*Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions," as shown in annotated Figure 1

the body of the user and a head portion for covering said base section of said helmet assembly;	below. *Id.* at 2:23-26, Fig. 1. *Bare* discloses a flexible shroud 200 that "is draped over the upper portion 150 and down beyond the rear portion 101 of the headgear 100 to completely envelop the head and shoulders of the wearer. Typically, the shroud extends past the lower surface of the jaw member 103 and the rear support arm 105 and is about 36 inches wide and 30 inches long. Of course, these dimensions are not limitative of the invention." *Id.* at 5:38-50; *see also id.* at Fig. 1 (depicting shroud 200 as including a head portion for covering upper portion 150 of the headgear structure 100).  FIG. 1 *Id.* at Fig. 1 (reproduced with annotations).
[125.d] a face shield	*Bare* discloses a transparent shield 201 (i.e., face shield)

mounted to said head portion of said gown to cover said facial opening thereby permitting the user to view through said head portion of said gown,	that permits the user to view through the head portion of the shroud 200. *Bare* discloses that "[a] substantially planar, transparent shield 201 is included in an opening in shroud 200 and mounted in front of the headgear 100. The shield 201 is mounted to the shroud 200 by means of stitching, tape or suitable fasteners 124. Typically, the shield 201 is fabricated of a thin, optically clear, lightweight sheet of plastic such as PETG film (which can be stamped, molded or the like) as well as radiation sterilized without discoloring. The shield can be sewn, taped, or otherwise secured in the shroud 200. In any event, the transparent shield 201 is curved only slightly around the face of the wearer so that peripheral vision is permitted. However, the curvilinear surface is curved in only one plane, preferably without any compound curvature, and adapted to produce very little visual distortion to the wearer." *Id.* at 5:51–65.
[125.e] said face shield including a first visual indicator on said face shield to enable the user to visually align said face shield with said helmet assembly;	*Bare* discloses a connection mechanism 275 (i.e., first visual indicator) on shroud 200. In particular, *Bare* discloses that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102. This mechanism operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof.

and	A complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175." *Id.* at 3:4-16, 5:38-40. As shown in Figure 1 below, connection mechanisms 175 and 275 are visible and allow for the shroud to be properly positioned in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. Given *Bare's* disclosure, in my opinion, a person of skill in the art would have understood at the time of the alleged invention that a tacky adhesive strip, snaps, or a hook-and-loop material such as Velcro on the inner surface of shroud 200 and headgear structure 100 would have been visible to a user and could have acted as a visual indicator to enable the user to visually align the shield 201 with the headgear structure 100. *Id.* at 3:7-10, 5:38-40, Fig. 1. In my opinion, a person of ordinary skill in the art would have also known to use a tacky adhesive strip, snaps, hook-and-loop material that would have been visible given that Velcro, for instance, is visible to a user. In my opinion, one of skill would have understood that a user would have used connection mechanism 275 as a visual and tactile guide to position shroud 200 and shield 201 in the preferred orientation.

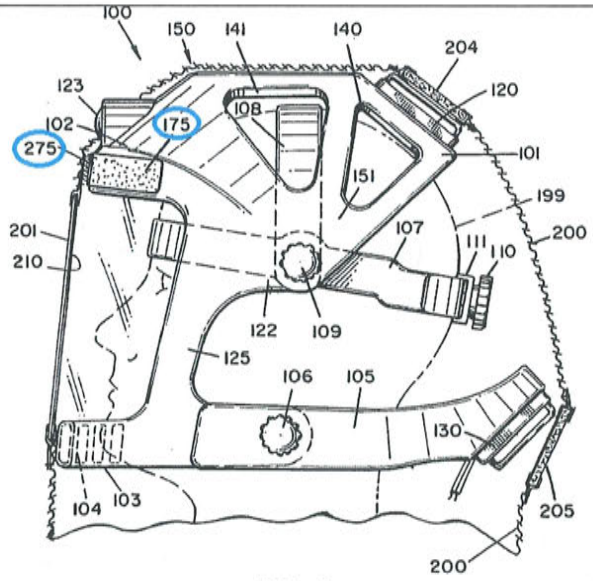
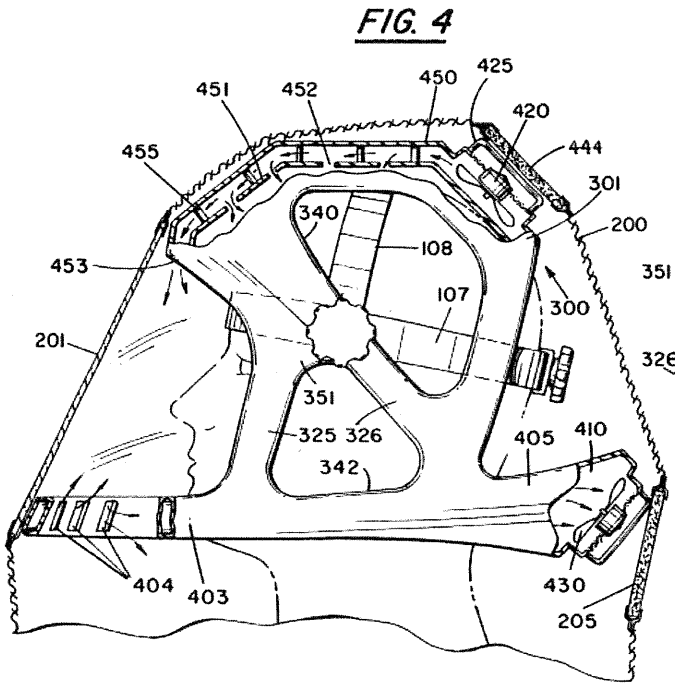


FIG. 1

Id. at Fig. 1 (reproduced with annotations).

Bare discloses that connection mechanism 275 is located on an inner surface of shroud 200 and mates with connection mechanism 175 placed on the surface of the upper front portion 102 of headgear structure 100. Figure 1 depicts connection mechanism 275 located above transparent shield 201. As shown in Figure 4, reproduced below, transparent shield 201 may be modified to extend past the upper front portion of the headgear structure.



Id. at Fig. 4.

In my opinion, one of skill in the art would have known that modifying transparent shield 201 of Figure 1 to extend past the upper front portion 102 of headgear structure 100, as disclosed in Figure 4, would have been a simple redesign of *Bare's* system given the disclosure of *Bare*. When transparent shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to locate connection mechanism 275 on transparent shield 201 to mate with connection mechanism 175 located on the upper front portion of the headgear structure. Since shield 201 is "sewn, taped, or otherwise secured" to shroud 200 in *Bare*,

	in my opinion, either shield 201 or shroud 200 can be mounted to the headgear structure 100 without affecting the assembly of the air filtration system in *Bare*. *Id.* at 5:58-62. As explained above, *Bare* discloses that its connection mechanisms allow for easy attachment of shield 201 to headgear structure 100 and "operate[] to retain shroud 200 in the preferred orientation . . . ." *Id.* at 3:11-12. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield, while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure.

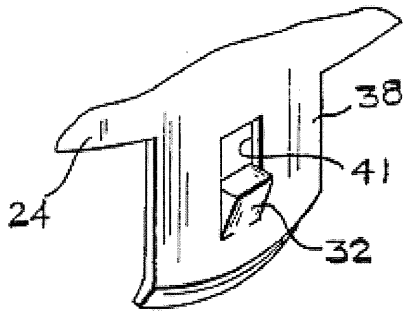


FIG. 7

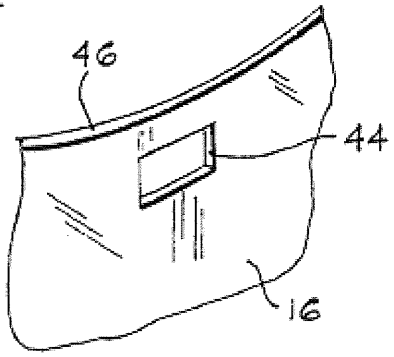


FIG. 7A

Id. at Figs. 7 and 7A.

In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper front portion 102 of headgear structure 100, similar to the central detent 32 in *Desy*.

	In my opinion, modifying *Bare* this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* to yield predictable results, since one of skill in the art would have recognized that providing a longer transparent shield 201 on which connection mechanism 275 is centrally located would have been a simple design choice, would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have centrally located connection mechanism 275 on shield 200. Such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip, or Velcro. Ex. 1004 at 3:7-11 (disclosing a "suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . ., or the like"), 5:38-40. *Desy* similarly discloses different types of connection mechanisms suitable for placement on the face shield itself. For example, *Desy*

	discloses a rectangular opening 44 centrally located on the faceshield 16, the rectangular opening 44 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to attach the faceshield 16 to the crown 12. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11). Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent 32 and rectangular opening 44 of *Desy*, respectively, to achieve a preferred alignment of shield 201 with headgear structure 100. In particular, in my opinion, one of skill in the art would have known to replace connection mechanism 275 with a rectangular opening 44 on the center of elongated shield 201 and connection mechanism 175 with wedge shaped central detent 32 on the corresponding center portion of the upper front portion 102 of headgear structure 100.

	As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. *Id.* at 2:5-17. In my opinion, doing so would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102 of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple redesign of *Bare's* system that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system.
[125.f] said base section of said helmet assembly including a second visual indicator positioned relative to said facial opening for alignment with said first visual	*Bare* discloses a connection mechanism 175 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100. *Bare* teaches that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102." Ex. 1004 at 3:11-13, 5:38-40. As shown in Fig. 1, the connection mechanism 175 is positioned relative to the facial opening in the headgear

indicator on said face shield to automatically center said face shield over said facial opening thereby assisting the single user is self-gowning while maintaining a relative position between said gown and face shield and said helmet assembly a's the user maintains sterility.[1]	structure 100 for alignment with the connection mechanism 275. *Id.* at Fig. 1. Further, as shown in Figure 1 below, connection mechanisms 175 and 275 are visible and allow for shroud 200 to be properly positioned in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. In my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, or hook-and-loop material such as Velcro to have been visible on the shroud and headgear structure 100 as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. In my opinion, a person of ordinary skill in the art would have also known to use snaps, a tacky adhesive strip, or hook-and-loop material that would have been visible given that Velcro, for instance, is typically visible to a user. In my opinion, one of skill would have understood connection mechanisms 175 and 275 would have enabled the user to visually and tactilely align the shield 201 with headgear structure 100. *Id.* at 3:7-10.

[1] I have analyzed claim 125 as if it reads: "as the user maintains sterility" rather than "a's the user maintains sterility," as the claim recites.

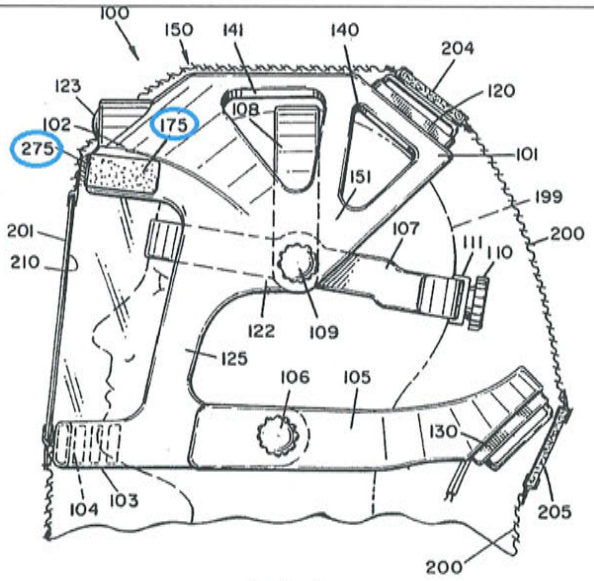
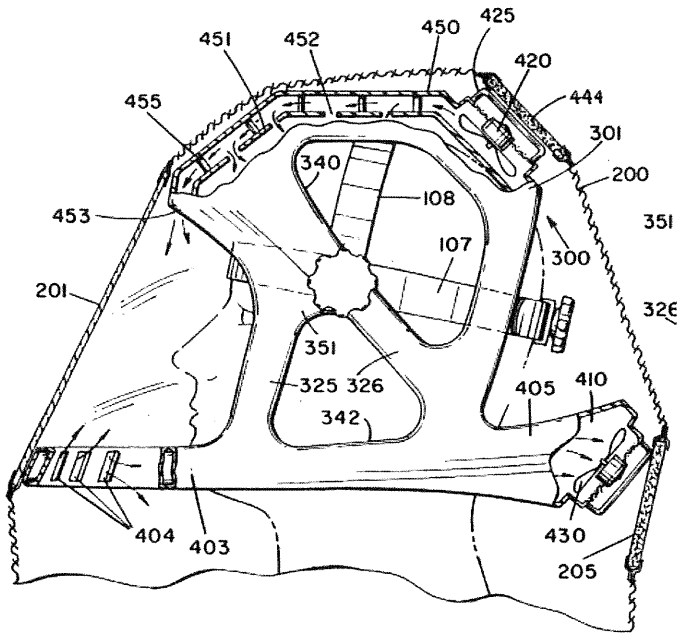


FIG. 1

Id. at Fig. 1 (reproduced with annotations).

Bare discloses that connection mechanism 275 is located on an inner surface of shroud 200 and mates with connection mechanism 175 placed on the surface of the upper front portion 102 of headgear structure 100. Figure 1 depicts connection mechanism 275 located above transparent shield 201.

As discussed above and shown in Figure 4, reproduced below, transparent shield 201 may be modified to extend past the upper front portion of the headgear structure. In my opinion, one of skill in the art would have known that modifying transparent shield 201 of Figure 1 to extend past the upper front portion 102 of headgear structure 100, as

	disclosed in Figure 4, would have been a simple design choice given the disclosure of *Bare*. When transparent shield 201 is modified to extend beyond the upper front portion 102 of the headgear structure 100 of Figure 1, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to locate connection mechanism 275 on transparent shield 201 to mate with connection mechanism 175 located on the upper front portion of the headgear structure. Since shield 201 is "sewn, taped, or otherwise secured" to shroud 200 in *Bare*, in my opinion, either shield 201 or shroud 200 can be mounted to the headgear structure 100 without affecting the assembly of the air filtration system in *Bare*. *Id.* at 5:58-62. FIG. 4  *Id.* at Fig. 4.

	Bare further discloses that connection mechanism 175 "operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. The use of snaps, for example, as taught by Bare, would center the faceshield on the helmet without any need for further adjustment. *Bare* also discloses additional visual indicators such as slot 453 positioned relative to the facial opening and under connection mechanism 175 in a location that is visible to a user wearing the helmet assembly. *Id.* at 7:26-29 ("[S]lot 453 [is] formed between the inner and outer surfaces, spaced near the forehead of the wearer directs air flow across the face of the wearer and the inside of the window."), Fig. 4. Since slot 453 is disposed near the forehead of the wearer at the underside of the headgear structure and in opposition to the connection mechanism 275, in my opinion, a skilled artisan would have understood that the wearer could see the slot 453 and use it for aligning

	connection mechanism 175 with connection mechanism 275 to automatically center the shield 201 over the facial opening. As explained above, *Bare* discloses that its connection mechanisms allow for easy attachment of shield 201 to headgear structure 100 and "operate[] to retain shroud 200 in the preferred orientation . . . ." *Id.* at 3:11-12. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield, while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure.

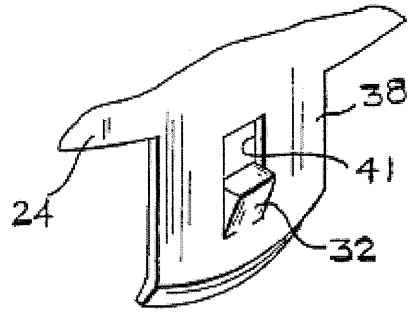


FIG. 7

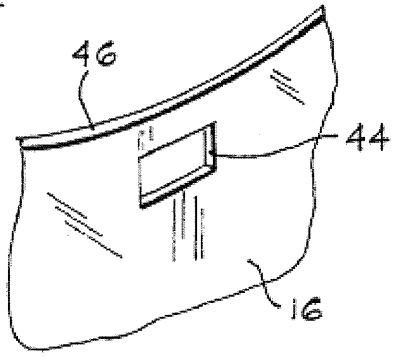


FIG. 7A

Id. at Figs. 7 and 7A.

In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper front portion 102 of headgear structure 100, similar to the central detent 32 in *Desy*.

	Modifying Bare this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* to yield predictable results, since one of skill in the art would have recognized that providing a longer transparent shield 201 on which connection mechanism 275 is centrally located would have been a simple design choice, would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have centrally located connection mechanism 275 on shield 200. In my opinion, such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip or Velcro. Ex. 1004 at 3:7-11 (disclosing a "suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . ., or the like"), 5:38-40. *Desy* similarly discloses different types of connection mechanisms suitable for placement on the face shield itself. For example, *Desy* discloses a rectangular opening 44 centrally located on the

	faceshield 16, the rectangular opening 44 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to attach the faceshield 16 to the crown 12. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent 32 and rectangular opening 44 of *Desy*, respectively, to achieve a preferred alignment of shield 201 with headgear structure 100. In particular, in my opinion, one of skill in the art would have known to replace connection mechanism 275 with a rectangular opening 44 on the center of elongated shield 201 and connection mechanism 175 with wedge shaped central detent 32 on the corresponding center portion of the upper front portion 102 of headgear structure 100.

	As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. *Id.* at 2:5-17. In my opinion, doing so would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102 of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple design choice that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. Further, *Bare* discloses that its "system [] includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the

	structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:21-26. *Bare* also discloses that its shroud and headgear systems are intended "for use in surgical or 'clean room' situations." *Id.* at 1:17-18; *see also id.* at 2:11-14 ("A protective system which is worn by a surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like.") *Bare* discloses a shroud 200 to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

3. Claim 126

39. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 126:

Claim Language	***Bare* and *Desy***
[126] A system as set forth in claim 125 wherein said first visual indicator is centered on said face shield and said second visual indicator is centered on said helmet assembly relative to said facial opening.	*Bare* discloses that the connection mechanism 275 and connection mechanism 175 operate to retain the shroud 200 (including the transparent shield 201) in the "*preferred orientation* and to prevent inadvertent movement thereof." Ex. 1004 at 3:4-16 (emphasis added). Figure 1 further depicts connection mechanism 175 as centered on headgear structure 100. *See id.* at Fig. 1. Given *Bare's* disclosure that connection mechanisms 175 and 275 operate to align shield 210 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that connection mechanisms 175 and 275 would have been centered on headgear structure 100 and shield 201, respectively, to enable proper positioning of transparent shield 201 relative to headgear structure 100. Figure 4 additionally shows that slot 453 (another example of a second visual indicator) is centered on the headgear structure 100. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield,

	while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure. In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper

	front portion 102 of headgear structure 100, similar to the central detent 32 in *Desy*. In my opinion, modifying *Bare* this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* to yield predictable results, since one of skill in the art would have recognized that centering connection mechanism 275 on shield 201 would have been a simple design choice, would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have centrally located connection mechanism 275 on shield 200. In my opinion, such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification of *Bare's* system. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip, or Velcro. Ex. 1004 at 3:7-11 (disclosing a "suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . ., or the like"), 5:38-40. *Desy* similarly discloses different types of connection mechanisms suitable

	for placement on the face shield itself. For example, *Desy* discloses a rectangular opening 44 centrally located on the faceshield 16, the rectangular opening 44 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to attach the faceshield 16 to the crown 12. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent 32 and rectangular opening 44 of *Desy*, respectively, to accomplish the same result of engaging and aligning shield 201 with headgear structure 100. In particular, in my opinion, one of skill in the art would have known to replace connection mechanism 275 with a rectangular opening 44 on the center of elongated shield 201 and connection mechanism 175 with wedge shaped central detent 32 on the corresponding center portion of the

	upper front portion 102 of headgear structure 100. As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. *Id.* at 2:5-17. In my opinion, doing so would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102 of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple redesign of *Bare's* system that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification of *Bare's* system.

4. Claim 127

40. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 127:

Claim Language	*Bare* and *Desy*
[127] A system as set forth in claim 125 wherein said helmet assembly further includes an inner and an outer shell extending between front and rear sections of said base section.	*Bare* discloses the upper portion 150 (i.e., base section) of the headgear structure 100, as shown in Figs. 1-2, can be formed of a hollow duct-like structure to direct airflow around the wearer's head, as shown in Figs. 3-4. Ex. 1004 at 5:12-20 (describing that the duct-like structure for directing airflow in the embodiment of Figs. 1-2 is shown in Figs. 3-4) and Figs. 1-4. The duct-like structure of the upper portion 150 has an inner surface (i.e., inner shell) and an outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) and back portion 101 (i.e., rear section) of the upper portion 150. *Id.* at 7:22-23; see also id. at 2:65-3:3, 3:59-64, 7:15-17, and 7:23-31.

5. Claim 128

41. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 128:

Claim Language	*Bare* and *Desy*
[128] A system as set	*Bare* discloses that its connection mechanism 175 (i.e.,

forth in claim 127 wherein said second visual indicator is disposed on one of said inner and outer shell of said helmet assembly.	second visual indicator) is disposed on the outer surface of the front portion 102 of the upper portion 150 (i.e., outer shell) of the headgear structure 100. *Bare* teaches that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102." Ex. 1004 at 3:7-13, 5:38-40. Figure 4 additionally shows that slot 453 (another example of the second visual indicator) is disposed on the outer surface of the headgear structure 100. As discussed above, in my opinion, one of ordinary skill in the art would also have understood that even if *Bare's* connection mechanism 175 were centrally placed as disclosed in *Desy*, connection mechanism 175 would have remained on the surface of the upper portion 150 of headgear structure 100, similar to central detent 32's placement in *Desy*. As further discussed above, in my opinion, one of ordinary skill in the art would have understood that even if *Bare's* connection mechanism 175 were replaced with *Desy's* central detent 32, the detent would have been disposed on the upper portion 150 (i.e., outer shell) similar to the detent structure's placement in *Desy* on the crown 12 of the helmet 14. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see*

	also id. at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11).

6. Claim 129

42. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 129:

Claim Language	***Bare* and *Desy***
[129.a] A helmet assembly adapted to be utilized with a visual positioning system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26.

[129.b] a base section;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses an upper portion 150 (i.e., base section). *Id.* at 2:56-60, Fig. 1.
[129.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[129.d] said base section including a second visual indicator positioned relative to the facial opening, said second visual indicator of said base section being adapted to align with a first visual indicator of the face shield to automatically center the face shield over	As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 38, *Bare* in combination with *Desy* teaches features such as connection mechanism 175 or slot 453 or central detent 32 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100. *Id.* at 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 38, the transparent shield 201 may include features such as a connection mechanism 275 or rectangular opening 44 (i.e., mounting mechanism) on shroud 200. Ex. 1004 at 3:4-16, 5:38-40, 5:38-40, 5:58-

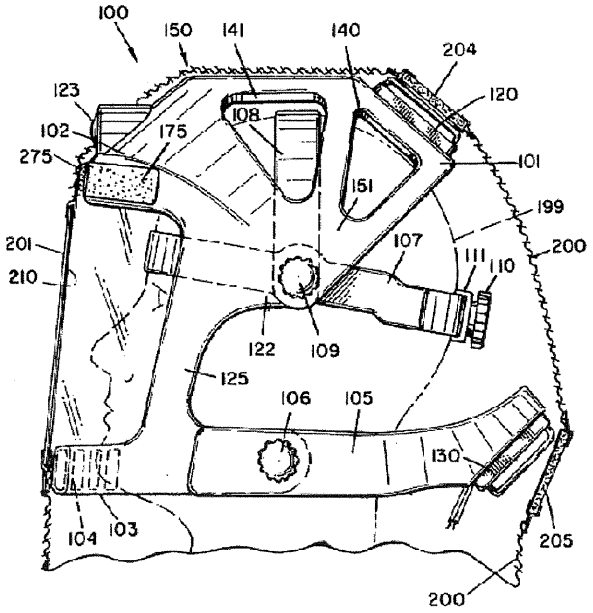
said facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the gown and face shield and said base section as the user maintains sterility.	62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim element [125.f] in paragraph 38, *Bare* further discloses that connection mechanism 175 "operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof." Ex. 1004 at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. As I explained above in connection with claim element [125.f] in paragraph 38, *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. Lastly, as I explained above in connection with claim element [125.f] in paragraph 38, given *Bare's* disclosure

	that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

7. Claim 48

43. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 48:

Claim Language	***Bare* and *Desy***
[48.a] A positioning and supporting system for assisting a single user in self-gowning as the user maintains sterility, said positioning and supporting system comprising:	*Bare* discloses a headgear structure with a shroud or hood draped over and attached to the structure for use in surgical settings. Ex. 1004 at Abstract, 2:11-26. *Bare* further discloses connection mechanisms 275 and 175 (i.e., positioning and supporting system) on a shroud 200 and headgear structure 100, respectively, for assisting a user in self-gowning as the user maintains sterility. As *Bare* explains, "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102. This mechanism operates to retain shroud 200 in the preferred

	orientation and to prevent inadvertent movement thereof. A complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175." *Id.* at 3:4-16; *see also id.* at 5:38-40 ("[t]the flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop fasteners, or the like.").  FIG. 1 *Id.* at Fig. 1. As shown in Figure 1 above, connection mechanisms 175 and 275 allow for the shroud to be properly positioned over the headgear structure 100. *See id.* at Fig. 1. . Given *Bare's* disclosure that its connection mechanisms 175 and 275 are formed of snaps, a tacky adhesive strip, hook-and-loop material, or the like, in my opinion, a person of skill in

	the art at the time of the alleged invention would have understood connection mechanisms 175 and 275 to have supported the shroud 200 on the headgear structure 100 as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. *Bare* also discloses that its shroud and headgear systems are intended "for use in surgical or 'clean room' situations." *Id.* at 1:17-18; *see also id.* at 2:11-14 ("A protective system which is worn by a surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like.") *Bare* discloses a shroud 200 to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

[48.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base section to define a facial opening;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1. As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* also discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section) along with a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58, Fig. 1.
[48.c] a gown including a body portion for covering at least a portion of the body of the user and a head portion for covering said base section of said helmet assembly;	As I explained above in connection with claim element [125.c] in paragraph 38, *Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26, 5:38-50, Fig. 1.
[48.d] a face shield mounted to said head portion of said gown to cover said facial opening thereby	As I explained above in connection with claim element [125.d] in paragraph 38, *Bare* discloses a transparent shield 201 (i.e., face shield) that permits the user to view through the head portion of the shroud 200. *Id.* at 5:51-65, Figs. 1, 4.

permitting the user to view through said head portion of said gown,	
[48.e] said face shield including a mounting mechanism on said face shield to support said face shield on said helmet assembly; and	*Bare* discloses a connection mechanism 275 (i.e., mounting mechanism) on shroud 200. In particular, *Bare* discloses that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102. This mechanism operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof. A complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175." *Id.* at 3:4-16; *see also id.* at 5:38-40 ("[t]the flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop fasteners, or the like."). As shown in Figure 1 below, connection mechanisms 175 and 275 allow for the shroud to be properly positioned in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. Given *Bare's* disclosure, in my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, or hook-and-loop material,

such as Velcro, on the inner surface of shroud 200 and on headgear structure 100 would support the shroud 200 including the transparent shield 201 on the headgear structure 100. *Id.* at 3:7-10, 5:38–40, Fig. 1.

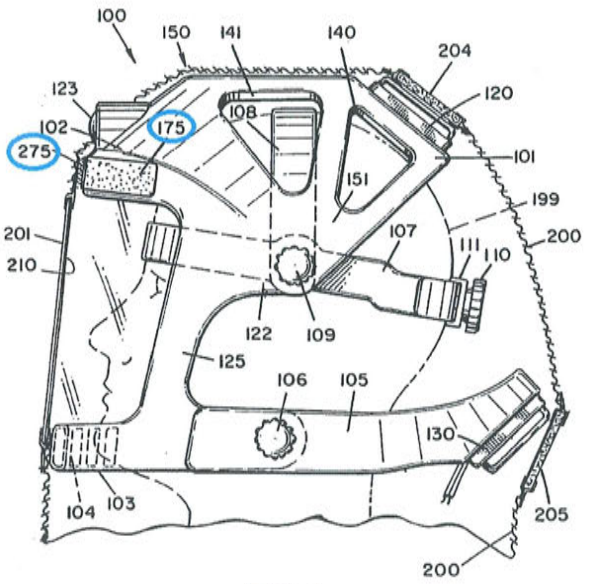
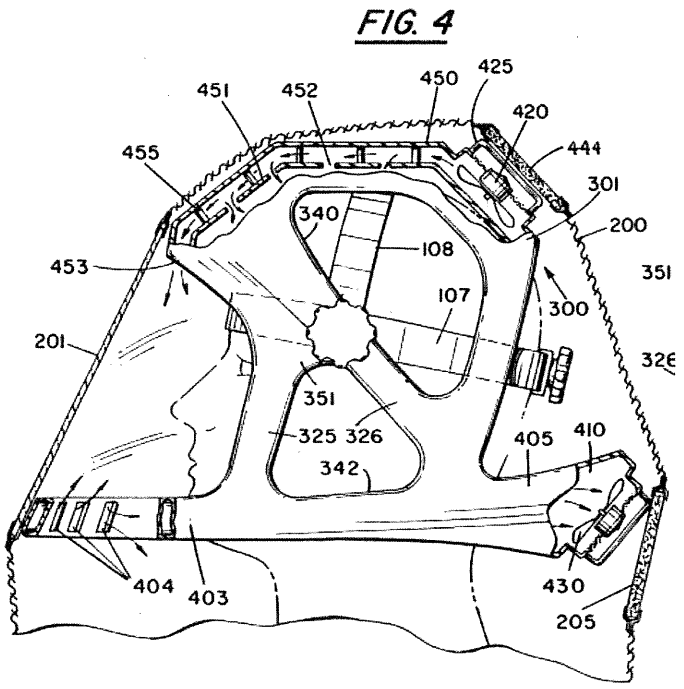


FIG. 1

Id. at Fig. 1 (reproduced with annotations).

Bare discloses that connection mechanism 275 is located on an inner surface of shroud 200 and mates with connection mechanism 175 placed on the surface of the upper front portion 102 of headgear structure 100. Figure 1 depicts connection mechanism 275 located above transparent shield 201. As shown in Figure 4, reproduced below, transparent shield 201 may be modified to extend past the upper front portion of the headgear structure.



Id. at Fig. 4.

In my opinion, one of skill in the art would have known that modifying transparent shield 201 of Figure 1 to extend past the upper front portion 102 of headgear structure 100, as disclosed in Figure 4, would have been a simple redesign of *Bare's* system given the disclosure of *Bare*. When transparent shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to locate connection mechanism 275 on transparent shield 201 to mate with connection mechanism 175 located on the upper front portion of the headgear structure. Since shield 201 is "sewn, taped, or otherwise secured" to shroud 200 in *Bare*,

	in my opinion, either shield 201 or shroud 200 can be mounted to the headgear structure 100 without affecting the assembly of the air filtration system in *Bare*. *Id.* at 5:58-62. As explained above, *Bare* discloses that its connection mechanisms allow for easy attachment of shield 201 to headgear structure 100 and "operate[] to retain shroud 200 in the preferred orientation . . . ." *Id.* at 3:11-12. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield, while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure.

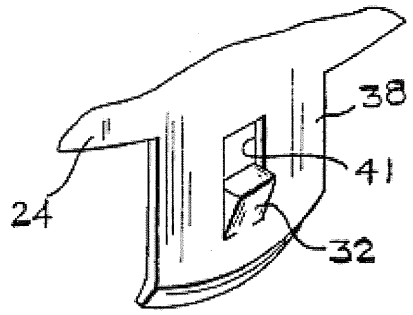


FIG. 7

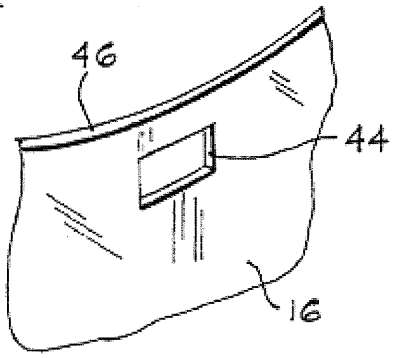


FIG. 7A

Id. at Figs. 7 and 7A.

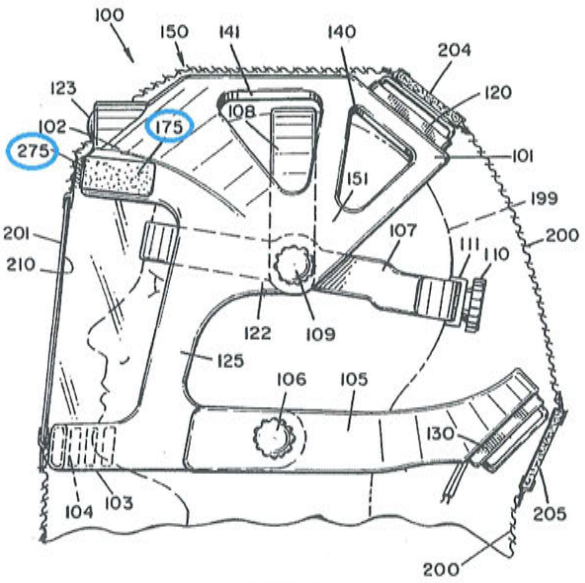
In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper front portion 102 of headgear structure 100, similar to the central detent 32 in *Desy*.

	In my opinion, modifying *Bare* this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* to yield predictable results, since one of skill in the art would have recognized that providing a longer transparent shield 201 on which connection mechanism 275 is centrally located would have been a simple design choice, would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have centrally located connection mechanism 275 on shield 200. In my opinion, such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip or Velcro. Ex. 1004 at 3:7-11 (disclosing a "suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . ., or the like"), 5:38-40 (disclosing that "[t]the flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop

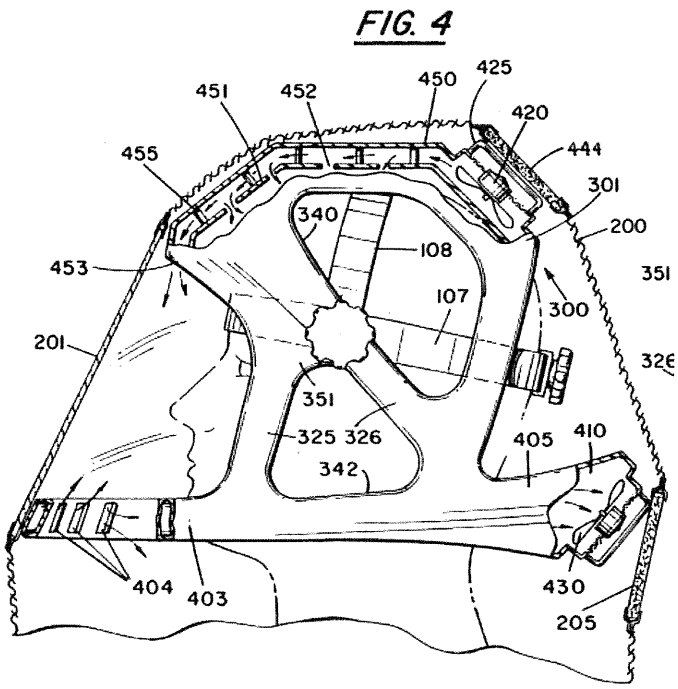
	fasteners, or the like."). *Desy* similarly discloses different types of connection mechanisms suitable for placement on the face shield itself. For example, *Desy* discloses a rectangular opening 44 centrally located on the faceshield 16, the rectangular opening 44 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to attach the faceshield 16 to the crown 12. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent 32 and rectangular opening 44 of *Desy*, respectively, given *Bare's* disclosure that its connection mechanisms need not be limited to snaps, a tacky adhesive strip, or a hook-and-loop fastener. Ex. 1004 at 3:7-10, 5:38–40. In particular, in my opinion, one of skill in the art would have known to replace connection mechanism 275

	with a rectangular opening 44 on the center of elongated shield 201 and connection mechanism 175 with wedge shaped central detent 32 on the corresponding center portion of the upper front portion 102 of headgear structure 100. As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. Ex. 1005 at 2:5-17. Doing so, in my opinion, would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102 of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple redesign of *Bare's* system that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. Further, as shown in Figure 1, connection mechanisms 175 and 275 allow for the shroud to be properly positioned in

	the "preferred orientation and to prevent inadvertent movement thereof." Ex. 1004 at 3:11-13. Given *Bare's* disclosure, in my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, a hook-and-loop material such as Velcro, or the like, on the inner surface of shroud 200 and headgear structure 100 would support the shroud 200 and transparent shield 201 on the headgear structure 100. *Id.* at 3:7-10, 5:38-40, Fig. 1.
[48.f] said base section of said helmet assembly including a mounting device positioned relative to said facial opening, said mounting device interlocking with said mounting mechanism on said face shield to automatically center said face shield over said facial opening and to support said gown and said face	*Bare* discloses a connection mechanism 175 (i.e., mounting device) on the upper front portion 102 of the headgear structure 100. *Bare* teaches that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102." *Id.* at 3:7-11; 5:38-40 ("As noted, flexible shroud 200 can be affixed to the headgear structure 100 by means of appropriate snaps, hook-and-loop fasteners, or the like."). As shown in Fig. 1, the connection mechanism 175 is positioned relative to the facial opening in the headgear structure 100 for interlocking with the connection mechanism 275. *Id.* at Fig. 1. Further, as shown in Figure 1 below, connection mechanisms 175 and 275 allow for shroud 200 to be properly positioned in the "preferred orientation and to

shield thereby assisting the single user in self-gowning while maintaining a relative position between said gown and face shield and said helmet assembly as the user maintains sterility.	prevent inadvertent movement thereof." *Id.* at 3:11-13. In my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, or hook-and-loop material such as Velcro to have supported the shroud 200 and transparent shield 201 as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. In my opinion, one of skill would have understood connection mechanisms 175 and 275 would have enabled the user to align the shield 201 with headgear structure 100. *Id.* at 3:7-10.  FIG. 1 *Id.* at Fig. 1 (reproduced with annotations). *Bare* discloses that connection mechanism 275 is located on an inner surface of shroud 200 and mates with

	connection mechanism 175 placed on the surface of the upper front portion 102 of headgear structure 100. Figure 1 depicts connection mechanism 275 located above transparent shield 201. As discussed above and shown in Figure 4, reproduced below, transparent shield 201 may be modified to extend past the upper front portion of the headgear structure. In my opinion, one of skill in the art would have known that modifying transparent shield 201 of Figure 1 to extend past the upper front portion 102 of headgear structure 100, as disclosed in Figure 4, would have been a simple redesign of *Bare's* system given the disclosure of *Bare*. When transparent shield 201 is modified to extend beyond the upper front portion 102 of the headgear structure 100 of Figure 1, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to locate connection mechanism 275 on transparent shield 201 to mate with connection mechanism 175 located on the upper front portion of the headgear structure. Since shield 201 is "sewn, taped, or otherwise secured" to shroud 200 in *Bare*, in my opinion, either shield 201 or shroud 200 can be mounted to the headgear structure 100 without affecting the assembly of the air filtration system in *Bare*. *Id.* at 5:58-62.



Id. at Fig. 4.

Bare further discloses that connection mechanism 175 "operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. The use of snaps, for example, as taught by *Bare*, would center the faceshield on the helmet without any need for further adjustment.

	As explained above, *Bare* discloses that its connection mechanisms allow for easy attachment of shield 201 to headgear structure 100 and "operate[] to retain shroud 200 in the preferred orientation . . . ." *Id.* at 3:11-12. *Desy* likewise discloses the strategic placement of connection mechanisms to automatically align a faceshield, while also allowing for easy assembly and disassembly of the faceshield and helmet. Ex. 1005 at 1:7-13, 3:8-32, 365-4:28. For example, *Desy* discloses a rectangular opening 44 centrally located on faceshield 16 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to align and attach faceshield 16 to the crown 12. *Id.* at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). In my opinion, one of ordinary skill in the art would have looked to *Desy* for guidance as to the proper placement of *Bare's* connection mechanisms on shield 201 to achieve *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure.

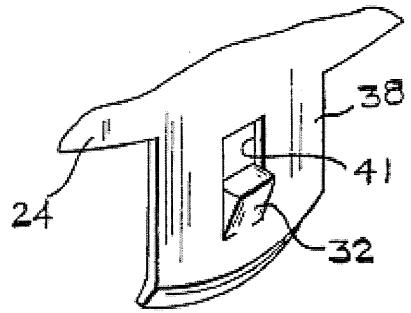


FIG. 7

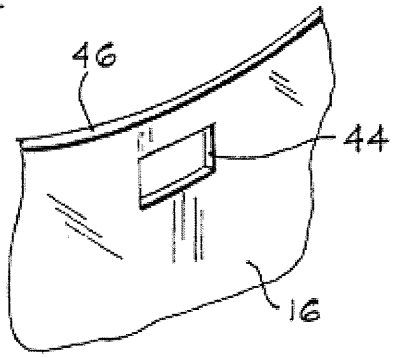


FIG. 7A

Id. at Figs. 7 and 7A.

In light of the disclosures of *Bare* and *Desy*, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have known to centrally dispose connection mechanism 275 on shield 201, similar to the rectangular opening 44 in *Desy*, when shield 201 is modified to extend beyond the upper front portion 102 of headgear structure 100 of Figure 1. Similarly, in my opinion, one of skill in the art would have known to centrally dispose connection mechanism 175 on the upper front portion 102 of headgear structure 100, similar to the central detent 32 in *Desy*.

	In my opinion, modifying *Bare* this way would merely require rearranging *Bare's* connection mechanisms 175 and 275 according to a known technique as disclosed by *Desy* to yield predictable results, since one of skill in the art would have recognized that providing a longer transparent shield 201 on which connection mechanism 275 is centrally located would have been a simple design choice, would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*, and would have furthered *Bare's* stated goal of achieving a preferred orientation of shield 200 with headgear structure 100. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have centrally located connection mechanism 275 on shield 200. In my opinion, such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification to *Bare's* system. *Bare* also discloses that its connection mechanisms need not be limited to snaps, a tacky adhesive strip, or Velcro. Ex. 1004 at 3:7-11 (disclosing a "suitable connection mechanism, such as a tacky adhesive strip, a hook-and-loop material . . ., or the like"), 5:38-40. *Desy* similarly discloses different types of connection mechanisms suitable for placement on the face shield itself. For example, *Desy* discloses a rectangular opening 44 centrally located on the

	faceshield 16, the rectangular opening 44 configured to engage with a wedge-shaped detent structure 32 located at a corresponding central position on the crown 12 of headgear 14 in order to attach the faceshield 16 to the crown 12. Ex. 1005 at 3:60-64, Figs. 1, 7, and 7A; *see also id.* at 4:58-5:4 (claim 1), 6:9-13 ("a central detent . . ."), and 6:16-21 (claim 11). Like the connection mechanisms of *Bare*, the central detent of *Desy* allows for easy assembly and disassembly of the face shield and helmet, but with lower material, manufacturing, and labor costs. *Id.* at 1:7-13, 2:5-17. Accordingly, in my opinion, a person of ordinary skill in the art at the time of the alleged invention would have also known to replace connection mechanisms 175 and 275 located on the modified transparent shield 201 of *Bare* with the central detent of *Desy* to accomplish the same result of engaging and aligning shield 201 with headgear structure 100. In particular, in my opinion, one of skill in the art would have known to replace connection mechanism 275 with a rectangular opening 44 on the center of elongated shield 201 and connection mechanism 175 with wedge shaped central detent 32 on the corresponding center portion of the upper front portion 102 of headgear structure 100.

	As *Desy* teaches, doing so would have decreased material, manufacturing, and labor costs. *Id.* at 2:5-17. In my opinion, oing so would also have been a simple substitution of one known element for another to obtain predictable results. In my opinion, one of skill would have understood that replacing *Bare's* connection mechanisms 175 and 275 with *Desy's* wedge shaped central detent 32 on the upper front portion 102 of headgear structure 100 and rectangular opening 44 on shield 201 of *Bare* would have been a simple redesign of *Bare's* system that would not have affected the functionality of headgear structure 100 and shroud 200 described in *Bare*. In my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that implementing such a modification to *Bare* in light of the teachings of *Desy* would have been a common sense modification of *Bare's* system. *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. Further, *Bare* discloses that its "system [] includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the

	structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:21-26. Lastly, *Bare* also discloses that its shroud and headgear systems are intended "for use in surgical or 'clean room' situations." *Id.* at 1:17-18; *see also id.* at 2:11-14 ("A protective system which is worn by a surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like.") *Bare* discloses a shroud 200 to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

8. Claim 56

44. As described below, the combination of *Bare* and *Desy* teaches or suggests the features of claim 56:

Claim Language	***Bare* and *Desy***
[56.a] A helmet assembly adapted to be utilized with a positioning and supporting system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	As I explained above in connection with claim elements [48.a] and [48.b] in paragraph 43, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., positioning and supporting system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [48.a] in paragraph 43, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26.
[56.b] a base section;	As I explained above in connection with claim element [48.b] in paragraph 43, *Bare* discloses an upper portion 150

	(i.e., base section). *Id.* at 2:56-60, Fig. 1.
[56.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [48.c] in paragraph 43, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[56.d] said base section including a mounting device positioned relative to the facial opening, said mounting device being adapted to interlock with the face shield to automatically center the face shield over said facial opening and to support the gown and the face shield thereby assisting the single user in self-gowning while maintaining a relative position	As I explained above in connection with claim elements [48.e] and [48.f] in paragraph 43, *Bare* in combination with *Desy* teaches features such as connection mechanism 175 or central detent 32 (i.e., mounting device) on the upper front portion 102 of the headgear structure 100. *Id.* at 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim elements [48.e] and [48.f] in paragraph 43, the transparent shield 201 may include features such as a connection mechanism 275 or rectangular opening 44 (i.e., mounting mechanism) on shroud 200. Ex. 1004 at 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim element [48.f] in paragraph 43, *Bare* further discloses that connection mechanism 175 "operates to retain shroud 200

between the gown and face shield and said base section as the user maintains sterility.	in the preferred orientation and to prevent inadvertent movement thereof." Ex. 1004 at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. As I explained above in connection with claim element [48.f] in paragraph 43, connection mechanisms 175 and 275 allow for the shroud to be properly positioned over the headgear structure 100. *See id.* at Fig. 1. Given *Bare's* disclosure that its connection mechanisms 175 and 275 are formed of snaps, a tacky adhesive strip, hook-and-loop material, or the like, in my opinion, a person of skill in the art at the time of the alleged invention would have understood connection mechanisms 175 and 275 to have supported the shroud 200 on the headgear structure 100 as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. As I explained above in connection with claim element [48.f] in paragraph 43, *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond

	the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. Lastly, as I explained above in connection with claim element [48.f] in paragraph 43, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

B. Ground 2: *Bare*, *Desy*, and *Bjorklund* Teach or Suggest All of the Features of Claims 48, 56, and 125-129

1. Overview of *Bare* , *Desy*, and *Bjorklund* and Reasons to Combine

45. *Bare* discloses a need to maintain sterility "in surgical or 'clean room' situations.'" Ex. 1004 at 2:11-14, 1:13-17. Accordingly, *Bare* discloses a headgear structure and shroud 200 with shield 201 that may be easily and readily engaged via connection mechanisms 175 and 275. *Id.* at 3:4-16. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection

mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. As discussed above, *Desy* discloses another type of connection mechanism that allows a user to easily assemble and disassemble a shield with a helmet. *See supra* Section []. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

46. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.*

47. *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object

of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23.

48. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, in my opinion, the

connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect.

49. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility.

2. Claim 125

50. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 125:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[125.a] A visual positioning system for assisting a single user in self-gowning as the user maintains sterility, said visual positioning system comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim

	element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to

	help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my

	opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*
[125.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base section to define a facial opening;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1. As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* also discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section) along with a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.*

	at 3:47-58, Fig. 1.
[125.c] a gown including a body portion for covering at least a portion of the body of the user and a head portion for covering said base section of said helmet assembly;	As I explained above in connection with claim element [125.c] in paragraph 38, *Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26, 5:38-50, Fig. 1.
[125.d] a face shield mounted to said head portion of said gown to cover said facial opening thereby permitting the user to view through said head portion of said gown,	As I explained above in connection with claim element [125.d] in paragraph 38, *Bare* discloses a transparent shield 201 (i.e., face shield) that permits the user to view through the head portion of the shroud 200. *Id.* at 5:51-65, Figs. 1, 4.
[125.e] said face shield including a first visual indicator on said face shield to enable the user to visually align said	As I explained above in connection with claim element [125.e] in paragraph 38, *Bare* in combination with *Desy* teaches a connection mechanism 275 or rectangular opening 44 (i.e., first visual indicator) on the transparent shield 201 to enable the user to visually align the transparent shield 201 with the headgear structure 100. .

face shield with said helmet assembly; and	*Id.* at 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 2:5-17, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A.
[125.f] said base section of said helmet assembly including a second visual indicator positioned relative to said facial opening for alignment with said first visual indicator on said face shield to automatically center said face shield over said facial opening thereby assisting the single user is self-gowning while maintaining a relative position between said gown and face shield and said helmet assembly a's the user	As I explained above in connection with claim element [125.f] in paragraph 38, *Bare* in combination with *Desy* teaches that the upper front portion 101 of the headgear structure 100 may include a connection mechanism 175 or slot 453 or central detent 32 (i.e., second visual indicator) positioned relative to the facial opening for alignment with the connection mechanism 275 or rectangular opening 44 (i.e., first visual indicator) on the transparent shield 201 to automatically center the transparent shield 201 over the facial opening thereby assisting the single user is self-gowning while maintaining a relative position between the shroud 200 and transparent shield 201 and the headgear structure as the user maintains sterility. Ex. 1004 at 2, :11-14, 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. Additionally, in my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or

maintains sterility.	shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to

	thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to

	allow a user to self-gown while maintaining sterility. *Id.*

3. Claim 126

51. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 126:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[126] A system as set forth in claim 125 wherein said first visual indicator is centered on said face shield and said second visual indicator is centered on said helmet assembly relative to said facial opening.	As I explained above in connection with claim 126 in paragraph 39, *Bare* in combination with *Desy* teaches that the connection mechanism 275 or rectangular opening 44 is centered on the transparent shield 201 and the connection mechanism 175 or slot 453 or central detent 32 is centered on the headgear structure 100 relative to the facial opening. Ex. 1004 at 2, :11-14, 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 2:5-17, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A.

4. Claim 127

52. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 127:

Claim Language	***Bare*, *Desy*, and *Bjorklund***

[127] A system as set forth in claim 125 wherein said helmet assembly further includes an inner and an outer shell extending between front and rear sections of said base section.	As I explained above in connection with claim 127 in paragraph 40, *Bare* in combination with *Desy* teaches that the upper portion 150 (i.e., base section) of the headgear structure 100, as shown in Figs. 1-2, can be formed of a hollow duct-like structure to direct airflow around the wearer's head, as shown in Figs. 3-4. Ex. 1004 at 5:12-20 and Figs. 1-4. The duct-like structure of the upper portion 150 has an inner surface (i.e., inner shell) and an outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) and back portion 101 (i.e., rear section) of the upper portion 150. *Id.* at 7:22-23, 2:65-3:3, 3:59-64, 7:15-17, 7:23-31.

5. Claim 128

53. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 128:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[128] A system as set forth in claim 127 wherein said second visual indicator is disposed on one of said inner and outer	As I explained above in connection with claim 128 in paragraph 41, *Bare* in combination with *Desy* teaches that the connection mechanism 175 or slot 453 or central detent 32 is disposed on one of an inner surface (i.e., inner shell) and an outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) and back portion 101

shell of said helmet assembly.	(i.e., rear section) of the upper portion 150. Ex. 1004 at 2:65-3:16, 3:59-64, 5:38-40, 7:15-31; Ex. 1005 at 3:60-64, 4:58-5:4, 6:9-13, 6:16-21, Figs. 1, 7, 7A.

6. Claim 129

54. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 129:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[129.a] A helmet assembly adapted to be utilized with a visual positioning system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a

	manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the

	shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet

	without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect.
[129.b] a base section;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses an upper portion 150 (i.e., base section). *Id.* at 2:56-60, Fig. 1.
[129.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[129.d] said base section including a second visual indicator positioned relative to the facial opening, said second visual indicator of said base section	As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 38, *Bare* in combination with *Desy* teaches features such as connection mechanism 175 or slot 453 or central detent 32 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100. *Id.* at 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A.

being adapted to align with a first visual indicator of the face shield to automatically center the face shield over said facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the gown and face shield and said base section as the user maintains sterility.	As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 38, the transparent shield 201 may include features such as a connection mechanism 275 or rectangular opening 44 (i.e., mounting mechanism) on shroud 200. Ex. 1004 at 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim element [125.f] in paragraph 38, *Bare* further discloses that connection mechanism 175 "operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof." Ex. 1004 at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. As I explained above in connection with claim element [125.f] in paragraph 38, *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond

	the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. Lastly, as I explained above in connection with claim element [125.f] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which

	allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23.

	Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

7. Claim 48

55. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 48:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[48.a] A positioning and supporting system for assisting a single user in self-gowning as the user maintains sterility, said positioning and supporting system comprising:	As I explained above in connection to claim element [48.a] in paragraph 43, *Bare* discloses a headgear structure with a shroud or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., positioning and supporting system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [48.a] in paragraph 43, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method.

	Bjorklund is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into

	the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect.

	In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*
[48.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base section to define a facial opening;	As I explained above in connection with claim element [48.b] in paragraph 43, *Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1. As I explained above in connection with claim element [48.b] in paragraph 43, *Bare* also discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section) along with a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58, Fig. 1.
[48.c] a gown including a body portion for covering at least a portion of the body of the user and a head portion for covering said base section of said helmet assembly;	As I explained above in connection with claim element [48.c] in paragraph 43, *Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26, 5:38-50, Fig. 1.

[48.d] a face shield mounted to said head portion of said gown to cover said facial opening thereby permitting the user to view through said head portion of said gown,	As I explained above in connection with claim element [48.d] in paragraph 43, *Bare* discloses a transparent shield 201 (i.e., face shield) that permits the user to view through the head portion of the shroud 200. *Id.* at 5:51-65, Figs. 1, 4.
[48.e] said face shield including a mounting mechanism on said face shield to support said face shield on said helmet assembly; and	As I explained above in connection with claim element [48.e] in paragraph 43, *Bare* in combination with *Desy* teaches a connection mechanism 275 or rectangular opening 44 (i.e., first visual indicator) on the transparent shield 201 to enable the user to visually align the transparent shield 201 with the headgear structure 100. . *Id.* at 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 2:5-17, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A.
[48.f] said base section of said helmet assembly including a mounting device positioned relative to said facial opening, said mounting device	As I explained above in connection with claim element [48.f] in paragraph 43, *Bare* in combination with *Desy* teaches that the upper front portion 102 of the headgear structure 100 may include a connection mechanism 175 or central detent 32 (i.e., mounting device) positioned relative to the facial opening for alignment with the connection mechanism 275 or rectangular opening 44 (i.e., first visual indicator) on the transparent shield 201 to automatically

interlocking with said mounting mechanism on said face shield to automatically center said face shield over said facial opening and to support said gown and said face shield thereby assisting the single user in self-gowning while maintaining a relative position between said gown and face shield and said helmet assembly as the user maintains sterility.	center the transparent shield 201 over the facial opening and to support said shroud 200 and transparent shield 201 thereby assisting the single user is self-gowning while maintaining a relative position between the shroud 200 and transparent shield 201 and the headgear structure as the user maintains sterility. Ex. 1004 at 2, :11-14, 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. Additionally, in my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35

	("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement

	of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

8. Claim 56

56. As described below, the combination of *Bare*, *Desy*, and *Bjorklund* teaches or suggests the features of claim 56:

Claim Language	***Bare*, *Desy*, and *Bjorklund***
[56.a] A helmet	As I explained above in connection with claim elements

assembly adapted to be utilized with a positioning and supporting system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	[48.a] and [48.b] in paragraph 43, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., positioning and supporting system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [48.a] in paragraph 43, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.*

	Bjorklund discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g.*, *Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the

	waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*
[56.b] a base section;	As I explained above in connection with claim element

	[48.b] in paragraph 43, *Bare* discloses an upper portion 150 (i.e., base section). *Id.* at 2:56-60, Fig. 1.
[56.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [48.c] in paragraph 43, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[56.d] said base section including a mounting device positioned relative to the facial opening, said mounting device being adapted to interlock with the face shield to automatically center the face shield over said facial opening and to support the gown and the face shield thereby assisting the single user in self-gowning	As I explained above in connection with claim elements [48.e] and [48.f] in paragraph 43, *Bare* in combination with *Desy* teaches features such as connection mechanism 175 or central detent 32 (i.e., mounting device) on the upper front portion 102 of the headgear structure 100. *Id.* at 3:4-16, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim elements [48.e] and [48.f] in paragraph 43, the transparent shield 201 may include features such as a connection mechanism 275 or rectangular opening 44 (i.e., mounting mechanism) on shroud 200. Ex. 1004 at 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1005 at 1:7-13, 3:8-32, 3:60-4:28, Figs. 1, 7, 7A. As I explained above in connection with claim element

while maintaining a relative position between the gown and face shield and said base section as the user maintains sterility.	[48.f] in paragraph 43, *Bare* further discloses that connection mechanism 175 "operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof." Ex. 1004 at 3:11-16. Because connection mechanism 175 and 275 operate to align shield 201 and headgear structure 100 in a "preferred orientation," in my opinion, one of ordinary skill in the art would have understood that when connection mechanisms 175 and 275 are properly mated, they would have automatically centered face shield 201 over the facial opening. As I explained above in connection with claim element [48.f] in paragraph 43, connection mechanisms 175 and 275 allow for the shroud to be properly positioned over the headgear structure 100. *See id.* at Fig. 1. Given *Bare's* disclosure that its connection mechanisms 175 and 275 are formed of snaps, a tacky adhesive strip, hook-and-loop material, or the like, in my opinion, a person of skill in the art at the time of the alleged invention would have understood connection mechanisms 175 and 275 to have supported the shroud 200 on the headgear structure 100 as shown in Figure 1. *Id.* at 3:7-10, 5:38-40. As I explained above in connection with claim element [48.f] in paragraph 43, *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet

	assembly. In particular, *Bare* discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." *Id.* at 3:4-7. As I explained above in connection with claim element [48.f] in paragraph 43, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14. Additionally, in my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are

	folded inside out to maintain sterility of the shroud. *See, e.g.*, *Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the

	outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, replacing connection mechanisms 175 and 275 with *Desy's* central detent 32 and rectangular opening 44 would have had the same affect. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

C. Ground 3: *Bare* and *Shedrow* Teach or Suggest All of the Features of Claims 125-129

1. Overview of *Bare* and *Shedrow* and Reasons to Combine

57. *Bare* discloses a headgear structure 100 and shroud 200 with shield 201 to protect a user such as a "surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like." Ex. 1004 at 2:11-14. Connection mechanisms 175 and 275 allow for shroud 200 to be properly positioned over headgear structure 100 in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. *Shedrow*, likewise, discloses a protective mask to protect a user in industry against, for instance, excessive dust, sparks, or metal shavings. *Shedrow* teaches the use of visual indicators to allow a user to easily align a corrective lens attaching means to a viewing glass of a protective mask so that "the mask itself locates the eyeglasses with respect to the wearer's eyes." *See supra* Section []; Ex. 1007 at Abstract. As shown in Figure 3, indicium 19 on attaching means 10 and vertical centerline 40 on viewing glass G of mask M allow a user to visually align attaching means 10 to glass G. *Id.* at 3:35-42, Fig. 1. Accordingly, both *Bare* and *Shedrow* recognize the importance of properly aligning transparent shield 201 and viewing glass G, respectively. Ex. 1004 at 3:11-13, Ex. 1006 at 3:35-42.

58. *Shedrow* discloses that indicium 19 (i.e., visual indicator) is a visual mark at the center of attaching means 10. *See, e.g.*, *id.* at 2:44-52, Fig. 3. *Shedrow* also discloses that vertical centerline 40 (i.e., visual indicator) is a visual mark at the center of the viewing glass G of mask M. *See, e.g.*, *id.* at 3:31-34, Fig. 3. A user aligns central indicium 19 with vertical centerline 40 to properly place attaching means 10 with respect to the glass G of the protective mask M. *Id.* at 3:31-42 ("The lower edge 41 of the attaching means 10 should be aligned with the perpendicular, and the indicium 19 should be aligned with the centerline 40. In this position, the attaching means 10 should be fixed to the glass G by an appropriate adhesive such as an epoxy glue.").

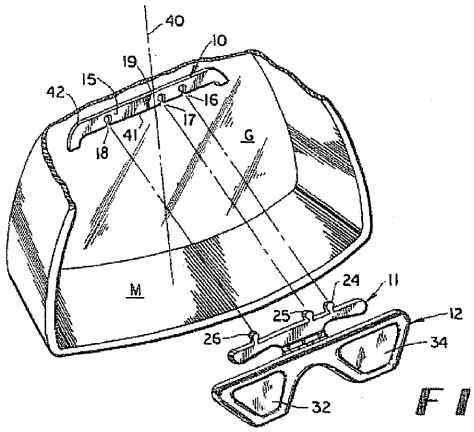


FIG 3

59. In view of *Shedrow's* disclosure of the use of central visual markings for proper alignment, in my opinion, one of ordinary skill in the art would have known to include similar markings on the shield and headgear structure of *Bare.* In particular, in my opinion, one of skill would have known to include features such as a vertical centerline marking on shield 201 of *Bare* at or under connection mechanism 275 like the vertical centerline 40 on the viewing glass G of *Shedrow.* In my opinion, one of skill in the art would have likewise known to include

features such as an indicium on headgear structure 100 of *Bare* at or under connection mechanism 175 like the indicium 19 on the attaching means 10 of *Shedrow*. In my opinion, doing so would have been use of a known technique to improve similar devices in the same way and would not have affected the functionality of the headgear structure 100 and shroud 200 described in *Bare*. Moreover, in my opinion, it would have been a common sense modification of *Bare's* system.

60. In my opinion, one of ordinary skill in the art would have understood that modifying *Bare's* headgear structure and shield to include features such as an indicium and vertical centerline would further *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure and could be used automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning. Ex. 1004 at 3:31-42.

2. Claim 125

61. As described below, the combination of *Bare* and *Shedrow* teaches or suggests the features of claim 125:

Claim Language	***Bare* and *Shedrow***
[125.a] A visual positioning system for assisting a single	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped

user in self-gowning as the user maintains sterility, said visual positioning system comprising:	over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26.
[125.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base section to define a facial opening;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1. As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* also discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section) along with a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at

	3:47-58, Fig. 1.
[125.c] a gown including a body portion for covering at least a portion of the body of the user and a head portion for covering said base section of said helmet assembly;	As I explained above in connection with claim element [125.c] in paragraph 38, *Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26, 5:38-50, Fig. 1.
[125.d] a face shield mounted to said head portion of said gown to cover said facial opening thereby permitting the user to view through said head portion of said gown,	As I explained above in connection with claim element [125.d] in paragraph 38, *Bare* discloses a transparent shield 201 (i.e., face shield) that permits the user to view through the head portion of the shroud 200. *Id.* at 5:51-65, Figs. 1, 4.
[125.e] said face shield including a first visual indicator on said face shield to enable the user to visually align said	*Bare* discloses a connection mechanism 275 (i.e., first visual indicator) on shroud 200. In particular, *Bare* discloses that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102. This mechanism

face shield with said helmet assembly; and	operates to retain shroud 200 in the preferred orientation and to prevent inadvertent movement thereof. A complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175." *Id.* at 3:4-16, 5:38-40. As shown in Figure 1 below, connection mechanisms 175 and 275 are visible and allow for the shroud to be properly positioned in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. Given *Bare's* disclosure, in my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, or a hook-and-loop material such as Velcro on the inner surface of shroud 200 and headgear structure 100 would have acted as a visual indicator to enable the user to visually align the shield 201 with the headgear structure 100. *Id.* at 3:7-10.

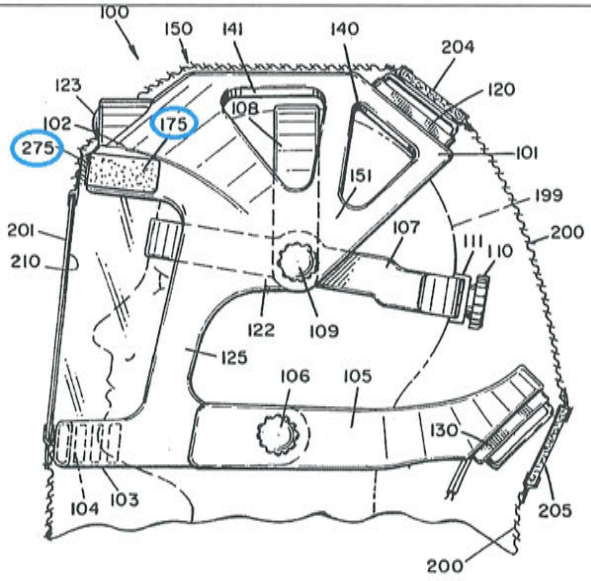
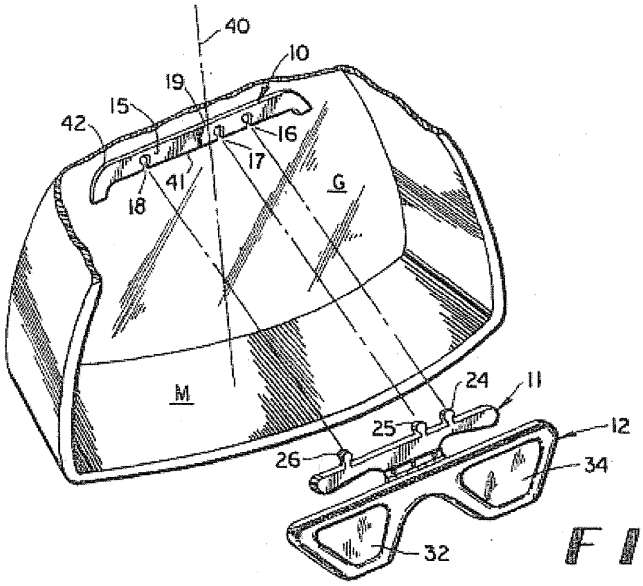


FIG. 1

Id. at Fig. 1 (reproduced with annotations).

Moreover, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have known to modify the headgear structure 100 and shroud 200 of *Bare* to include features such as a visual indicator in view of the teachings of *Shedrow*.

Shedrow discloses the use of visual indicators to align a corrective lens attaching means to a viewing glass of a protective mask so that "the mask itself locates the eyeglasses with respect to the wearer's eyes." *See* Ex. 1007 at Abstract. *Shedrow* teaches that "[t]here are numerous occasions on which it is either desirable or necessary for a person to wear some form of protective mask having a

	substantially transparent window or viewing glass." *Id.* at 1:9-12. *Shedrow* discloses that there is a need to provide a corrective lens attaching means that is properly aligned with the glass so that wearers with corrective lenses may simply align their lenses with the attaching means. *See id.* at 3:49-58. In particular, as shown in Figure 3 below, indicium 19 on attaching means 10 and vertical centerline 40 on viewing glass G of mask M allow a user to visually align attaching means 10 to glass G. *Id.* at 3:35-42 and Fig. 1.  FIG 3 *Id.* at Fig. 3. *Shedrow* discloses that indicium 19 (i.e., visual indicator) is a visual mark on attaching means 10. *See, e.g., id.* at Fig. 1.

	Shedrow discloses that its "attaching means 10 comprises a straight bar 15 having a plurality of notches 16, 17 and 18. There is an indicium 19 to indicate the center of the bar 15 (FIG. 3)." *Id.* at 2:44-52. *Shedrow* also discloses that vertical centerline 40 (i.e., visual indicator) is a visual mark on the viewing glass G of mask M. *See, e.g.*, *id.* at Fig. 1. *Shedrow* teaches that "the viewing glass G of the mask M should be marked with a crayon or the like to indicate the vertical centerline 40; then, a perpendicular should be constructed at the upper portion of the viewing glass G." *Id.* at 3:31-34. *Shedrow* further discloses using indicium 19 and vertical centerline 40 to align the attaching means 10 to the glass G of the protective mask M. In particular, *Shedrow* discloses that "[t]he lower edge 41 of the attaching means 10 should be aligned with the perpendicular, and the indicium 19 should be aligned with the centerline 40. In this position, the attaching means 10 should be fixed to the glass G by an appropriate adhesive such as an epoxy glue." *Id.* at 3:31-42. In view of *Shedrow's* disclosure of the use of visual markings, indicium 19 and vertical centerline 40, to properly align an attachment means 10 to a viewing glass G, in my opinion, one of ordinary skill in the art would have

	known to include similar markings on the shield and headgear structure of *Bare*. In particular, in my opinion, one of skill in the art at the relevant time would have known to include features such as a vertical centerline marking on shield 201 of *Bare* at or under connection mechanism 275. In my opinion, one of skill in the art would have likewise known to include features such as an indicium on headgear structure 100 of *Bare* at or under connection mechanism 175 to further enable visual alignment of the shield with the headgear structure. In my opinion, doing so would have been use of a known technique to improve similar devices in the same way and would not have affected the functionality of the headgear structure 100 and shroud 200 described in *Bare*. In other words, in my opinion, one of ordinary skill in the art would have been capable of applying the known method of enhancing the alignment mechanism disclosed in *Shedrow* to the base device disclosed in *Bare* and the results would have been predictable to one of ordinary skill in the art. Indeed, both *Bare* and *Shedrow* are directed to protective gear technology designed to minimize the wearer's contact with the outside environment. For example, *Bare* discloses "A protective system which is worn by a surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like." Ex.

	1004 at 2:11-20. *See also id.* at 2:21-26 ("The system also includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions."). Similarly, *Shedrow* discloses that "[t]here are numerous occasions on which it is either desirable or necessary for a person to wear some form of protective mask having a substantially transparent window or viewing glass. Such masks are common, for example, in work areas where there is a hazard of excessive dust, sparks or the like as in the grinding of metal, and such masks are very common to enable a person to see clearly under water." Ex. 1007 at 1:9-16. Moreover, both *Bare* and *Shedrow* recognize the importance of properly aligning the transparent shield 201 and viewing glass G, respectively. *Bare* discloses preserving the "preferred orientation" of the headgear structure 100 and shield 201 using the connection mechanisms 175/275 to guide a user. Ex 1004 at 3:4-16. Likewise, *Shedrow* discloses the use of the indicium 19 and other markings on the viewing glass G such as vertical centerline 40 to ensure proper alignment between the viewing glass G, mask M, and the eyeglasses 12. Ex. 1007 at 3:31-42.

	Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that modifying *Bare* in view of *Shedrow* to include *a visual indicator* such as the vertical centerline 40 marking on glass G of *Shedrow* to the shield 201 of *Bare* would have been a common sense modification of *Bare's* system.
[125.f] said base section of said helmet assembly including a second visual indicator positioned relative to said facial opening for alignment with said first visual indicator on said face shield to automatically center said face shield over said facial opening thereby assisting the single user is self-gowning while maintaining a relative position	*Bare* discloses a connection mechanism 175 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100. *Bare* teaches that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102." Ex. 1004 at 3:11-13. As shown in Fig. 1, the connection mechanism 175 is positioned relative to the facial opening in the headgear structure 100. *Id.* at Fig. 1. Further, as shown in Figure 1, the connection mechanisms 175 and 275 are visible and allow for the shroud to be properly positioned in the "preferred orientation and to prevent inadvertent movement thereof." *Id.* at 3:11-13. In my opinion, a person of skill in the art would have understood at the time of the alleged invention that snaps, a tacky adhesive strip, or hook-and-loop material such as Velcro could have been visible on the shroud and headgear

between said gown and face shield and said helmet assembly a's the user maintains sterility.	structure 100 and thus would have enabled the user to visually align the shield 201 with the headgear structure 100. *Id.* at 3:7-10. Moreover, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have known to modify the headgear structure 100 and shroud 200 of *Bare* to include such a visual indicator in view of the teachings of *Shedrow*, as explained above. For example, *Shedrow* discloses the use of visual indicators to align a corrective lens attaching means to a viewing glass of a protective mask so that "the mask itself locates the eyeglasses with respect to the wearer's eyes." *See* Ex. 1007 at Abstract. *Shedrow* teaches that "[t]here are numerous occasions on which it is either desirable or necessary for a person to wear some form of protective mask having a substantially transparent window or viewing glass." *Id.* at 1:9-12. *Shedrow* discloses that there is a need to provide a corrective lens attaching means that is properly aligned with the glass so that wearers with corrective lenses may simply align their lenses with the attaching means. *See id.* at 3:49-58. In particular, as shown in Figure 3 below, indicium 19 on

attaching means 10 and vertical centerline 40 on viewing glass G of mask M allow a user to visually align attaching means 10 to glass G. *Id.* at 3:35-42 and Fig. 1.

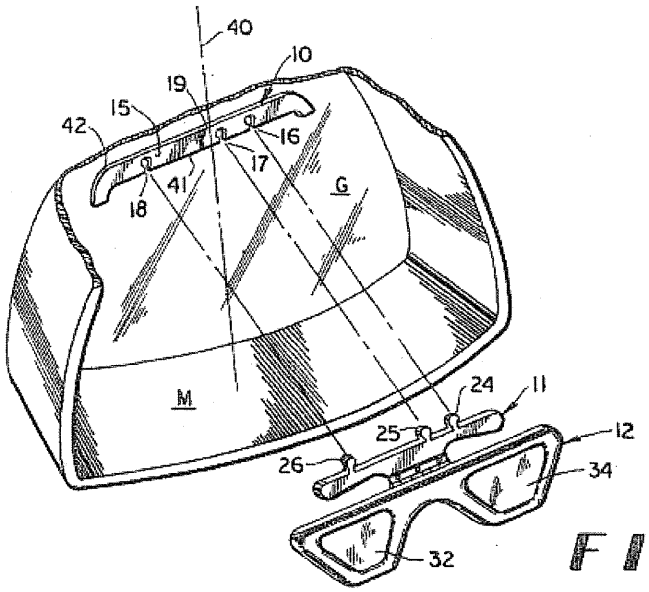


FIG 3

Id. at Fig. 3.

Shedrow discloses that indicium 19 (i.e., visual indicator) is a visual mark on attaching means 10. *See, e.g., id.* at Fig. 1. *Shedrow* discloses that its "attaching means 10 comprises a straight bar 15 having a plurality of notches 16, 17 and 18. There is an indicium 19 to indicate the center of the bar 15 (FIG. 3)." *Id.* at 2:44-52.

Shedrow also discloses that vertical centerline 40 (i.e., visual indicator) is a visual mark on the viewing glass G of mask M. *See, e.g., id.* at Fig. 1. *Shedrow* teaches that "the

	viewing glass G of the mask M should be marked with a crayon or the like to indicate the vertical centerline 40; then, a perpendicular should be constructed at the upper portion of the viewing glass G." *Id.* at 3:31-34. *Shedrow* further discloses using indicium 19 and vertical centerline 40 to align the attaching means 10 to the glass G of the protective mask M. In particular, *Shedrow* discloses that "[t]he lower edge 41 of the attaching means 10 should be aligned with the perpendicular, and the indicium 19 should be aligned with the centerline 40. In this position, the attaching means 10 should be fixed to the glass G by an appropriate adhesive such as an epoxy glue." *Id.* at 3:31-42. In view of *Shedrow's* disclosure of the use of visual markings, indicium 19 and vertical centerline 40, to properly align an attachment means 10 to a viewing glass G, in my opinion, one of ordinary skill in the art would have known to include similar markings on shield 201 and headgear structure 100 of *Bare* to achieve a "preferred orientation" of shield 201 with headgear structure 100, as *Bare* teaches. Ex. 1004 at 3:11-13. In particular, one of skill in the art at the relevant time would have known to include features such as a vertical centerline marking on shield 201 of *Bare* at or under connection mechanism 275. In my opinion, one of skill in the art would have likewise

	known to include features such as an indicium on headgear structure 100 of *Bare* at or under connection mechanism 175. In addition, in my opinion, one of skill in the art at the relevant time would have known to include features such as an indicium on the inner side of the upper portion 150 of the headgear structure 100 of *Bare* at or under connection mechanism 175 to further enable the user to visually align the shield with the headgear structure in light of *Shedrow's* disclosure. For instance, *Shedrow* discloses that both indicium 19 and vertical centerline 40 are visible to the user. In my opinion, modifying *Bare* to include features such as an indicium on the inner side of the upper portion 150 of headgear structure 100 would have been use of a known technique to improve similar devices in the same way and would not have affected the functionality of the headgear structure 100 and shroud 200 described in *Bare*. In other words, in my opinion, one of ordinary skill in the art would have been capable of applying the known method of enhancing the alignment mechanism disclosed in *Shedrow* to the base device disclosed in *Bare* and the results would have been predictable to one of ordinary skill in the art. Indeed, both *Bare* and *Shedrow* are directed to protective gear technology designed to minimize the wearer's contact with the outside environment. For example, *Bare* discloses "A protective system which is worn by a surgeon during a

	surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like." Ex. 1004 at 2:11-20; *see also id.* at 2:21-26 ("The system also includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions."). Similarly, *Shedrow* discloses that "[t]here are numerous occasions on which it is either desirable or necessary for a person to wear some form of protective mask having a substantially transparent window or viewing glass. Such masks are common, for example, in work areas where there is a hazard of excessive dust, sparks or the like as in the grinding of metal, and such masks are very common to enable a person to see clearly under water." Ex. 1007 at 1:9-16. Moreover, both *Bare* and *Shedrow* recognize the importance of properly aligning the transparent shield 201 and viewing glass G, respectively. *Bare* discloses preserving the "preferred orientation" of the headgear structure 100 and shield 201 using the connection mechanisms 175/275 to guide a user. Ex. 1004 at 3:4-16. Likewise, *Shedrow* discloses the use of the indicium 19 and other markings on the viewing glass G such as vertical centerline 40 to ensure proper alignment between the viewing glass G, mask M, and

	the eyeglasses 12. Ex. 1007 at 3:31-42. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that modifying *Bare* in view of *Shedrow* to include *a visual indicator* such as the indicium 19 on attaching means 10 of *Shedrow* to the headgear structure 100 of *Bare* would have been a common sense modification of *Bare's* system. *Shedrow*, as noted above, discloses that "[t]he lower edge 41 of the attaching means 10 should be aligned with the perpendicular, and the indicium 19 should be aligned with the centerline 40. In this position, the attaching means 10 should be fixed to the glass G by an appropriate adhesive such as an epoxy glue." *Id.* at 3:31-42. Since *Shedrow* discloses using indicium 19 and vertical centerline 40 to align the attaching means 10 to the glass G of the protective mask M, in my opinion, one of ordinary skill in the art would have understood that the indicium and vertical centerline, once included on the headgear structure and shield of *Bare*, could be used automatically center the shield 201 over the facial opening, assisting the user in self gowning. *Bare* also discloses maintaining a relative position between the gown, face shield, and helmet assembly. In particular,

	Bare discloses that "[t]he front portion 102 [of the headgear structure 100] extends beyond the face of the wearer so that the shroud 200 (or hood) depends from structure 100 but is spaced away from the wearer's face." Ex. 1004 at 3:4-7. Further, *Bare* discloses that its "system [] includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:21-26. *Bare* further discloses that the "complementary connection mechanism 275 is, typically, provided on the inner surface of the shroud 200 to mate with connection mechanism 175," indicating that connection mechanism 275 would be visible to a wearer in self-gowning. *Id.* at 3:13-16. Indeed, in my opinion, a person of skill in the art at the time of the alleged invention would have understood that the placement of the connection mechanism 275 on the inner surface of shroud 200, where a wearer could easily access it and see it, would assist a wearer in self-gowning. *Bare* also discloses that its shroud and headgear systems are intended "for use in surgical or 'clean room' situations." *Id.* at 1:17-18; *see also id.* at 2:11-14 ("A protective system which is worn by a surgeon during a surgical procedure, a

	technician during an assembly process, a worker during handling of toxic wastes, or the like.") *Bare* discloses a shroud 200 to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions." *Id.* at 2:23-26. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

3. Claim 126

62. As described below, the combination of *Bare* and *Shedrow* teaches or suggests the features of claim 126:

Claim Language	***Bare* and *Shedrow***
[126] A system as set forth in claim 125	*Shedrow* discloses that indicium 19 is centered on attachment means 10 and that vertical centerline 40 is

wherein said first visual indicator is centered on said face shield and said second visual indicator is centered on said helmet assembly relative to said facial opening.	centered on viewing glass G to ensure proper alignment between the viewing glass G, mask M, and the eyeglasses 12. Ex. 1007 at 2:44-52, 3:31-42, 49-58. In view of *Shedrow's* disclosure of the use of visual markings, indicium 19 and vertical centerline 40, to properly align an attachment means 10 to a viewing glass G, in my opinion, one of ordinary skill in the art would have known to include similar markings centered on shield 201 and headgear structure 100 of *Bare* to achieve a "preferred orientation" of shield 201 with headgear structure 100, as *Bare* teaches. Ex. 1004 at 3:11-13. In particular, in my opinion, one of skill in the art at the relevant time would have known to include features such as a vertical centerline marking centered on shield 201 of *Bare* at or under connection mechanism 275. In my opinion, one of skill in the art would have likewise known to include features such as an indicium centered on headgear structure 100 of *Bare* at or under connection mechanism 175. In my opinion, one of skill in the art at the relevant time would have also known to include features such as an indicium centered on the inner side of the upper portion 150 of the headgear structure 100 of *Bare* at or under connection mechanism 175 to further enable the user to visually align the shield with the headgear structure. In my opinion, doing so would have been use of a known technique to improve similar devices in the same

	way and would not have affected the functionality of the headgear structure 100 and shroud 200 described in *Bare*. In other words, in my opinion, one of ordinary skill in the art would have been capable of applying the known method of enhancing the alignment mechanism disclosed in *Shedrow* to the base device disclosed in *Bare* and the results would have been predictable to one of ordinary skill in the art. Indeed, both *Bare* and *Shedrow* are directed to protective gear technology designed to minimize the wearer's contact with the outside environment. For example, *Bare* discloses "A protective system which is worn by a surgeon during a surgical procedure, a technician during an assembly process, a worker during handling of toxic wastes, or the like." Ex. 1004 at 2:11-20; *see also id.* at 2:21-26 ("The system also includes a relatively limp or flaccid fabric-like shroud which is adapted to be attached to or draped over the structure to completely cover the structure and, as well, to cover a portion of the wearer in order to maintain sterile, non-contaminating conditions."). Similarly, *Shedrow* discloses that "[t]here are numerous occasions on which it is either desirable or necessary for a person to wear some form of protective mask having a substantially transparent window or viewing glass. Such masks are common, for example, in work areas where there is a hazard of excessive dust, sparks

	or the like as in the grinding of metal, and such masks are very common to enable a person to see clearly under water." Ex. 1007 at 1:9-16. Moreover, both *Bare* and *Shedrow* recognize the importance of properly aligning the transparent shield 201 and viewing glass G, respectively. *Bare* discloses preserving the "preferred orientation" of the headgear structure 100 and shield 201 using the connection mechanisms 175/275 to guide a user. Ex. 1004 at 3:4-16. Likewise, *Shedrow* discloses the use of the indicium 19 and other markings on the viewing glass G such as vertical centerline 40 to ensure proper alignment between the viewing glass G, mask M, and the eyeglasses 12. Ex. 1007 at 3:31-42. Therefore, in my opinion, one of ordinary skill in the art at the time of the alleged invention would have understood that modifying *Bare* in view of *Shedrow* to include *visual indicators* such as the indicium 19 centered on attaching means 10 and vertical centerline 40 centered on viewing glass G of *Shedrow* to the headgear structure 100 and shield 201 of *Bare* would have been a common sense modification of *Bare's* system.

4. Claim 127

63. As described below, the combination of *Bare* and *Shedrow* teaches or suggests the features of claim 127:

Claim Language	*Bare* and *Shedrow*
[127] A system as set forth in claim 125 wherein said helmet assembly further includes an inner and an outer shell extending between front and rear sections of said base section.	*Bare* discloses the upper portion 150 (i.e., base section) of the headgear structure 100, as shown in Figs. 1-2, can be formed of a hollow duct-like structure to direct airflow around the wearer's head, as shown in Figs. 3-4. Ex. 1004 at 5:12-20 and Figs. 1-4. The duct-like structure of the upper portion 150 has an inner surface (i.e., inner shell) and an outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) and back portion 101 (i.e., rear section) of the upper portion 150. *Id.* at 7:22-23; see also id. at 2:65-3:3, 3:59-64, 7:15-17, and 7:23-31.

5. Claim 128

64. As described below, the combination of *Bare* and *Shedrow* teaches or suggests the features of claim 128:

Claim Language	*Bare* and *Shedrow*
[128] A system as set forth in claim 127 wherein said second visual indicator is	*Bare* discloses that its connection mechanism 175 (i.e., second visual indicator) is disposed on the outer surface (i.e., outer shell) of the front portion 102 of the upper portion 150 of the headgear structure 100. *Bare* teaches

disposed on one of said inner and outer shell of said helmet assembly.	that "a suitable connection mechanism 175, such as a tacky adhesive strip, a hook-and-loop material (such as sold under the Trademark VELCRO), or the like, is placed on the surface of the upper front portion 102." Ex 1004 at 3:7-11. Under the above-described modification of *Bare* in light of *Shedrow* in which features such an indicium is included on headgear structure 100 of *Bare* at or under connection mechanism 175 to further enable visual alignment of the shield with the headgear structure, in my opinion, the skilled artisan would have also known to include features such as an indicium on the inner surface (i.e., inner shell) of the upper portion 150 of the headgear structure 100 of *Bare* at or under connection mechanism 175 to further enable the user to visually align the shield with the headgear structure in light of *Shedrow's* disclosure. For instance, *Shedrow* discloses that both indicium 19 and vertical centerline 40 are visible to the user. In my opinion, modifying *Bare* to include features such as an indicium on the inner surface of the upper portion 150 of headgear structure 100 would have been use of a known technique to improve similar devices in the same way and would not have affected the functionality of the headgear structure 100 and shroud 200 described in *Bare*.

6. Claim 129

65. As described below, the combination of *Bare* and *Shedrow* teaches or suggests the features of claim 129:

Claim Language	*Bare* and *Shedrow*
[129.a] A helmet assembly adapted to be utilized with a visual positioning system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26.
[129.b] a base section;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses an upper portion

	150 (i.e., base section). *Id.* at 2:56-60, Fig. 1.
[129.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[129.d] said base section including a second visual indicator positioned relative to the facial opening, said second visual indicator of said base section being adapted to align with a first visual indicator of the face shield to automatically center the face shield over said facial opening thereby assisting the single user in self-	As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 61, *Bare* in combination with *Shedrow* teaches features such as connection mechanism 175 or indicium 19 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100, the second visual indicator being adapted to align with features such as connection mechanism 275 or vertical centerline 40 on the transparent shield 201 to automatically center the shield 201 over said facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the shroud 200 and shield 201 and the upper front portion of the headgear structure 100 as the user maintains sterility. *Id.* at 2:11-14, 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1007 at Abstract, 1:9-12, 3:35-42, 3:49-58, Figs. 1, 3.

gowning while maintaining a relative position between the gown and face shield and said base section as the user maintains sterility.	

D. Ground 4: *Bare*, *Shedrow*, and *Bjorklund* Teach or Suggest All of the Features of Claims 125-129

1. Overview of *Bare*, *Shedrow*, and *Bjorklund* and Reasons to Combine

66. *Bare* discloses a need to maintain sterility "in surgical or 'clean room' situations.'" Ex. 1004 at 2:11-14, 1:13-17. Accordingly, *Bare* discloses a headgear structure and shroud 200 with shield 201 that may be easily and readily engaged via connection mechanisms 175 and 275. *Id.* at 3:4-16. In my opinion, a person of ordinary skill in the art would have appreciated that because shroud 200 is intended for use in surgical procedures, and because connection mechanism 275 is provided on the inner surface of shroud 200 and easily mates with connection mechanism 175, shroud 200 allows for self-gowning while maintaining sterility. Given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, in my opinion, a skilled

artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 2:11-14.

67. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See Bjorklund* at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.*

68. *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Bjorklund* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Bjorklund* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of

the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their bare hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23.

69. Given *Bjorklund*'s disclosure as to how to self-gown while maintaining sterility and *Bare*'s disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, modifying *Bare*'s headgear structure and shield to include features such as an indicium 19 and

vertical centerline 40 as disclosed by *Shedrow* would have furthered *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure and could be used to automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning.

70. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

71. Given *Bare* and *Shedrow*'s disclosures of connection mechanisms and visual markers that easily allow a user to align a shield with a helmet assembly and *Bare*'s disclosure of the importance of maintaining sterility in a surgical or clean room setting, in my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* and the visual indicium of *Shedrow* to allow a user to self-gown while maintaining sterility. *Id.*

2. Claim 125

72. As described below, the combination of *Bare*, *Shedrow*, and *Bjorklund* teaches or suggests the features of claim 125:

Claim Language	***Bare*, *Shedrow*, and *Bjorklund***
[125.a] A visual positioning system for assisting a single user in self-gowning as the user maintains sterility, said visual positioning system comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the

	alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take

	hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, modifying *Bare*'s headgear structure and shield to include features such as an indicium 19 and vertical centerline 40 as disclosed by *Shedrow* would have furthered *Bare's* stated goal of

	achieving a preferred orientation of the shield and headgear structure and could be used to automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*
[125.b] a helmet assembly adapted to be mounted on a head of the user, said helmet assembly including a base section and a facial section extending from said base section to define a facial opening;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 "which is adapted to be placed over the head of the wearer." *Id.* at 2:56-60, Fig. 1. As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* also discloses that the headgear structure 100 includes an upper portion 150 (i.e., base section) along with a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58, Fig. 1.
[125.c] a gown including a body portion for covering at least a portion of	As I explained above in connection with claim element [125.c] in paragraph 38, *Bare* discloses a shroud 200 (i.e., gown) to "completely cover the [helmet] structure and, as well, to cover a portion of the wearer in order to maintain

the body of the user and a head portion for covering said base section of said helmet assembly;	sterile, non-contaminating conditions." *Id.* at 2:23-26, 5:38-50, Fig. 1.
[125.d] a face shield mounted to said head portion of said gown to cover said facial opening thereby permitting the user to view through said head portion of said gown,	As I explained above in connection with claim element [125.d] in paragraph 38, *Bare* discloses a transparent shield 201 (i.e., face shield) that permits the user to view through the head portion of the shroud 200. *Id.* at 5:51-65, Figs. 1, 4.
[125.e] said face shield including a first visual indicator on said face shield to enable the user to visually align said face shield with said helmet assembly; and	As I explained above in connection with claim element [125.e] in paragraph 61, *Bare* discloses a transparent shield 201 (i.e., face shield) including a connection mechanism 275 or vertical centerline 40 (i.e., first visual indicator) to enable the user to visually align the transparent shield 201 with the headgear structure 100. *Id.* at 3:4-16, 5:38-40, Figs. 1, 4; Ex. 1007 at Abstract, 1:9-12, 3:35-42, 3:49-58, Figs. 1, 3.
[125.f] said base section of said	As I explained above in connection with claim element [125.f] in paragraph 61, *Bare* in combination with *Shedrow*

helmet assembly including a second visual indicator positioned relative to said facial opening for alignment with said first visual indicator on said face shield to automatically center said face shield over said facial opening thereby assisting the single user is self-gowning while maintaining a relative position between said gown and face shield and said helmet assembly a's the user maintains sterility.	teaches that the upper portion 150 (i.e., base section) of the headgear structure 100 includes a connection mechanism 175 or indicium 19 (i.e., second visual indicator) positioned relative to the facial opening for alignment with the connection mechanism 275 or vertical centerline 40 (i.e., first visual indicator) on the transparent shield 201 to automatically center the transparent shield 201 over the facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the shroud 200 and shield 201 and headgear structure 100 as the user maintains sterility. Ex. 1004 at 3:4-16, 5:38-40, Figs. 1, 4; Ex. 1007 at Abstract, 1:9-12, 3:35-42, 3:49-58, Figs. 1, 3. Additionally, in my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded

	protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while

	maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, modifying *Bare*'s headgear structure and shield to include features such as an indicium 19 and vertical centerline 40 as disclosed by *Shedrow* would have furthered *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure and could be used to automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

3. Claim 126

73. As described below, the combination of *Bare*, *Shedrow*, and *Bjorklund* teaches or suggests the features of claim 126:

Claim Language	***Bare* and *Shedrow***
[126] A system as set forth in claim 125 wherein said first visual indicator is centered on said face shield and said second visual indicator is centered on said helmet assembly relative to said facial opening.	As I explained above in connection with claim 126 in paragraph 62, Bare in combination with Shedrow teaches that the connection mechanism 275 or vertical centerline 40 (i.e., first visual indicator) is centered on the transparent shield 201 and the connection mechanism 175 or indicium 19 (i.e., second visual indicator) is centered on the headgear structure 100 relative to the facial opening. Ex. 1004 at 3:4-16, 5:38-40, Figs. 1, 4; Ex. 1007 at 2:44-52, 3:11-13, 3:31-42, 49-58, Figs. 1, 3.

4. Claim 127

74. As described below, the combination of *Bare*, *Shedrow*, and *Bjorklund* teaches or suggests the features of claim 127:

Claim Language	***Bare* and *Shedrow***
[127] A system as set forth in claim 125	As I explained above in connection with claim 127 in paragraph 63, *Bare* discloses the upper portion 150 (i.e.,

wherein said helmet assembly further includes an inner and an outer shell extending between front and rear sections of said base section.	base section) of the headgear structure 100, as shown in Figs. 1-2, can be formed of a hollow duct-like structure to direct airflow around the wearer's head, as shown in Figs. 3-4. Ex. 1004 at 5:12-20 and Figs. 1-4. The duct-like structure of the upper portion 150 has an inner surface (i.e., inner shell) and an outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) and back portion 101 (i.e., rear section) of the upper portion 150. *Id.* at 7:22-23; *see also id.* at 2:65-3:3, 3:59-64, 7:15-17, and 7:23-31.

5. Claim 128

75. As described below, the combination of *Bare*, *Shedrow*, and *Bjorklund* teaches or suggests the features of claim 128:

Claim Language	***Bare* and *Shedrow***
[128] A system as set forth in claim 127 wherein said second visual indicator is disposed on one of said inner and outer shell of said helmet assembly.	As I explained above in connection with claim 128 in paragraph 64, *Bare* in combination with *Shedrow* teaches that the connection mechanism 175 or indicium 19 (i.e., second visual indicator) is disposed on one of the inner surface (i.e., inner shell) and outer surface (i.e., outer shell) extending from the front portion 102 (i.e., front section) of the headgear structure 100 . Ex 1004 at 3:7-11; Ex. 1007 at Abstract, 1:9-12, 3:35-42, 3:49-58, Figs. 1, 3.

6. Claim 129

76. As described below, the combination of *Bare*, *Shedrow*, and *Bjorklund* teaches or suggests the features of claim 129:

Claim Language	***Bare* and *Shedrow***
[129.a] A helmet assembly adapted to be utilized with a visual positioning system having a gown and a face shield wherein said helmet assembly assists a single user in self-gowning as the user maintains sterility, said assembly comprising:	As I explained above in connection with claim elements [125.a] and [125.b] in paragraph 38, *Bare* discloses a headgear structure 100 with a shroud 200 or hood draped over and attached to the structure for use in surgical settings, the headgear structure 100 is adapted to be utilized with connection mechanisms 275 and 175 (i.e., visual positioning system). Ex. 1004 at Abstract, 2:11-26, :4-16, 5:38-40, and 5:51–65. Further, as I explained above in connection with claim element [125.a] in paragraph 38, given *Bare's* disclosure that its system was intended for use in conditions requiring the maintenance of sterility, in my opinion, a skilled artisan would have understood that a surgeon or other user would have known to self-gown or gown with assistance in a manner that ensured sterility. *Id.* at 1:17-18, 2:11-14, 2:23-26. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the

	alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . ."), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user's head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 ("When the user puts the garment on, he can thus take

	hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment."), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund's* disclosure as to how to self-gown while maintaining sterility and *Bare's* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion, one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, modifying *Bare*'s headgear structure and shield to include features such as an indicium 19 and vertical centerline 40 as disclosed by *Shedrow* would have furthered *Bare's* stated goal of

	achieving a preferred orientation of the shield and headgear structure and could be used to automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*
[129.b] a base section;	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses an upper portion 150 (i.e., base section). *Id.* at 2:56-60, Fig. 1.
[129.c] a facial section extending from said base section to define a facial opening for receiving the face shield; and	As I explained above in connection with claim element [125.b] in paragraph 38, *Bare* discloses a lower front portion 103 and a strut 125 (i.e., collectively, the facial section), extending from the upper portion 150 to define a facial opening. *Id.* at 3:47-58. *Id.* at 2:56-60, Fig. 1.
[129.d] said base section including a second visual indicator positioned relative to the facial opening, said second visual indicator of	As I explained above in connection with claim elements [125.e] and [125.f] in paragraph 61, *Bare* in combination with *Shedrow* teaches features such as connection mechanism 175 or indicium 19 (i.e., second visual indicator) on the upper front portion 102 of the headgear structure 100, the second visual indicator being adapted to align with features such as connection mechanism 275 or vertical

said base section being adapted to align with a first visual indicator of the face shield to automatically center the face shield over said facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the gown and face shield and said base section as the user maintains sterility.	centerline 40 on the transparent shield 201 to automatically center the shield 201 over said facial opening thereby assisting the single user in self-gowning while maintaining a relative position between the shroud 200 and shield 201 and the upper front portion of the headgear structure 100 as the user maintains sterility. Ex. 1004 at 2:11-14, 3:4-16, 5:38-40, 5:38-40, 5:58-62, Figs. 1, 4; Ex. 1007 at Abstract, 1:9-12, 3:35-42, 3:49-58, Figs. 1, 3. In my opinion, techniques for self-gowning while maintaining sterility were well-known at the time of the alleged invention. *Bjorklund* discloses one such method. *Bjorklund* is directed to maintaining sterility of a protective garment for use in hospital settings both prior to its use and during gowning. *See* Ex. 1006 at 1:4-8, 1:26-35. In particular, *Bjorklund's* method involves a gown or shroud that is worn by lifting the garment over one's head. *Id.* *Bjorklund* discloses that it was known that the inner surface of a shroud was considered not sterile and that shrouds are folded inside out to maintain sterility of the shroud. *See, e.g., Id.* at 1:47-2:2. *Bjorklund* further discloses a folded protective garment used, e.g., in hospital operations which allows the user to unfold and put on the garment without assistance and while maintaining sterility. *Id.* at 1:4-35 ("An essential disadvantage with the known, folded

	protective gown is thus that it requires an extra person to help the user put the gown on. The object of the present invention is to eliminate this disadvantage . . . .”), 2:2-15. According to *Bjorklund*, a user lifts the shroud from the sterile field by touching only the inner surface of the shroud and then places their arms into the sleeves of the shroud to self-gown without compromising the sterility of the outer surface of the shroud. The shroud can then be eased down over a user’s head and body without a user contacting the outer surface of the shroud with their *Bare* hands. *Id.* at 2:2-15 (“When the user puts the garment on, he can thus take hold of the collar and put his hands into the opening situated at the side edge of the package. The folded garment can then be lifted up with the hands such that the garment folds out, allowing hands and arms to thrust further into it, after which it can be lifted up further and eased down over the head simultaneously as the arms are moved out into its sleeves and it falls down around the waist of the user. All these operations can be carried out without the user's fingers coming into contact with the outside of the garment.”), 3:19-27, 3:48-4:8, 5:18-22, 5:36-6:3, 6:18-23. Given *Bjorklund’s* disclosure as to how to self-gown while maintaining sterility and *Bare’s* disclosure of the placement of connection mechanism 175/275 under shroud 200 and on the inner surface of shroud 200, respectively, in my opinion,

	one of skill in the art would have understood how to self-gown while maintaining sterility—especially given the ease with which connection mechanisms 175 and 275 interlock. For instance, the connection mechanisms would have aided alignment of the face shield with the helmet without repeated adjustment of the face shield, which could otherwise provide an opportunity for the wearer to compromise sterility. In my opinion, modifying *Bare*'s headgear structure and shield to include features such as an indicium 19 and vertical centerline 40 as disclosed by *Shedrow* would have furthered *Bare's* stated goal of achieving a preferred orientation of the shield and headgear structure and could be used to automatically center shield 201 over the facial opening of headgear structure 100, assisting the user in self gowning. In my opinion, one of ordinary skill in the art would have known to use a folding technique and self-gowning method like that disclosed in *Bjorklund* with the shroud of *Bare* to allow a user to self-gown while maintaining sterility. *Id.*

IX. CONCLUSION

77. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: November 25, 2015 By: 

Michael L. Jones

Appendix A

D E S I G N
DEVELOPMENT
& FABRICATION, INC.

Michael Jones
215 Esplanade
San Clemente, CA 92672

Fax: 949 – 429-5706
Tel: 949 – 370-3152
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OBJECTIVE:

Design, Development & Fabrication, Inc. is a full service engineering firm. We provide project management, product design and development as well as fabrication capabilities to companies in the medical device market. We have had extensive experience as outlined below. Additional resources can be gathered from an existing network of engineers and scientists to provide services required for any particular job. We specialize in early phase product and process development. Our goal is to provide additional design resources and speed up the product development cycle. We work very hard to satisfy our customer's demand for schedule and quality. We know that time is money and realize the best recommendation we can have is given by our satisfied customers.

FIELDS OF EXPERTISE:

Product Design and Development
- Defining product requirements
- Customer input/interface
- Scheduling and budgeting
- Design and construction
- Plastic part design

Prototyping
- Prototype mold fabrication
- Plastic and Rubber
- Prototype molding: Thermoplastics, Silicone, Polyurethane

Patent Assessment
- Patent Searches
- Technology Assessment

Material Selection and Processing
- Resorbable Polymers
- Thermoplastics
- Latex Rubber
- Silicone Rubber
- Polyurethanes
- Plastisol

Balloon Development
- Blow Molding
- Molding
- Dipping
- Machinery and Fixturing

Process Development
- Machinery and tooling design and fabrication for production, process or QC

Materials Selection
- Metals, Al, Stainless Steel, Titanium and alloys
- Thermoplastics
- Thermoset polymers

Small Blower Design
- Miniature DC motor selection
- Efficiency optimization
- Impeller design and refinement

Air Filtration and Purification
Optical Packaging Design
Electronic Packaging

CAPABILITIES:

Haas CNC Mills (2)
CNC Lathe (2)
Benchtop CNC Mills (2)
Acra Knee Mill
Tool Room Lathe
Surface Grinder
Prototype Injection Molding
Prototype Sinker EDM
Sheet Metal Fabrication
Microscopes
Laboratory Ovens
Inspection Capabilities
SolidWorks, CamWorks, BobCAD, AutoCAD

EDUCATION:

M.S. California State University, Long Beach, M.S. Engineering, Mechanics and Materials, January, 1995.
Thesis: "Design and Development of a Belt Mounted Powered Air-Purifying Respirator."

B.S. University of California, Berkeley, B.S. Chemical Engineering, May, 1984

PROFESSIONAL EXPERIENCE:

1/08 to Present Salt Creek Medical Device Development, LLC, San Clemente, California
Managing Partner responsible for R&D, manufacturing, facility and financial systems for this medical device incubator. Provide project management and support for project teams on various projects ranging from automated equipment for the In-Vitro Fertilization Laboratory, surgical implants to neurologic counter stimulation devices. Organize and direct project teams composed of project managers, scientists, technicians, mechanical, electrical engineers, chemists, quality and regulatory specialists.

3/97 to Present Design Development and Fabrication, Inc., San Clemente, California
Contract mechanical engineering focusing on product design and development. Projects have included; prototype design of minimally invasive, surgical and implantable devices, development and fabrication for surgical devices, test fixture design and fabrication, process validation in support of PMA filings. Specific tasks have included development of resorbable biopsy site markers, surgical clamp design, optical fiber polishing equipment, opto-mechanical systems, electro-mechanical systems, electronic packaging, production floor tooling, machinery design and fabrication, plastic molded part design, plastic injection mold design, fabrication process development, and material expertise for bioresorbable polymers, plastic and metals. Intellectual property development, patent searches, and expert witness activities for patent infringement disputes. Key clients include: Edwards Lifescience Inc., SenoRx Inc, Vascular Control Systems Inc, Fallbrook Engineering, International Bioview, Micro Therapeutics (now Covidien/Medtronic), Neuroperfusion, and Neurocare Group, Cornerstone Engineering, Indian Wells Medical, and Research Medical.

8/94 to 3/97 Micro Therapeutics, Inc., San Clemente, California
Senior Project Engineer responsible for all Interventional Neuro Radiology product development. Directing product and process development from conception to market introduction for the following products: Implantable materials for embolizing AVMs and aneurysms. Catheter for treatment of thrombo-embolic stroke. Catheter for treatment of subarachnoid hemorrhage. Balloon catheter for treating vascular spasm. Work with leading physicians to define product need and function. Organize and execute extensive animal evaluations of products. Oversee patent applications and utility for neuro product line. Directing the team effort to generate product specifications and move product through the regulatory process and into market introduction. Developed manufacturing process and equipment for fabrication of catheters.

4/92 to 8/94 Applied Medical Resources, Laguna Hills, California
Manager, Urology Product Development responsible for completing the product and process qualification and introduction to market of the ACUCISE electrosurgical balloon catheter. Also responsible for product and process development of Applied Urology ureteral stent product line. Additionally directed product development of Applied Urology endoscopes, generating optical requirements for scopes, coordinating the optical design and mechanical design while integrating onto the manufacturing floor.

9/91 to 4/92 Laparomed Inc., Irvine, California
Project Engineer, responsible for taking laparoscopic surgical products to the production floor. Planned the product build schedule and equipment needs, designed manufacturing equipment and fixtures, completed process development qualification.

8/89 to 9/91 Survivair Inc., Santa Ana, California
Project Engineer responsible for design and development programs for a half-mask air purifying respirator and powered air purifying respirator. Planned the project schedule, capital budget, and preliminary product costing. Performed all design tasks, machined prototype plastic parts to verify performance initiated production tooling and performed qualification testing for both products.

9/86 to 9/89 Baxter Healthcare, Technology and Ventures Division, Irvine, California
Project Engineer responsible for product design and development for implantable drug pump, gallstone dissolution device, urological balloon catheters, and other catheter based products.

11/85 to 9/86 Shiley, Irvine, California
Process Engineer responsible for process improvement on embolectomy catheter, endo tracheal and tracheostomy tube product lines. Additionally was responsible for the transfer of technology from Schneider Medintag to Shiley for angioplasty catheter development and fabrication.

8/84 to 11/85 Mentor Corp, Goleta, California
Manufacturing Engineer responsible for the manufacturing support and manufacturing supervision of breast implants. Implemented process improvements that saved approximately $500,000 annually in scrap and tooling repair costs.

PATENTS:

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"Implantable Drug Pump", US Patent 4,898,585, February 6, 1990
"Angioplasty Catheter System and Method for Making", WO 95/31142, November 23, 1995
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"Cellulose Diacetate Composition for use in Embolizing Blood Vessels", US Patent 5,580,568, December 5, 1996
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"Device and Method for Ablation of Tissue", US Patent 6,112,123, August 29, 2000
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"Methods and Chemical Prep. for Time-Limited Marking of Biopsy Sites", US Patent 6,161,034, Dec 12, 2000
"Electrosurgical Biopsy Device and Method", US Patent 6,261,241, July 17, 2001
"Methods for Occlusion of the Uterine Artery", US Patent 6,254,601, July 3, 2001
"Breast Biopsy System and Method", US Patent 6,331,166, Dec 18, 2001
"Echogenic Coating", US Patent 6,506,156, Jan 14, 2003
"Device and Method for Controlling Injection of Liquid Embolic Composition", US Patent 6,511,468, Jan 28, 2003
"Methods and Apparatus for Securing Medical Instruments to Desire Locations", US Patent 6,540,693, April 1, 2003
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"Method for Non-Permanent Occlusions of a Uterine Artery, US Patent 6,550,482, April 22, 2003
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"Methods and Chemical Prep for Time-limited Marking of Biopsy Sites", US Patent 6,567,689, May 20, 2003
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REFERENCES:

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