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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 IPR2018-01742
Patent 6,159,192

Before BARRY L. GROSSMAN, TIMOTHY J. GOODSON, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

GOODSON, *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 1–7 of U.S. Patent No. 6,159,192 (Ex. 1001, "the '192 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 1–7 of the '192 patent.

A. Related Matters

Patent Owner is asserting the '192 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 4, 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 IPR2018-01744, challenging U.S. Patent No. 6,852,103. *See id.*

B. The '192 Patent

The '192 patent is titled "Sliding Reconstitution Device with Seal." Ex. 1001, at [54]. The '192 patent explains that to enhance stability, drugs are often stored in a powdered form. *Id.* at 1:11–14. 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.* at 1:14–20. The patent refers to the process of placing a powdered drug in liquid form, or further diluting a liquid drug, as reconstitution. *Id.* at 1:25–28.

In the Background of the Invention, the '192 patent describes several prior art techniques and devices for reconstitution. *See id.* at 1:43–4:6. Figure 1 of the '192 patent, reproduced below, depicts one such known reconstitution device from a prior art reference called Zdeb[1]:

[1] U.S. Patent No. 4,898,209, Ex. 1009.

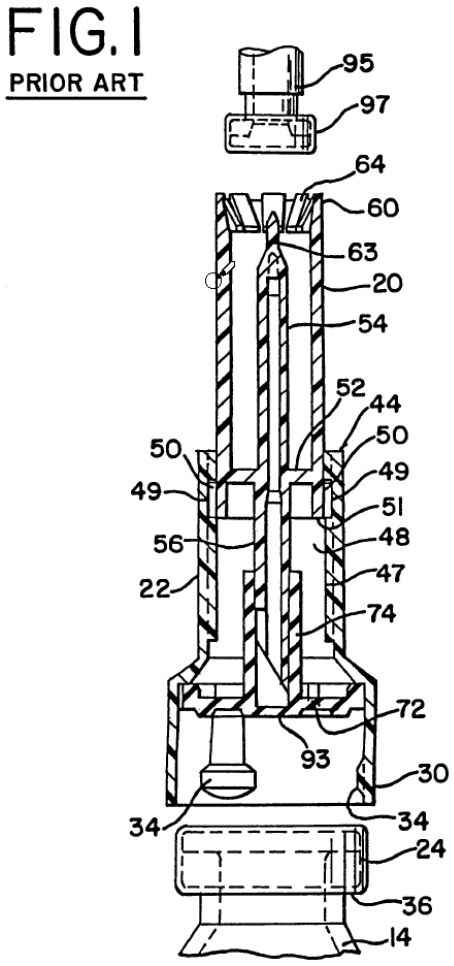


Figure 1 shows a cross section of the Zdeb device.

As described in the ’192 patent, Zdeb includes “a first sleeve member [22] that is mounted concentrically about a second sleeve member [20]. The sleeve members can be moved axially with respect to each other to cause a needle or cannula to pierce a drug container and a diluent container to place the containers in fluid communication with each other.” *Id.* at 2:58–63. A drawback of Zdeb, according to the ’192 patent, is that “the connector could be relatively easily removed from the vial. Removal of the vial could remove all evidence that the reconstitution step had occurred and, possibly, lead to a second unintended dosage of medicine being administered.” *Id.* at 3:31–35.

Figure 2 of the ’192 patent is reproduced below:

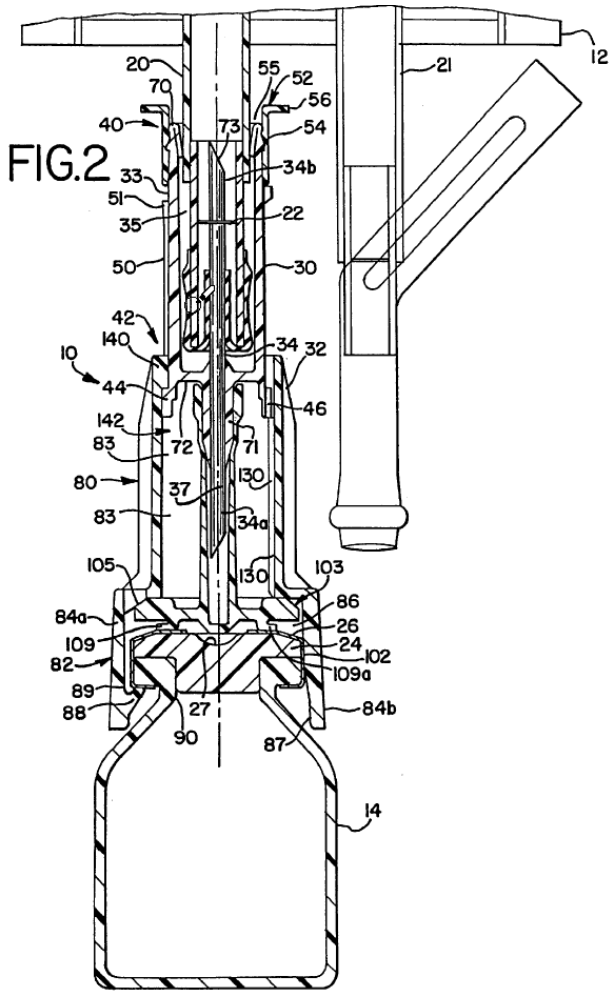


Figure 2 is a cross sectional view of connector device 10 in the inactivated position. *Id.* at 5:30–33.

Figure 2 shows connector device 10, first container 12, and second container 14. *Id.* at 5:30–32, 6:8–12. First container 10 is a flexible bag that contains diluent, and second container 14 is a vial containing a drug to be reconstituted. *Id.* at 6:8–30. Connector device 10 has first and second sleeve members 30 and 32 which can move axially relative to one another from an inactivated position to an activated position. *Id.* at 6:45–49. 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 6:49–54.

Figure 6 of the '192 patent is reproduced below:

FIG.6

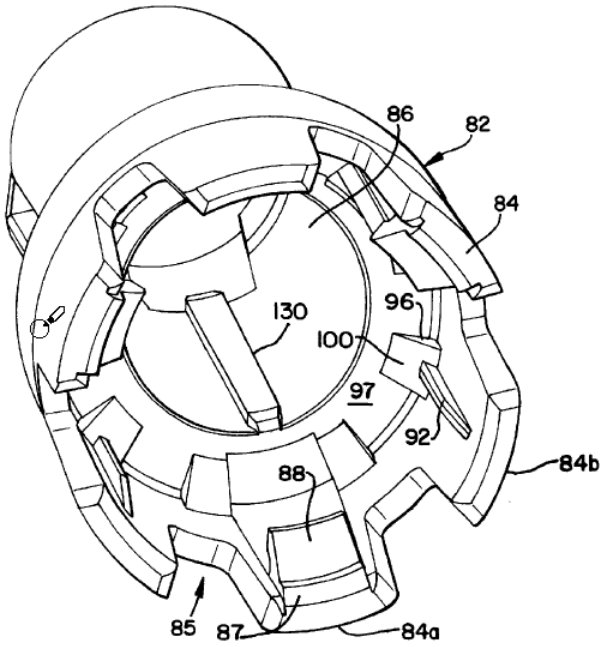


Figure 6 is an end view of a vial connection end of connector 10. *Id.* at 5:42–43.

Figure 6 depicts second portion 82 of second sleeve 32, which includes

> means for attaching, and preferably means for fixedly attaching, the device to the vial 14 or a second attaching member. The means shown is six circumferentially disposed and axially segmented fingers 84 for connecting to the vial 14. The segmented fingers 84 are generally trapezoidal in shape and are separated by gaps 85 to define a vial receiving chamber 86 for receiving a top of the vial 14.

Id. at 8:61–9:2.

C. Prosecution History of the '192 Patent

During prosecution, the Examiner rejected the original claims as anticipated or rendered obvious by Zdeb. *See* Ex. 1002, 86–87. In response,

the applicant amended certain claims and argued that each of the independent claims (as amended) required fixedly attaching a drug container to the reconstitution device. *See id.* at 117–18. The applicant argued that this feature was beneficial because "[b]y fixedly attaching the reconstitution device to a drug container, an operator cannot detach a drug container and later inadvertently reconstitute another dosage of drug, thereby possibly overdosing the patient." *Id.* at 117. According to the applicant, this feature distinguished Zdeb, because Zdeb's flange members 34 "function to *releasably* attach the end portion 28 to the vial 14" rather than fixedly attaching the vial 14 to the outer sleeve member 22. *Id.* at 117–18. The Examiner then allowed the claims, offering the following statement as the reason for allowance: "the prior art of [Zdeb] fails to disclose the step of fixedly attaching a drug container to the present reconstitution device, whereby an operator cannot detach a drug container and later inadvertently reconstitute another dosage of drug." *Id.* at 155.

D. Challenged Claims

Petitioner challenges claims 1–7, of which claim 1 is the sole independent claim. Claim 1 is reproduced below with bracketed labels added by Petitioner for ease of reference, and with bold italics added to emphasize the phrase that is the focus of the discussion below:

> 1. [a] A method of connecting a reconstitution device to a drug container having a top and a closure, the method comprising the steps of:
>
> [b] providing a reconstitution device having first and second ends, [c] the second end having a receiving chamber dimensioned to receive the top of the container for ***fixedly attaching*** the device to the container, [d] the device having a central channel housing a piercing member, [e] the device further having first and second sleeve members capable of sliding

> axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber; and
>
> [f] inserting the top of the container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

Ex. 1001, 13:46–63 (emphasis and bracketed labels added).

E. Alleged Grounds of Unpatentability

Petitioner contents that the challenged claims are unpatentable based on the following grounds:

	Reference(s)	Basis	Claim(s) Challenged
1.	Honda[2]	§ 102	1, 4, 7
2.	Honda	§ 103	1–7
3.	Honda and Forman[3]	§ 103	1–7
4.	Honda, Forman, and Reynolds[4]	§ 103	2, 3
5.	Gustavsson[5]	§ 102	1
6.	Gustavsson	§ 103	1–3
7.	Gustavsson and Reynolds	§ 103	2, 3
8.	Gustavsson and Honda	§ 103	4–6

See Pet. 10–11.

[2] US 5,342,346, issued Aug. 30, 1994 (Ex. 1005).
[3] US 4,759,756, issued July 26, 1988 (Ex. 1006).
[4] US 5,364,369, issued Nov. 15, 1994 (Ex. 1007).
[5] US 4,564,054, issued Jan. 14, 1986 (Ex. 1008).

II. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art 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. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that an ordinarily skilled artisan at the time of the invention of the '192 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. 8 (citing Ex. 1003 ¶ 16). 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. 5–6 (citing Ex. 2001 ¶ 15).

The parties' proposals are very similar 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

The parties agree that the '192 patent is expired and, therefore, in this proceeding, the claims should be given a district court type claim

construction. *See* Pet. 8–9; Prelim. Resp. 6 n.1. "The Board construes claims of an expired patent in accordance with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Under that standard, words of a claim are generally given their ordinary and customary meaning. . . . Claims also are read in light of the patent's specification, of which they are a part." *Wasica Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017) (citing *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360 (Fed. Cir. 2015)).

We determine that the phrase "fixedly attaching" in claim 1 is the only term requiring construction for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

Petitioner proposes that we should construe "fixedly attached" to mean "attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector." Pet. 10. To support its proposed construction, Petitioner relies on the Specification's description of the configuration of tabs 70, the collective force of which as they attempt to spring back to an outwardly extending position

> secures the connector 10 to the port tube 20 such that it cannot be detached without using a force considerably in excess of that normally used to operate the device. Such a force likely would break, detach or noticeably deform one or more of the tabs 70 or other portions of the connector in the process. Thus, the means fixedly attaches the connector to the first container.

Id. at 9 (quoting Ex. 1001, 8:16–29) (emphasis omitted). Petitioner argues that with this description, the patentees acted as their own lexicographers as

to the meaning of "fixedly attach." *Id.* at 9 (citing *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017)).

Patent Owner argues that Petitioner's proposed construction should be rejected because it encompasses subject matter that the '192 patent teaches is excluded from being "fixedly attached." Prelim. Resp. 10. Specifically, Patent Owner asserts that in contrast to the description that segmented fingers 84 "fixedly attach" the vial, the '192 patent describes several examples where a component is "releasably" attached, including attachments that are released by tearing or breaking away certain structures. *Id.* at 8–9 (citing Ex. 1001, 7:46–48, 7:66–8:6, 10:45–58). These examples show, according to Patent Owner, that removing a releasably attached component can include breaking, detaching, or deforming structures without falling within the scope of a fixedly attached connection. *Id.* at 9. Patent Owner also calls attention to the following statement in the '192 patent:

> What is meant by "fixedly attaching" is that in order to remove the vial from the connector one would have to exert a force considerably in excess of that normally used to operate the device. Such a force likely would break, detach, or noticeably deform one or more of the segmented fingers 84 or other portions of the connector in the process.

Ex. 1001, 9:7–12; *see also* Prelim. Resp. 8 (quoting same).

After reviewing the parties' arguments and the cited evidence, we agree with Petitioner that the patentees set forth an express definition of "fixedly attach," but we find that they did so in the portion of column 9 just quoted rather than the column 8 description that Petitioner relies on. By expressly setting out in the Specification "[w]hat is meant by 'fixedly attaching,'" the patentee clearly signaled what meaning was intended. Ex. 1001, 9:7–10. We construe "fixedly attaching" to mean "attaching such

that removal requires a force considerably in excess of that normally used to operate the device."[6] Patent Owner presents persuasive reasons why an ordinarily skilled artisan reviewing the Specification would understand that components designed to be removed using pull-away tabs or break away closures are releasably attached, not fixedly attached. *See* Ex. 1001, 10:50–58; Ex. 2001 ¶ 29.

C. Legal Standards

1. Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Whether a reference discloses the claimed subject matter is assessed from the perspective of an ordinarily skilled artisan. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) ("'[T]he dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching' that every claim element was disclosed in that single reference.").

2. Obviousness

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103

[6] We note that this construction leaves some ambiguity, insofar as the force normally used to operate the device is not quantified. We express no opinion on whether that ambiguity presents an indefiniteness issue, as questions of compliance with § 112 are outside the scope of this *inter partes* review proceeding. *See* 35 U.S.C. § 311(b) (providing that a petitioner may request cancellation "only on a ground that could be raised under section 102 or 103").

that requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007). We note that we addressed the first *Graham* factor in Section II.A., and that at this stage, neither party has presented evidence or argument concerning the fourth *Graham* factor. The second and third *Graham* factors are discussed below.

D. Honda-Led Challenges

1. Summary of Honda

Honda describes "a fluid container capable of preserving a dry drug . . . and a solvent in separated conditions and of aseptically mixing them just before use to administer it as a liquid medicine to a patient." Ex. 1005, 1:7–12. Figure 1 is reproduced below:

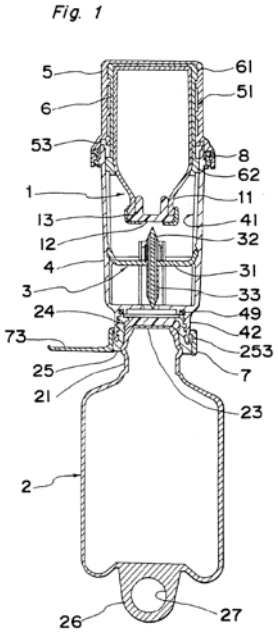


Figure 1 is a schematic sectional view of a fluid container. *Id.* at 3:26–28.

As shown in Figure 1, the fluid container includes drug container 1, solvent container 2, and double-pointed hollow needle 3 that provides fluid communication between drug container 1 and solvent container 2 just before use. *Id.* at 4:34–39. Guide capsule 4 is "removably coupled to the solvent container 2 at one end thereof." *Id.* at 4:40–41. Specifically, "guide capsule 4 is removably coupled to the mouth 21 of the solvent container 2 at a connecting portion 42 thereof by the lock ring 7 and at the opposite end sealed by the cap 5." *Id.* at 7:48–51. The purpose of lock ring 7 is "to avoid accidental disengagement of the guide capsule 4 from the solvent container." *Id.* at 8:23–25. Lock ring 7 includes weakened part 74, which is designed to break when a user applies sufficient pulling force to pulling tab 73, thereby allowing guide capsule 4 to be removed from solvent container 2. *Id.* at 8:33–40.

To operate the device, drug container 1 is moved downward, causing upper piercing needle 32 of double-pointed needle 3 to pierce rubber stopper 12 of drug container 1, and lower piercing needle 33 to pierce rubber stopper 24 of solvent container 2. *Id.* at 9:19–37. The fluid container is turned upside down so that the solvent flows into drug container 1, and then turned upside down again so that the mixed drug solution is returned to solvent container 2. *Id.* at 9:42–48.

> After removing the lock ring 7 from the guide capsule 4 and then releasing the fastening lobes 253 from the stepped portions 43 of the guide capsule 4, the guide capsule 4 is then unscrewed by turning and then removed from the solvent container 2. Then, the solvent container 2 is hanged at its tab 26 on a hanger . . . and then connected to an infusion set by piercing a needle of the infusion set into the rubber stopper 24 on the mouth 21 of the solvent container 2.

Id. at 9:54–62.

2. Anticipation by Honda

In arguing that Honda teaches each element of claim 1, Petitioner relies on Honda's connecting portion 42 of guide capsule 4 as disclosing a second end "for fixedly attaching the device to the container," as recited in limitation [c]. *See* Pet. 15–16. Petitioner points to Honda's disclosure that guide capsule 4 cannot be removed from solvent container 2 unless lock ring 7 is broken. *See id.* (citing Ex. 1005, 8:23–40). Applying its proposed construction of "fixedly attaching," Petitioner argues that a skilled artisan would have understood that guide capsule 4 is fixedly attached to solvent container 2 because solvent container 2 cannot be removed without breaking lock ring 7. *Id.* at 16 (citing Ex. 1003 ¶¶ 27–31). Patent Owner counters that Honda repeatedly teaches that guide capsule 4 is "removably coupled" to solvent container 2, which is distinct from being fixedly attached. Prelim. Resp. 13–15 (citing Ex. 1005, 4:32–46, 5:32–46, 7:48–51, 8:14–20). Patent Owner asserts that Honda is designed to remove guide capsule 4 from solvent container 2 by removing ring lock 7. *Id.* at 15 (citing Ex. 1005, 7:40–47, 8:23–33).

As discussed in Section II.B, we construe "fixedly attaching" to mean "attaching such that removal requires a force considerably in excess of that normally used to operate the device." Under that construction, we agree with Patent Owner that Honda's connecting portion 42 of guide capsule 4 is not a second end for fixedly attaching the device to the container, as recited in limitation [c] of claim 1. Honda explains that breaking lock ring 7 in order to remove guide capsule 4 from solvent container 2 is part of the normal and intended operation. Ex. 1005, 7:40–51, 8:23–40, 9:54–58. Because lock ring 7 is designed to be broken, *see id.* at 8:33–37, the force

required to remove guide capsule 4 from solvent container 2 is not in excess of that used in normal operation of the device.

Accordingly, Petitioner has not shown a reasonable likelihood of prevailing in its Honda-based anticipation challenge against claim 1 or either its dependent claims 4 and 7.

3. Obviousness Based on Honda

Petitioner's obviousness argument based on Honda largely relies on the evidence cited in its anticipation ground. *See* Pet. 19 ("Honda discloses the elements of claims 1, 4, and 7 for the reasons discussed in [the section discussing anticipation].") Petitioner does not present any evidence or explanation regarding limitation [c] of claim 1 apart from the conclusory assertion that "if the Board disagrees with [Petitioner]'s proposed construction of 'fixedly attached,' any differences between the Board's construction and the attachment taught by Honda would be inconsequential." *Id.* at 20. This undeveloped and unsupported argument does not identify specific differences between Honda and the claimed subject matter or explain why those differences would have been obvious to an ordinarily skilled artisan. Thus, Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge based on Honda against claim 1 or any of its dependent claims 2–7.

4. Obviousness Based on Honda and Forman

Petitioner argues that if Honda does not disclose the "fixedly attaching" requirement in limitation [c] of claim 1, Forman discloses such an attachment with its permanent coupling between vial 32 and liquid container 34. *See* Pet. 25–27 (citing Ex. 1006, Abstr., 12:53–58). Petitioner argues that replacing Honda's attachment mechanism with Forman's vial adapter

would have been obvious as "merely the substitution of one known component for another" and because "[d]oing so would allow a POSITA to adapt the Honda device for use with vials whose tops are dimensioned to fit the Forman adapter." *Id.* at 27 (citing Ex. 1003 ¶ 55). Patent Owner responds that Petitioner's proposed combination would change Honda's principle of operation and render it inoperable for its intended purpose. *See* Prelim Resp 17–21. Specifically, Patent Owner contends that if Honda's solvent container 2 were fixedly attached to guide capsule 4, solvent container 2 could not be removed and plugged in to the infusion set via stopper 24. *Id.* at 20.

We agree with Patent Owner that Petitioner's obviousness arguments are unpersuasive because the proposed modification would render Honda inoperable for its intended purpose. *See Tec Air, Inc. v. Denso Mtg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) ("If when combined, the references 'would produce a seemingly inoperative device,' then they teach away from their combination.") (quoting *In re Sponnoble*, 405 F.2d 578, 587 (CCPA 1969)); *In re Fritch*, 972 F.2d 1260, 1265 n.12 (Fed. Cir. 1992) (explaining that a proposed modification is inappropriate for obviousness "when the modification render[s] the prior art reference inoperable for its intended purpose").

Honda describes that after the drug in drug container 1 has been mixed with the solvent in solvent container 2 and the drug solution is returned to solvent container 2, lock ring 7 is removed and guide capsule 4 is removed from solvent container 2. *See* Ex. 1005, 9:40–58. Solvent container 2 is "then connected to an infusion set by piercing a needle of the infusion set into the rubber stopper 24 on the mouth 21 of the solvent

container 2." *Id.* at 9:60–62. If guide capsule 4 were permanently coupled to solvent container 2, as Petitioner proposes, rubber stopper 24 on solvent container 2 would remain enclosed and a clinician would not be able to connect an infusion set via rubber stopper 24 as Honda contemplates. *See id.* at Fig. 1; *see also* Ex. 2001 ¶¶ 39–40. This modification would make Honda inoperable for its intended purpose of aseptically mixing and administering a liquid medicine to a patient. *See* Ex. 1005, 1:10–12. As such, we determine that Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge based on the combination of Honda and Forman against any of claim 1 or its dependent claims 2–7.

5. Obviousness Based on Honda, Forman, and Reynolds

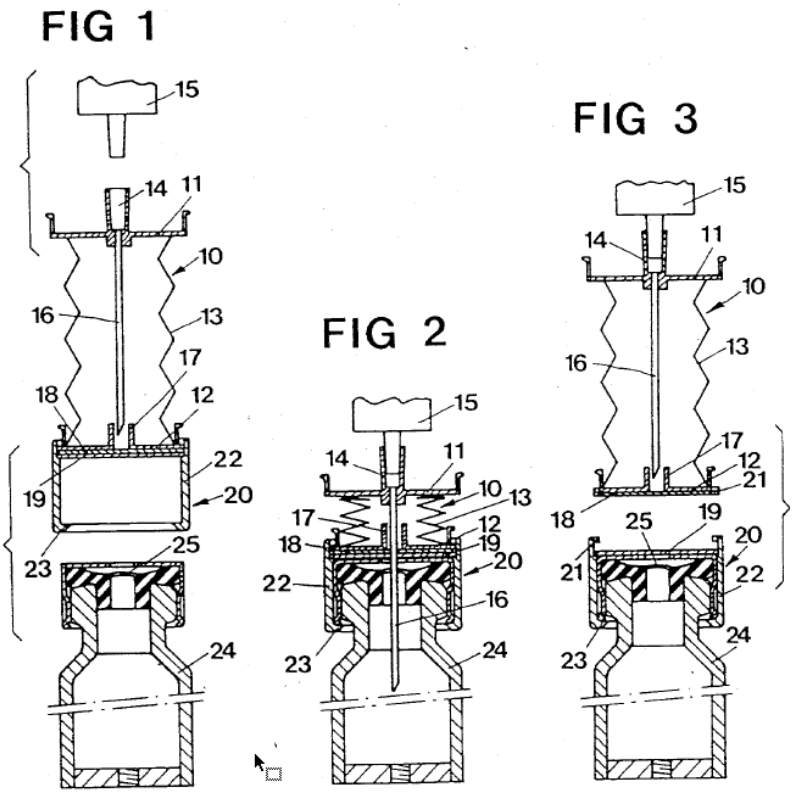
Petitioner's obviousness ground based on Honda, Forman, and Reynolds challenges dependent claims 2 and 3. *See* Pet. 30–34. In this ground, Petitioner adds Reynolds to the base combination of Honda and Forman, arguing that if the limitations of claims 2 and 3 are not obvious based on Honda and Forman, Reynolds teaches those limitations. *See id.* Petitioner's arguments in this ground do not address the deficiency discussed above with respect to combining Honda and Forman so as to arrive at the method recited in claim 1. Therefore, Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge based on the combination of Honda, Forman, and Reynolds against claims 2 or 3.

E. Gustavsson-Led 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. 1008, 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 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. "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 shown in FIG. 3. The second membrane makes a tight seal to the ampoule 24 and is appropriately thrown away with it." *Id.* at 2:66–3:5.

2. Anticipation by Gustavsson

For its argument that Gustavsson discloses a second end "for fixedly attaching the device to the container," as recited in limitation [c] of claim 1, Petitioner relies on the "snap fastened" connection between second member 20 and ampoule 24. *See* Pet. 38–39 (citing Ex. 1008, 2:41–50, 2:66–3:5, Figs. 1–3). Petitioner also points out that Gustavsson teaches that "second member 20 is allowed to remain on the ampoule" while first member 10 is attached, and second membrane 19 "is appropriately thrown away" with ampoule 24. *See id.* (citing Ex. 1008, 2:66–3:5). According to Petitioner, an ordinarily skilled artisan "would have understood that second member 20 is fixedly attached to ampoule 24, as second member 20 is snap fit onto ampoule 24 and subsequently thrown away while still attached to the ampoule." *Id.* at 38 (citing Ex. 1003 ¶¶ 41–44).

Patent Owner responds that the disclosures in Gustavsson on which Petitioner relies do not show that the snap fastened attachment provides a fixed attachment as opposed to a releasable attachment. Prelim. Resp. 23 (citing Ex. 2001 ¶ 42). Patent Owner argues that Gustavsson's snap

fastening using inwardly directed flange 23 is similar to Zdeb's releasable lock provided by flange members 34, which was described in the background of the '192 patent as being "relatively easily removed from the [drug container] vial." *Id.* (citing Ex. 1001, 3:31–32).

In an anticipation analysis, we consider whether the reference expressly or inherently teaches every limitation. *Verdegaal Bros.*, 814 F.2d at 631. Petitioner has not shown that Gustavsson expressly teaches "fixedly attaching" the device to the container under the construction we have adopted. That Gustavsson's second member 20 is snap fastened onto ampoule 24 and the two items are discarded while still attached does not indicate how much force would be needed to remove second member 20 from ampoule 24. As Patent Owner's declarant notes, "snap buttons on a coat . . . are snap fastened but are releasably attached." Ex. 2001 ¶ 45.

Petitioner also has not shown that "fixedly attaching" is inherently disclosed by Gustavsson. It is possible that Gustavsson's second member 20 is fixedly attached to ampoule 24, given that Gustavsson's operation has no apparent need for them to be removed and discloses that they can be thrown away still attached. But for inherency, "mere possibility is not enough." *Personal Web Techs., LLC v. Apple, Inc.*, __ F.3d __, Case No. 2018-1599, slip op. at 10 (Fed. Cir. Mar. 8, 2019) (citing *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014)). It is also possible that Gustavsson's configuration provides a releasable attachment, as shown by its structural similarity to Zdeb, which has "flange members 34 that function to releasably lock the end portion 28 on the vial 14." Ex. 1009, 5:48–51, Fig. 2; *see also* Ex. 2001 ¶ 44 (testifying that Gustavsson's inwardly directed flange 23 is similar to Zdeb's plurality of bumps or flange members 34).

Zdeb was distinguished in the Specification of the ’192 patent and during prosecution of the ’192 patent on the basis that it has an easily removable connection rather than a fixed attachment. *See* Ex. 1001, 3:31–32; Ex. 1002, 117–18, 155.

Because Petitioner has not shown that a fixed attachment is either expressly described or necessarily present in Gustavsson, Petitioner has not presented a reasonable likelihood of prevailing in its anticipation challenge to claim 1.

3. Obviousness Based on Gustavsson, Alone or with Secondary References

Like the anticipation ground based on Gustavsson, Petitioner’s remaining grounds continue to rely on Gustavsson as teaching the “fixedly attaching” feature of limitation [c] of claim 1. *See* Pet. 41 (“Gustavsson discloses the elements of claim 1 for the reasons discussed in [the section addressing anticipation]”); *id.* at 43–45 (relying on secondary references only to teach limitations in dependent claims 2–6). For the reasons discussed above in connection with the Gustavsson-based anticipation ground, we are not persuaded that Gustavsson teaches that limitation. Further, Petitioner does not present any evidence or persuasive reasoning as to why that limitation would have been obvious to an ordinarily skilled artisan in view of Gustavsson’s teachings. Petitioner’s conclusory assertion that “if the Board disagrees with [Petitioner]’s proposed claim construction of ‘fixedly attached,’ any differences between the Board’s construction and the attachment taught by Gustavsson would be inconsequential” (*id.* at 41) is unsupported and unpersuasive. Accordingly, Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenges to claims

1–3 based on Gustavsson, claims 2 and 3 based on Gustavsson and Reynolds, and claims 4–6 based on Gustavsson and Honda.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied.

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