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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

BAXTER INTERNATIONAL, INC.,
Patent Owner.

Case IPR2018-01744
Patent 6,852,103

Before BARRY L. GROSSMAN, MICHAEL L. WOODS, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1, 11, 14, 15, 17, 19–28, and 30 of U.S. Patent No. 6,852,103 (Ex. 1001, "the '103 patent"). Patent Owner filed a Preliminary Response. Paper 6 ("Prelim. Resp."). We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). For the reasons stated herein, we determine that Petitioner has not shown a reasonable likelihood of prevailing on its asserted grounds of unpatentability against any challenged claim. Accordingly, we do not institute an *inter partes* review of claims 1, 11, 14, 15, 17, 19–28, and 30 of the '103 patent.

A. Related Matters

Patent Owner is asserting the '103 patent against Petitioner in *Baxter Int'l Inc. v. Becton, Dickinson & Co.*, No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois. *See* Pet. 2; Paper 3, 1. The parties also list two proceedings at the Board as related matters: Case IPR2018-01741, challenging U.S. Patent 5,989,237; and Case IPR2018-01742, challenging U.S. Patent No. 6,159,192. *See id.*

B. The '103 Patent

The '103 patent relates generally to a device for reconstituting powdered drugs into a liquid form to allow the drug to be delivered intravenously. Ex. 1001, 1:14–28. The disclosed device also may be used for diluting liquid drugs. *Id.* at 1:30–36.

The '103 patent explains that to enhance stability, drugs are often stored in a powdered form. *Id.* at 1:20–28. Before powdered drugs can be given intravenously to a patient, they must be placed in liquid form, which is

accomplished by mixing the drug with a diluent such as saline solution. *Id.* The patent refers to the process of placing a powdered drug in liquid form, or further diluting a liquid drug, as "reconstitution." *Id.* at 1:34–37.

A particular feature of the disclosed and claimed device at issue in this proceeding is a color-based visual indicator indicating that the device is in the activated position. Because the color-based visual indicator is integrated into the basic structure of the reconstitution device, we first describe this basic structure, followed by a more specific description of the visual indicator.

Figure 2 of the '103 patent is reproduced below.

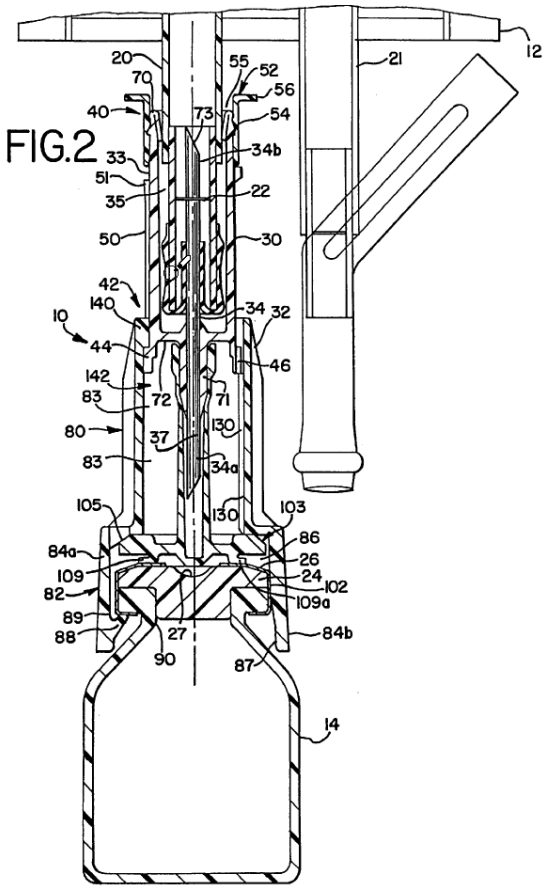
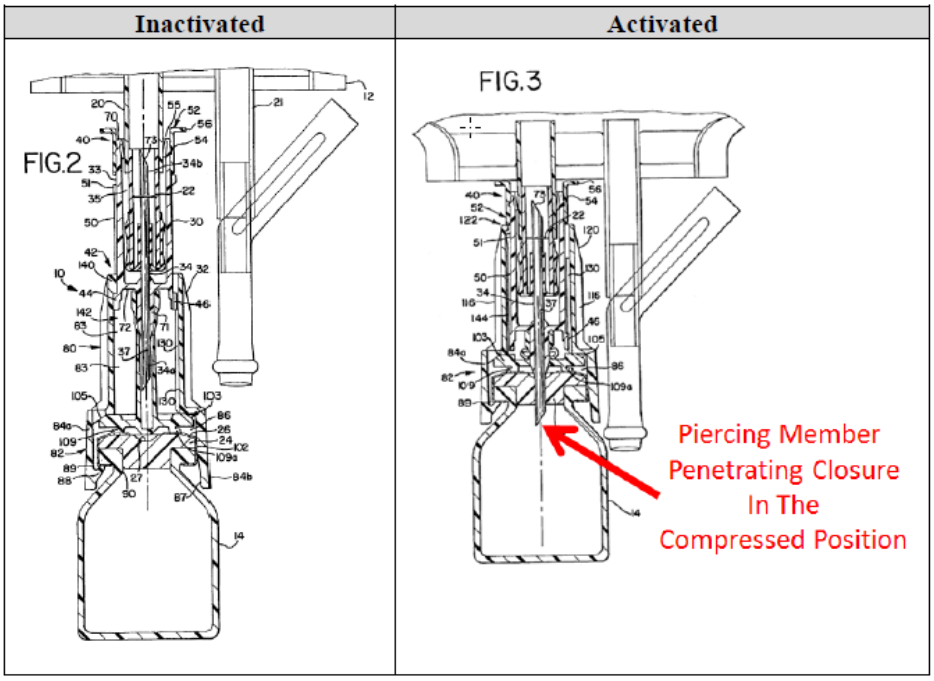


Figure 2 is a cross sectional view of connector device 10 in the inactivated position. *Id.* at 5:30–33.

Figure 2 shows connector 10, first container 12, and second container 14. *Id.* at 6:18–22. First container 12 is a flexible bag that contains a diluent solution. *Id.* It is in fluid communication with second container 14, a vial, containing a drug to be diluted or reconstituted. *Id.*, 6:40–41.

Connector 10 connects to both flexible bag 12 and vial 14 and places the contents of each into fluid communication with one another. *Id.* at 6:53–56. Connector 10 has first and second sleeves 30 and 32, respectively, which can move axially relative to one another from an inactivated position, shown in Figure 2, to an activated position, shown in Figure 3. *Id.* at 6:56–60. In the activated position, piercing member 34 penetrates stopper 24 of vial 14, placing the flow channel of piercing member 34 in communication with the enclosed volume of vial 14. *Id.* at 6:60–65. An annotated comparison of Figures 2 and 3 from Patent Owner's Preliminary Response (*see* Prelim. Resp. 8) is reproduced below.



Annotated comparison of Figures 2 and 3 from the '103 patent illustrating a partial cross section of a reconstitution device docked to a drug vial and parenteral container, shown in the inactivated and activated positions.

Neither party provided colored, annotated drawings of the '103 patent's color-based visual indicator. Thus, we rely on the written description to describe the color-based visual indicator.

The entire disclosure of the color-based visual indicator in the 13 column written description of the '103 patent is limited to two paragraphs, one paragraph in the Summary of the Invention section of the patent (Ex. 1001, 5:15–24), and one paragraph in the Detailed Description section (*id.* at 12:47–58).

The Summary of the Invention section states that portions of first sleeve 30, which are *not visible* when in the activated position, are a different color than portions of first sleeve 30 that *are visible* when in the activated position. *Id.* at 5:17–22. Thus, in the inactivated position, one can see two different colors on sleeve 30. *Id.* at 5:22–24. In the activated

position, however, only one color is visible. *Id.* This first disclosed embodiment uses two different colors on first sleeve 30.

As stated in the Detailed Description, in a preferred form, the connector uses a color coding system wherein the first sleeve member 30 is one color, such as blue, and the second sleeve member 32 is another color, such as white. *Id.* at 12:47–52. Bushing 52 is a different color than first sleeve member 30. *Id.* at 12:52–53. When first sleeve member 30 and second sleeve member 32 are fully in the activated position, the color of first sleeve member 30, in this case blue, will not be visible. *Id.* at 12:53–56. If any color, in this case blue, shows, the medical personnel will immediately know that the device 10 is not fully activated. *Id.* at 12:56–58. This second disclosed embodiment uses different colors on each of first sleeve 30 and second sleeve 32. As discussed below, all the challenged claims recite the structure of this second embodiment. *See*, *id.*, at 14:7–8 ("wherein one of the sleeve members has a first color, the other sleeve member has a second color").

The disclosed reconstitution device also includes a second visual indicator that indicates whether the device is in the locked or unlocked position. *Id.* at 11:12–13, 12:6–11. In a preferred form, when gripping ribs 116 of second sleeve 32 are aligned with locking ribs 50 of first sleeve 30, gripping ribs 116 provide a visual indicator that first and second sleeves 30 and 32 are positioned for axial movement. *Id.* at 11:13–17. To move from the locked position to an unlocked position, first sleeve 30 is rotated with respect to second sleeve 32. *Id.* at 11:65–12:6.

Thus, the disclosed *activation* visual indicator is distinct from the disclosed *locking* visual indicator.

C. Challenged Claims

Petitioner challenges claims 1, 11, 14, 15, 17, 19–28, and 30. Pet. 3. Claim 1, the sole independent claim, is reproduced below, with bold italics added to emphasize the phrase that is the focus of this Decision:

> 1. A connector device for establishing fluid communication between a first container and a second container comprising:
>
> a first sleeve member having a first end and a second end, the first sleeve member adapted to attach to the first container;
>
> a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and movable with respect thereto from an inactivated position to an activated position, the second sleeve member adapted to attach to the second container;
>
> a piercing member having a first and second end projecting from one of the first and second sleeve members and for providing a fluid flow path between the first container and the second container; and,
>
> ***means for visually indicating that the connector is in the activated position comprising a color indication wherein one of the sleeve members has a first color, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position.***

Ex. 1001, 13:56–14:10 (emphasis added).

D. Alleged Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable under 35 U.S.C. § 103(a)[1] based on the following grounds:

	References	Claim(s) Challenged
1.	Gustavsson[2] and Lynn[3]	1, 11, 14, 15, 17, 19
2.	Gustavsson, Lynn, and van de Veerdonk[4]	19–21
3.	Gustavsson, Lynn, and Dudar[5]	22–28, 30
4.	Zdeb[6] and Lynn	1, 11, 14, 15, 17
5.	Zdeb, Lynn, and van de Veerdonk	19–21
6.	Zdeb, Lynn, and Dudar	22–28, 30

See Pet. 19. Petitioner also relies on the Declaration testimony of James L. Sertic. Ex. 1005.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2012. The changes to 35 U.S.C. §§ 102 and 103 in the AIA do not apply to any application filed before March 16, 2013. Because the application for the patent at issue in this proceeding has an effective filing date before either of these dates, we refer to the pre-AIA version of the statute.
[2] US 4,564,054, issued Jan. 14, 1986 (Ex. 1007).
[3] U.S. 4,946,445, issued Aug. 7, 1990 (Ex. 1008).
[4] U.S. 3,995,630, issued Dec. 7, 1976 (Ex. 1009).
[5] U.S. 5,100,394, issued Mar. 31, 1992 (Ex. 1010).
[6] U.S. 4,898,209, issued Feb. 6, 1990 (Ex. 1011).

1350, 1355 (Fed. Cir. 2001) ("the level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention").

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art: (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id*. Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007).

Petitioner asserts that an ordinarily skilled artisan at the time of the invention of the '103 patent would have had "at least a bachelor's of science in mechanical engineering, or a related field, and at least five years of work experience in device design, including medical device design and experience in plastic part design including plastic molding limitations and polymer material properties." Pet. 10 (citing Ex. 1005 ¶ 17). Mr. Sertic, Petitioner's

declarant, testifies that he has been retained "as a technical expert." Ex. 1005 ¶ 1. Mr. Sertic repeats Petitioner's argued level of skill "[b]ased on [his] experience in the field." *Id.* ¶ 17. Neither Petitioner nor Mr. Sertic considered the factors that provide a guide to determining the level of ordinary skill in the art. Mr. Sertic does not provide the underlying facts or data on which his opinion is based. 37 C.F.R. § 42.65(a). Accordingly, his testimony on this issue is entitled to little weight.

Patent Owner's proposed level of ordinary skill in the art is: "(1) a bachelor's of science degree in mechanical engineering or a related field, and (2) at least five years of work experience in medical device design, including in plastic part design," but "an individual with an advanced degree in a related field would require less industry experience." Prelim. Resp. 5 (citing Ex. 2001 ¶¶ 12–13). Exhibit 2001 is the Declaration testimony of John Booras. We have not been directed to any assertion that Mr. Booras has been offered as an expert in this case. Neither Patent Owner nor Mr. Booras considered the typical factors that provide a guide to determining the level of ordinary skill in the art.

The parties' proposals are very similar, reasonably based on the patent and prior art in this proceeding, and any differences do not affect our analysis in this Decision. For purposes of this Decision, we adopt Patent Owner's proposal because we agree that an advanced degree can substitute for industry experience.

B. Claim Construction

Petitioner asserts that the '103 patent expired on December 4, 2017. Pet. 10. Patent Owner does not comment on the expiration of the patent. The '103 patent was filed on January 16, 2003, claiming priority of

December 4, 1997, based on two continuation applications. Ex. 1001, [63]. We agree with Petitioner; the '103 patent is expired.

Because the challenged claims are expired, we construe the claims in accordance with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279 (Fed. Cir. 2017) ("The Board construes claims of an expired patent in accordance with *Phillips*.").

Under the *Phillips* standard, words of a claim are generally given their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312 ("the words of a claim are generally given their ordinary and customary meaning") (citations and internal quote marks omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Id*.

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

1. "Means for Visually Indicating"

A color-based visual indicator, indicating that the claimed connector device is in the activated position, is fundamental to the issues argued by the parties. With respect to this indicator, claim 1 recites:

> ***means for visually indicating that the connector is in the activated position*** comprising a color indication wherein one of the sleeve members has a first color, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position.

Ex. 1001, 14:5–10 (emphasis added) (the "activated indicator clause").

Petitioner asserts that the activated indicator clause is *not* a "means-plus-function element, and is instead structural." Pet. 11 (citing *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008)).

Patent Owner does not dispute Petitioner's proposed construction. Prelim. Resp. 11.

Claim construction is a question of law. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346 (Fed. Cir. 2015) (en banc). Use of the word "means" in a patent claim, as in the activation indicator clause, creates a presumption that 35 U.S.C. § 112, ¶ 6 applies. *Id.* at 1349. "If, in addition to the word 'means' and the functional language, the claim recites sufficient structure for performing the described functions in their entirety, the presumption of § 112 ¶ 6 is overcome—the limitation is not a means-plus-function limitation." *TriMed*, 514 F.3d at 1259. "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *Id.* at 1259–60.

The activated indicator clause in the '103 patent clearly uses the word "means" ("means for visually indicating . . ."). Thus, there is a presumption that 35 U.S.C. § 112, ¶ 6 applies to this clause. It also recites, however, the following structure: "wherein one of the sleeve members has a first color, the other sleeve member has a second color, wherein only one color is

visible when the connector is in the activated position." Ex. 1001, 14:7–10. We determine that the quoted claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure. *See id.* at 12:47–58.

Accordingly, we agree with Petitioner that the activated indicator clause is *not* a means-plus-function element; it recites specific structural elements that perform the function of "visually indicating that the connector is in the activated position."

2. Other Terms

Petitioner also proposes specific construction of several other claim terms. Pet. 11–18. For purposes of its Preliminary Response, Patent Owner asserts that construction of these other claim terms is "irrelevant to Patent Owner's arguments." Prelim. Resp. 11.

We determine that an explicit construction of the other claim terms proposed by Petitioner is not necessary for the purposes of determining whether there is a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the Petition.

C. Legal Standards of Obviousness

Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR*, 550 U.S. at 406. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences

between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, evidence such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls."). The Court in *Graham* explained that these factual inquiries promote "uniformity and definiteness," for "[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." 383 U.S. at 18.

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id*. at 417. To reach this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc*., 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id*.; *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273 (Fed. Cir. 2018) ("The question is not whether the various references separately taught components of the '330 Patent formulation, but whether the prior art suggested the selection and combination achieved by the '330 inventors.").

In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason *why* a person of skill in the art would have made the combination. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017).

"A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect." *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

As a factfinder, we also must be aware "of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR*, 550 U.S. at 421. This does not deny us, however, "recourse to common sense" or to that which the prior art teaches. *Id*.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

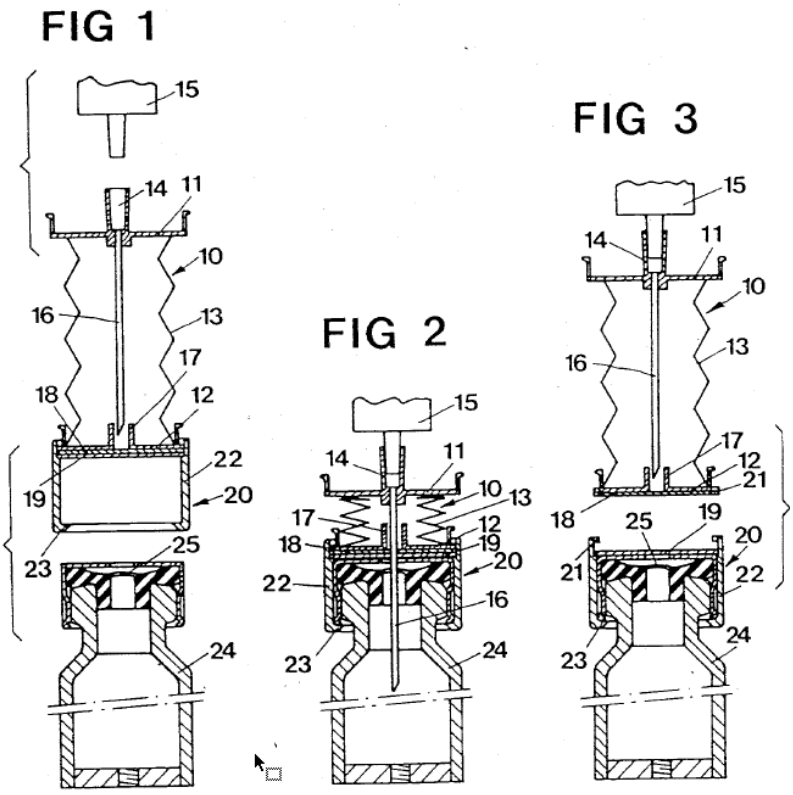
Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

D. Gustavsson- and Lynn-Based Challenges

1. Summary of Gustavsson

Gustavsson seeks to address the problem of contamination when a substance in a vessel is drawn into an injection syringe and then injected into

a patient or an infusion bottle. Ex. 1007, 1:21–27, 1:55–59. Figures 1–3 of Gustavsson are reproduced below:



Figures 1–3 are sectional views of the device in different positions of use.

As shown in Figures 1–3, the device includes "two detachably coupled together members," first member 10 and second member 20. *Id.* at 2:29–30. First member 10 includes plates 11 and 12, flexible side walls 13, needle 16, and first membrane 18. *Id.* at 2:30–40. Second member 20 includes "second membrane 19, which is placed in tight apposition against the first membrane 18." *Id.* at 2:44–45. Gustavsson describes that second "membrane 19 is fastened in a ring shaped part 22, which on top is terminated by the coupling part to the first member 10 and on the bottom is terminated by an inwardly directed flange 23, so that part 20 can be snap fastened on an ampoule 24 containing a dry substance or a solution." *Id.* at

2:45–50. As shown in Figure 2, needle 16 penetrates membranes 18 and 19 and rubber membrane 25 of ampoule 24. *Id.* at 2:57–60. The substance in ampoule 24 is sucked into syringe 15. Gustavsson explains that

> When the substance has been sucked up into the injection syringe 15[,] the needle 16 is withdrawn through the membranes 18 and 19 and the second member 20 is allowed to remain on the ampoule 14 [sic – 24] while the first member 10, which is attached to the injection syringe 15 is detached, as is shown in FIG. 3. The second membrane 19 makes a tight seal to the ampoule 24 and is appropriately thrown away with it.

Id. at 2:66–3:5.

Gustavsson is concerned primarily with preventing air contamination when transferring a substance from one vessel to a second vessel. *Id.* at Abstract, 1:9–10. Petitioner has not directed us to any disclosure in Gustavsson that discloses or suggests a color-based or other visual indicator indicating that the Gustavsson device is in an "activated position."

2. Summary of Lynn

Lynn discloses an intravenous line coupling device. Ex. 1008, Abstract. As explained in Lynn, generally, an intravenous tubing system includes a long segment of tubing attached at one end to an elevated bag or bottle of fluid and attached at the other end to an intravascular catheter. *Id.* at 1:8–11. A secondary system or conduit may be connected to the primary system. *Id.* at 1:12–13. The secondary system allows for the administration of additional medication at frequent intervals without disconnecting the primary system and without discontinuing fluid flow through the primary system. *Id.* at 1:26–30.

Figure 2 from Lynn is reproduced below.

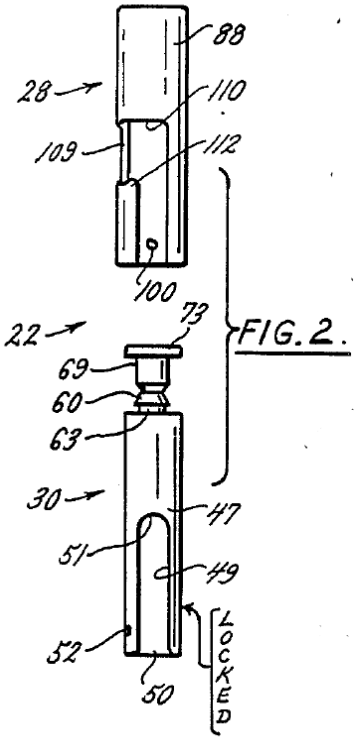
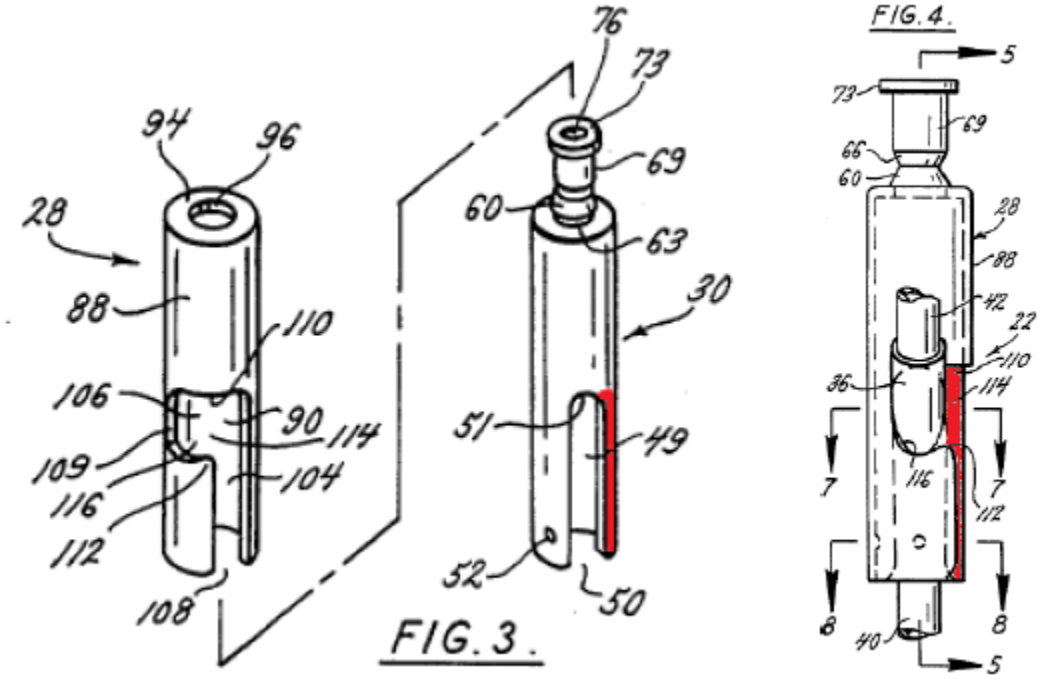


Figure 2 from Lynn is an exploded elevation view of the disclosed coupling device, showing toward the bottom the inner mount tube, and above the outer mount tube. Ex. 1008, 4:45–47.

As shown in Figure 2, coupling device 22 includes outer mount tube 28 and inner mount tube 30. Ex. 1008, 5:14–20. Outer tube 28 can be mounted about inner tube 30, with both tubes extending about junction tube 24 (not numbered in the drawings) in the unlocked position, such as depicted in Figure 9, and in a locked position, such as depicted in Figures 1, 4, and 5. *Id.* Although junction tube 24 is not identified in the drawings with a reference number, angular tubular arm 36 of junction tube 24 is shown in Figure 1. *Id.* at 5:24–25. When tubes 28 and 30 are mounted or assembled, the tubes are permitted to rotate relative to each other. *Id.* at 7:8–12. The two tubes also may be locked to inhibit rotation. In the "locked" position, outer tube nub 100 fits within dimple 53 (*see* Figure 11). This is a first

"locked" position. This "locks" tubes 28 and 30 to each other by a force of low resistance so that the tubes are held in fixed position relative to one another. *Id.* at 7:25–29. This "locking" helps to "inhibit non-volitional rotation" of tubes 28 and 30 relative to one another. *Id.* at 7:29–31. The "lock" of nib 100 with dimple 53, however, is such that "tubes 28 and 30 can easily be rotated by the hand relative to each other." *Id.* at 7:31–33.

Petitioner provides the following annotated Figures 3 and 4 from Lynn (Pet. 21):



Figures 3 and 4 from Lynn,
annotated by Petitioner (color added).

According to Petitioner, and as shown in Petitioner's annotated Figures 3 and 4, "Lynn teaches that *a bright color* on the inner tube becomes visible when the outer tube is rotated, indicating that the device is in a locked position." Pet. 21 (emphasis added). Petitioner acknowledges that

that Lynn discloses using only a single color ("a bright color") to indicate the locked status shown in Figure 4.

As explained in the written description of Lynn, when tubes 28 and 30 are mounted to junction tube 24 as shown in FIG. 9, device 22 can then be moved to a "second locked position" (Ex. 1008, 7:50) relative to arm 36. This is done by rotating outer tube 28 relative to inner tube 30 so that junction tube arm 36 slides into transverse slot 106. Ex. 1008, 7:34–41. In this position, inner tube section 47 (*see* Figure 7) blocks outer tube slot 104. *Id.* at 7:41–43. A bright color, such as red, or the word "LOCKED" can be provided on the portion of inner tube section 47. The bright color or "LOCKED" is visible to an observer when in the locked position. *Id.* at 7:44–49. In this second locked position, nub 100 is received within dimple 52 of inner tube 30 (*see* Fig. 8). *Id.* at 7:50–51.

2. Obviousness Based on Gustavsson and Lynn

Independent claim 1 in the '103 patent, from which all the challenged claims depend, recites that "one of the sleeve members has a first color, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position." Ex. 1001, 14:7–10. Thus, claim 1 clearly requires that the two sleeves be two different colors. Independent claim 1 does *not* require any locking structure. Moreover, the claims in the '103 patent, and the written description, distinguish between locking the sleeve members and indicating that the connector is in the activated position. *See e.g., Id.* at 14:40–41 (dependent claim 12, reciting that the device recited in claim 1 further comprises "means for locking the connector in the activated position."). Dependent claim 13 recites further details of the locking structure. *See also id.* at 11:12–17 (disclosing that in

addition to a color-based visual indicator indicating that the device is in the activated position, the connector in the '103 patent "*further includes* means for visually indicating that the device is in the unlocked position." (emphasis added)).

Petitioner asserts that it would have been obvious to a person of ordinary skill "to modify Gustavsson's connector device to incorporate features of Lynn's connector device, such as its inclusion of different colors on the inner and outer sleeves of the device to indicate whether the connector is in an activated position." Pet. 22. Petitioner mischaracterizes Lynn's disclosure.

Lynn discloses the use of a single color on one of the two tubes or sleeves used in Lynn's connector device. Ex. 1008, 7:44–45 ("A bright color, such as red, or the word "LOCKED' can be provided on the portion of inner tube section"). This discloses one color on one tube or sleeve. The challenged claims recite two sleeves, each of which is a different color. Petitioner has not directed us to any persuasive evidence that Lynn discloses or suggests the inclusion of different colors on the inner *and* outer sleeves of the connector device to indicate whether the connector is in an activated position, as recited specifically in claim 1. *See* Ex. 1001, 14:7–10 ("wherein one of the sleeve members has a first color, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position."). Nor has Petitioner directed us to any persuasive evidence that using two different colors on the two sleeves recited in claim 1 would have been obvious. In its claim chart comparing claim 1 to Lynn, Petitioner states that Lynn discloses "a colored or labeled portion of the inner tube (30) becomes visible, indicating the tubes are in a locked

position." Pet. 28. Petitioner's argument addresses only the fact that Lynn discloses one color on one tube or sleeve. *Id.*

Thus, Lynn is missing a specifically claimed structural feature recited in claim 1.

The Petition also lacks a persuasive rationale or motivation for why a person of ordinary skill would have modified the references as proposed by Petitioner. The fact that the cited references are "analogous art" (Pet. 22) does not establish why it would have been obvious to combine their features as proposed by Petitioner.

As discussed above, the '103 patent discloses and claims separate and distinct structures for visually indicating the locked/unlocked status, and visually indicating its activation status. *See supra* Parts I.B, I.C. Petitioner asserts that the motivation for the proposed modification is that it is "merely a combination of prior art elements according to known methods to yield predictable results. Pet. 22 (citing Ex. 1005 ¶ 70). This is a conclusory label that that does not substitute for a fact-based analysis in the Petition establishing what is being modified, and why it would have been obvious to a person of ordinary skill to make the modification. Petitioner must show some reason why a person of ordinary skill in the art would have thought to combine particular available elements of knowledge, as evidenced by the prior art, to reach the claimed invention. *KSR*, 550 U.S. at 418. There is no persuasive evidence why a person of ordinary skill would have used Lynn's locking structure and color indicator in the '103 patent, which already has a separate and distinct structure and visual indicator that the connector device is unlocked. *See* Ex. 1001, 11:12–17. Also, there is no persuasive evidence

why a person of ordinary skill would have used Lynn's color-based locking indicator as an activation indicator.

E. Zdeb- and Lynn-Based Challenges

Petitioner relies on Zdeb for the basic structure of a connector and on Lynn for the disclosure of a color-based visual indicator indicating that the device is in the activated position. Petitioner repeats its analysis of Lynn's structure. Pet. 52 ("The disclosure of Lynn is discussed in Section VI(A)(ii), above."), 57 ("Lynn discloses element 1f for the reasons discussed in Section VI(A)(iv).").

The rational and motivation asserted by Petitioner also are the same. Pet. 52–53. It differs slightly only in its characterization of Lynn as disclosing "a bright color on one of the device sleeves." This does not cure the deficiencies noted above, nor does it change the outcome. For the reasons stated above, the combination of Zdeb and Lynn is missing a specifically claimed structural feature recited in claim 1, and the Petition also lacks a persuasive rationale or motivation for why a person of ordinary skill would have modified the references as proposed by Petitioner.

III. CONCLUSION

Upon consideration of the Petition and Preliminary Response, we are not persuaded that the record before us demonstrates a reasonable likelihood that Petitioner will prevail in establishing that at least one challenged claim would have been obvious under 35 U.S.C. § 103(a) based on the cited references. Accordingly, we deny the Petitions and do not institute an *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied and *inter partes* review is not instituted.

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