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. 6,852,103

Issue Date: February 8, 2005

Title: SLIDING RECONSTITUTION DEVICE WITH SEAL

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,852,103

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

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Petitioner Becton, Dickinson and Company (hereinafter "BD" or "Petitioner") respectfully petitions for *inter partes* review of claims 1, 11, 14, 15, 17, 19-28, and 30 of U.S. Patent No. 6,852,103 ("the '103 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 '103 patent. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '103 patent. The '103 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 U.S. Patent Nos. 5,989,237 and 6,159,192 on November 3, 2017, captioned No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois. (*See* Ex. 1015, Affidavit of Service.) A copy of Baxter International, Inc.'s ("Baxter") original Complaint is attached as Exhibit 1014. On May 14, 2018, Baxter filed and served a Second Amended Complaint introducing allegations of infringement of the '103

patent. A copy of Baxter's Second Amended Complaint is attached as Exhibit 1016.

Because the date of this petition is less than one year from both the service of the Complaint and the Second Amended Complaint, 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 '103 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 6,159,192, which are asserted in the district court lawsuit along with the '103 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 Fredrikson & Byron, P.A. 200 South 6th Street, Suite 4000 Minneapolis, MN 55402	Adam R. Steinert *pro hac vice* to be filed asteinert@fredlaw.com (612) 492-7436 Katherine J. Rahlin Reg. No. 75,181 krahlin@fredlaw.com (612) 492-7370 Fredrikson & Byron, P.A. 200 South 6th Street, Suite 4000 Minneapolis, MN 55402

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, 11, 14, 15, 17, 19-28, and 30 of U.S. Patent No. 6,852,103 ("the '103 patent"), titled "Sliding Reconstitution Device with Seal," issued on February 8, 2005, to Fowles et al. and assigned to Baxter. The '103 patent is attached as Exhibit 1001. The '103 patent

is generally directed to "a connector device for establishing fluid communication between a first container and a second container," which can be used to reconstitute a drug dose. (*See* Ex. 1001 at Abstract, 1:14-17.)

Claim 1 of the '103 patent is an independent claim. Claim 1 is an apparatus claim and representative of the alleged invention:

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

(Ex. 1001 at Cl. 1.)

The prior art references cited and discussed in this petition for *inter partes* review are U.S. Patent No. 4,564,054 to Gustavsson ("Gustavsson") (Ex. 1007), U.S. Patent No. 4,946,445 to Lynn ("Lynn") (Ex. 1008), U.S. Patent No. 3,995,630 to van de Veerdonk ("van de Veerdonk") (Ex. 1009), U.S. Patent No. 5,100,394 to Dudar et al. ("Dudar") (Ex. 1010), and U.S. Patent No. 4,898,209 to Zdeb ("Zdeb") (Ex. 1011).

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. 1007 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).

Lynn is a U.S. patent directed to an intravenous line coupling device that attaches to a primary intravenous tubing system to create a fluid connection between a secondary fluid source (such as a medication) and a catheter for delivering the secondary fluid to a patient. (*See, e.g.*, Ex. 1008 at Abstract, 1:5-30.) It issued on August 7, 1990. Accordingly, Lynn is prior art under at least 35 U.S.C. § 102(b).

Van de Veerdonk is a U.S. patent directed to a pre-loaded injection syringe with a telescopic assembly that allows fluid to flow between a cartridge attached to the syringe at one end of the assembly and a vial attached to the other end of the

assembly. (*See, e.g.*, Ex. 1009 at 3:14-40.) It issued on December 7, 1976. Accordingly, van de Veerdonk is prior art under at least 35 U.S.C. § 102(b).

Dudar is a U.S. patent directed to an injection site coupling system for transferring materials from a vial to a syringe. (*See, e.g.*, Ex. 1010 at Abstract, 1:12-20, 7:52-66, 14:1-16.) It issued on March 31, 1992. Accordingly, Dudar is prior art under at least 35 U.S.C. § 102(b).

Zdeb is a U.S. patent directed to a coupling device for establishing fluid communication between two containers to reconstitute a drug. (*See, e.g.*, Ex. 1011 at Abstract, 3:32-37.) It issued on February 6, 1990. Accordingly, Zdeb is prior art under at least 35 U.S.C. § 102(b).

Additionally, Gustavsson, Dudar, and Zdeb are all admitted as prior art on the face of the ’103 patent. The file history of the ’103 patent does not indicate the examiner performed any substantive analysis of the Gustavsson and Dudar references, nor did Baxter highlight their relevance to the claims of the ’103 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 ’103 patent should be granted.

III. BACKGROUND OF THE '103 PATENT

A. Effective Filing and Priority Dates of the '103 patent

The '103 patent issued from U.S. Application No. 10/346,902 ("the '902 application"), with a filing date of January 16, 2003. The '902 application is a continuation of U.S. Application No. 09/566,033 ("the '033 application"), filed on May 8, 2000, now U.S. Pat. No. 6,610,040, which is a continuation of U.S. Application No. 08/986,580 ("the '580 application"), filed on December 4, 1997, now U.S. Pat. No. 6,071,270 ("the '270 patent"). Accordingly, the earliest possible priority date for the '103 patent is December 4, 1997.

B. Relevant Prosecution History of the '103 patent

The file history for the '103 patent is particularly helpful in understanding what Baxter claims it invented. The file history is attached as Exhibit 1002.

The '103 patent, its file history, and the file history of its parent applications (Exhibits 1003 and 1004) demonstrate that Baxter's alleged invention was limited to ***a means for visually indicating that the connector is in the activated position,*** a small improvement over Baxter's own prior art, Zdeb patent (Ex. 1011).[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. 1011.) While the '103 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 '580 application over Zdeb. (Ex. 1003 at 0097-98.) The examiner found that Zdeb disclosed every limitation and thus anticipated claim 1 – an independent claim that as filed included limitations similar to those of claim 1 of the '103 patent but **did not** include a means for visually indicating that the connector is in the activated position. (*Compare id*. at 0039, *with* Ex. 1001 at Cl. 1.) The examiner found no need to address any other prior art patent. (*See* Ex. 1003 at 0097-98.)

After an interview with the examiner, Baxter limited its claims by adding a ***"means for visually indicating that the connector is in the activated position"*** to claim 1 and two other independent claims of the '580 application. (*Id.* at 0126, 0129-30, 0135-36.) Baxter did not make any arguments with respect to Zdeb and simply stated that the claims had been amended in light of the examiner interview.[2] (*Id.* at 0135-36.) The examiner allowed the claims with Baxter's newly-added limitation to issue as the '270 patent. (*Id.* at 0142-43.)

A month before the '270 patent issued, Baxter filed the '033 application. (*See* Ex. 1004 at 0006.) The examiner rejected the claims based only on double patenting and Section 112. (*Id.* at 0121-23.) Baxter filed a terminal disclaimer, corrected the Section 112 issues, and added an independent claim with a "means

[2] The file history of the '580 application does not indicate the substance of the examiner interview, only that claim amendments were discussed. (*Id.* at 0126.)

for visually indicating that the connector is in the activated position" similar to that of claim 1 of the '103 patent. (*Id.* at 0126-28, 0129-36; *compare id.* at 131, *with* Ex. 1001 at Cl. 1.) The examiner subsequently allowed the claims to issue as the '040 patent. (Ex. 1004 at 0139-45.)

While the '033 application was pending, Baxter filed the'902 application. (Ex. 1002 at 0001.) The claims were subject to a restriction requirement. (*Id.* at 0174-77.) The set of claims Baxter elected to have examined included claim 1 as issued in the '103 patent. (*Id.* at 0157, 0180-82.) The only differences between claim 1 of the '103 patent and claim 1 of the '270 patent is that claim 1 of the '103 patent recites a single piercing member instead of two piercing members, lacks a hermetic sealing limitation, and provides more detail on the means for visually indicating that the connecter is in an activated position. (*Compare* Ex. 1001 at Cl. 1, *with* Ex. 1003 at 0177.)

The examiner rejected the elected claims of the '902 application based on double patenting over, among other things, the '270 patent, but did not make any substantive rejections. (Ex. 1002 at 0185-88.) Baxter filed a terminal disclaimer, and the '902 application was allowed. (*Id.* at 0208-221.)

Accordingly, Baxter's ***means for visually indicating that the connector is in the activated position*** 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 '103 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 1005, ¶ 17.)

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

The '103 patent expired on December 4, 2017, twenty years after its priority date. 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. "Means for Visually Indicating that the Connector is in the Activated Position"

Claim 1 of the '103 patent recites "means for visually indicating that the connector is in the activated position comprising a color indication wherein one of the sleeve members has a first color, the other sleeve member has a second color,

wherein only one color is visible when the connector is in the activated position." Although the use of the phrase "means for" creates a presumption that this is a means-plus-function limitation, the limitation includes an express recitation of the structure used to perform the function. Accordingly, this element is *not* a means-plus-function element, and is instead structural. *See TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008).

Following the express language of the claim, it should be interpreted as requiring the two sleeve members to have different colors, only one of which is visible when the device is in the activated position. (*See* Ex. 1001 at 5:22-24 ("in the inactivated position one can see two different colors, but in the activated position only one color is visible"); 12:53-58 ("When the first sleeve member 30 and the second sleeve member 32 are fully in the activated position, none of the color of the first sleeve member 30, in this case blue, will be visible. If any of the color, in this case blue, shows, the medical personnel will immediately know that the device 10 is not fully activated.").)

B. "The First and Second Connectors"

Claim 15 of the '103 patent refers to "the first and second connectors," which has no antecedent basis and makes no sense in the context of the claim. The entire claimed device is referred to as "the connector," and thus there is no "second connector" contemplated by the '103 patent. Based on the context of the claim,

this phrase appears to be a typographical error. The phrase "first and second sleeve members" appears elsewhere in the claim, has proper antecedent basis, and makes logical sense in this part of the claim as well. Accordingly, the phrase "the first and second connectors" should be construed as "the first and second sleeve members" to correct the typographical error and avoid indefiniteness. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003).

C. "Means … for Preventing the First Sleeve Member from Becoming Disassociated from the Second Sleeve Member"

Claim 19 of the '103 patent recites "means associated with the connector for preventing the first sleeve member from becoming disassociated from the second sleeve member." This is a means-plus-function limitation, governed by pre-AIA 35 U.S.C. §112 paragraph 6. The recited function is "preventing the first sleeve member from becoming disassociated from the second sleeve member when moving from the inactivated position to the activated position."

The '103 specification identifies various circular and cylindrical stop elements that can be used to prevent the two telescoping sleeves from separating from each other. For example, the specification states that "[a] bushing having a diameter greater than that of the second sleeve member is connected to the proximal end of the first sleeve member, preventing it from becoming disassociated when being moved from the inactivated position to the activated position." (Ex. 1001 at 5:30-34.) As discussed in Section IV(D), the specification

redefines "bushing" to give it a broad meaning. Regardless, the specification also states that in addition to a bushing, "[t]he means for stopping could be another structure such as a ring or washer associated with the first or second sleeve members 30 and 32 to prevent them from sliding apart." (*Id.* at 8:6-9.) Thus, the corresponding structure should be construed as "a radially-symmetric stop, such as a sleeve, ring, or washer."

D. "Bushing"

Claims 20 and 21 of the '103 patent recite "a bushing."

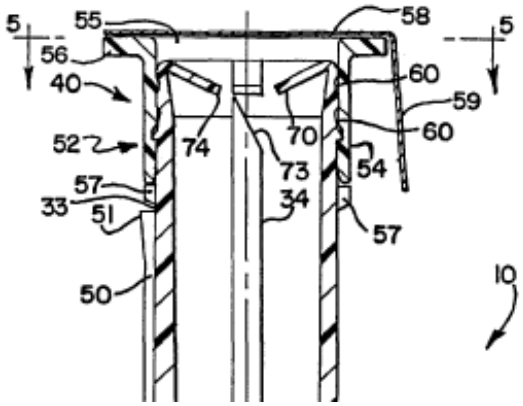
Merriam-Webster's Collegiate Dictionary (10th ed. 2002) defines a "bushing" as "1: a usu. removable cylindrical lining for an opening (as of a mechanical part) used to limit the size of the opening, resist abrasion, or serve as a guide 2: an electrically insulating lining for a hole to protect a through conductor." (Ex. 1012 at 154.) The American Heritage College Dictionary (4th ed. 2002) similarly defines a "bushing" as "A fixed or removable cylindrical metal lining used to constrain, guide, or reduce friction. 2. *Electricity* An insulating lining for an aperture through which a conductor passes. 3. An adapter threaded to permit joining of pipes with different diameters." (Ex. 1013 at 196.) The '103 patent uses the term "bushing" in a manner that is inconsistent with its dictionary definitions, and accordingly the patentees have acted as their own lexicographers to redefine

the term. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017).

The '103 specification describes "bushing 52" as follows:

> A **bushing 52** is provided at the first end 40 of the first sleeve 30. The bushing 52 has a bushing sleeve 54, an aperture 55, a flange 56 circumjacent the aperture 55, and a foil closure 58. (FIG. 4). **The bushing sleeve 54 slides over the cylindrical wall 33 and forms an interference fit therewith**. A stop 57 is provided on the first sleeve 30 to abut an end of the bushing sleeve 54. The stop 57 includes several circumferentially spaced bumps. Preferably, the bushing sleeve 54 has an interior surface having two axially spaced annular ribs or ridges 60 (FIG. 4), that provide a hermetic seal with the cylindrical wall 33. The flange 56, as will be explained below, acts as a means for stopping the first and second sleeve members 30 and 32 from becoming disassociated from one another when the connector is in the activated position and also provides a hand-hold for moving first and second sleeves 30 and 32 axially with respect to one another. The means for stopping could be another structure such as a ring or washer associated with the first or second sleeve members 30 and 32 to prevent them from sliding apart.

FIG.4



(Ex. 1001 at 7:57-8:9 (emphasis added) & Fig. 4.)

Thus, although the ordinary definition of a "bushing" is a "lining," the '103 patent describes a "bushing" that is fitted to the *outside* of a cylindrical sleeve. Likewise, the "bushing" described in the '103 patent does not perform the traditional functions of a bushing – it does not resist abrasion, limit the size of the opening at the end of the cylindrical sleeve, or act as a guide for items passing through the sleeve. (*See* Ex. 1005, ¶¶ 30-31.) The only "bushing-like" aspects of component 52 in the '103 patent specification are that it is "cylindrical" and that it "forms an interference fit" with cylindrical sleeve 30. (*See id.*) Accordingly, a POSITA reviewing the patent specification would understand that the patentees acted as their own lexicographers and redefined "bushing" to mean "a cylindrical component that attaches to an opening in another component by forming an interference fit." (*See id.*, ¶ 32.)

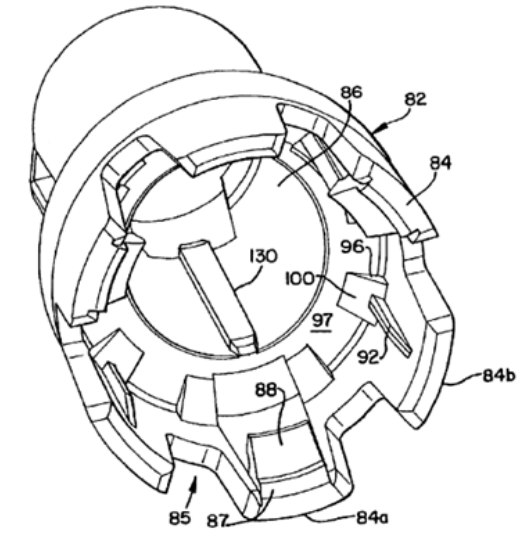
E. "Standing Ribs"

Claims 26-30 of the '103 patent recite "standing ribs." This is a unique phrase coined by the patent specification and accordingly should be construed as having the meaning that the specification gives it. *See Phillips*, 415 F.3d at 1316.

The '103 specification describes the "standing ribs" as follows:

> As best seen in FIG. 6, the remaining three fingers 84b have **axially extending, standing ribs 92** extending from a generally wedge shaped gusset 96…. In a preferred form, the standing ribs 92 extend axially-outwardly beyond a distal end of the tabs 88 to assist in aligning the vial with the vial receiving chamber 86 during insertion. The **standing ribs 92 are capable of indenting one or more sidewall portions 102 of the metal crimp 26 of the vial 14** in order to inhibit the vial 14 the elastomeric closures 22 and 24 of the vial 14 and the flexible container 12 by the piercing member 34.

FIG.6



(Ex. 1001 at 9:41-56 (emphasis added) & Fig. 6.)

Accordingly, a POSITA reviewing the patent specification would understand that the patentees acted as their own lexicographers and coined the phrase "standing ribs" to mean "elongated, axially extending structures that indent the metal crimp of a vial to inhibit its movement." (*See* Ex. 1005, ¶¶ 33-35.)

F. "Gusset"

Claim 27 of the '103 patent recites "a gusset on the annular shelf." This is a unique phrase coined by the patent specification and accordingly should be construed as having the meaning that the specification gives it. *See Phillips*, 415 F.3d at 1316.

Merriam-Webster's Collegiate Dictionary defines a "gusset" as "1: a usu. diamond-shaped or triangular insert in a seam (as of a sleeve, pocketbook, or shoe upper) to provide expansion or reinforcement 2: a plate or bracket for strengthening an angle in framework (as in a building or bridge)." (Ex. 1012 at 518.) The '103 patent does not use the term "gusset" consistently with its dictionary definitions, and accordingly the patentees have acted as their own lexicographers to redefine the term. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017).

The '103 specification describes the "gusset" as follows:

> As best seen in FIG. 6, the remaining three fingers 84b have axially extending, standing ribs 92 extending from a generally wedge shaped gusset 96. **The gusset 96 spaces the standing ribs 92 from the**

> **annular shelf 97.** The front, axially-inward end of the gusset 98 is essentially flush with the annular shelf 97. The gusset has an upwardly sloping deck 100 from which the standing ribs 92 extend from a generally central portion thereof.

(Ex. 1001 at 9:41-48 (emphasis added).) Notably, the patent makes no reference to the "gusset" providing expansion or reinforcement to the fingers or the annular shelf. The only function attributed to the "gusset" in the '103 patent is spacing the standing ribs from the annular shelf. (Ex. 1005, ¶ 39.) Although not expressly discussed, it appears that the gussets will contact chamfer 105 on the edge of sealing member 103, creating space between annular shelf 97 and sealing member 103 in the positions where there is no gusset. (*See id.*, ¶ 40.) Accordingly, a POSITA reviewing the patent specification would understand that the patentees acted as their own lexicographers and redefined the term "gusset" to mean "a component adjoining the standing ribs and annular shelf that creates space above the annular shelf."

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

BD respectfully requests the cancellation of claims 1, 11, 14, 15, 17, 19-28, and 30 of the '103 patent. The statutory grounds for the challenge are set forth below (all citations are to pre-AIA statues):

Ground	35 USC §	Claims	References
1	103(a)	1, 11, 14, 15, 17, 19	Gustavsson (Ex. 1007, U.S. 4,564,054) in view of Lynn (Ex. 1008, U.S. 4,946,445)
2	103(a)	19-21	Gustavsson in view of Lynn and van de Veerdonk (Ex. 1009, U.S. 3,995,630)
3	103(a)	22-28, 30	Gustavsson in view of Lynn and Dudar (Ex. 1010, U.S. 5,100,394)
4	103(a)	1, 11, 14, 15, 17	Zdeb (Ex. 1011, U.S. 4,898,209) in view of Lynn
5	103(a)	19-21	Zdeb in view of Lynn and van de Veerdonk
6	103(a)	22-28, 30	Zdeb in view of Lynn and Dudar

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

A. Ground 1: Obviousness of Claims 1, 11, 14, 15, 17, and 19 Based on Gustavsson in Combination with Lynn

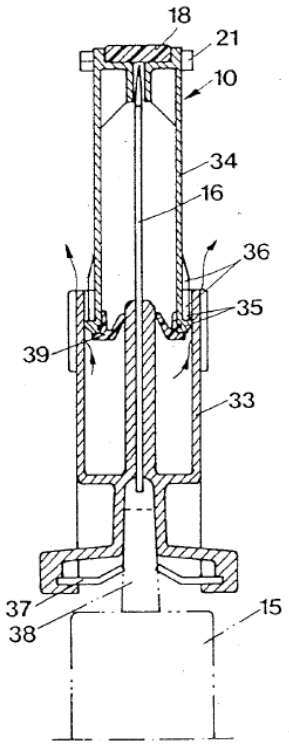
Claims 1, 11, 14, 15, 17, and 19 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson and Lynn as set forth below.

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. 1007 at Abstract, 1:54-68.) Gustavsson 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.) In one embodiment, the connector device includes an inner telescoping sleeve that fits slidingly within an outer telescoping sleeve, with a needle extending from the outer sleeve into the inner sleeve. (*See, e.g.*, *id.* at 4:9-39 & Fig. 7.)

When the device is compressed, the needle extends past the inner sleeve. (*See, e.g.*, *id.* at 4:9-39, 2:56-3:27.) This results in the needle puncturing the seals at the end of the inner sleeve 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 Figure 7:

FIG 7



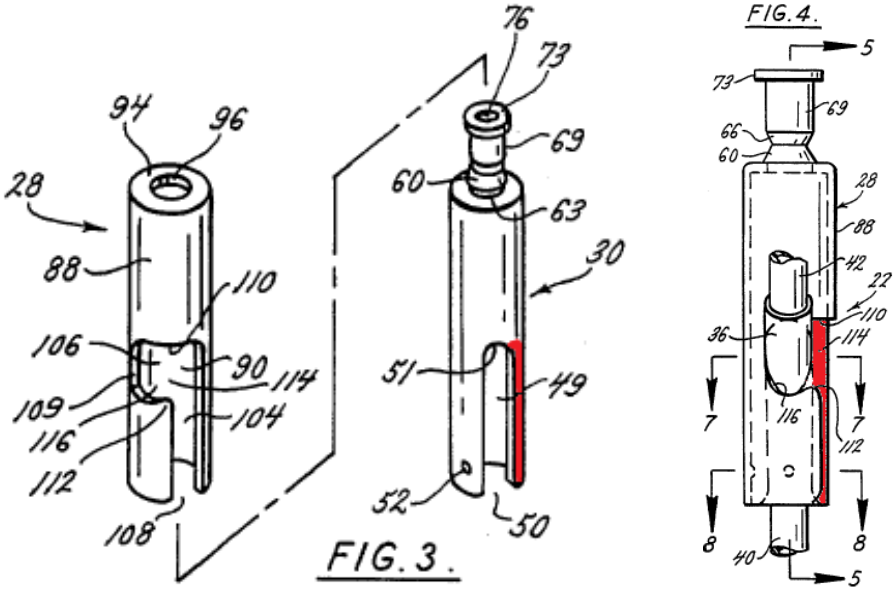
(*Id.* at Fig. 7.)

ii. Disclosure of Lynn

Lynn is directed to an intravenous line coupling device that attaches to a primary intravenous tubing system. (*See, e.g.*, 1008 at Abstract, 1:5-30.) The Lynn device creates a secure connection between a primary fluid system and a y-

shaped junction tube connected to a secondary fluid source. (*See, e.g.*, *id.* at 1:61-2:5.) The coupling device includes telescoping inner and outer tubes with slots that align with one another to receive the junction tube. (*See, e.g.*, *id.* at 7:13-24.) Once the junction tube is aligned, the outer tube rotates to lock the junction tube within the coupling device. (*See, e.g.*, *id.* at 7:34-49.)

Lynn teaches that a bright color on the inner tube becomes visible when the outer tube is rotated, indicating that the device is in a locked position. (*See, e.g.*, *id.*) Once the junction tube is locked, a secondary fluid such as a medication can be injected into the primary fluid system through the junction tube. (*See, e.g.*, *id.* at 8:9-28.) An embodiment of the Lynn device is shown in Figures 3 and 4:



(*Id.* at Figs. 3, 4 (color added).)

iii. Rationale for Combining the Teachings of Gustavsson and Lynn

A POSITA would have readily understood the motivation to combine the teachings of Gustavsson and Lynn. First, Gustavsson and Lynn are analogous art, as they both disclose fluid transfer devices for delivering medication. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation of success combining Gustavsson and Lynn, as both disclose the use of telescoping connectors to establish a fluid connection between, for example, a syringe and a container or catheter. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Gustavsson's connector device to incorporate features of Lynn's connector device, such as its inclusion of different colors on the inner and outer sleeves of the device to indicate whether the connector is in an activated position. 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; (*see* Ex. 1005, ¶ 70).

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 new designs. (*See* Ex. 1005, ¶ 71.) Additionally, the '103 patent acknowledges that known problems with Baxter's prior Zdeb device included a lack of "any structure for the device from becoming inadvertently

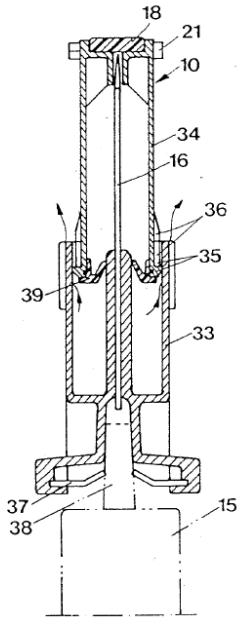
disassembled when being moved to the activated position" and that it "does not provide a visual indication that the device is in the activated position." (*See* Ex. 1001 at 3:13-34.) These deficiencies in Baxter's prior product had already been solved by devices such as those disclosed in Gustavsson and Lynn. Thus, a POSITA would have been motivated to look to the existing prior art solutions to these well-known problems. (*See* Ex. 1005, ¶ 72.)

iv. Comparison of Claims 1, 11, 14, 15, 17, and 19 to Gustavsson and Lynn

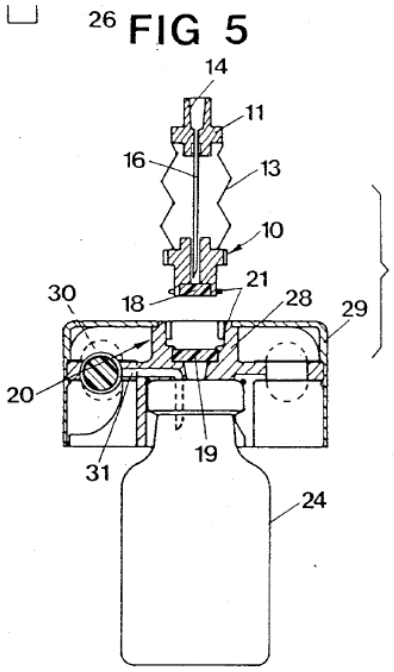
The claim chart below specifies where each element of claims 1, 11, 14, 15, 17, and 19 is found in Gustavsson in combination with Lynn.

'103 Claim Language	Citations to Gustavsson and Lynn
1[a]. A connector device for establishing fluid communication between a first container and a second container comprising:	Gustavsson is titled "FLUID TRANSFER SYSTEM." (*See also, e.g.*, Ex. 1007 at Abstract ("A device is disclosed for preventing air contamination when transferring a substance from one vessel to a second vessel."), 1:54-58 ("The purpose of the present invention is to provide a device of the type previously mentioned and with which one can transfer without contamination a substance from a vessel to the desired application, for example injection into a patient or other application.").) Lynn discloses a fluid coupling device for administering fluids to patients: The invention comprises a member which can be mounted with the junction tube so that a secure relationship is established with the member and the arm of the "y" shaped junction section or tube to prevent inadvertent removal of the member from the junction tube. The member can have a conduit

	for extension into liquid flow connection with the junction tube. In an embodiment, the conduit can comprise a needle having a flow channel, with the needle being mounted with the member. When the member is mounted to the junction tube to lock with the arm, the needle can extend within the trunk of the junction tube. The member further can have means for receiving liquid from the external liquid source. This means can comprise a receptacle associated with the tube which can be integral with the tube, or a separate component mounted with the tube, for example. (Ex. 1008 at 1:60-2:10.)
[1b] a first sleeve member having a first end and a second end, the first sleeve member adapted to attach to the first container;	Gustavsson teaches attaching a first sleeve (outer part 33) to a container (injection syringe 15): 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 injection syringe 15 is firmly locked to the outer part 33 by means of a disc 37 of e.g. metal attached to said part and provided with a central slotted opening with sharp edges and into which the conical connection piece 38 is passed, at which the the [sic] material portions between the slots will be bent upwards as seen in FIG. 7.** An attempt to withdraw the injection syringe 15 from the part 33 will result in that the sharp edges surrounding the opening in the disc 37 will be pressed into the walls of the connection piece 38 and a withdrawal is effectively prevented….

	FIG 7  (Ex. 1007 at 4:9-39 (emphasis added) & Fig. 7.)
[1c] a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and movable with respect thereto from an inactivated position to an activated position,	Gustavsson teaches a second sleeve member (inner part 34) that is associated with outer part 33 and is movable between inactivated and activated positions with respect to part 33. For example, Gustavsson states: 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. At the end portions facing each other the telescoping parts 33 and 34 are fluted 36 in the axial direction for preventing the parts from being rotated relative to each other in the most extended position.** (Ex. 1007 at 4:13-24 (emphasis added) & Fig. 7.)

	Gustavsson teaches compressing the device such that needle 16 penetrates through a seal/membrane 18 of the connector device and a seal/membrane 19 of a medicine container (ampoule 24) attached to the connector and in contact with the device's membrane. (*See, e.g.*, *id.* at 2:66-3:27 & Fig. 3.) 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. (*See* Ex. 1005, ¶¶ 42-44.) 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. (*See id.*)
[1d] the second sleeve member adapted to attach to the second container;	Gustavsson teaches attaching an end of telescoping part 34 to a container using a bayonet coupling: > 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. (Ex. 1007 at 4:13-18.) Gustavsson also teaches that "[i]n FIG. 5 is shown a modified variant of the device according to the invention, where the second member 20 is integral with the closure means 28 of an ampoule 24.":

	 (*Id.* at 3:32-35 & Fig. 5.) Thus, in the embodiment shown in Figures 7 and 5 of Gustavsson, member 20 in Figure 5 is an "integral" part of the medicine container, to which bayonet coupling 21 attaches.
[1e] a piercing member having a first and second end projecting from one of the first and second sleeve members and for providing a fluid flow path between the first container and the second container; and,	Gustavsson teaches needle 16 projecting from telescoping part 33: "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." (Ex. 1007 at 4:9-12.) A POSITA would have understood that the needle provides a fluid flow path from the injection syringe 15 to a container such as ampoule 24 shown in Fig. 5. (*See* Ex. 1005, ¶¶ 42-43.)
[1f] means for visually indicating that the connector is in the activated position comprising a color indication wherein one of the sleeve members	As discussed in Section IV(A), this element is *not* a means-plus-function element and should be interpreted as requiring the two sleeve members to have different colors, only one of which is visible when the device is in the activated position. Lynn discloses locking means movable from an unlocked

has a first color, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position.	position to a locked position to lock and unlock the junction tube to and from the coupling device: As shown clearly in FIGS. 2 and 3, coupling device 22 comprises an outer mount tube 28 and an inner mount tube 30. **The outer tube 28 can be mounted about the inner tube 30, with both tubes extending about the junction tube 24 in the unlocked position, such as depicted in FIG. 9, and in a locked position, such as depicted in FIGS. 1, 4, and 5.** (Ex. 1008 at 5:14-20 (emphasis added).) Lynn discloses that when the outer tube (28) is rotated to a locked position, a colored or labeled portion of the inner tube (30) becomes visible, indicating the tubes are in a locked position: In this FIG. 9 position the outer tube nub 100 fits within the dimple 53 (FIG. 11). This locks the two tubes 28 and 30 to each other by a force of low resistance so that the tubes are held in fixed position relative to one another. This locking helps to inhibit non-volitional rotation of the two tubes 28 and 30 relative to one another. Yet the lock of nib 100 with dimple 53 is such that tubes 28 and 30 can easily be rotated by the hand relative to each other. When the two tubes 28 and 30 are mounted to junction tube 24 as shown in FIG. 9, device 22 can then be moved to a locked position relative to arm 36. This is done by rotating outer tube 28 counterclockwise relative to junction tube 24 and inner tube 30 (from the view looking at FIG. 7) so that junction tube arm 36 slides along b slot edge 110 to compress nib 112 and thence move into the transverse slot 106, such positioning being illustrated clearly in FIGS. 4 and 5. In this

position, inner tube section 47 occludes the outer tube slot section 104. **A bright color, such as red,** or the word "LOCKED" can be provided on the portion of inner tube section 47 which occludes the longitudinal slot section 104. **The bright color or "LOCKED" is visible to an observer through slot section 104 when the locked position is achieved.**

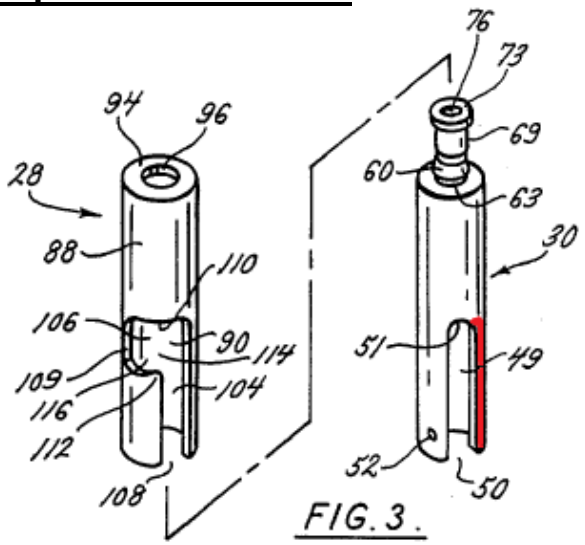


FIG. 3.

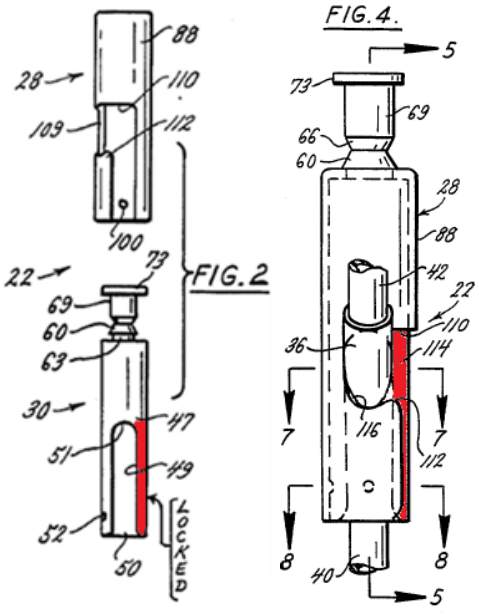
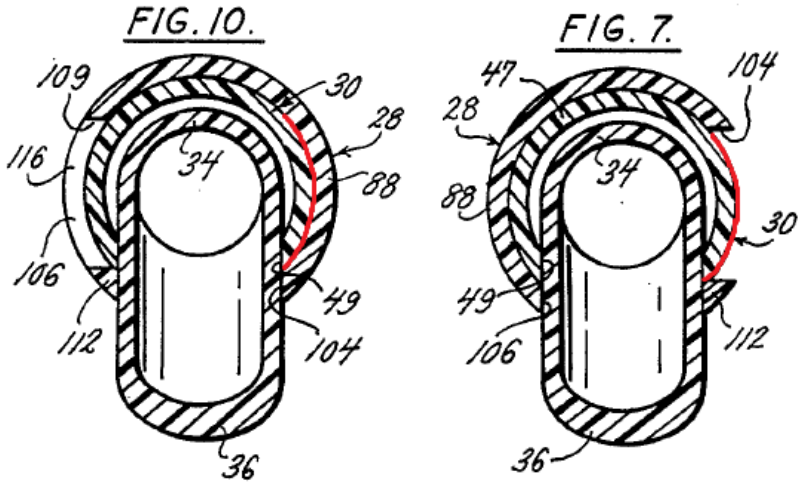


FIG. 2

FIG. 4.

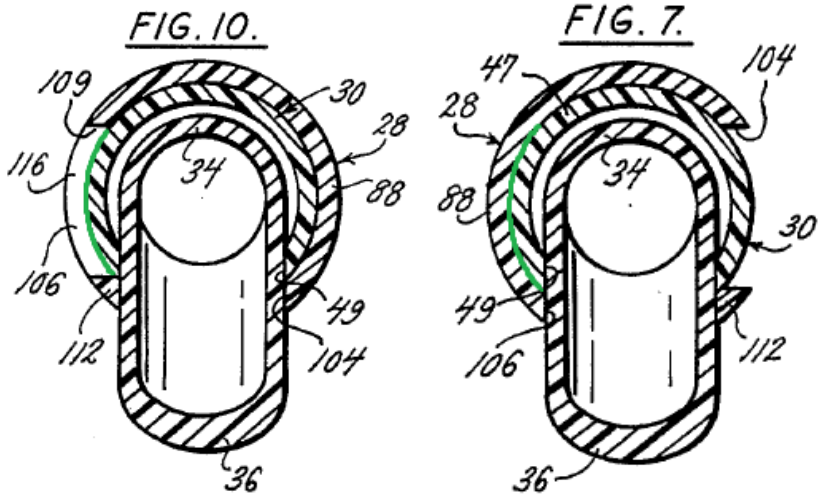
(*Id.* at 7:25-49 (emphasis added) & Figs. 2-4 (color added).)

The unlocked and locked positions are also shown in Figures 10 and 7, respectively:



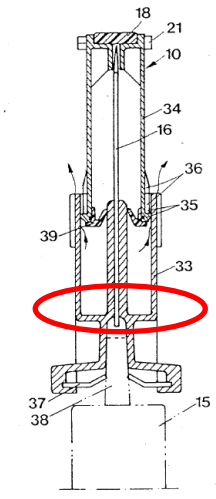
(*Id.* at Figs. 10, 7 (color added).)

It would have been obvious to a POSITA to make the color or label visible in the unlocked position, and make a single color visible in the locked position, for example by placing a color such as green on the portion of inner tube 30 that is covered by outer tube 28 in the locked position:



(*See* Ex. 1005, ¶¶ 46-49; Ex. 1010 at Figs. 10, 7 (color added).)

11. The device of claim 1 wherein the first and second sleeve members each have a generally cylindrically shaped wall having inner and outer surfaces.	Gustavsson and Lynn render **claim 1** obvious, as discussed above. *See* ***elements 1b and 1c***. Further, Gustavsson teaches that "first member 10… in this case is designed as a cylinder." (Ex. 1007 at 4:44-45; *see also id.* at 8:26-33.)
14. The device of claim 11 wherein the first sleeve member is slidingly mounted within the second sleeve member for relative axial and rotational movement therein.	Gustavsson and Lynn render **claim 11** obvious, as discussed above. *See* ***elements 1b and 1c***. Specifically, "[i]n FIG. 7 is shown an embodiment, in which the first member 10 comprises a **pair of telescoping parts**[.]" (Ex. 1007 at 4:9-12 (emphasis added).) Further, "[a]t the end portions facing each other the telescoping parts 33 and 34 are fluted 36 in the axial direction for preventing the parts from being rotated relative to each other in the most extended position." (*Id.* at 4:20-24.)
15. The device of claim 14 wherein the connector is movable between locked and unlocked positions, wherein in the locked position the first and second sleeve members are blocked from relative axial movement, and wherein in the unlocked position, the first and second connectors are capable of relative axial movement.	Gustavsson and Lynn render **claim 14** obvious, as discussed above. As discussed in Section IV(B), there is no antecedent basis for the phrase "first and second connectors," which should properly be construed as "first and second sleeve members." *See* ***element 1f***. As discussed, Lynn teaches that "device 22 can then be moved to a locked position…. This is done by rotating outer tube 28 counterclockwise relative to junction tube 24 and inner tube 30…." (Ex. 1008 at 7:34-42.) A POSITA would have understood that when outer tube 28 is rotated relative to inner tube 30 into a locked position, outer tube 28 and inner tube 30 are blocked from relative axial movement. (*See* Ex. 1005, ¶¶ 46-47.) As also discussed, Lynn teaches that when "tubes 28 and 30 are mounted, the outer surface of inner tube body 47 is telescopically received within outer tube bore 90 for snug fitting, but yet the fit allows rotation of

	the tubes 28 and 30 relative to each other." (Ex. 1008 at 8-12; *see also id.* at 7:25-33.) A POSITA would have understood that in this unlocked position where tubes 28 and 30 are capable of rotating relative to one another, tubes 28 and 30 would likewise be capable of relative axial movement. (*See* Ex. 1005, ¶¶ 46-47.)
17. The device of claim 15 wherein the connector is moved between the locked and unlocked position by rotating the first sleeve member with respect to the second sleeve member.	Gustavsson and Lynn render **claim 15** obvious, as discussed above. *See **claim 15***.
19. The device of claim 14 further comprising means associated with the connector for preventing the first sleeve member from becoming disassociated from the second member when moving from the inactivated position to the activated position.	This is a means-plus-function element governed by 35 U.S.C. § 112 ¶ 6. The claimed function is "preventing the first sleeve member from becoming disassociated from the second sleeve member when moving from the inactivated position to the activated position." As discussed in Section IV(C), the corresponding structure is "a radially-symmetric stop, such as a sleeve, ring, or washer." As shown in Gustavsson Figure 7, the first end of telescoping member 33 includes a shelf: FIG 7 

	(Ex. 1007 at Fig. 7.) A POSITA would have understood that the shelf acts as a stop preventing telescoping member 34 from becoming disassociated from telescoping member 33 when member 34 is compressed within member 33, moving the device into an activated position. (*See* Ex. 1005, ¶ 45.) At a minimum, using the shelf in this manner would have been obvious. (*See id.*)

B. Ground 2: Obviousness of Claims 19-21 Based on Gustavsson in Combination with Lynn and van de Veerdonk

Claims 19-21 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson, Lynn, and van de Veerdonk as set forth below.

i. Disclosure of Gustavsson

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

ii. Disclosure of Lynn

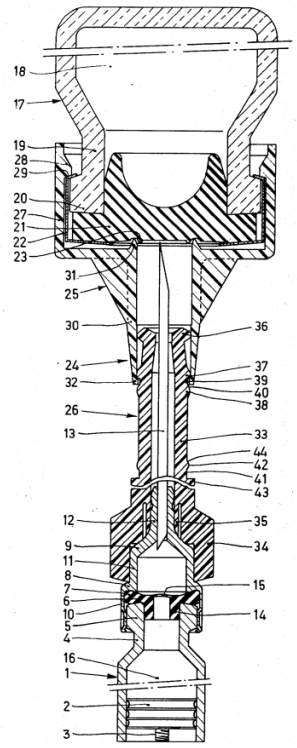
The disclosure of Lynn is discussed in Section VI(A)(ii), above.

iii. Disclosure of van de Veerdonk

Van de Veerdonk is directed to a pre-loaded syringe with a telescopic assembly that allows fluid to flow between the syringe cartridge at one end of the assembly and a vial at the other end. (*See, e.g.*, Ex. 1009 at 3:14-40.) The van de Veerdonk device includes an outer telescopic member connected to the vial and an inner telescopic member connected to the cartridge. (*Id.* at 1:17-21.) Van de Veerdonk teaches that the telescopic members can be held together by a cam on

the outer telescopic member that engages a groove on the inner telescopic member. (*Id.* at 1:63-2:2.)

When the device is compressed, the syringe needle penetrates the vial to create a fluid connection between the cartridge and the vial. (*See id.* at 3:14-45.) The telescopic assembly of van de Veerdonk is shown in the Figure:



(*Id.* at Figure.)

iv. Rationale for Combining the Teachings of Gustavsson, Lynn, and van de Veerdonk

As discussed in Section VI(A)(iii), a POSITA would have readily understood the motivation to combine Gustavsson and Lynn. Gustavsson and van de Veerdonk are likewise analogous art, as they both disclose similar fluid transfer

devices. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation of success combining Gustavsson and van de Veerdonk, as both disclose telescoping connectors that compress to insert a needle into a sealed vial. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Gustavsson's connector device to incorporate features of the connector device of van de Veerdonk, such as its use of multiple ridges, grooves, and flanges that act as stops to prevent the disassociation of telescoping cylinders. 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. 1005, ¶¶ 68-69).

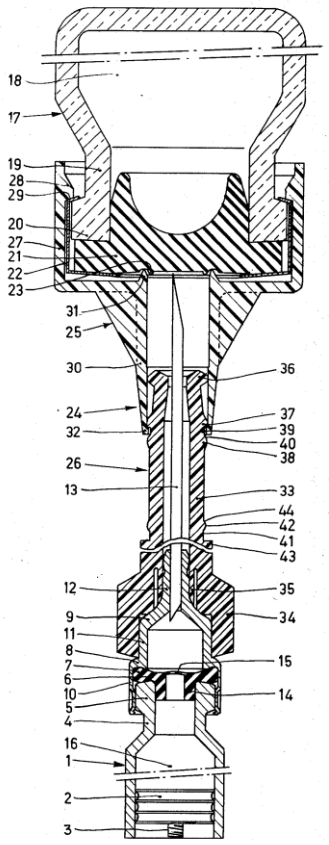
As discussed, it was the practice of engineers working in the drug reconstitution and fluid transfer fields to import features from other drug reconstitution and fluid transfer devices. (*See* Ex. 1005, ¶ 71.) The '103 patent acknowledges that a known problem with Baxter's prior Zdeb device was a lack of structure preventing inadvertent disassembly of the device in the activated position. (*See* Section IV(A)(iii).) This deficiency had already been solved by devices such as the van de Veerdonk device. Thus, a POSITA would have been motivated to look to the existing prior art solutions to these well-known problems. (*See* Ex. 1005, ¶ 72.)

v. Comparison of Claims 19-21 to Gustavsson, Lynn, and van de Veerdonk

The claim chart below specifies where each element of claims 19-21 is found in Gustavsson in combination with Lynn and van de Veerdonk.

'103 Claim Language	Citations to Gustavsson, Lynn, and van de Veerdonk
19. The device of claim 14 further comprising means associated with the connector for preventing the first sleeve member from becoming disassociated from the second member when moving from the inactivated position to the activated position.	Gustavsson and Lynn render **claim 14** obvious, as discussed in Section VI(A)(iv). This is a means-plus-function element governed by 35 U.S.C. § 112 ¶ 6. The claimed function is "preventing the first sleeve member from becoming disassociated from the second sleeve member when moving from the inactivated position to the activated position." As discussed in Section IV(C), the corresponding structure is "a radially-symmetric stop, such as a sleeve, ring, or washer." Gustavsson discloses the additional element of **claim 19**, as discussed in Section VI(A)(iv). Van de Veerdonk teaches the use of multiple ridges, grooves, and flanges that act as stops to prevent the disassociation of telescoping cylinders. For example, van de Veerdonk states: Cartridge 1 and vial 18 are mutually connected by a telescopic assembly which is denoted by the general reference numeral 24. Assembly 24 consists of an outer telescopic member 25 and an inner telescopic member 26. Member 25 comprises a jacket 27 which is snapped around capsule 22 and which for this purpose is provided with an edge 28 with a conical surface 29. The **member 25 further comprises a guide element 30** and a circular edge 31 which penetrates the rubber stopper 21. The **guide element 30 is**

	provided with a cam 32 at the end which is remote from the jacket 27…. **Near said end body 33 is provided with two ridges 37, 38 between which a groove 39 is formed.** The side wall 40 of ridge 38 has a conical shape. **Cam 32 of the outer telescopic member 24 engages with groove 39. At some distance from ridges 37, 38 the cylindrical body 33 is provided with a second groove 41 which is disposed between a ridge 42 and a thickened wall portion 43.** Wall portion 44 of ridge 42 is conically shaped. When the injection syringe according to the invention is used cartridge 1 and vial 17 are moved towards each other. Owing to the force which is exerted, cam 32 is released from groove 39 via the conical surface 40 of rib 38. **As a result of this the outer telescopic member 26 is moved in the inner telescopic member 25, the guide ridge 36 of member 26 sliding along the inner surface of guide element 30.** During this movement needle 13 penetrates the rubber stopper 21. **The movement of cartridge and vial towards each other continues until cam 32 touches the thickened wall portion 43 of the member 26. In this extreme position cam 32 engages with groove 41.** Needle 13 then has fully pierced stopper 21 of vial 17 with the bevelled [sic] end.

	 (Ex. 1009 at 2:48-3:28 (emphasis added) & Fig.) A POSITA would have understood that guide element 30 and cam 32 act as a stop to prevent disassociation of outer telescopic member 25 and inner telescopic member 26 when cam 32 engages with groove 39 in an inactivated (extended) position and when cam 32 engages with groove 41 in an activated (compressed) position. (*See* Ex. 1005, ¶¶ 50-53.)
20. The device of claim 19 wherein the means for preventing the first and second sleeve members from becoming disassociated comprises a bushing connected to the first end of the first sleeve	Gustavsson, Lynn, and van de Veerdonk render **claim 19** obvious, as discussed above. As discussed in Section IV(D), a bushing as used in the '103 patent is "a cylindrical component that attaches to an opening in another component by forming an interference fit." Van de Veerdonk teaches an "outer telescopic member

member.	25" with a "cam 32" that forms an interference fit with ridges and grooves on "inner telescoping member 26." The "outer telescopic member" is thus a "bushing" as defined by the '103 patent. *See* ***claim 19***. A POSITA would have understood that guide element 30 and cam 32 form a bushing that acts a stop to prevent disassociation of outer telescopic member 25 and inner telescopic member 26 when cam 32 engages with groove 39 or groove 41. (*See* Ex. 1005, ¶¶ 50-53.)
21. The device of claim 20 further comprising: a bushing connected to the first end of the first sleeve member, the bushing having an interior and exterior surface and a set of axially spaced annular ridges on the interior surface of the bushing.	Gustavsson, Lynn, and van de Veerdonk render **claim 20** obvious, as discussed above. *See* ***claim 20***. A POSITA would have understood cam 32 on the inner surface of guide element 30 is an annular ridge for the purpose of securing guide element 30 to telescopic member 26. (*See* Ex. 1005, ¶¶ 50-53.) It would have been obvious to a POSITA to include an additional ridge on the inner surface of guide element 30 such that there would be a set of axially spaced annular ridges on the interior surface of guide element 30 to further secure guide element 30 to telescopic member 26. (*See id.*, ¶ 54.)

C. Ground 3: Obviousness of Claims 22-28 and 30 Based on Gustavsson in Combination with Lynn and Dudar

Claims 22-28 and 30 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Gustavsson, Lynn, and Dudar as set forth below.

i. Disclosure of Gustavsson

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

ii. Disclosure of Lynn

The disclosure of Lynn is discussed in Section VI(A)(ii), above.

iii. Disclosure of Dudar

Dudar is directed to an injection site coupling system for transferring materials from a vial to a syringe. (*See, e.g.*, Ex. 1010 at Abstract, 1:12-20, 7:52-66, 14:1-16.) In one embodiment, Dudar discloses a connector device with a vial adapter at one end that attaches to a standard drug vial. (*See, e.g.*, *id.* at 12:12-28.) Dudar teaches that the vial adapter includes slots that create axially extending and segmented fingers from skirts, which engage a vial using a combination of bumps, undercuts, and nibs in order to prevent the vial from becoming disengaged from the connector. (*See, e.g.*, *id.* at 13:18-14:9.) An embodiment of Dudar's connector device and vial adapter is shown in Figures 30 and 36:

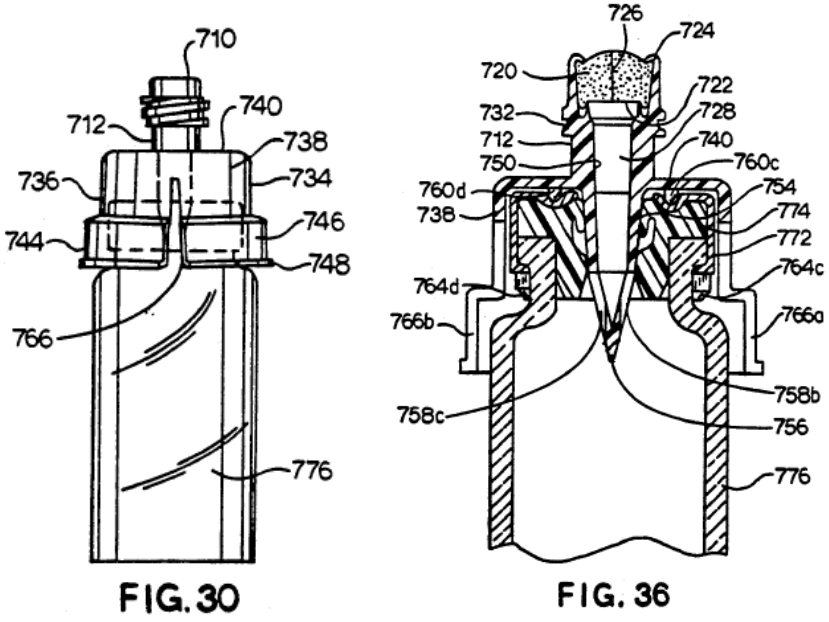


FIG. 30 FIG. 36

(*Id.* at Figs. 30, 36.)

iv. Rationale for Combining the Teachings of Gustavsson, Lynn, and Dudar

As discussed in Section VI(A)(iii), a POSITA would have readily understood the motivation to combine Gustavsson and Lynn. Gustavsson and Dudar are likewise analogous art, as they both disclose similar fluid transfer devices. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation of success combining Gustavsson and Dudar, as both disclose connector devices with similar structures, including attachments for containers at each end of the connector device and a needle that establishes a fluid connection between the containers. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Gustavsson's connector device to incorporate the particular vial attachment disclosed in Dudar. 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; (*see* Ex. 1005, ¶ 68).

As discussed, it was the practice of engineers working in the drug reconstitution and fluid transfer fields to import features from other drug reconstitution and fluid transfer devices. (*See* Ex. 1005, ¶ 71.) A POSITA looking for alternative mechanisms to attach the Gustavsson device to the top of a vial would thus have been motivated to substitute the attachment mechanism disclosed in Dudar for that disclosed in Gustavsson.

v. Comparison of Claims 22-28 and 30 to Gustavsson, Lynn, and Dudar

The claim chart below specifies where each element of claims 22-28 and 30 is met by Gustavsson in combination with Lynn and Dudar.

'103 Claim Language	Citations to Gustavsson, Lynn, and Dudar
22. The device of claim 14 wherein the second end of the second sleeve member comprises: a plurality of circumferentially spaced and axially extending segmented fingers on the second end of the second sleeve member, the fingers being adapted to engage the second container.	Gustavsson and Lynn render **claim 14** obvious, as discussed in Section VI(A)(iv). Dudar teaches a vial adapter 736 with slots 766a and 766b that create axially extending and segmented fingers from skirts 734 and 744, which engage a vial: **The vial adapter 736 is provided with preferably two slots, 766a and 766b located from ridge 748 through the skirts 734 and 744 terminating prior to top member 740.** … As adapter spike 752 continues through stopper 774, undercuts 762a-762d meet the top of vial closure 772 with resistance. **Extending into first skirt member 734, slots 766a and 766b also permit the expansion of first skirt member 734 to assist in overcoming the initial resistance of undercuts 762a-762d.** This initial resistance can then be overcome by a slight increase in insertion force as first skirt member 734 expands over vial closure 772. As the user continues to press device 700 into stopper 774, bump portions 764a-764d will each create indentations in the soft aluminum vial closure 772. Each undercut 762a-762d passes along the newly created indentations. **As illustrated in FIG. 36, bump portions 764a-764d will come to rest in part under the lower edge of vial closure 772. In this position, bump portions**

764a-764d provide resistance against device 700 from being disengaged from vial 776.

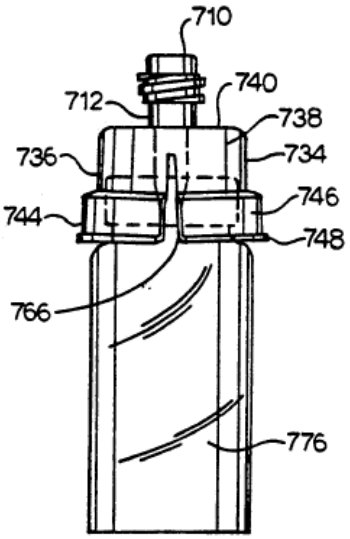


FIG. 30

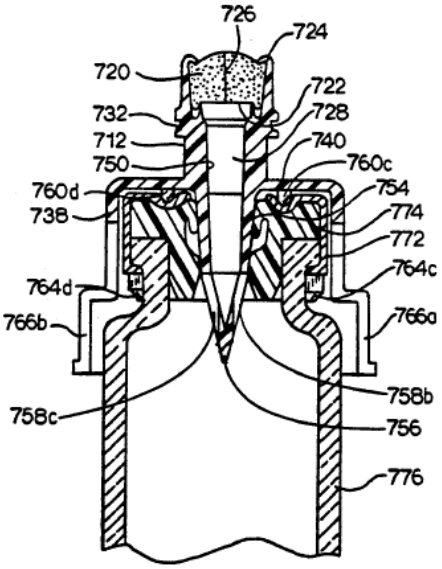


FIG. 36

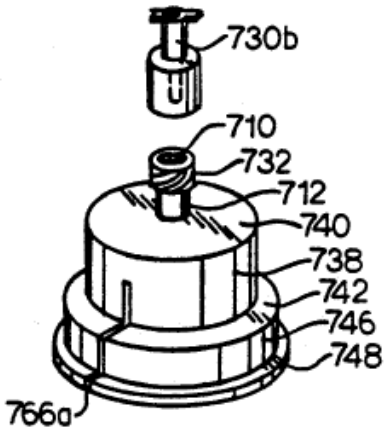
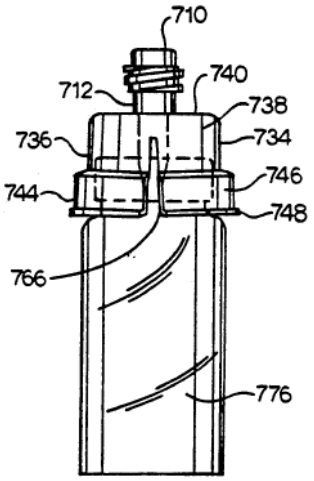
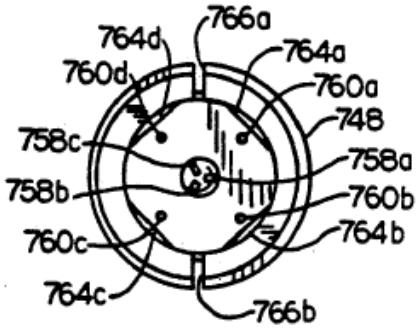
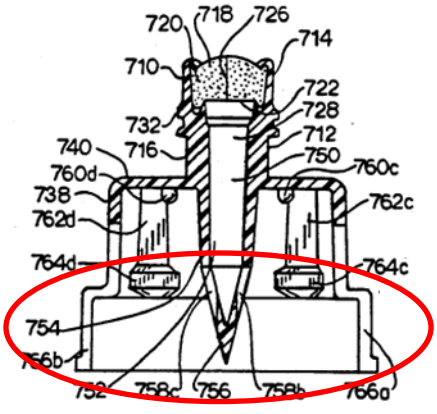


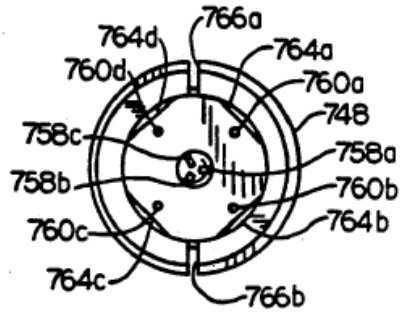
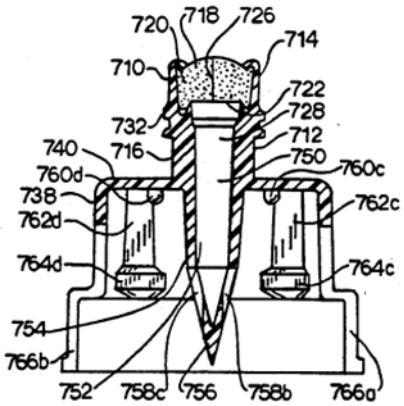
FIG. 38

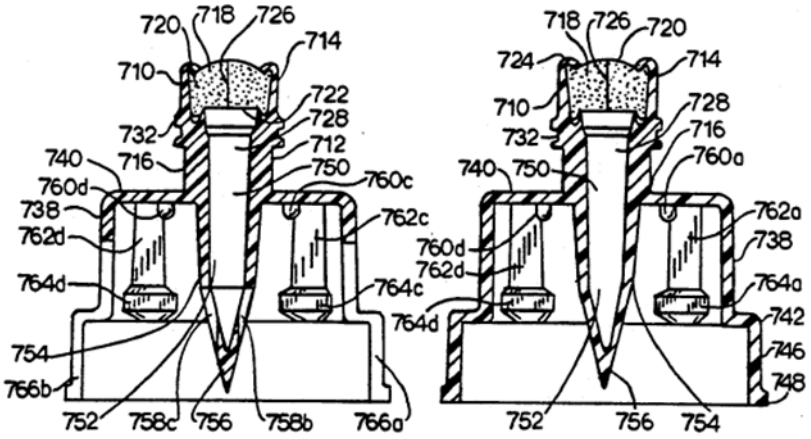
(Ex. 1010 at 13:18-14:9 (emphasis added) & Figs. 30, 36, 38.)

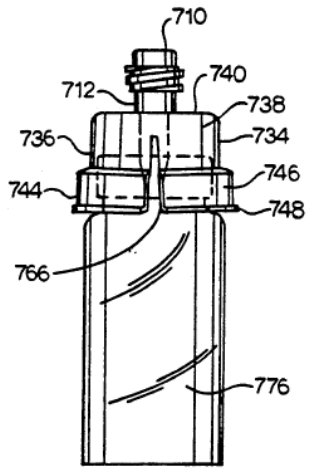
The ’103 patent explains that while “the present device utilizes six segmented fingers 84, it can be appreciated by one of reasonable skill in the art that more or fewer fingers could be utilized without departing from the scope of the present invention.” (Ex. 1001 at 9:13-17.) Thus, a prior art device having two fingers, such as the

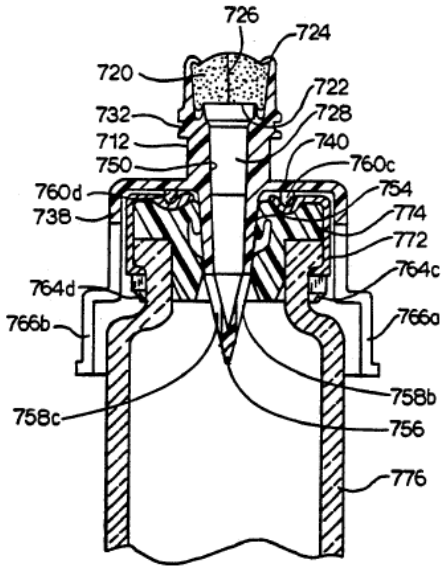
	device of Dudar, falls within the scope of the claim. (Ex. 1005, ¶¶ 55-56.) Likewise, it would have been obvious to add additional slits to the skirts disclosed by Dudar to create additional fingers. (*Id.*)
23. The device of claim 22 wherein the fingers have a proximal end and a distal end, the distal end having a flat lead-in section.	Gustavsson, Lynn, and Dudar render **claim 22** obvious, as discussed above. Each of the fingers of vial adapter 736 include a flat lead-in section (cylindrical wall 746 of skirt 744) on the two fingers:  FIG. 30  FIG. 33  FIG. 34 (Ex. 1010 at Figs. 30, 33, and 34.)

24. The device of claim 22 wherein each adjacent set of fingers defines a gap therebetween.	Gustavsson, Lynn, and Dudar render **claim 22** obvious, as discussed above. As explained with respect to claim 22, "[t]he vial adapter 736 is provided with preferably two slots, 766a and 766b located from ridge 748 through the skirts 734 and 744 terminating prior to top member 740." (Ex. 1010 at 13:18-20.) "Slots 766a and 766b permit second skirt member 744 to expand so to slightly increase in diameter, compensating for dimensional variations among vial closures on standard drug vials." (*Id.* at 13:41-44.)
25. The device of claim 22 wherein a plurality of the fingers have radially inwardly tapering tabs extending from the lead-in section.	Gustavsson, Lynn, and Dudar render **claim 22** obvious, as discussed above. The '103 patent describes the tabs: Three of the fingers 84a also include, adjacent to the flat lead-in section 87, radially inwardly tapering resilient tabs 88, from a distal end to a proximal end, past which the medical professional must urge a neck 90 of the vial 14 in order to connect it to the second sleeve member 32. It can be appreciated that the tabs are capable of flexing and the fingers are capable of independently flexing to accommodate varying diameter vial closures…. The tabs 88 shown have a space 89 between the distal end of the tab and the finger. **However, the tabs 88 could also be formed as solid bumps without departing from the invention.** (Ex. 1001 at 9:27-41 (emphasis added).) Dudar discloses bump portions 764a-764d, each of which is tapered and extends radially inward from cylindrical wall 746 of skirt 744:

	As most clearly illustrated in FIGS. 33-36, the inner surface of top member 740 is provided with nib protrusions 760, preferably four protrusions, 760a-760d. Spaced evenly from one another, nib protrusions 760a-760d are positioned between the joinder of first skirt wall 738 with top member 740 and hole 750. Preferably aligned with nib protrusions 760a-760d are undercuts 762a-762d raised along the inner surface of first skirt wall 738. **Each undercut 762a-762d terminates immediately adjacent to step 742 in a bump portion 764a-764d.**  FIG. 33  FIG. 34 (Ex. 1010 at 13:7-17 (emphasis added) & Figs. 33, 34.)
26. The device of claim 25 wherein a plurality of the fingers have standing ribs.	Gustavsson, Lynn, and Dudar render **claim 25** obvious, as discussed above. As discussed in Section IV(E), "standing ribs" as used in the '103 patent are "elongated, axially extending structures that indent the metal crimp of a vial to inhibit its movement." Dudar discloses undercuts 762a-762d, which are ribs raised along the inner surface of the vial adapter 36: As most clearly illustrated in FIGS. 33-36, the

	inner surface of top member 740 is provided with nib protrusions 760, preferably four protrusions, 760a-760d. Spaced evenly from one another, nib protrusions 760a-760d are positioned between the joinder of first skirt wall 738 with top member 740 and hole 750. **Preferably aligned with nib protrusions 760a-760d are undercuts 762a-762d raised along the inner surface of first skirt wall 738.** Each undercut 762a-762d terminates immediately adjacent to step 742 in a bump portion 764a-764d.  FIG. 34 FIG. 35 (Ex. 1010 at 13:7-17 (emphasis added) & Figs. 34, 35; *see also id.* at 9:42-58.)
27. The device of claim 26 wherein the fingers extend from an annular shelf and wherein the standing ribs extend axially from a gusset on the annular shelf outward to a position proximate the distal end of the fingers to act as a guide adapted to assist in connecting to	Gustavsson, Lynn, and Dudar render **claim 26** obvious, as discussed above. As discussed in Section IV(F), a "gusset" as used in the '103 patent is "a component adjoining the standing ribs and annular shelf that creates space above the annular shelf." The '103 patent describes the function of the standing ribs: The standing ribs 92 are capable of indenting one

the second container.	or more sidewall portions 102 of the metal crimp 26 of the vial 14 in order to inhibit the vial 14 the elastomeric closures 22 and 24 of the vial 14 and the flexible container 12 by the piercing member 34. (Ex. 1001 at 9:52-56 (emphasis added).) Dudar discloses that "[t]he vial adapter 736 is provided with preferably two slots, 766a and 766b located from ridge 748 through the skirts 734 and 744 terminating prior to top member 740." (Ex. 1010 at 13:18-20.) Figure 30 shows two fingers extending from top member 740, which is an annular shelf:  FIG. 30 (Ex. 1010 at Fig. 30.) Dudar teaches nib protrusions 760a-760d aligned with undercuts 762a-762d: As most clearly illustrated in FIGS. 33-36, the inner surface of top member 740 is provided with nib protrusions 760, preferably four protrusions, 760a-760d. **Spaced evenly from one another, nib protrusions 760a-760d are positioned between the joinder of first skirt wall 738 with top member 740 and hole 750. Preferably aligned**

	with nib protrusions 760a-760d are undercuts 762a-762d raised along the inner surface of first skirt wall 738. Each undercut 762a-762d terminates immediately adjacent to step 742 in a bump portion 764a-764d. … As bump portions 764a-764d are positioned under vial closure 772, **top member 740 covers and, in some instances, may be in direct contact with the upper portion of vial closure 772 which carries stopper 774. Nib protrusions 760a-760d indent the aluminum upper portion of vial closure 772**, preventing device 700 from rotating on vial 776.  FIG. 36 (*Id.* at 13:7-68 (emphasis added) & Fig. 36.) It would have been obvious to a POSITA that nib protrusions 760a-760d could be used to space undercuts 762a-762d from top member 740 with the undercuts extending from the nib protrusions. (Ex. 1005, ¶¶ 57-59.) The undercuts 762a-762d of Dudar act as guide when

	connecting the vial adapter 736 to a vial: As adapter spike 752 continues through stopper 774, undercuts 762a-762d meet the top of vial closure 772 with resistance. Extending into first skirt member 734, slots 766a and 766b also permit the expansion of first skirt member 734 to assist in overcoming the initial resistance of undercuts 762a-762d. This initial resistance can then be overcome by a slight increase in insertion force as first skirt member 734 expands over vial closure 772. **As the user continues to press device 700 into stopper 774, bump portions 764a-764d will each create indentations in the soft aluminum vial closure 772. Each undercut 762a-762d passes along the newly created indentations.** As illustrated in FIG. 36, bump portions 764a-764d will come to rest in part under the lower edge of vial closure 772. In this position, bump portions 764a-764d provide resistance against device 700 from being disengaged from vial 776. (Ex. 1010 at 13:45-61 (emphasis added).)
28. The device of claim 26 wherein the standing ribs taper radially inwardly proximate the distal end of the fingers.	Gustavsson, Lynn, and Dudar render **claim 26** obvious, as discussed above. Dudar teaches tabs (bump portions 764a-764d) and standing ribs (undercuts 762a-762d) extending from the tabs. It would have been obvious to a POSITA to alternate between tabs and standing ribs around the circumference of vial adapter 736 of Dudar. (Ex. 1005, ¶¶ 60-61.) As discussed with respect to claim 25, Dudar discloses a radially inward taper on bump portions 764a-764d. Thus, it would have been obvious to a POSITA to include a similar radially inward taper on undercuts 762a-762d when alternating between tabs and standing ribs around the circumference of vial adapter 736. (*Id.*, ¶¶ 62-63.)

30. The device of claim 22 wherein at least one of the fingers has a standing rib.	Gustavsson, Lynn, and Dudar render **claim 22** obvious, as discussed above. As discussed in Section IV(E), "standing ribs" as used in the '103 patent are "elongated, axially extending structures that indent the metal crimp of a vial to inhibit its movement." *See* ***claim 26***.

D. Ground 4: Obviousness of Claims 1, 11, 14, 15, and 17 Based on Zdeb in Combination with Lynn

Claims 1, 11, 14, 15, and 17 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Zdeb and Lynn as set forth below.

i. Disclosure of Zdeb

Zdeb is directed to a coupling device for establishing fluid communication between two containers to reconstitute a drug. (*See, e.g.*, Ex. 1011 at Abstract, 3:32-37.) The device attaches to a flexible bag at one end and a vial containing a drug to be reconstituted at the other end. (*See, e.g.*, *id.* at 5:1-21.) The connector device includes two telescoping sleeves with a double-ended needle mounted at their center. (*See, e.g.*, *id.* at 5:61-63, 7:20-33.)

When the device is compressed, the needle punctures the bag and the vial, creating a fluid connection between them. (*See, e.g.*, *id.* at 5:22-38, 7:20-33.) The Zdeb connector is shown in Figure 2:

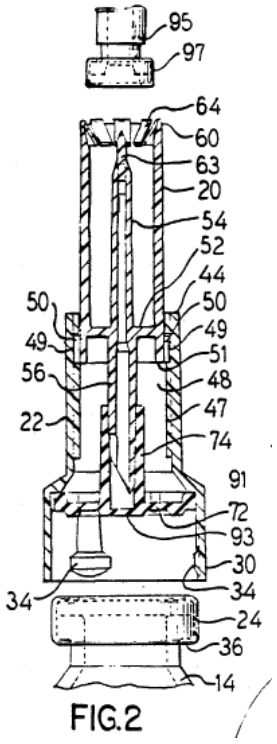


FIG.2

(*Id.* at Fig. 2.)

ii. Disclosure of Lynn

The disclosure of Lynn is discussed in Section VI(A)(ii), above.

iii. Rationale for Combining the Teachings of Zdeb and Lynn

A POSITA would have readily understood the motivation to combine the teachings of Zdeb and Lynn. First, Zdeb and Lynn are analogous art, as they both disclose fluid transfer devices for delivering medication. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation of success combining Zdeb and Lynn, as both disclose the use of telescoping connectors to establish a fluid connection between, for example, a syringe and a container or catheter. (*See id.*) Thus, it would have been obvious to a POSITA at the time of

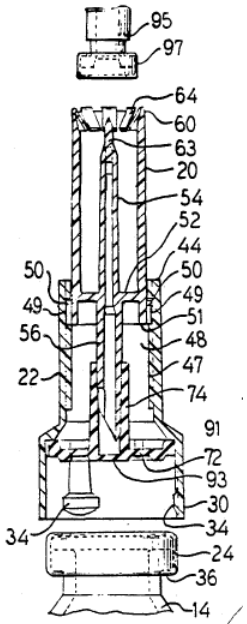
Baxter's alleged invention in 1997 to modify Zdeb's connector device to incorporate features of the connector device of Lynn, such as its inclusion of a bright color on one of the device sleeves as an indicator of whether the connector is in an activated position. Such a modification is merely a combination of prior art elements according to known methods to yield predictable results. *See, e.g.*, M.P.E.P. § 2143; (*see* Ex. Ex. 1005, ¶ 70).

As discussed, it was the practice of engineers working in the drug reconstitution and fluid transfer fields to import features from other drug reconstitution and fluid transfer devices. (*See* Ex. 1005, ¶ 71.) The '103 patent acknowledges that a known problem with Baxter's prior Zdeb device was a lack of visual indication that the device is in the activated position. (*See* Section IV(A)(iii).) This deficiency had already been solved by devices such as the Lynn device. Thus, a POSITA would have been motivated to look to the existing prior art solutions to these well-known problems. (*See* Ex. 1005, ¶ 72.)

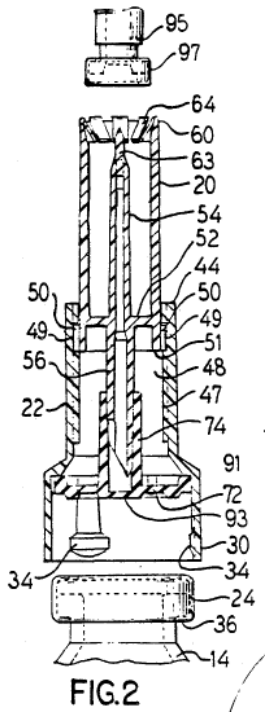
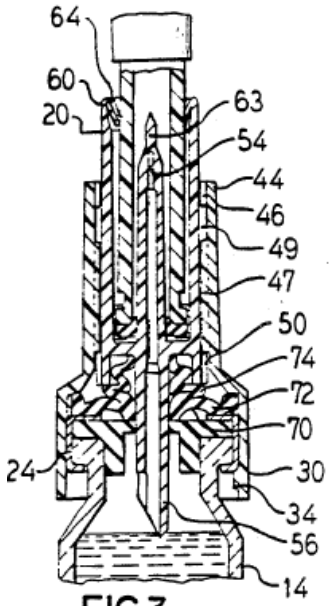
iv. Comparison of Claims 1, 11, 14, 15, and 17 to Zdeb and Lynn

The claim chart below specifies where each element of claims 1, 11, 14, 15, and 17 is found in Zdeb in combination with Lynn.

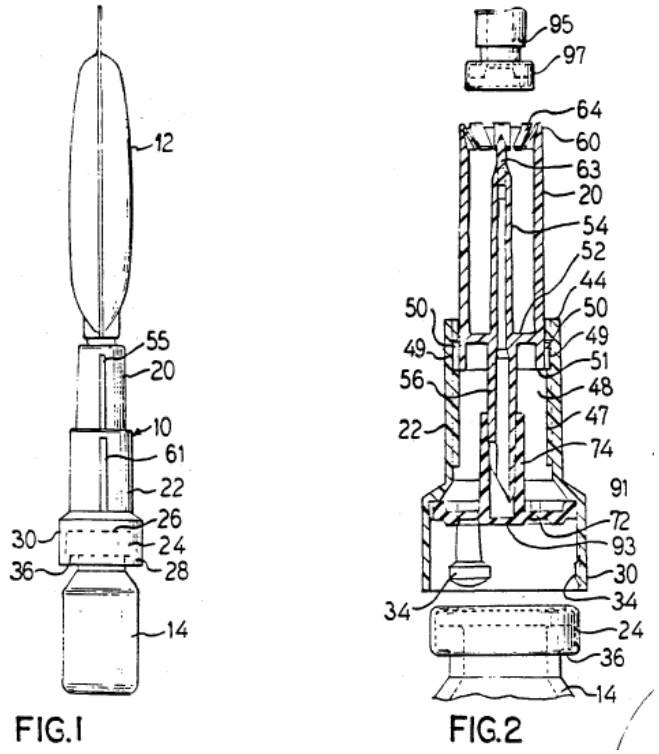
'103 Claim Language	Citations to Zdeb and Lynn
1[a]. A connector device for establishing fluid communication between a first	Zdeb is titled "SLIDING RECONSTITUTION DEVICE WITH SEAL." (*See also* Ex. 1011 at Abstract ("A coupling device for establishing fluid communication between a first container and a second container is

container and a second container comprising:	provided."), 5:2-5 ("The device 10 is adapted to place a container, such as a flexible bag 12 containing a fluid source therein, in fluid communication with a container 14 containing a drug to be reconstituted.").) Lynn discloses ***element 1a*** for the reasons discussed in Section VI(A)(iv).
[1b] a first sleeve member having a first end and a second end, the first sleeve member adapted to attach to the first container;	Zdeb teaches attaching a first sleeve (inner sleeve 20) to a container (flexible plastic bag 12): In the embodiment of the present invention illustrated, the **inner sleeve 20 includes at a second axial end 60 means for engaging and securing a receptacle or port 62 of the flexible plastic bag 12**. To this end, located within the inside of the second axial end 60 of the inner sleeve 20, are a plurality of locking barbs 64 that engage the port 62 of the flexible plastic bag 12. It can be appreciated that the barbs 64 allow entry of the port 62 into the inner sleeve 20 but prevent retraction of the port 62 therefrom. Thus, the port 62 is securely held within the inner sleeve 20.  FIG.2

	(Ex. 1011 at 7:57-67 (emphasis added) & Fig. 2; *see also id.* at Abstract ("[t]he device includes a first sleeve member including at a first end thereof, a member for connecting and securing the first sleeve member to a first container."), 3:27-29 ("The inner sleeve includes means, at one axial end, for being coupled to a first container, such as, for example, a flexible parenteral bag."), 5:23-24, 6:11-12, 7:58-60.)
[1c] a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and movable with respect thereto from an inactivated position to an activated position,	Zdeb teaches a second sleeve (outer sleeve 22) that is movable with respect to inner sleeve 20 from an inactivated (extended) position (Fig. 2) to an activated (compressed) position (Fig. 3): The connector device 10 includes two sleeve members, a first inner sleeve 20 and a second outer sleeve 22.…The inner and outer sleeves 20 and 22 are so constructed and arranged that they allow relative axial movement therebetween. The **sleeves 20 and 22 are adapted to move from a first inactivated position to a second activated position.** In a first, inactivated position, illustrated in FIG. 2, the connector device 10 is inactivated and fluid communication is not established between the bag 12 and the vial 14 even though the connector 10 is secured to the bag 12 and vial 14. In a second activated position, illustrated in FIG. 3, the connector device 10 establishes fluid communication between the bag 12 and the vial 14 allowing a drug contained in the vial 14 to be reconstituted.

	 FIG.2  FIG.3 (Ex. 1011 at 5:22-38 (emphasis added) & Figs. 2, 3; *see also id.* at Abstract ("A second sleeve member is provided and is so constructed and arranged that it receives a portion of the first sleeve, and is operatively adapted for axial sliding engagement thereon…."), 3:52-54.)
[1d] the second sleeve member adapted to attach to the second container;	Zdeb teaches attaching outer sleeve 22 to a vial: "The outer sleeve is adapted at one axial end to be releasably connect [sic] to a second container, such as, for example, a vial." (Ex. 1011 at 3:29-31; *see also id.* at Abstract, 5:42-46 ("The outer sleeve 22 is constructed at one end 28 thereof, so that it can receive and engage the projection or neck 24 of the vial 14. To secure the outer sleeve 22 to the vial, the end 28 of the outer sleeve 22 includes a locking portion.").) Zdeb teaches the use of bumps or flanges to lock outer sleeve 22 onto a vial: As illustrated in FIG. 2, **located on the inside surface of the end portion 28 of the outer sleeve**

	member 22 are a plurality of bumps or flange members 34 that function to releasably lock the end portion 28 on the vial 14. Because the outer sleeve 22 is made of plastic, it has some resiliency and therefore, the vial 14 can be securely engaged within the end portion 28 by urging the rim 32 portion of the vial 14 into the locking end portion 28 until the flange members 34 engage an underside 36 of the rim 32 of the vial 14. During the insertion process, the wall 30 of the end portion 28 of the outer sleeve 22 will give slightly to permit entry of the rim 32 of the vial 14. (*Id.* at 5:48-60 (emphasis added).)
[1e] a piercing member having a first and second end projecting from one of the first and second sleeve members and for providing a fluid flow path between the first container and the second container; and,	Zdeb teaches that "[p]iercing members located within an area defined by the first and second sleeves are provided for providing fluid flow from the first container to the second container." (Ex. 1011 at Abstract.) Zdeb also discloses: Piercing means for providing fluid flow from the first and second containers is provided within one of the sleeves. Preferably, the piercing means is located at a second axial end of the inner sleeve and includes oppositely axially directed first and second hollow piercing members that are in fluid communication with each other. (*Id.* at 3:31-37.)
[1f] means for visually indicating that the connector is in the activated position comprising a color indication wherein one of the sleeve members has a first color, the other sleeve member	Lynn discloses ***element 1f*** for the reasons discussed in Section VI(A)(iv).

has a second color, wherein only one color is visible when the connector is in the activated position.	
11. The device of claim 1 wherein the first and second sleeve members each have a generally cylindrically shaped wall having inner and outer surfaces.	Zdeb and Lynn render **claim 1** obvious, as discussed above. *See **elements 1b** and **1c**.* Zdeb teaches that inner and outer sleeves 20 and 22 have generally cylindrical walls:  FIG.1 FIG.2 (*See, e.g.*, Ex. 1011 at Figs. 1, 2.)
14. The device of claim 11 wherein the first sleeve member is slidingly mounted within the second sleeve member for relative axial and rotational movement	Zdeb and Lynn render **claim 11** obvious, as discussed above. *See **elements 1b** and **1c**.* Zdeb teaches that "the inner sleeve 20 is slidingly mounted within the outer sleeve 22 for relative axial movement therein and to cooperate therewith." (Ex. 1011 at 5:61-63.) Zdeb also teaches:

therein.	The **gaps 57 are sufficiently wide so as to allow a limited amount of relative rotational movement between the inner sleeve 20 and the outer sleeve 22**. A detent 59 is located in a center portion of each of the gaps 57 and serves to releasably lock the inner and outer sleeves 20 and 22 in a first or second rotational position. The detents 59 only hinder the relative rotational movement of the inner sleeve 20 by releasably engaging the ribs 55 as they travel from one side of the gaps 57 to the other. Due to the resiliency of the plastic material, **a sufficient rotational torque can be exerted to overcome the detents 59 allowing the inner and outer sleeves 20 and 22 to rotate relative to each other.** (*Id.* at 6:30-42 (emphasis added); *see also id.* at 4:18-20.)
15. The device of claim 14 wherein the connector is movable between locked and unlocked positions, wherein in the locked position the first and second sleeve members are blocked from relative axial movement, and wherein in the unlocked position, the first and second connectors are capable of relative axial movement.	Zdeb and Lynn render **claim 14** obvious, as discussed above. As discussed in Section IV(B), there is no antecedent basis for the phrase "first and second connectors," which should properly be construed as "first and second sleeve members." Zdeb discloses rotating inner sleeve 20 and outer sleeve 22 relative to each other to lock and unlock the sleeves for axial movement: **In a first rotational position**, when the flange 50 is positioned within the gap 49 between the outer sleeve ribs 47 and the outer sleeve flange 46, and the gaps 53 are aligned with ribs 47, **the inner sleeve 20 and outer sleeve 22 are free to travel axially relative to each other**. Thus, in the first rotational position, the inner and outer sleeves 20 and 22 are not locked together. **However, by rotating the inner and**

	outer sleeves 20 and 22 relative to each other, when the flange 50 is located within the gap 49, the gap 53 in the flange 50 is caused to rotate so as to no longer be aligned with the ribs 47. When the gaps 53 are no longer aligned with the ribs 47, **the inner and outer sleeves 20 and 22 are prevent [sic] from moving axially relative to each other because the axial end of the flange 50 abuts against the edges of the ribs 47. Thus, in the second rotational position, the inner and outer sleeves 20 and 22 are locked in the first inactivated position**. A similar, second bayonet socket arrangement is formed at the opposite ends of the ribs 47…. The top of the vial 14 and ribs 47 define a gap 81 within which flange 50 can be received. Accordingly, **once the flange 50 is aligned with the ribs 47, the inner and outer sleeves 20 and 22 can move axially relative to each other until the flange 50 abuts against the seal 70** that is compressed against the top of the vial 14. At that point, the flange 50 is received within a gap formed between the top side of the vial 14 and the edges of the ribs 47. As illustrated in FIG. 3, **relative rotation of the inner and outer sleeves 20 and 22 from the first rotational position to the second rotational position again causes misalignment of the gaps 53 relative to the ribs 47. Thus, the inner and outer sleeves 20 and 22 are locked in a second activated position.** (Ex. 1011 at 6:43-7:9 (emphasis added).) Lynn discloses the additional element of **claim 15**, as discussed in Section VI(A)(iv).

17. The device of claim 15 wherein the connector is moved between the locked and the unlocked position by rotating the first sleeve member with respect to the second sleeve member.	Zdeb and Lynn render **claim 15** obvious, as discussed above. *See **claim 15***. Lynn discloses the additional element of **claim 15**, as discussed in Section VI(A)(iv).

E. Ground 5: Obviousness of Claims 19-21 Based on Zdeb in Combination with Lynn and van de Veerdonk

Claims 19-21 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Zdeb, Lynn, and van de Veerdonk as set forth below.

i. Disclosure of Zdeb

The disclosure of Zdeb is discussed in Section VI(D)(i), above.

ii. Disclosure of Lynn

The disclosure of Lynn is discussed in Section VI(A)(ii), above.

iii. Disclosure of van de Veerdonk

The disclosure of van de Veerdonk is discussed in Section VI(B)(iii), above.

iv. Rationale for Combining the Teachings of Zdeb, Lynn, and van de Veerdonk

As discussed in Section VI(D)(iii), a POSITA would have readily understood the motivation to combine Zdeb and Lynn. Zdeb and van de Veerdonk are likewise analogous art, as they both disclose similar fluid transfer devices. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation

of success combining Zdeb and van de Veerdonk, as both disclose telescoping connectors that compress to insert a needle into a sealed vial. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Zdeb's connector device to incorporate features of the connector device of van de Veerdonk, such as its use of multiple ridges, grooves, and flanges that act as stops to prevent the disassociation of telescoping cylinders. 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; (*see* Ex. Ex. 1005, ¶¶ 68-69).

As discussed, it was the practice of engineers working in the drug reconstitution and fluid transfer fields to import features from other drug reconstitution and fluid transfer devices. (*See* Ex. 1005, ¶ 71.) As discussed, the van de Veerdonk device also solved the known problem with Baxter's prior Zdeb device of lacking a structure preventing inadvertent disassembly of the device in the activated position. Thus, a POSITA would have been motivated to look to the existing prior art solutions to these well-known problems. (*See* Ex. 1005, ¶ 72.)

v. Comparison of Claims 19-21 to Zdeb, Lynn, and van de Veerdonk

The claim chart below specifies where each element of claims 19-21 is found in Zdeb in combination with Lynn and van de Veerdonk.

'103 Claim Language	Citations to Zdeb, Lynn, and van de Veerdonk
19. The device of claim 14 further comprising means associated with the connector for preventing the first sleeve member from becoming disassociated from the second member when moving from the inactivated position to the activated position.	Zdeb and Lynn render **claim 14** obvious, as discussed in Section VI(D)(iv). Van de Veerdonk discloses the additional element of **claim 19**, as discussed in Section VI(B)(v).
20. The device of claim 19 wherein the means for preventing the first and second sleeve members from becoming disassociated comprises a bushing connected to the first end of the first sleeve member.	Zdeb, Lynn, and van de Veerdonk render **claim 19** obvious, as discussed above. Van de Veerdonk discloses the additional element of **claim 20**, as discussed in Section VI(B)(v).
21. The device of claim 20 further comprising: a bushing connected to the first end of the first sleeve member, the bushing having an interior and exterior surface and a set of axially spaced annular ridges on the interior surface of the bushing.	Zdeb, Lynn, and van de Veerdonk render **claim 20** obvious, as discussed above. Van de Veerdonk renders the additional element of **claim 21** obvious, as discussed in Section VI(B)(v).

F. Ground 6: Obviousness of Claims 22-28 and 30 Based on Zdeb in Combination with Lynn and Dudar

Claims 22-28 and 30 would have been obvious to a POSITA under 35 U.S.C. § 103(a) in view of Zdeb, Lynn, and Dudar as set forth below.

i. Disclosure of Zdeb

The disclosure of Zdeb is discussed in Section VI(D)(i), above.

ii. Disclosure of Lynn

The disclosure of Lynn is discussed in Section VI(A)(ii), above.

iii. Disclosure of Dudar

The disclosure of Dudar is discussed in Section VI(C)(iii), above.

iv. Rationale for Combining the Teachings of Zdeb, Lynn, and Dudar

As discussed in Section VI(D)(iii), a POSITA would have readily understood the motivation to combine Zdeb and Lynn. Zdeb and Dudar are likewise analogous art, as they both disclose similar fluid transfer devices. (*See* Ex. 1005, ¶¶ 66-67.) Additionally, a POSITA would have a reasonable expectation of success combining Zdeb and Dudar, as both disclose connector devices with similar structures, including attachments for containers at each end of the connector device and a needle that establishes a fluid connection between the containers. (*See id.*) Thus, it would have been obvious to a POSITA at the time of Baxter's alleged invention in 1997 to modify Zdeb's connector device to

incorporate the particular vial attachment disclosed in Dudar. 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; (*see* Ex. 1005, ¶ 68).

As discussed, it was the practice of engineers working in the drug reconstitution and fluid transfer fields to import features from other drug reconstitution and fluid transfer devices. (*See* Ex. 1005, ¶ 71.) A POSITA looking for alternative mechanisms to attach the Zdeb device to the top of a vial would thus have been motivated to substitute the attachment mechanism disclosed in Dudar for that disclosed in Zdeb.

v. Comparison of Claims 22-28 and 30 to Zdeb, Lynn, and Dudar

The claim chart below specifies where each element of claims 22-28 and 30 is met by Zdeb in combination with Lynn and Dudar.

'103 Claim Language	Citations to Zdeb, Lynn, and Dudar
22. The device of claim 14 wherein the second end of the second sleeve member comprises: a plurality of circumferentially spaced and axially extending segmented fingers on the second end of the second sleeve member, the fingers being adapted to engage the second	Zdeb and Lynn render **claim 14** obvious, as discussed in Section VI(D)(iv). Dudar at least renders the additional element of **claim 22** obvious, as discussed in Section VI(C)(v).

container.	
23. The device of claim 22 wherein the fingers have a proximal end and a distal end, the distal end having a flat lead-in section.	Zdeb, Lynn, and Dudar render **claim 22** obvious, as discussed above. Dudar discloses the additional element of **claim 23**, as discussed in Section VI(C)(v).
24. The device of claim 22 wherein each adjacent set of fingers defines a gap therebetween.	Zdeb, Lynn, and Dudar render **claim 22** obvious, as discussed above. Dudar discloses the additional element of **claim 24**, as discussed in Section VI(C)(v).
25. The device of claim 22 wherein a plurality of the fingers have radially inwardly tapering tabs extending from the lead-in section.	Zdeb, Lynn, and Dudar render **claim 22** obvious, as discussed above. Dudar discloses the additional element of **claim 25**, as discussed in Section VI(C)(v).
26. The device of claim 25 wherein a plurality of the fingers have standing ribs.	Zdeb, Lynn, and Dudar render **claim 25** obvious, as discussed above. Dudar discloses the additional element of **claim 26**, as discussed in Section VI(C)(v).
27. The device of claim 26 wherein the fingers extend from an annular shelf and wherein the standing ribs extend axially from a gusset on the annular shelf outward to a position proximate the distal end of the fingers to act as a guide adapted to assist in connecting to	Zdeb, Lynn, and Dudar render **claim 26** obvious, as discussed above. Dudar at least renders the additional element of **claim 27** obvious, as discussed in Section VI(C)(v).

the second container.	
28. The device of claim 26 wherein the standing ribs taper radially inwardly proximate the distal end of the fingers.	Zdeb, Lynn, and Dudar render **claim 26** obvious, as discussed above. Dudar at least renders the additional element of **claim 28** obvious, as discussed in Section VI(C)(v).
30. The device of claim 22 wherein at least one of the fingers has a standing rib.	Zdeb, Lynn, and Dudar render **claim 22** obvious, as discussed above. *See **claim 26***. Dudar discloses the additional element of **claim 30**, as discussed in Section VI(C)(v).

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, 11, 14, 15, 17, 19-28, and 30 be canceled as unpatentable.

Respectfully submitted,

Dated: September 17, 2018

/s/ Kurt J. Niederluecke

Kurt J. Niederluecke
Registration No. 40,102
Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,852,103

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 – 1016, to be served in their entirety by electronic mail and/or UPS on the following counsel of record for patent owner:

Email and UPS
Douglas J. Nash
John D. Cook
Hoda Rifai-Bashjawish
BARCLAY DAMON LLP
Barclay Damon Tower
125 East Jefferson Street
Syracuse, New York 13202

UPS
K&L Gates LLP-Chicago
Baxter
70 West Madison Street, Suite 3300
Chicago, Illinois 60602-4207

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

Dated: September 17, 2018

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,852,103

Attachment B:

List of Evidence and Exhibits Relied Upon in Petition

Exhibit #	Reference Name
1001	U.S. Patent No. 6,852,103
1002	File History of U.S. Patent No. 6,852,103
1003	File History of U.S. Patent No. 6,071,270
1004	File History of U.S. Patent No. 6,610,040
1005	Declaration of James L. Sertic Regarding '103 Patent
1006	*Curriculum Vitae* of James L. Sertic
1007	U.S. Patent No. 4,564,054 to Gustavsson
1008	U.S. Patent No. 4,946,445 to Lynn
1009	U.S. Patent No. 3,995,630 van de Veerdonk
1010	U.S. Patent No. 5,100,394 to Dudar
1011	U.S. Patent No. 4,898,209 to Zdeb
1012	Merriam-Webster's Collegiate Dictionary (10th ed. 2002)
1013	The American Heritage College Dictionary (4th ed. 2002)
1014	Baxter's Complaint in Case No. 1:17-cv-07576 in the U.S. District Court for the Northern District of Illinois
1015	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
1016	Baxter's Second Amended 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. 6,852,103

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 13,936 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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