

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

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**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing  
(day/month/year)

**27 APR 2017**

Applicant's or agent's file reference  
CLRS02601WO

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

PCT/US17/17014

International filing date (day/month/year)

08 February 2017 (08.02.2017)

Priority date (day/month/year)

10 February 2016 (10.02.2016)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61F 9/00, 2/00, 2/28, 2/46; A61B 19/02; B65D 25/14, 77/04, 77/08, 77/20, 81/20 (2017.01)

CPC - A61F 9/0017, 2/0095, 2/4601, 2/4644; A61B 50/30, 50/33, 90/94

Applicant **CLEARSIDE BIOMEDICAL, INC.**

## I. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Date of completion of this opinion

10 April 2017 (10.04.2017)

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300  
PCT OSP: 571-272-7774

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## Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- the international application in the language in which it was filed.
- a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2.  This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).3.  With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:a.  forming part of the international application as filed: in the form of an Annex C/ST.25 text file. on paper or in the form of an image file.b.  furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.c.  furnished subsequent to the international filing date for the purposes of international search only: in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)). on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).4.  In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-46	YES
	Claims	1	NO
Inventive step (IS)	Claims	2, 4-46	YES
	Claims	1, 3	NO
Industrial applicability (IA)	Claims	1-46	YES
	Claims	NONE	NO

2. Citations and explanations:

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by US 2002/0112981 A1 to Cooper et al. (hereinafter 'Cooper').

As per claim 1, Cooper discloses an apparatus, comprising: a first tray member defining a first volume (outer tray 32 (a first tray member) includes an interior volume, as shown in figure 3; figures 3, 4A; paragraph [0071]) and an opening providing access to the first volume (tray 32 is open at the top surface to provide access to the interior, as shown; figure 3); a second tray member defining a second volume (inner tray 22 (a second tray member) includes a second volume, as shown in figure 3; figures 3, 4A; paragraph [0071]), a wall of the second tray member including a retainer configured to retain at least a portion of a medicament delivery device within the second volume (tray 22 a snap-holding space 23 (a retainer), on a side wall as shown in figure 4A, for holding a delivery tool 12 and/or a syringe (a medicament delivery device); paragraphs [0052], [0071], [0084]), the second tray member configured to be disposed within first volume such that the wall of the second tray member and a wall of the first tray member enclose the medicament delivery device within the first volume (tray 22 is housed within tray 32, and encloses the tool 12 and/or syringe within the wall confines of both trays, as indicated in figures 4A and 4B; figures 4A-B; paragraph [0072]); and a cover member coupled to the first tray member about the opening (the outer tray includes a lid; paragraph [0090]), the cover member configured to maintain sterility of the first volume (outer tray contains the inner tray for the purpose of keeping the inner tray sterile, and the outer tray lid is a TYVEK(R) that in turn is used to maintain a sterile condition, and so the cover member is capable of maintaining sterility of the first volume; paragraphs [0024], [0065], [0067], [0088], [0090]).

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over Cooper in view of US 6,059,111 A to Davilla et al. (hereinafter 'Davilla').

As per claim 3, Cooper discloses the apparatus of claim 1. Cooper does not disclose wherein: the first tray member includes a locking portion configured to matingly engage a flange of the second tray member to couple the second tray member within the first volume of the first tray member; and an outer surface of the first tray member including an actuation portion against which an actuation force is applied, the actuation portion configured to deform to release the flange from the locking portion when the actuation force is applied. Davilla discloses wherein: the first tray member includes a locking portion configured to matingly engage a flange of the second tray member to couple the second tray member within the first volume of the first tray member (outer tray 10 includes anchors 14 (locking portion) that each mate with a respective opening 22 on a corner ledge (flange) of the inner tray 20, as shown, to lock the trays; figures 2, 3; column 5, lines 12-20); and an outer surface of the first tray member including an actuation portion against which an actuation force is applied (upper surface (an actuation portion) of the outer tray 10 includes anchors 14 that are raised to create a frictional lock (an actuation force) when mated with openings 22; figure 2; column 5, lines 12-20), the actuation portion configured to deform to release the flange from the locking portion when the actuation force is applied (the raised anchors 14 provide a frictional force that locks an opening 22 to a raised anchor 14, with the material of the outer tray comprising polystyrene having 5 to 7 percent rubber, and wherein the inner tray 20 is removable, and so the upper surfaces with the raised anchors 14 are capable of deforming to release the flange from the locking portion when the actuation force is applied; column 5, lines 3-4, 12-20, 34-35). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the apparatus of Cooper to include the locking portion of Davilla for the advantage of providing a means of removably locking the inner and outer trays together.

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**Box No. VII** Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 5 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect in the form or contents thereof: Claim 5 has a typographical error in the terms "when the when the". For the purposes of this Written Opinion, the assumption has been made that the language should read "when the", as this provides proper sentence structure.

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 5 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 5 is indefinite for the following reason: claim 5 lacks antecedent basis for the terms "the third volume". For the purpose of this Written Opinion, claim 5 is interpreted to read "a third volume".

Claim 39 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 39 is indefinite for the following reason: claim 39 lacks antecedent basis for the terms "the second volume". For the purpose of this Written Opinion, claim 39 is interpreted to read "a second volume".

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## Supplemental Box

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Claims 2, and 4-46 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed matter.

Claim 2 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; wherein the opening of the first tray member is obstructed by the wall of the second tray member and an opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member.

As per claim 2, Cooper discloses the apparatus of claim 1, and Cooper further discloses wherein the opening of the first tray member is obstructed by the wall of the second tray member (when placed in the outer tray 32, the opening of the outer tray 32 is obstructed by the lower wall of tray 22 when housed within tray 32, as shown; figure 4A). Cooper does not teach or fairly suggest; an opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member.

US 2007/0178197 A1 to LaRue et al. (hereinafter 'LaRue') discloses wherein an opening providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member (aperture 815 (an opening) in the tray 810 (second tray) provides access to the inner volume of tray 810 is covered by the lower wall of tray 820 (first tray member), as shown in figure 8C, when tray 810 is placed within tray 820; figures 8a-c; paragraph [0082]). However, LaRue does not teach or fairly suggest wherein the opening is defined by the second tray, since the aperture of LaRue is located at the base wall of the second tray, as shown in figure 8C.

US 4,226,328 A (BEDDOW) discloses an opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member (inner tray 12 (second tray) includes an upper opening (an opening defined by the second tray), as shown in figure 1 is covered by the upper, outer wall of the outer tray 11, as shown upon inversion of the inner tray 12 onto the outer tray 11 in figure 4; figures 1, 2, 4; column 2, lines 31-33; column 4, lines 50-53). However, Beddow does not teach or fairly suggest wherein the opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member (Beddow discloses that the inverted inner tray 12 is placed on top of the outer tray 11, as shown in figure 4, and also teaches that the inner (second) tray is nested within the outer (first) tray; abstract, but does not teach that the opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member).

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Cooper, LaRue and Beddow, such that an opening defined by the second tray and providing access to the second volume is covered by the wall of the first tray member when the second tray member is disposed within the first tray member, as described, because the references of record fail to disclose all of the elements of the inventive apparatus.

Claim 4 meets the criteria set out in PCT Article 33(2)-(3), because it is dependent upon claim 2.

Claim 5 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; wherein: the wall of the first tray member includes a protrusion; and the retainer of the second tray member defines a retainer opening configured to receive a portion of the medicament delivery device, the protrusion and the retainer configured to maintain the medicament delivery device in a fixed position within a third volume when the second tray member is disposed within the first tray member.

As per claim 5, Cooper discloses the apparatus of claim 1, and Cooper further discloses and the retainer of the second tray member defines a retainer opening configured to receive a portion of the medicament delivery device (tray 22 a snap-holding space 23, is a hollow opening for holding a delivery tool 12 and/or a syringe, as shown in figure 4A). Cooper does not teach or fairly suggest wherein: the wall of the first tray member includes a protrusion, the protrusion and the retainer configured to maintain the medicament delivery device in a fixed position within a third volume when the second tray member is disposed within the first tray member.

Davilla discloses wherein: the wall of the first tray member includes a protrusion (outer tray 10 includes an anchor; figure 2; column 5, lines 12-20). Davilla does not teach or fairly suggest wherein: the retainer of the second tray member defines a retainer opening configured to receive a portion of the medicament delivery device, the protrusion and the retainer configured to maintain the medicament delivery device in a fixed position within a third volume when the second tray member is disposed within the first tray member.

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US 2007/0225654 A1 to Hess et al. (hereinafter 'Hess') discloses the wall of the first tray member includes a protrusion; (tray 82 includes a bump 358; figure 13; paragraph [0070]). Hess does not teach or fairly suggest wherein: the protrusion and the retainer configured to maintain the medicament delivery device in a fixed position within a third volume when the second tray member is disposed within the first tray member (Hess teaches that the protrusion is contained within the first tray; figure 13, but does not teach that the medicament delivery device is maintained in a fixed position within a third volume when a second tray member is disposed within the first tray member, since the medicament delivery device of Hess is contained in the first tray; figure 13).

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Cooper, Davilla and Hess, such that a protrusion and a retainer are configured to maintain the medicament delivery device in a fixed position within a third volume when the second tray member is disposed within the first tray member, as described, because the references of record fail to disclose all of the elements of the inventive apparatus.

Claims 6 and 7 meet the criteria set out in PCT Article 33(2)-(3), because they are dependent upon claim 5.

Claim 8 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; wherein the first tray member defines a container volume configured to receive a medicament container, the container volume being exposed when the cover member is coupled to the first tray member, the apparatus further comprising: a sleeve configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume.

As per claim 8, Cooper discloses the apparatus of claim 1. Cooper does not teach or fairly suggest; wherein the first tray member defines a container volume configured to receive a medicament container, the container volume being exposed when the cover member is coupled to the first tray member, the apparatus further comprising: a sleeve configured to be disposed about the first tray member, when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume.

Beddow discloses wherein the first tray member defines a container volume configured to receive a medicament container (outer tray 11 (the first tray) defines a container volume, as indicated in figure 1, and holds syringe 14, and so is capable of receiving a medicament container; figure 1; column 2, lines 50-52). Beddow does not teach or fairly suggest; wherein the container volume being exposed when the cover member is coupled to the first tray member, the apparatus further comprising: a sleeve configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume (Beddow teaches that the inner and outer trays are enclosed within a transparent plastic film (a sleeve); column 2, lines 33-38, but does not teach that the sleeve is configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume).

Davilla discloses a sleeve (sleeve wrapper comprising "shrink wrap" material; figure 6; column 6, lines 8-10). Davilla does not teach or fairly suggest; wherein the container volume being exposed when the cover member is coupled to the first tray member, the apparatus further comprising: a sleeve configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Cooper, Beddow and Davilla, such that the first tray member defines a container volume configured to receive a medicament container and wherein the container volume of the first tray is exposed when the cover member is coupled to the first tray member, and further wherein a sleeve is configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume, as described, because the references of record fail to disclose all of the elements of the inventive apparatus.

Claims 9-12 meet the criteria set out in PCT Article 33(2)-(3), because they are dependent upon claim 8.

Claim 13 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; an apparatus, comprising: a first tray member having a first portion and a second portion, the first portion defining a first volume, the second portion defining a container volume, the container volume configured to receive a medicament container; a second tray member defining a second volume, the second tray member including a retainer configured to retain a medicament delivery device within the second volume, the second tray member configured to be coupled within the first volume such that the medicament delivery device is disposed within the first volume; and a cover member configured to be coupled to the first tray member about the first volume, the cover member configured to maintain sterility of the first volume, the container volume being exposed when the cover member is coupled to the first tray member.

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As per claim 13, Cooper discloses an apparatus, comprising: a first tray having a first portion (outer tray 32 (a first tray member) includes an open interior (a first portion) encompassing the bulk of the interior volume, as shown in figure 3; figures 3, 4A; paragraph [0071]) and a second portion (a depressed volume surrounds the lip of the container tray 32, as shown in figure 3), the first portion defining a first volume (the interior of the outer tray 32 defines a volume, as shown in figure 3; figures 3, 4A; paragraph [0071]), a second tray member defining a second volume (inner tray 22 (a second tray member) includes a second volume, as shown in figure 3; figures 3, 4A; paragraph [0071]), the second tray member including a retainer configured to retain a medicament delivery device within the second volume (tray 22 a snap-holding space 23 (a retainer), on a side wall as shown in figure 4A, for holding a delivery tool 12 and/or a syringe (a medicament delivery device); paragraphs [0052], [0071], [0084]), the second tray member configured to be coupled within the first volume such that the medicament delivery device is disposed within the first volume (tray 22 is housed within tray 32, and encloses the tool 12 and/or syringe within the wall confines of both trays, as indicated in figures 4A and 4B; figures 4A-B; paragraph [0072]); and a cover member configured to be coupled to the first tray member about the first volume (the outer tray includes a lid (cover member), and so is capable of being coupled to the first tray member about the first volume; paragraph [0090]), the cover member configured to maintain sterility of the first volume, (outer tray contains the inner tray for the purpose of keeping the inner tray sterile, and the outer tray lid is a TYVEK(R) that in turn is used to maintain a sterile condition, and so the cover member is capable of maintaining sterility of the first volume; paragraphs [0024], [0065], [0067], [0088], [0090]). Cooper does not teach or fairly suggest; the second portion defining a container volume (the second volume of Cooper retains the inner tray, as shown in figures 3 and 4A; however there is no portion of the first tray that is capable of defining a container volume, since the inner volume is occupied by the inner tray, as shown in figure 4A), the container volume configured to receive a medicament container; the container volume being exposed when the cover member is coupled to the first tray member.

Beddow discloses a second portion defining a container volume (recess 28 (a second volume) is a portion of the volume of tray 12, that is used to retain container 26 (defining a container volume), as shown in figure 1), the container volume configured to receive a medicament container (container 26 that is used for holding lubricating jelly 27, and so the container volume is capable of receiving a medicament container; figure 1; column 3, lines 11-16). Beddow does not teach or fairly suggest; the container volume being exposed when a cover member is coupled to the first tray member (Beddow teaches that the inner and outer trays are enclosed within a transparent plastic film (a sleeve); column 2, lines 33-38, but does not teach that the sleeve is configured to be disposed about the first tray member when the second tray member is coupled within first volume, the sleeve configured to cover the container volume and a portion of the cover member disposed about the first volume).

US 2004/0215347 A1 (HAYES) discloses; the volume being exposed when the cover member is coupled to the first tray member, (the tray includes trays a transparent tray cover; paragraph [0033]). Hayes does not teach or fairly suggest; the container volume being exposed when a cover member is coupled to the first tray member.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Cooper, Beddow and Hayes, such that the second portion defining a container volume is configured to receive a medicament container; the container volume being exposed when the cover member is coupled to the first tray member, as described, because the references of record fail to disclose all of the elements of the inventive apparatus.

Claims 14-24 meet the criteria set out in PCT Article 33(2)-(3), because of direct or indirect dependencies upon claim 13.

Claim 25 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; a method, comprising: orienting a tray assembly such that an opening defined by a first tray member is spaced apart from and facing a sterile surface, the tray assembly including the first tray member and a second tray member, the first tray member defining a first volume, the opening of the first tray member providing access to the first volume, the second tray member defining a second volume within which a medicament delivery device is retained, the second tray member coupled within the first volume such that a wall of the second tray member and a wall of the first tray member enclose the medicament delivery device; and releasing the second tray member from within the first volume to place the second tray member on the sterile surface such that an opening defined by the second tray member and providing access to the second volume is facing opposite the sterile surface, a retainer of the second tray member maintaining the medicament delivery device in a fixed position within the second volume.

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As per claim 25, Cooper discloses a method, comprising: orienting a tray assembly such that an opening defined by a first tray member is spaced apart from and facing a sterile surface (trays include an outer tray 32 (a first tray member) that defines an interior volume, as shown in figure 3, and wherein the tray 32 is covered with an outer tray lid which in turn is used to maintain a sterile condition (such that an opening defined by a first tray member is spaced apart from and facing a sterile surface); figures 3, 4A; paragraphs [0024], [0065], [0067], [0088], [0090]), the tray assembly including the first tray member and a second tray member (outer tray 32 (first tray member) and inner tray 22 (second tray member); figures 3, 4A; paragraph [0071]), the first tray member defining a first volume (outer tray 32 includes an interior volume, as shown in figure 3; figures 3, 4A; paragraph [0071]), the opening of the first tray member providing access to the first volume (tray 32 is open at the top surface to provide access to the interior, as shown; figure 3), the second tray member defining a second volume within which a medicament delivery device is retained (inner tray 22 includes a second volume comprising a snap-holding space 23 for retaining a delivery tool 12 and/or a syringe (a medicament delivery device); figures 3, 4A; paragraphs [0052], [0071], [0084]), the second tray member coupled within the first volume such that a wall of the second tray member and a wall of the first tray member enclose the medicament delivery device (tray 22 is housed within tray 32 (coupled within the first volume), and encloses the tool 12 and/or syringe within the wall confines of both trays, as indicated in figures 4A and 4B; figures 4A-B; paragraph [0072]), a retainer of the second tray member maintaining the medicament delivery device in a fixed position within the second volume (tray 22 a snap-holding space 23 (a retainer), on a side wall as shown in figure 4A, for holding a delivery tool 12 and/or a syringe (a medicament delivery device); paragraphs [0052], [0071], [0084]). Cooper does not teach or fairly suggest; releasing the second tray member from within the first volume to place the second tray member on the sterile surface such that an opening defined by the second tray member and providing access to the second volume is facing opposite the sterile surface.

US 2011/0004265 A1 to Wenger et al. (hereinafter 'Wenger') discloses releasing the second tray member from within the first volume (tearing of electrical interface 50 allows inner tray 104 to be removed from outer tray 114; paragraph [0070]), a sterile surface (a surface of the sterilizable package; paragraph [0071]). Wenger does not teach or fairly suggest; releasing the second tray member from within the first volume to place the second tray member on the sterile surface such that an opening defined by the second tray member and providing access to the second volume is facing opposite the sterile surface.

US 6,622,864 B1 to Debbs et al. (hereinafter 'Debbs') discloses releasing the second tray member from within the first volume (the inner tray is removed from the recess of the outer tray; claims 16, 27). Debbs does not teach or fairly suggest; releasing the second tray member from within the first volume to place the second tray member on the sterile surface such that an opening defined by the second tray member and providing access to the second volume is facing opposite the sterile surface.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Cooper, Wenger and Debbs, such that the second tray member is released from within the first volume to place the second tray member on the sterile surface such that an opening defined by the second tray member and providing access to the second volume is facing opposite the sterile surface, as described, because the references of record fail to disclose all of the elements of the inventive method.

Claims 26-38 meet the criteria set out in PCT Article 33(2)-(3), because of direct or indirect dependencies upon claim 25.

Claim 39 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a motivation to combine the prior arts.

As per claim 39, Beddow discloses a kit (a catheterization package 10; figure 1; column 2, lines 28-29), comprising: a medical injector (syringe 14; figure 1; column 2, lines 51-52); a medicament container (container 26 contains jelly 27; figure 1; column 3, lines 12-13); and a tray assembly (a set of trays; figure 1), the tray assembly including: a first tray member defining a first volume (outer tray 11 defines a volume, as shown in figure 1), the medicament container retained within a second volume (container 26 (a medicament container) is disposed in recess 28 (a second volume), as shown in figure 1); a second tray member defining a second volume (inner tray 12 (second tray member) includes an upper opening (defining a second volume), as shown in figure 1); the second tray member coupled within first volume such that the wall of the second tray member and a wall of the first tray member enclose the medical injector (when coupled together, as shown in figure 4, the wall of the inner tray 12 is mated with the wall of the outer tray 11 at the lip 38, and thereby encloses the contents tray 11, which includes the syringe 14; figure 4; column 4, lines 50-55). Beddow does not teach or fairly suggest; a first tray member defining a container volume (Beddow discloses that a catheter (container) is disposed in the outer tray 11; figure 1; column 4, lines 17-18, but does not teach that the catheter is contained within a container volume); a second tray member defining a second volume within which the medical injector is disposed (Beddow discloses that the syringe 14 is contained within the first tray; figure 1), a wall of the second tray member including a retainer that retains the medical injector within the second volume; and a cover member coupled to the first tray member about the first volume, the cover member configured to maintain sterility of the first volume.

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Cooper discloses a kit, comprising: a medical injector (a syringe; paragraph [0025]); and a tray assembly (inner and outer trays; figure 3), the tray assembly including: a first tray member defining a first volume (outer tray 32 (a first tray member) includes an interior volume, as shown in figure 3; figures 3, 4A; paragraph [0071]); a second tray member defining a second volume within which the medical injector is disposed (inner tray 22 (a second tray member) includes a snap-holding space 23 (a second volume) for holding the syringe, as shown in figure 3; figures 3, 4A; paragraph [0071]), a wall of the second tray member including a retainer that retains the medical injector within the second volume (the snap-holding (retainer) space 23, on a side wall as shown in figure 4A, for holding the syringe; paragraphs [0052], [0071], [0084]), the second tray member coupled within first volume such that the wall of the second tray member and a wall of the first tray member enclose the medical injector (tray 22 is housed within tray 32, and encloses the tool 12 and/or syringe within the wall confines of both trays, as indicated in figures 4A and 4B; figures 4A-B; paragraph [0072]); and a cover member coupled to the first tray member about the first volume (the outer tray includes a lid; paragraph [0090]), the cover member configured to maintain sterility of the first volume (outer tray contains the inner tray for the purpose of keeping the inner tray sterile, and the outer tray lid is a TYVEK(R) that in turn is used to maintain a sterile condition, and so the cover member is capable of maintaining sterility of the first volume; paragraphs [0024], [0065], [0067], [0088], [0090]). Cooper does not teach or fairly suggest; a medicament container; a first tray member defining a container volume, the medicament container retained within a second volume.

Hess discloses a medicament container (wet ingredient container 60, not shown; paragraph [0056]), the medicament container retained within a second volume (compartment 74 (a second volume) is designed to hold wet ingredient container 60; figure 6; paragraph [0056]). Hess does not teach or fairly suggest a medical injector; a second tray member defining a second volume within which the medical injector is disposed, a wall of the second tray member including a retainer that retains the medical injector within the second volume, the second tray member coupled within first volume such that the wall of the second tray member and a wall of the first tray member enclose the medical injector; and a cover member coupled to the first tray member about the first volume, the cover member configured to maintain sterility of the first volume.

Nonetheless, it would not have been obvious to one of ordinary skill in the art at the time of the invention to create the claimed kit, since the tray arrangement of Beddow is not directly compatible with the tray arrangement disclosed by Cooper, since the two arrangements have fundamentally different functions and associated functional arrangements. Specifically, the trays of Cooper are designed to function interactively so as to mix bone graft particles within a mixing bowl; paragraph [0020], and without any inversion of the trays, whereas the trays of Beddow are designed to store catheterization devices, in a leak-resistant engagement between the two trays, upon inversion of the inner tray upon the outer tray; abstract; figure 4. Moreover, Hess only discloses one tray (tray 82; figure 6; paragraph [0058]), and so it would not be clear how a second tray would be incorporated into such a unitary design, and therefore incorporating the tray of Hess with the inner tray of Cooper, is not immediately obvious to one of ordinary skill in the art.

Claims 40-46 meet the criteria set out in PCT Article 33(2)-(3), because of direct or indirect dependencies upon claim 39.

Claims 1-46 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.