UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,

Petitioner,

v.

BAXTER INTERNATIONAL, INC.,

Patent Owner.

Patent No. 6,159,192

Issue Date: December 12, 2000

Title: SLIDING RECONSTITUTION DEVICE WITH SEAL

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,159,192

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1-.80 & 42.100-.123

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Attachment C. Word Count Compliance Certificate

Petitioner Becton, Dickinson and Company (hereinafter "BD" or "Petitioner") respectfully petitions for *inter partes* review of claims 1-7 of U.S. Patent No. 6,159,192 ("the '192 patent") (Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. COMPLIANCE WITH REQUIREMENTS FOR A PETITION FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 CFR § 42.104 (a))

Petitioner certifies it is not barred or estopped from requesting *inter partes* review of the '192 patent. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '192 patent. The '192 patent has not been the subject of a prior *inter partes* review by Petitioner or a privy of Petitioner.

Petitioner also certifies this petition for *inter partes* review is filed within one year of the date of service of a complaint alleging infringement of a patent. Petitioner was served with a complaint alleging infringement of the '192 patent on November 3, 2017, captioned No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois. (*See* Ex. 1014, Affidavit of Service.) A copy of Baxter International, Inc.'s ("Baxter") Complaint is attached as Exhibit 1013.

Because the date of this petition is less than one year from November 3, 2017, this petition complies with 35 U.S.C. § 315(b).

B. Fee for *Inter Partes* Review (37 CFR § 42.15(a))

The Director is authorized to charge the fee specified by 37 CFR § 42.15(a) to Deposit Account No. 06-1910.

C. Mandatory Notices (37 CFR § 42.8(b))

i. Real Party in Interest (37 CFR § 42.8(b)(1))

The real party in interest for this petition is Petitioner Becton, Dickinson and Company, located at 1 Becton Drive, Franklin Lakes, New Jersey 07417.

ii. Related Matters (37 CFR § 42.8(b)(2))

The '192 patent is the subject of a civil action in the U.S. District Court for the Northern District of Illinois, captioned *Baxter International, Inc. v. Becton, Dickinson and Company*, No. 1:17-cv-07576 ("the district court lawsuit"). Petitioner is contemporaneously filing two additional *inter partes* review petitions for U.S. Patent Nos. 5,989,237 and 6,852,103, which are asserted in the district court lawsuit along with the '192 patent.

iii. Designation of Counsel and Service Information (37 CFR §§ 42.8(b)(3)-(4))

Petitioner identifies the following counsel (a power of attorney accompanies this Petition):

Lead Counsel	Backup Counsel
Kurt J. Niederluecke Reg. No. 40,102 kniederluecke@fredlaw.com (612) 492-7328	Adam R. Steinert *pro hac vice* to be filed asteinert@fredlaw.com (612) 492-7436

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Service information for counsel is provided above. Counsel may also be served by fax at (612) 492-7077.

D. Proof of Service (37 CFR §§ 42.6(e) and 42.105(a))

Proof of service of this Petition is provided in **Attachment A**.

II. INTRODUCTION AND IDENTIFICATION OF THE CLAIMS BEING CHALLENGED (37 CFR § 42.104(B)(1))

This is a petition for *inter partes* review of claims 1-7 of U.S. Patent No. 6,159,192 ("the '192 patent"), titled "Sliding Reconstitution Device with Seal," issued on December 12, 2000, to Fowles et al. and assigned to Baxter. The '192 patent is attached as Exhibit 1001. The '192 patent is generally directed to a method for connecting a reconstitution device to a drug container to reconstitute a medication dose. (*See* Ex. 1001 at 1:6-9, Cl. 1.)

Claim 1 of the '192 patent is an independent claim. Claim 1 is a method claim and representative of the alleged invention:

> 1. A method of connecting a reconstitution device to a drug container having a top and a closure, the method comprising the steps of:

providing a reconstitution device having first and second ends, the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container, the device having a central channel housing a piercing member, 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

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 at Cl. 1.)

The prior art references cited and discussed in this petition for *inter partes* review are U.S. Patent No. 5,342,346 to Honda et al. ("Honda"), U.S. Patent No. 4,759,756 to Forman et al. ("Forman"), U.S. Patent No. 5,364,369 to Reynolds ("Reynolds"), and U.S. Patent No. 4,564,054 to Gustavsson ("Gustavsson").

Honda is a U.S. patent directed to a fluid container that includes separate vessels for a dry drug and a solvent, which can be mixed together by compressing the container so that a double-pointed needle pierces the vessels and creates a fluid path between them. (Ex. 1005 at Abstract.) It issued on August 30, 1994. Accordingly, Honda is prior art under at least 35 U.S.C. § 102 (b).

Forman is a U.S. patent directed to a reconstitution device that connects a liquid container to a drug container and places them in fluid communication with each other. (*See, e.g.*, Ex. 1006 at 3:29-35.) It issued on July 26, 1988. Accordingly, Forman is prior art under at least 35 U.S.C. § 102(b).

Reynolds is a U.S. patent directed to a system for preparing a dosage from one or two component medicines (one of which may be a solid) that includes a syringe, a connector, and a vial. (*See, e.g.*, Ex. 1007 at 2:10-23.) It issued on November 15, 1994. Accordingly, Reynolds is prior art under at least 35 U.S.C. § 102 (b).

Gustavsson is a U.S. patent directed to a connector device for establishing fluid communication between two vessels in order to transfer a substance between the two vessels without air contamination. (*See, e.g.*, Ex. 1008 at Abstract, 1:54-68.) It issued on January 14, 1986. Accordingly, Gustavsson is prior art under at least 35 U.S.C. § 102(b).

Additionally, Honda, Reynolds, Forman, and Gustavsson are all admitted as prior art on the face of the ’192 patent. The file history of the ’192 patent does not indicate the examiner performed any substantive analysis of these references, nor did Baxter highlight their relevance to the claims of the ’192 patent.

The references relied on herein raise a reasonable likelihood that BD will prevail with respect to at least one challenged claim, and BD's petition for *inter partes* review of the '192 patent should be granted.

III. BACKGROUND OF THE '192 PATENT

A. Effective Filing and Priority Dates of the '192 patent

The '192 patent issued from U.S. Application No. 08/984,795 ("the '795 application"), with a filing date of December 4, 1997. The '795 application does not claim priority to any earlier patent or application. Accordingly, the earliest possible priority date for the '192 patent is December 4, 1997.

B. Relevant Prosecution History of the '192 patent

The file history for the '192 patent is particularly helpful in understanding what Baxter claims it invented. The file history is attached as Exhibit 1002.

The '192 Patent and its file history demonstrate that Baxter's alleged invention was limited to ***"fixedly attaching"*** the device to a container, a small improvement over Baxter's own prior art, U.S. Patent No. 4,898,209 ("Zdeb", attached as Ex. 1009).[1]

[1] The Zdeb patent was initially issued listing the inventor's name as "Zbed," which was subsequently corrected in a Certificate of Correction. (*See* Ex. 1009.) While the '192 specification correctly refers to "Zdeb," the file history refers to "Zbed." To minimize confusion, all references in this Petition other than direct quotations identify the reference as "Zdeb."

The examiner initially rejected Baxter's '795 application over Zdeb. The examiner found that Zdeb disclosed every limitation and thus anticipated each independent claim, along with a majority of the dependent claims. (Ex. 1002 at 0086.) The examiner also found that sterilizing the containers, the additional limitation in claims 4-6, would have been obvious in light of Zdeb. (*Id.* at 0087.) The examiner found no need to address any other prior art patent.

In response, Baxter amended its independent claims so that each required at least one end of the device to be fixedly attached to a container. (*See, e.g.*, *id.* at 0115 ("the first end of the device being [connected] fixedly attached to the closure of the first [second] container . . ."), 0116 ("the first end of the device having a connecting member for [connecting to] fixedly attaching to the closure of the first container . . .").) Baxter argued that its invention, as amended, required fixedly attaching at least one end of the device to a container. (*Id.* at 0117-18.) Baxter explained, "[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.*)

Baxter distinguished its invention over Zdeb, which Baxter argued *releasably* attached the device to the container. (*Id.* (Zdeb "does not disclose fixedly attaching the vial 14 to the outer sleeve member 22"); *see also* Ex 1001 at 3:31-32 (the Zdeb "connector could be relatively easily removed from the vial").)

Baxter did not identify any other differences between its claimed invention and Zdeb. (*See* Ex 1002 at 0117-18.)

The examiner allowed all the claims as amended. His reasons for allowance mirrored Baxter's argument:

> the prior art of Zbed '909 [sic] 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 0155) Accordingly, Baxter's ***"fixedly attaching"*** limitation is the sole reason the claims were allowed and the heart of the alleged invention.

C. Person of Ordinary Skill in the Art (POSITA)

A POSITA in the field of the '192 patent in the 1997 time frame would have been someone with 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. (*See* Declaration of James L. Sertic, Exhibit 1003, ¶ 16.)

IV. CLAIM CONSTRUCTION (37 CFR § 42.104(B)(3))

The '192 patent expired on December 4, 2017, twenty years after the '795 application was filed. The claims should thus be construed according to their "ordinary and customary meaning as understood by a person of ordinary skill in

the art at the time of the invention." *Google Inc. v. CreateAds LLC*, IPR2014-00200, Paper No. 19, at 2 (July 16, 2014) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)).

Unless stated otherwise below, BD contends that each term in the claims should be given its plain and ordinary English meaning.

A. "Fixedly Attaching"

Claim 1 of the '192 patent recites "fixedly attaching" the top of a container within the device's receiving chamber. The '192 specification describes "fixedly attaching" as follows:

> The first end 40 of the first sleeve member 30 has means for attaching to the first container or a first attaching member. In a preferred form, the means includes eight inwardly and downwardly extending resilient tabs 70. The tabs 70 fold inward and downward when the connector 10 is docked to port tube 20. The collective force of the tabs attempting to spring back to their original 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.

(Ex. 1001 at 8:16-29 (emphasis added).) By providing an express meaning for "fixedly attach," the patentees have acted as their own lexicographers. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017)

(concluding that the court is "bound by the patentee's lexicography"). As discussed above, the patentees also relied on this element to distinguish the prior art and secure issuance of the claims. (*See* Section III(B).) Accordingly, in the context of the '192 patent, the phrase "fixedly attached" should be construed to mean "attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector."

B. "Hermetic Seal"

Claim 7 of the '192 patent recites "a hermetic seal at the first end of the device." The plain English meaning of "hermetic" is "airtight." (*See, e.g.*, Ex. 1010 at 542.) The patent uses "hermetic" consistently with its ordinary meaning. Accordingly, a "hermetic seal" is an "airtight seal."

V. IDENTIFICATION OF SPECIFIC STATUTORY GROUNDS FOR CHALLENGE (37 CFR § 42.104(B)(2))

BD respectfully requests the cancellation of claims 1-7 of the '192 patent. The statutory grounds for the challenge are set forth below (all citations are to pre-AIA statues):

Ground	35 USC §	Claims	References
1	102(b)	1, 4, 7	Honda (Ex. 1005, U.S. 5,342,346)
2	103(a)	1-7	Honda
3	103(a)	1-7	Honda in view of Forman (Ex. 1006, U.S. 4,759,756)
4	103(a)	2-3	Honda in view of Forman and Reynolds (Ex. 1007, U.S. 5,364,369)
5	102(b)	1	Gustavsson (Ex. 1008, U.S. 4,564,054)
6	103(a)	1-3	Gustavsson

7	103(a)	2-3	Gustavsson in view of Reynolds
8	103(a)	4-6	Gustavsson in view of Honda

VI. DETAILED EXPLANATION AND EVIDENCE SUPPORTING GROUNDS FOR CHALLENGE (37 CFR §§ 42.104(B)(4)-(5))

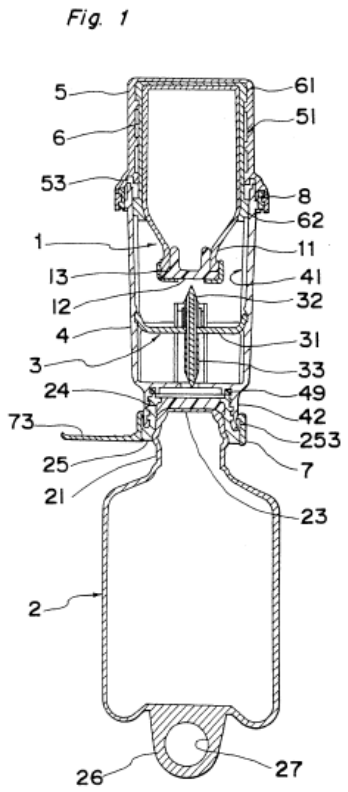
A. Ground 1: Anticipation of Claims 1, 4, and 7 Based on Honda

Claims 1, 4, and 7 are anticipated under 35 U.S.C. § 102 in view of Honda as set forth below.

i. Disclosure of Honda

Honda is directed to a fluid container that includes separate vessels for a dry drug and a solvent, which can be mixed together by compressing the container so that a double-pointed needle pierces the vessels and created a fluid path between them. (Ex. 1005 at Abstract.) Honda teaches that the solvent vessel is attached to the connector using a lock ring that prevents the solvent vessel from being detached without breaking the weakest part of the lock ring. (*See, e.g.*, *id.* at 5:32-41, 7:33-47, 8:14-40.)

The device includes a double-pointed needle held between the drug vessel and the solvent vessel. (*See, e.g.*, *id.* at 2:49-52, 5:51-53.) When the connector is compressed, the needle pierces both vessels to establish a fluid connection between them. (*See, e.g.*, *id.* at 9:27-39.) An embodiment is shown in Figure 1:

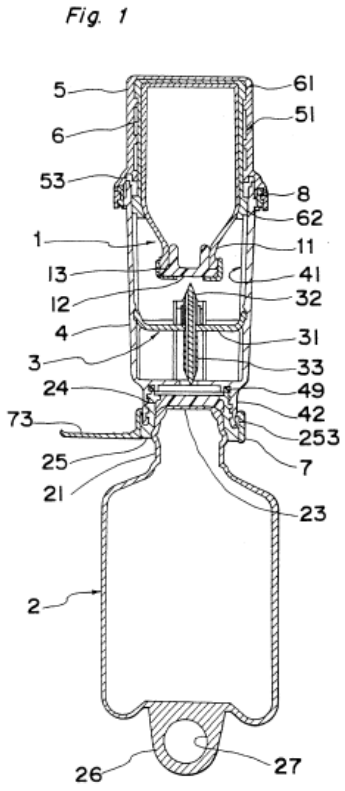


(*Id.* at Fig. 1.)

ii. Comparison of Claims 1, 4, and 7 to Honda

The claim chart below specifies where each element of claims 1, 4, and 7 is found in Honda.

'192 Claim Language	Citations to Honda
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:	Honda is directed to "a fluid container and, more particularly a fluid container capable of…aseptically mixing [a dry drug and a solvent] just before use to administrate it as a liquid medicine to a patient."

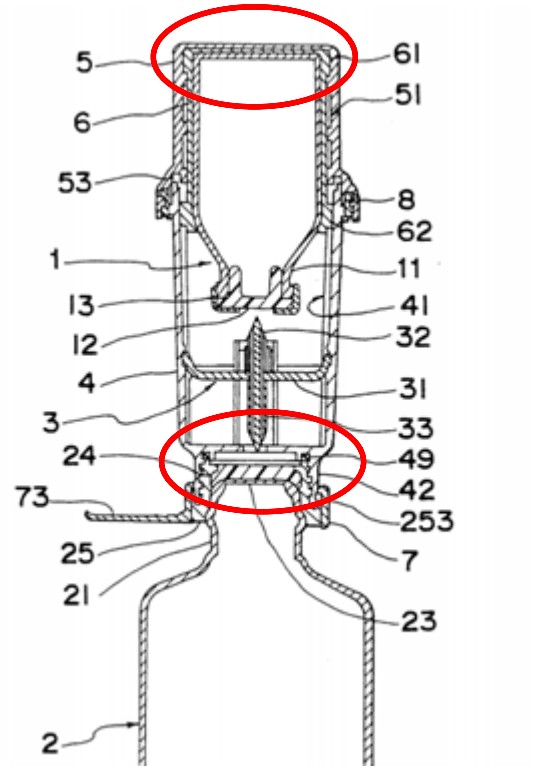


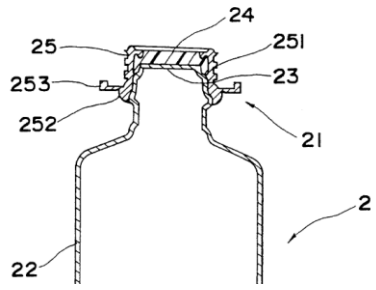
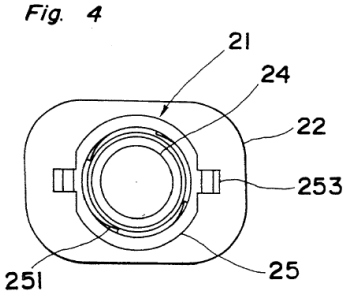
(Ex. 1005 at 1:6-12 & Fig. 1.)

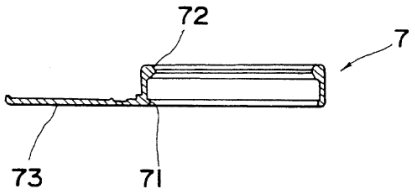
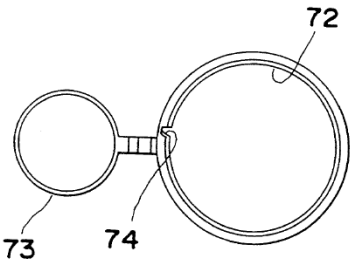
The fluid container of Honda includes a connector device for establishing fluid communication between a drug container and a solvent container:

> A fluid container comprises a drug container, a deformable solvent container, a double-pointed hollow needle having a sharp piercing edge at each end and being arranged between the drug container and the solvent container, a guide capsule with a cap rotatably mounted thereon, and a means for converting rotary motion of the cap to a linear motion of the drug container to push the drug container toward the solvent container in cooperation with the cap and the guide capsule so that a fluid communication is made between two containers through the needle.

(*Id.* at Abstract.)

[1b] providing a reconstitution device having first and second ends,	The fluid container of Honda includes first and second ends: [A] fluid container…that comprises a drug container 1 such as vial; a solvent container 2; a double-pointed hollow needle 3…; a cylindrical guide capsule 4 removably coupled to the solvent container 2 at one end thereof, said guide capsule 4 having an open end at one end …; a cap 5 attached to the guide capsule 4 to close the open end thereof; and a vial guide 6 movably held in the cap 5[.]  (Ex. 1005 at 4:33-49 & Fig. 1.)
[1c] the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the	As discussed in Section IV(A), the ’192 patent specification defines “fixedly attached” as “attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector.”

container,	The connector disclosed by Honda falls within that definition: The connecting portion 42 of the guide capsule 4 is provided with a female screw 421 for engagement with the solvent container 2, that is engaged with a male screw 251 provided on the mouth 21 of the solvent container 2. At a lower part of the connecting portion 42 there are provided two stepped portions 43 adapted to be engaged with fastening lobes 253 of the solvent container 2. **Thus, the guide capsule 4 is so designed that it is incapable of being removed from the solvent container 2 except on condition that the fastening lobes 253 of the solvent container 2 are disengaged from the stepped portions 43 of the guide capsule 4. The fastening lobes 253 are fixed in place by a lock ring 7** for guide capsule, mentioned later in connection with FIG. 14, so that they are not displaced from the stepped portions 43. Fig. 3  Fig. 4  (Ex. 1005 at 7:33-47 (emphasis added), & Figs. 3-4; *see also id*. at Fig. 1.) Honda describes lock ring 7 as follows: The **lock ring 7 has been provided to avoid accidental disengagement of the guide capsule 4 from the solvent container 2**. As shown in FIGS. 14 and 15, the lock ring 7 has first and second

	annular projections 71 and 72 and a pulling tab 73 integrally formed therewith. The first projections 71 is adapted to be engaged with the covering member 25 fitted on the mouth of the solvent container 2, while the second projection 72 is adapted to be engaged with the upper end of the fastening lobes 253 engaged with the stepped portion 43 of the guide capsule 4. Also, **the ring 7 is provided with a weakened part 74 to make it breakable. When removing the guide capsule 4 from the solvent container 2, the ring 7 is removed by pulling the pulling tab 73 until the weakened part 74 is broken**, disconnecting the fastening lobes 253 from the stepped portions 43 of the guide capsule 4, and then turning the guide capsule 4 in the direction of loosening the screw. Fig. 14  Fig. 15  (*Id.* at 8:23-40 (emphasis added) & Figs. 14-15; *see also id.* at 11:37-49 & Figs. 20-21, 13:19-34 & Fig. 28.) A POSITA 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. (*See* Ex. 1003, ¶¶ 27-31.)
[1d] the device having a central channel housing a piercing member,	Honda discloses "a double-pointed hollow needle having a sharp piercing edge at each end, said needle being arranged between the mouth of said drug container and that of the solvent container." (Ex. 1005 at 2:49-52.) "The double-pointed needle 3 is arranged between the drug container 1 and the solvent container 2 and held in the guide capsule 4." (*Id.* at 5:51-53; *see also id.* at Fig.

	1, 10:9-14 ("the double-pointed hollow needle 3 of FIG. 1 is provided with two passages 35 to allow the solvent to flow into the drug container 1 without causing deformation of the solvent container, but it is also possible to use a double-pointed hollow needle with one passage 35.").)
[1e] 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	Honda discloses two sleeve members (vial guide 6 and guide capsule 4) that slide axially from an inactivated position where needle 3 is outside the receiving chamber to an activated position where the piercing member is inside the receiving chamber: [T]he drug container 1 held in the **vial guide 6 is moved downwardly along the guide grooves 41 of the guide capsule 4** without causing rotary motion. **During downward movement of the vial guide 6, the rubber stopper 12 fitted in the mouth 11 of the drug container 1 is pierced by the upper piercing needle 32 of the double-pointed needle 3, while the rubber stopper 24 and sealing membrane 23 of the solvent container 2 are pierced by the lower piercing needle 33 of the double-pointed needle 3**. Thus, a fluid communication is made between the drug container 1 and solvent container 2 through the double-pointed hollow needle 3. (Ex. 1005 at 9:27-39 (emphasis added).)
[1f] 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.	As discussed in Section IV(A), the '192 patent specification defines "fixedly attached" as "attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector." The connector disclosed by Honda falls within that definition. Honda discloses fixedly attaching guide capsule 4 to solvent container 2. *See* ***element 1c***. Honda also teaches:

	The above fluid container may be assembled by hermetically and removably **fitting the guide capsule 4 on the solvent container** 2, fitting the lock ring 7 on the connecting portion 42 of the guide capsule 4, **placing the double-pointed hollow needle 3 in the guide capsule 4**, and hermetically fitting the cap 5 with drug container 1 on the open end of the guide capsule 4. (Ex. 1005 at 8:14-20 (emphasis added).) A POSITA 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. (*See* Ex. 1003, ¶¶ 27-31.)
4. The method of claim 1 further comprising the step of sterilizing the top of the container and the receiving chamber.	Honda discloses **claim 1** for the reasons discussed above. Honda teaches "a fluid container which…makes it possible to aseptically mix a drug with a solvent." (Ex. 1005 at 2:33-37.) Further, Honda discloses "aseptically holding the double-pointed hollow needle 3 in place." (*Id.* at 4:42-43.) In addition, Honda states that the rubber stopper 24 in solvent container 2 "may be covered with a thin plastic film to prevent its surface from contamination." (*Id.* at 12:60-13:2.) "The…fluid container may be assembled by hermetically and removably fitting the guide capsule 4 on the solvent container 2…and hermetically fitting the cap 5 with drug container 1 on the open end of the guide capsule 4." (*Id.* at 8:14-22.) Thus, a POSITA would have understood that the top of container 2 and guide capsule 4 are both sterilized, because aseptic technique would not be possible without sterilization. (Ex. 1003, ¶ 33; *see also* Exs. 1011-1012.)
7. The method of claim 1 wherein the device further comprises a hermetic seal at the	Honda discloses **claim 1** for the reasons discussed above. As discussed in Section IV(B), a "hermetic seal" is an "airtight seal."

first end of the device.	Honda teaches that "[t]he cap 5 serves…as a hermetic sealing means for the guide capsule 4[.]" (Ex. 1005 at 7:52-54). Further, "[t]he above fluid container may be assembled by…hermetically fitting the cap 5 with drug container 1 on the open end of the guide capsule 4." (*Id.* at 8:14-20.) Honda also discloses an embodiment in which "[t]he cap 5 is provided at its lower end of its skirt 55 with an annular groove 54 in which a sealing member 53 is fitted to form a hermetic seal between the cap 5 and the guide capsule 4." (*Id.* at 14:6-15.)

B. Ground 2: Obviousness of Claims 1-7 Based on Honda

Claims 1-7 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Honda as set forth below.

i. Disclosure of Honda

The disclosure of Honda is discussed in Section VI(A)(i), above.

ii. Obviousness of Claims 1, 4, and 7 Based on Honda

Honda discloses the elements of claims 1, 4, and 7 for the reasons discussed in Section VI(A)(ii). Accordingly, claims 1, 4, and 7 would also have been obvious to a POSITA because "anticipation is the epitome of obviousness." *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002).

Furthermore, to the extent that the Board believes any differences exist between the claims and Honda, such differences are inconsequential. For example, to the extent that Honda does not expressly teach sterilizing the top of the container and the receiving chamber, sterilization of medical devices to prevent

contamination followed by aseptic handling of the sterilized component was common practice and well-known to a POSITA. (*See* Ex. 1003, ¶¶ 21-22, 33.) Indeed, sterilization was so ubiquitous that it was mandated by standards that would have been followed by a POSITA. (*See id*.; Exs. 1011-1012.) Additionally, if the Board disagrees with BD's proposed claim construction of "fixedly attached," any differences between the Board's construction and the attachment taught by Honda would be inconsequential.

iii. Comparison of Claims 2, 3, 5, and 6 to Honda

The claim chart below specifies where each element of claims 2, 3, 5, and 6 is found in Honda.

'192 Claim Language	Citations to Honda
2. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done manually.	Honda at least renders **claim 1** obvious for the reasons discussed in Section VI(A)(ii) and above. *See* ***element 1f***, discussed in Section VI(A)(ii). A POSITA would have known that there were only two ways to attach the connector: manually and using a machine. (Ex. 1003, ¶ 32.) Accordingly, it would have been at least obvious to a POSITA to insert the container into the chamber manually. (*See id*.)
3. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done by a machine.	Honda at least renders **claim 1** obvious for the reasons discussed in Section VI(A)(ii) and above. *See* ***element 1f***, discussed in Section VI(A)(ii). A POSITA would have known that there were only two ways to attach the connector: manually and using a

	machine. (Ex. 1003, ¶ 32.) Accordingly, it would have been at least obvious to a POSITA to insert the container into the chamber by machine. (*See id*.)
5. The method of claim 4 wherein the step of sterilizing is done prior to the step of inserting the top of the container into the receiving chamber.	Honda at least renders **claim 4** obvious for the reasons discussed in Section VI(A)(ii) and above. It would have been obvious to a POSITA based on the disclosure of Honda to sterilize the top of solvent container 2 prior to inserting the top of the container into guide capsule 4. (Ex. 1003, ¶¶ 33-34.)
6. The method of claim 4 wherein the step of sterilizing is done simultaneously with the step of inserting the top of the container into the receiving chamber.	Honda at least renders **claim 4** obvious for the reasons discussed in Section VI(A)(ii) and above. It would have been obvious to a POSITA based on the disclosure of Honda to sterilize the top of solvent container 2 at the same time as inserting the top of the container into guide capsule 4, after removing the thin plastic film covering the surface of the container. (Ex. 1003, ¶¶ 33-34.)

C. Ground 3: Obviousness of Claims 1-7 Based on Honda in Combination with Forman

Claims 1-7 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Honda and Forman as set forth below.

i. Disclosure of Honda

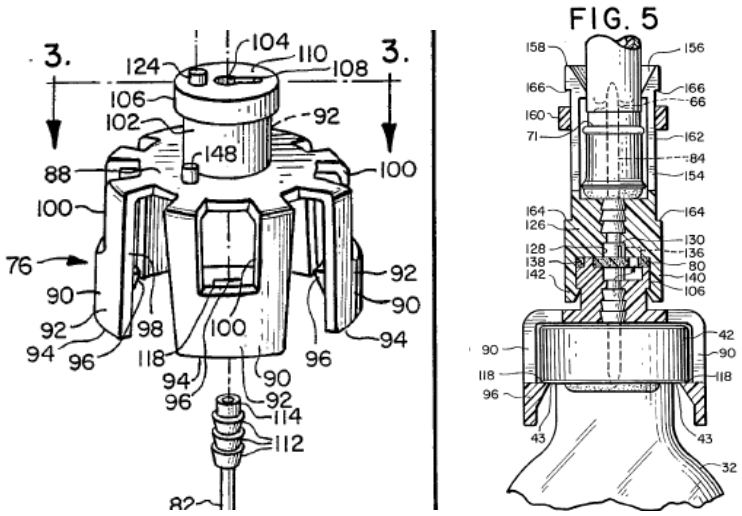
The disclosure of Honda is discussed in Section VI(A)(i), above.

ii. Disclosure of Forman

Forman is directed to a reconstitution device that forms a fluid communication path between a liquid container and a drug container. (*See, e.g.*,

Ex. 1006 at 3:29-35.) The Forman device has securing means at either end that prevent inadvertent detachment from the containers and a double-ended needle to create the flow path between the containers. (*See, e.g.*, *id.* at 3:4-4:49.)

Forman teaches that the means for securing the drug container can be a vial adapter with ridges that snap into the underside of the vial mount, creating a mechanical interlock between the connector and the drug vial. (*See, e.g.*, *id.* at 6:68-7:3, 9:66-10:10). An embodiment of Forman's connector device and vial adapter is shown in Figures 2 and 5:



(*Id.* at Figs. 2, 5.)

iii. Rationale for Combining the Teachings of Honda and Forman

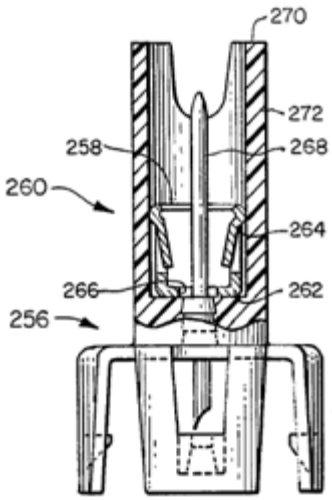
A POSITA would have readily understood the motivation to combine the teachings of Honda and Forman. First, Honda and Forman are analogous art, as they both disclose connector devices for establishing fluid communication between two containers to reconstitute a drug dose. (*See* Ex. 1003, ¶¶ 48-49.) Additionally,

a POSITA would have a reasonable expectation of success combining Honda and Forman, as both disclose connector devices with similar structures, including attachments for containers at each end of the connector device and a double-ended needle that establishes the fluid connection. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Honda's connector device to incorporate the particular vial attachment disclosed in Forman. Such a modification is merely a combination of prior art elements according to known methods to yield predictable results. *See, e.g.*, M.P.E.P. § 2143; (Ex. 1003, ¶ 50).

Furthermore, it was the practice of engineers working in the drug reconstitution and fluid transfer fields during the relevant time period to look at other patents and devices for drug reconstitution and fluid transfer and import features from them into other drug reconstitution and fluid transfer devices. (*See* Ex. 1003, ¶ 53.) Additionally, the specification of the '192 patent acknowledges that one of the known problems with Baxter's prior Zdeb device was that "the connector could be relatively easily removed from the vial." (*See* Ex. 1001 at 2:54-3:39.) This problem had already been solved, however, by the attachment mechanisms disclosed in the prior art, including Baxter's own Forman patent. Thus, a POSITA would have been motivated to look to Baxter's own prior art that provided a well-known solution to a well-known problem. (*See* Ex. 1003, ¶ 54.)

iv. Comparison of Claims 1-7 to Honda and Forman

The claim chart below specifies where each element of claims 1-7 is met by Honda in combination with Forman.

'192 Claim Language	Citations to Honda and Forman
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:	Honda at least renders ***element 1a*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii). Forman is titled "RECONSTITUTION DEVICE" and teaches a method for connecting a reconstitution device to a drug container having a top and a closure:  (*See, e.g.*, Ex. 1006 at Fig. 17.) Forman states: > The invention is further directed to a reconstitution device which includes means for securing the device to both a liquid container and a drug container, piercing means for piercing both the injection site of the liquid container and the access site of the drug container, and flow path means for placing the chambers of the drug and liquid containers into open communication.

	(*Id.* at 3:29-35.)
[1b] providing a reconstitution device having first and second ends,	Honda at least renders ***element 1b*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).
[1c] the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container,	Honda at least renders ***element 1c*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii). Forman teaches connecting the reconstitution device to a drug container in a manner that prevent inadvertent detachment: > The invention is directed to a device for reconstituting a substance such as a drug, which includes means to secure the device to both first and second containers, such that each securing means includes an interlock that **prevents inadvertent detachment** of the device from either the first or the second container. (Ex. 1006 at 3:4-10 (emphasis added).) More specifically, Forman teaches permanently coupling a vial adapter 76 to a vial 32:

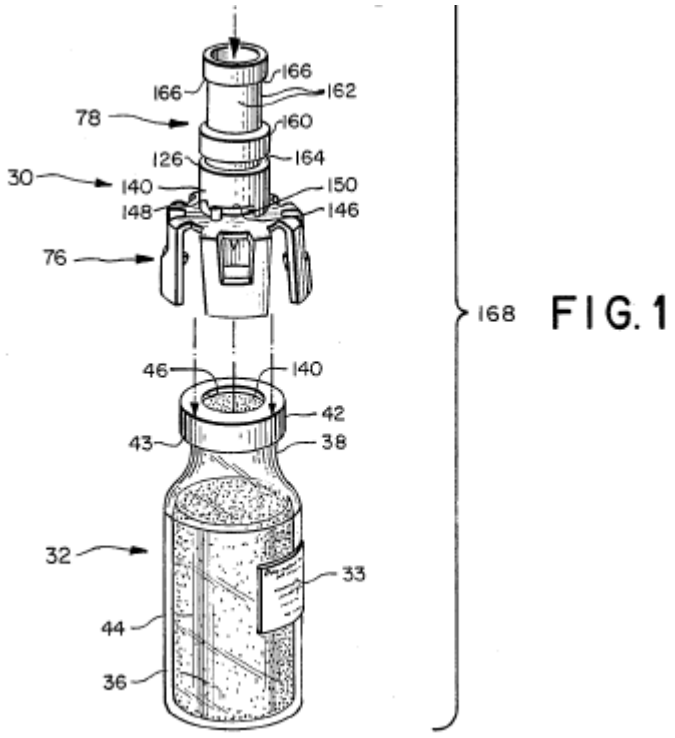
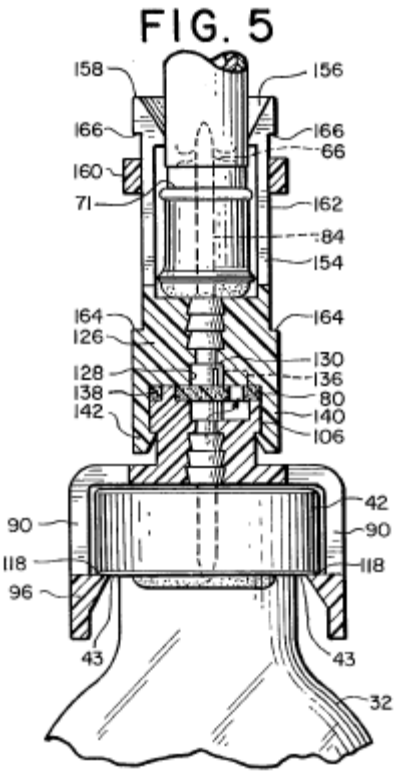


FIG. 1

(*See, e.g.*, *id.* at FIG. 1, *see also id*. at Abstract ("the reconstitution device 30 includes an improved vial adapter 76 and bag adapter 78 which permit the **permanent coupling** of the vial 32 and liquid container 34.") (emphasis added).)

Forman further explains that "[t]he reconstitution device 30 includes means for securing the device to the first container such as the drug container 32…. The drug container securing means is noted generally by vial adapter 76….The vial adapter 76 is secured over the mouth 38 of the drug vial 32." (*Id.* at 6:40-47.) As shown in Figure 5, when "[t]he ridges 96 snap into the underside 43 of the vial mouth 38 to create a mechanical interlock, securing the vial adapter 76 to the vial 32….":

	 (*Id.* at 6:68-7:3 & Fig. 5; *see also id.* at 12:53-58 ("This interlock construction makes removal of the vial adapter 188 from the vial 32 impossible or extremely difficult, possibly requiring the use of a prying tool, such as a screwdriver… Such a forced removal may break the adapter 188."), 12:6-9 (explaining that vial adapter 188 is "identical to the vial adapters 76").) It would have been obvious to replace the attachment mechanism of Honda with Forman's vial adapter, which is merely the substitution of one known component for another. (Ex. 1003, ¶ 55.) Doing so would allow a POSITA to adapt the Honda device for use with vials whose tops are dimensioned to fit the Forman adapter. (*Id.*)
[1d] the device having a central channel housing a piercing member,	Honda at least renders ***element 1d*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).

[1e] 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	Honda at least renders ***element 1e*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).
[1f] 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.	Honda at least renders ***element 1f*** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii). *See* ***element 1c***. Forman further teaches that "[i]n operation, the reconstitution device is typically first attached to the drug vial 32, by pushing the first needle 82 through the rubber stopper 40, simultaneously urging the wall portions 92 of the vial adapter skirt 90 over the mouth 38 of the vial including the metal band 42." (Ex. 1006 at 9:66-10:3.)
2. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done manually.	Honda and Forman render **claim 1** obvious, as discussed above. Honda renders the additional element of **claim 2** obvious, as discussed in Section VI(B)(iii). Even if the additional element of **claim 2** were not obvious based on the disclosure of Honda, it would have been obvious based on the disclosure of Forman. (Ex.

	1003, ¶¶ 35-37.) *See* ***element 1f***. Forman further teaches that "[t]he reconstitution device 186 may be coupled to a drug vial 32 in a hospital pharmacy… The vial and reconstitution device assembly may then be sent to the proper nursing station where a nurse or other hospital personnel…connects the bag adapter 190 to a liquid container 34 shortly before use." (Ex. 1006 at 12:26-32.) "The operator, for example a hospital pharmacist, then attaches the reconstitution device 30 to the parenteral solution container 34." (*Id.* at 10:12-14.) Based on Forman's teaching of the manual connection of bag adapter 190 to a liquid container 34, it would have at least been obvious to manually insert, for example, drug vial 32 into vial adapter 76. (Ex. 1003, ¶ 37.)
3. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done by a machine.	Honda and Forman render **claim 1** obvious, as discussed above. Honda renders the additional element of **claim 3** obvious, as discussed in Section VI(B)(iii).
4. The method of claim 1 further comprising the step of sterilizing the top of the container and the receiving chamber.	Honda and Forman render **claim 1** obvious, as discussed above. Honda at least renders the additional element of **claim 4** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).
5. The method of claim 4 wherein the step of sterilizing is done prior to the step of inserting the top of the container into the receiving chamber.	Honda and Forman render **claim 4** obvious, as discussed above. Honda renders the additional element of **claim 5** obvious, as discussed in Section VI(B)(iii).
6. The method of claim 4 wherein the step of sterilizing is done simultaneously with the	Honda and Forman render **claim 4** obvious, as discussed above. Honda renders the additional element of **claim 6** obvious,

step of inserting the top of the container into the receiving chamber.	as discussed in Section VI(B)(iii).
7. The method of claim 1 wherein the device further comprises a hermetic seal at the first end of the device.	Honda and Forman render **claim 1** obvious, as discussed above. Honda at least renders the additional element of **claim 7** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).

D. Ground 4: Obviousness of Claims 2-3 Based on Honda in Combination with Forman and Reynolds

Claims 2-3 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Honda, Forman, and Reynolds as set forth below.

i. Disclosure of Honda

The disclosure of Honda is discussed in Section VI(A)(i), above.

ii. Disclosure of Forman

The disclosure of Forman is discussed in Section VI(C)(ii), above.

iii. Disclosure of Reynolds

Reynolds is directed to a system for preparing a dosage from one or two component medicines (one of which may be a solid) that includes a syringe, a connector, and a vial. (*See, e.g.*, Ex. 1007 at 2:10-23.) Reynolds teaches preparing a dose, by connecting a vial to a connector with a double-ended needle in order to establish fluid communication with an additional container (such as a syringe or

capsule with a diluent). (*See, e.g.*, *id.* at Abstract.) An embodiment of the system of Reynolds is shown in Fig. 22E:

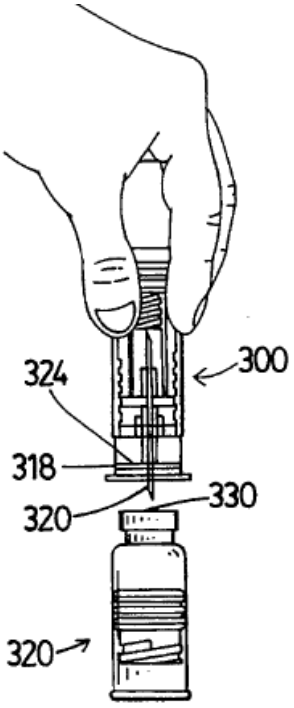


FIG. 22E

(*Id.* at Fig. 22E.)

iv. Rationale for Combining the Teachings of Honda, Forman, and Reynolds

A POSITA would have readily understood the motivation to combine the teachings of Honda, Forman, and Reynolds. As discussed in Section VI(C)(iii), a POSITA would have readily understood the motivation to combine the teachings of Honda and Forman. A POSITA would also have readily understood the motivation to combine the teachings of Honda, Forman, and Reynolds. First, Honda, Forman, and Reynolds are analogous art, as they all disclose connector

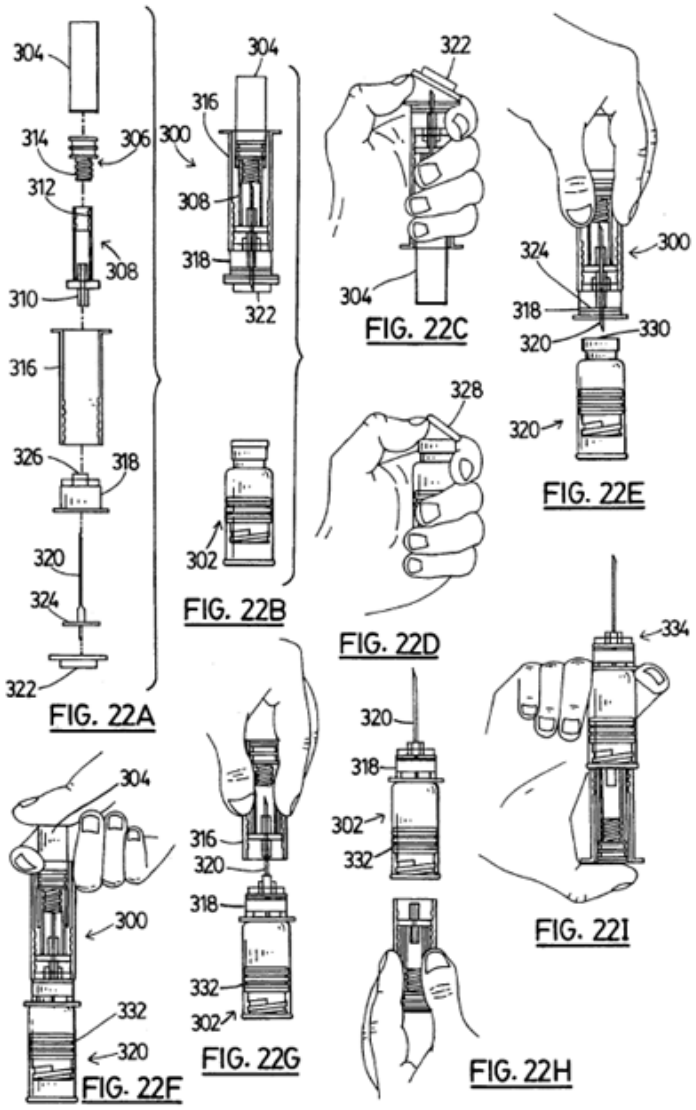
devices for establishing fluid communication between two containers via a double-ended needle. (*See* Ex. 1003, ¶ 48-49.) Additionally, a POSITA would have a reasonable expectation of success in combining Honda, Forman, and Reynolds, as they all disclose connector devices with similar structures. (*See id.*)

Thus, it would have been obvious to a POSITA to follow Reynolds' teachings regarding how to assemble the devices taught by Honda and Forman. (*Id.*, ¶ 52.)

v. Comparison of Claims 2-3 to Honda, Forman, and Reynolds

The claim chart below specifies where each element of claims 2-3 is met by Honda in combination with Forman and Reynolds.

'192 Claim Language	Citations to Honda, Forman, and Reynolds
2. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done manually.	Honda and Forman render **claims 1** obvious, as discussed in Section VI(C)(iv). Honda and Forman render the additional element of **claim 2** obvious, as discussed in Section VI(C)(iv). Even if manually inserting the top of the fluid container into the receiving chamber were not obvious based on the disclosures of Honda and Forman, it would have been obvious based the disclosure of Reynolds. (Ex. 1003, ¶¶ 38-39.) Figures 22A-22I of Reynolds illustrate manual assembly and operation of the device. Specifically, Figure 22E illustrates manually inserting the top of a drug container into a receiving chamber for the top of the container:

	 (Ex. 1007 at Figs. 22A-22I.)
3. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done by a machine.	Honda and Forman render **claim 1** obvious, as discussed in Section VI(C)(iv). Honda renders the additional element of **claim 3** obvious, as discussed in Section VI(B)(iii). Even if inserting the top of the fluid container into the receiving chamber using a machine were not obvious based on the disclosure of Honda, it would have been obvious based the disclosure of Reynolds. (Ex. 1003,

	¶ 40.) Reynolds teaches "handling of the vials by conventional vial sterilizing, filling and capping machinery." (Ex. 1007 at Abstract.) Reynolds further teaches a vial that can be "conveyed, filled and capped reliably by conventional vial sterilization, filling and handling equipment such as is already possessed by most pharmaceutical manufacturers." (*Id.* at 2:33-38.) It would thus at least have been obvious to a POSITA that the step of inserting the top of the container into the chamber could have been done by a conventional vial-handling machine. (Ex. 1003, ¶ 40.)

E. Ground 5: Anticipation of Claim 1 Based on Gustavsson

Claim 1 is anticipated under 35 U.S.C. § 102 in view of Gustavsson as set forth below.

i. Disclosure of Gustavsson

Gustavsson is directed to a connector device for transferring liquid medication between two vessels without air contamination. (*See, e.g.*, Ex. 1008 at Abstract, 1:54-68.) Gustvasson teaches a connector device that attaches to a syringe at one end and a medicine vial at the other end. (*See, e.g.*, *id.* at 4:9-39.) The medicine container is attached to the connector using a snap fit locking mechanism. (*See, e.g.*, *id.* at 2:41-50, 2:66-3:5.)

The connector device includes a needle that extends through the device from the syringe end to the medicine container end. (*See, e.g.*, *id.* at 2:27-56.) When the device is compressed, the needle extends past the connector. (*See, e.g.*, *id.* at 2:56-

3:27.) This results in the needle puncturing the seals at the end of the connector and the mouth of the vial, and creates a fluid connection between the vial and the syringe. (*See, e.g.*, *id.*) An embodiment of the Gustavsson invention is shown in Figures 1-3:

FIG 1

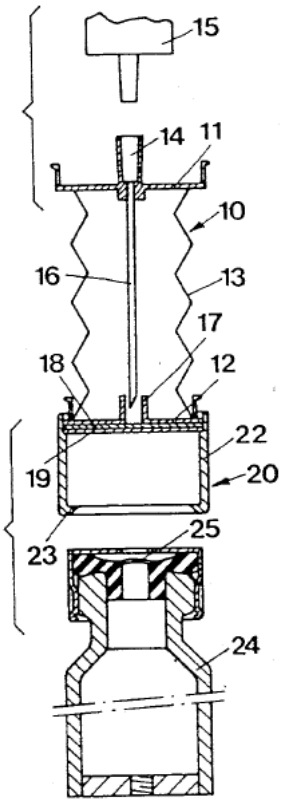


FIG 2

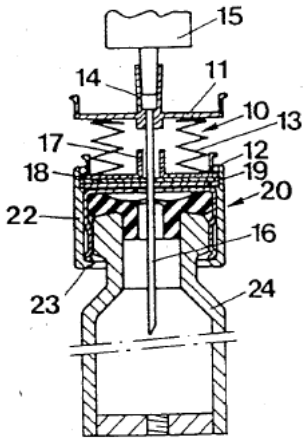
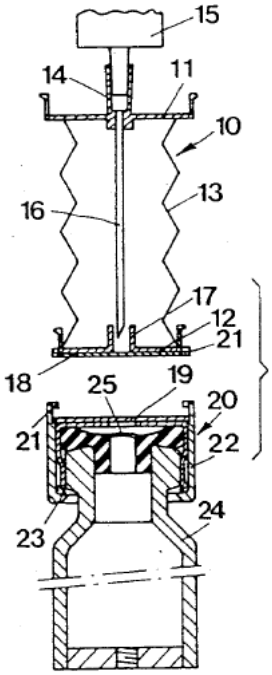


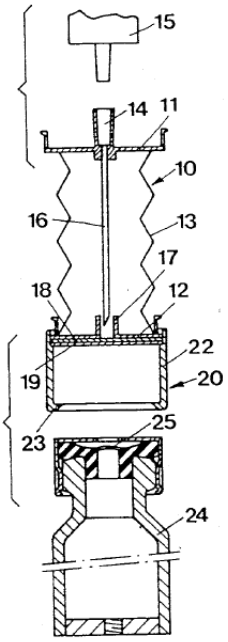
FIG 3



(*Id.* at Figs. 1-3.)

ii. Comparison of Claim 1 to Gustavsson

The claim chart below specifies where each element of claim 1 is found in Gustavsson.

'192 Claim Language	Citations to Gustavsson
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:	The invention disclosed by Gustavsson may be used to reconstitute a drug, such as a drug in dry form. For example, Gustavsson states: By pressing together the flexible side walls 13 axially, as shown in FIG. 2, the needle 16 penetrates the two membranes 18 and 19 and the rubber membrane 25 of the ampoule 24 and is inserted into the ampoule. **If this contains a dry substance this can be dissolved by a solvent contained in the injection syringe and thereafter can be sucked up into the injection syringe.** If the ampoule contains medicine in solution this is directly sucked up into the injection syringe 15. (Ex. 1008 at 2:57-65 (emphasis added).)
[1b] providing a reconstitution device having first and second ends,	Gustavsson teaches a device with two ends (*see, e.g.*, elements 14 and 20 in Figure 1) that may be used to reconstitute a drug, such as a drug in dry form: FIG 1  (Ex. 1008 at Fig. 1; *see also id.* at 2:57-65.)

[1c] the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container,	As discussed in Section IV(A), the '192 patent specification defines "fixedly attached" as "attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector." The connector disclosed by Gustavsson falls within that definition. Gustavsson discloses that member 20 at one end of the device is dimensioned to receive the top of a medicine container and remain fixedly attached to it. For example, Gustavsson states: The second member 20 of the device, which is connected to the first member 10 by a bayonet coupling 21, Luer lock coupling or the like contains a second membrane 19, which is placed in tight apposition against the first membrane 18. The 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**…. … 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 [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.**

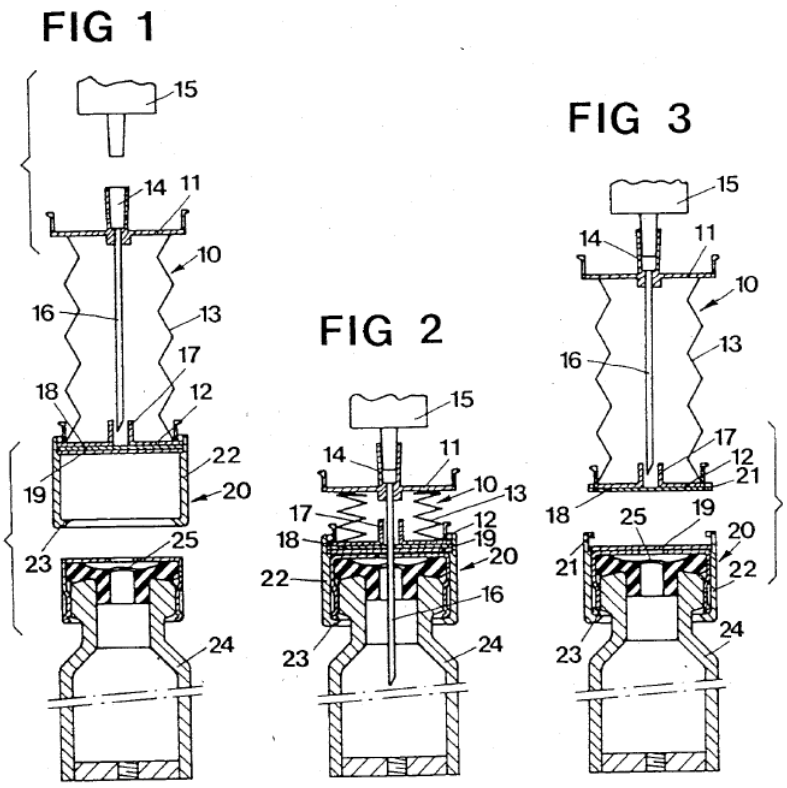
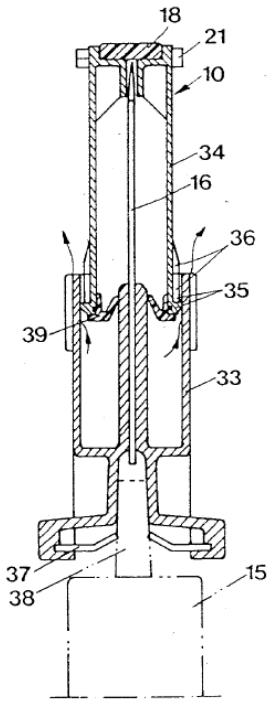
	 (Ex. 1008 at 2:41-50, 2:66-3:5, & Figs. 1-3 (emphasis added).) A POSITA would have understood that second member 20 is fixedly attached to ampoule 24, as second member 20 is snap fit onto ampoule 24 and subsequently thrown away while still attached to the ampoule. (*See* Ex. 1003, ¶¶ 41-44.)
[1d] the device having a central channel housing a piercing member,	Gustavsson states: In FIG. 7 is shown an embodiment, in which the first member 10 comprises a **pair of telescoping parts, the outer 33 of which having e [sic] needle 16 attached thereto** and being arranged to receive an injection syringe 15.

	FIG 7  (Ex. 1008 at 4:9-39 & Fig. 7 (emphasis added).)
[1e] 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	Gustavsson states: In FIG. 7 is shown an embodiment, in which the first member 10 comprises a **pair of telescoping parts, the outer 33 of which having e [sic] needle 16 attached thereto** and being arranged to receive an injection syringe 15. **The inner part 34 is provided with a first membrane 18 at its end facing away from the outer part 33 and is arranged to be coupled together with the second member 20 of the device, e.g. in a corresponding manner as is shown in FIG. 5** by means of a bayonet coupling 21 or the like. The telescoping parts 33 and 34 are each provided with stop lugs 35 preventing the parts from being separated from each other. (Ex. 1008 at 4:9-39 (emphasis added).) Likewise, Gustavsson teaches:

	By pressing together the flexible side walls 13 axially, as shown in FIG. 2, **the needle 16 penetrates the two membranes 18 and 19 and the rubber membrane 25 of the ampoule 24 and is inserted into the ampoule.** If this contains a dry substance this can be dissolved by a solvent contained in the injection syringe and thereafter can be sucked up into the injection syringe. If the ampoule contains medicine in solution this is directly sucked up into the injection syringe 15. (*Id.* at 2:57-65 (emphasis added).) A POSITA would have understood that when telescoping parts 33 and 34 are extended with respect to one another such that the end of needle 16 remains within inner part 34 (as shown in Figure 7), inner part 34 is in an inactivated position. (Ex. 1003, ¶¶ 46-47.) A POSITA would likewise have understood that when inner part 34 is compressed towards the first end of outer part 33, causing needle 16 to extend through membrane 18 into a container, inner part 34 is in an activated position. (*Id.*)
[1f] 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.	As discussed in Section IV(A), the '192 patent specification defines "fixedly attached" as "attached in a manner that prevents removal without breaking, detaching, or noticeably deforming part of the connector." The connector disclosed by Gustavsson falls within that definition. Gustavsson discloses inserting the top of a medicine container into member 20 to fixedly attach it. *See* ***element 1c***. A POSITA 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. (*See* Ex. 1003, ¶¶ 41-44.)

F. Ground 6: Obviousness of Claims 1-3 Based on Gustavsson

Claims 1-3 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson as set forth below.

i. Disclosure of Gustavsson

The disclosure of Gustavsson is discussed in Section VI(E)(i), above.

ii. Obviousness of Claim 1 Based on Gustavsson

Gustavsson discloses the elements of claim 1for the reasons discussed in Section VI(E)(ii). Accordingly, claim 1would also have been obvious to a POSITA because "anticipation is the epitome of obviousness." *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002).

Furthermore, to the extent that the Board believes any differences exist between the claim and Gustavsson, such differences are inconsequential. For example, if the Board disagrees with BD's proposed claim construction of "fixedly attached," any differences between the Board's construction and the attachment taught by Gustavsson would be inconsequential.

iii. Comparison of Claims 2-3 to Gustavsson

The claim chart below specifies where each element of claims 2-3 is found in Gustavsson.

'192 Claim Language	Citations to Gustavsson
2. The method of claim 1 wherein the step of inserting the top of the	Gustavsson at least renders **claim 1** obvious for the reasons discussed in Section VI(E)(ii) and above.

container into the chamber is done manually.	A POSITA reading Gustavsson's disclosure would have understood the disclosed method of attaching member 20 to the top of a medicine container as well-suited to be performed manually. (Ex. 1003, ¶ 45.)
3. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done by a machine.	Gustavsson at least renders **claim 1** obvious for the reasons discussed in Section VI(E)(ii) and above. It would have at least been obvious to a POSITA to insert the container into the chamber by machine, as a POSITA would have understood that if attaching member 20 to the top of a container were not performed manually, it would be done by a machine. (Ex. 1003, ¶ 45.)

G. Ground 7: Obviousness of Claims 2-3 Based on Gustavsson in Combination with Reynolds

Claims 2-3 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson and Reynolds as set forth below.

i. Disclosure of Gustavsson

The disclosure of Gustavsson is discussed in Section VI(E)(i), above.

ii. Disclosure of Reynolds

The disclosure of Reynolds is discussed in Section VI(D)(iii), above.

iii. Rationale for Combining the Teachings of Gustavsson and Reynolds

A POSITA would have readily understood the motivation to combine the teachings of Gustavsson and Reynolds. First, Gustavsson and Reynolds are analogous art, as they both disclose connector devices for establishing fluid

communication between two containers to transfer medicine between them. (*See* Ex. 1003, ¶¶ 48-49.) Additionally, a POSITA would have a reasonable expectation of success combining Gustavsson and Reynolds, as both disclose connector devices with similar structures, including attachments for containers at each end of the connector device and a needle that establishes the fluid connection. (*See id.*) Thus, it would have been obvious to a POSITA to follow Reynolds' teachings regarding how to assemble the device taught by Gustavsson. (*Id.*, ¶ 52.)

iv. Comparison of Claims 2-3 to Gustavsson and Reynolds

The claim chart below specifies where each element of claims 2-3 is met by Gustavsson in combination with Reynolds.

'192 Claim Language	Citations to Gustavsson and Reynolds
2. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done manually.	Gustavsson at least renders **claim 1** obvious for the reasons discussed in Sections VI(E)(ii) and VI(F)(ii). Gustavsson renders the additional element of **claim 2** obvious, as discussed in Section VI(F)(iii). Even if manually inserting the top of the fluid container into the receiving chamber were not obvious based on the disclosure of Gustavsson, it would have been obvious based the disclosure of Reynolds, as discussed in Section VI(D)(v). (Ex. 1003, ¶¶ 38-39.)
3. The method of claim 1 wherein the step of inserting the top of the container into the chamber is done by a machine.	Gustavsson at least renders **claim 1** obvious for the reasons discussed in Sections VI(E)(ii) and VI(F)(ii). Gustavsson renders the additional element of **claim 3** obvious, as discussed in Section VI(F)(iii).

	Even if inserting the top of the fluid container into the receiving chamber using a machine were not obvious based on the disclosure of Gustavsson, it would have been obvious based the disclosure of Reynolds,, as discussed in Section VI(D)(v). (Ex. 1003, ¶ 40.)

H. Ground 8: Obviousness of Claims 4-6 Based on Gustavsson in Combination with Honda

Claims 4-6 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson and Honda as set forth below.

i. Disclosure of Gustavsson

The disclosure of Gustavsson is discussed in Section VI(E)(i), above.

ii. Disclosure of Honda

The disclosure of Honda is discussed in Section VI(A)(i), above.

iii. Rationale for Combining the Teachings of Gustavsson and Honda

A POSITA would have readily understood the motivation to combine the teachings of Gustavsson and Honda. First, Gustavsson and Honda are analogous art, as they both disclose connector devices for establishing fluid communication between two containers to transfer medicine between them. (*See* Ex. 1003, ¶¶ 48-49.) Additionally, a POSITA would have a reasonable expectation of success in combining Gustavsson and Honda, as they both disclose connector devices with similar structures. (*See id.*) Thus, it would have been obvious to a POSITA to

follow Honda's teachings regarding how to assemble the devices taught by Gustavsson. (*Id.*, ¶ 51.)

iv. Comparison of Claims 4-6 to Gustavsson and Honda

The claim chart below specifies where each element of claims 4-6 is met by Gustavsson in combination with Honda.

'192 Claim Language	Citations to Gustavsson and Honda
4. The method of claim 1 further comprising the step of sterilizing the top of the container and the receiving chamber.	Gustavsson at least renders **claim 1** obvious for the reasons discussed in Sections VI(E)(ii) and VI(F)(ii). Honda at least renders the additional element of **claim 4** obvious, as discussed in Sections VI(A)(ii) and VI(B)(ii).
5. The method of claim 4 wherein the step of sterilizing is done prior to the step of inserting the top of the container into the receiving chamber.	Gustavsson and Honda render **claim 4** obvious, as discussed above. Honda renders the additional element of **claim 5** obvious, as discussed in Section VI(B)(iii).
6. The method of claim 4 wherein the step of sterilizing is done simultaneously with the step of inserting the top of the container into the receiving chamber.	Gustavsson and Honda render **claim 4** obvious, as discussed above. Honda renders the additional element of **claim 6** obvious, as discussed in Section VI(B)(iii).

VII. CONCLUSION

Because the information presented in this petition shows that there is a reasonable likelihood that Petitioner BD will prevail with respect to at least one of the claims challenged in the petition, BD respectfully requests that a Trial be instituted and that claims 1-7 be canceled as unpatentable.

Respectfully submitted,

Dated: September 17, 2018

/s/ Kurt J. Niederluecke

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PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,159,192

Attachment A:

Proof of Service of the Petition

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of September 2018, I caused a copy of this Petition, including all attachments, appendices and exhibits 1001 – 1014, to be served in their entirety by electronic mail and/or UPS on the following counsel of record for patent owner:

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Dated: September 17, 2018

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,159,192

Attachment B:

List of Evidence and Exhibits Relied Upon in Petition

Exhibit #	Reference Name
1001	U.S. Patent No. 6,159,192
1002	File History of U.S. Patent No. 6,159,192
1003	Declaration of James L. Sertic Regarding '192 Patent
1004	*Curriculum Vitae* of James L. Sertic
1005	U.S. Patent No. 5,342,346 to Honda
1006	U.S. Patent No. 4,759,756 to Forman
1007	U.S. Patent No. 5,364,369 to Reynolds
1008	U.S. Patent No. 4,564,054 to Gustavsson
1009	U.S. Patent No. 4,898,209 to Zdeb
1010	Merriam-Webster's Collegiate Dictionary (10th ed. 2002)
1011	Quality Systems - Medical Devices - Particular Requirements for the Application of ISO 9001, ANSI/AAMI/ISO 13485:1996
1012	Medical Device Good Manufacturing Practices Manual (5th ed. 1991)
1013	Baxter's Complaint in Case No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois
1014	Affidavit of Service of Baxter's Complaint in Case No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,159,192

Attachment C:

Word Count Compliance Certificate

WORD COUNT COMPLIANCE CERTIFICATE

I certify that this Petition conforms to the requirements of 37 CFR § 42.24(a)(1)(i). The length of this Petition, counted in compliance with § 42.24(a)(1) and relying on the word count of the word-processing system, is 9,025 words. This Petition was prepared using Microsoft Word 2010 and the word processing program has been applied specifically to include all text, including headings, footnotes, and quotations for word count purposes.

By: /s/ Kurt J. Niederluecke
Kurt J. Niederluecke

Dated: September 17, 2018

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