Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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HYPERBRANCH MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

CONFLUENT SURGICAL, INC.,
Patent Owner.

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Case IPR2018-01099
Patent 8,876,021 B2

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Before LINDA E. HORNER, BARBARA A. PARVIS, and JASON W. MELVIN, *Administrative Patent Judges.*

HORNER, *Administrative Patent Judge.*

# DECISION
Institution of *Inter Partes* Review
*35 U.S.C. § 314(a)*

HyperBranch Medical Technology, Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 14 and 15 of U.S. Patent No. 8,876,021 B2 (Ex. 1001, "the '021 patent"). Paper 1 ("Pet."). Confluent Surgical, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a) an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Moreover, a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

Considering the Petition and the Preliminary Response, we conclude the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one challenged claim. Thus, we institute an *inter partes* review as to all challenged claims of the '021 patent on all grounds raised in the Petition. We base our factual findings and conclusions at this stage of the proceeding on the evidentiary record developed so far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims 14 and 15. Any final decision will be based on the record as fully developed during trial.

## I. BACKGROUND

### *A. The '021 Patent*

The '021 patent relates to applicator assemblies for mixing and applying two or more components. Ex. 1001, 1:18–21. The patent describes that in applicator assemblies used to dispense reactive components mixing of the components does not occur until the solution is ready to be applied to avoid premature hardening of the mixture. *Id.* at 1:26–34. The patent

describes that these applicator assemblies have one or more active or passive mixing means for mixing the components before application and may have a spray assembly through which the mixed solution is ejected. *Id.* at 1:34–40. The patent teaches that "[t]horough mixing of the two or more components prior to application is important to ensure that the solution will perform as intended." *Id.* at 1:40–42.

In the applicator assembly of the '021 patent, first and second components pass from component sources through separate channels in a manifold and through separate lumens in an elongated shaft. *Id.* at 1:46–56. Then, the components mix within a tip assembly before being ejected from an outlet in the tip assembly. *Id.* at 1:56–63. The tip assembly defines a first chamber configured to receive a distal end of the elongated shaft, an intermediate or second chamber configured to receive an insert, and a final chamber configured to receive the partially mixed components. *Id.* The insert is a substantially cylindrical body. *Id.* at 2:9–10.

The '021 patent describes an embodiment of the applicator assembly shown in Figure 7 reproduced below.

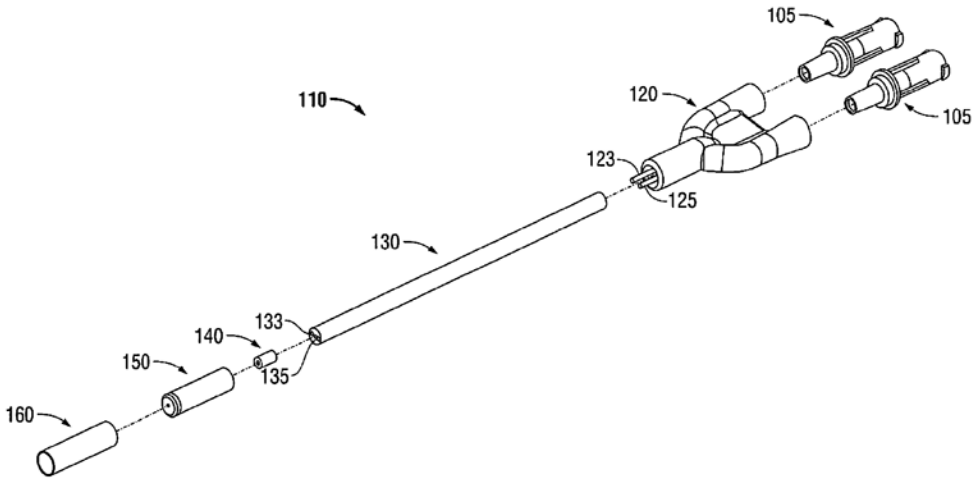


FIG. 7

Figure 7 shows an exploded perspective view of applicator assembly 110. *Id.* at 2:61–63. Applicator assembly 110 includes manifold 120 configured to receive check valves 105, elongated shaft 130 extending from manifold 120, spray tip assembly 150 positioned on a distal end of elongated shaft 150, insert 140 received within spray tip assembly 150, and shrink tube 160 received about spray tip assembly 150. *Id.* at 5:28–35. First and second component channels 123, 125 extend from manifold 120 and are in fluid communication with first and second component lumens 133, 135 extending through elongated shaft 130. *Id.* at 5:36–40.

The '021 patent describes that an alternate embodiment of spray tip assembly 50 includes first chamber 54, intermediate chamber 56, and final chamber 58. *Id.* at 4:9–11. These chambers are shown below in Figure 3.

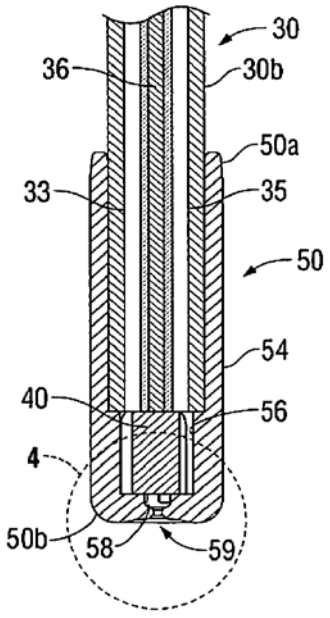


FIG. 3

Figure 3 is a cross-sectional side view of spray tip assembly 50 of applicator assembly 10. *Id.* at 2:48–49. The patent describes that (1) first chamber 54 defines a substantially cylindrical cavity for receiving a distal end of

elongated shaft 30, (2) intermediate chamber 56 defines a substantially cylindrical cavity configured to receive insert 40, and (3) final chamber 58 defines a substantially cylindrical cavity which receives the partially mixed first and second components from intermediate chamber 56, and through which the components pass to outlet 59. *Id.* at 4:11–13, 19–20, 36–37, 44–46, 50–51. The '021 patent states that applicator assembly 110 is substantially similar to applicator assembly 10. *Id.* at 5:26–27. Thus, we understand spray tip assembly 150 includes the same three chambers as discussed above in spray tip assembly 50. *Id.*, Fig. 10.

Returning to applicator assembly 110 shown in Figure 7, the '021 patent describes insert 140 in more detail with reference to Figures 9 and 10, reproduced below.

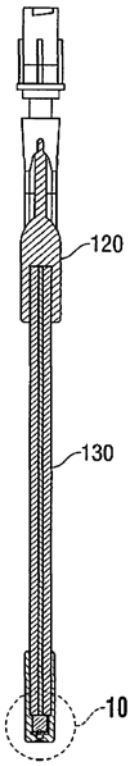


FIG. 9

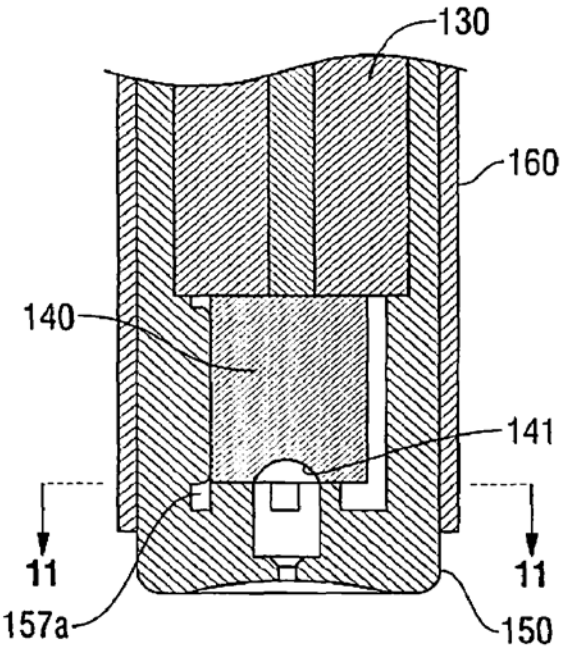


FIG. 10

Figure 9 is a cross-sectional side view of applicator assembly 110, and Figure 10 is an enlarged sectional view of section 10 of Figure 9. *Id.* at 2:66–3:2. The '021 patent describes that insert 140 is a substantially cylindrical member positioned within spray tip assembly 150 to force the first and second components to flow around the insert. *Id.* at 4:23–26 (discussing insert 40 of first embodiment), 5:43–46 (describing insert 150 as substantially similar to insert 40). In the embodiment of Figures 7–11, insert 140 includes hemispherical recess 141 on one end. *Id.* at 5:46–49. The patent teaches that recess 141 creates turbulence in the flow of the first and second components prior to the mixture being ejected through the spray tip assembly outlet. *Id.* at 5:49–52.

### *B. Challenged Claims*

Challenged claims 14 and 15 are reproduced below.

> 14. An applicator assembly for dispensing a mixture, the assembly comprising:
>
> a first portion defining first and second component lumens each having proximal and distal ends, the proximal ends of the first and second component lumens being configured for fluid communication with respective first and second sources of component;
>
> a second portion defining a mixing chamber, the distal end of the first and second component lumens being in fluid communication with the mixing chamber,
>
> a third portion defining an outlet in fluid communication with the mixing chamber, and
>
> an insert disposed within the mixing chamber between the first and second component lumens and the outlet, the insert including a cylindrical member having a recess formed in a first end thereof.

Ex. 1001, 6:52–67.

> 15. The applicator assembly of claim 14, wherein an outer diameter of the insert is uniform along an entire length of the insert.

*Id.* at 7:1–3.

*C. References*

Petitioner relies on the following prior art references in the asserted grounds of unpatentability:

a) *Spero*: U.S. Patent Application Pub. No. 2003/0069537 A1, published April 10, 2003, filed in the record as Exhibit 1005.

b) *Haber*: U.S. Patent No. 5,341,993, issued August 30, 1994, filed in the record as Exhibit 1007.

c) *Kitabayashi*: Japanese Unexamined Utility Model Publication No. JP H03-032959 U, published March 29, 1991, filed in the record as Exhibit 1008, and certified translation filed in the record as Exhibit 1009.

d) *Capozzi*: U.S. Patent No. 5,116,315, issued May 26, 1992, filed in the record as Exhibit 1011.

e) *Dodge*: U.S. Patent No. 7,037,289 B2, issued May 2, 2006, filed in the record as Exhibit 1012.

f) *Voegele*: U.S. Patent Application Pub. No. 2008/0121657 A1, published May 29, 2008, filed in the record as Exhibit 1013.

*D. Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 14 and 15 of the '021 patent on each of the following grounds (Pet. 3):

| Ground | Statutory Basis | Reference(s) |
|---|---|---|
| 1 | § 103 | Spero and Haber |
| 2 | § 103 | Spero and Kitabayashi |

| Ground | Statutory Basis | Reference(s) |
|---|---|---|
| 3 | § 103 | Capozzi |
| 4 | § 103 | Dodge and Haber |
| 5 | § 102 | Voegele |

Petitioner supports its challenge with a Declaration of Paul Hattan, filed as Exhibit 1003 ("Hattan Declaration").

*E. Real Parties in Interest*

Petitioner identifies itself and Stryker Corporation as real parties in interest. Pet. 1; Petitioner's Updated Mandatory Notices (Paper 10). Patent Owner identifies itself, Integra LifeSciences Corp., and Integra LifeSciences Sales LLC as real parties in interest. Patent Owner's Mandatory Notices Under 37 C.F.R. § 42.8 (Paper 5).

*F. Related Matters*

Patent Owner has asserted the '021 patent against Petitioner in the United States District Court for the District of Delaware in *Confluent Surgical, Inc., et al. v. HyperBranch Med. Tech., Inc.*, C.A. No. 17-688-LPS-CJB (D. Del.). Pet. 1; Paper 5.

The '021 patent is a continuation of U.S. Patent No. 8,387,899, which is a continuation of U.S. Patent No. 8,803,483 ("the '483 patent"). In addition to the current Petition for *inter partes* review of the '021 patent, Petitioner also filed a petition for *inter partes* review of the '483 patent. IPR2018-01097 (filed May 15, 2018). Patent Owner also asserts the '483 patent in the above-referenced district court litigation.

Petitioner also filed petitions for *inter partes* review of three other patents involved in the above-referenced district court litigation, i.e., U.S. Patent No. 8,210,453 B2 (IPR2018-01168, filed May 29, 2018), U.S. Patent No. 9,517,478 B2 (IPR2018-01191, filed June 6, 2018), and U.S. Patent No.

9,700,290 B2 (IPR2018-01192, filed June 6, 2018). Although these three patents are not related by a claim to priority to the '021 patent, the subject matter of the challenged claims in these three patents, each of which is directed to a spray assembly, is similar to the subject matter of challenged claims 14 and 15 in the present case.

## II. ANALYSIS

### *A. Legal Standards*

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.[1] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review

[1] Patent Owner does not offer objective evidence of non-obviousness or argue any secondary considerations.

petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")); *see also* 37 C.F.R. § 42.104(b) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon). Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

*B. Level of Ordinary Skill in the Art*

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation marks and citation omitted). Petitioner contends that a person having ordinary skill in this art would have either:

> (1) a master's degree in the field of mechanical engineering and/or a related field having at least one year of educational or work experience in the design and development of liquid mixing and dispensing applicator systems; (2) a bachelor's degree in the field of mechanical engineering and/or a related field and at least 2 years of work experience in the design and development of liquid mixing and dispensing applicator systems; or (3) any education and experience equivalent to (1) or (2).

Pet. 15–16 (citing Ex. 1003 ¶¶ 68). Patent Owner does not dispute Petitioner's proposed definition of the level of ordinary skill in the art. For purposes of this Decision, we adopt the definition of a person of ordinary skill in the art as proposed by Petitioner.

*C. Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear.[2] 37 C.F.R. § 42.100 (2016). Under the broadest reasonable interpretation standard, claim terms generally are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner and Patent Owner present positions as to the following claim terms:

*1. "A First End"*

Petitioner asserts that "a first end" is "an end" and "can refer to either the proximal or the distal end of the insert." Pet. 14–15 (citing Ex. 1001, 6:52–67; Ex. 1003 ¶¶ 59–60).

For purposes of the preliminary response, Patent Owner does not contest Petitioner's proposed construction. Prelim. Resp. 15–16.

We do not need to construe the term "a first end" to institute this proceeding.

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[2] This Petition was filed before the effective date of the amendment to 37 C.F.R. § 42.100 that changed the claim construction standard applied in *inter partes* reviews. *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 FR 51340 (Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42). Thus, we use the broadest reasonable interpretation claim construction standard for this proceeding.

*2. "Insert"*

Petitioner does not offer a construction for the claim term "insert." Pet. 14–15. Implicit in the position taken by Petitioner in asserted ground 3, Petitioner considers an extension formed integrally with a body of a spray assembly as satisfying the claimed "insert." *Id.* at 64–65.

Patent Owner asserts that "insert" refers to "an inserted piece." Prelim. Resp. 39. Patent Owner argues that a piece formed integrally with a spray head or spray assembly does not constitute an "insert." *Id.*

We interpret "insert" to address the parties' conflicting positions. The '021 patent describes that the applicator assembly includes a tip assembly defining an intermediate or second chamber "configured to receive an insert." Ex. 1001, 1:56–59. The intermediate chamber may include ribs "for maintaining the insert in a spaced relationship from a wall of the chamber." *Id.* at 1:66–2:1.

The '021 patent describes that insert 40 is "configured to be received within spray tip assembly 50" and that intermediate chamber 56 "defines a substantially cylindrical cavity configured to receive insert 40." *Id.* 3:14–15, 4:19–20, Figs. 1, 3, 4 (depicting insert 40 as a separate piece from spray tip assembly 50). The '021 patent describes that intermediate chamber includes ribs 56*a* "for maintaining insert 40 (shown in phantom in FIG. 6) centered within intermediate chamber 56." *Id.* at 4:21–23. The '021 patent describes that, prior to use of applicator assembly 10, "insert 40 is received within intermediate chamber 56 of spray tip assembly 50." *Id.* at 4:57–59. The patent describes that insert 140 "is substantially similar to insert 40, including a substantially cylindrical member configured to be received within spray tip assembly 150." *Id.* at 5:43–46; *see also id.* at 5:33–34

(describing insert 140 is "received within spray tip assembly 150"); Figs. 7–10 (depicting insert 140 as a separate piece from spray tip assembly 150).

An ordinary meaning of "insert" (noun) is "something that is inserted." Ex. 3001, *Insert Definition*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/insert (last visited November 19, 2018). The ordinary meaning of "insert" (transitive verb) includes: (1) "to put or thrust in," (2) "to put or introduce into the body of something," (3) to set in and make fast, and (4) "to place into action (as in a game)." *Id.*

The use of "insert" in the '021 patent is consistent with the ordinary meaning of the term as a thing that is introduced into the body of something else. We could not find, and Petitioner has not directed us to any, disclosure in the '021 patent to support an interpretation of an "insert" that, contrary to its plain and ordinary meaning, encompasses a piece formed integrally with the part within which it resides. *See* 37 C.F.R. § 42.104(b)(3) (requiring Petition to identify how the challenged claim is to be construed). Thus, we do not adopt Petitioner's interpretation of "insert" that is implicit in asserted ground 3.

*3. "Cylindrical Member"*

Petitioner does not offer a construction for the claim term "cylindrical member." Pet. 14–15. Implicit in the position taken by Petitioner in asserted ground 5, Petitioner considers a mixer having rounded top and bottom sections that form a portion of a cylinder as satisfying the claimed "cylindrical member." *Id.* at 84–85.

Patent Owner asserts that an interpretation of a "cylindrical member" that encompasses a member forming a portion of a cylinder is unreasonably broad because it is not supported by the Specification of the '021 patent and

is at odds with the plain and ordinary meaning of the term.[3] Prelim. Resp. 61–62.

The parties have proposed conflicting positions for the scope of the term "cylindrical member." We interpret "cylindrical" to address the parties' conflicting positions. An ordinary meaning of "cylindrical" is "relating to or having the form or properties of a cylinder." Ex. 3002, *Cylindrical Definition*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/cylindrical (last visited November 19, 2018). "Cylinder" is defined as "the surface traced by a straight line moving parallel to a fixed straight line and intersecting a fixed planar closed curve." Ex. 3003, *Cylinder Definition*, https://www.merriam-webster.com/dictionary/cylinder, Definition 1a (last visited November 19, 2018).

The '021 patent describes various features of the applicator assembly as being "substantially cylindrical." Ex. 1001, 3:48–49 (describing spray tip assembly 50 as defining "a substantially cylindrical body 52"); *id.* at 4:11–12 (describing first chamber 54 as defining a "substantially cylindrical cavity"); *id.* at 4:19–20 (describing intermediate chamber 56 as defining a "substantially cylindrical cavity"); *id.* at 4:23–24 (describing insert 40 as including "a solid, substantially cylindrical member"); *id.* at 4:36–37 describing final chamber 58 as defining a "substantially cylindrical cavity having a tapered distal portion 58*a*"); *id.* at 5:43–45 (describing insert 140 as including a "substantially cylindrical member"). In each instance, the

[3] Patent Owner does not proffer a dictionary definition of the term "cylindrical member."

feature described as being "substantially cylindrical" includes a circular cross-section. *Id.* at Figs. 6, 6A, 11.

Thus, the '021 patent uses the term "cylindrical" in a manner consistent with its ordinary meaning, to refer to a member that is in the shape of a surface traced by a straight line moving parallel to a fixed straight line and intersecting a fixed planar closed curve. In other words, we do not interpret a "cylindrical member" to encompass a member that has the shape of a portion of a cylinder.

With these claim interpretations in mind, we now examine the grounds asserted in the Petition.

*D. Overview of Analysis*

Petitioner has shown a reasonable likelihood that at least one claim of the '021 patent is unpatentable under at least the first asserted ground. As explained in our discussion below, we do not find a sufficient basis to use our discretion to deny institution under 35 U.S.C. § 325(d) for this ground.

Per *SAS*, the decision to institute is "a binary choice—either institute review or don't." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018). Having decided to institute on the first asserted ground as to at least one challenged claim, under *SAS*, we institute on all asserted grounds and all challenged claims. *Id.*

In addition to explaining our reasons for instituting based on the asserted first ground, we address the remaining grounds below to provide guidance to Petitioner and Patent Owner in the ensuing proceeding.

*E. Obviousness over Spero and Haber (Ground 1)*

*1. 35 U.S.C. § 325(d)*

Patent Owner argues that the Board should deny institution of the first ground because Spero was considered during prosecution of the '021 patent,

and because the disclosure in Spero overlaps substantially with Hagmann (Ex. 2001), which the Examiner applied to reject the initial claims during prosecution of the grandparent '483 patent. Prelim. Resp. 6.

We weigh the following factors when deciding whether to exercise our discretion under section 325(d): (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *See Becton, Dickinson and Company v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 17–18 (PTAB December 15, 2017) (Paper 8) (informative).

Spero was before the Examiner during examination of the '021 patent. Ex. 1001, section (56) (listing Spero under "References Cited"). Also, the disclosure of Spero overlaps with the disclosure of Hagmann. For instance, Figures 1–18 of Spero are the same as Figures 1–18 of Hagmann. *Compare* Ex. 1005, Figs. 1–18, *with* Ex. 2001, Figs. 1–18. During prosecution of the grandparent '483 patent, the Examiner rejected the initial claims as anticipated by Hagman or unpatentable over Hagman in view of additional prior art. Ex. 2007 at 112–113. Applicant amended prosecution claim 20 to recite "an insert received in the second chamber, the insert including a

substantially cylindrical member having a recess formed in a distal end thereof." *Id.* at 127. The Examiner then allowed this claim. *Id.* at 145. We infer from this action that the Examiner found that Hagman does not disclose the claimed insert having a recess formed in a distal end.

Petitioner is not seeking to revisit this finding in the asserted combination of Spero and Haber. Instead, Petitioner is filling this gap in the teachings of Spero by providing the teachings of Haber. Pet. 39 (acknowledging that Spero's insert does not include a recess in a first end).

Haber was not before the Examiner during examination of the '021 patent. Patent Owner does not contend that Haber, which teaches a swirl atomizer insert, is cumulative of any references considered and/or applied by the Examiner during prosecution of the '021 patent. Prelim. Resp. 7 (Patent Owner arguing only that Haber does not "give[] rise to a meritorious obviousness ground").

The Examiner does not appear to have considered the combined teachings of Spero and Haber during examination of the '021 patent. Patent Owner cites no arguments during prosecution of the grandparent '483 patent or any member of the '483 patent family that overlap with Petitioner's arguments regarding Spero and the Spero/Haber combination in this proceeding.

For these reasons, we do not exercise our discretion under 35 U.S.C. § 325(d) to deny institution. We now turn to a review of the proposed ground.

*2. Spero*

Spero describes laparoscopic spray device 10 that includes interface member 12 in fluid communication with elongated body 14 that is attached

to spray head 16. Ex. 1005 ¶ 34. Spray device 10 is shown below in Figure 1.

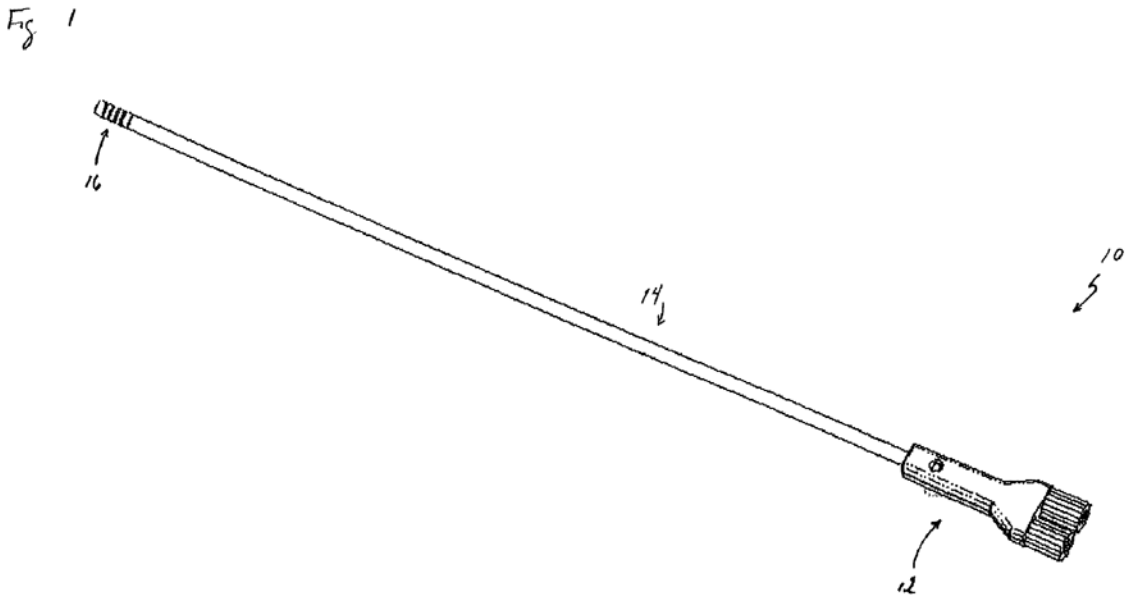



Figure 1 shows a perspective view of laparoscopic spray device 10. *Id.* ¶ 13. Spray device 10 can be used to dispense multiple components from material applicator 34. *Id.* ¶ 40, Fig. 6 (shown below).

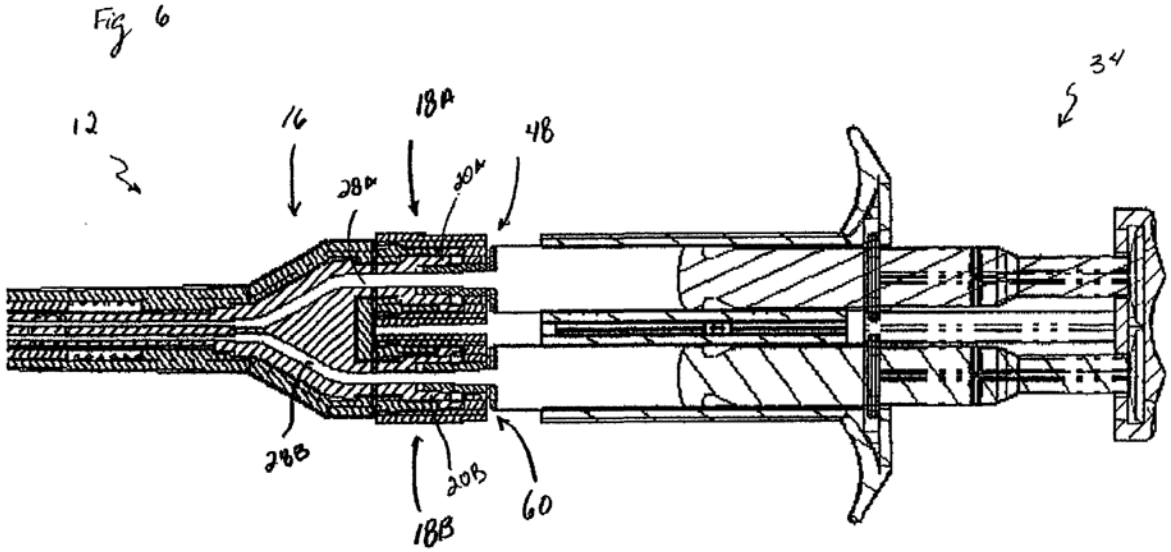



Figure 6 shows a cross-sectional view of multiple syringe material applicator 34 coupled to interface member 12. *Id.* ¶ 18. Each syringe stores

a component. *Id.* ¶¶ 38–39. Interface member 12 includes coupling members 18A, 18B having receiving apertures 20A, 20B sized to receive material applicator 34. *Id.* ¶ 35. Receiving apertures 20A, 20B are in fluid communication with transport lumens 28A, 28B located within interface member 12. *Id.* ¶ 36. Elongate body 14 includes body lumens 32A, 32B engaged with and in fluid communication with transport lumens 28A, 28B. *Id.* ¶ 44.

Spray tip 16 is configured to mount detachably to elongated body 14. Ex. 1005 ¶ 47, Figs. 17, 18 (shown below).

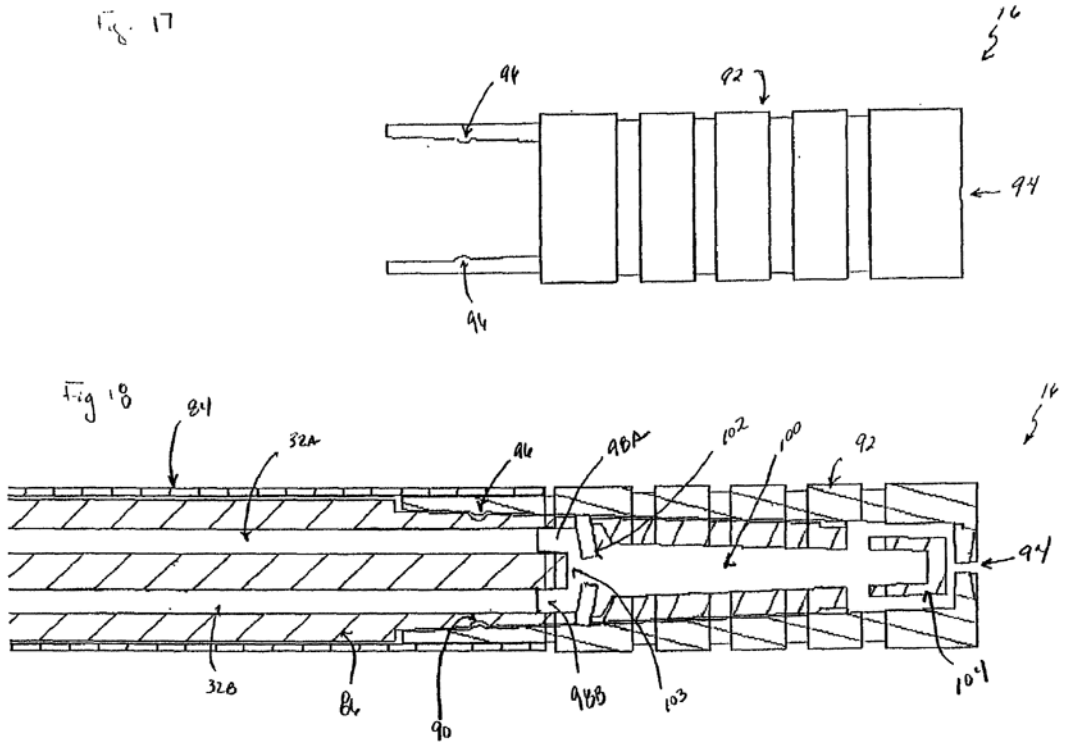



Figure 17 shows a side view of detachable spray tip 16, and Figure 18 shows a cross-sectional view of spray tip 16 attached to elongate body 14. *Id.* ¶¶ 29–30. Spray tip 16 includes a tip body having lumen receivers 98A, 98B to receive elongated body lumens 32A, 32B. *Id.* ¶ 48. Spray tip 16 also includes mixing chamber 100 in communication with lumen receivers 98A,

98B, at least one flexible mixing member 102 positioned within mixing chamber 100 proximate the lumen receivers, and spray regulator 104 positioned within mixing chamber 100 proximate to spray aperture 94. *Id.* ¶ 49–50.

Spero describes that flexible mixing member 102 "assists in causing impingement mixing of the at least two material components by forming a turbulent flow within the mixing chamber 100." *Id.* ¶ 49 (describing that mixing member 102 forms a "narrowing element" to force the components together within mixing chamber 100 and resistance applied by mixing member 102 combined with forward advancement of the material results in generation of "turbulent flow"). Spero describes that spray regulator 104 "further ensures that the material located within the mixing chamber 100 [is] adequately mixed and provides impedance within the mixing chamber 100 to aid in forming a material spray." *Id.* ¶ 50.

Consistent with the disclosure described above, the Petition provides annotated figures of Spero and citations to the disclosure in Spero sufficient to present a reasonable likelihood of showing that Spero discloses all elements of challenged claim 14 except for the specific configuration of the insert as recited in the claim. Pet. 33–39. For instance, Petitioner shows a reasonable likelihood that Spero discloses an applicator assembly comprising a first portion (12, 14) defining first and second component lumens (28A + 32A, 28B + 32B) in fluid communication with first and second sources of components (Fig. 6), a second portion (part of spray tip 16) defining a mixing chamber (100) in fluid communication with the first and second component lumens, a third portion (part of spray tip 16) defining an outlet (94) in fluid communication with the mixing chamber (100), and an insert (104) within the mixing chamber (100) between the first and second

component lumens (28A + 32A, 28B + 32B) and the outlet (94). *Id.* Although Spero's spray regulator 104 is an insert within the mixing chamber (100) defined by second portion (16), Petitioner proposes to replace Spero's insert with Haber's insert, which Petitioner asserts is a cylindrical insert with a recess in a first end of the insert. *Id.* at 39–40.

*3. Haber*

Haber discloses a hand-held topical sprayer for application of atomized liquids via a spray tip. Ex. 1007, 2:31–34. Haber shows a perspective view of an embodiment of this topical sprayer in Figure 1 and a cross-sectional view of sprayer 2 in Figure 4, both reproduced below. *Id.* at 3:40–42, 49–53.

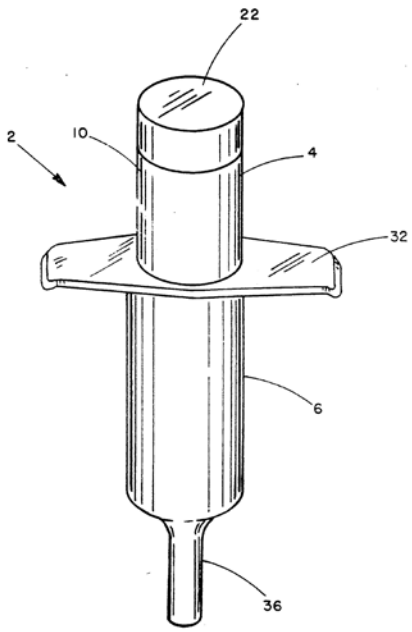



FIG. 1

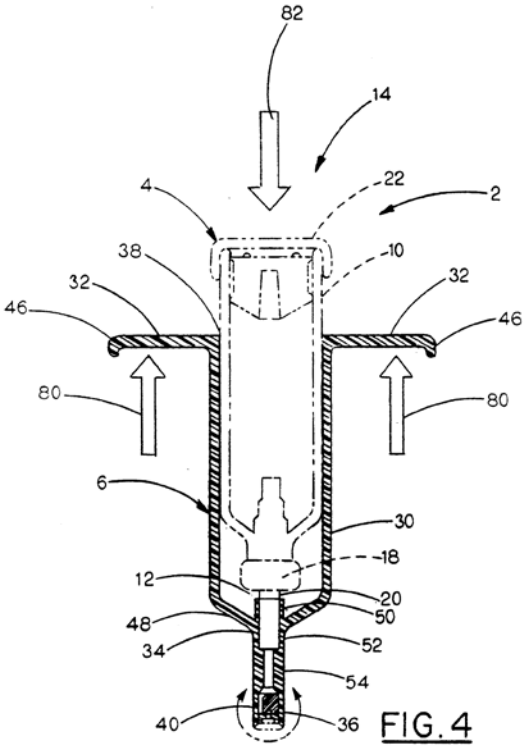



FIG. 4

Figure 1 shows topical sprayer 2 including sprayer sub-assembly 4 inserted into spray head adapter 6. *Id.* at 4:6–11. Figure 4 shows spray head adapter 6 including body 30, which tapers to nose 34 and terminates at the

distal end with spray tip 36. *Id.* at 5:18–22. Spray tip 36 houses swirl atomizer 40 and nozzle 42. *Id.* at 5:24–25.

Haber shows details of the structure of swirl atomizer 40 in Figures 5 through 7, reproduced below.

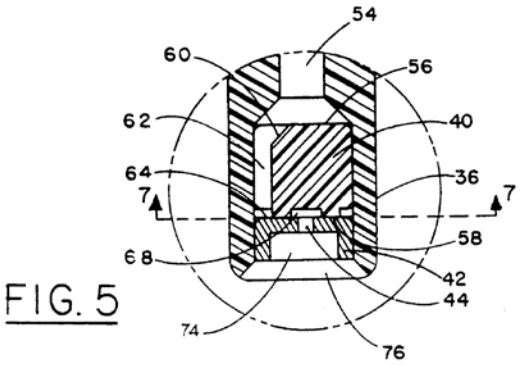



FIG. 5

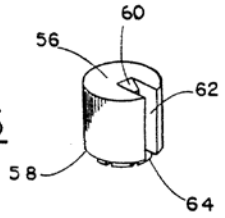



FIG. 6

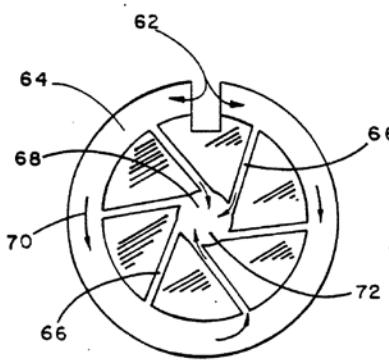



FIG. 7

Figure 5 shows a magnified cross-sectional view of spray tip 36 and swirl atomizer 40. *Id.* at 6:36–38. Figure 6 shows a perspective view of swirl atomizer 40. *Id.* at 3:57–58. Figure 7 shows a front view of swirl atomizer taken along line A–A of Figure 5. *Id.* at 3:59–60. Haber describes,

"[e]xiting liquid flows from the upstream end 56 to the downstream end 58 of swirl atomizer 40 and exits spray tip 36 through spray aperture 44 of nozzle 42." *Id.* at 6:43–46. Swirl atomizer 40 channels liquid via recessed slope 60 into and through side channel 62 and then around ring channel 64, as indicated by arrows 70 in Figure 7. *Id.* at 6:51–54, 60–62. The liquid then divides and passes through spoke channels 66, which "tangentially converge" to central aperture 68. *Id.* at 6:64–67, Fig. 7. Haber describes, "[t]he configuration of spoke channels 66 cause[s] the plurality of liquid jet streams to collide at angles relative to one another at high pressure and velocity and thereby atomize under turbulence within central aperture 68 and exit through spray aperture 44 of nozzle 42." *Id.* at 6:67–7:4. Haber recognizes that "alternative spray tip nozzles and channel geometry could be used with spray head adapter 6 as desired for adaption to liquids of different viscosities." *Id.* at 7:13–16.

Consistent with the disclosure described above, the Petition provides annotated figures of Haber and citations to the disclosure in Haber sufficient to present a reasonable likelihood of showing that Haber discloses a dispenser spray nozzle that houses an insert (40) having a recess formed in its distal end. Pet. 40–42. For instance, Petitioner shows a reasonable likelihood that Haber's insert (40) includes recesses (ring channel 64, spoke channel 66, and central aperture 68) in its distal end. *Id.*

Further, the Petition provides adequate reasoning supported by sufficient evidence to present a reasonable likelihood of showing that it would have been obvious to modify Haber's swirl atomizer to include a cylindrical member. Haber's insert 40, which includes recessed slope 60 and side channel 62, is substantially cylindrical. Petitioner presents a reasonable likelihood that it would have been an obvious design choice

within the ordinary skill in the art to remove the recessed slope 60 and side channel 62 and make Haber's insert a solid cylinder, as evidenced by known prior art solid cylindrical swirl atomizer inserts. Pet. 41 (citing Ex. 1003 ¶ 116; Ex. 1010 (Green); Ex. 1008 (Kitabayashi)). Petitioner presents a reasonable likelihood that a person of ordinary skill in the art would have recognized to make the outer diameter of swirl atomizer 40 smaller to allow for an annular space between the insert and the walls of the mixing chamber to allow fluids to flow along the insert around its circumference to reach the recesses on the distal end. *Id.* at 41–42 (citing Ex. 1003 ¶ 116) (explaining other prior art swirl atomizer inserts employed such a flow path using an annular space, including Spero).

As to dependent claim 15, Petitioner has presented sufficient evidence in the Petition to show a reasonable likelihood that Haber's swirl atomizer renders obvious the claimed subject matter. Pet. 50–52. Petitioner asserts that if the claim language "an entire length" is interpreted to mean the entire length of the insert, then a person having ordinary skill would be motivated, in the process of modifying Haber's insert to make it a solid cylindrical member, to eliminate ring channel 64 in addition to eliminating recessed slope 60 and side channel 62, and to extend spoke channels 66 to the outer diameter of the insert. *Id.* at 51–52 (citing Ex. 1007, Figs. 6 & 7 and Ex. 1003 ¶ 148). Patent Owner does not address substantively Petitioner's challenge to this dependent claim. Prelim. Resp. 16–29.

*4. Proposed Combination*

Petitioner provides several reasons why it would have been obvious to one having ordinary skill in the art to replace Spero's spray regulator 104 with Haber's swirl atomizer. Pet. 42–47. Petitioner asserts that Spero provides motivation to replace spray regulator 104 because it teaches that

spray regulator 104 and spray aperture 94 affect the spray behavior and it suggests that alternative spray tips can be used. *Id.* at 42 (citing Ex. 1005 ¶¶ 50, 54). Thus, Petitioner asserts that a person of ordinary skill in the art would understand Spero to suggest modifying its spray regulator and/or spray tip "to achieve desired mixing and spraying characteristics." *Id.* (citing Ex. 1003 ¶ 117). Based on this suggestion in Spero, Petitioner asserts that replacing Spero's spray regulator 104 with Haber's swirl atomizer would be (1) simple substitution of one known element for another to obtain predictable results; (ii) use of a known technique to improve similar devices in the same way; (iii) applying a known technique to a known device ready for improvement to yield predictable results; and (iv) obvious to try. *Id.* at 42–43 (citing Ex. 1003 ¶ 118).

In addition to the suggestion found in Spero, Petitioner also asserts that selecting from a number of well-known, successful design options, including Haber's swirl atomizer, is a matter of routine design choice within the skill of the art and provides no novel or unexpected results. *Id.* at 43 (citing Ex. 1003 ¶¶ 119, 121). Petitioner also asserts that a person having ordinary skill in the art would have been motivated to replace Spero's spray regulator 104 with Haber's swirl atomizer 40 "to improve mixing and atomization of the adhesive components." *Id.* at 43–44 (citing Ex. 1003 ¶ 120) (asserting that depiction of spray regulator 104 in Spero is "incomplete" and that spray regulator 104, as depicted, was "a sub-optimal solution" for achieving the stated goals). Petitioner asserts that one having ordinary skill in the art would understand that Haber's swirl atomizer would more effectively and efficiently achieve Spero's objectives than Spero's spray regulator 104. *Id.* at 45 (citing Ex. 1003 ¶¶ 120–121, 123–129). Petitioner asserts that one having ordinary skill would desire enhanced

mixing and atomization because (1) "components that are more thoroughly mixed and better atomized . . . provide a more uniform sealant layer, which beneficially decreases the likelihood of thin spots that may fail prematurely thereby . . . promoting wound healing," (2) components that are more thoroughly mixed and better atomized "reduce component waste." *Id.* at 46 (citing Ex. 1003 ¶¶ 122, 130–134).

Petitioner provides that a person having ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Spero and Haber because (1) spray regulator 104 and swirl atomizer 40 are "similarly situated elements with similar structures," (2) the effects of swirl atomizers on fluid flow were well known at the time of filing of the '021 patent, and (3) the substitution would have required only routine skill. *Id.* at 47–50 (citing Ex. 1003 ¶¶ 135–136, 139–145).

*5. Patent Owner's Contentions*

Patent Owner does not challenge Petitioner's assertions about the scope and content of Spero and Haber. Patent Owner contests only Petitioner's proposed combination of the teachings of Spero and Haber. Prelim. Resp. 16–29 (arguing the combination is based on impermissible hindsight reconstruction). As explained below, we find, at this stage, that the Petition presents a reasonable likelihood of success based on the Petition's explanation of the obviousness of the proposed combination.

Patent Owner argues that Petitioner ignores the different aims of Spero and Haber. *Id.* at 19–20. Specifically, Patent Owner argues that Spero focuses on mixing multiple components and dispensing a spray while avoid clogging problems, but Haber focuses on atomizing a single liquid component medication. *Id.* (citing Ex. 1005 ¶¶ 7, 50; Ex. 1007, 1:15−19, 2:31–32). Petitioner provides sufficient evidence to show a reasonable

likelihood that one having ordinary skill in the art at the time of the invention was aware of the use of swirl atomizers to mix and atomize dual components in applicators similar to Spero's device. Pet. 43; Ex. 1003 ¶¶ 119, 121 (citing Ex. 1011, 7:15–23; Ex. 1039, 5:18–23, Fig. 6; Ex. 1019, 6:49–58; Ex. 1006 ¶ 25 (supporting assertion that a person of ordinary skill "would have recognized that other prior art dual component applicators employed similar swirl atomizer geometries and/or swirling flows to achieve mixing and atomization of the components").

Patent Owner argues that Petitioner fails to adequately support the assertion that one having ordinary skill would have recognized Spero's spray regulator 104 as "a sub-optimal solution." Prelim. Resp. 20–21 (arguing Mr. Hattan's testimony lacks underlying facts or data). Petitioner's expert explains that Spero's spray regulator 104 is a smooth plug that would force the flow of materials around the plug before exiting spray aperture 94. Ex. 1003 ¶ 120 (citing Ex. 1005 ¶ 50, Fig. 18). Upon reaching the distal end of spray regulator 104, the material would be forced to change direction and flow radially inwards along the smooth walls of the distal end of spray regulator 104 and the interior of mixing chamber 100, which do not otherwise channel the flow or impart a substantial swirling component to the flow. *Id.* Based on this interpretation of the flow of material in Spero, the expert opines that a person of ordinary skill would have recognized the structure described in Spero was sub-optimal for ensuring adequate mixing and spray formation. *Id.* (citing Ex. 1021, 20). The cited reference discusses the use of swirl atomizers for mixing two components with gas. Ex. 1021, 20. The expert provides that a person having ordinary skill would have recognized that the recesses forming the well-known simplex swirl atomizer geometry of the Haber insert would act to induce a turbulent

swirling flow for more effective and efficient mixing and atomization of the components in Spero. *Id.* We find that Petitioner has supported its assertion that Spero's spray regulator 104 would have been understood to be sub-optimal with explanation by an expert declarant with reference to supporting technical literature. This assertion is adequately supported to establish a motivation to modify Spero with Haber's insert.

Patent Owner argues that Petitioner fails to provide adequate evidence to show that Haber's swirl atomizer would effectively carry-out Spero's multi-component mixing function. Prelim. Resp. 21–23 (arguing the exhibits cited in paragraphs 123–129 of the Hattan Declaration do not mention that atomization is effective for mixing multiple components). Paragraph 123 of the Hattan Declaration cites five exhibits to support the assertion that the recess configuration in swirl atomizers was well known to provide good vorticity and swirling and to impart turbulence to the flow. Ex. 1003 ¶ 123 (citing Exs. 1020, 1025, 1028, 1029, and 1032). This paragraph also cites seven exhibits to support the assertion that this swirling flow was known to result in thorough mixing and good atomization. *Id.* (citing Exs. 1019, 1020, 1030, 1031, and 1035–1037). The ensuing paragraphs describe further details about the teachings of the cited exhibits and other teachings in the art and provide technical reasoning to support the assertions in paragraph 123. *Id.* ¶¶ 124–129 (additionally citing Exs. 1021, 1038, 1040–1047). This evidence is adequate to provide a reasonable likelihood that Petitioner would prevail in proving that the proposed modification would suffice for Spero's multi-component mixing function. Patent Owner will have the opportunity to contest Petitioner's reliance on these exhibits during trial. The factual underpinnings of these assertions are

best resolved based on a fully developed record, after opportunity for cross-examination in a trial.

Patent Owner also argues that Petitioner provides a deficient explanation for how to accomplish the proposed modification. Prelim. Resp. 23–25 (arguing that because the construction of Spero's spray tip differs from Haber's structure, the combination is "not a case of simple substitution of one known element for another"). The Petition explains that replacement of Spero's spray regulator with Haber's swirl atomizer "requires an understanding of only basic engineering principles and manufacturing techniques" and "would require only minimal, if any, modification of Spero's spray tip 16." Pet. 47 (citing Ex. 1003 ¶¶ 135–136). Petitioner annotates Figure 18 of Spero to depict the proposed modification and explains how Haber's insert should be placed in Spero's mixing chamber. *Id.* at 48. We are not convinced at this stage in the proceeding that the structures of Spero's spray tip and spray regulator and Haber's spray tip and swirl atomizer are so different as to be incompatible, or that the proposed modification is beyond the level of ordinary skill in the art. Patent Owner will have the opportunity to question Petitioner's expert about the proposed modification during trial. The feasibility of the proposed modification is based on factual questions that are best resolved based on a fully developed record, after opportunity for cross-examination in a trial.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to "mix and match" the parts in Spero and Haber as proposed, and Haber provides no suggestion that its swirl atomizer "would have useful application in the sprayer of Spero." Prelim. Resp. 25–26. As discussed above, Petitioner provides adequate evidence in the form of expert testimony accompanied by numerous exhibits demonstrating the knowledge

of one having ordinary skill in the art to support the asserted motivation to make the proposed modification. Patent Owner will have the opportunity to contest Petitioner's motivation explanations during trial.

Patent Owner also argues that the Petition fails to account for the effect the different mechanisms for driving the fluid flow in each device would have on design of a suitable spray tip. *Id.* at 27–29 (contrasting Spero's syringe pushers that use lower pressures and no dosage control with Haber's pump-action device). Patent Owner argues that because Spero's device has "no inherent dosage control . . . manual pressure applied must be carefully controlled/limited [and] it would be expected that much lower pressures would result." *Id.* at 29. This assertion creates an issue of fact that is best resolved upon a full record during a trial.

Patent Owner's challenges to the proposed combination of Spero and Haber raise complex technical issues and factual issues about the understanding of a person of ordinary skill in the art that are not properly decided at this stage. Those issues are appropriately resolved after the record is fully developed, including deposition testimony of Petitioner's expert. At present, Petitioner's evidence stands unrebutted and is sufficient to present a reasonable likelihood of prevailing as to this first ground.

*6. Conclusion*

Based on the record before us, Petitioner has presented adequate evidence to show a reasonable likelihood that the elements of claims 14 and 15 are disclosed in the combined teachings of Spero and Haber and has presented adequate reasoning to show a reasonable likelihood that one having ordinary skill in the art would have been led to modify Spero with the teachings of Haber in the manner claimed. Petitioner has demonstrated a

reasonable likelihood of prevailing in a determination of unpatentability of claims 14 and 15 over Dodge in view of Haber.

*F. Obviousness over Spero and Kitabayashi (Ground 2)*

*1. 35 U.S.C. § 325(d)*

Patent Owner's arguments under 35 U.S.C. § 325(d) are the same arguments discussed above in the first ground. Prelim. Resp. 6 (arguing the Board should deny institution because Spero was considered during prosecution of the '021 patent, and because the disclosure in Spero overlaps substantially with Hagmann). Similar to the analysis above, Petitioner is not seeking in this second ground to revisit this Examiner's finding as to the deficiencies of Spero's disclosure. Instead, Petitioner is filling this gap in the teachings of Spero by providing the teachings of Kitabayashi. Pet. 39 (acknowledging that Spero's insert does not include a recess in a first end).

Kitabayashi was not before the Examiner during examination of the '021 patent. Patent Owner does not contend that Kitabayashi, which teaches a spray nozzle insert, is cumulative of any references considered and/or applied by the Examiner during prosecution of the '021 patent. Prelim. Resp. 7 (Patent Owner arguing only that Kitabayashi does not "give[] rise to a meritorious obviousness ground"). The Examiner does not appear to have considered the combined teachings of Spero and Kitabayashi during examination of the '021 patent. Patent Owner cites no arguments during prosecution of the grandparent '483 patent or any member of the '483 patent family that overlap with Petitioner's arguments regarding Spero and the Spero/Kitabayashi combination in this proceeding. For these reasons, we do not exercise our discretion under 35 U.S.C. § 325(d) to deny institution. We now turn to a review of the proposed ground.

*2. Kitabayashi*

Kitabayashi describes a spray nozzle for various types of liquids operated using manually applied pressure such as finger pressure. Ex. 1009, 2. An object of Kitabayashi is to obtain fine particle sprays without the use of organofluorine liquefied gases as a propellant by improving the structure of the spray nozzle. *Id.* at 2–3. Kitabayashi's spray nozzle includes piece 3 having recess 32 and cut grooves 34 formed in both front wall surface 35 and rear wall surface 36 of piece 3, as shown below in Figures 5 and 6. *Id.* at 3.

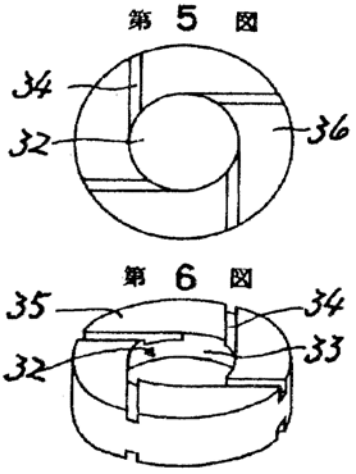



Figure 5 is a rear view and Figure 6 is a perspective view of piece 3. *Id.* at 6. Kitabayashi describes that when a piece like piece 3 is fixed within an injection passage, cut grooves 34 form a swirling flow inside recess 32, and under pressure, turbulence forms and breaks up the liquid into particles to form a spray. *Id.* at 4. Kitabayashi describes that in its spray nozzle, piece 3 is "loosely inserted" into cylindrical chamber 12 and piece 3 rotates as liquid passes through it. *Id.* at 4–5. This rotation allows for a faster swirling flow of pressurized liquid, which allows for discharge of a fine mist from the spray nozzle at lower pressures using no propellant at all. *Id.* at 5.

Consistent with the disclosure described above, the Petition provides annotated figures of Kitabayashi and citations to the disclosure in Kitabayashi sufficient to present a reasonable likelihood of showing that Kitabayashi discloses a spray nozzle that houses an insert having a cylindrical member and a recess formed in a first end. Pet. 53–55. For instance, Petitioner shows a reasonable likelihood that Kitabayashi's insert (3) includes a cylindrical member having recesses (central recess 32 and cut grooves 34) in its proximal and distal ends. *Id.*

Petitioner also has presented sufficient evidence in the Petition to show a reasonable likelihood of prevailing on the unpatentability of dependent claim 15 over Spero in view of Kitabayashi. Pet. 58. Petitioner presents evidence to show that Kitabayashi's piece 3 has a uniform outer diameter along an entire length of the insert. *Id.* (citing Ex. 1009, Figs. 3–6 (annotated) and Ex. 1003 ¶ 168). Patent Owner does not address substantively Petitioner's challenge to this dependent claim. Prelim. Resp. 29–37.

*3. Proposed Combination*

Petitioner provides reasons similar to the reasons presented in support of the first ground to explain why it would have been obvious to one having ordinary skill in the art to replace Spero's spray regulator 104 with Kitabayashi's insert "to improve both mixing and atomization of the components." Pet. 55–58 (citing Ex. 1003 ¶¶ 117–119, 152–167).

*4. Patent Owner's Contentions*

Patent Owner raises many of the same arguments raised against the first proposed ground. Prelim. Resp. 29–37. For the reasons discussed above, we conclude that Petitioner's asserted ground is sufficient for purposes of instituting trial.

Also, Patent Owner argues, "Petitioner provides no plausible explanation for how or why [Spero's spray tip with a fixed spray regulator 104] would be modified to including Kitabayashi's loosely fitted, rotatable columnar piece 3." *Id.* at 35. It appears, however, that the Petition is relying on Kitabayashi's teaching that piece 3, even if fixed within a flow channel, would provide swirling flow and turbulence sufficient to mix and atomize fluid flowing through it. Pet. 29. Thus, the Petition does not propose a modification in which Kitabayashi's insert rotates within the mixing chamber of Spero. In any event, Patent Owner will have an opportunity to question Petitioner's expert about the feasibility of the proposed modification and the applicability of teachings of Kitabayashi to the spray nozzle of Spero during trial.

*5. Conclusion*

Based on the record before us, Petitioner has presented adequate evidence to show a reasonable likelihood that the elements of claims 14 and 15 are disclosed in the combined teachings of Spero and Kitabayashi and has presented adequate reasoning to show a reasonable likelihood that one having ordinary skill in the art would have been led to modify Spero with the teachings of Kitabayashi in the manner claimed. Petitioner has demonstrated a reasonable likelihood of prevailing in a determination of unpatentability of claims 14 and 15 over Spero in view of Kitabayashi.

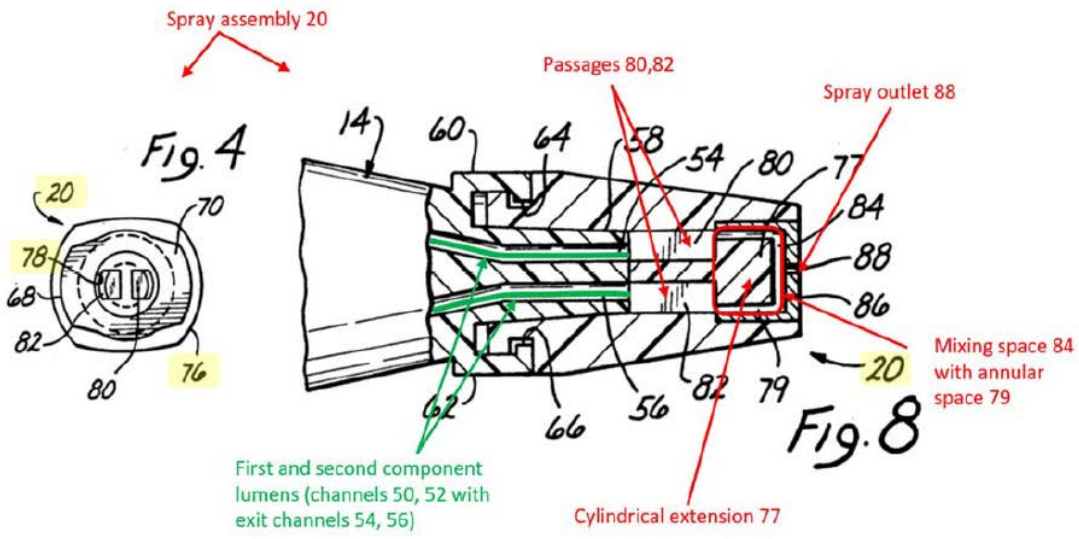
*G. Obviousness over Capozzi (Ground 3)*

Petitioner does not demonstrate, based on the record before us now, a reasonable likelihood of prevailing in proving that Capozzi discloses an "insert," as recited in claim 14. Ex. 1001, 7:64 (reciting an applicator assembly including "an insert disposed within the mixing chamber"). Petitioner asserts in the third proposed ground that Capozzi's "[c]ylindrical

extension 77 is an insert that 'extends into the mixing space 84,' which is configured to receive this insert." Pet. 61 (citing Ex. 1011, 6:48–51); *see also id.* at 64–65 and Ex. 1003 ¶ 178 (identifying cylindrical extension 77 as the claimed "insert").

Patent Owner argues that because Capozzi's cylindrical extension 77 is "formed integrally with body 76," it is not an "insert." Prelim. Resp. 39 (noting that "Petitioner has not asserted any modification of cylindrical extension 77 to be an 'insert' as claimed").

As explained above, we do not interpret "insert," for purposes of this institution decision, to encompass a piece formed integrally with the part within which it resides. Petitioner does not show, based on the record before us now, a reasonable likelihood of success in proving that Capozzi discloses an insert. Petitioner's showing consists of annotated copies of Figures 4 and 8 of Capozzi, reproduced below. Pet. 65.




Petitioner annotated Figure 8, shown above, with a red square outlining a portion of body 76 defining a mixing space and a red arrow pointing to cylindrical extension 77 of body 76 as an insert disposed within the mixing

chamber. Pet. 65; Ex. 1003 ¶¶ 169, 178. Petitioner contends, "Capozzi discloses cylindrical extension 77, which is an insert." Pet. 64. Petitioner also states, "[c]ylindrical extension 77 'extends into the mixing space 84'" and thus is an insert "disposed within the mixing chamber between the first and second component lumens and the outlet." *Id.* at 64–65.

Capozzi describes, "Body 76 of the discharge assembly includes a solid cylindrical extension 77 best depicted in FIG. 2, which extends into the mixing space 84." Ex. 1011, 6:48–51. Figure 2 of Capozzi is reproduced below.

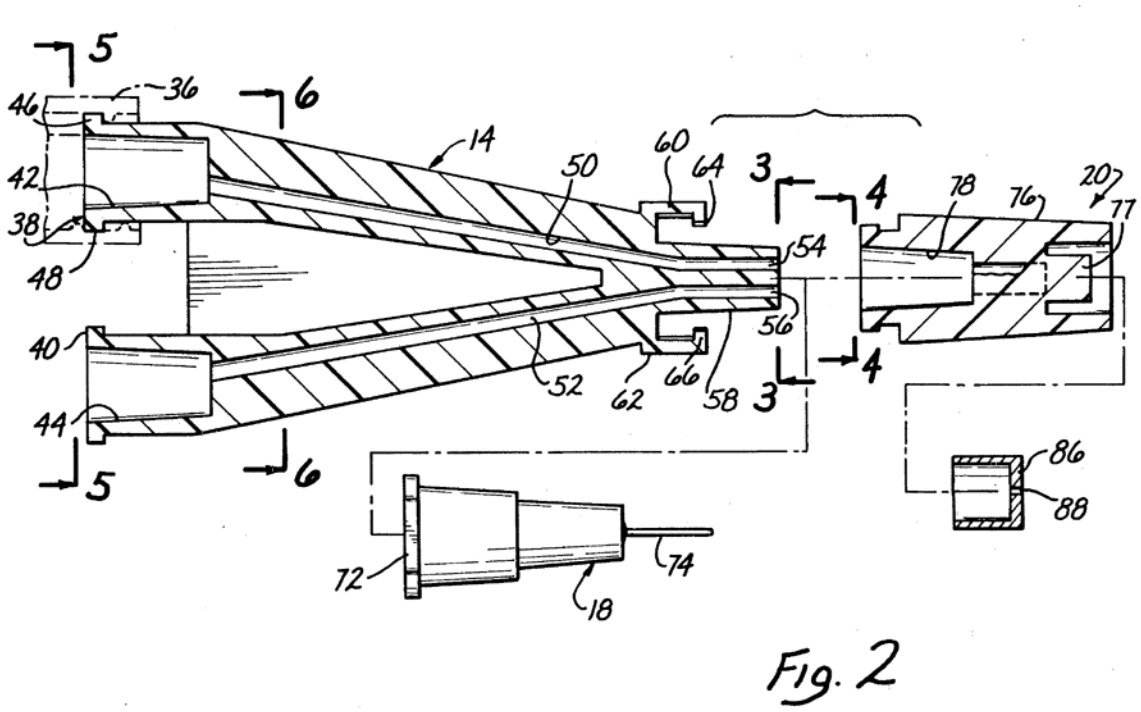



Fig. 2

Figure 2 is an enlarged cross-sectional, exploded view of manifold 14, spray assembly 20 having spray nozzle 86, and alternative needle assembly 18. Ex. 1011, 3:63–64, 4:19–23, 5:38–40. As seen above, cylindrical extension 77 of spray assembly 20 has the same cross-hatching as the remainder of body 76 of spray assembly 20. Rather than showing a separate piece inserted within the body of the spray assembly, Capozzi discloses a one-

piece spray body that defines both a mixing chamber within the body and the cylindrical extension residing within the mixing chamber.

Petitioner has failed to show adequately on the record before us how Capozzi's cylindrical extension 77, formed integrally with body 76 of spray assembly 20, is an insert disposed within the mixing chamber of the spray assembly 20. Petitioner offers only a conclusory assertion that cylindrical extension 77 is an insert. Pet. 64–65. Petitioner fails to explain how to interpret "insert" to read on Capozzi's integral cylindrical extension 77. Thus, the figures and description within Capozzi cited in the Petition, and relied on by Petitioner's declarant, do not support adequately Petitioner's assertion that Capozzi discloses an insert disposed within the mixing chamber defined in the second portion of the applicator assembly, as recited in challenged claim 14.

Petitioner does not offer any evidence or reasoning to explain why it would have been obvious to modify Capozzi's cylindrical extension 77 to make it in the form of an insert. Pet. 65–67 (proposing to modify Capozzi to add a recess on the distal end of cylindrical extension 77). For this reason, Petitioner has not demonstrated, based on the record before us now, a reasonable likelihood of success in proving that Capozzi renders unpatentable the subject matter of challenged claims 14 and 15.

### *H. Obviousness over Dodge and Haber (Ground 4)*

#### *1. 35 U.S.C. § 325(d)*

Patent Owner argues that the Board should deny institution of the fifth ground because Dodge is not any more relevant than the prior art that was before the Examiner during prosecution of the '021 patent. Prelim. Resp. 12–13. Patent Owner asserts that Dodge is cumulative of the references before the Examiner teaching a dual-syringe dispenser with a

static mixer in the dispensing tip, such as U.S. Patent No. 6,648,852 to Wirt (Ex. 2002), which the Examiner considered during prosecution. *Id.*

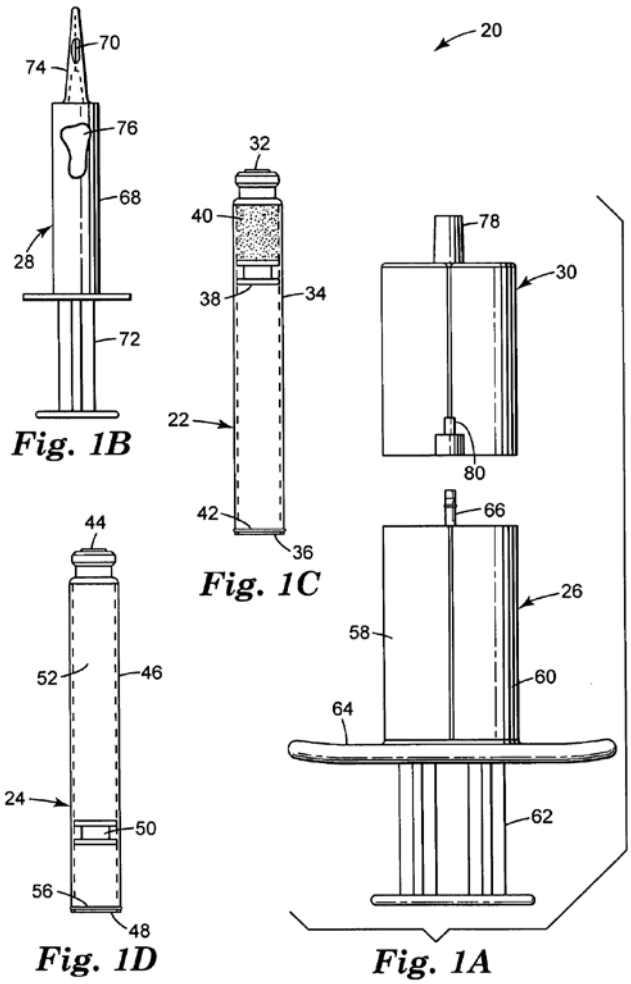
Neither Dodge nor Haber was before the Examiner during examination of the '021 patent. Wirt was before the Examiner during examination of the '021 patent, and we agree with Patent Owner that Dodge is cumulative of Wirt. Ex. 1001, section (56) (listing Wirt under "References Cited"). For instance, many of the figures in Wirt and Dodge are the same, including Figure 14 showing a dual component mixer and dispenser with a static mixer. Ex. 1012, Fig. 14; Ex. 2002, Fig. 14. Although Wirt was considered by the Examiner, the Examiner did not rely on Wirt in a rejection of the claims during examination of the '021 patent or in any of the applications to which the '021 patent claims benefit of priority. Wirt simply being of record, but not applied in any rejection by the Examiner during examination of the '021 patent, provides little impetus for us to exercise our discretion to deny institution under § 325(d).

Patent Owner does not contend that Dodge is cumulative of Hagmann, Reidel, or any other art applied by the Examiner during examination. Patent Owner also does not contend that Haber, which teaches a swirl atomizer insert, is cumulative of any references considered and/or applied by the Examiner during prosecution of the '021 patent. Prelim. Resp. 13 (Patent Owner arguing only that Haber "does not give rise to a meritorious obviousness ground in combination with Dodge"). Thus, the Examiner does not appear to have considered the combined teachings of Dodge and Haber during examination of the '021 patent.

For these reasons, we do not exercise our discretion under 35 U.S.C. § 325(d) to deny institution. We now turn to a review of the proposed ground.

*2. Dodge*

Dodge discloses a dispenser for dispensing multi-part tissue sealants that require separation of the components until just prior to application to the tissue surface. Ex. 1012, (57), Figures 1A through 1D, reproduced below, show side views of elements of dispenser kit 20.




These Figures show dispenser kit 20 including first carpule 22 (Figure 1C), second carpule 24 (Figure 1D), dual syringe body 26 for receiving the first and second carpules (Figure 1A), syringe 28 (Figure 1B), and manifold 30 (Figure 1D). Ex. 1012, 7:8–11. Carpules 22, 24 hold first and second components 40, 52, respectively. *Id.* at 7:11–17, 37–42. Manifold 30

receives dual syringe body 26 so that the manifold operably engages with carpules 22, 24. *Id.* at 7:57–67, Figs. 1A, 10, 11. Manifold 30 includes piercers 116, 118 with hollow central bores, and includes plenums 124, 126. *Id.* at 9:7–9, 17–20, Fig. 10. Manifold 30 further includes dual nozzle 78, which extends from the body of manifold 30 and includes conduits 128, 130 to fluidly connect plenums 124, 126 and openings 108, 110. *Id.* at 8:13–16, 9:17–20, Fig. 10.

Dodge describes that dispenser kit may include dispensing tip 150 that fits onto nozzle 78. *Id.* at 10:15–17, Figs. 11, 12. Dodge describes that dispensing tip 150 preferably includes fluidic element 160 at the tip to provide a final mixing of the two liquid components just before dispensing. *Id.* at 10:22–24.

A cross-sectional view of one embodiment of a dispenser kit, including dispensing tip 150B, is shown in Figures 13 and 14, reproduced below.

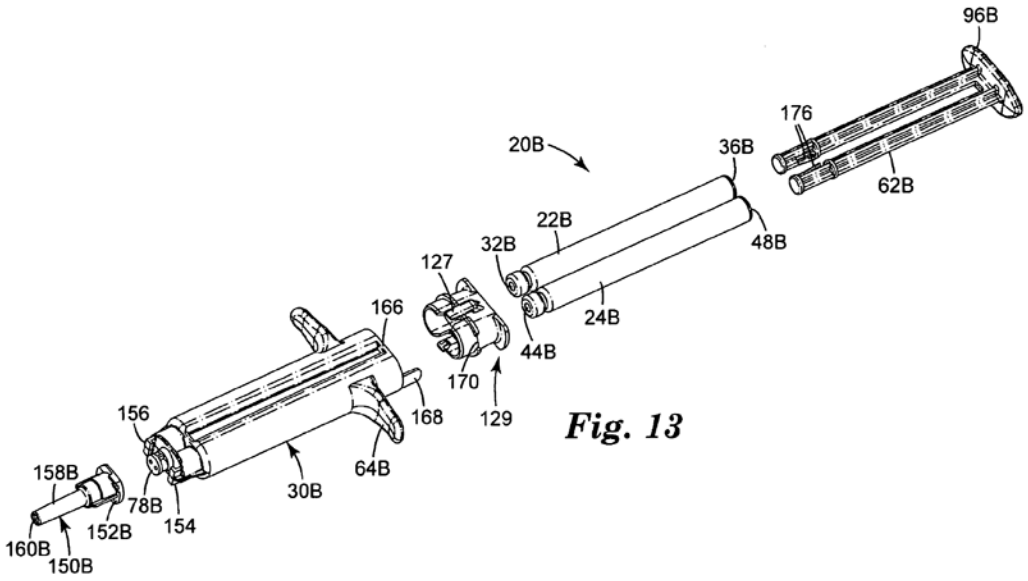



*Fig. 13*

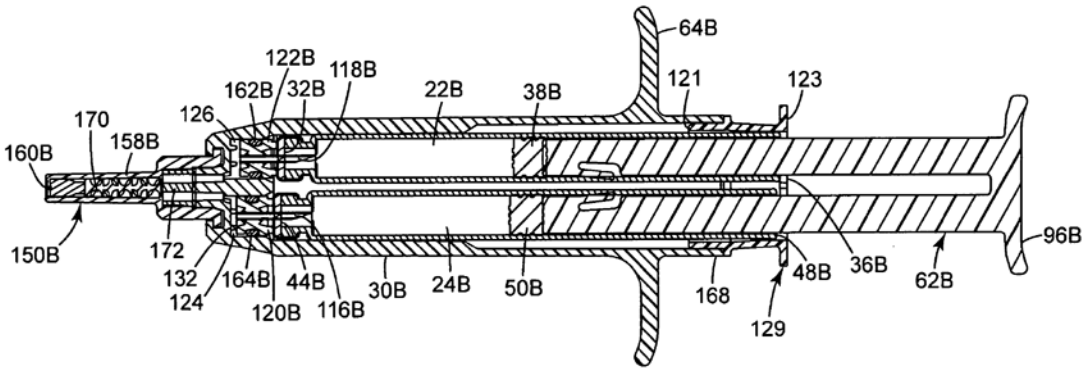



***Fig. 14***

Figure 13 shows a perspective exploded view of elements of dispenser kit 20B, and Figure 14 shows a cross-sectional front view of the assembled dispenser. *Id.* at 6:7–10. Dispenser kit 20B includes carpules 22B, 24B, manifold 30B, dual nozzle 78B, and dispenser tip 150B. *Id.* at 11:9–12:44, Figs. 13, 14. Dodge describes that dispenser tip 150B houses a static mixer 170 and contains an opening 160B. *Id.* at 12:47–48, 51–52. As shown in Figures 13 and 14, a portion of dispenser tip 150B defines a chamber configured to receive the distal end of nozzle 78B. Another portion of dispenser tip 150B downstream of nozzle 78B defines a chamber configured to receive static mixer 170. And a portion of dispenser tip 150B downstream of static mixer 170 defines a chamber through which the adhesive components travel after passing through static mixer 170.

Consistent with the disclosure described above, the Petition provides annotated figures of Dodge and citations to the disclosure in Dodge sufficient to present a reasonable likelihood of showing that Dodge discloses all elements of challenged claim 14 except for the specific configuration of the insert as recited in the claim. Pet. 69–75. For instance, Petitioner shows a reasonable likelihood that Dodge discloses an applicator assembly comprising a first portion (manifold 30 and nozzle 78) defining first

component lumen (piercer 116A, plenum 124, and passageway 128) and second component lumen (piercer 118A, plenum 126, and passageway 130) for fluid communication with sources of components (carpules 22, 24), a second portion (dispensing tip 150) defining a mixing chamber (barrel 158) in fluid communication with the first and second component lumens, a third portion (the distal end of dispensing tip 150) defining an outlet (dispensing tip orifice) in fluid communication with mixing chamber (barrel 158), and an insert (static mixer 170) disposed within the mixing chamber between the component lumens and the outlet. Pet. 69–74.

Although Dodge's static mixer 170 is an insert within a second chamber defined by dispensing tip 150B, Petitioner acknowledges that Dodge does not disclose an insert having a cylindrical member with a recess in a first end of the insert. *Id.* at 75. As discussed above, Petitioner has shown reasonable likelihood of success in finding that Haber's insert renders obvious this missing element, as recited in claims 14 and 15.

*3. Proposed Combination*

Petitioner asserts that it would have been obvious to one having ordinary skill in the art to replace or modify Dodge's static mixer 170, based on the teachings of Haber, to improve mixing of the components, enhance atomization, and decrease the likelihood of dispensing tip 150 clogging. Pet. 75 (citing Ex. 1003 ¶¶ 196–214).

Petitioner contends that one having ordinary skill would have understood that Haber's swirl atomizer would provide better mixing than Dodge's static mixer 170:

> While static mixers, such as mixer 107 taught by Dodge, provide mixing on a macroscale, a POSA would have known that the swirl atomizer recess configuration in Haber would provide mixing on a microscale via the turbulent, swirling

> flows it induces, which was known to result in intimate mixing and good atomization. (Ex. 1003, ¶¶197-200.) Thus, a POSA would have known that Haber's recess configuration would provide a more uniformly and intimately mixed composition important for dual-component bioadhesives, and improve the attainment of the objectives identified by Dodge. (*Id.*, ¶¶201-203.)

*Id.* at 75–76.

Petitioner also notes that Dodge identifies a problem in the art of dual-adhesive applicators of clogging of the dispenser tip. *Id.* at 76 (citing Ex. 1012, 14:32–41). Petitioner contends that a person having ordinary skill in the art would have been led to replace Dodge's static mixer 170 with Haber's swirl atomizer insert "to decrease component residence time in the dispenser tip and decrease the likelihood of clogging the tip during component mixing." *Id.* (citing Ex. 1003 ¶ 204).

Petitioner also contends that Dodge provides motivation to replace or modify static mixer 170 because Dodge teaches making the dispensing tip "in accordance with, e.g., the teachings of [*Atomization and Sprays*, by Arthur H. Lefebvre]." *Id.* at 76–77 (citing Ex. 1012, 10:62–66).

Petitioner provides evidence to show that a person having ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Dodge and Haber and that the results of the proposed combination would have been predictable. *Id.* at 77–78 (citing Ex. 1003 ¶¶ 206–214).

*4. Patent Owner's Contentions*

Patent Owner challenges Petitioner's assertions about the content of Dodge and about the proposed combination. As to the content of Dodge, Patent Owner contends that Petitioner's challenge is insufficient because Dodge's static mixer 170 does not include a "cylindrical member." Prelim.

Resp. 52. Patent Owner's contention does not detract from the ground presented in the Petition because Petitioner does not assert that Dodge shows an insert having a cylindrical member. Pet. 74–75 (contending that Dodge's static mixer 170 is an insert "disposed within barrel 158 of mixing tip 150"). Petitioner relies on Haber to show or render obvious the claimed cylindrical member with a recess in its distal end. *Id.* at 75 (citing Ex. 1003 ¶ 114–116, 187, 194).

As to the combination, Patent Owner argues that Petitioner fails to explain how the proposed modification would achieve any of the asserted benefits, i.e., improved mixing, enhanced atomization, less clogging. Prelim. Resp. 54. Patent Owner contends that Haber does not support Petitioner's position because Haber is silent as to mixing and clogging. *Id.* Patent Owner contends that the expert's declaration does not provide any support for the contention that Haber's swirl atomizer provides mixing on a microscale as opposed to the macroscale mixing provided by Dodge's static mixer. *Id.* (citing Ex. 1003 ¶¶ 197–200). Patent Owner also argues that Petitioner's expert testimony that Dodge's static mixer is a sub-optimal solution lacks underlying facts or data upon which it is based. *Id.* (citing Ex. 1003 ¶ 197).

The Petition and accompanying expert declaration provide an adequate explanation, and identify the underlying facts and data upon which it is based, to show a reasonable likelihood of prevailing on a determination of obviousness. Haber's lack of express teachings as to use of its swirl atomizer for mixing multiple components or for preventing clogging of the spray nozzle are not determinative because Petitioner's asserted ground does not purport to rely on any such teaching. Rather, Petitioner relies on the background knowledge of one having ordinary skill in the art as to the

structure and function of static mixers and swirl chambers. *See* Pet. 69 ("The obviousness of this combination would be informed by the knowledge of a POSA."). The Hattan Declaration cites multiple technical articles to support knowledge of one having ordinary skill as to dispersive mixing on a microscale provided by Haber's atomizing insert. Ex. 1003 ¶ 197 (citing Ex. 1042, 732; Ex. 1035, 380; Ex. 1028, 180–181; and Ex. 1041, 83). The Hattan Declaration also cites evidence of other prior art devices that use swirl atomizer geometry and/or swirling flows similar to Haber to mix dual-component bioadhesives. Ex. 1003 ¶ 121 (cross-referenced in ¶ 197) (citing Ex. 1011, 7:15–23, Fig. 10; Ex. 1039, 5:18–23, Fig. 6; Ex. 1019, 6:49–58; and Ex. 1006 ¶ 25). The Hattan Declaration goes well beyond merely parroting the explanation provided in the Petition. Mr. Hattan provides factual underpinnings for the statements made in paragraphs 121–129 and 197–205 of the declaration that support his testimony on the obviousness of the claimed subject matter. These factual underpinnings are best resolved based on a fully developed record, after opportunity for cross-examination in a trial.

Patent Owner further attacks Petitioner's assertion that a person having ordinary skill in the art would have had a reasonable expectation of success in making the proposed modification. Prelim. Resp. 55. Patent Owner contends, "Petitioner has not provided any competent evidence that Haber's 'swirl atomizer' would effectively serve to mix two components" such as the components disclosed in Dodge. *Id.* As noted above, Petitioner provided evidence of prior art swirl atomizers and/or swirling flows used for mixing components in dual-component bioadhesive applicators. Ex. 1003, ¶¶ 121, 197. Patent Owner does not address this evidence directly in its Preliminary Response to explain why this evidence is not competent to

support Petitioner's assertion. Again, this contention is best resolved based on a fully developed record, after opportunity for cross-examination in a trial.

Patent Owner argues that Dodge "teaches away from replacing static mixer 170 with a swirl atomizer, such as Haber's" because Dodge identifies a static mixer as the preferred mixing mechanism in its dispensing tip. Prelim. Resp. 55–56. We understand Dodge to prefer using a static mixing element within the barrel of the dispensing tip as opposed to using a barrel that has no mixing element at all. Ex. 1012, 10:15–22. We do not agree that Dodge's stated preference for a static mixing element inside the barrel of the dispensing tip teaches away from using another type of mixing element inside the barrel. In fact, Dodge's suggestion that dispensing tip 150 may be made in accordance with the teachings of Lefebvre (Ex. 1029) suggests that there existed known techniques for achieving mixing of the components within the dispensing tip other than the preferred static mixer. Ex. 1012, 10:62–66 (citing pages 112–121 of Lefebvre). The pages of Lefebvre referenced in Dodge discuss simplex and duplex nozzles that use swirl chambers with tangential ports to atomize fluid flowing through the nozzle. Ex. 1029 at 112–121.

Patent Owner also contends that a "POSA would understand that even a very small difference in design or dimension (let alone the substantial modifications set forth by Petitioner) would have a considerable impact of the flow dynamics of the resultant spray, potentially rendering the device unacceptable for its intended purpose." Prelim. Resp. 56 (arguing that Petitioner fails to provide evidence of prior art dual-component bioadhesives applicators that employed similar swirl atomizer geometries to mix and atomize components); *see also id.* at 26 (citing Ex. 1020, 1; Ex. 1021, 15).

As noted above, Petitioner provided evidence of prior art swirl atomizers and/or swirling flows used for mixing components in dual-component bioadhesive applicators. Ex. 1003 ¶¶ 121, 197. If Patent Owner has evidence that tends to refute the evidence relied on by Petitioner's expert, Patent Owner will have an opportunity to cross-examine Mr. Hattan on his testimony during trial.

Patent Owner also argues that "Petitioner fails to provide any explanation for how [the proposed modification] would have been accomplished." Prelim. Resp. 56–57; *see also id.* at 58 (arguing inoperability of placing a spray atomizer upstream of Dodge's fluidic element 160). Petitioner's expert explained in adequate detail that a person having ordinary skill in the art could have modified Dodge's dispensing tip 150 with the teachings of Haber by replacing Dodge's static mixer 170 with Haber's swirl atomizer 40 within dispensing tip 150. Ex. 1003 ¶¶ 207; *see also id.* ¶¶ 209–210 (describing simple substitution), ¶¶ 211–212 (discussing predictability of combining function of Dodge's static mixer with Haber's recesses). Patent Owner will have an opportunity during trial to cross-examine Mr. Hattan about any potential inoperability of the proposed modified dispensing tip 150.

Patent Owner's challenges to the proposed combination of Dodge and Haber raise complex technical issues and the issue of the understanding of a person of ordinary skill in the art that are not properly decided at this stage. Those issues are appropriately resolved after the record is fully developed, including, deposition testimony of Petitioner's expert.

*5. Conclusion*

Based on the record before us, Petitioner has presented adequate evidence to show a reasonable likelihood that the elements of claims 14 and

15 are disclosed in the combined teachings of Dodge and Haber and has presented adequate reasoning to show a reasonable likelihood that one having ordinary skill in the art would have been led to modify Dodge with the teachings of Haber in the manner claimed. Petitioner has demonstrated a reasonable likelihood of prevailing in a determination of unpatentability of claims 14 and 15 over Dodge in view of Haber.

*I. Anticipation by Voegele (Ground 5)*

Petitioner does not demonstrate, based on the record before us now, a reasonable likelihood of prevailing in proving that Voegele discloses an "insert including a cylindrical member," as recited in claim 14. Ex. 1001, 7:64–66 (reciting a system including "an insert disposed within the mixing chamber between the first and second component lumens and the outlet, the insert including a cylindrical member having a recess formed in a first end thereof"). Petitioner contends in the fifth proposed ground that Voegele's mixer 293 is the claimed insert "including a cylindrical member." Pet. 85 (citing Ex. 1013, Fig. 16); *see also* Ex. 1003 ¶ 221. Petitioner contends, "mixer 293 has two cylindrical portions—the rounded top and bottom portions" and these cylindrical portions "allow[] it to fit snugly within the interior cylindrical cavity of tip 294." Pet. 84.

Patent Owner argues, "Separated rounded top and bottom sections [of Voegele's mixer 293] do not constitute a cylindrical member in any reasonable sense." Prelim. Resp. 61. Patent Owner asserts that no basis exists to read "cylindrical member" to encompass "cylinder portions." *Id.*

As explained above, we do not interpret "cylindrical member," for purposes of this institution decision, to encompass an element that forms only a portion of a cylinder.

We agree with Patent Owner's characterization of Voegele's mixer 293 as having a dumbbell or "I" shape. Prelim. Resp. 61. Figure 16 of Voegele, which shows mixer 293, is reproduced below.

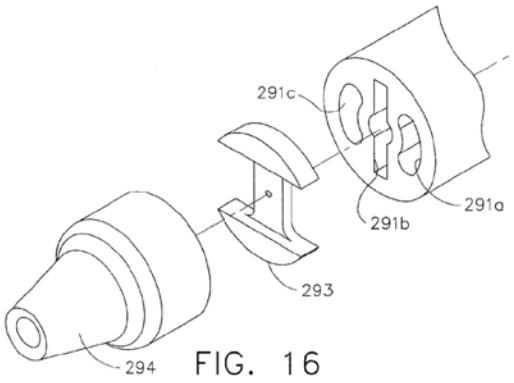


FIG. 16

Figure 16 is an isometric exploded view of a gas assisted mixing nozzle. Ex. 1013 ¶ 32. As seen above, mixer 293 is I-shaped, having a vertical rectangular section and rounded top and bottom ends. *Id.*, Fig. 16.

Petitioner has failed to demonstrate adequately on the record before us how Voegele's I-shaped mixer 293 includes a cylindrical member. Petitioner offers only a conclusory assertion that the rounded top and rounded bottom sections of mixer 293 form portions of a cylinder, and thus, a cylindrical member. Pet. 84–85. Petitioner fails to explain sufficiently how to interpret "cylindrical" based on the ordinary meaning of the word or the description provided in the '021 patent to read it on the cylinder portions disclosed in Voegele.

Thus, Petitioner has not adequately supported its assertion that Voegele discloses an insert including a cylindrical member, as recited in challenged claims 14 and 15.

## III. CONCLUSION

On this record, for the reasons provided above, we are persuaded that Petitioner has shown a reasonable likelihood of prevailing on its assertion that claims 14 and 15 are unpatentable over Spero in view of Haber, Spero in view of Kitabayashi, and Dodge in view of Haber. Given our determination, we institute trial on all challenged claims and all grounds raised in the Petition. *See SAS Inst.*, 138 S. Ct. at 1359–60 (2018).

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 14 and 15 of the '021 patent is instituted with respect to all grounds presented in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '021 patent shall commence on the entry date of this Decision, and, notice is hereby given of the institution of a trial.

For PETITIONER:

Orion Armon
Joseph E. Van Tassel
Adam M. Pivovar
COOLEY LLP
oarmon@cooley.com
jvantassel@cooley.com
apivovar@cooley.com
zpatdcdocketing@cooley.com
zHyperBranchIPR@cooley.com

For PATENT OWNER:

Christopher L. McKee
John P. Iwanicki
Paul M. Rivard
Robert F. Altherr, Jr.
Jason S. Shull
Camille D. Sauer
BANNER & WITCOFF, LTD.
cmckee@bannerwitcoff.com
jiwanicki@bannerwitcoff.com
privard@bannerwitcoff.com
raltherr@bannerwitcoff.com
jshull@bannerwitcoff.com
csauer@bannerwitcoff.com
IntegravHyperBranch@bannerwitcoff.com.

# insert verb

in·sert | \in-ˈsərt\

**inserted**; **inserting**; **inserts**

## Definition of *insert* (Entry 1 of 2)

*transitive verb*

1 : to put or thrust in
*II insert* the key in the lock

2 : to put or introduce into the body of something : INTERPOLATE
*II insert* a change in a manuscript

3 : to set in and make fast
*especially* : to insert by sewing between two cut edges

4 : to place into action (as in a game)
*II insert* a new pitcher

*intransitive verb*

*of a muscle* : to be in attachment to the part to be moved

# insert noun

in·sert | \ˈin-ˌsərt\

## Definition of *insert* (Entry 2 of 2)

: something that is inserted

*especially* : written or printed material inserted (as between the leaves of a book)

# cylindrical

adjective

cy·lin·dri·cal | \sə-ˈlin-dri-kəl\

variants: or less commonly cylindric \ sə-ˈlin-drik \

## Definition of *cylindrical*

**:** relating to or having the form or properties of a cylinder

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## Other Words from *cylindrical*

cylindrically \ sə-ˈlin-dri-k(ə-)lē \ adverb

## Examples of *cylindrical* in a Sentence

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Each speaker has seven microphones which are arrayed so the *cylindrical* speaker can pick up voice commands from far away or even in noisy rooms with lots of conversations going on.— Elizabeth Weise, *USA TODAY*, "Alexa creepily recorded a family's private conversations, sent them to business associate," 24 May 2018 The *cylindrical* structure flows into a duller, funnel-like cone, which tapers into a tower with rocket nozzles.— Sarah Scoles, *WIRED*, "Inside the Test Chamber for NASA's Astronaut Vehicle Double," 12 July 2018

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# cylinder

noun
cyl·in·der | \ˈsi-lən-dər\

## Definition of *cylinder*

1a **:** the surface traced by a straight line moving parallel to a fixed straight line and intersecting a fixed planar closed curve

b **:** a solid or surface bounded by a cylinder and two parallel planes cutting all its elements especially **:** right circular cylinder — see Volume Formulas Table

2 **:** a cylindrical body or space: such as

a **:** the turning chambered breech of a revolver

b(1) **:** the piston chamber in an engine

(2) **:** a chamber in a pump from which the piston expels the fluid

c **:** any of various rotating members in a press (such as a printing press) especially **:** one that impresses paper on an inked form

d **:** a cylindrical clay object inscribed with cuneiform inscriptions

on all cylinders

**:** with maximum effort or intensity **:** at full capacity or speed the economy is running *on all cylinders*

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## Other Words from *cylinder*

cylindered \ˈsi-lən-dərd\ adjective