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April 4, 2023

VIA EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington D.C. 20436

Re: *Certain Liquid Transfer Devices with an Integral Vial Adapter*, Inv. No. 337-TA-_____

Dear Secretary Barton:

In accordance with the Commission's Temporary Change to Filing Procedures dated March 16, 2020, West Pharmaceutical Services, Inc. and West Pharma. Services IL, Ltd. (collectively, the "Complainants") submit the following documents in support of their request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain liquid transfer devices with an integral vial adapter.

Complainants submit the following documents for filing:

1. One (1) electronic copy of Complainants' verified complaint, pursuant to Commission Rule 210.8(a)(1)(i).

2. One (1) electronic copy of the public exhibits to the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9), including

    a. One (1) electronic copy of the certified versions of United States Patent Nos. 10,688,295 ("the '295 Patent"), U.S. Design Patent No. D767,124, U.S. Design Patent No. D765,837, and U.S. Design Patent No. D630,732 (collectively, "the Asserted Patents") and U.S. Trademark Registration No. 5,810,583 ("the Asserted Mark"), referenced in the Complaint as Exhibits 1–5, pursuant to Commission Rule 210.12(a)(9)(i).

b. One (1) electronic copy of the certified versions of the assignment records for the Asserted Patents and Asserted Mark referenced in the Complaint as Exhibits 6–10, respectively, pursuant to Commission Rule 210.12(a)(9)(ii);

3. One (1) electronic copy of the confidential exhibit to the Complaint, referenced in the Complaint as Confidential Exhibit 12C, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii).

4. One (1) electronic copy of the certified prosecution histories of each of the Asserted Patents and Asserted Marks included as Appendices A–E to the Complaint, pursuant to Commission Rule 210.12(c)(1).

5. One (1) electronic copy of each patent and technical reference mentioned in the prosecution histories of each of the Asserted Patents as Appendix F, pursuant to Commission Rule 210.12(c)(2).[1]

6. A letter and certification pursuant to Commission Rules 201.6(b) and 210.5(d) requesting confidential treatment of information appearing in Confidential Exhibit No. 12C.

7. A Statement of the Public Interest regarding the remedial orders sought by Complainants, pursuant to Commission Rule 210.8(b)

Please contact me if you have any questions regarding this submission. Thank you for assistance in this matter.

Sincerely,

Domingo Manuel LLagostera
Partner

[1] There are hundreds of patents and technical references cited in all four prosecution histories of the Asserted Patents. Rather than submit those references four times in a separate appendix for each Asserted Patent, Appendix F includes copies of each patent and technical reference cited in any of the prosecution histories for the four Asserted Patents.

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April 4, 2023

VIA EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington D.C. 20436

Re: *Certain Liquid Transfer Devices with an Integral Vial Adapter*, Inv. No. 337-TA-_____

Dear Secretary Barton:

Pursuant to Commission Rules 201.6 and 210.5, 19 C.F.R. §§ 201.6 and 210.5, Complainants West Pharmaceutical Services, Inc. and West Pharma. Services IL, Ltd. (collectively, the "Complainants") respectfully request confidential treatment for the confidential business information contained in Confidential Exhibit 12C to the Verified Complaint.

Confidential Exhibit 12 C is a declaration from Mr. Martin McGarry that contains confidential business information about Complainants' business operations, proprietary business relationships, and financial investments and expenditures. The information in Confidential Exhibit 12C qualifies as confidential information pursuant to 19 C.F.R. § 201.6 because (1) it is not available to the public, (2) the unauthorized disclosure of such information would cause substantial harm to Complainants' competitive position, and (3) its disclosure would impair the Commission's ability in the future to obtain such types of information in performance of its statutory function. I certify that substantially identical information is not reasonably available to the public.

A non-confidential version of this exhibit with the confidential information redacted is being filed concurrently.

Please contact me if you have any questions, or if this request is not granted in full.

Thank you for your assistance in this matter.

Sincerely,

Domingo Manuel LLagostera
Partner

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON DC

In the Matter of CERTAIN LIQUID TRANSFER DEVICES WITH AN INTEGRAL VIAL ADAPTER	Investigation No. 337-TA-_____

PUBLIC INTEREST STATEMENT OF COMPLAINANTS WEST PHARMACEUTICAL SERVICES, INC. AND WEST PHARMA. SERVICES IL, LTD. IN SUPPORT OF THEIR COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

Pursuant to 19 C.F.R. § 210.8(b), West Pharmaceutical Services, Inc. and West Pharma. Services IL, Ltd. (collectively "West") respectfully submit this Statement on the Public Interest in support of their Complaint concurrently filed against Advcare Medical, Inc. ("Advcare"), Dragon Heart Medical, Inc., Dragon Heart Medical Devices Co., Ltd., and Summit International Medical Technologies, Inc. (collectively, the "Proposed Respondents"). The investigation involves the importation, sale for importation, and/or sale after importation into the United States of certain liquid transfer devices with integral vial adapters that infringe one or more of U.S. Patent No. 10,688,295, U.S. Design Patent No. D767,124, U.S. Design Patent No. D765,837, and U.S. Design Patent No. D630,732 ("collectively, the "Asserted Patents") and/or U.S. Trademark Registration No. 5,810,583 (the "Asserted Mark"). To remedy Proposed Respondents' continuing and unlawful violation of Section 337, West seeks an exclusion order and cease and desist orders against these infringing products.

The public interest does not warrant a departure from the standard practice of excluding all products found to infringe under Section 337 for two principal reasons. First, the requested remedial orders will not have an adverse effect on the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Second, the public interest

heavily favors protecting West's intellectual property rights and domestic industry from further infringement. *See, e.g.*, *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op. at l50 (June 19, 2007) ("We must take into account the strong public interest in enforcing intellectual property rights.").

Although the accused products are used in the healthcare industry, this investigation does not present a situation in which the Commission, the parties, or the public should expend the time or resources to undertake discovery and trial on the public interest. As explained below, there are no credible arguments that any such public interest would be harmed by the requested relief. Indeed, the requested remedial orders serve, rather than harm, the public interest. As a result, the Commission's consideration of the public interest during the remedy phase of the investigation is sufficient and delegation of this issue to the presiding ALJ is unnecessary.

I. Explanation of How the Accused Products Potentially Subject to the Requested Remedial Orders are Used in the United States

The accused products are liquid transfer devices with an integral vial adapter. The accused products may be used for drug reconstitution and transfer of liquids between a vial and intravenous (IV) bag at the point of care prior to administering the drug to a patient.

II. There are No Public Health, Safety, or Welfare Concerns Relating to the Requested Remedial Orders

Issuance of the requested remedial orders would not pose any health, safety, or welfare concerns in the United States with respect to the accused products.

The accused products are liquid transfer devices with an integral vial adapter. These products could be replaced without delay by West or competitors with non-infringing devices. Indeed, this investigation has no impact on non-infringing devices. Non-infringing devices

include Baxter's Vial-Mate Adapter, BBraun's addEASE, and Pfizer's ADD-Vantage System. Because this investigation only impacts a subset of the liquid transfer device market, it cannot pose a health, safety, or welfare risk to the public.

Based on publicly available information, West cannot determine Proposed Respondents' exact share, if any, of the market for drug reconstitution and liquid transfer devices. But, on information and belief, West believes that share to be low as, for example, Advcare only received 510(k) clearance on August 19, 2022 (Ex. 15 at 1), and the accused products take six weeks to ship because of backlog (Ex. 32 at ¶11). Combining this with West's manufacturing capabilities and the availability of non-infringing devices, West and non-infringing competitors are more than capable of satisfying the U.S. demand for drug reconstitution and liquid transfer devices if the accused products are excluded. Thus, there are no public interest concerns. *See, e.g.*, *Certain Inkjet Ink Supplies & Components Thereof*, Inv. No. 337-TA-691, Comm'n Op. at 15 (Jan. 28, 2011) (holding public interest concerns do not bar issuance of remedial orders because "[t]here is no evidence that domestic demand for [complainant's] inkjet cartridges cannot be met by [complainant] and its [non-infringing] competitors"); *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. at 46 (Jun. 1, 1991) (holding public interest concerns do not bar granting relief because "[complainant] has sufficient capacity and resources to satisfy all domestic demand for cefadroxil" and "the availability of other cephalosporins will not be affected by the issuance of relief").

III. Identification of Like or Directly Competitive Products that West and Third Parties Make that Could Replace the Accused Products if They Were to be Excluded

West has designed, researched, and developed two products covered by the Asserted Patents and/or the Asserted Mark: Vial2Bag Advanced® 20mm and 13mm admixture devices. West currently manufactures and sells the Vial2Bag Advanced® 20mm admixture device in the

United States through its exclusive U.S. distributor. It expects to finish commercializing its Vial2Bag Advanced® 13mm admixture device and sell that device through its U.S. distributor as well. If the accused products are excluded, they could be replaced immediately by West's Vial2Bag Advanced® 20mm admixture device and competitors with non-infringing devices (*see supra* at §II), and later by West's Vial2Bag Advanced® 13mm admixture device.

The accused products are not only covered by the Asserted Patents and/or Asserted Mark, but, as admitted by Advcare, are near technical copies of West's Vial2Bag Advanced® 20mm admixture device. In its 510(k) clearance application, Advcare represented to the FDA the accused products have the same technical characteristics as West's Vial2Bag Advanced® 20mm admixture device and any differences in technical characteristics did not raise any new issues of safety or efficacy. Ex. 15 at 4–8. Advcare's 510(k) application is an admission that the Vial2Bag Advanced® 20mm admixture device would be a suitable replacement for the accused products.

Thus, the availability of like or directly competitive articles indicates that the remedial orders requested by West would not adversely impact competitive conditions in the United States, or otherwise be contrary to public interest.

IV. Identification of Whether West and/or Third Parties Have the Capacity to Replace the Volume of Articles Subject to the Requested Remedial Orders in a Commercially Reasonable Time in the United States

As discussed above, on information and belief, the Proposed Respondents' market share of drug reconstitution and liquid transfer devices is limited. Further, their capacity to fulfill orders on the accused products is challenged because it currently takes them six weeks to ship products due to a backlog. Ex. 32 at ¶11. West and non-infringing competitors have the capacity to replace the limited volume of accused products with like or functionally substitutable

articles with no delay in availability for consumers.

V. The Requested Remedial Orders Would Not Adversely Impact U.S. Consumers

Consumers in the U.S. will not experience any adverse impact as a result of West's requested remedial orders. As explained above, West and non-infringing competitors have the capacity to fill any void left by the exclusion of the accused products. U.S. consumers will also benefit from the quality of devices West provides. Further, the requested remedial orders will serve U.S. consumers by enforcing U.S. intellectual property rights and protecting them from unfair competition. Thus, West's requested remedial orders will not adversely impact U.S. consumers.

Dated: April 4, 2023

Respectfully submitted,

/s/ Domingo M. LLagostera

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COUNSEL FOR COMPLAINANTS

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON DC

In the Matter of CERTAIN LIQUID TRANSFER DEVICES WITH AN INTEGRAL VIAL ADAPTER	Investigation No. 337-TA-_____

COMPLAINT OF WEST PHARMACEUTICAL SERVICES, INC. AND WEST PHARMA. SERVICES IL, LTD. UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

COMPLAINANTS:

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Exton, PA 19341
610-594-2900

West Pharma. Services IL, Ltd.
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Ra'anana 4366411, Israel
972-9-777-8666

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PROPOSED RESPONDENTS:

Advcare Medical, Inc.
No. 36, Sinsing St.,
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New Taipei City, Taiwan 23877
Tel: 886-2-3501-7479 ext. 1208

Dragon Heart Medical Devices Co., Ltd.
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Kaiping City, Guangdong Province,
China 529375
Tel: 86-750-2517333
Fax: 86-750-2510688

Dragon Heart Medical, Inc.
901 South Rohlwing Rd Unit H,
Addison, IL 60101
Tel: (630) 833-6998

Summit International Medical Technologies, Inc.
101 Constitution Blvd.
Franklin, MA 02038
Tel: (508) 528-3065

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TABLE OF EXHIBITS

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2	Certified copy of U.S. Design Patent No. D767,124
3	Certified copy of U.S. Design Patent No. D765,837
4	Certified copy of U.S. Design Patent No. D630,732
5	Certified copy of U.S. Trademark Registration No. 5,810,583
6	Certified copy of patent assignment, recorded at Patent Reel/Frame 037685/0164, for U.S. Patent No. 10,688,295
7	Certified copy of change of name document, recorded at Patent Reel/Frame 046069/0444, for the Asserted Patents
8	Certified copy of patent assignment, recorded at Patent Reel/Frame 031914/0203, for U.S. Design Patent No. D767,124
9	Certified copy of patent assignment, recorded at Patent Reel/Frame 031914/0312, for U.S. Design Patent No. D765,837
10	Certified copy of patent assignment, recorded at Patent Reel/Frame 023296/0780, for U.S. Design Patent No. D630,732
11	West's 510(k) FDA Clearance for the Vial2Bag Advanced® 20mm Admixture Device
12C	CONFIDENTIAL Declaration of Martin McGarry
12	Public version of Declaration of Martin McGarry
13	Photograph of West's Vial2Bag Advanced® 20mm admixture device
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21	FDA's Establishment Registration and Device Listing records, dated October 23, 2022, for Advcare
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25	'295 Patent Infringement Claim Chart for the accused VDB 20mm admixture device
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43	Summit marketing brochure downloaded from Advcare's website
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C	Certified copy of the prosecution history of U.S. Design Patent No. D765,837
D	Certified copy of the prosecution history of U.S. Design Patent No. D630,732
E	Certified copy of the prosecution history of U.S. Trademark Registration No. 5,810,583
F	Technical references identified in the prosecution histories of the Asserted Patents

I. INTRODUCTION

1. Complainants West Pharmaceutical Services, Inc. ("West US") and West Pharma. Services IL, Ltd. ("West Israel" and collectively, "West") request that the United States International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act, as amended, 19 U.S.C. §1337. West brings this action to remedy the unlawful, unfair, and unauthorized importation into the United States, sale for importation into the United States, and/or sale in the United States after importation of certain liquid transfer devices that infringe one or more of the asserted claims of U.S. Patent No. 10,688,295 ("the '295 Patent"), U.S. Design Patent No. D767,124 ("the D'124 Patent"), U.S. Design Patent No. D765,837 ("the D'837 Patent"), and U.S. Design Patent No. D630,732 ("the D'732 Patent" and collectively, the "Asserted Patents"), and/or U.S. Trademark Registration No. 5,810,583 ("the '583 Mark" or the "Asserted Mark"). Certified copies of the Asserted Patents are attached as Exhibits 1-4. A certified copy of the Asserted Mark is attached as Exhibit 5.

2. Proposed Respondents are Advcare Medical, Inc. of New Taipei City, Taiwan ("Advcare"), Dragon Heart Medical, Inc. of Addison, Illinois ("DHM US"), Dragon Heart Medical Devices Co., Ltd. of Guangdong Province, China ("DHM China"), and Summit International Medical Technologies, Inc. of Franklin, Massachusetts ("Summit" and collectively "Proposed Respondents"). DHM US and DHM China are collectively referred to herein as "DHM".

3. Founded in 1923, West designs and manufactures pharmaceutical packaging and delivery systems and products, including reconstitution and liquid transfer devices. It is a recognized leader in this space.

4. Medications, whether in dry form (e.g., powders) or concentrated liquid form,

typically must be reconstituted, or mixed with a fluid, called a diluent, before they are administered to a patient. Originally, hospitals reconstituted drug formulations in large batches in their pharmacies. The large batch of reconstituted medication was then divided and delivered to patients for bedside administration. There was a substantial disadvantage to this process. A medication once reconstituted often has a short shelf-life and must be discarded if not administered before expiration. Discarded medication results in expensive waste and can be especially costly during periods of drug shortages.

5. To overcome the afore-mentioned disadvantage of reconstitution, it was discovered that medication could be reconstituted at the point of care using a liquid transfer device that included an intravenous ("IV") spike, an administration port, and a valve that could be screw threaded to a syringe, vial, or other medical equipment containing medication. By allowing medication to be reconstituted at the point of care, the medication is reconstituted when it is needed and in the amount needed by the patient. Further, the prior art device's valve provided flexibility in the device's use at the point of care. For example, at the point of care different types of medical equipment could be screwed to the device via the valve's threads. Moreover, at the point of care multiple types of medical equipment could be screwed to and unscrewed from the device via the valve's threads in instances where a patient required multiple additions of medicant. However, the prior art device's valve also had its drawbacks. Because the valve was designed to attach to and detach from medical equipment, the valve design was complex. Complexity can result in unreliability, such as inadvertent leakage, contamination, or incorrect dosage of medicament, which in the medical field are virtually unacceptable risks. Furthermore, the complexity of the valve design adds cost to the manufacture of the product. Finally, any time there is a system that allows for the attaching and detaching of medical

equipment containing medicaments, it increases the chance of human error. For example, at the point of care it is possible a healthcare professional could introduce a medicant, remove the equipment that administered the medicant, and a subsequent healthcare professional could re-dose the patient with the same medicament. There is also a risk that contamination may occur at the connection site between the valve and the medical equipment as a result of human error.

6. West has developed several admixture devices that overcome the afore-mentioned disadvantages of the prior art device. Its most recent developed device is the innovative Vial2Bag Advanced® admixture devices. The Vial2Bag Advanced® admixture devices are fluid transfer devices that have a trifurcated connector body with an integral vial adapter. Because the Vial2Bag Advanced® vial adapter is integral to the fluid transfer device, the fluid transfer device can only be used with a vial and for only one administration of medicine. The Vial2Bag Advanced® admixture device may be used with an infusion liquid container (e.g., IV bag). Fluid (e.g., infusion liquid) may be transferred through the device between the infusion liquid container (e.g., IV bag) and the vial to reconstitute the medicant. Further, once the vial is attached to a Vial2Bag Advanced® admixture device, it is not intended to be removed. This decreases the chance of human error that could result in a patient receiving two doses of the same medicament. Specifically, a subsequent healthcare professional would not re-dose the patient with the same medicine because he/she would see the vial already attached to the device and know the medicament had been administered. In other words, the Vial2Bag Advanced® admixture devices are single-purpose and single-use devices. Unlike the prior art device discussed above, the Vial2Bag Advanced® admixture devices have an integral vial adapter rather than a valve with screw threads for attaching a Luer Lock syringe or detachable vial adapter. Thus, the Vial2Bag Advanced® admixture devices have a less complex design, are

simpler to use, and are more cost effective than the prior art device. Further, because the vial adapter is integral with the trifurcated body, it is a more reliable design than the design having a valve. The design of the Vial2Bag Advanced® admixture devices prevents inadvertent leakage of medication and potential contamination as a result of human error by eliminating assembly steps.

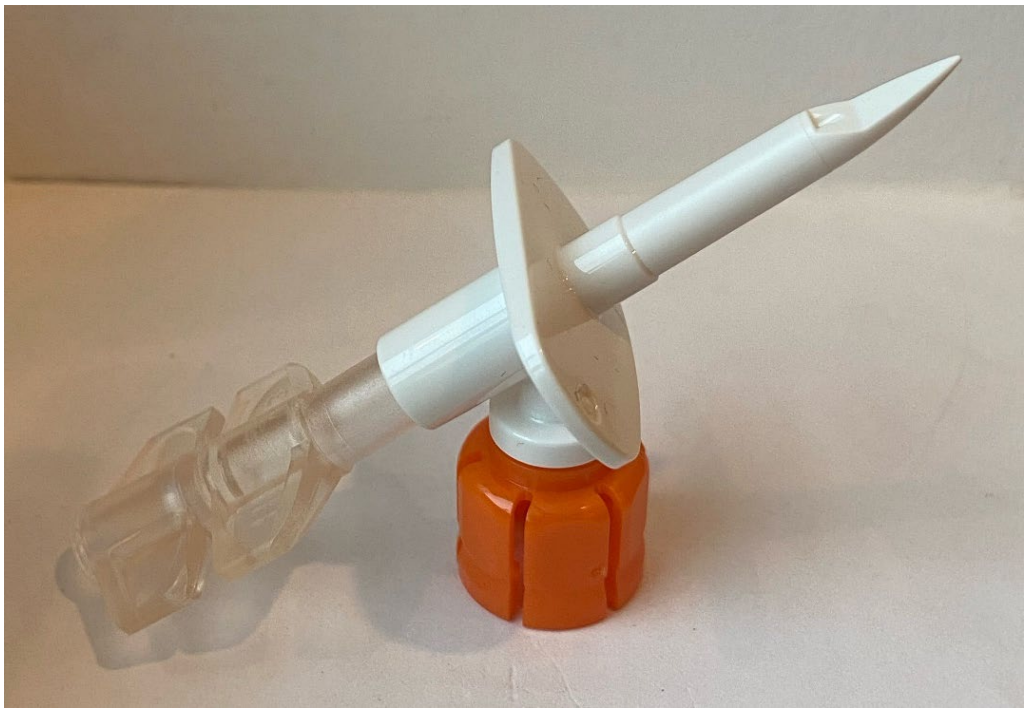
7. West US currently sells a 20mm version of its Vial2Bag Advanced® admixture device in the United States. That device has 510(k) clearance from the U.S. Food and Drug Administration ("FDA"). Ex. 11. As explained in detail in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12), West is preparing the application to seek 510(k) clearance for the 13mm version of its Vial2Bag Advanced® admixture device to sell that version of its device in the United States as well.

8. West has protected its innovative products and cutting-edge technologies, including its Vial2Bag Advanced® admixture devices, through a broad range of intellectual properties. For example, its Vial2Bag Advanced® admixture devices are protected by the Asserted Patents and/or the Asserted Mark.

9. A photograph of West's Vial2Bag Advanced® 20mm admixture device is provided as Exhibit 13 and shown below.[1]

[1] West is unable to submit physical exhibits due to the Commission's restrictions on in-person filings in response to COVID-19. To the extent practical and necessary, West will submit physical exhibits of West's Vial2Bag Advanced® 20mm device, West's Vial2Bag Advanced® 13mm device, and the Accused Products (as defined below in ¶11) when the Commission lifts the restrictions or provides alternative instructions.

10. A photograph of West's Vial2Bag Advanced® 13mm admixture device is provided as Exhibit 14 and shown below.



11. Unfortunately, opportunist companies, like Proposed Respondents, took note of West's novel and innovative Vial2Bag Advanced® admixture device and introduced copycat devices into the marketplace that infringe West's intellectual property. Those copycat devices include Proposed Respondents' vial direct to bag ("VDB") needle-free admixture devices with a vial adapter ("the Accused Products"). As explained below in ¶38 (incorporated herein by reference), Proposed Respondent Advcare admitted the Accused Products are near technical copies of West's Vial2Bag Advanced® 20mm admixture device. *See* Ex. 15 at 4–8. Specifically, in its application for 510(k) clearance, Advcare represented to the FDA that the Accused Products have the same technical characteristics as West's Vial2Bag Advanced® 20mm admixture device and any differences in technical characteristics did not raise any new issues of safety or efficacy. *Id.*

12. The Accused Products are imported and sold in the United States in two sizes: 13mm and 20mm. The sizes correspond to the diameters of the vial adapters of the Accused Products.[2] On information and belief, each of the Proposed Respondents manufacture for importation into the United States, import into the United States, sell for importation into the United States, and/or sell within the United States after importation the Accused Products that infringe West's asserted intellectual property. Specifically, pursuant to Commission Rule 210.12(a)(9)(vii), West asserts the Accused Products infringe one or more of the asserted claims of the Asserted Patents and/or the Asserted Mark:

[2] Photographs of the accused VDB 20mm admixture device and the accused VDB 13mm admixture device are attached as Exhibits 16 and 17, respectively.

Asserted IP	Accused Product(s)[3]
Claim 1 of the ’295 Patent	VDB 13mm admixture device VDB 20mm admixture device
The D’124 Patent	VDB 13mm admixture device
The D’837 Patent	VDB 20mm admixture device
The D’732 Patent	VDB 13mm admixture device
The ’583 Mark	VDB 13mm admixture device VDB 20mm admixture device

13. A domestic industry as required and defined by 19 U.S.C. §§1337(a)(2) and (3) exists relating to West’s Vial2Bag Advanced® 20mm and 13mm admixture devices (collectively “DI Products”), which are protected by the Asserted Patents and/or Asserted Mark. West, directly or through subsidiaries of West US, has made significant investments in plant and equipment and significant employment of labor and capital with respect to the DI Products. Such investments include, among other things, the researching, developing, and commercializing of these devices in the United States and validating and setting up the equipment at its manufacturing facility in Puerto Rico to manufacture its 20mm device in the United States.[4]

14. In the alternative, a domestic industry as required and defined by 19 U.S.C. §§1337(a)(2) and (3) is in the process of being established relating to West’s Vial2Bag Advanced® 20mm admixture device. In addition to making the significant investments referenced above in ¶13 (incorporated herein by reference), West, directly or through subsidiaries of West US, is actively engaged in the steps leading to the exploitation of the Asserted Patents and Asserted Mark and there is a significant likelihood that an industry will be

[3] West reserves the right to add to the list of Accused Products should other infringing products become known during discovery.

[4] Puerto Rico is considered part of the U.S. for purposes of establishing domestic industry under Section 337. 19 U.S.C. § 1337(m); Harmonized Tariff Schedule of the United States, General Note 2 (2014) (“The term ‘customs territory of the United States’, as used in the tariff schedule, includes only the States, the District of Columbia and Puerto Rico.”).

established imminently, if not already established. For example, West will start manufacturing the Vial2Bag Advanced® 20mm admixture device in Puerto Rico.

15. To remedy Proposed Respondents' continuing and unlawful violation of Section 337, West seeks a limited exclusion order barring from entry all infringing liquid transfer devices imported, by or on behalf of, each of the Proposed Respondents.

16. Pursuant to 19 U.S.C. §1337(f), West also seeks cease and desist orders prohibiting each Proposed Respondent and their subsidiaries, predecessors, affiliates, agents, successors, and assigns from engaging in the (a) importation, sale for importation, and/or sale within the United States after importation of infringing liquid transfer devices, (b) marketing, distributing, offering for sale, selling, or otherwise transferring (except for exportation) in the United States the infringing liquid transfer devices, (c) advertising of such infringing liquid transfer devices, (d) soliciting U.S. agents, retailers, resellers, or distributors for such infringing liquid transfer devices, and (e) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of such articles.

17. Pursuant to 19 U.S.C. §1337(j), West seeks the imposition of a bond on Proposed Respondents' importation of infringing liquid transfer devices during the 60-day Presidential review period to prevent further injury to West.

II. COMPLAINANTS

18. West US is a Pennsylvania corporation with its principal place of business at 530 Herman O. West Drive, Exton, PA 19341.

19. West Israel is an indirect subsidiary of West US. West Israel is an Israel corporation with its principal place of business at 4 Hasheizaf St. Ra'anana 4366411, Israel.

West Israel is the owner/assignee of the intellectual property asserted in this investigation. Exhibits 6–10.

20. West US has an implied license to use the Asserted Patents and Asserted Mark per this corporate relationship.

III. PROPOSED RESPONDENTS

A. Advcare Medical, Inc.

21. On information and belief, Proposed Respondent Advcare Medical, Inc. ("Advcare") is a Taiwanese corporation with a place of business at No. 36, Sinsing St., Shulin District, New Taipei City, Taiwan 23877.[5] On information and belief, Meng Tan is the CEO of Advcare. *See, e.g.*, Ex. 15 at 1.

22. On information and belief, Advcare manufactures abroad, imports into the U.S., markets to the U.S., sells for importation into the U.S., and/or sells after importation in the U.S. medical devices, including the Accused Products. Advcare targets potential customers based in the United States with its English-language version of its website: https://advcare-med.com/.

23. On information and belief, Advcare has import and export qualifications in Taiwan.

24. On information and belief, Advcare and Summit designed the Accused Products together. Ex. 42 (Letter, dated June 17, 2021 from Summit's attorney to Ms. Ryberg associate general counsel for West US) at 1. On June 17, 2021, Summit's attorney, Christopher J. Lutz, sent Betty Ryberg, former associate general counsel for West US, a "drawings [sic] of a new

[5] This is the address Advcare provided to the FDA in connection with its 510(k) clearance application. Ex. 15 at 5. During the prosecution of the '295 Patent, the examiner cited an Advcare article disclosing, on information and belief, a prior version of the Accused Product. Appx A, Part 20 at 295. Advcare's address on that article is No. 36, Xinxing St., Shulin District, New Taipei City, Taiwan 23877. *Id.*

product design by Summit and ADVCARE." *Id.* at 3. On information and belief, this drawing is of the accused VDB 20mm admixture device.

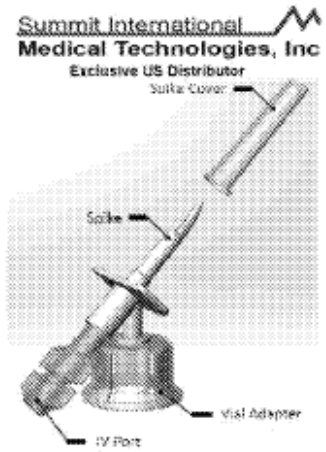
25. On information and belief, Advcare and Summit have worked together on other VDB admixture devices. During the prosecution of the '295 Patent, the examiner cited an Advcare article disclosing, on information and belief, a prior version of the Accused Product. Appx A, Part 20 at 295. The article states Summit's "Vial Direct to Bag Spike" device was "designed by His-Chin Tsai, Advcare Med." *Id.* at 295–96. Michael Merchant is identified as the author of this article. *Id.* at 295. On information and belief, Mr. Merchant is the President, Owner, and Regional Sales Manager of Summit. https://summitmedtech.com/about-us/. Summit is identified as Advcare's "Exclusive US Distributor" in the article. Appx A, Part 20 at 295 (reproduced in part below).

ADV CARE
Innovation Experts. Advancing Healthcare. www.advcare-med.com

An engineered control device for needle free reconstitution and transfer of compounded sterile intravenous drug solutions for immediate use to assist in complying with United States Pharmacopeia Chapter <797> standards.

November 3, 2018

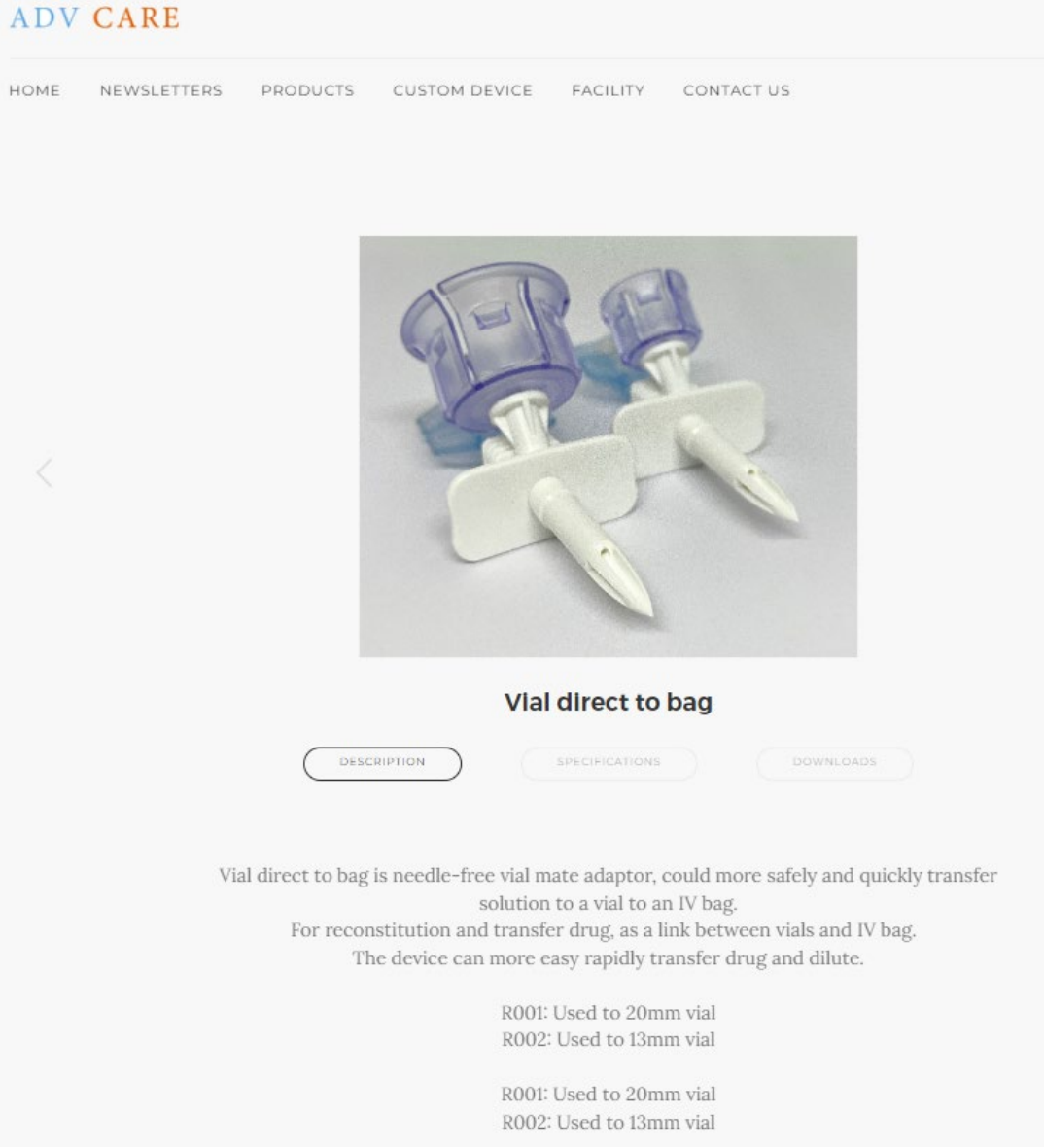
By Michael Merchant



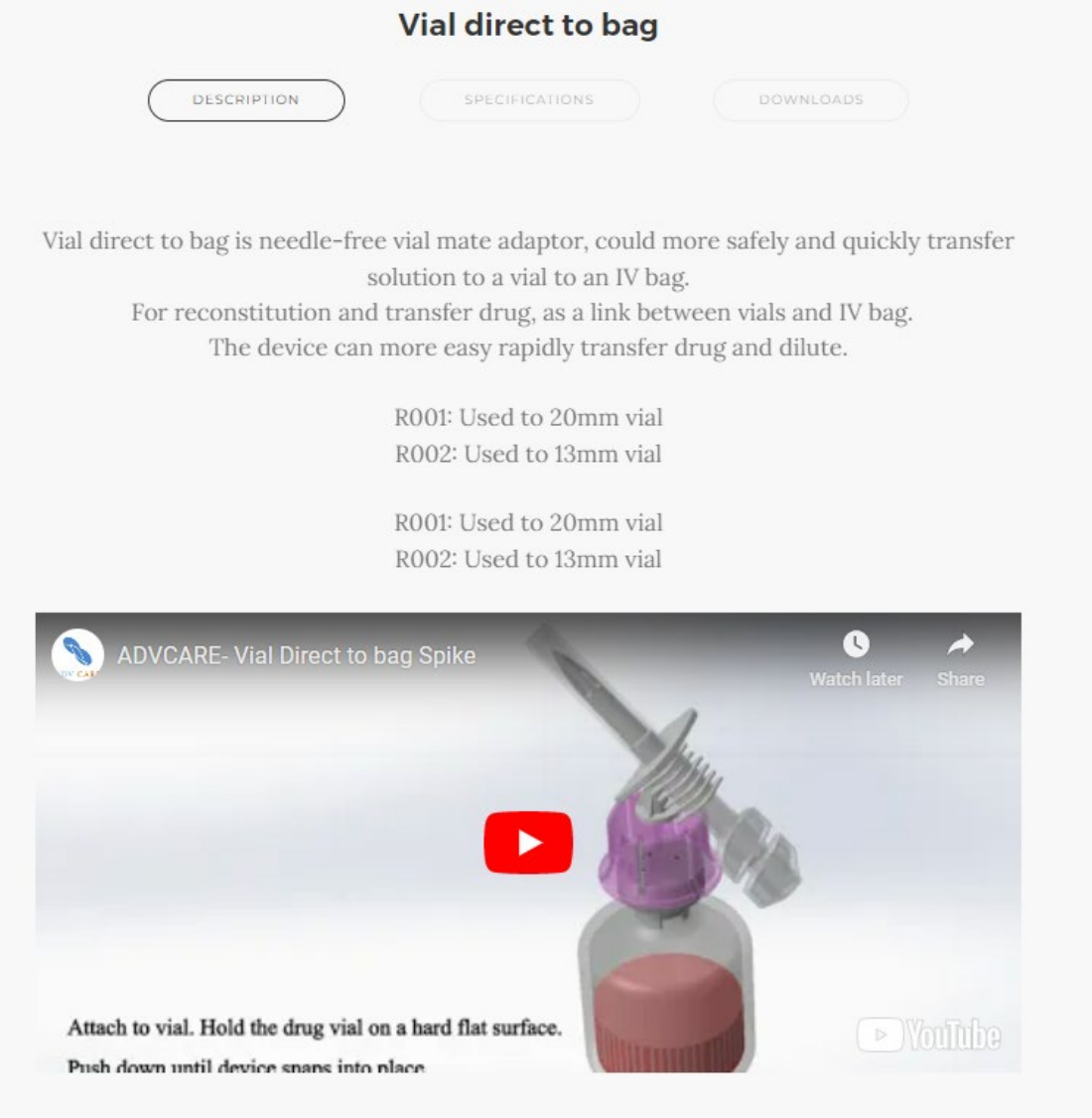
Summit Recon Vial Direct To Bag Spike

Id. at 295.

26. On its website, Advcare markets and identifies the accused VDB 20mm admixture device with product specification number "R001" and the accused VDB 13mm admixture device with product specification number "R002." *See* https://advcare-med.com/products/2 (reproduced in part below).

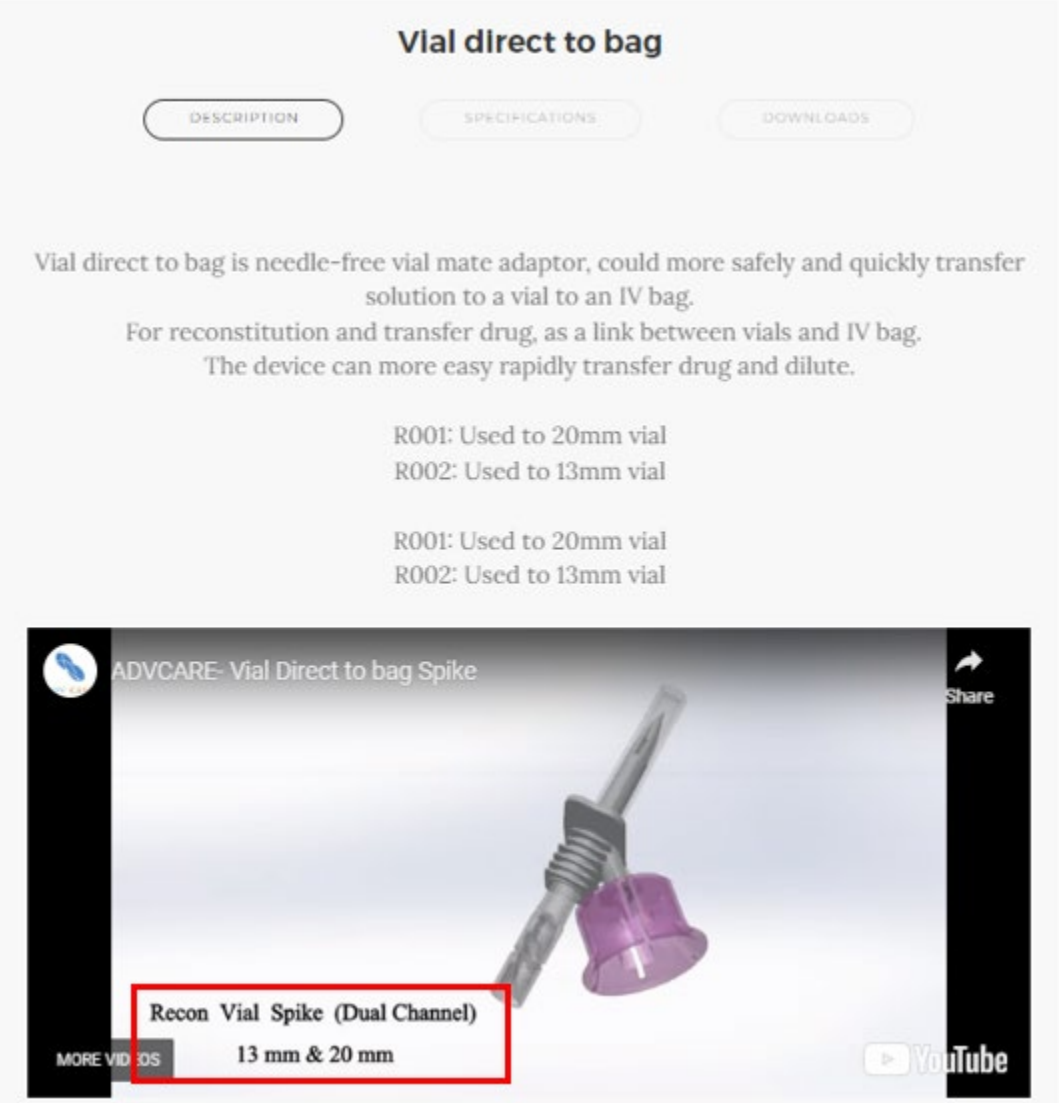


27. Advcare has an Instructions for Use ("IFU") video on its website and YouTube channel that through graphics provides step-by-step instructions in English how to use the Accused Products. *See* https://advcare-med.com/products/2; https://www.youtube.com/@advcaremed2577. A screenshot of that video on Advcare's website is shown below.



https://advcare-med.com/products/2.

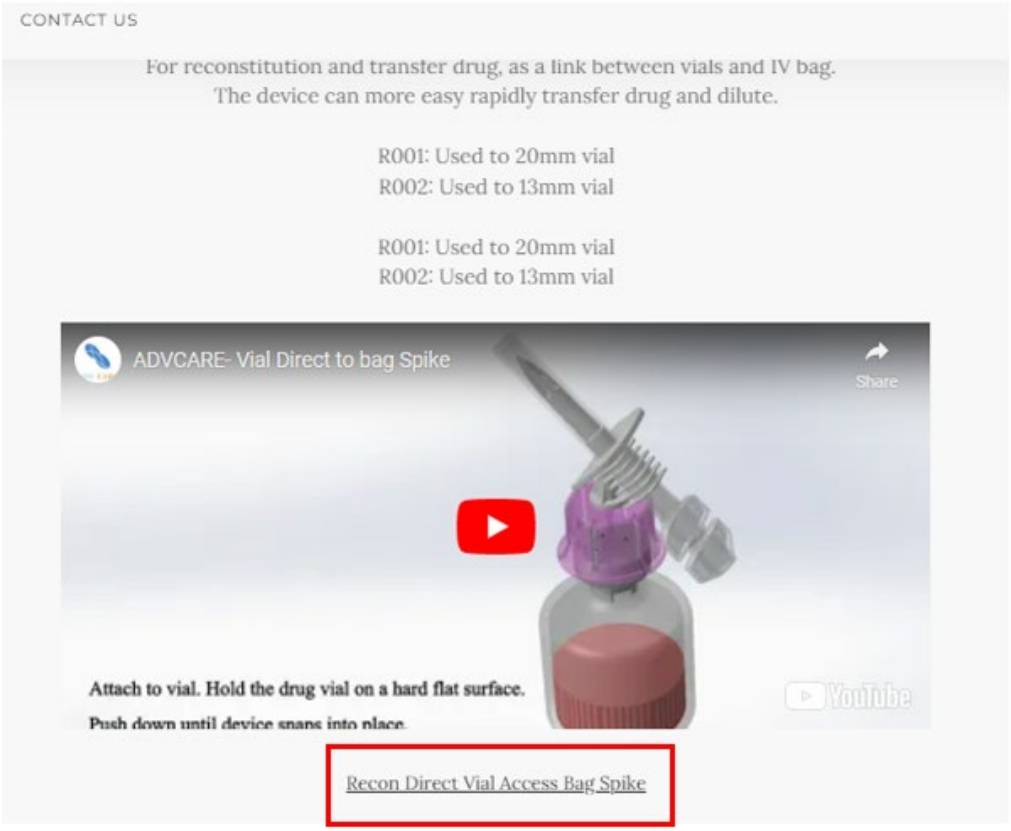
28. Upon information and belief, Advcare's IFU graphics video applies to and provides instructions for using both the accused VDB 20mm admixture device and the accused VDB 13mm admixture device. Another screenshot (annotations added) of that video from Advcare's website is shown below.



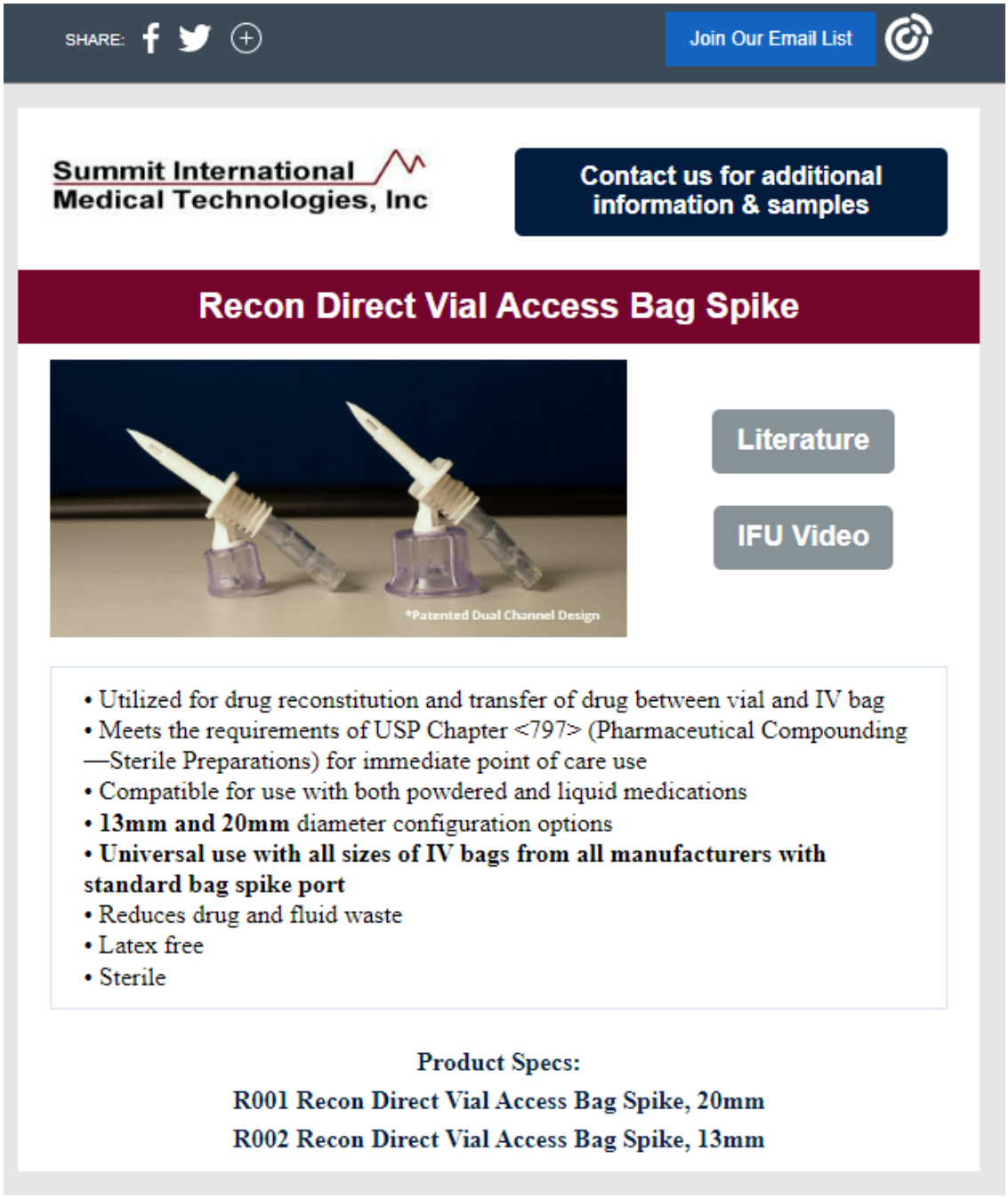
https://advcare-med.com/products/2.

29. Advcare has a Summit marketing brochure on its website that describes the Accused Products. https://advcare-med.com/uploads/product_file/url/4/Recon_Direct_Vial_Access__Bag_Spike_lit_Oct_2020.pdf. A copy of that Summit marketing brochure, as downloaded from Advcare's website, is attached as Exhibit 43.

30. As shown in the graphic below (annotations added), Advcare's website also includes a hyperlink.

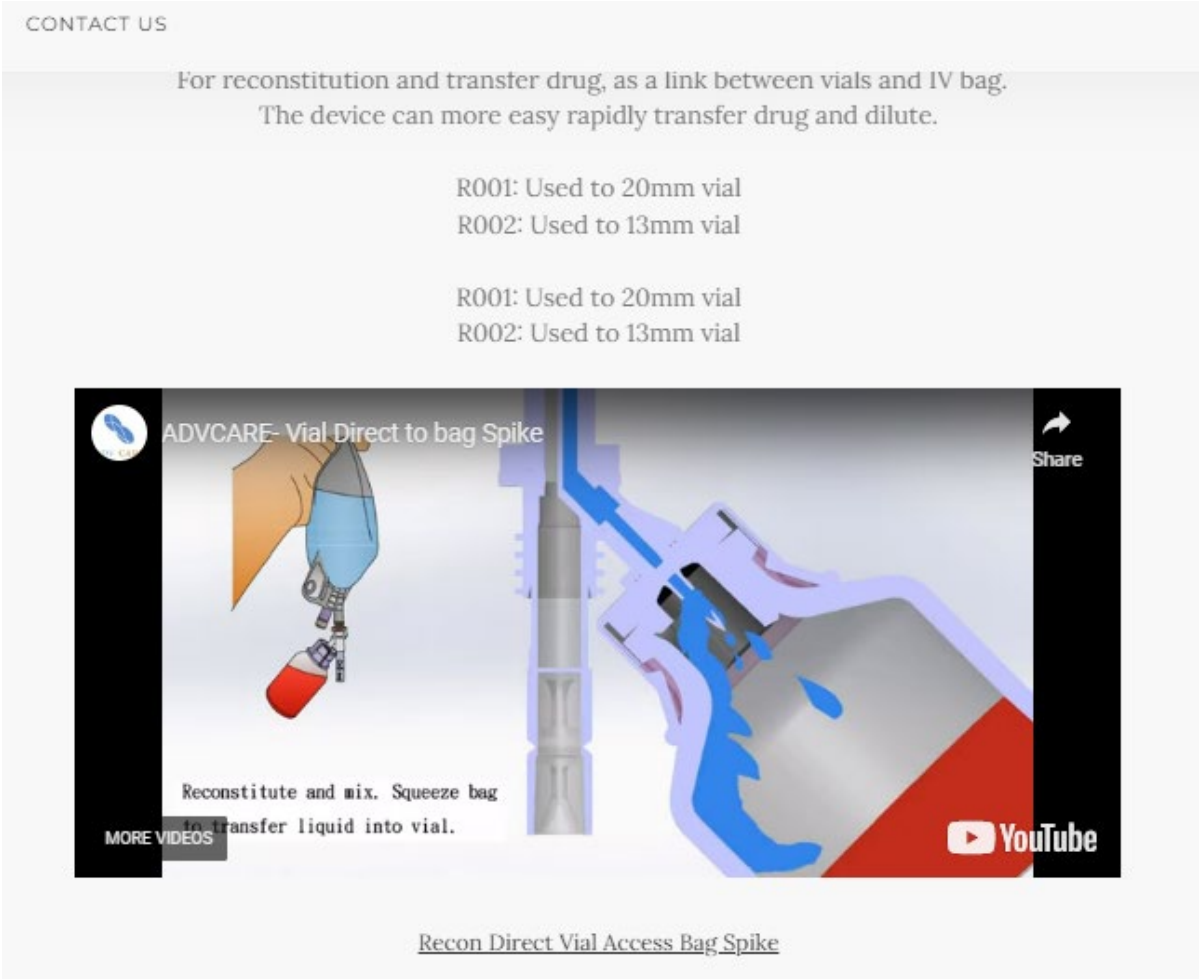


31. That hyperlink connects to a Summit website for the Accused Products. http://myemail.constantcontact.com/Universal-13mm---20mm-Vial-Access-Bag-Spike.html?soid=1130820804001&aid=aVHk4UJsbfE (reproduced below).

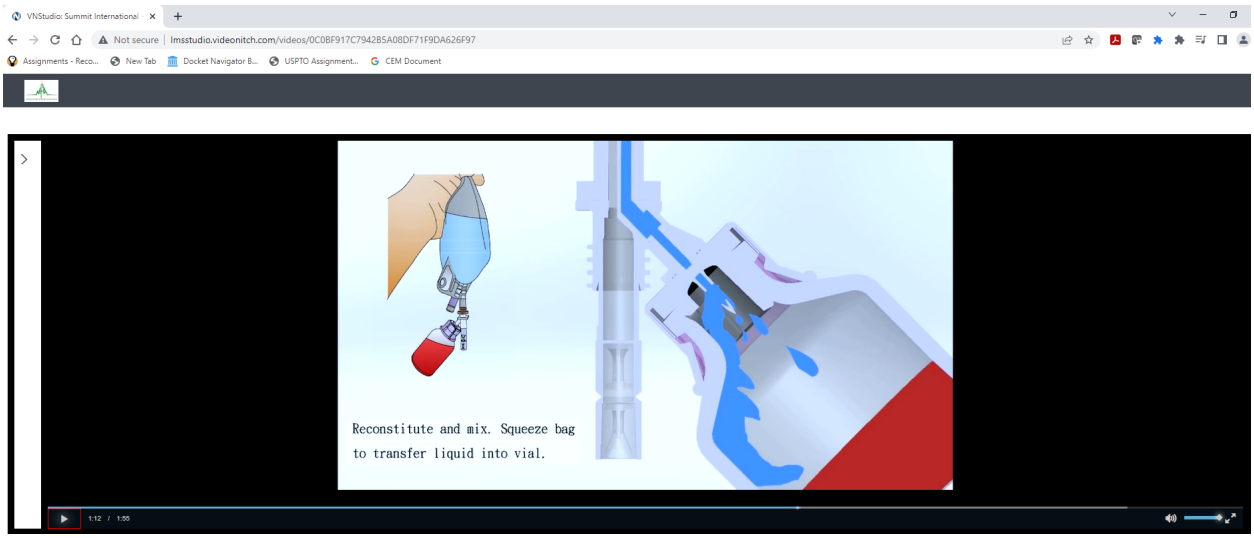


32. The Summit website includes hyperlinks for "additional information & samples" about the Accused Products (https://summitmedtech.com/contact/), literature about the Accused Products (https://files.constantcontact.com/1ad1c2a4701/acbcdfb2-0e6f-46d4-a449-c175212567c3.pdf), and an IFU video for the Accused Products (http://lmsstudio.videonitch.com/videos/0C0BF917C7942B5A08DF71F9DA626F97).

33. In the IFU video, a person demonstrates how to use an Accused Product. http://lmsstudio.videonitch.com/videos/0C0BF917C7942B5A08DF71F9DA626F97. The IFU video also includes graphics that are in Advcare's IFU graphics video on its webpage and YouTube channel. One of those graphics is shown below.

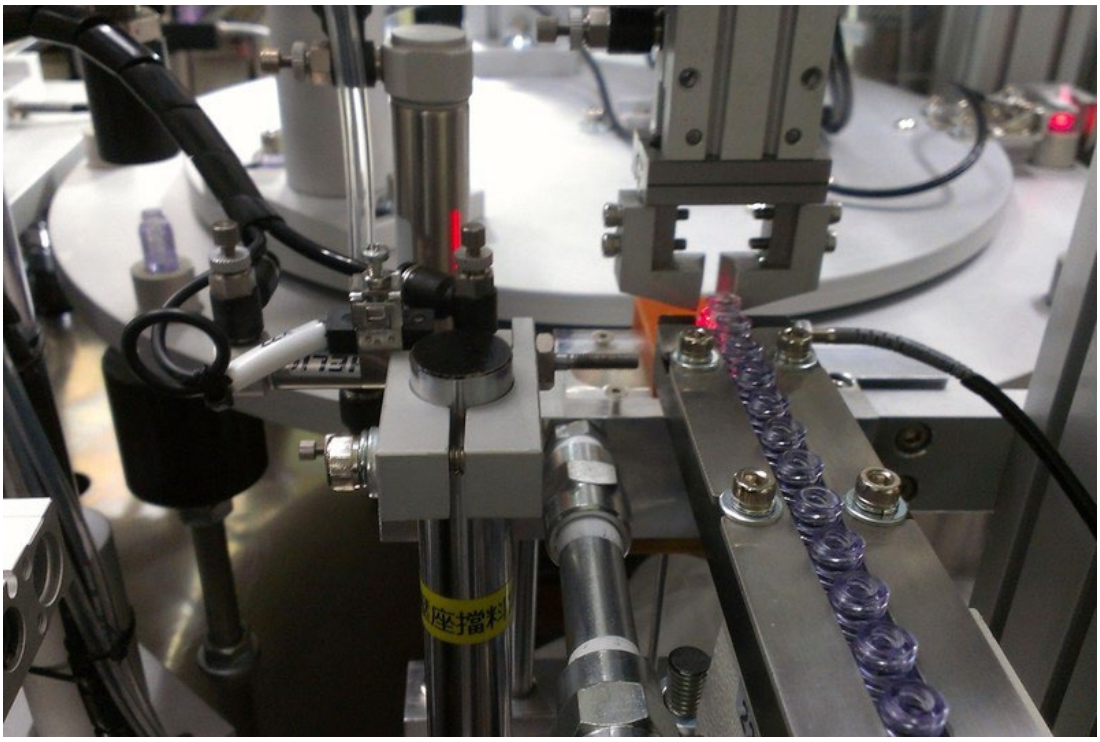


https://advcare-med.com/products/2 (at 0:23 / 1:04)



http://lmsstudio.videonitch.com/videos/0C0BF917C7942B5A08DF71F9DA626F97 (at 1:12 / 1:55)

34. Advcare's website indicates it has manufacturing facilities in Taiwan and China. *See* https://advcare-med.com/facility. Several photos of its manufacturing facilities, including the one below, are shown on its website.



35. The FDA regulates the Accused Products.

36. Specifically, under Section 510(k) of the Food, Drug, and Cosmetic Act, certain device manufacturers must notify the FDA of their intent to introduce into commercial distribution and market a medical device in the United States at least 90 days in advance. *See, e.g.*, https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances. This is known as Premarket Notification. *Id.* This allows the FDA to determine whether the device is equivalent to another device that has already been classified, i.e., the predicate device. *Id.*

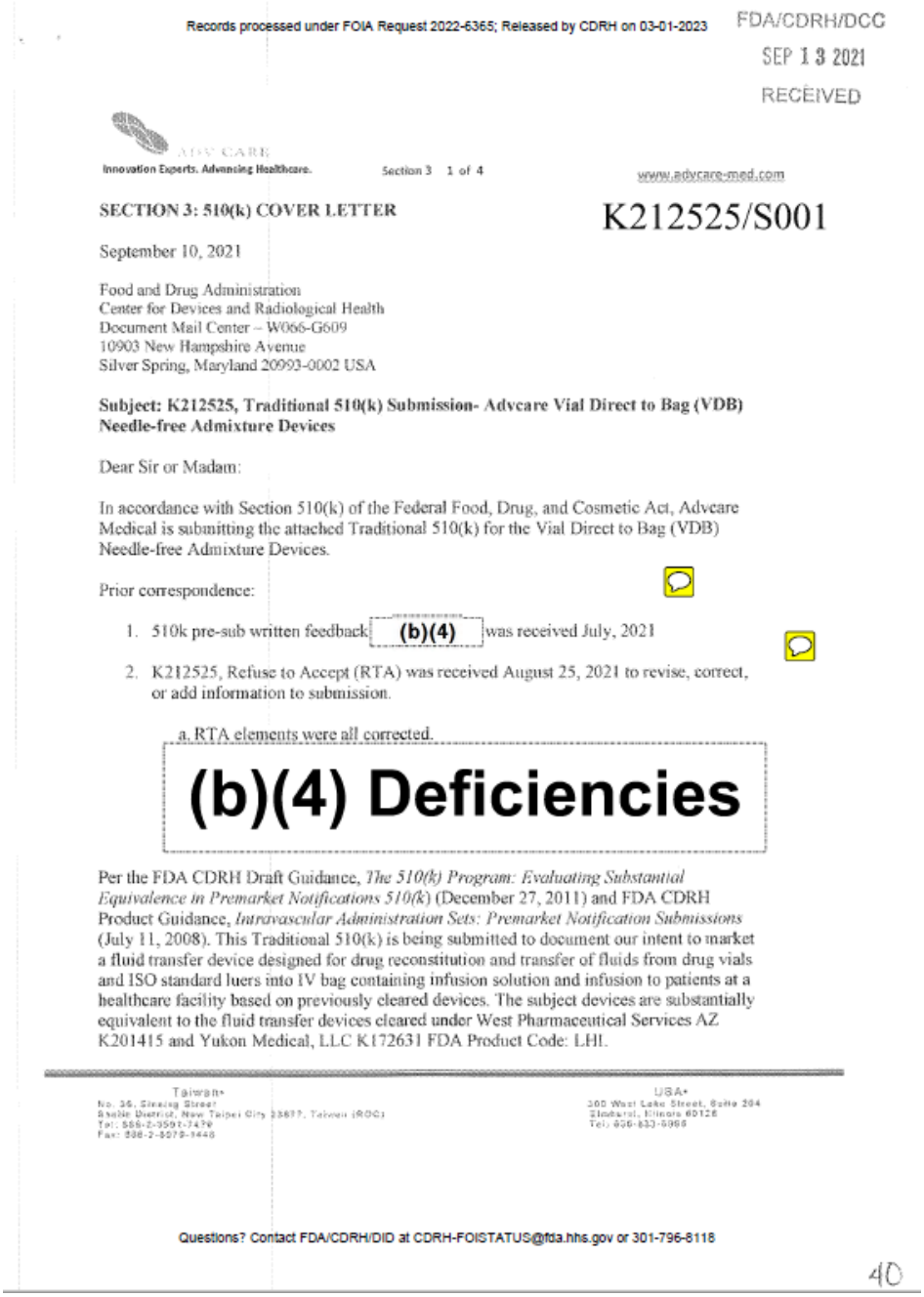
37. Advcare applied for 510(k) clearance from the FDA on the Accused Products (i.e., the VDB 13mm admixture device and the VDB 20mm admixture device). Ex. 15 at 1. On information and belief, Advcare filed its application on August 5, 2021. *See id.* It received 510(k) clearance on August 19, 2022. *Id.* On information and belief, Advcare sought 510(k) clearance because it intends to and does have the Accused Products manufactured for import into the United States, imported into the United States, sold for importation into the United States, and/or sold within the United States after importation.

38. Advcare relied on West's Vial2Bag Advanced® 20mm admixture device as the predicate device for its 510(k) clearance for the Accused Products. Ex. 15 at 4–8. To do so, Advcare represented to the FDA that the Accused Products have the same technical characteristics as West's Vial2Bag Advanced® 20mm admixture device and any differences in technical characteristics did not raise any new issues of safety or efficacy. *Id.*

39. West obtained a redacted copy of Advcare's application for 510(k) clearance for the Accused Products from the FDA via a Freedom of Information Act (FOIA) request. Ex. 44.[6]

[6] The pages in this exhibit are not in chronological order because this is how the FDA sent the document to West.

Advcare sent several documents to the FDA during its application process. *See, e.g.*, *id.* at 131–134. Advcare's letterhead includes two addresses: No. 36, Sinsing St., Shulin District, New Taipei City, Taiwan 23877 and 300 West Lake Street, Suite 204 Elmhurst, Illinois. *Id.* at 131 (reproduced below). On information and belief, the first address is Advcare's address and the second address is an address for DHM US.



Records processed under FOIA Request 2022-6365; Released by CDRH on 03-01-2023

FDA/CDRH/DCC
SEP 13 2021
RECEIVED

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Section 3 1 of 4

www.advcare-med.com

SECTION 3: 510(k) COVER LETTER

K212525/S001

September 10, 2021

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002 USA

Subject: K212525, Traditional 510(k) Submission- Advcare Vial Direct to Bag (VDB) Needle-free Admixture Devices

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, Advcare Medical is submitting the attached Traditional 510(k) for the Vial Direct to Bag (VDB) Needle-free Admixture Devices.

Prior correspondence:

1. 510k pre-sub written feedback (b)(4) was received July, 2021
2. K212525, Refuse to Accept (RTA) was received August 25, 2021 to revise, correct, or add information to submission.

a. RTA elements were all corrected.

(b)(4) Deficiencies

Per the FDA CDRH Draft Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)* (December 27, 2011) and FDA CDRH Product Guidance, *Intravascular Administration Sets: Premarket Notification Submissions* (July 11, 2008). This Traditional 510(k) is being submitted to document our intent to market a fluid transfer device designed for drug reconstitution and transfer of fluids from drug vials and ISO standard luers into IV bag containing infusion solution and infusion to patients at a healthcare facility based on previously cleared devices. The subject devices are substantially equivalent to the fluid transfer devices cleared under West Pharmaceutical Services AZ K201415 and Yukon Medical, LLC K172631 FDA Product Code: LHI.

Taiwan•
No. 36, Sinsing Street
Shulin District, New Taipei City 23877, Taiwan (ROC)
Tel: 886-2-3591-7479
Fax: 886-2-8073-1448

USA•
300 West Lake Street, Suite 204
Elmhurst, Illinois 60126
Tel: 630-833-5966

Questions? Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

40

B. Dragon Heart Medical, Inc. and Dragon Heart Medical Devices Co., Ltd.

40. On information and belief, Proposed Respondent Dragon Heart Medical, Inc. ("DHM US") is an Illinois corporation with a place of business at 901 South Rohlwing Road Unit H, Addison, IL 60101. This address appears on DHM's website.[7] http://www.dragonheartmedical.com/.

41. On information and belief, Proposed Respondent Dragon Heart Medical Devices Co., Ltd. ("DHM China") is a Chinese corporation with a place of business at 28 Ruliang Road, Baihe Town, Kaiping City, Guangdong Province, China 529375.

42. DHM US and DHM China are collectively referred to herein as "DHM".

43. On its website, DHM China describes itself as "a leading medical device manufacturer in China specializing in product research, development and manufacturing." https://en.dragonheart-ltd.com/about.html. "Production is conducted in its ISO 9000, ISO 13485 certified, EU CE approved and US FDA registered facilities." *Id.*

44. On information and belief, DHM China targets potential customers based in the United States with its English-language version of its website: https://en.dragonheart-ltd.com/.

45. On its website, DHM China states "[i]n 2002, Dragon Heart Medical, Inc. USA was established in Chicago to better develop and service North American markets." https://en.dragonheart-ltd.com/about.html. On information and belief, DHM US is a subsidiary of DHM China.

[7] As discussed below in ¶51 (incorporated herein by reference), according to the FDA's publicly available records, DHM US is Advcare's US Agent for FDA purposes. The address Advcare provided to the FDA for DHM US is different than the address on DHM US's website. The address Advcare gave the FDA is "300 West Lake Street, Suite 204 Elmhurst, IL, US 60126." Ex. 21 at 1 (FDA's Establishment Registration & Device Listing records, last updated 10/23/2022, identifying DHM US as Advcare's US agent in 2022); Ex. 22 at 1 (FDA's Establishment Registration & Device Listing records, last updated 01/23/2023, identifying DHM US as Advcare's US agent in 2023).

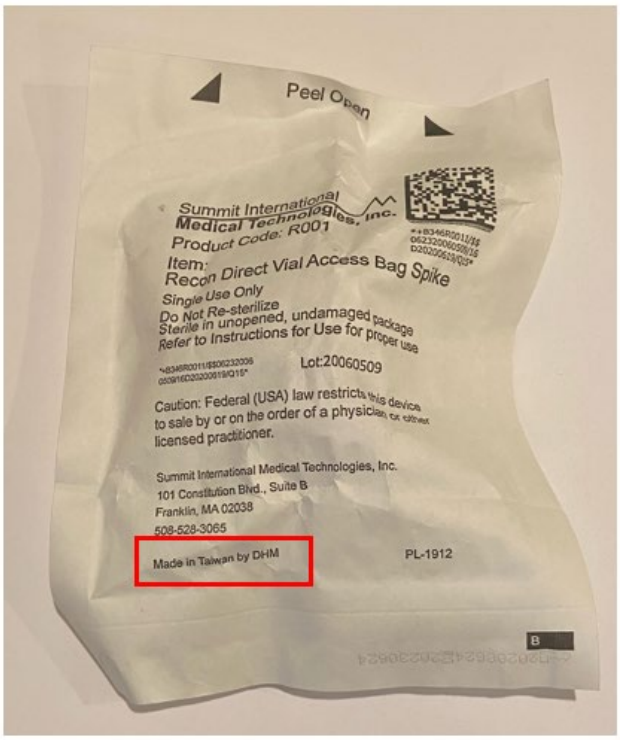
46. On its website, DHM US describes itself as "a leading manufacturer and distributor of original equipment manufacturer (OEM) medical products and quality disposable medical supplies with over 20 years of experience." *See* http://www.dragonheartmedical.com/.

47. On its website, DHM US states all of its manufacturing facilities are "ISO 9001 certified, CE approved, and FDA registered." *Id.* It further states it has "certified facilities in Asia." Its website also includes a link to its factory website. *Id.* The link for the factory website is www.dragonheart-ltd.com. *Id.*

48. On information and belief, DHM China is DHM US's factory.

49. On information and belief, DHM manufactures and sells for importation into the U.S. and/or imports into the U.S. medical devices, including the Accused Products.

50. As shown in the photos below, at least some of the Accused Products are "Made in Taiwan by DHM." Upon information and belief, "DHM" on the packaging stands for Dragon Heart Medical. The left photo (annotation added) is an accused VDB 20mm admixture device in its packaging. The right photo (annotation added) is an accused VDB 13mm admixture device in its packaging.



51. According to the FDA's publicly available records, DHM US is Advcare's US Agent for FDA purposes. Ex. 21 at 1 (FDA's Establishment Registration & Device Listing records, last updated 10/23/2022, identifying DHM US as Advcare's US agent in 2022); Ex. 22 at 1 (FDA's Establishment Registration & Device Listing records, last updated 01/23/2023, identifying DHM US as Advcare's US agent in 2023). The FDA only allows a foreign entity, like Advcare, to designate one U.S. agent. https://www.fda.gov/medical-devices/device-registration-and-listing/us-agents. Thus, upon information and belief, DHM US is Advcare's US Agent for FDA purposes with respect to the Accused Products.

52. On information and belief, DHM US's responsibilities as Advcare's US Agent include:

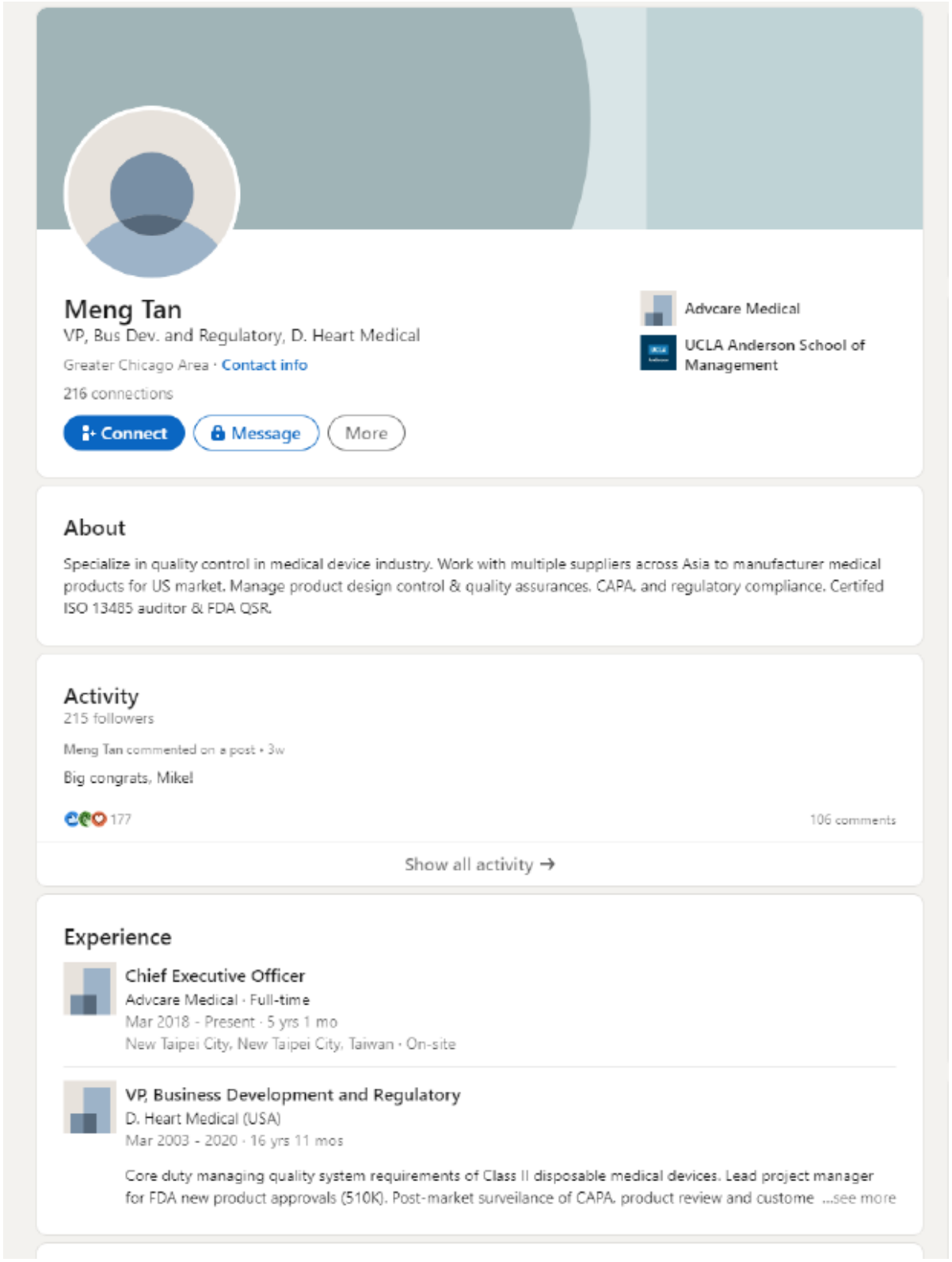
- assisting FDA in communications with Advcare,
- responding to questions concerning Advcare's devices, including the Accused Products, that are imported or offered for import into the United States,

- assisting FDA in scheduling inspections of Advcare and
- if FDA is unable to contact Advcare directly or expeditiously, FDA may provide information or documents to DHM US, and such an action shall be considered to be equivalent to providing the same information or documents to Advcare.

See https://www.fda.gov/medical-devices/device-registration-and-listing/us-agents.

53. On information and belief, the FDA addressed the 510(k) clearance for the Accused Products to Advcare and not DHM US (*see* Ex. 15 at 1) because Advcare is the entity that applied for the clearance. Meng Tan is identified as the "Application Correspondent" for the 510(k) clearance. *Id.* at 4.

54. On information and belief, Meng Tan, the CEO of Advcare (*see supra* at ¶21, incorporated herein by reference) and the "Application Correspondent" for the 510(k) clearance (*see supra* at ¶53, incorporated herein by reference), is also the "VP, Bus Dev. and Regulatory, D. Heart Medical." *See* https://www.linkedin.com/in/meng-tan-3bb6a84. Mr. Tan represents that he works and/or has worked for both Advcare and D. Heart Medical on his LinkedIn page. *Id.* (reproduced in part below). Mr. Tan's tenure at these two companies has overlapped. *Id.* On information and belief, "D. Heart Medical" on Mr. Tan's Linked In page stands for Dragon Heart Medical.



Meng Tan
VP, Bus Dev. and Regulatory, D. Heart Medical
Greater Chicago Area · Contact info
216 connections
Connect Message More

Advcare Medical
UCLA Anderson School of Management

About

Specialize in quality control in medical device industry. Work with multiple suppliers across Asia to manufacturer medical products for US market. Manage product design control & quality assurances. CAPA, and regulatory compliance. Certifed ISO 13485 auditor & FDA QSR.

Activity
215 followers

Meng Tan commented on a post • 3w

Big congrats, Mike!

177 106 comments

Show all activity →

Experience

Chief Executive Officer
Advcare Medical · Full-time
Mar 2018 - Present · 5 yrs 1 mo
New Taipei City, New Taipei City, Taiwan · On-site

VP, Business Development and Regulatory
D. Heart Medical (USA)
Mar 2003 - 2020 · 16 yrs 11 mos

Core duty managing quality system requirements of Class II disposable medical devices. Lead project manager for FDA new product approvals (510K). Post-market surveilance of CAPA, product review and custome ...see more

C. Summit International Technologies, Inc.

55. On information and belief, Proposed Respondent Summit International Technologies, Inc. ("Summit") is a Massachusetts corporation with its principal place of business at 101 Constitution Blvd., Franklin, MA 02038. On information and belief, Michael Merchant is the President, Owner, and Regional Sales Manager of Summit. https://summitmedtech.com/about-us/.

56. On information and belief, Summit imports, markets, and/or sells after importation medical devices, including the Accused Products, in the U.S.

57. As discussed above in ¶24 (incorporated herein by reference), on information and belief, Advcare and Summit designed the Accused Products together. Ex. 42 at 1.

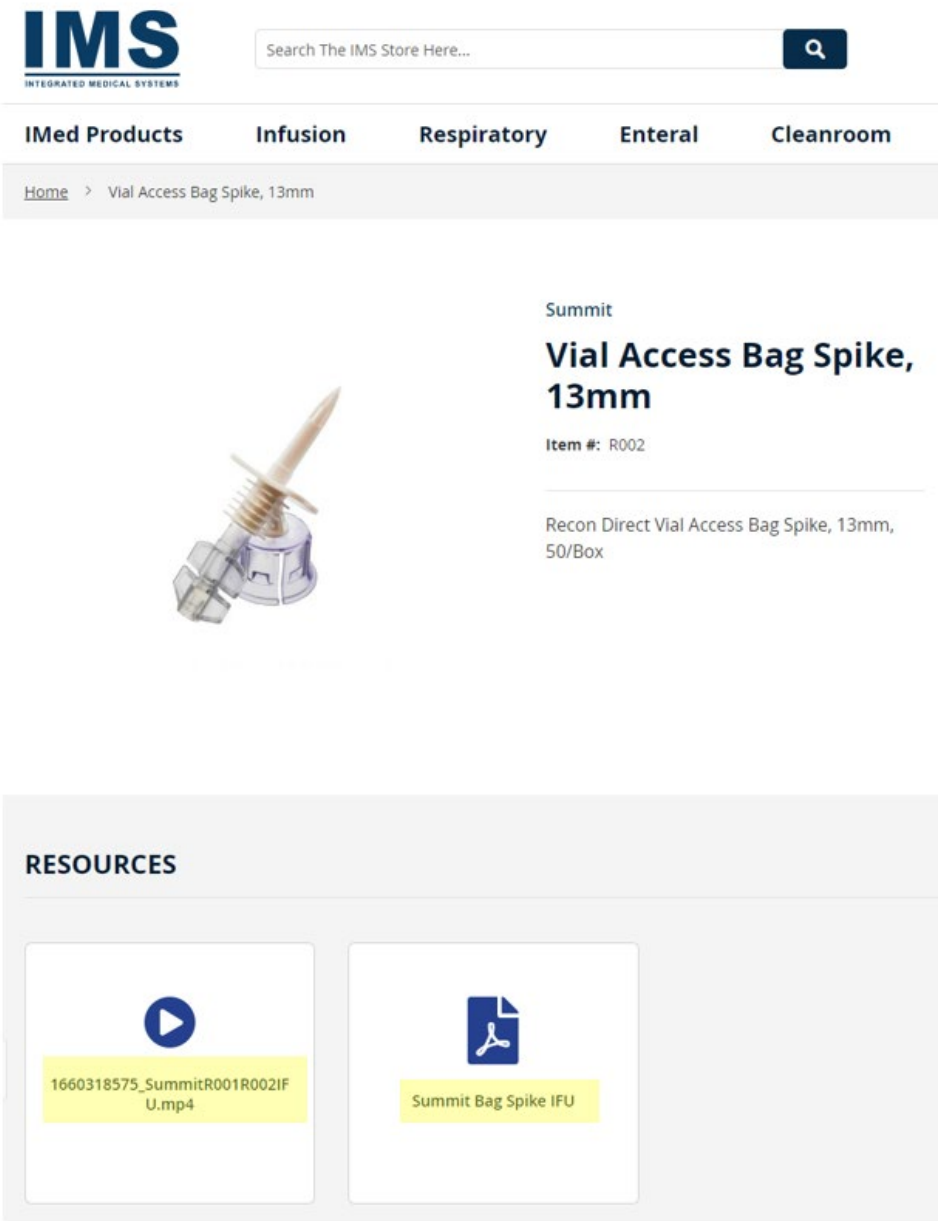
58. As discussed above in ¶25 (incorporated herein by reference), on information and belief, Summit and Advcare have worked together on other VDB admixture devices. For example, in an Advcare article disclosing, on information and belief, a prior version of the Accused Product, Summit was identified as Advcare's "Exclusive U.S. Distributor" and Advcare was identified as the designer of the product. Appx A, Part 20 at 295.

59. In correspondence with West, Summit has on more than one occasion referred to its VDB admixture devices and that product line as the "Summit/ADVCARE products" and "Summit/ADVCARE product line." Ex. 18 (Letter, dated April 17, 2019, from Summit's attorney to Ms. Ryberg, former associate general counsel for West US) at 1; Ex. 19 (Letter, dated July 17, 2019, from Summit's attorney to Ms. Ryberg, former associate general counsel for West US) at 1.

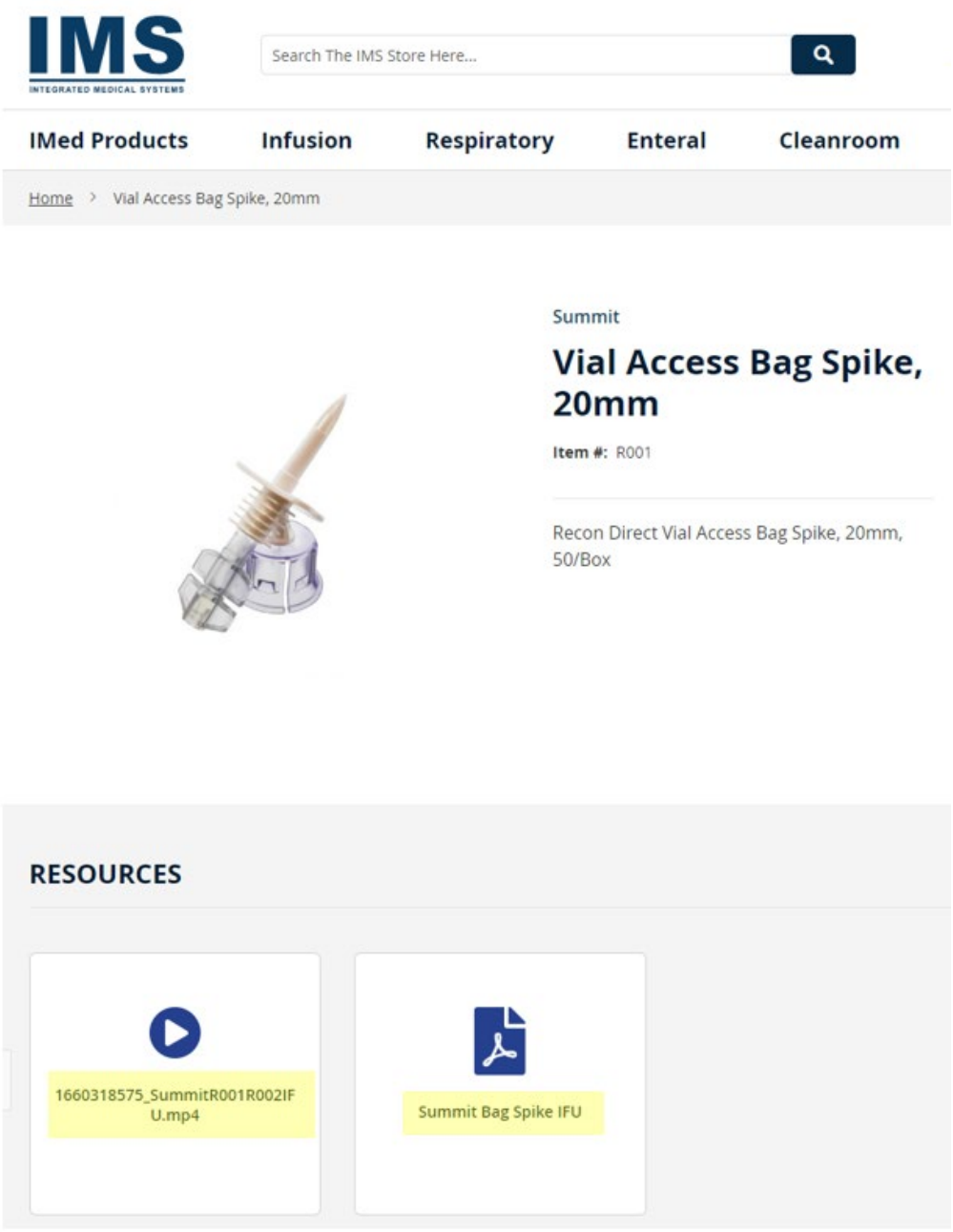
60. On information and belief, Integrated Medical Systems, Inc. ("IMS") is Summit's distributor of the Accused Products in the U.S. (On information and belief, IMS is an Illinois

corporation headquartered in Bolingbrook, Illinois.)

61. Summit provides an IFU graphics video and presentation that offers step-by-step instructions how to use the Accused Products. A copy of the IFU graphics presentation is attached as Exhibit 23. As shown in the screenshots below (highlighting added), Summit's IFU graphics video and graphics presentation are also available on the IMS's website.



https://www.integratedmedsys.com/r002 (accused VDB 13mm admixture device).



https://www.integratedmedsys.com/r001 (accused VDB 20mm admixture device).

62. Upon information and belief, Summit's IFU graphics video and presentation available on IMS's website for the accused VDB 20 admixture device are the same as Summit's IFU graphics video and presentation available on IMS's website for the accused VDB 13mm device. In other words, upon information and belief, Summit's IFU graphics video and

presentation apply to and provide instructions for using both the accused 20mm VDB admixture device and the accused VDB 13mm admixture device.

63. On information and belief, Summit's IFU graphics video is identical in all material respects to Advcare's IFU graphics video for the Accused Products. *Compare* https://www.integratedmedsys.com/r001 (Summit IFU graphics video), *with* https://advcare-med.com/products/2 (Advcare IFU graphics video).

64. At least three images in Summit's IFU graphics video and graphics presentation are also in a draft IFU Advcare submitted to the FDA when it filed its application for 510(k) clearance for the Accused Products. *Compare, e.g.*, Ex. 23 (Summit IFU graphics presentation) at 5, 7, and 8, *with* Ex. 44 (Advcare's redacted application for 510(k) clearance) at 628.

65. Summit has a marketing brochure on its website that describes the Accused Products. https://summitmedtech.com/clinical-resources/summit-medical-clinical-resources/vial-direct-to-bag-spike-literature/. A copy of that marketing brochure, as downloaded from Summit's website, is attached as Exhibit 20. The Summit marketing brochure that may be downloaded from Summit's website is virtually the same as the Summit marketing brochure that may be downloaded from Advcare's website.

IV. THE ACCUSED PRODUCTS

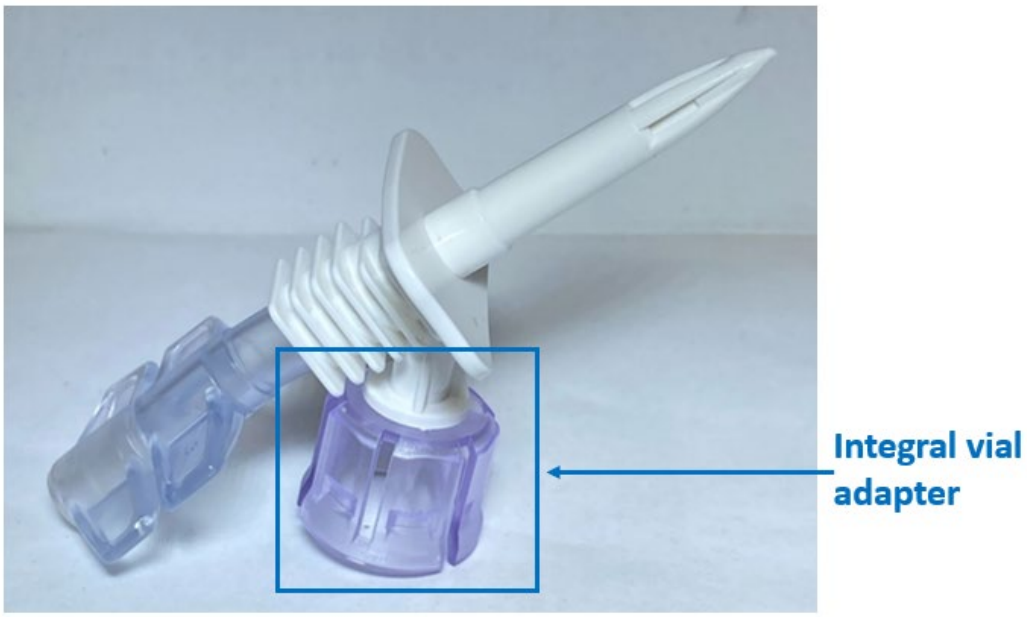
66. Pursuant to 19 C.F.R. §210.12(a)(12), the category of the Accused Products may be plainly described as liquid transfer devices with an integral vial adapter. The Accused Products may be used for drug reconstitution and transfer of liquids between a vial, containing medication, and an infusion liquid container (e.g., IV bag containing an infusion liquid) at the point of care prior to administering the drug to a patient via an infusion set (e.g., IV set). More specifically, in use, the integral vial adapter is mounted on a drug vial. Because the vial adapter

is integral to the Accused Products, they may only be used with a vial. Fluid (e.g., infusion liquid) may be transferred through the Accused Product between the infusion liquid container (e.g., IV bag) and the vial to reconstitute/dilute the medication in the vial and form a medicated infusion liquid. The infusion set (e.g., IV set) may be attached to an administration port of the Accused Product to administer the medicated infusion liquid to the patient.

67. The Accused Products come in two sizes: 13mm and 20mm. These sizes correspond to the diameters of the vial adapters of the Accused Products (**blue** arrow in below photos).

68. A photograph of the accused VDB 20mm admixture device is provided as Exhibit 16 and shown below (annotations added).

69. A photograph of the accused VDB 13mm admixture device is provided as Exhibit 17 and shown below.



70. The only distinction between the two accused devices is the size and design of their respective vial adapters. The Accused Product shown in ¶68 has a vial adapter with a 20mm diameter while the other Accused Product shown in ¶69 has a vial adapter with a 13mm diameter. These diameters correspond to the size of the medicinal vial used with each Accused Product.

71. On information and belief, healthcare professionals (e.g., hospitals and pharmacies) typically purchase the Accused Products.

72. As explained below in Sections VI.A.i, VI.A.iii, and VI.B (incorporated herein by reference), the accused VDB 20mm admixture device infringes claim 1 of the ’295 Patent, D’837 Patent, and the Asserted Mark.

73. As explained below in Sections VI.A.i, VI.A.ii, VI.A.iv, and VI.B (incorporated herein by reference), the accused VDB 13mm admixture device infringes claim 1 of the ’295 Patent, D’124 Patent, D’732 Patent, and the Asserted Mark.

74. The foregoing description of the Accused Products is intended purely for

illustration and is not intended to limit the scope of the investigation. Any remedy should extend, regardless of model number and regardless of source, to all present and future infringing products.

V. THE INTELLECTUAL PROPERTY AT ISSUE

A. U.S. Patent No. 10,688,295

75. On June 23, 2020, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '295 Patent, entitled "Liquid Transfer Devices for Use with Infusion Liquid Containers." Ex. 1. The named inventors of the '295 Patent are Nimrod Lev, Niv Ben Shalom, and Hugh Zachary Marks. *Id.* at (72). The '295 Patent issued from the '347 Application, filed February 5, 2016. *Id.* at (21), (86). The '295 Patent is valid, enforceable, and currently in full force and effect. The '295 Patent expires on January 17, 2036.

76. Pursuant to Commission Rule 210.12(c)(1), this Complaint is accompanied by one certified copy of the prosecution history of the '295 Patent. Appendix A. Pursuant to Commission Rule 210.12(c)(2), this Complaint is accompanied by four copies of each technical reference identified in the prosecution history of the '295 Patent. Appendix F.

i. Assignment and Ownership of the '295 Patent

77. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the '295 Patent. West Israel is an indirect subsidiary of West US. West US has an implied license to use the '295 Patent per this corporate relationship.

78. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the assignment records for the '295 Patent are attached as Exhibits 6–7.

ii. Foreign Counterparts to the ’295 Patent

79. Pursuant to Commission Rule 210.12(a)(9)(v), West identifies below the known foreign counterparts to the ’295 Patent:

Country	Application No.	Filing Date	Status
PCT	PCT/IL2014/050680	July 25, 2014	Expired February 7, 2016
Israel	227849	August 7, 2013	Application abandoned on May 1, 2016
Israel	243896	July 25, 2014	Granted, expires July 25, 2034
Brazil	1120166001905-9	July 25, 2014	Granted, expires July 25, 2034
China	201490000949.5	July 25, 2014	Granted, expires July 25, 2024
Denmark	2016 00035	July 25, 2014	Granted, expires July 25, 2024
Germany	212014000169	July 25, 2014	Granted, expires July 25, 2024
France	3009495	August 7, 2014	Granted, expires August 7, 2024
Great Britain	1602766.6	July 25, 2014 (lodged February 17, 2016)	Granted, expires July 25, 2034
Great Britain	2002233.1	July 25, 2014 (lodged February 18, 2020)	Granted, expires July 25, 2034
India	201617006753	July 25, 2014	Pending
Italy	202016000101296	July 25, 2014	Granted, expires July 25, 2024
Japan	2016-600070	July 25, 2014	Granted, expires July 25, 2024
Korea	20-2016-7000008	July 25, 2014	Granted, expires July 25, 2024

80. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the afore-mentioned patent applications.

iii. Non-Technical Description of the ’295 Patent

81. As explained above in ¶5 (incorporated herein by reference), the prior admixture or liquid transfer device used to introduce pharmaceuticals for IV administration at the point of care had an IV spike, an administration port, and a valve that could be screw threaded to a syringe, vial, or other medical equipment containing medication. *See* Ex. 1 (’295 Patent) at Fig. 2A (reproduced below). The prior art device’s valve had several drawbacks. The valve design

was complex because the valve was designed to attach to and detach from several types of medical equipment. Complexity increases the cost to manufacture the device and can result in unreliability, such as inadvertent leakage of medicament at the valve, contamination at the connection site between the valve and medical equipment, or a double dosage of medicament. This latter scenario could occur because the system allows for the attaching and detaching of medical equipment containing medicament. This increases the chance of human error. For example, a healthcare professional may introduce a medicant and remove the medical equipment that administered the medicant. After which, a subsequent healthcare professional could re-dose the patient with the same medicament. These types of risks are virtually unacceptable in the medical field.

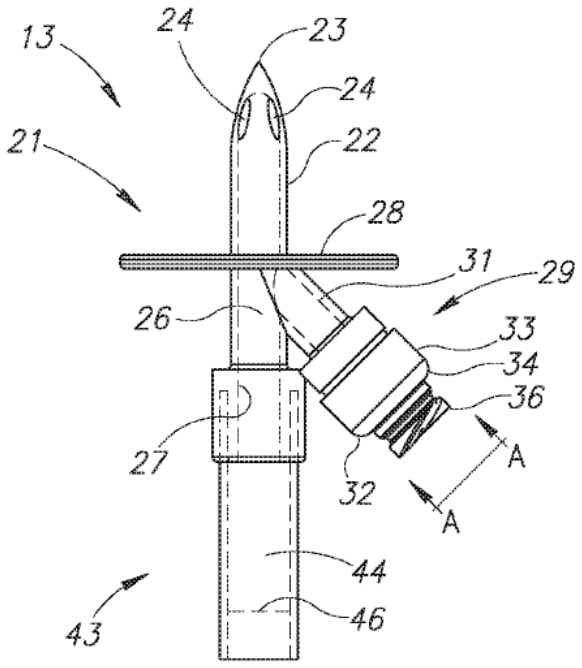


FIG.2A
(PRIOR ART)

Id. at Fig. 2A.

82. Pursuant to Commission Rule 210.12(a)(9)(vi), in non-technical terms,[8] the '295 Patent is directed to a liquid transfer device 101 (**grey**) that allows for the reconstitution and transfer of liquids between a drug vial, containing medication, and an IV bag, containing an infusion solution, and administration of the reconstituted drug (i.e., medicated infusion solution) to a patient through the administration port of the device. The device 101 (**grey**) includes an integral trifurcated connector body 130 (**purple**), a single IV spike 22 (**red**), an integral vial adapter 102 (**blue**) with a puncturing cannula 106 (**green**), and an administration port 43 (**orange**).

[8] The non-technical description of the '295 Patent is presented for general background purposes only. Such statements are not intended to be used, nor should be used, for purposes of patent claim interpretation.

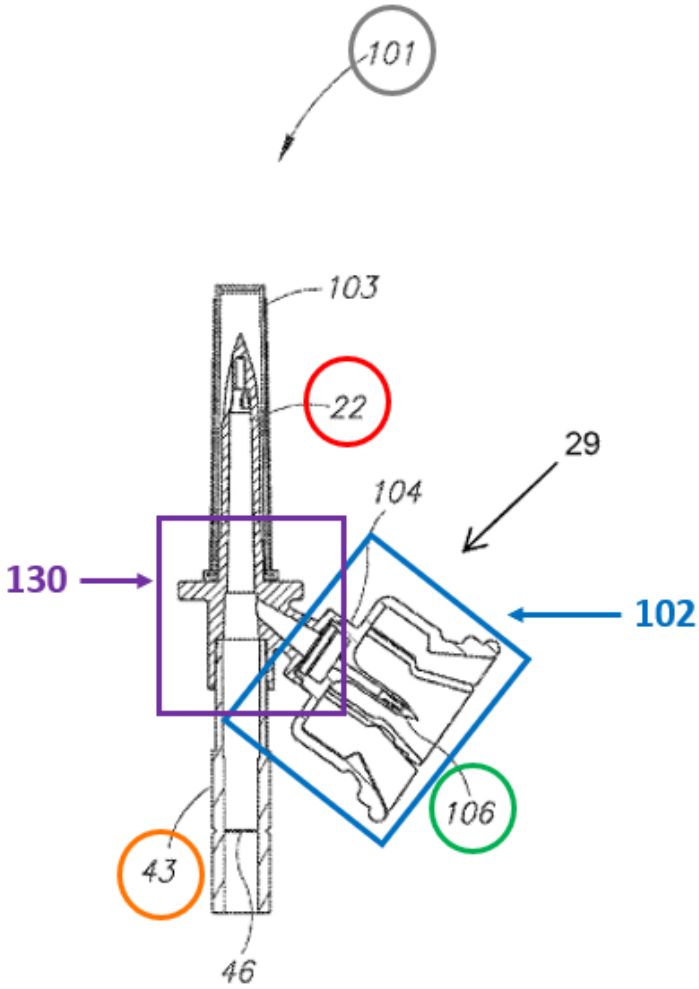
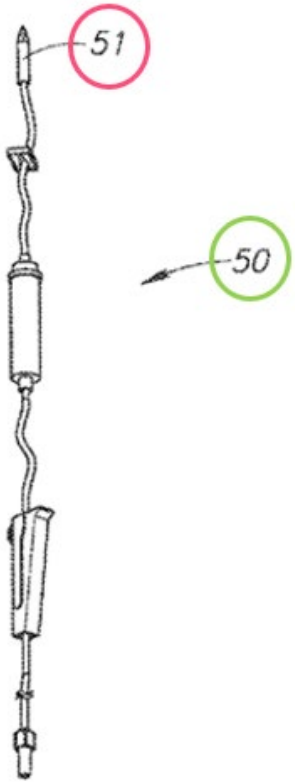


FIG.5B

Id. at Fig. 5B.

83. In use, the single IV spike 22 (**red**) is inserted into an IV port of an IV bag, containing an infusion solution. The vial adapter 102 (**blue**) is mounted on a drug vial, preferably in a way that precludes its subsequent removal. The mounting causes the vial adapter's puncturing cannula 106 (**green**) to puncture the vial stopper (lid) of the vial. This allows fluid to be transferred from the IV bag to the drug vial to reconstitute/dilute the

medication and form a medicated infusion liquid. The vial's contents may then be transferred back to the IV bag through the device's single IV spike 22 (**red**) by, for example, inverting the IV bag. Thereafter, an IV spike 51 (**pink**) of an infusion (administration) set 50 (**light green**) may be inserted into the device's administration port 43 (**orange**). *Id.* at Fig. 4 (reproduced in part below).



84. The other end of the infusion set 50 (**light green**) connects to a port in the patient's arm, for example. This allows the medicated infusion liquid to be given to the patient. Specifically, the medicated infusion liquid flows from the IV bag through the device's single IV spike 22 (**red**) and the infusion set 50 (**light green**), including its IV spike 51 (**pink**), to the patient.

85. As explained above in ¶6 (incorporated herein by reference), the '295 patented technology overcame the drawbacks of the prior art liquid transfer device that had a valve for use

with multiple types of different medical equipment and allowed multiple additions of medicant. Because the innovative liquid transfer device is a trifurcated connector body with an integral vial adapter, it is a single-use and single-purpose device and is less complex and less costly than the prior art device. Ex. 1 ('295 Patent) at 2:25-33. It can only be used with a vial and only for administration of one medicine. Further, once the vial is attached to the claimed device, it is not intended to be removed. *Id.* at 2:37-38. Because the device does not allow for the attaching and detaching of medical equipment containing medicaments, it lowers the chance of human error resulting in incorrect dosages. For example, after a healthcare professional introduced a medicant, a subsequent healthcare professional should not re-dose the patient with the same medicant because he/she would see the vial already attached to the claimed device and know the medicant had been administered. *Id.* at 2:37-40. Thus, the design of the claimed device lowers the risk of a patient receiving an incorrect dosage of medication. Further, because the vial adapter is integral with the trifurcated connector body, the claimed device has a more reliable design than the design having a valve and prevents inadvertent leakage or contamination of medication.

B. U.S. Design Patent No. D767,124

86. On September 20, 2016, the USPTO duly and legally issued U.S. Design Patent No. D767,124 ("the D'124 Patent"), entitled "Liquid Transfer Device with Integral Vial Adapter." Ex. 2. The named inventors of the D'124 Patent are Nimrod Lev and Niv Ben Shalom. *Id.* at (72). The D'124 Patent issued from U.S. Design Patent Application No. 29/478,723, filed January 8, 2014. *Id.* at (21), (22). The D'124 Patent is valid, enforceable, and currently in full force and effect. The D'124 Patent expires on September 9, 2030.

87. The D'124 Patent claims an ornamental design for a liquid transfer device with

integral vial adapter, as shown and described in the figures of the patent. By way of example, Figure 1 of the D'124 Patent is produced below. The D'124 Patent is non-functional because the appearance of the claimed design is not dictated by the use or purpose of the article.

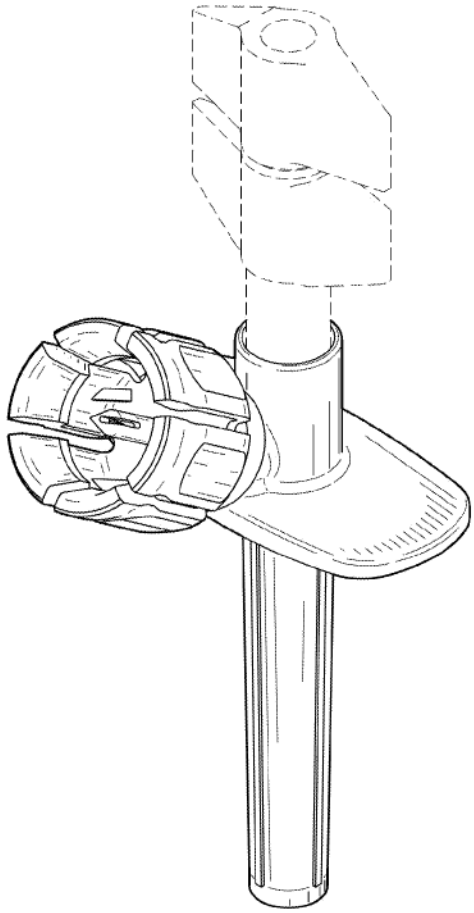


FIG.1

88. Pursuant to Commission Rule 210.12(c)(1), this Complaint is accompanied by one certified copy of the prosecution history of the D'124 Patent. Appendix B. Pursuant to Commission Rule 210.12(c)(2), this Complaint is accompanied by four copies of each technical reference identified in the prosecution history of the D'124 Patent. Appendix F.

i. Assignment and Ownership of the D'124 Patent

89. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the D'124 Patent. West Israel is an indirect subsidiary of West US. West US has an implied license to use the D'124 Patent per this corporate relationship.

90. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the assignment records for the D'124 Patent are attached as Exhibits 7–8.

ii. Foreign Counterparts to the D'124 Patent

91. Pursuant to Commission Rule 210.12(a)(9)(v), West identifies below the known foreign counterparts to the D'124 Patent:

Country	Application No.	Filing Date	Status
Israel	54442	August 7, 2013	Registered, term expires August 7, 2038
China	201330626512.5	December 16, 2013	Registered, term expires December 16, 2028
Europe	002446062-0001	April 14, 2014	Registered, term expires April 14, 2024 (extendible to April 14, 2034)
Great Britain	90024460620001	April 14, 2014	Registered, term expires April 14, 2024 (extendible to April 14, 2034)
India	259301	January 9, 2014	Registered, term expires August 7, 2023 (extendible to August 7, 2028)

92. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the afore-mentioned design applications.

C. U.S. Design Patent No. D765,837

93. On September 6, 2016, the USPTO duly and legally issued U.S. Design Patent No. D765,837 ("the D'837 Patent"), entitled "Liquid Transfer Device with Integral Vial Adapter." Ex. 3. The named inventors of the D'837 Patent are Nimrod Lev and Niv Ben Shalom. *Id.* at (72). The D'837 Patent issued from U.S. Design Patent Application No.

29/478,726, filed January 8, 2014. *Id.* at (21), (22). The D'837 Patent is valid, enforceable, and currently in full force and effect. The D'837 Patent expires on September 6, 2030.

94. The D'837 Patent claims an ornamental design for a liquid transfer device with integral vial adapter, as shown and described in the figures of the patent. By way of example, Figure 1 of the D'837 Patent is produced below. The D'837 Patent is non-functional because the appearance of the claimed design is not dictated by the use or purpose of the article.

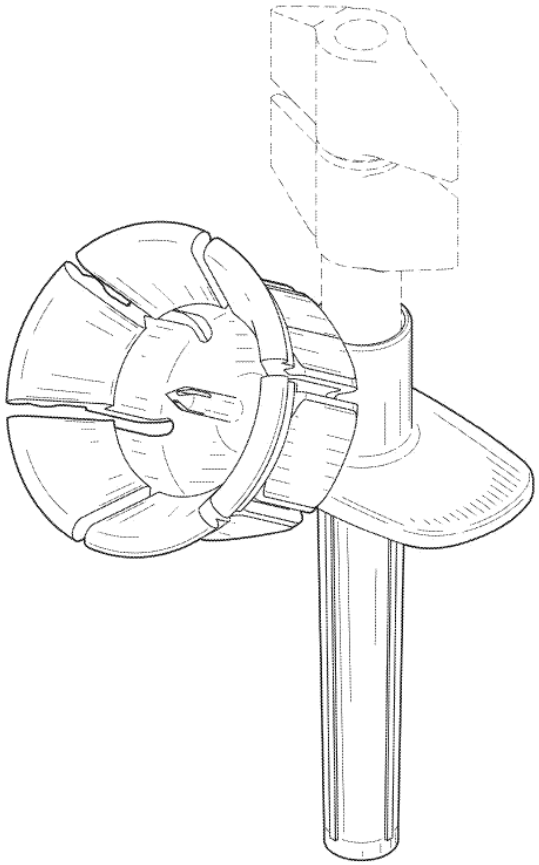


FIG.1

95. Pursuant to Commission Rule 210.12(c)(1), this Complaint is accompanied by one certified of the prosecution history of the D'837 Patent. Appendix C. Pursuant to Commission Rule 210.12(c)(2), this Complaint is accompanied by four copies of each technical reference identified in the prosecution history of the D'837 Patent. Appendix F.

i. Assignment and Ownership of the D'837 Patent

96. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the D'837 Patent. West Israel is an indirect subsidiary of West US. West US has an implied license to use the D'837 Patent per this corporate relationship.

97. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the assignment records for the D'837 Patent are attached as Exhibits 7 and 9.

ii. Foreign Counterparts to the D'837 Patent

98. Pursuant to Commission Rule 210.12(a)(9)(v), West identifies below the known foreign counterparts to the D'837 Patent:

Country	Application No.	Filing Date	Status
Israel	54443	August 7, 2013	Registered, term expires August 7, 2038
China	201330626605.8	December 16, 2013	Registered, term expires December 16, 2028
Europe	002446062-0002	April 14, 2014	Registered, term expires April 14, 2024 (extendible to April 14, 2034)
Great Britain	90024460620002	April 14, 2014	Registered, term expires April 14, 2024 (extendible to April 14, 2034)
India	259302	January 9, 2014	Registered, term expires August 7, 2023 (extendible to August 7, 2028)

99. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the afore-mentioned design applications.

D. U.S. Design Patent No. D630,732

100. On January 11, 2011, the USPTO duly and legally issued U.S. Design Patent No. D630,732 ("the D'732 Patent"), entitled "Vial Adapter with Female Connector." Ex. 4. The named inventors of the D'732 Patent are Nimrod Lev and Moshe Gilboa. *Id.* at (75). The D'732 Patent issued from U.S. Design Patent Application No. 29/344,390, filed September 29, 2009.

Id. at (21), (22). The D'732 Patent is valid, enforceable, and currently in full force and effect. The D'732 Patent expires on January 11, 2025.

101. The D'732 Patent claims an ornamental design for a vial adapter with female connector, as shown and described in the figures of the patent. By way of example, Figure 1 of the D'732 Patent is produced below. The D'732 Patent is non-functional because the appearance of the claimed design is not dictated by the use or purpose of the article.

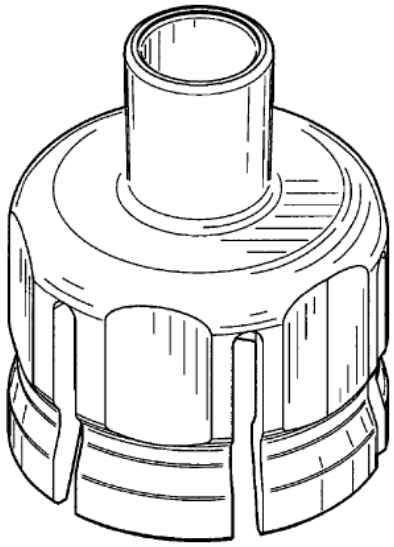


FIG.1

102. Pursuant to Commission Rule 210.12(c)(1), this Complaint is accompanied by one certified copy of the prosecution history of the D'732 Patent. Appendix D. Pursuant to Commission Rule 210.12(c)(2), this Complaint is accompanied by four copies of each technical reference identified in the prosecution history of the D'732 Patent. Appendix F.

i. Assignment and Ownership of the D'732 Patent

103. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the D'732 Patent. West Israel is an indirect subsidiary of West US. West US has an implied license to use the D'732 Patent per this corporate relationship.

104. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the assignment records for the D'732 Patent are attached as Exhibits 7 and 10.

ii. Foreign Counterparts to the D'732 Patent

105. Pursuant to Commission Rule 210.12(a)(9)(v), West identifies below the known foreign counterpart to the D'732 Patent:

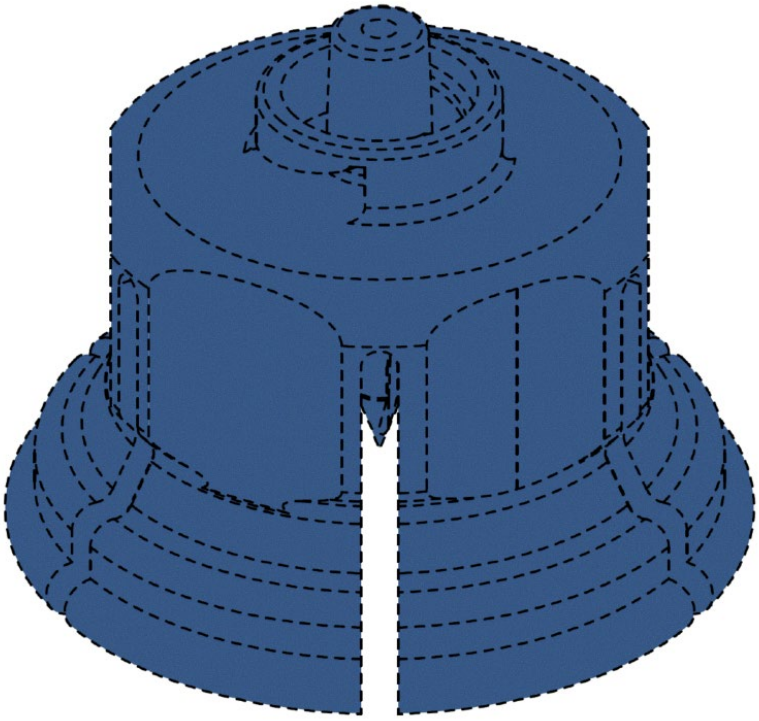
Country	Application No.	Filing Date	Status
Europe	001680703-0002	March 12, 2010	Registered, term expires March 12, 2025 (extendible to March 12, 2030)
Great Britain	90016807030002	March 12, 2010	Registered, term expires March 12, 2025 (extendible to March 12, 2030)

106. West Israel is the owner, by valid assignment, of the entire right, title, and interest to the afore-mentioned design application.

E. U.S. Trademark Registration 5,810,583

107. U.S. Trademark Registration 5,810,583 ("the '583 Mark" or the "Asserted Mark") is registered on the Principal Register with the USPTO. Ex. 5. The '583 Mark was filed on June 26, 2018 and registration issued on July 23, 2019 under Section 2(f) of the Lanham Act. *Id.* The '583 Mark identifies a first use in U.S. interstate commerce of May 2005, and a first use anywhere of May 2005. *Id.*

108. The '583 Mark consists of the color blue as applied to the goods in their entirety. *Id.* The matter shown in dotted lines is not claimed as part of the mark and serves only to indicate placement of the mark on the goods. *Id.* The goods identified in the registration of the '583 Mark are International Class 10: "medical devices, namely, disposable vial adapters for use in compounding pharmaceutical preparations and for use in the dispensing of pharmaceutical preparations into patients." *Id.* The '583 Mark is shown below:



109. Pursuant to Commission Rule 210.12(d), this Complaint is accompanied by one certified copy of the prosecution history of the ’583 Mark.

Appendix E.

i. Ownership of the ’583 Mark

110. West Israel is the owner of the ’583 Mark. Exhibit 5. West Israel is an indirect subsidiary of West US. West US has an implied license to use the ’583 Mark per this corporate relationship

ii. Foreign Counterparts to the ’583 Mark

111. Pursuant to Commission Rule 210.12(a)(9)(v), West identifies below the known foreign counterpart to the ‘583 Mark:

Country	Application No.	Filing Date	Status
Mexico	2147758	January 7, 2019	Registered
Canada	1,940,316	December 27, 2019	Pending

Australia	1977472	December 21, 2018	Application abandoned on October 1, 2020
China	35555379	December 26, 2018	Application abandoned on July 31, 2019
Israel	312038	December 23, 2018	Application abandoned on January 19, 2020

112. West Israel is the owner of the entire right, title, and interest to the afore-mentioned trademarks.

F. Licensees Relating to the Asserted Patents and Asserted Mark

113. West Israel is an indirect subsidiary of West US. West US has an implied license to use the Asserted Patents and Asserted Mark per this corporate relationship. There are no third-party licensees.

VI. PROPOSED RESPONDENTS' UNLAWFUL AND UNFAIR ACTS

114. On information and belief, Proposed Respondents have engaged and are engaging in unlawful and unfair acts including manufacturing for import into the United States, importing into the United States, selling for importation into the United States, and/or selling within the United States after importation the Accused Products that infringe one or more of the asserted claims of the Asserted Patents and/or the Asserted Mark.

A. Patent Infringement

i. Proposed Respondents infringe the '295 Patent

115. On information and belief, Proposed Respondents infringe claim 1 of the '295 Patent by importing into the U.S., selling for importation in the U.S., and/or selling after importation in the U.S. the Accused Products in violation of 35 U.S.C. §271. Specifically, Proposed Respondents have and continue to directly infringe claim 1 of the '295 Patent.

116. Exhibits 25 and 26 show that the Accused Products meet each and every limitation of claim 1 of the '295 Patent, literally or under the doctrine of equivalents. The

photographs in these exhibits are photographs of the samples of the Accused Products that West obtained at the ASHP Midyear Clinical Meeting in Las Vegas, Nevada, USA in early December 2022 ("the ASHP Conference"). *See infra* at ¶¶145–148 (incorporated herein by reference). In Exhibit 25, West identifies elements of the accused VDB 20mm admixture device that meet the claim limitations of claim 1 of the '295 Patent. In Exhibit 26, West identifies elements of the accused VDB 13mm admixture device that meet the claim limitations of claim 1 of the '295 Patent. The only differences between these products are the size and design of the integral vial adapter, which are not germane to infringement, i.e., claim 1 of the '295 Patent is not limited to a vial adapter size or design.

117. On information and belief, Proposed Respondents have and continue to directly infringe claim 1 of the '295 Patent by making, using, selling, offering to sell, and/or importing the Accused Products in or into the U.S. in violation of 35 U.S.C. §271(a).

ii. Proposed Respondents infringe the D'124 Patent

118. On information and belief, Proposed Respondents infringe the D'124 Patent by importing into the U.S., selling for importation in the U.S., and/or selling after importation in the U.S. the Accused Products in violation of 35 U.S.C. §271. Specifically, Proposed Respondents have and continue to directly infringe the D'124 Patent.

119. Exhibit 27 compares the accused VDB 13mm admixture device to the design claimed in the D'124 Patent. The photographs in this exhibit are photographs of the sample of the accused VDB 13mm admixture device that West obtained at the ASHP Conference. *See infra* at ¶¶145–148 (incorporated herein by reference). The comparison shows the accused VDB 13mm admixture device infringes the D'124 Patent because, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, the accused VDB 13mm admixture device is

the same or substantially the same as the design claimed in the asserted D'124 Patent, such that an ordinary observer would be deceived into believing he/she is buying the claimed design when he/she purchases the accused VDB 13mm admixture device.

120. On information and belief, Proposed Respondents have and continue to directly infringe the D'124 Patent by making, using, selling, offering to sell, and/or importing the accused VDB 13mm admixture device in or into the U.S. in violation of 35 U.S.C. §271(a).

iii. Proposed Respondents infringe the D'837 Patent

121. On information and belief, Proposed Respondents infringe the D'837 Patent by importing into the U.S., selling for importation in the U.S., and/or selling after importation in the U.S. the Accused Products in violation of 35 U.S.C. §271. Specifically, Proposed Respondents have and continue to directly infringe the D'837 Patent.

122. Exhibit 28 compares the accused VDB 20mm admixture device to the design claimed in the D'837 Patent. The photographs in this exhibit are photographs of the sample of the accused VDB 20mm admixture device that West obtained at the ASHP Conference. *See infra* at ¶¶145–148 (incorporated herein by reference). The comparison shows the accused VDB 20mm admixture devices infringes the D'837 Patent because, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, the accused VDB 20mm admixture device is the same or substantially the same as the design claimed in the asserted D'837 Patent, such that an ordinary observer would be deceived into believing he/she is buying the claimed design when he/she purchases the accused VDB 20mm admixture device.

123. On information and belief, Proposed Respondents have and continue to directly infringe the D'837 Patent by making, using, selling, offering to sell, and/or importing the accused VDB 20mm admixture device in or into the U.S. in violation of 35 U.S.C. §271(a).

iv. Proposed Respondents infringe the D'732 Patent

124. On information and belief, Proposed Respondents infringe the D'732 Patent by importing into the U.S., selling for importation in the U.S., and/or selling after importation in the U.S. the Accused Products in violation of 35 U.S.C. §271. Specifically, Proposed Respondents have and continue to directly infringe the D'732 Patent.

125. Exhibit 29 compares the vial adapter of the accused VDB 13mm admixture device to the design claimed in the D'732 Patent. The photographs in this exhibit are photographs of the sample of the accused VDB 13mm admixture device that West obtained at the ASHP Conference. *See infra* at ¶¶145–148 (incorporated herein by reference). The comparison shows the vial adapter of the accused VDB 13mm device infringes the D'732 Patent because, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, the vial adapter of the accused VDB 13mm admixture device is the same or substantially the same as the design claimed in the asserted D'732 Patent, such that an ordinary observer would be deceived into believing he/she is buying the claimed design when he/she purchases the accused VDB 13mm admixture device with the vial adapter.

126. On information and belief, Proposed Respondents have and continue to directly infringe the D'732 Patent by making, using, selling, offering to sell, and/or importing the accused VDB 13mm admixture device in or into the U.S. in violation of 35 U.S.C. §271(a).

B. Trademark Infringement/Lanham Act

127. The Asserted Mark is on the Principal Register pursuant to Section 2(f) as U.S. Trademark Registration No. 5,810,583 and such registration is prima facie evidence of ownership and validity, as well as secondary meaning. 15 U.S.C. §§1052(f), 1057(b).

128. The Asserted Mark consists of the color blue as applied to the goods in their entirety. It is a non-functional, distinctive trade dress.

129. West has used the Asserted Mark in commerce since at least as early as May 2005, including in connection with West's Vial2Bag Advanced® 20mm admixture device. Appendix E is a certified copy of the prosecution history of the Asserted Mark. It contains screenshots of West's website and materials showing West's use of its blue trademark. Appendix E at Exhibit V. West Israel submitted these screenshots of West's website and materials to the USPTO to establish its blue trademark has acquired distinctiveness. Two such screenshots are reproduced below in part.

screenshot-www.westpharma.com-2018.10.22-11-34-26
https://www.westpharma.com/products/reconstitution-and-transfer-systems/vial-adapters
22.10.2018

We use cookies to deliver the best possible experience on our website. To learn more, visit our Privacy Policy. By continuing to use this site, or closing this box, you consent to our use of cookies.

ABOUT WEST CAREERS INVESTORS GLOBAL LOCATIONS LANGUAGE SIGN IN
CONTACT US NEWS & EVENTS

West By your side for a healthier world

SEARCH

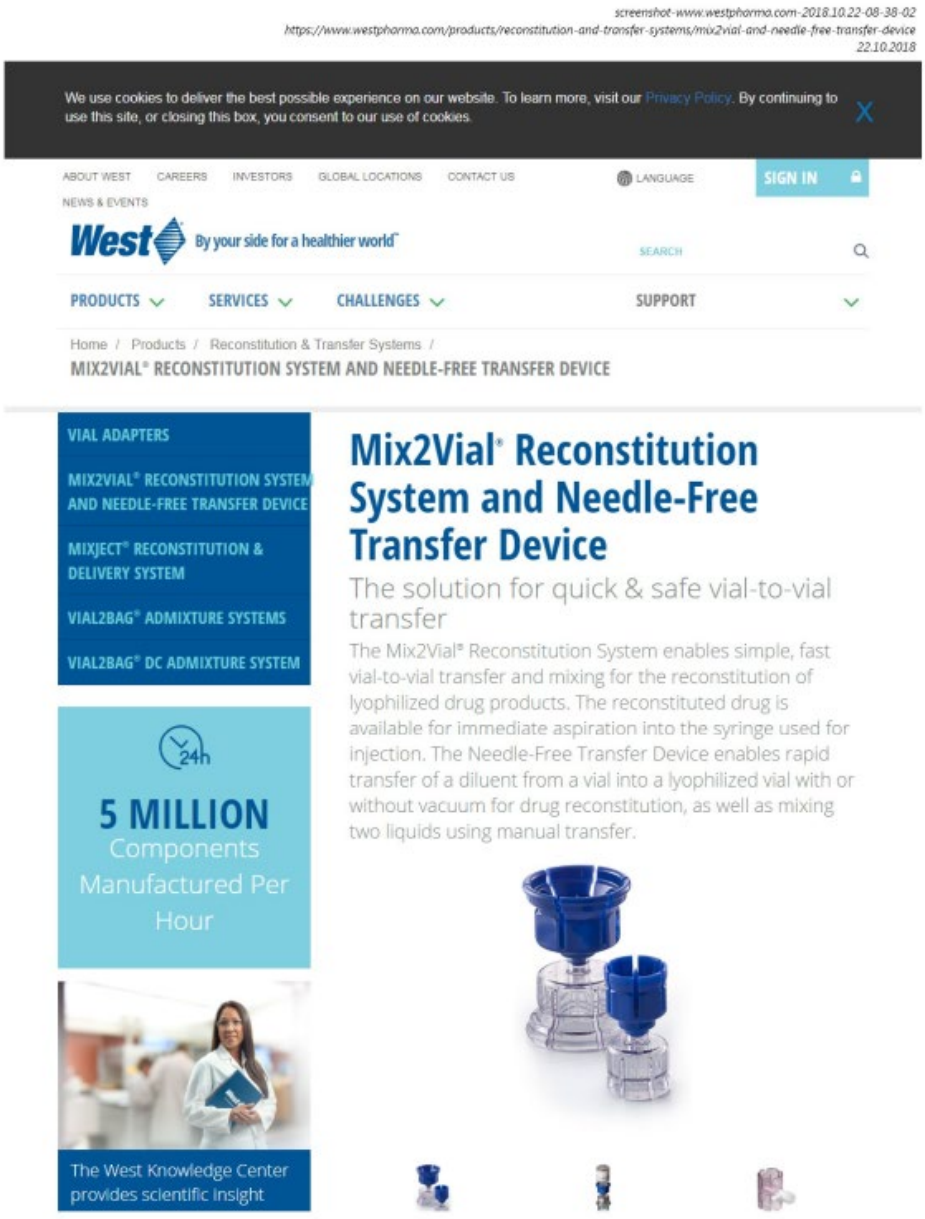
PRODUCTS SERVICES CHALLENGES SUPPORT

Home / Products / Reconstitution & Transfer Systems /
VIAL ADAPTERS

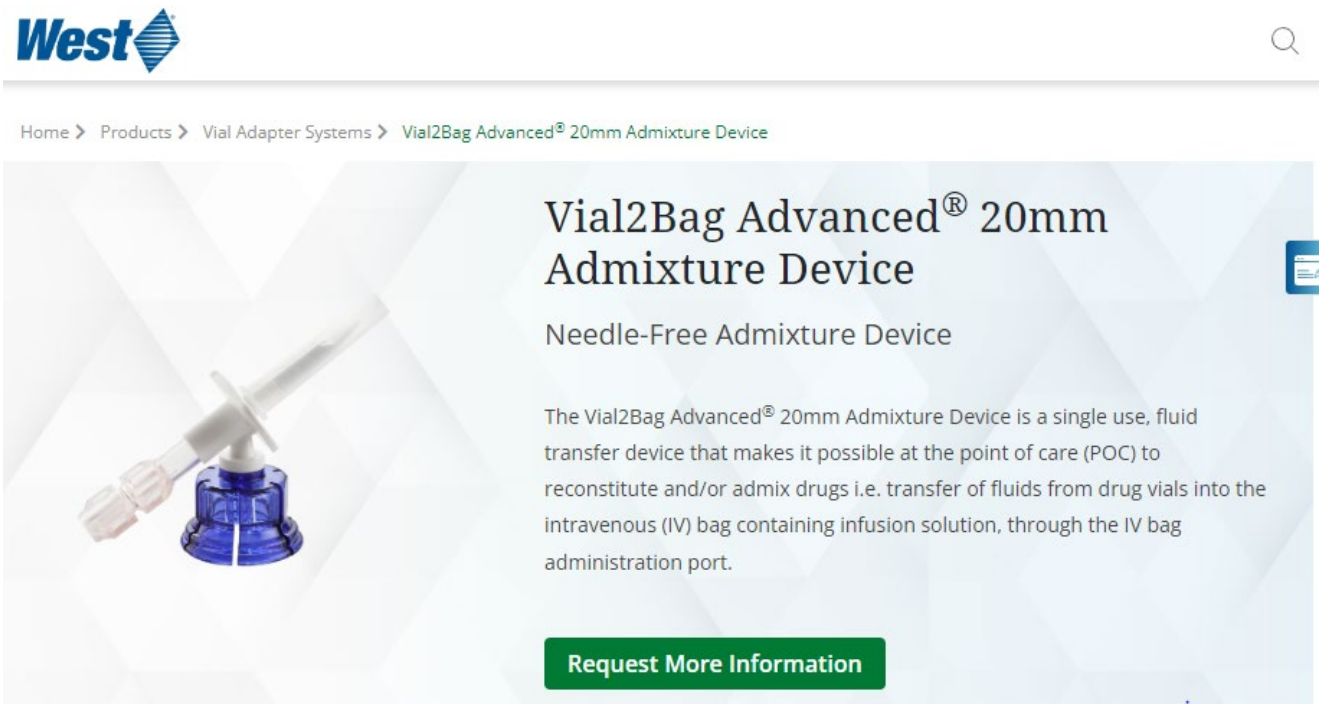
Vial Adapters

The solution for quick & safe transfer from vials

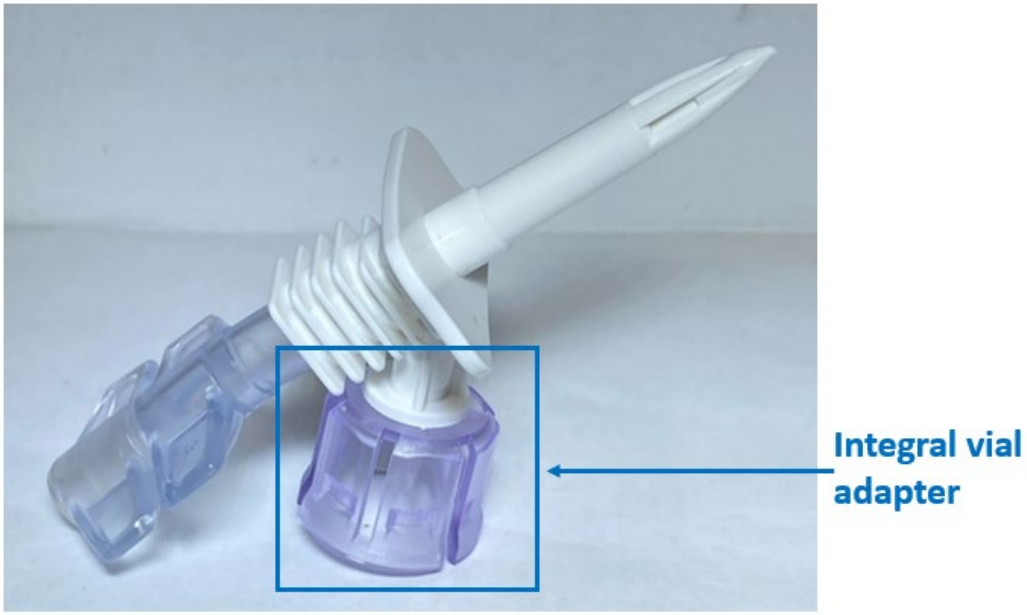
Vial adapters are a cost-effective solution for the safe and rapid transfer and reconstitution of drugs between vials and syringes. Vial adapter spike technology provides a reproducible engineered depth for drug and diluent aspiration, which greatly reduces the end-user variability associated with traditional needle aspirations and helps minimize vial overfill.



130. West actively markets, advertises, and sells its Vial2Bag Advanced® 20mm admixture device with a blue vial adapter. *See, e.g.*, https://www.westpharma.com/products/vial-adapter-systems/vial2bag-advanced (reproduced below in part).



131. As demonstrated below, the Accused Products include blue vial adapters. The first photo (annotations added) is an accused VDB 20mm admixture device. The second photo (annotations added) is an accused VDB 13mm admixture device.



132. Exhibits 30 and 31 show infringing use of the ’583 Mark by Proposed Respondents for the Accused Products. The photographs in these exhibits are photographs of the samples of the Accused Products that West obtained at the ASHP Conference. *See infra* at

¶¶145–148 (incorporated herein by reference).

133. Proposed Respondents' use of the '583 Mark, consisting of the color blue, is without the consent of West Israel.

134. Proposed Respondents' use of blue with their vial adapter is likely to cause confusion and mistake and to deceive potential consumers and the public as to the source, origin, sponsorship, or approval of Proposed Respondents' Accused Products. Proposed Respondents' use of blue with their vial adapter is also likely to cause confusion and mistake as to affiliation, connection, or association between Proposed Respondents and/or their liquid transfer devices with a vial adapter, on one hand, and West and/or its liquid transfer devices with a vial adapter, on the other hand.

135. Further, as explained in detail below, at least two pharmacists have actually confused the Accused Products with the Vial2Bag Advanced® admixture devices. Ex. 32 (Sanjeev Seenath Declaration), ¶¶12–15.

136. Specifically, Progressive Medical, Inc. ("PMI"), West's exclusive U.S. distributor of the Vial2Bag Advanced® admixture devices, attended the ASHP Conference in Las Vegas, Nevada, USA in early December 2022. *Id.*, ¶¶4–5. ASHP is the largest global gathering of pharmacy professionals, with more than 20,000 pharmacy professionals attending the event. Ex. 33(Abruzzese Declaration), ¶5.

137. PMI was advertising and displaying West's Vial2Bag Advanced® 20mm admixture device at the ASHP Conference. Ex. 32 (Seenath Declaration), ¶7.

138. Proposed Respondent Summit also attended the ASHP Conference. Shown in the below photographs was Summit's booth at the ASHP Conference, advertising and displaying the Accused Products. Ex. 33 (Abruzzese Declaration), ¶¶6–7; *see also* Ex. 32 (Seenath

Declaration), ¶¶5, 8. As shown in the second photo below, it had marketing brochures for and samples of the Accused Products available at its booth.

139. At the ASHP Conference, two pharmacists separately approached Sanjeev Seenath, Manager of R&D, Clinical Development at West US. Ex. 32 (Seenath Declaration), ¶¶12–15. Both pharmacists explained they had seen liquid transfer devices at Summit's booth and PMI's booth and were confused as to whom the liquid transfer devices belonged. *Id.*

140. Specifically, the first pharmacist saw West's Vial2Bag Advanced® 20mm admixture device at PMI's booth. *Id.*, ¶13. He asked Mr. Seenath if this was West's device because he thought he saw that same West device at a nearby booth. *Id.* Summit's booth was

located about four booths away from PMI's booth. *Id.*, ¶14.

141. The second pharmacist saw West's Vial2Bag Advanced® 20mm admixture device at PMI's booth and said it seems like a lot of people are selling that device because she saw a similar device at another booth. *Id.*, ¶15.

142. Because Proposed Respondents have used in commerce, without the consent of West Israel, a reproduction, counterfeit, copy, or colorable imitation of the '583 Mark in connection with the sale, offering for sale, distribution, and/or advertising of the Accused Products in a manner likely to (and which has actually begun to) cause confusion, mistake or deception, Proposed Respondents are in violation of Section 32 of the Lanham Act. 15 U.S.C. §1114.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION

143. On information and belief, Proposed Respondents manufacture, import into the United States, sell for importation, and/or sell within the United States after importation the Accused Products.

144. On information and belief, the Accused Products are manufactured abroad. The Accused Products are then sold for importation into the United States, imported into the United States, and/or sold within the United States after importation.

145. West obtained samples of the accused VDB 13mm admixture device and accused VDB 20mm admixture device in the United States.

146. Specifically, as explained above ¶¶136–138 (incorporated herein by reference), both PMI and Summit had product display booths at the ASHP Conference in Las Vegas, Nevada in early December 2022. Summit had the Accused Products physically on display at its booth. Ex. 32 (Seenath Declaration), ¶8.

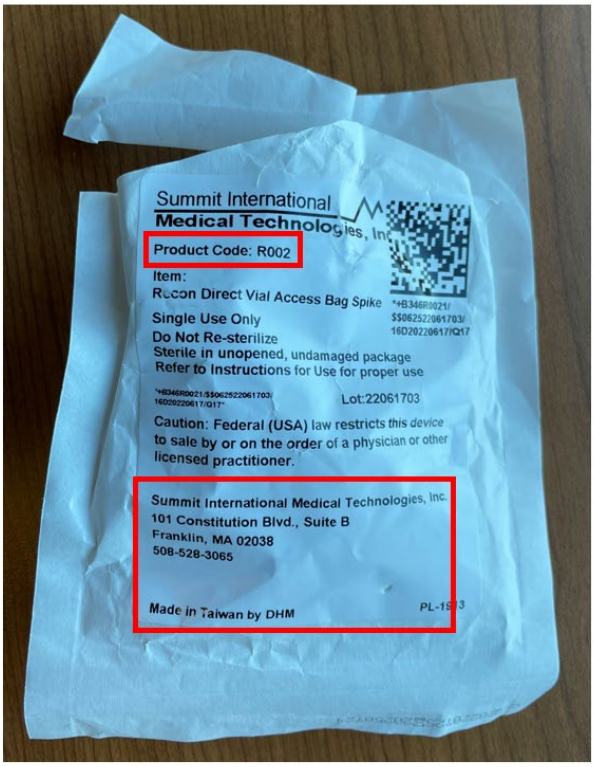
147. As shown in the photo above in ¶138 (incorporated herein by reference) and below, Summit also had free samples of the Accused Products available for conference attendees. *Id.*, ¶9; Ex. 32 (Abruzzese Declaration), ¶8.

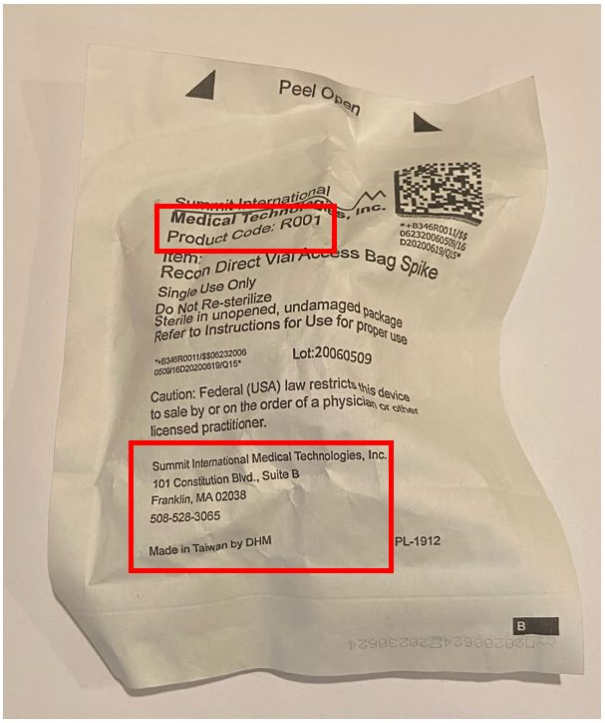
148. Mr. Seenath obtained a sample of the accused VDB 20mm admixture device from Summit at the ASHP Conference. Ex. 32 (Seenath Declaration), ¶9. Luigi Abruzzese, Director, Strategic Marketing, IV Market & Hospital Channel at West US, was provided a sample of the accused VDB 13mm admixture device from Summit at the ASHP Conference. Ex. 33 (Abruzzese Declaration), ¶8.

149. Mr. Abruzzese was also provided a Summit marketing brochure for the Accused Products at the ASHP Conference. Ex. 33 (Abruzzese Declaration), ¶9. A photograph of that brochure is attached as Exhibit 24. The marketing brochure that Summit had available at the ASHP conference is virtually the same as the Summit marketing brochures that may be downloaded from Advcare's website and Summit's website. *Compare* Ex. 24 (Summit

marketing brochure from ASHP Conference), *with* Ex. 43 (Summit marketing brochure from Advcare's website) *and* Ex. 20 (Summit marketing brochure from Summit's website). The marketing brochure that Summit had available at the ASHP Conference appears to be a more detailed (or updated) version of the Summit marketing brochure available on Advcare's website.

150. As shown in the photos below (annotations added), the product packaging for each sample Accused Product includes Summit's name, address, and phone number, includes a product code, and states the product was "Made in Taiwan by DHM." Upon information and belief, "DHM" refers to Dragon Heart Medical. The first row of photos (annotation added) is an accused VDB 13mm admixture device in its packaging. The second row of photos (annotation added) is an accused VDB 20mm admixture device in its packaging.





151. As shown in the above photos, the product code on the product packaging for the accused VDB 13mm admixture device is R002. The product code on the product packaging for the accused VDB 20mm admixture device is R001. As shown above in ¶26 (incorporated herein by reference), Advcare uses these exact same product numbers on its website for these same devices. https://advcare-med.com/products/2.

152. As shown in the below photo (annotations added), the product packaging for the accused VDB 20mm admixture device includes a primary device identifier number that is searchable in the AccessGUDID portal. That number is B346R0011.

153. The National Library of Medicine, in collaboration with the FDA, has created the AccessGUDID portal, which allows the public to search for a medical device using a primary device identifier number to obtain key information about the device that was submitted by device companies to the FDA. https://accessgudid.nlm.nih.gov/about-gudid. "The FDA is establishing [this] unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use." https://accessgudid.nlm.nih.gov/.

154. When the primary device identifier number (i.e., B346R0011) for the accused VDB 20mm admixture device is searched in the AccessGUDID portal, it returns the following information:

Ex. 34 at 1 (highlighting added); https://accessgudid.nlm.nih.gov/devices/B346R0011.

155. As shown in the above screenshot (highlighting added), the brand name for the accused VDB 20mm admixture device is "Summit Medical," the product number is "R001," and the company name is "Dragon Heart Medical, Inc." On information and belief, this information was submitted by Advcare to the FDA because Advcare is the specific entity that has 510(k) clearance for the accused VDB 20mm admixture device. Further, as shown above in ¶26

(incorporated herein by reference), Advcare uses this exact same product number on its website for this same device. https://advcare-med.com/products/2.

156. As shown in the below photo (annotations added), the primary device identifier number for the accused VDB 13mm admixture device is B346R0021.

157. When that primary device identifier number (i.e., B346R0021) for the accused VDB 13mm admixture device is searched in the AccessGUDID portal, it returns the following information:

Ex. 35 at 1 (highlighting added); https://accessgudid.nlm.nih.gov/devices/B346R0021.

158. As shown in the above screenshot (highlighting added), the brand name for the accused VDB 13mm admixture device is "Summit Medical," the product number is "R002," and the company name is "Dragon Heart Medical, Inc." On information and belief, this information was submitted by Advcare to the FDA because Advcare is the specific entity that has 510(k) clearance for the accused VDB 13mm admixture device. Further, as shown above in ¶26 (incorporated herein by reference), Advcare uses this exact same product number on its website for this same device. https://advcare-med.com/products/2.

VIII. CLASSIFICATION OF THE ACCUSED PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE

159. On information and belief, the Accused Products fall within at least the following classifications of the Harmonized Tariff Schedule of the United States: 9018.39.0500.

160. West's citation to this classification is intended for illustrative purposes only and is not intended to restrict the scope of the investigation, the Accused Products, the Asserted Patents, and/or the Asserted Mark.

IX. THE DOMESTIC INDUSTRY REQUIREMENT

161. Pursuant to 19 C.F.R. §210.12(a)(6)(i), a domestic industry as required by 19 U.S.C. §1337(a)(2) and as defined by 19 U.S.C. §1337(a)(3) exists in the United States in connection with each of the Asserted Patents and Asserted Mark and the products protected thereby. As explained above in Section I (incorporated herein by reference), West designs, develops, manufactures, and commercializes its Vial2Bag Advanced® 20mm and 13mm admixture devices. As shown in the table below, each of these devices is covered by one or more of the asserted claims of the Asserted Patents and/or the Asserted Mark.

Asserted IP	Protected Product(s)
Claim 1 of the '295 Patent	Vial2Bag Advanced® 20mm admixture device Vial2Bag Advanced® 13mm admixture device
The D'124 Patent	Vial2Bag Advanced® 13mm admixture device
The D'837 Patent	Vial2Bag Advanced® 20mm admixture device
The D'732 Patent	Vial2Bag Advanced® 13mm admixture device
The '583 Mark	Vial2Bag Advanced® 20mm admixture device

162. As explained below in Section IX.B (incorporated herein by reference), West, directly or through subsidiaries of West US, has made significant investments in plant and equipment and made significant employment of labor or capital with respect to, the Asserted Patents and Asserted Mark, through significant domestic activities related to West's Vial2Bag

Advanced® 20mm and 13mm admixture devices that are covered by the Asserted Patents and/or Asserted Mark. In the alternative, West is in the process of establishing a domestic industry relating to its Vial2Bag Advanced® 20mm admixture device, which is protected by the '295 Patent, the D'837 Patent, and Asserted Mark.

A. Technical Prong

163. Exhibit 36 is a chart comparing claim 1 of the '295 Patent to West's Vial2Bag Advanced® 20mm admixture device. Exhibit 36 shows that device is covered by the '295 Patent, either literally or under the doctrine of equivalents.

164. Exhibit 37 is a chart comparing claim 1 of the '295 Patent to West's Vial2Bag Advanced® 13mm admixture device. Exhibit 37 shows that device is covered by the '295 Patent, either literally or under the doctrine of equivalents.

165. Exhibit 38 is a chart comparing the design claimed in the D'837 Patent to West's Vial2Bag Advanced® 20mm admixture device. Exhibit 38 shows that device is covered by the D'837 Patent.

166. Exhibit 39 is a chart comparing the design claimed in the D'124 Patent to West's Vial2Bag Advanced® 13mm admixture device. Exhibit 39 shows that device is covered by the D'124 Patent.

167. Exhibit 40 is a chart comparing the design claimed in the D'732 Patent to West's Vial2Bag Advanced® 13mm admixture device. Exhibit 40 shows that device is covered by the D'732 Patent.

168. Exhibit 41 is a chart comparing the mark in the '583 Mark to West's Vial2Bag Advanced® 20mm admixture device. Exhibit 41 shows that device is marked with the '583 Mark.

B. Economic Prong

169. A domestic industry with respect to the each of the Asserted Patents and Asserted Mark, exists under 19 U.S.C. §1337(a)(3)(A) and (B), by virtue of West's significant domestic investments in plant and equipment and significant domestic employment of labor and capital made in connection with its Vial2Bag Advanced® 20mm and 13mm admixture devices. West's significant domestic expenditures include at least those detailed in the Confidential Declaration of Martin McGarry (Confidential Ex. 12). Summarized below are some of West's significant investments in plant and equipment and employment of labor and capital.

170. In early 2019, West started designing, researching, and developing the Vial2Bag Advanced® 20mm and 13mm admixture devices. Confidential Ex. 12 (McGarry Declaration), ¶9. The FDA regulates these devices.

171. In 2020, West Pharmaceutical Services AZ, Inc. ("West AZ"), a wholly owned subsidiary of West US, received 510(k) clearance from the FDA for West's Vial2Bag Advanced® 20mm admixture device. *Id.*, ¶12; Ex. 11 (West's 510(k) clearance for the Vial2Bag Advanced® 20mm admixture device). West AZ is an Arizona corporation with its principal place of business at 14677 N. 74th Street, Scottsdale, AZ 85260. Confidential Ex. 12 (McGarry Declaration), ¶12.

172. West US markets and sells its Vial2Bag Advanced® 20mm admixture device under FDA 510(k) number K201415. *Id.*, ¶14; Ex. 11.

173. West is preparing its 510(k) clearance application for its Vial2Bag Advanced® 13mm admixture device, should receive 510(k) clearance from the FDA, and will start selling this device in the United States. Confidential Ex. 12 (McGarry Declaration), ¶15. Set forth in

the Confidential Declaration of Mr. McGarry are the dates West expects each of these events to occur. *Id.*

174. As explained in detail in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12), West, directly or through subsidiaries of West US, has made and continues to make significant investments in plant and equipment under Section 337(a)(3)(A) with respect to the Vial2Bag Advanced® 20mm and 13mm admixture devices. *Id.*, ¶¶8–81.

175. For example, West, directly or through West AZ, has allocated square footage at the West US Office and the West AZ Office for work related to the research, development, and commercialization of the Vial2Bag Advanced® 20mm and 13mm admixture devices. *Id.*, ¶¶16, 19–22. Set forth in the Confidential Declaration of Mr. McGarry is the amount of square footage allocated. *Id.*, ¶¶20–22. The Confidential Declaration of Mr. McGarry also includes the amount West incurs directly or through West AZ in building related costs and equipment costs for this work. *Id.*, ¶¶17–28.

176. As another example, as detailed in the Confidential Declaration of Mr. McGarry, West will start manufacturing the Vial2Bag Advanced® 20mm admixture device at its manufacturing facility in Puerto Rico. *Id.*, ¶¶29–35. West, directly or through West Contract Manufacturing, LLC ("West Puerto Rico"), has allocated square footage at that Puerto Rico manufacturing facility for work related to the U.S. manufacture of its Vial2Bag Advanced® 20mm admixture device. *Id.*, ¶36. Set forth in the Confidential Declaration of Mr. McGarry is the amount of square footage allocated and the amount West incurs directly or through West Puerto Rico in building related costs and equipment costs for this work. *Id.*, ¶¶36–42.

177. West Puerto Rico is a Delaware limited liability company, with its principal place of business at State Rd. #1 Km. 48.7, Bo. Beatriz, Cidra, Puerto Rico 00739. Confidential Ex. 12

(McGarry Declaration), ¶30. It is an indirect subsidiary of West US. *Id.*

178. Set forth in the Confidential Declaration of Mr. McGarry is the number of units West expects to manufacture annually at the Puerto Rico manufacturing facility initially and once the facility's two assembly lines are operational. *Id.*, ¶¶31–35; *see also* ¶¶54–57. The Confidential Declaration of Mr. McGarry also includes the dates when West expects each assembly line to be operational. *Id.*, ¶¶34–35.

179. As explained in detail in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12), West, directly or through subsidiaries of West US, has also made and continues to make significant employment of labor or capital under Section 337(a)(3)(B) with respect to its Vial2Bag Advanced® 20mm and 13mm admixture devices. *Id.*, ¶¶43–70. For example, set forth in the Confidential Declaration of Mr. McGarry is the amount West has incurred directly or through a subsidiary of West US in payroll and benefits costs for (1) the Vial2Bag Advanced® 20mm admixture device research and development team in the United States, (2) the Vial2Bag Advanced® 13mm admixture device research and development team in the United States, and (3) employees setting up the U.S. manufacture of the Vial2Bag Advanced® 20mm admixture device at West Puerto Rico's manufacturing facility. *Id.*, ¶¶44–57.

180. West's investment in its Vial2Bag Advanced® 20mm admixture device, which is already being sold in the United States, constitutes not only an existing domestic industry with respect to the '295 Patent, D'837 Patent, and the Asserted Mark for at least the reasons discussed above and in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12). But it also constitutes a domestic industry in the process of being established because, as explained in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12), West is actively engaged in the steps leading to the exploitation of its rights in the '295 Patent, D'837 Patent, and the Asserted

Mark Patent, and there is a significant likelihood that an industry will be established in the future, if not already established. For example, West will start manufacturing the Vial2Bag Advanced® 20mm admixture device in Puerto Rico.[9] *Id.*, ¶¶29–35.

181. West's investment in its Vial2Bag Advanced® 13mm admixture device, which is presently under development, constitutes an existing domestic industry with respect to the '295 Patent, D'124 Patent, and D'732 Patent for at least the reasons discussed above and in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12).

182. As discussed above and in the Confidential Declaration of Mr. McGarry (Confidential Ex. 12), West's totals for investments under 337(a)(3)(A) and (B) are both significant. For example, the investments are a significant percentage of actual and projected annual sales revenue of the DI Products. In addition, the relied upon activities are not those of a "mere importer" as they could be performed overseas, but West has chosen to perform them in the U.S.

X. LITIGATION

183. Pursuant to 19 C.F.R. §210.12(a)(5), the alleged unfair methods of competition and unfair acts have not been and are not the subject of foreign or domestic litigation in any court or agency.

XI. RELIEF REQUESTED

WHEREFORE, pursuant to Commission Rule 210.12(a)(11), West respectfully requests that the United States International Trade Commission:

A. Institute an immediate investigation pursuant to Section 337(b)(1) of the Tariff Act of 1930, as amended, 19 C.F.R. §1337, into Proposed Respondents' violation of Section 337

[9] As noted above, Puerto Rico is considered part of the U.S. for purposes of establishing domestic industry under Section 337.

based on their importation into the United States, sale for importation, and/or sale within the United States after importation of the Accused Products that infringe at least one of the Asserted Patents and/or the Asserted Mark;

B. Schedule and conduct a hearing pursuant to Section 337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and following the hearing, determine that there has been a violation of Section 337;

C. Issue a permanent limited exclusion order, pursuant to 19 U.S.C. §1337(d)(1), forbidding entry into the United States, all liquid transfer devices imported, sold for importation, and/or sold after importation by or on behalf of Proposed Respondents that infringe at least one of the Asserted Patents and/or the Asserted Mark;

D. Issue permanent cease and desist orders, pursuant to 19 U.S.C. §1337(f), directing each Proposed Respondent, or other acting on their behalf, to cease and desist from importing, selling, offering for sale, marketing, advertising, packaging, inventorying, distributing, demonstrating, using, transferring (except for export), and/or soliciting any sale by Proposed Respondents of all liquid transfer devices that infringe at least one of the Asserted Patents and/or the Asserted Mark;

E. Impose a bond, pursuant to 19 U.S.C. §1337(j), upon Proposed Respondents' importation of any liquid transfer devices that infringe at least one of the Asserted Patents and/or the Asserted Mark during the 60-day Presidential review period to prevent further injury to West's domestic industry relating to the Asserted Patents and Asserted Mark; and

F. Grant all such other and further relief as the Commission deems appropriate based on the facts complained of herein and as determined by the investigation.

Dated: April 4, 2023

Respectfully submitted,

/s/ Domingo M. LLagostera

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COUNSEL FOR COMPLAINANTS

VERIFICATION OF COMPLAINT

I, Kimberly MacKay, SVP, General Counsel and Corporate Secretary for West Pharmaceutical Services, Inc., for and on behalf of West Pharmaceutical Services, Inc. and West Pharma Services IL, Ltd., in accordance with Commission Rule 210.4 and 210.2(a), under penalty of perjury, declare that the foregoing is true and correct:

1. I am duly authorized to execute this verification.
2. I have read the foregoing Complaint and am aware of its contents.
3. To the best of my knowledge, information, and belief, formed after reasonable inquiry under the circumstances, the claims and other legal contentions in the Complaint are warranted by existing law or by a good faith nonfrivolous argument for the extension, modification, or reversal of existing law, or by establishment of new law.
4. To the best of my knowledge, information, and belief, formed after reasonable inquiry under the circumstances, the allegations and other factual contentions in the Complaint have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.
5. This document is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceedings.

Executed on April 3, 2023

Kimberly MacKay