UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYPERBRANCH MEDICAL TECHNOLOGY, INC.
Petitioner

v.

CONFLUENT SURGICAL, INC.
Patent Owner

Case No. IPR2018-01099

Patent No. 8,876,021

Filing Date: February 4, 2013
Issue Date: November 4, 2014

Title: SILICONE SPRAY TIP

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,876,021

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,876,021("the '021 patent")
1002	File history of the '021 patent
1003	Expert Declaration of Mr. Paul Hattan
1004	U.S. Provisional Patent Appl. No. 61/047,826
1005	U.S. Patent Pub. No. 2003/0069537 ("Spero")
1006	U.S. Patent Pub. No. 2007/0005007 ("Hoogenakker")
1007	U.S. Patent No. 5,341,993 ("Haber")
1008	Japanese Utility Model Publication No. 3-32959 (Japanese version)
1009	Japanese Utility Model Publication No. 3-32959 (certified translation) ("Kitabayashi")
1010	U.S. Patent No. 3,112,074 ("Green")
1011	U.S. Patent No. 5,116,315 ("Capozzi")
1012	U.S. Patent No. 7,037,289 ("Dodge")
1013	U.S. Patent Pub. No. 2008/0121657 ("Voegele")
1014	U.S. Patent Pub. No. 2006/0189944 ("Campbell")
1015	U.S. Patent No. 4,826,048 ("Skorka")
1016	Gerard Marx, *Evolution of Fibrin Glue Applicators*, Transfusion Medicine Reviews, Vol 17, No. 4, 287-98 (October 2003) ("Marx")
1017	Certified true and accurate copy of printouts of Micromedics Archived Website obtained using Internet Archive.
1018	U.S. Patent Pub. No. 2004/0225077 ("Gravett")
1019	U.S. Patent No. 6,874,657 ("Metzner")
1020	A. Mandal et al., *Flow of power-law fluids in simplex atomizers*, International Journal of Heat and Fluid Flow 29, 1494-503 (2008) ("Mandal")
1021	G.G. Nasr et al., *Industrial Sprays and Atomization Design, Analysis and Applications*, Springer (2002) (Excerpts of Chapters 2 and 3) ("Nasr")
1022	U.S. Patent No. 4,706,888 ("Dobbs")

1023	Chun-Lang Yeh, *Numerical Simulation of a Turbulent Liquid Jet Emanating from a Plain-Orifice Atomizer and a Pressure-Swirl Atomizer*, Numerical Heat Transfer, Part A:Applications, 51:12, 1187-212 (2007) ("Yeh")
1024	Azhar Abdul Aziz & Mas Fawzi Ali, *Numerical Investigation on the Needle-Shape of Hollow-Cone Pressure-Swirl Type Gasoline Direct Injector*, SAE Technical Paper (2006) ("Aziz")
1025	Y. Liao et al., *A Comprehensive Model to Predict Simplex Atomizer Performance,* Journal of Engineering for Gas Turbines and Power (1999) ("Liao")
1026	M. Gavaises & C. Arcoumanis, *Modelling of Sprays from high-pressure swirl atomizers*, International Journal of Engine Research Vol 2, No. 2, 95-117 (2001) ("Gavaises")
1027	Gerhard Dickneite et al., *A comparison of fibrin sealants in relation to their in vitro and in vivo properties*, Thrombosis Research 112, 73-82 (2003) ("Dickneite")
1028	Yuriy I. Khavkin, *Theory and Practice of Swirl Atomizers*, Taylor & Francis Books (2004) (excerpts) ("Khavkin")
1029	Arthur H. Lefebvre, *Atomization and Sprays*, 105-27 (1998) ("Lefebvre")
1030	A.T. Sakman et al., *Parametric Study of Simplex Fuel Nozzle Internal Flow and Performance*, AIAA Journal Vol. 38 No. 7, 1214-18 (Jul. 2000) ("Sakman")
1031	L. Valdenazzi, *On the form of a jet issuing from a swirl atomizer*, Ingenieur-Archiv, Vol. 24, No. 5, 330-40 (1956) ("Valdenazzi")
1032	J. Xue et al., *Effect of Geometric Parameters on Simplex Atomizer Performance*, AIAA Journal Vol. 42, No. 12, 2408-15 (Dec. 2004) ("Xue")
1033	U.S. Patent Pub. No. 2008/0121738 ("Togashi")
1034	U.S. Patent No. 4,071,196 ("Burke")
1035	H. Hartridge & F. J. W. Roughton, *A Method of Measuring the Velocity of Very Rapid Chemical Reactions*, Proceedings of the Royal Society of London. Series A, 376-94 (1923) ("Hartridge")
1036	Peter Regenfuss et al., *Mixing Liquids in microseconds*, Review of Scientific Instruments 56, 283-90 (1985) ("Regenfuss")

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1038	F. A. Holland & F. S. Chapman, *Liquid mixing and Processing in Stirred Tanks*, 1-2, Reinhold Publishing Corp. (1966) ("Holland")
1039	PCT Pub. No. WO2007/131371 ("Keller")
1040	Q. H. Gibson & L. Milnes, *Apparatus for Rapid and Sensitive Spectrophotometry*, Journal of Biochemistry Vol. 91, 61-71 (1964) ("Gibson")
1041	Joseph A. Schetz & Allen E. Fuhs, *Handbook of Fluid Dynamics and Fluid Machinery*, Vol. 1, 83-85 (1996) ("Schetz")
1042	Geoffrey F. Hewitt et al., *International Encyclopedia of Heat & Mass Transfer*, at 148, 731-32 (1997) ("Hewitt")
1043	H. Redl et al., *Methods of Fibrin Seal Application*, The Thoracic and cardiovascular surgeon 30.04, 223-27 (1982) ("Redl")
1044	Jaromir J. Ulbrecht & Gary K. Patterson, *Mixing of Liquids by Mechanical Agitation*, 29-36, Vol. 1, Taylor & Francis (1985) ("Ulbrecht")
1045	P.V. Dankwerts, *The effect of incomplete mixing on homogeneous reactions*, Chemical Engineering Science Vol. 8. Nos. 1-2, 93-102 (1958) ("Dankwerts")
1046	Günther Schlag & Heinz Redi, *Fibrin Sealant in Orthopedic Surgery*¸Clinical orthopaedics and related research, No. 227, at 269-85 (1988) ("Schlag")
1047	William D. Spotnitz et al., *Reduction of Perioperative Hemorrhage by Anterior Mediastinal Spray Application of Fibrin Glue during Cardiac Operations*, The Annals of Thoracic Surgery, Vol. 44 No. 5, 529-31 (1987) ("Spotnitz")
1048	Joseph W. Baker et al., *A Technique for Spray Application of Fibrin Glue During Cardiac Operations*, he Annals of Thoracic Surgery, Vol. 43 No. 5, 564-65 (1987) ("Baker")
1049	David Sierra et al., *Modulation of mechanical properties in multiple-component tissue adhesives*, Journal of Biomedical Materials Research: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials Vol. 52 No.3, 534-542 (2000) ("Sierra")

1050	K.G. Hansen et al., *A computational and experimental study of the internal flow in a scaled pressure-swirl atomizer*, Zaragoza 9-11 (2002) ("Hansen")
1051	*21.4.1 Atomizer Models*, Fluent Inc. (2008) ("Fluent Manual")
1052	U.S. Patent No. 5,810,885 ("Zinger")
1053	E. B. Nauman & B. A. Buffham, *Mixing in Continuous Flow Systems*, 134-35, 217, John Wiley & Sons, Inc. (1983) ("Nauman")

I. INTRODUCTION

HyperBranch Medical Technology, Inc. ("HyperBranch" or "Petitioner") petitions for *inter partes* review ("IPR") under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42 of claims 14 and 15 of U.S. Patent No. 8,876,021 ("the '021 patent," Ex. 1001), owned by Confluent Surgical, Inc. ("Patent Owner").

The '021 patent is directed to an applicator assembly for mixing and spraying two or more components, e.g., bioadhesives. (Ex. 1001, 1:18-21.) Applicators for mixing and applying dual-component bioadhesives were not novel, as is recognized in the background section of the '021 patent. (*Id.* at 1:23-29.)

As shown below, Claims 14 and 15 are invalid as anticipated and/or obvious because they recite nothing more than known components of applicator assemblies.

II. MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))

A. REAL PARTY-IN-INTEREST (37 C.F.R. § 42.8(B)(1))

HyperBranch is the real party-in-interest.

B. RELATED MATTERS (37 C.F.R. § 42.8(B)(2))

Patent Owner asserts infringement of the '021 patent by Petitioner in: *Confluent Surgical, Inc.., et al., v. HyperBranch Med. Tech., Inc.*, C.A. No. 17-688-LPS-CJB (D. Del.).

C. LEAD AND BACK-UP COUNSEL (37 C.F.R. § 42.8(B)(3))

Lead Counsel	Backup Counsel
Orion Armon Reg. No. 65,421 Cooley LLP 380 Interlocken Crescent, Suite 900 Broomfield, CO 80021-8023 Tel: 720-566-4119 Fax: 720-566-4099 Email: oarmon@cooley.com zHyperBranchIPR@cooley.com	Jonathan Graves *Pro hac vice* (application to be filed) Cooley LLP 11951 Freedom Drive Reston, VA 20190-5656 Tel: 703-456-8119 Email: jgraves@cooley.com Adam Pivovar *Pro hac vice* (application to be filed) Cooley LLP 1299 Pennsylvania Avenue, NW Washington, DC 20004 Tel: 202-842-7998 Email: apivovar@cooley.com

D. SERVICE INFORMATION

Petitioner may be served at the above addresses provided in Section II.C and consents to electronic service at the e-mail addresses provided above.

E. POWER OF ATTORNEY (37 C.F.R. § 42.10(B))

Filed concurrently with this Petition.

III. PAYMENT OF FEES (37 C.F.R. § 42.103)

Petitioner paid petition and post-institution fees of $30,500. 37 C.F.R. § 42.15(a). Petitioner authorizes the Board to charge any additional fees to Deposit Account 501283.

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW (37 C.F.R. §§ 42.104, 42.108)

A. GROUNDS FOR STANDING (37 C.F.R. § 42.104(A))

Petitioner certifies that the '021 patent is eligible for *inter partes* review, and that the Petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified in the present Petition.

B. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B)) AND STATEMENT OF RELIEF REQUESTED

Petitioner requests *inter partes* review of claims 14 and 15 on the following grounds and requests that the Board find each claim unpatentable under 35 U.S.C. §§ 102 and 103 (pre-AIA):

Ground	Claims	Basis for Unpatentability
Ground I	14 and 15	Obvious under 35 U.S.C. § 103 over Spero in view of Haber
Ground II	14 and 15	Obvious under 35 U.S.C. § 103 over Spero in view of Kitabayashi
Ground III	14 and 15	Obvious under 35 U.S.C. § 103 over Capozzi
Ground IV	14 and 15	Obvious under 35 U.S.C. § 103 over Dodge in view of Haber
Ground V	14 and 15	Anticipated under 35 U.S.C. § 102 by Voegele

Spero is listed as a reference cited on the face of the '021 patent and Capozzi is a continuation-in-part of another reference cited on the face of the patent. The examiner did not make any rejections based on either of these references (or any other reference in the above listed grounds) and did not consider the references in combination with the other references listed in the above listed grounds. None of the

proposed grounds above were substantively considered during prosecution of the '021 patent. *Inter partes* review should be instituted on all claims and grounds because this Petition establishes a reasonable likelihood that Petitioner will prove invalid at least one of the petitioned claims.

V. TECHNICAL BACKGROUND – STATE OF THE ART

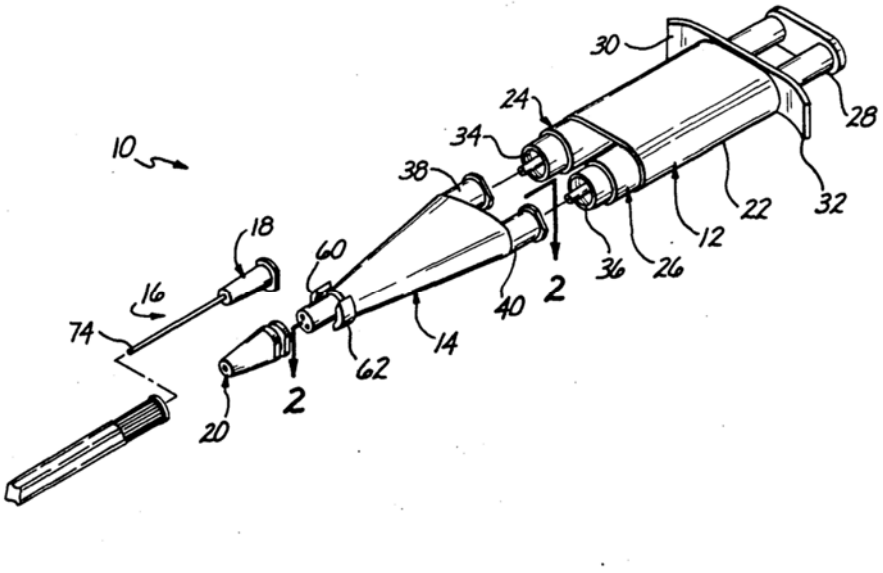
A. Two-Component Spray Applicators with Distal-End Mixing Chambers

Spray applicator assemblies for mixing and applying two-component adhesives, including bioadhesives for wound closure, have been known in the art for many years. (Ex. 1003, ¶24.) A two-component liquid adhesive can generally be described as a sealant that starts as two precursor liquids. The precursors are mixed together by the user shortly before application, initiating a chemical reaction that converts the liquid precursors into a solid or semi-solid adhesive seal. (*Id*.)

When the two precursors are mixed, they immediately begin to react and transition into the final glue/sealant. The time required for complete transition for many common medical sealants may be anywhere from a few seconds to several minutes. (*Id*., ¶25.)

Accordingly, two-component adhesive products are commonly packaged with an applicator to help efficiently mix and/or apply the product. A fully assembled applicator includes two liquid reservoirs (e.g., syringes) wherein each precursor is

separately stored. (*Id*., ¶¶26-30.) Some examples of such prior art applicators are shown below:



(Ex. 1011 (Capozzi) at Fig. 1.)

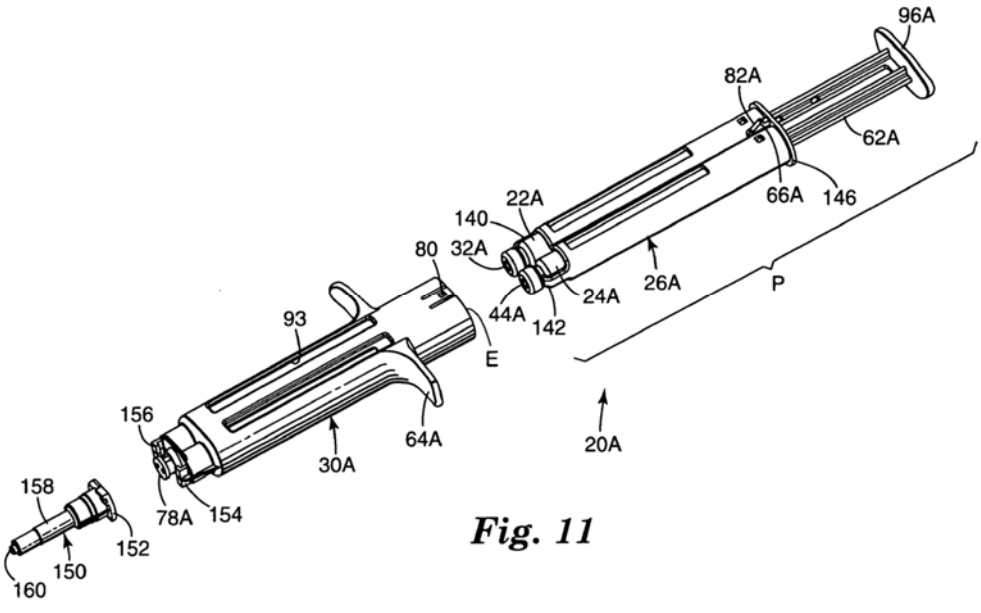
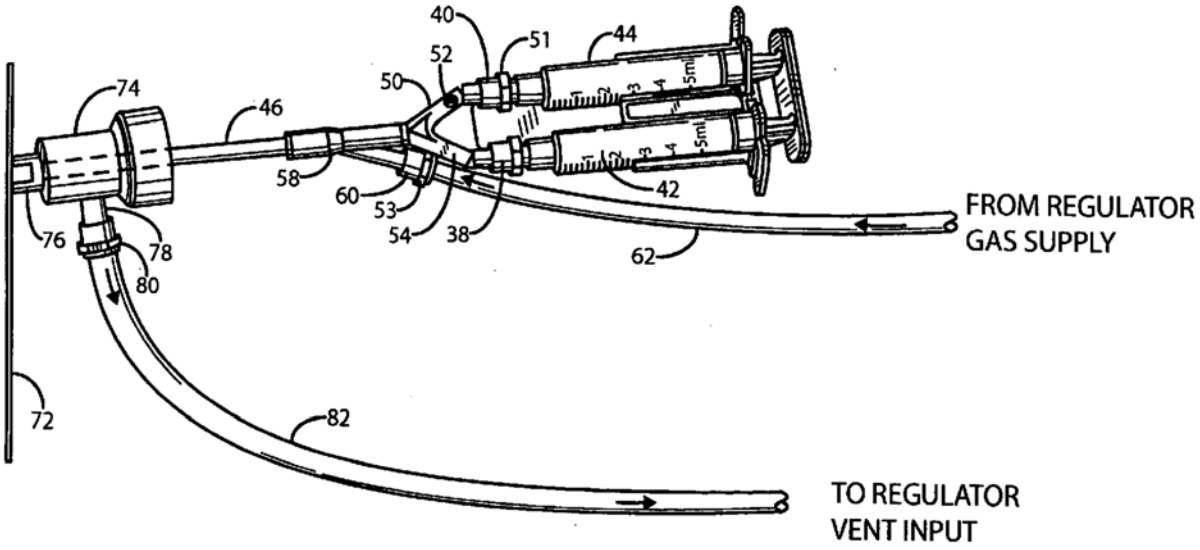


Fig. 11

(Ex. 1012 (Dodge) at Fig. 11.)



(Ex. 1006 (Hoogenakker) at Fig. 4.)

When pressure is applied to the reservoirs, the precursors to outflow through reservoir exits and through separate fluidic passages that lead into a common "mixing chamber" located near the distal end of the device where the precursors are exposed to one another and then mixed and sprayed. (Ex. 1003, ¶31.) The mixing chamber often includes features intended to increase mixing of the precursors as they flow. The exit of the mixing chamber is the dispensing tip of the device. (*Id*., ¶¶32-33.)

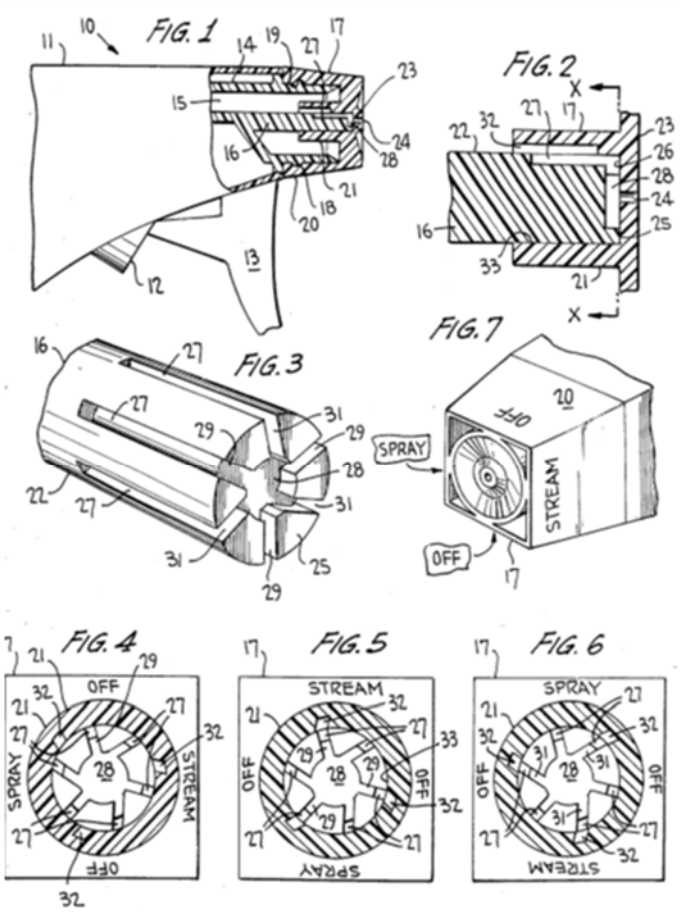
Applicators for fast-curing adhesives must keep the precursors separated as long as possible, then rapidly and effectively mix and dispense before the adhesive hardens inside the device. One method employed by numerous prior art applicators to ensure that the components were rapidly and intimately mixed was to induce a

turbulent, swirling flow within the mixing chamber. (*Id*., ¶34.) Mixing tips were also commonly designed to be removable so that the tip could be replaced if clogged. (*Id*., ¶35.)

B. Spray Applicators with Swirl Atomization

The process of breaking up a liquid into small droplets or a mist is called *atomization*. Devices that create atomization are called *atomizers* or *spray nozzles*. Many of the prior art references that disclose dual-component mixing applicators recognize the benefits of atomizing a spray of the mixed components. (*Id*., ¶36.)

One of the most common types of spray nozzles is the swirl atomizer due to its simplicity, efficiency, and adaptability for various fluids and purposes. A swirl atomizer utilizes flow channels to provide a cone–shaped spray by causing a liquid to swirl as it is ejected from a spray outlet. The design features related to the shapes, sizes, and geometry of a swirl atomizer are predictable and well within the common understanding of a person of ordinary skill in the art. (*Id*., ¶¶37, 45.) Devices that use swirl atomizers have been used for decades, and common examples include spray heads for garden hoses and household cleaning products with a "pull trigger to spray" actuation mechanism, as shown below.



(*See, e.g.*, Ex. 1022 (Dobbs) at Figs. 1-6.) Swirl atomizers are also used in the fuel injectors in most gasoline engines and gas turbines. Because of the potential for significant economic and environmental gains in this particular application, swirl atomizers have undergone decades of intense research and development by government labs, academia, and the auto industry. (Ex. 1003, ¶¶38-40.)

To understand how a swirl atomizer works, consider the familiar process of rapidly stirring or swirling a liquid inside a kitchen blender. As the liquid swirls faster, it is forced more strongly towards the walls, pushing the liquid vertically up

the sidewalls and forming a depression in the center of the liquid vortex. If the liquid is swirled fast enough, it will crest the top of the blender and fly outwards radially, breaking apart into smaller drops as it flies away. (*Id*., ¶41.)

In a swirl atomizer, the liquid is swirled inside a circular chamber that is immediately adjacent to an exit orifice. Like a kitchen blender with no lid, the swirling liquid is thrown out radially once it reaches the exit hole. By continually feeding liquid into the circular "swirl chamber", the radially-thrown liquid forms a continuous hollow cone of spray exiting the orifice. (*Id*., ¶42.) The figures below illustrate some of the common features of a swirl atomizer—*i.e*., tangential inlets, a swirl chamber, and an exit orifice. (*Id*., ¶43.)

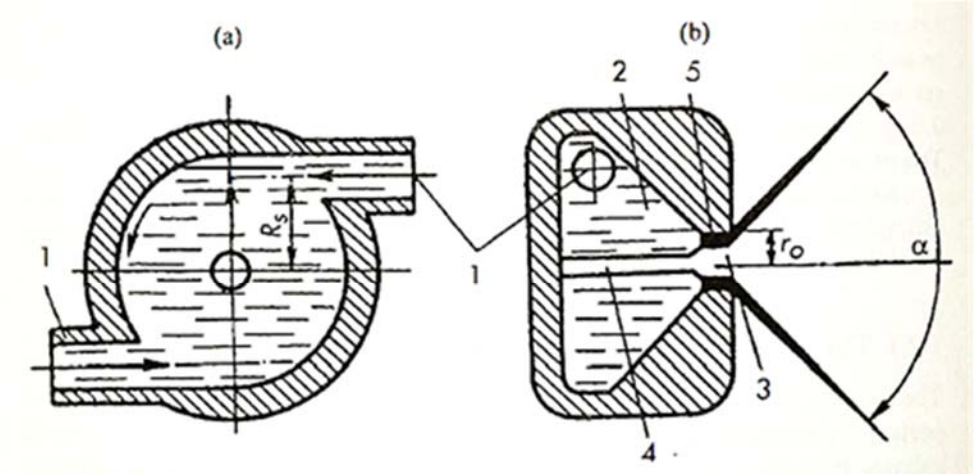


Figure 1.2 Section view of a swirl atomizer: 1) fuel entrance channels; (2) swirl chamber; (3) exit orifice; (4) air vortex; (5) ann lar thin fluid layer.

(Ex. 1028 (Khavkin) pg. 4.)

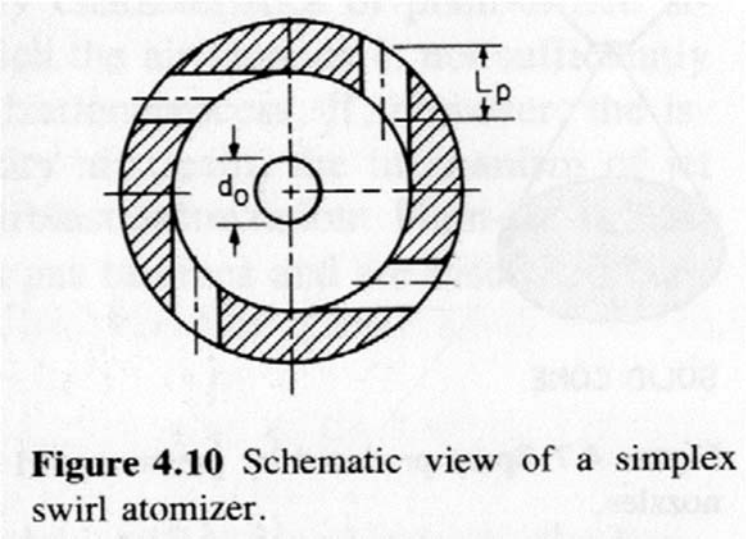


Figure 4.10 Schematic view of a simplex swirl atomizer.

(Ex. 1029 (Lefebvre) pg. 114.)

Swirl atomizers use a variety of designs and construction methods to create the swirling flow. Often, a substantially cylindrical plug or insert is placed into the nozzle very close to the exit orifice such that the outer walls of the insert contact the inner walls of the nozzle, blocking most of the flow through the nozzle. The nozzle walls and/or plug walls include channels or grooves to impart rotation on the fluid. (Ex. 1003, ¶¶46-48.) Examples of such swirl atomizer inserts are depicted below:

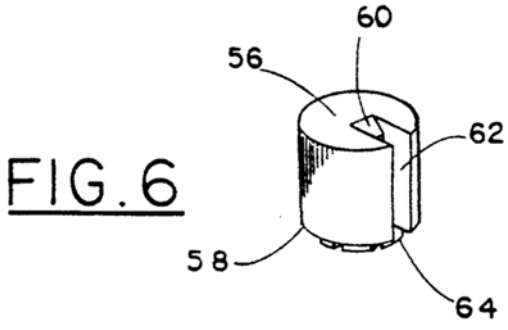


FIG. 6

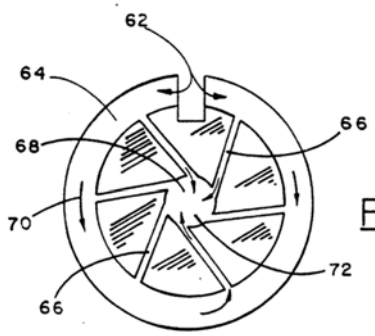
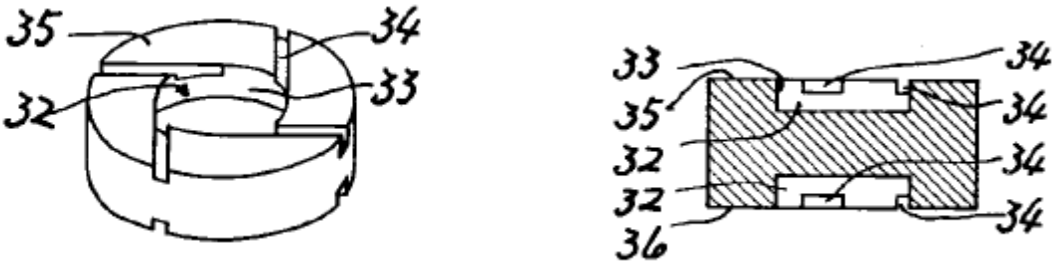
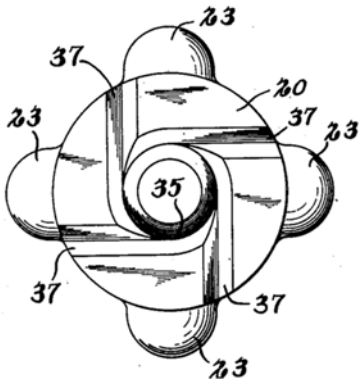


FIG. 7

(Ex. 1007 (Haber) at Figs. 6-7.)



(Ex. 1009 (Kitabayashi) at Figs. 4 and 6.)



(Ex. 1010 (Green) at Fig. 3.)

Swirl atomizers offer several benefits including small power consumption, good spray quality, and simple geometry. (Ex. 1003, ¶49.) In situations where two or more fluids need to be mixed as well as atomized for spray application, such as a dual-component applicator, a swirl atomizer's efficient creation of a swirling flow is especially beneficial, since it is well known that rapidly swirling flows also thoroughly mix the liquids contained therein. (*Id*., ¶50.)

Having been the subject of intense research and development since the 1950s, the behavior of swirl atomizers is well understood and predictable. The quality of atomization is determined by the overall flow rate of the fluid, the fluid's properties, and the geometry of the atomizer. (*Id*., ¶45.) Variations in atomizer designs may

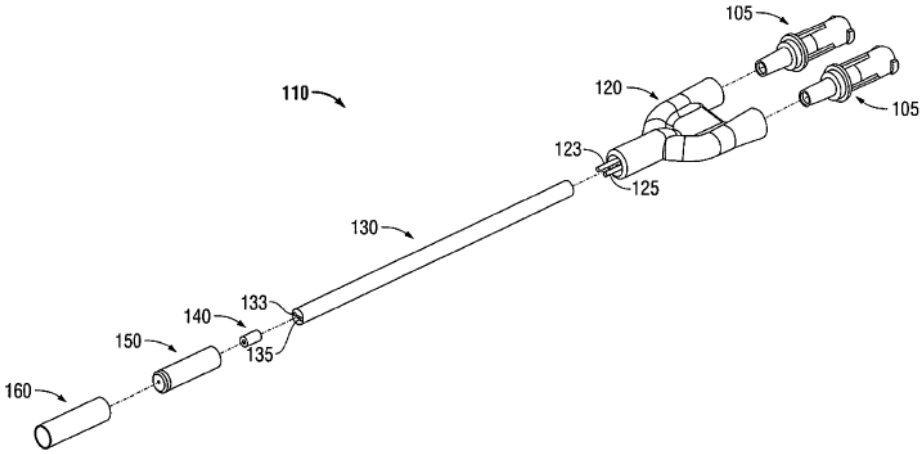
include the shape of the swirl chamber, the quantity of chamber inlet channels, the shape and angle of inlet channels, and the relative sizes of these various flow elements. Any engineer skilled in fluid mechanics would understand how to modify a swirl atomizer to achieve a desired spray or to adapt it for use with different fluids. (*See id.*)

VI. THE '021 PATENT

A. The '021 Patent

The '021 patent is entitled "Silicone Spray Tip." It describes an applicator assembly for mixing and applying dual component solutions, such as bioadhesives (Ex. 1001 at Abstract). The disclosed devices include a spray tip assembly with an internal mixing chamber that contains a recessed insert. (*Id*. at 5:36-63.)

Figure 7 illustrates a representation of the applicator assembly. The applicator includes manifold 120 configured to couple to first and second components (not pictured), elongated shaft 130, and spray tip assembly 150. (*Id*. at 5:24-35). The manifold and the elongated shaft include channels 123, 125 and lumens 133, 135 that transport the first and second



components from their respective reservoirs to the spray tip. (*Id.* at 5:36-40.) The spray tip assembly includes a chamber configured to receive an insert. (*Id.* at 4:19-26.) Insert 140 includes a recess on its distal end, which is described as configured to create turbulence in the flow of the two components. (*Id.* at 5:43-52.)

B. Prosecution History of the '021 Patent

The '021 patent issued on November 4, 2014 from U.S. Application No. 13/758,198 (the "'198 application"), filed on February 4, 2013. The '198 application was a continuation of and claims priority to two earlier non-provisional applications, the earliest of which, U.S. Application No. 12/427,965, was filed on April 22, 2009. The '198 application also claims priority to U.S. Provisional Application No. 61/047,826, filed on April 25, 2008.

Applicant added claims 14 and 15 following a non-final rejection that previously submitted claims were anticipated by U.S. Patent No. 5,605,255 (Reidel) and argued that new claim 14 was patentable over Reidel because, according to Applicant, Reidel failed to disclose "an insert including a cylindrical member having a recess formed in a first end thereof." Following the filing of a terminal disclaimer to overcome an obviousness-type double patenting rejection, the examiner allowed claims 14 and 15. None of the references or combinations of references relied upon below were cited by or relied upon by the examiner during prosecution.

VII. CLAIM CONSTRUCTION (37 C.F.R. § 42.104(B)(3))

A claim subject to *inter partes* review must be given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Accordingly, the constructions proposed in this Petition represents the broadest reasonable interpretation that a POSA would assign to the terms below.[1] For the claim terms not addressed below, Petitioner has applied the plain and ordinary meaning of the term.

A. Terms for construction

1. "a first end"

As used in the '021 patent, the broadest reasonable construction of "a first end" is "an end." This term applies to "the insert including a cylindrical member having a recess formed in a first end thereof." There is no language in the claims or the specification that would limit the construction of this term to one end in

[1] Petitioner is aware that the Patent Office is considering replacing the broadest reasonable interpretation standard in *inter partes* review with the claim construction standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) applicable in federal courts. The constructions proposed in this Petition are also in accord with the *Phillips* standard and would remain the same should this standard be adopted by the Patent Office.

particular, as between the proximal and distal ends of the insert. In other words, the term "a first end" can refer to either the proximal or the distal end of the insert. A construction that does not limit "a first end" to either end of the insert is supported by the surrounding claim language which specifically refers to the proximal and distal ends of other elements. (*See* Ex. 1001 at cl. 14 (6:52-67) (claiming first and second component lumens "having proximal and distal ends" with the proximal ends of these lumens being in fluid communication with sources of components and the distal ends being in fluid communication with the mixing chamber).) If the Applicant had meant to limit the recess on the insert to one end (proximal or distal) in particular, Applicant could have done so, and Applicant's use of broader, non-limiting language supports a non-limiting construction of this term. Accordingly, the broadest reasonable construction of "a first end" is thus "an end." (*See* Ex. 1003, ¶¶59-60.)

VIII. PERSON OF ORDINARY SKILL IN THE ART

As of the presumptive April 22, 2009 priority date of the '021 patent (and for several years prior), a POSA would be a person with 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 two 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). (Ex. 1003, ¶68.)

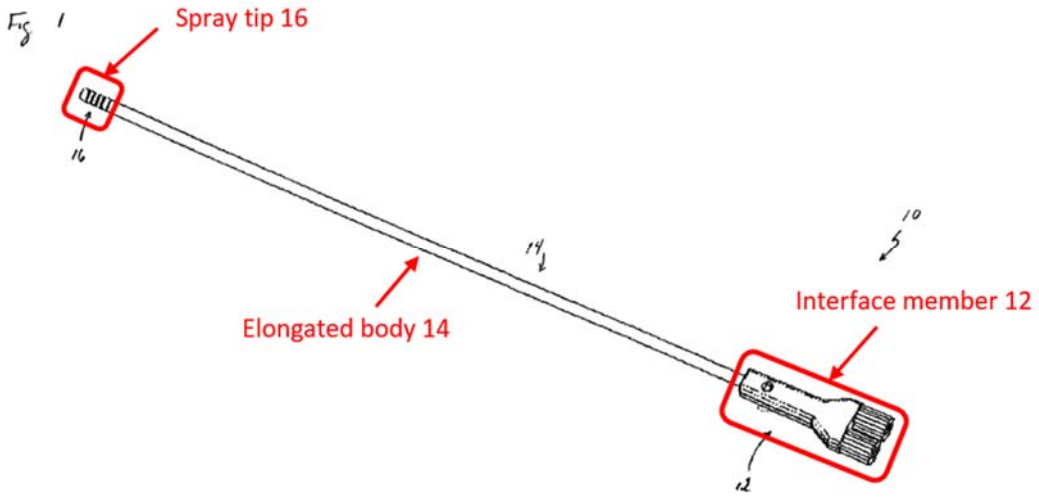
IX. THE SCOPE AND CONTENT OF THE PRIOR ART

Numerous prior art references teach the same or a similar applicator configuration as the ’021 patent and an insert with a distal recess for mixing and/or atomization. Petitioner relies on a subset of these prior art references, described below and in the accompanying declaration of Mr. Hattan:

A. Spero (Ex. 1005)

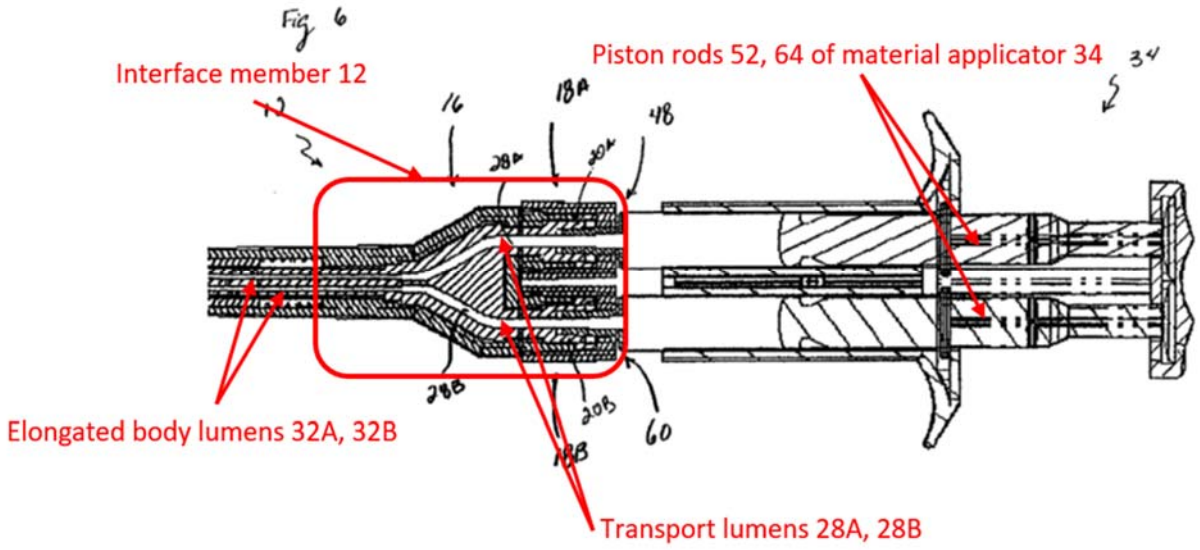
Spero is a patent publication that published on April 10, 2003, from an application filed on October 5, 2001. Spero qualifies as prior art under 35 U.S.C. §102(b) because it published more than one year before April 25, 2008, the earliest possible filing date of the ’021 patent.

Spero discloses a “laparoscopic spray device for selectively applying a multiple component material dispensed from a multiple component material applicator to a surgical site in vivo”. (Ex. 1005, Abstract.) Spero’s device includes a material applicator 34, an interface member 12, an elongated body 14, and a spray tip 16. (*Id*. at Figs. 1, 5; *see also* Ex. 1003, ¶¶71-75.)



(Ex. 1005 at Fig.1 (annotated).)

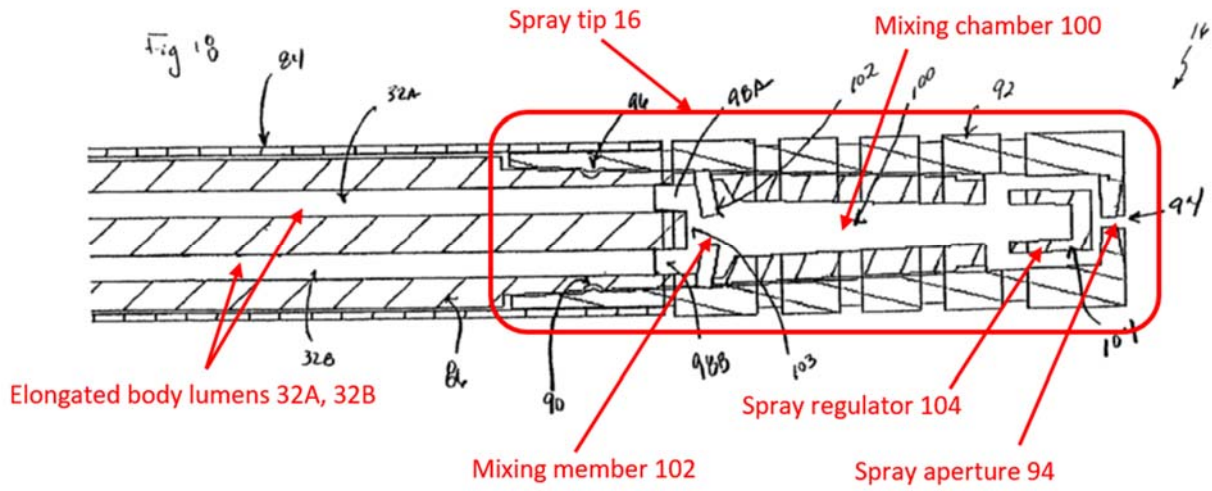
In use, piston rods 52, 64 of the syringe-type material applicator are depressed and the components stored therein are advanced through transport lumens 28A, 28B of interface member 12 to elongated body lumens 32A, 32B. (*Id*. at [0053].)



(*Id*. at Fig. 6 (annotated).)

The two components enter mixing chamber 100 in spray tip 16 and mixing

member 102 begins mixing the two components and "forms a turbulent flow" in the mixing chamber. (*Id.* at [0053].) The components then reach spray regulator 104, which further mixes the components and "provides an impedance within the mixing chamber 100 to aid in forming a material spray." (*Id.* at [0053], [0050].) The mixed components are expelled from the device through spray aperture 94 as a spray. (*Id.* at [0053].)



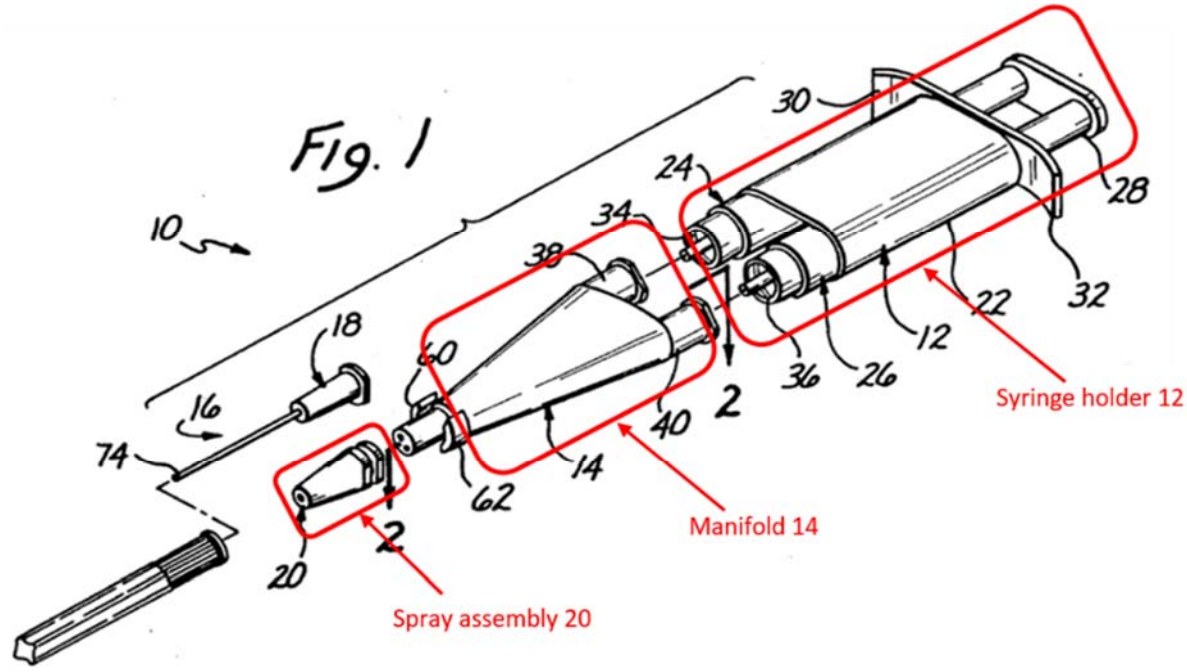
(*Id*. at Fig. 18 (annotated).)

B. Capozzi (Ex. 1011)

Capozzi is a patent that issued on May 26, 1992, from an application filed on December 29, 1989. Capozzi qualifies as prior art under 35 U.S.C. §102(b) because it issued more than one year before the '021 patent's earliest possible priority date of April 25, 2008.

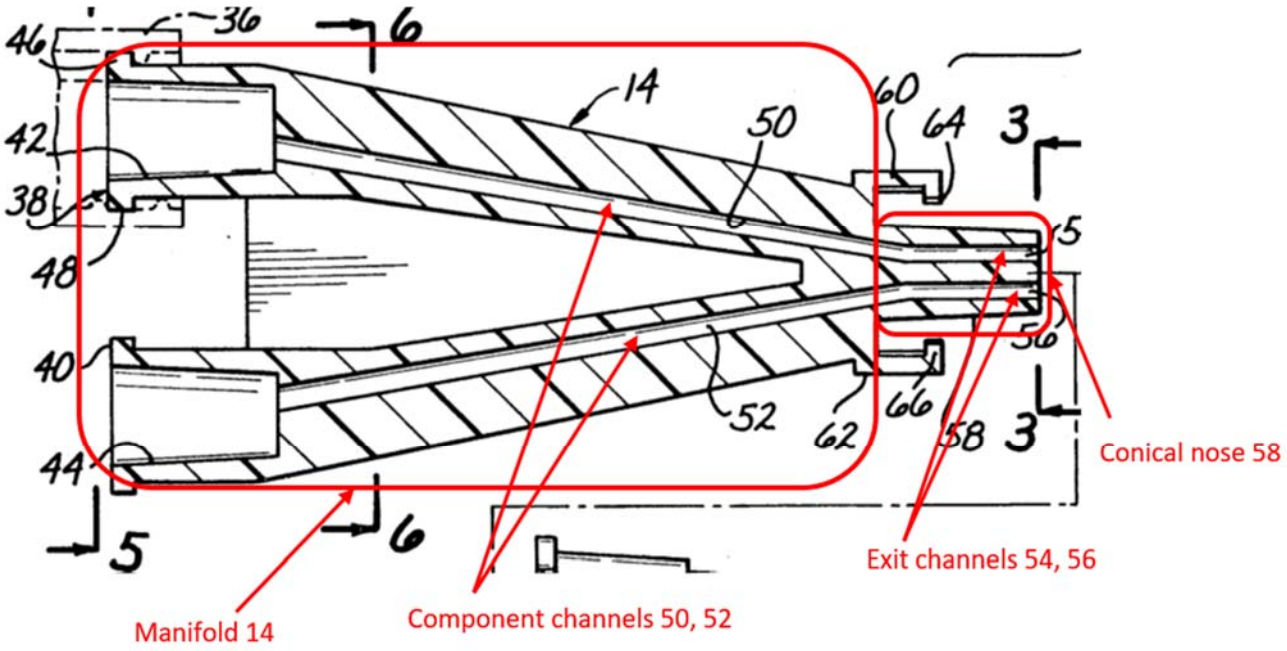
Capozzi discloses a "biological syringe system for delivering a first and

second fluid in a mixed composition" as a spray. (Ex. 1011, Abstract.) Capozzi's device includes a syringe holder 12, a manifold 14, and a spray assembly 20. (*Id*. at Fig. 1; *see also* Ex. 1003, ¶¶76-81.)

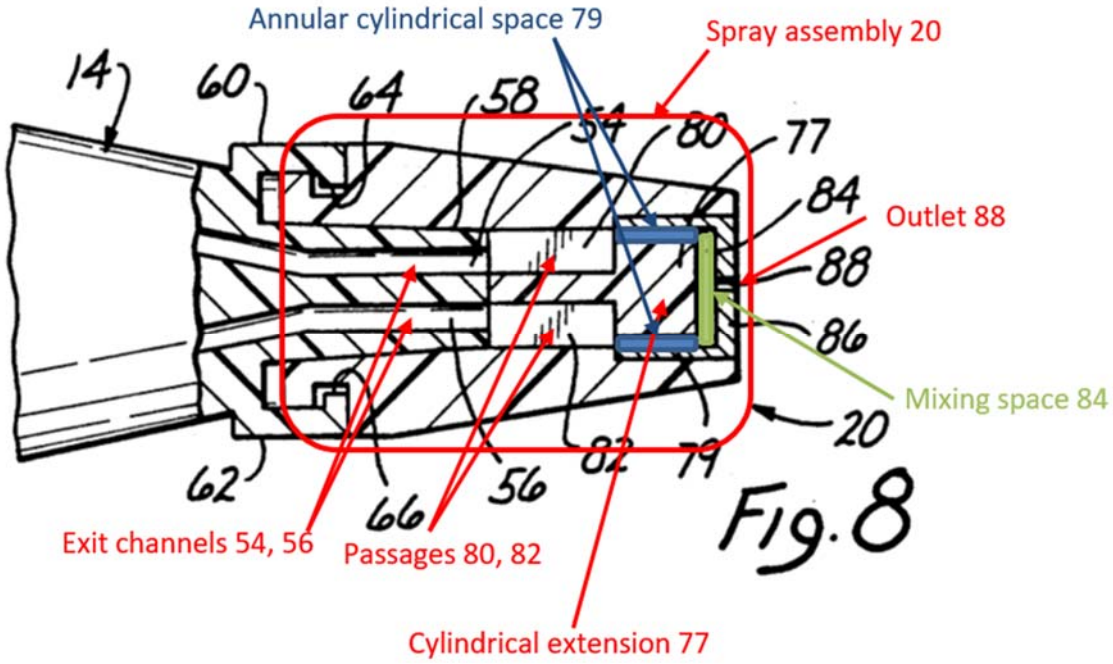


(Ex. 1011 at Fig. 1 (annotated).)

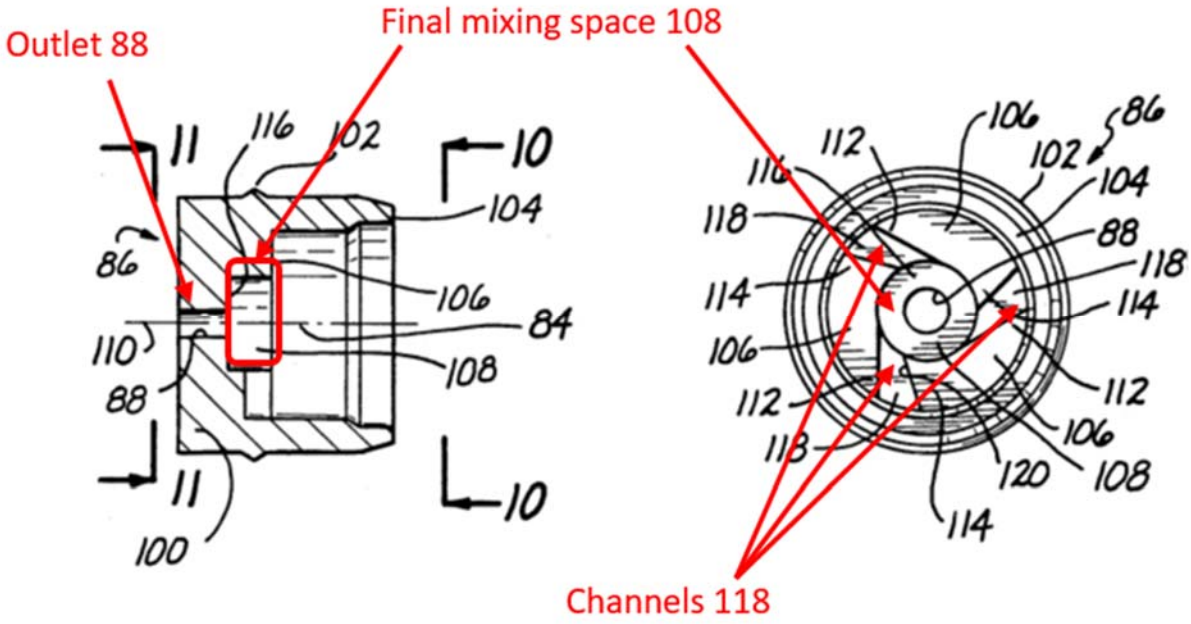
In use, the two components travel from their syringes, through component channels 50, 52 and exit channels 54, 56 in manifold 14 and conical nose 58, respectively.



(*Id*. at partial Fig. 2 (annotated).) The components then enter passages 80, 82 in spray assembly 20, leading to annular cylindrical space 79 formed around cylindrical extension 77, where the two components first make contact and begin mixing before flowing into mixing space 84. (*Id*. at 6:48-59; Fig. 8.)



(*Id*. at Fig. 8 (annotated).) The partially mixed components contact the inner surface of the nozzle body which delivers a portion of the components to channels 118, which transport the components into to final mixing space 108. The channels approach circular mixing space 108 in a generally tangential direction, imparting rotational fluid flow within the mixing space. After mixing, the mixture is ejected as an atomized spray through outlet 88. (*Id*. at 7:3-25.)



(*Id*. at Figs. 9-10 (annotated).)

C. Dodge (Ex. 1012)

Dodge is a patent that issued on May 2, 2006, from an application filed on September 12, 2001. Dodge qualifies as prior art under 35 U.S.C. §102(b) because it issued more than one year before the '021 patent's earliest possible priority date of April 25, 2008.

Dodge discloses a "dispenser" and kit for "dispensing multi-part tissue sealants" and "other liquid preparations, including those requiring mixing immediately before use." (Ex. 1012, Abstract, 1:8-9.) Dodge's device includes a dual syringe body 26, a manifold 30 with a dual-lumen nozzle 78, and a dispensing tip 150. (*Id*. at Fig. 11; *see also* Ex. 1003, ¶¶82-86.)

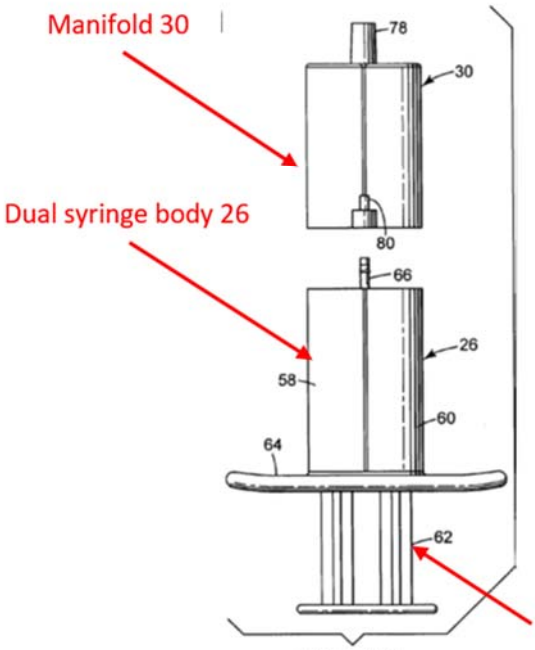


Fig. 1A

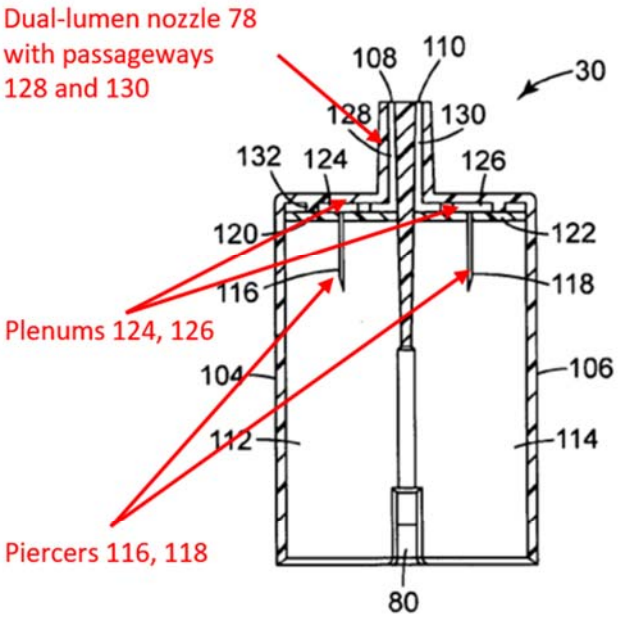


Fig. 10

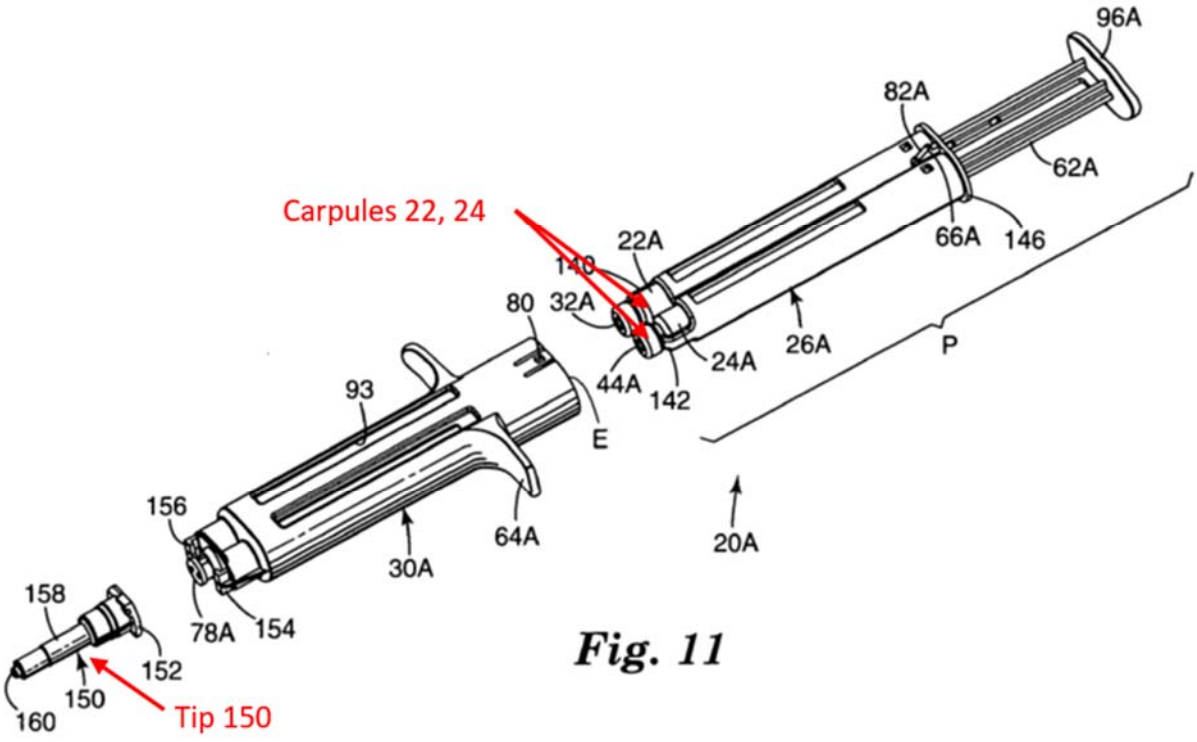


Fig. 11

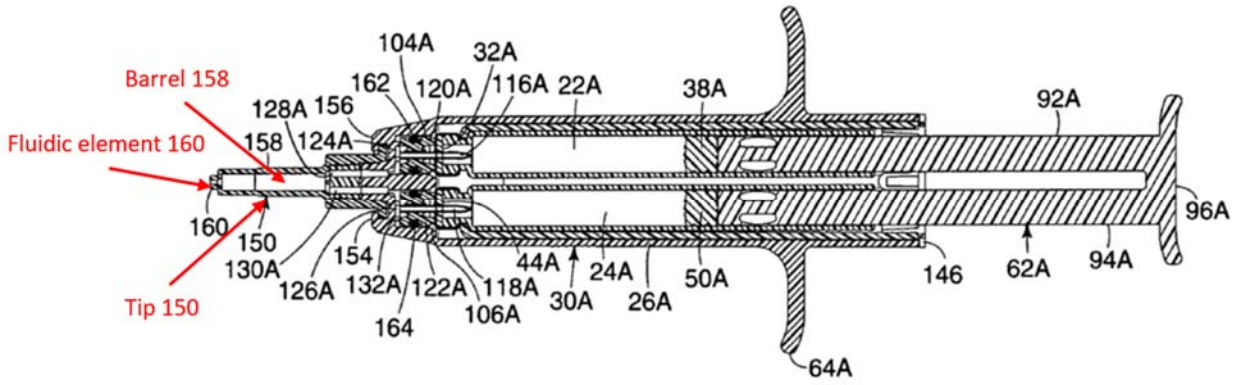


Fig. 12

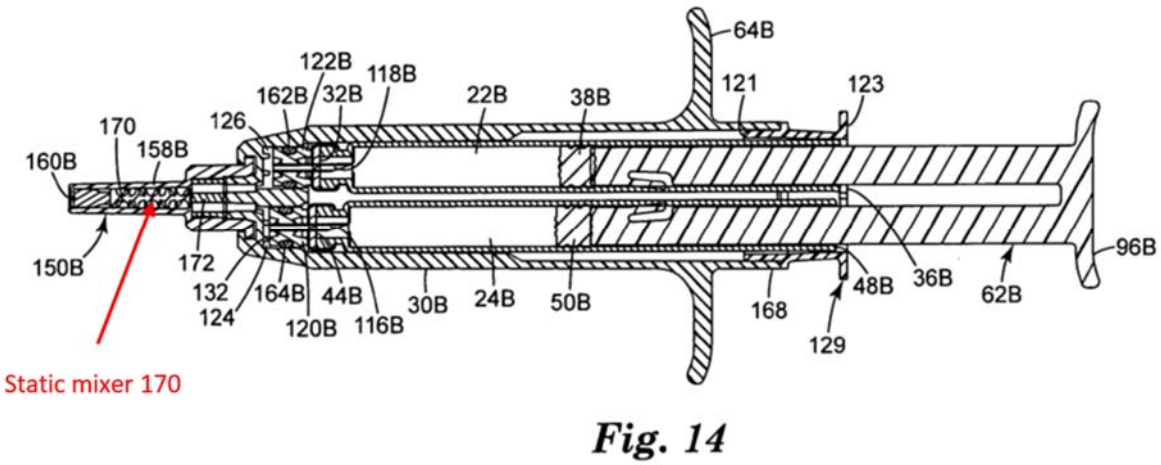


Fig. 14

(Ex. 1012 at Figs. 1A, 10, 11-12, 14 (annotated).)

In use, dual piston 62 is inserted into carpules 22, 24 in dual syringe body 26 and depressed to separately advance the first and second components through hollow central bores in piercers 116, 118 and plenums 124, 126, and ultimately through passageways 128, 130 in dual nozzle 78 to dispensing tip 150. (*Id*. at 7:60-65; 8:11-16; 8:63-66; 9:17-20, Fig. 12.) The two components enter barrel 158 of the

dispensing tip, where static mixer 170 begins mixing the two components, and subsequently travel to fluidic element 160 for final mixing before being dispensed through the orifice. (*Id.* at 10:15-29, 10:66-11:1.)

D. Haber (Ex. 1007)

Haber is a patent that issued on August 30, 1994, from an application filed on December 21, 1992. Haber qualifies as prior art under 35 U.S.C. §102(b) because it issued more than one year before the '021 patent's earliest possible priority date of April 25, 2008.

Haber describes a topical sprayer with a spray tip for the application of atomized liquids, with particular emphasis on the spray application of atomized medications for medical treatment. (Ex. 1007, 1:9-20, 2:31-39.) The spray tip 36 includes spray channel 54 that houses swirl atomizer 40 and nozzle 42. (*Id.*, 6:38-43.)

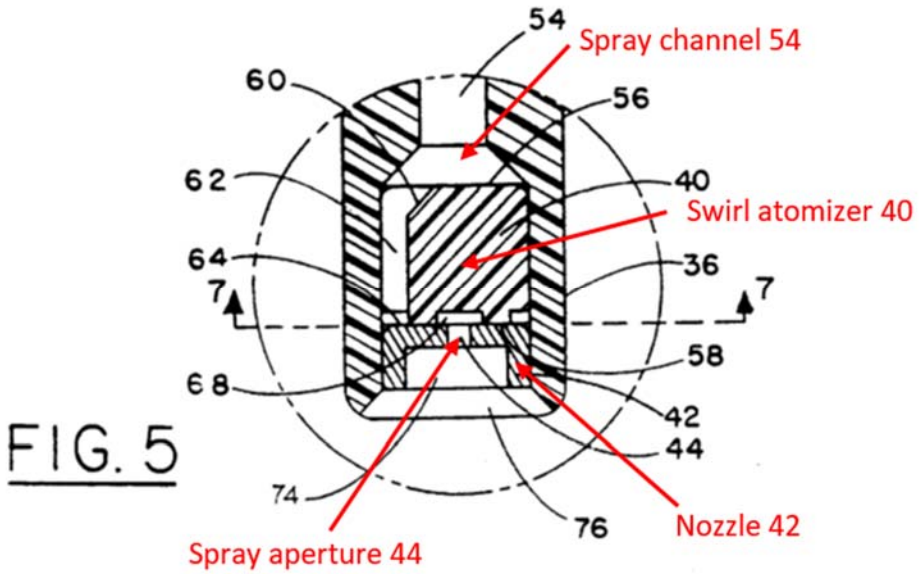


FIG. 5

(*Id.* at Figs. 5 (annotated).)

In use, pressurized liquid flows from spray channel 54 to the proximal end 56 of swirl atomizer 40, through side channel 62 to the distal end 58 of the swirl atomizer where the fluid pressure causes the liquid to evenly disperse around ring channel 64, divide, and pass through the plurality of spoke channels 66 to converge at the central aperture 68. (*Id.*, 6:60-67.)

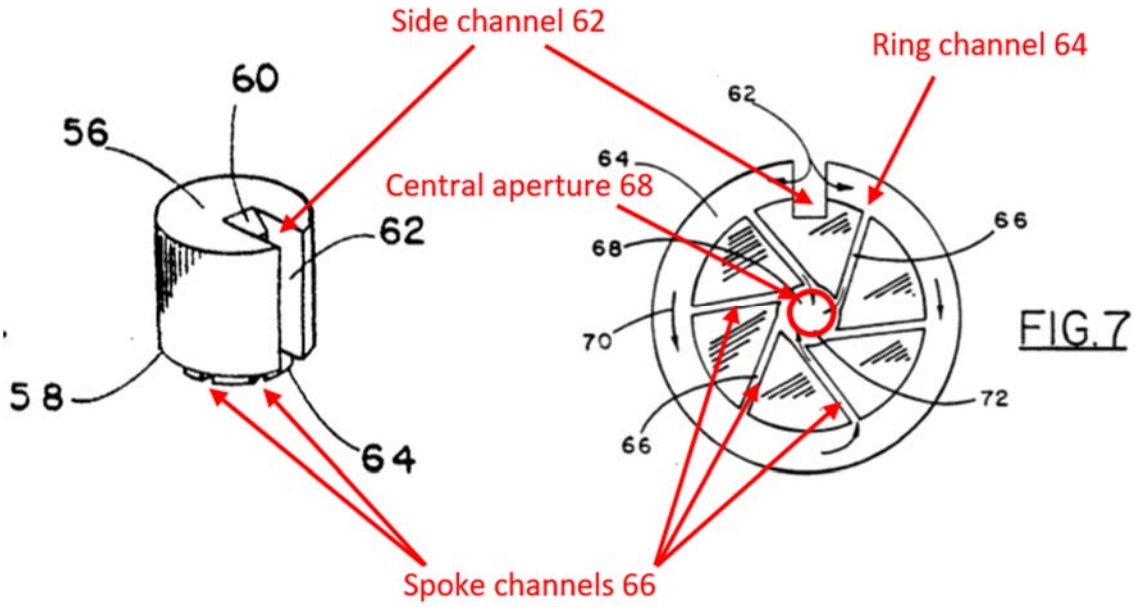


FIG.7

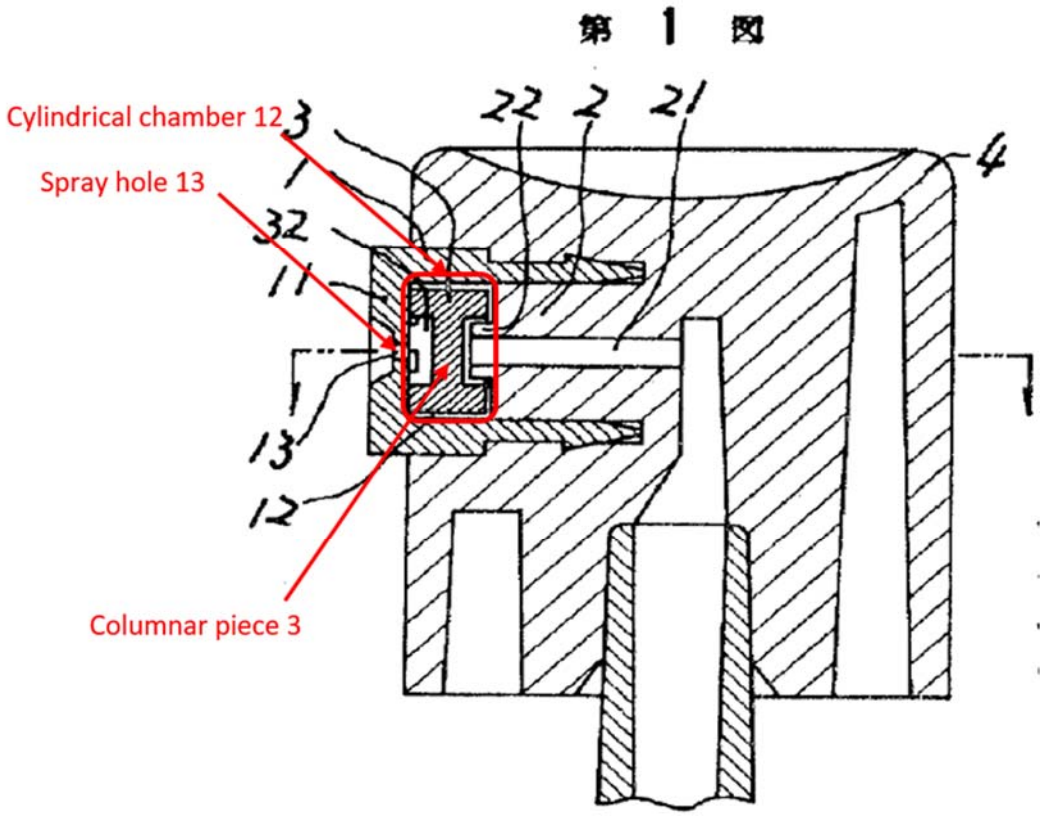
(*Id*. at Figs 6-7 (annotated).) "The configuration of the spoke channels 66 cause the plurality of liquid jet streams to collide at angles relative to one another at high pressure and velocity and thereby atomize under turbulence within the central aperture 68 and exit through spray aperture 44 of nozzle." (*Id*., 6:67-7:3, Fig. 7.) The swirl atomizer 40 thus mixes and atomizes the liquid, causing it to exit the spray tip as a spray or mist. (*See id*., 3:23-27; *see also* Ex. 1003, ¶¶87-91.)

E. Kitabayashi (Ex. 1008; Ex. 1009 (certified translation))

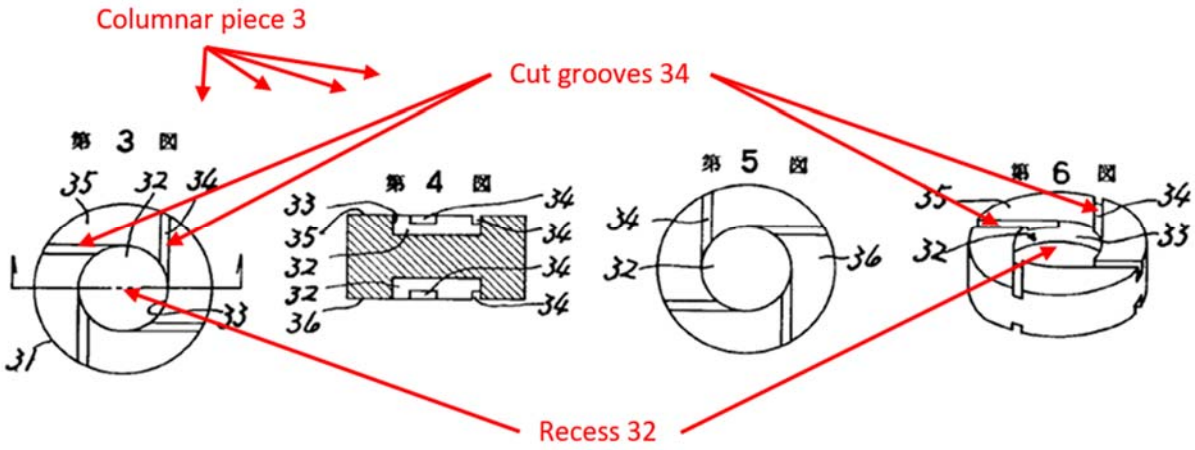
Kitabayashi is a Japanese utility model application publication that published on March 29, 1991, from an application filed on August 3, 1989. Kitabayashi qualifies as prior art under 35 U.S.C. §102(b) because it published more than one year before the '021 patent's earliest possible priority date of April 25, 2008.

Kitabayashi describes an improved spray nozzle mechanism for achieving an

atomized spray or "mist of fine particles" when spraying various types of liquids from an aerosol or pump type products. (Ex. 1009, at 2¶3, 3¶2.) Kitabayashi discloses a nozzle with columnar piece 3 disposed within cylindrical chamber 12 proximal of spray hole 13. (*Id*. at 3¶3, Fig. 1.)



(*Id*. at Fig. 1 (annotated).) Columnar piece 3 has a centered recess 32 and cut grooves 34 that lead to recess 32. (*Id*. at 3 ¶3, Figs. 3-6.) Recess 32 and cut grooves 34 can be included on both the distal end 35 and the proximal end 36 of the columnar piece. (*Id*. at 3¶4.)



(*Id.* at Figs. 3-6 (annotated).)

In use, pressurized liquid is introduced into the cylindrical chamber 12 and reaches the recess 32 formed in the distal end of piece 3 from the peripheral surface 31 of piece 3 via cut grooves 34. (*Id.* at 4¶3.) When piece 3 is "fixed in the usual manner" the pressurized fluid introduced into recess 32 via cut grooves 34 forms a turbulent, swirling flow in the recess which forms a spray upon exiting spray hole 13. (*Id.* at 4¶4.) Kitabayashi further teaches that when columnar piece 3 is allowed to rotate within cylindrical chamber 12, the swirling flow created from the pressurized fluid entering recess 32 from cut grooves 34 is faster and is accompanied by vibrations from the columnar piece that further disrupt the liquid. (*Id.* at 5¶2.) According to Kitabayashi, this faster swirling flow and these vibrations cause a spray of a fine mist of part to exit the spray hole. (*Id.* at 5¶3; Ex. 1003, ¶¶92-96.)

F. Voegele (Ex. 1013)

Voegele is a U.S. Patent Publication that published on May 29, 2008, from an

application filed on November 10, 2006. Voegele qualifies as prior art under 35 U.S.C. §§ 102(a) and/or 102(e) because it published before the April 22, 2009 effective filing date of the '021 patent and was filed before the April 25, 2008 filing date of Provisional Application No. 61/047,826.

Voegele describes "[a] number of surgical devices for the mixing and dispensing of a dual component surgical adhesive onto tissue." (Ex. 1013 (Voegele), Abstract.) Voegele's dispensing device includes a double syringe system that has "a handle and a first chamber containing a first adhesive component and a second chamber containing a second adhesive component." (*Id*., [0007], Fig. 15.) In one embodiment, depicted in Figs. 11-17, an "adhesive dispensing device 225" "combines a gas assisted mixer system 200 to pressurize, mix, and dispense the adhesive components 80, 81 from a pair of adhesive chambers 262 within a gas actuator handle 226 that feed a pair of empty chambers 272 within an empty replaceable gas cartridge 270." (*Id*., [0063]).

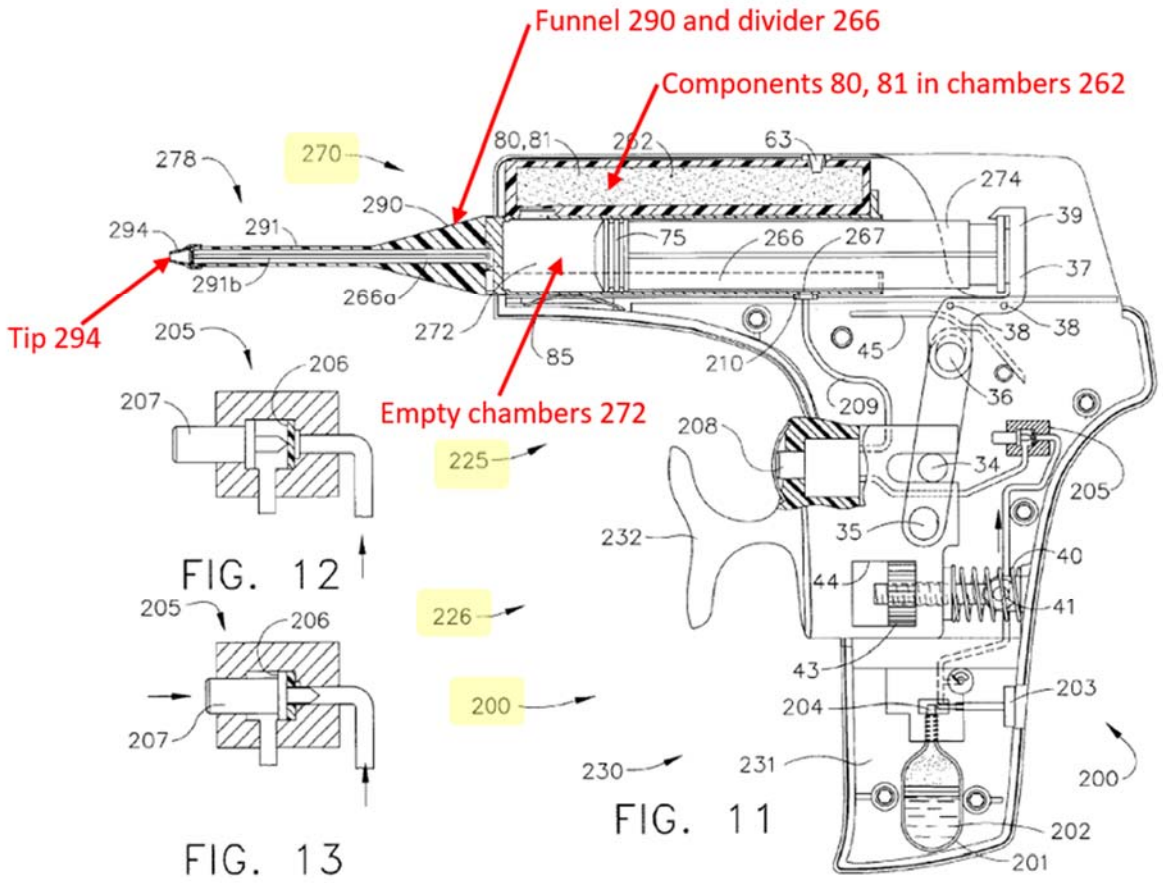

Funnel 290 and divider 266
Components 80, 81 in chambers 262
Tip 294
Empty chambers 272
278
270
290
294
291
291b
266a
272
85
80,81
262
63
274
39
75
266
267
37
38
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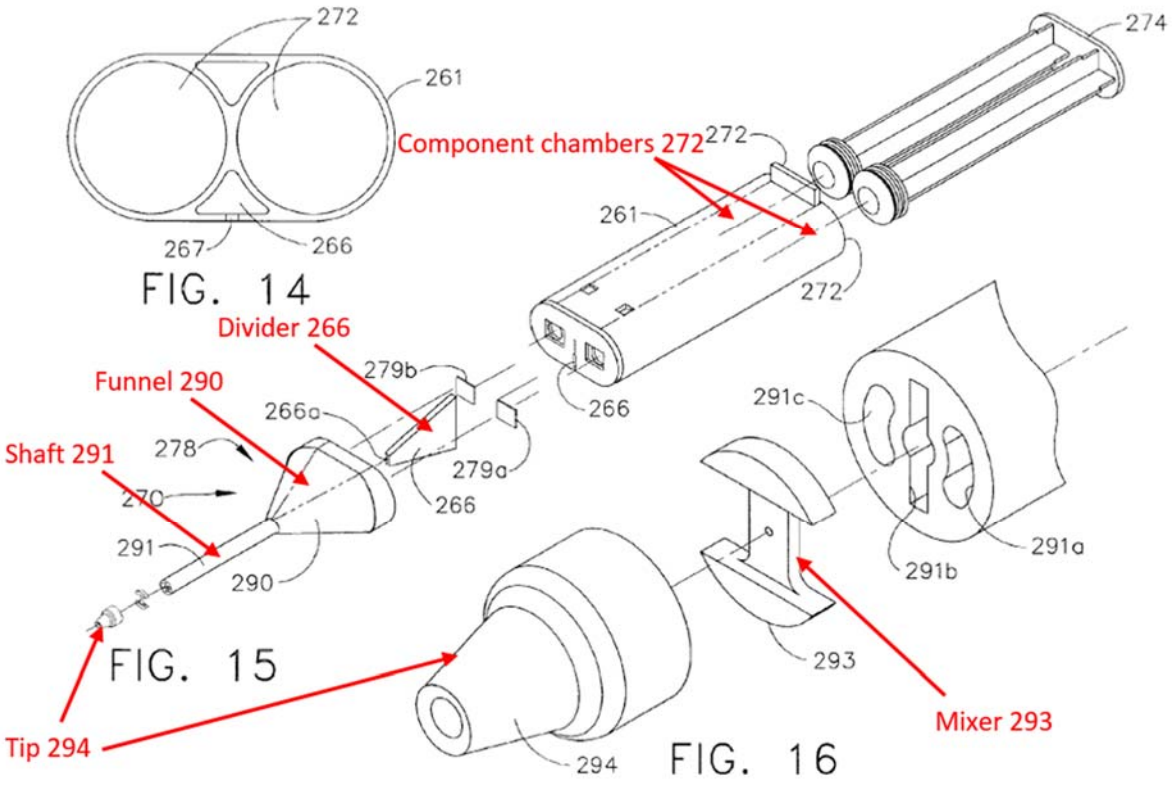
FIG. 12
FIG. 13
FIG. 11



(*Id*. at Figs. 11-16 (annotated).) Voegele discloses sources of a first and second component (80 and 81, held within chambers 272) in fluid communication with a manifold (funnel 290 and divider 266) which is operably connected to a tip 294 with an insert (mixer 293) via an elongated shaft 291. (*Id*., [0063], [0066], Figs. 11, 14-16; *see also* Ex. 1003, ¶¶216-221.)

G. References are Analogous Art

Each of the prior art references combined in this Petition is analogous art to the '021 patent and to the other cited prior art, as each reference is in the same field of endeavor as the '021 patent. (Ex. 1003, ¶97.) The '021 patent is directed to the

field of spray nozzles and fluid applicators. Each of Spero, Capozzi, Dodge, Haber, Kitabayashi, and Voegele are similarly directed to devices for applying and/or spraying fluids.

H. Additional Prior Art Confirming the General Knowledge of the POSA

In addition to the specific references discussed above, Mr. Hattan's declaration (Ex. 1003 at ¶¶24-50) addresses additional prior art confirming the general knowledge of the POSA as of the presumptive April 22, 2009 priority date of the '021 patent (and several years prior).

X. THERE IS A REASONABLE LIKELIHOOD THAT CLAIMS 14 AND 15 OF THE '021 PATENT ARE OBVIOUS AND/OR ANTICIPATED

A. Ground I: Claims 14 and 15 Obvious Under § 103(a) Over Spero in view of Haber

As discussed below, Spero in view of Haber discloses or renders obvious all of the limitations of claims 14 and 15. (*See id.*, ¶¶98-148.)

1. Independent claim 14

a. Spero discloses claim element 14[a]

14[a]	An applicator assembly for dispensing a mixture, the assembly comprising:

To the extent the preamble is limiting, Spero discloses a "laparoscopic spray device for selectively applying a multiple component material dispensed from a multiple component material applicator". (Ex. 1005, Abstract.) The spray device

includes a spray tip with a mixing chamber. (*Id.*)

b. Spero discloses claim element 14[b]

14[b]	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;

Spero discloses a laparoscopic spray device 10 that comprises an interface member 12 in fluid communication with an elongated body 14 having a spray head 16 attached at the distal end of elongated body 14. (*Id.*, [0034].) Interface member 12 contains "two transport lumens 28A, 28B located within the member body 16" of interface member 12. (*Id.* at [0036], Figs. 2-4, 6.) Spero further discloses an elongated body 14 that extends distally from the interface member 12 that includes "at least two elongated body lumens 32A, 32B." (*Id.* at [0044].) The elongated body lumens extend the length of the elongated body. (*Id.* at [0044], Figs. 4, 6, 12-16.) The "elongated body lumens 32A, 32B are capable of engaging the transport lumens 28A, 28B positioned within the interface member 12." (*Id.* at [0044].)

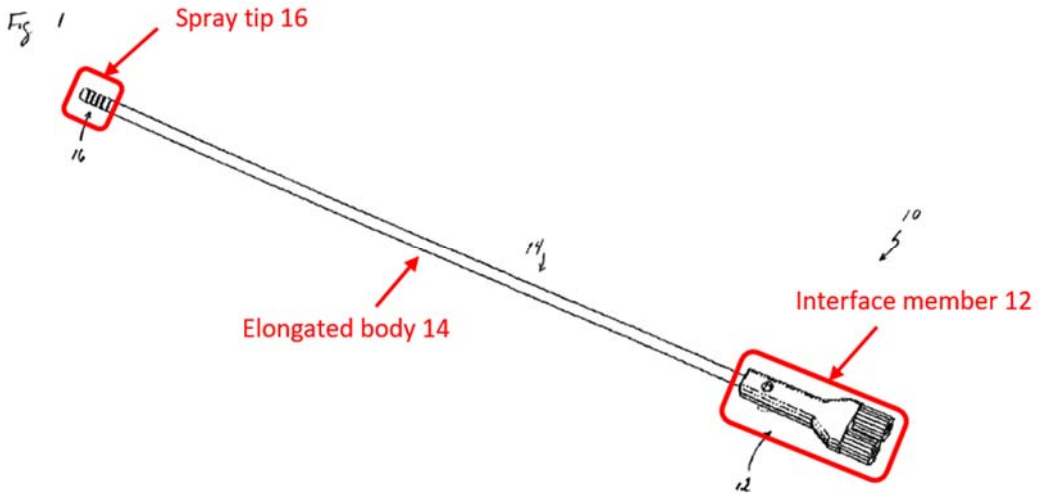


Fig 1
Spray tip 16
Elongated body 14
Interface member 12

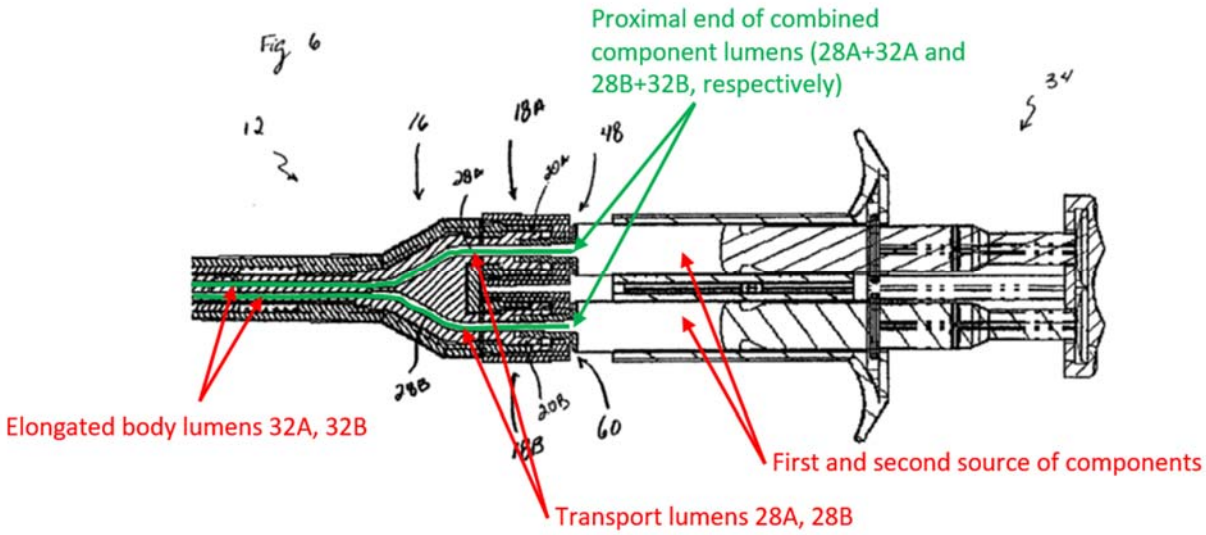
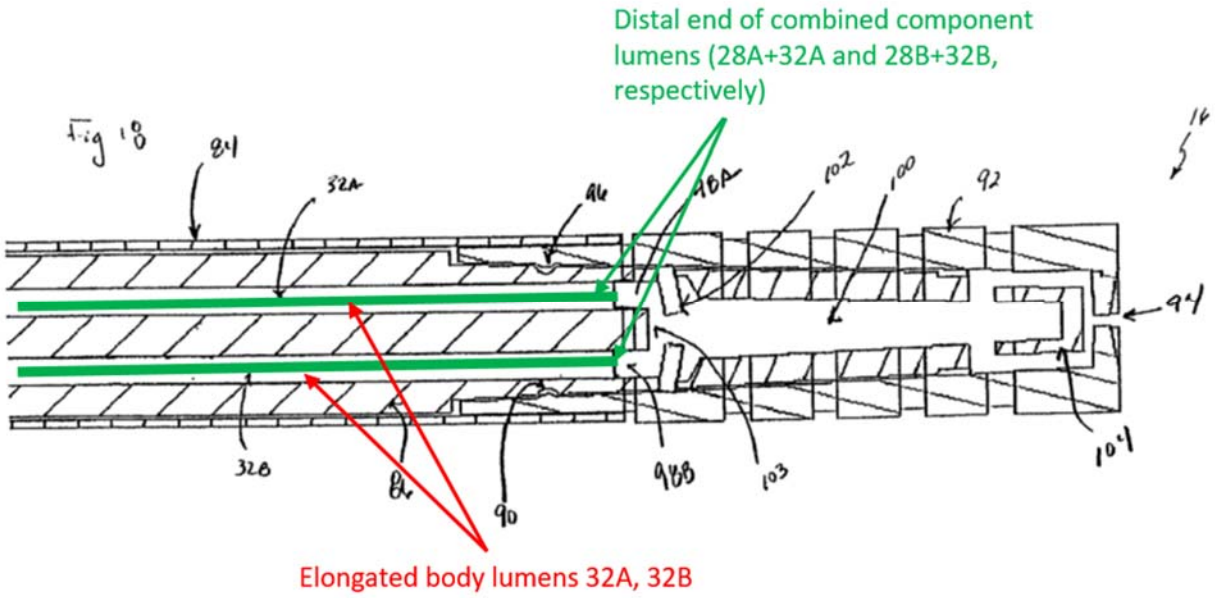


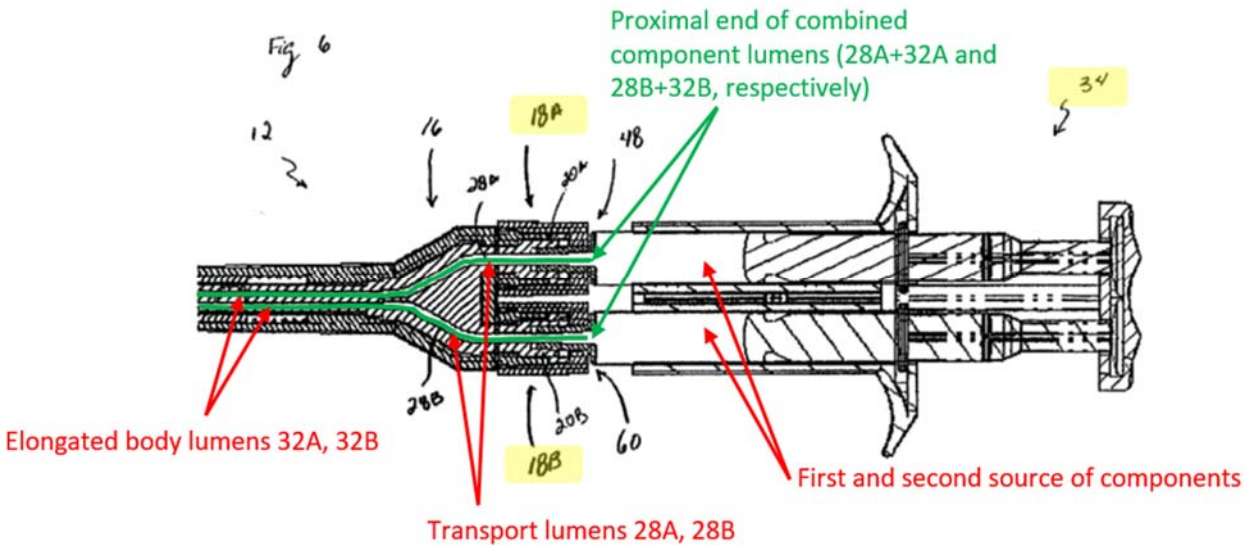
Fig 6
Proximal end of combined component lumens (28A+32A and 28B+32B, respectively)
Elongated body lumens 32A, 32B
First and second source of components
Transport lumens 28A, 28B



(*Id*. at Figs. 1, 6, 18 (annotated).) Spero thus discloses that the transport lumens 28A and 28B in the interface member 12 are fluidly connected to the elongated body lumens 32A and 32B, respectively, and thereby form first and second component lumens (28A+32A and 28B+32B) extending from the proximal end of the transport lumens to the distal end of the elongated body lumens. Thus, Spero discloses a first portion defining first and second component lumens each having proximal and distal ends.

Spero further discloses that interface member 12 couples to applicator 34. (*Id.* at [0040], Fig. 6.) More specifically, the interface member includes a member body 16 with two coupling members 18A, 18B, within which the tips of the first and second syringes "are slideably positioned." (*Id.* at [0035], [0040], Figs. 2-4, 6.) The two transport lumens are in fluid communication with the coupling members, which

are coupled to the first and second sources of components.



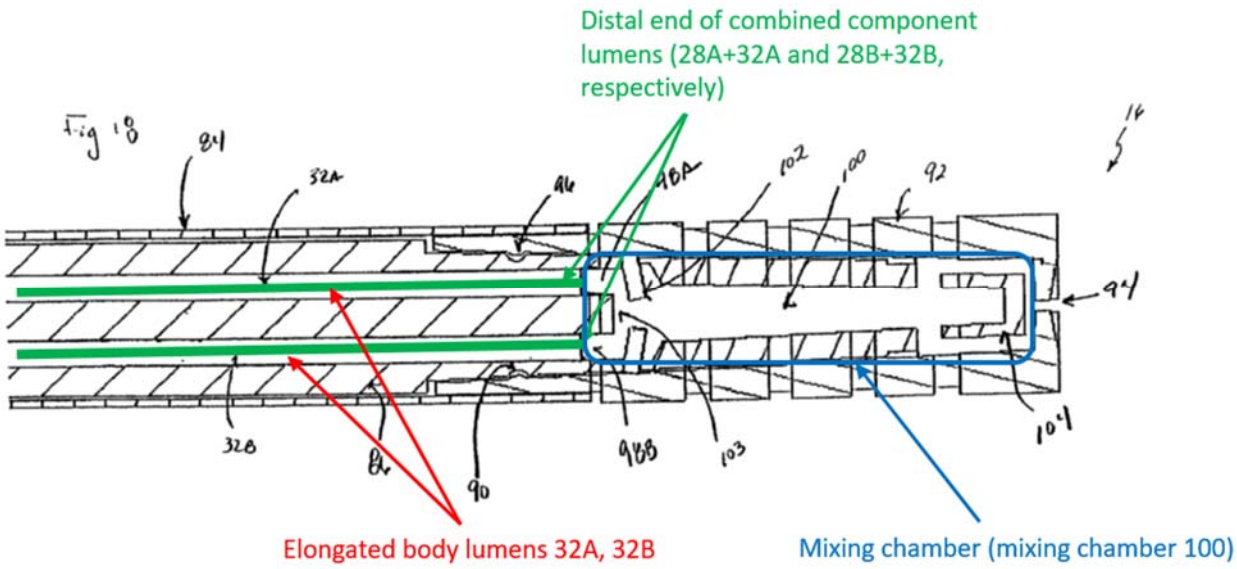
(*Id*. at Fig. 6 (annotated).) Accordingly, Spero discloses that the first and second component lumens (combined lumens 28A+32A and 28B+32B) have proximal ends configured for fluid communication with first and second sources of component, respectively.

c. Spero discloses claim element 14[c]

14[c]	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 shown in Figure 18 below, the spray tip includes mixing chamber 100 in fluid communication with elongated body lumens 32A, 32B via lumen receivers, 98A and 98B respectively. (*Id.* at [0047]-[0049].) Spero thus discloses a second portion defining a mixing chamber (*i.e*., mixing chamber 100 within spray tip 16)

with the distal end of the first and second component lumens (i.e., combined lumens 28A+32A and 28B+32B) being in fluid communication with the mixing chamber.

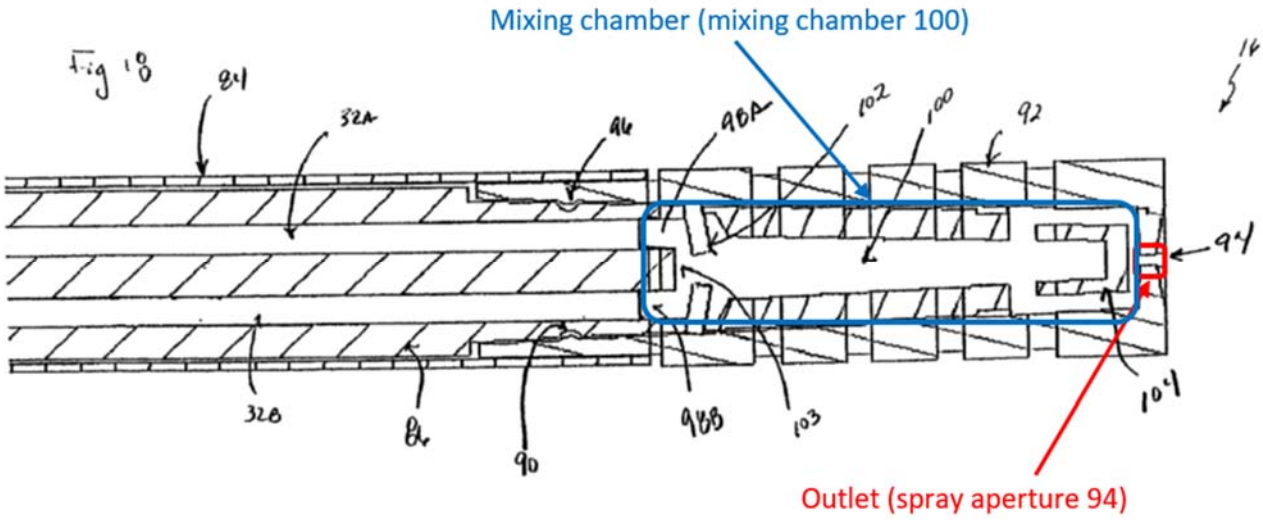


(*Id*. at Fig. 18 (annotated).)

d. Spero discloses claim element 14[d]

14[d]	a third portion defining an outlet in fluid communication with the mixing chamber; and

Spero discloses that as materials are mixed in the mixing chamber 100 via mixing member 102 and spray regulator 104, the "continued application of force expels the mixed material as a spray mixture through the spray aperture 94. (*Id*. at [0049]-[0050], [0053], Fig. 18.)



(*Id*. at Fig. 18 (annotated).) Spero thus discloses a third portion defining an outlet in fluid communication with the mixing chamber in the form of spray aperture 94.

e. It would have been obvious to include claim element 14[e] in Spero's system in view of the teachings of Haber

14[e]	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.

Spero's system includes spray regulator 104, which a POSA would recognize as an insert that is disposed within the mixing chamber 100 between the first and second component lumens and the outlet (spray aperture 94). (*See* Ex. 1005 (Spero) at Fig. 18; Ex. 1003, ¶¶113-114.) For the reasons discussed below, a POSA would have been motivated to replace Spero's insert with the insert disclosed by Haber, with a reasonable expectation of success in doing so.

Haber teaches a spray nozzle configuration that has a cylindrical insert with a recess in the distal end (i.*e.*, an end of the insert, in accord with Petitioner's proposed construction of "a first end"). (Ex. 1007 (Haber) at 6:34-7:9.)

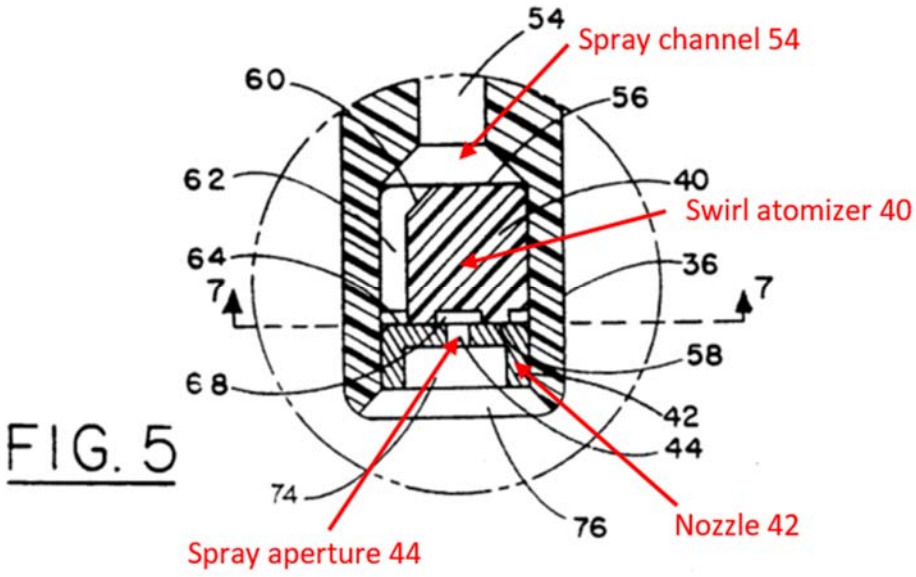


FIG. 5

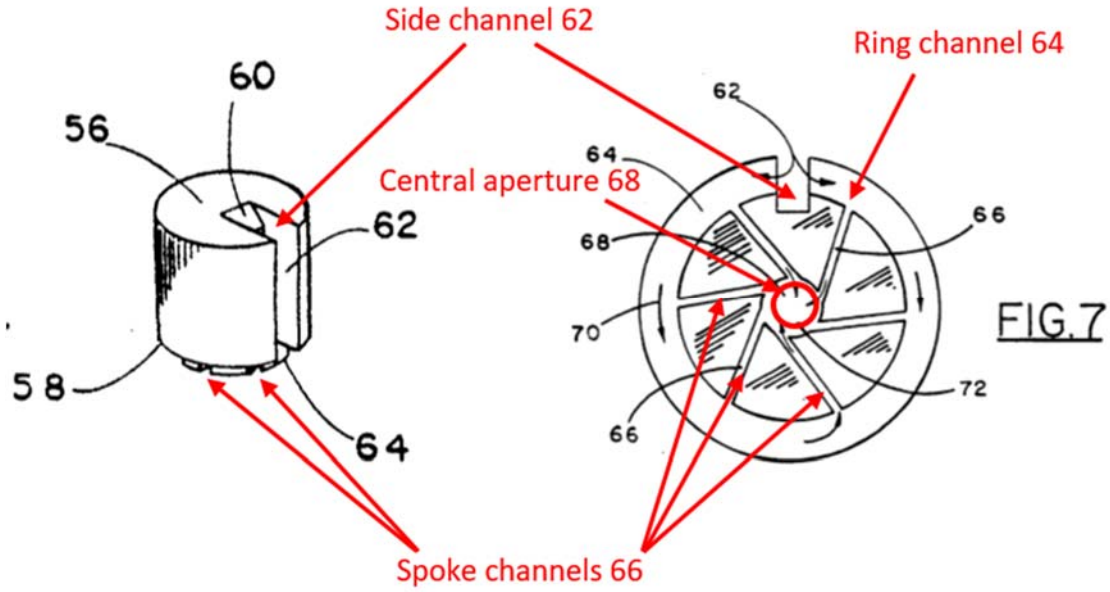


FIG. 7

(*Id.* at Figs. 5-7 (annotated).) In particular, Haber teaches that swirl atomizer 40 is housed within spray channel 54 and that the distal end of swirl atomizer 40 contains

recesses in the form of ring channel 64 and spoke channels 66, which tangentially converge to central aperture 68. (*Id*.) Finally, as can be seen in Figures 6 and 7, the insert—swirl atomizer 40—is cylindrical in shape. (*Id*. at Figs. 6-7.) Thus, Haber discloses an insert including a cylindrical member having a recess formed in a first end thereof, and when substituted for Spero's spray regulator, it would be disposed in a mixing chamber between the first and second component lumens and the outlet.

In the alternative, if recessed slope 60 and/or side channel 62 are viewed as making the insert (swirl atomizer 40) not "include[]" a "cylindrical member," Haber nonetheless teaches a substantially cylindrical member and renders including a "cylindrical member" obvious. (Ex. 1003, ¶116.) It would have been an obvious design choice within the ordinary skill of the art to remove these longitudinal channels and make this portion of the Haber insert a solid cylinder, as evidenced, for example, by the solid cylindrical swirl atomizer inserts disclosed by Green and Kitabayashi, as well as numerous other prior art references. (*Id*.) The obviousness of this modification would be informed by the knowledge of a POSA. (*Id*. at ¶¶24-50.) Accompanying this obvious modification, a POSA would have recognized that one would simply make the outer diameter of swirl atomizer 40 somewhat smaller so that there was an annular space between the insert and the walls of mixing chamber 100 that would allow fluids to flow along the insert around the entire circumference of the insert (as opposed through channel 62) to reach the recesses on

the distal end. (*Id*., ¶116.) Indeed, other prior art swirl atomizer inserts employed such a flow path using an annular space such as this, and this modification would serve to make the flow path around the Haber insert match even more closely the flow path around the insert—spray regulator 40—via an annular space around the circumference of the insert depicted by Spero in Figure 18, above. (*Id*.)

(1) Motivation to Combine Spero and Haber

Spero itself provides motivation or suggestion to replace spray regulator 104. Spero recognizes that those skilled in the art will appreciate that characteristics of spray regulator 104 and spray aperture 94 affect the spray behavior and that alternative spray tips can be used. (Ex. 1005 (Spero) at [0050], [0054].) Accordingly, a POSA would understand Spero to teach or suggest modifying the spray regulator and/or spray tip to achieve desired mixing and spraying characteristics, and that Spero's design was compatible with alternative spray tip designs such as Haber's. (Ex. 1003, ¶117.) Based on Spero's teachings alone, incorporating the teachings of Haber's recessed insert would be nothing more than (i) simple substitution of one known element for another to obtain predictable results; (ii) use of a known technique to improve similar devices (methods, or products) in the same way; (iii) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; and (iv) obvious to try – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of

success. (*See* M.P.E.P. § 2143; Ex. 1003, ¶118.)

The use of an insert with a recess on its distal end within the tip of a dual-component sprayer provides no novel or unexpected results. The manner by which a spray tip performs its mixing and spray functions was an obvious matter of design choice among well-known options within the skill of the art. (Ex. 1003, ¶119.) This knowledge and skill of a POSA is demonstrated, for example, by a prior art dual-component bioadhesive applicator reference, Dodge, that provides that its dispensing tip "may be made in accordance with, e.g., the teachings of" a book entitled Atomization and Sprays by Arthur Lefebvre, which describes a number of spray nozzle design choices, including examples of swirl atomizers that (like Haber) use inserts with recesses on their distal end. (Ex. 1012 (Dodge) at 2:17-20, 10:62-66; Ex. 1029 (Lefebvre) at 112-117; Ex. 1003, ¶119.) A POSA also would have recognized that other prior art dual component applicators employed similar swirl atomizer geometries to achieve mixing and atomization of the components. (*See id.*, ¶¶119, 121.) Picking and choosing from a number of well-known, successful design options, including the swirl atomizer design taught by Haber, is not inventive but rather is a matter of routine design choice within the skill of the art. (Ex. 1003, ¶119.)

Further, a POSA would have been motivated to make such a routine design choice and replace Spero's spray regulator 104 based on the teachings of Haber to improve both mixing and atomization of the adhesive components. The purpose of

spray regulator 104 according to Spero was: (i) to further ensure that the material located within the mixing chamber was adequately mixed and (ii) to provide impedance within the mixing chamber to aid in the formation of a material spray, but a POSA would have recognized that the depiction of spray regulator 104 was incomplete, and that a POSA would have needed to modify certain elements or add elements not shown, such as a means of affixing disclosed spray regulator 104 within the mixing chamber, for the spray regulator to perform these stated functions and for the device to function as designed. (*Id*. at ¶120.) Further a POSA would have recognized that the spray regulator 104 as depicted was a sub-optimal solution for achieving these stated goals, as it is shown as having a smooth distal end that faces the distal wall of mixing chamber 100 which is also shown to be smooth. The flow in the tip would change direction when reached the distal end of the spray regulator and flow radially inwards towards the spray tip opening, but because there are no structures to channel the flow in this space, the flow would effectively converge uniformly from all directions and the spray regulator would not act to impart a substantial swirling component to the flow. (*Id*.) In contrast, a POSA would recognize that Haber's insert provided such structure to channel the flow and impart a substantial, advantageous swirling component to the flow at the distal end of the insert just prior to the mixture exiting the tip opening. (*Id*.)

Haber teaches a spray nozzle that incorporates a swirl atomizer. A POSA would be motivated by Spero's teaching or suggestion (i) that alternative spray tips can be used that alternative spray tips can be used (Ex. 1005 (Spero) at [0050], [0054]), and (ii) that the purpose of Spero's spray regulator 104 was to ensure that the material located within the mixing chamber was adequately mixed and to provide impedance within the mixing chamber to aid in the formation of a material spray (*Id*. at [0050]), to apply Haber's teachings to Spero. User Haber's cylindrical insert in Spero's spray tip, as it has been in other prior art dual-component applicators, would more effectively and efficiently achieve Spero's objectives when compared to the disclosed spray regulator 104 (Ex. 1003, ¶¶120-121.) The recess configuration in swirl atomizers, and thus Haber's recess configuration, was well known to provide good vorticity and swirling, which were known to result in: 1) thorough, intimate mixing and 2) good atomization (i.e., formation of a small particle spray or fine mist). (*Id.*, ¶¶123-129.) Haber focuses on the atomization effects provide by its cylindrical insert, but a POSA would understand that the swirl atomizer 40 taught by Haber would also be highly effective at intimately mixing two or more pressurized fluids, such as bioadhesive precursors, via the turbulent, swirling flow that this well-known swirl atomizer geometry induces. (*Id*., ¶123.) Indeed, other prior art dual-component applicators employed similar swirl atomizer geometries and/or swirling flows to mix precursor components for this reason. (*See id.*, ¶121.)

A POSA would be motivated to enhance the mixing and atomization capabilities of the spray tip because components that are more thoroughly mixed and better atomized (e.g., applied as a thin film or in a fine mist) provide a more uniform sealant layer, which beneficially decreases the likelihood of thin spots that may fail prematurely thereby (for the dual-component bioadhesives described in Spero) promoting wound healing. (Ex. 1005 (Spero), [0005]; Ex. 1003, ¶¶122, 130-133.)

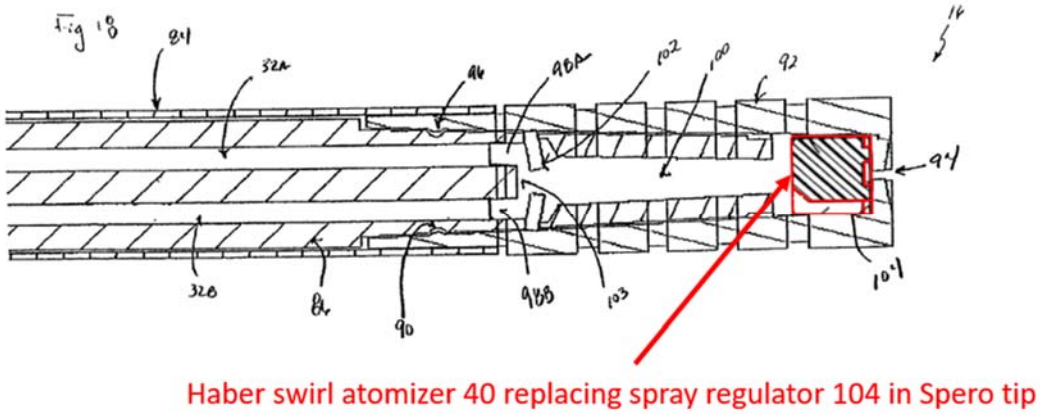
A POSA would have known that better mixing and better atomization reduce component waste by increasing the bonding strength of the adhesive and increasing control over the thickness of the applied layers. (Ex. 1003, ¶133.) Thus, a POSA designing an applicator for a bioadhesive would be motivated to choose a design that would better mix and/or atomize the components, and therefore would have been motivated to replace Spero's spray regulator 104 based on the teachings of Haber. (*Id*., ¶¶133-134.)

Moreover, spray regulator 104 and swirl atomizer 40 are described as serving similar purposes. Spero teaches that the purpose of the spray regulator 104 is to mix the components and aid in forming a spray. Haber teaches that the purpose of swirl atomizer 40 is to impart a turbulent, swirling motion to the fluid to enhance atomization and thus aid in forming a finer particle spray (and, as discussed above, it was well known that this swirling motion would also result in effective, intimate mixing). (Ex. 1005 (Spero) at [0050]; Ex. 1007 (Haber) at 6:60-7:9; Ex. 1003 ¶134.)

Additionally, both Spero and Haber teach using their devices to spray fluids in a medical setting. (Ex. 1005 (Spero) at Abstract; Ex. 1007 (Haber) at 1:9-34, 2:31-34; Ex. 1003, ¶137.)

(2) Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in combining the teachings of Spero and Haber. Replacing the spray regulator 104 in Spero based on the teachings in Haber requires an understanding of only basic engineering principles and manufacturing techniques. For example, the spray regulator 104 and swirl atomizer 40 are similarly situated elements with similar structures and thus replacement of the spray regulator 104 with the swirl atomizer 40 would require only minimal, if any, modification of Spero's spray tip 16. (Ex. 1003, ¶¶135-136.) Indeed, as illustrated in modified Spero Figure 18 below, a POSA could simply replace Spero's spray regulator 104 with the Haber swirl atomizer 40 with little to no modification of either the swirl atomizer insert or the interior of the Spero mixing chamber.



(*See* Ex. 1005 (Spero) at Fig. 18 (annotated and modified by superimposing a portion of Ex. 1007 (Haber) Fig. 5.)

A POSA would understand that the substituted insert should be placed in the mixing chamber 100 such that its distal end abuts the distal wall of the mixing chamber and that the central swirl aperture 68 shares the same central axis as the exit orifice, spray aperture 94. (*See, e.g.*, Ex. 1007 (Haber) at 6:60-7:9, Figs. 5, 7.) Fluids passing around the Haber insert (via one or multiple longitudinal channels or an annular space around its circumference, as discussed above) would then be forced through the spoke channels 66 of the insert, tangentially converging on central aperture 68 at high pressure and velocity to form a turbulent, swirling flow prior to exiting the spray tip, and the improved spray tip thus would function as designed. (Ex. 1003, ¶136.)

The effects of swirl atomizers on fluid flow were well known at the time of the filing of the ’021 patent, and thus the effects of substituting swirl atomizer 40 for

spray regulator 104 would have been predictable. (*Id.*, ¶¶139-141.) In particular, a POSA would have expected such a modification to induce a turbulent swirling flow within the spray tip, which would enhance the mixing and atomization of the components. (*Id*.) Additionally, a POSA would have been familiar with various methods to evaluate, optimize, or predict the behavior of fluidic systems, such as prototype experimentation or computational fluid dynamics (CFD), and would have been able to use these tools to confirm that this substitution resulted in the expected improvements to component mixing and atomization. (*Id*., ¶142.)

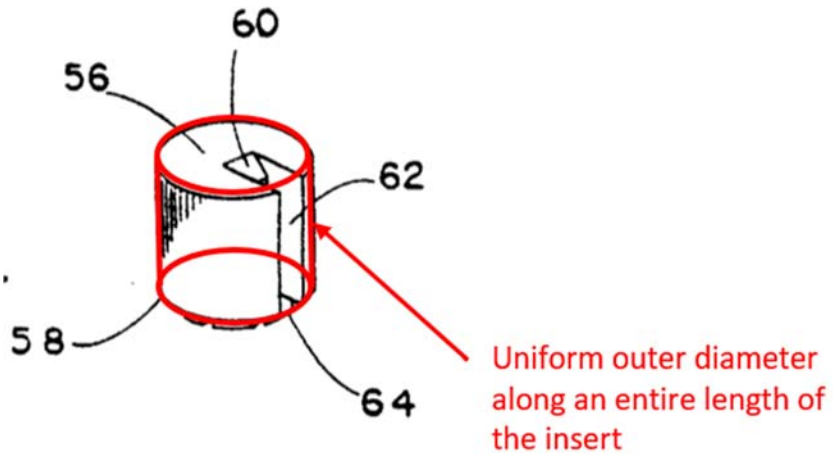
Finally, as discussed above, such a substitution would have required no more than routine skill to accomplish. Spero notes the routine nature of the modification by observing that alternative spray tip designs could be used. (Ex. 1005 (Spero) at [0050], [0054].) Additionally, Spero's spray regulator and Haber's swirl atomizer are positioned in similar locations (centered in a cylindrical chamber just proximal to a spray outlet), so no significant changes would be needed for the fluid flow path around the insert, and the internal structure of the mixing chamber of Spero's spray tip 16 would require little or no modification. (Ex. 1003, ¶143.) Moreover, to the extent that small modifications to the internal structure of Spero's spray tip were necessary to accommodate Haber's insert and have the device function properly, a POSA could simply look to Haber and modify Spero's mixing chamber to match the chamber that houses the swirl atomizer insert, as disclosed by Haber. (*Id*.) Further,

a POSA would have also been able to use the tools discussed above—*e.g.*, prototype testing; CFD—to optimize well-known design variables regarding swirl atomizer design (to the extent any modification or optimization was necessary) and ensure that the spray tip functioned as desired and designed. (*Id.*, ¶144.)

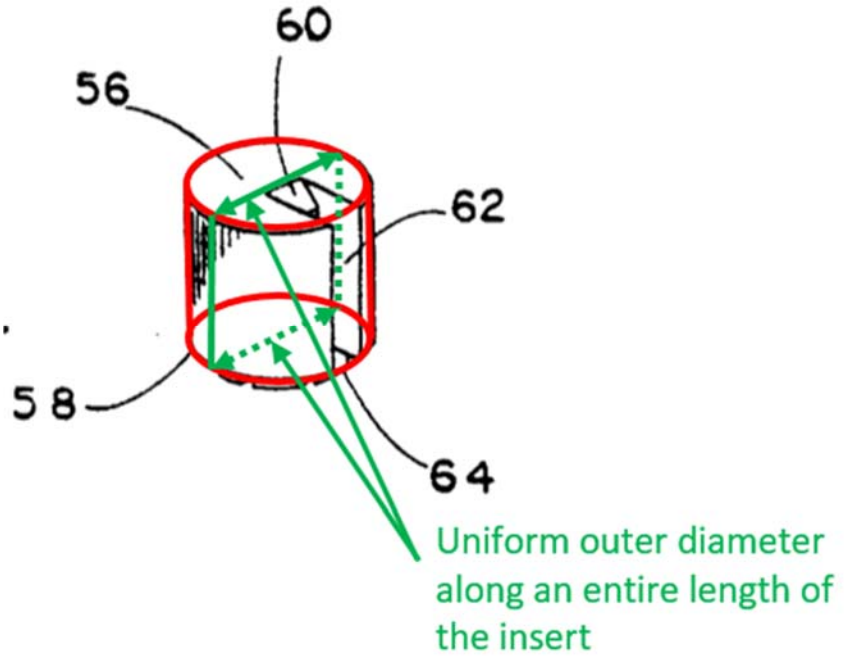
For these reasons, a POSA would have a reasonable expectation of success—*i.e.*, a functional spray applicator as taught by Spero with improved mixing and spray capabilities—in substituting Haber's swirl atomizer 40 for Spero's spray regulator 104. (Ex. 1003, ¶145.)

2. Dependent claim 15

Haber also discloses the additional limitation recited in dependent claim 15. As shown in Figure 6 below, the insert—swirl atomizer 40—has a uniform diameter along an entire length of the insert. In particular, swirl atomizer 40 is depicted as a cylinder of uniform diameter between its proximal end 56 and portion of the insert where ring channel 64 begins.



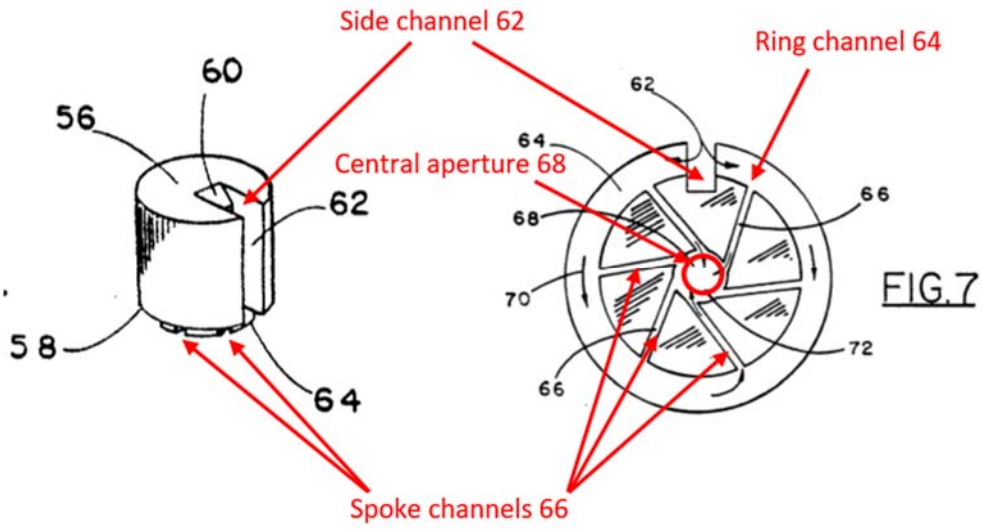
(Ex. 1007 (Haber) at Fig. 6 (annotated); Ex 1003, ¶146.) Further, even when recessed slope 60 and/or side channel 62 are considered, there is still (at minimum) an outer diameter of the insert that is uniform along an entire length of the insert, namely, the diameter of the insert that is perpendicular to the axis of side channel 62 and recessed slope 60, as illustrated below.



(Ex. 1007 (Haber) at Fig. 6 (annotated; Ex. 1003, ¶147.)

Moreover, if the limitation of "an entire length" of the insert is interpreted to mean "the entire length" of the insert, the teachings of Haber, combined with the knowledge of a POSA still would render this limitation obvious. In particular, if the fluid flowed around a modified Haber insert as discussed above via an annular space around the circumference of the insert, rather than through channel 62, there would

be no longer be need for ring channel 64 to distribute the fluid around the outer circumference at the distal end of the swirl atomizer. (*Id*., ¶148.)



(Ex. 1007 at Figs. 6-7 (annotated).) The Haber insert thus could be further modified to expand wedge-like pieces that form spoke channels 66 to reach outer diameter of the insert such that spoke channels inlets would now begin at the outer diameter of the modified insert and the entire length of the insert would have a uniform outer diameter. (Ex. 1003, ¶148.) Modifying well-known design variables that affect the behavior of swirl atomizers, such as the shape and length of the tangential inlets, is an act of routine optimization, not invention, and is within the skill of the art. (*Id*., ¶¶45-46, 144, 148.)

B. Ground II: Claims 14 and 15 are Obvious Under § 103 over Spero in view of Kitabayashi

Claims 14 and 15 are invalid as obvious in light of Spero and Kitabayashi. Kitabayashi discloses a cylindrical insert that has a recess formed in a first end

thereof that also meets the other requirements of claim element 14[e]. Further, a POSA would have been motivated to use Kitabayashi's insert within Spero's device, and a POSA would have had a reasonable expectation of success in doing so. (*See* Ex. 1003, ¶¶149-168.) The obviousness of this combination would be informed by the knowledge of a POSA. (*Id*. at ¶¶24-50.)

1. Independent claim 14

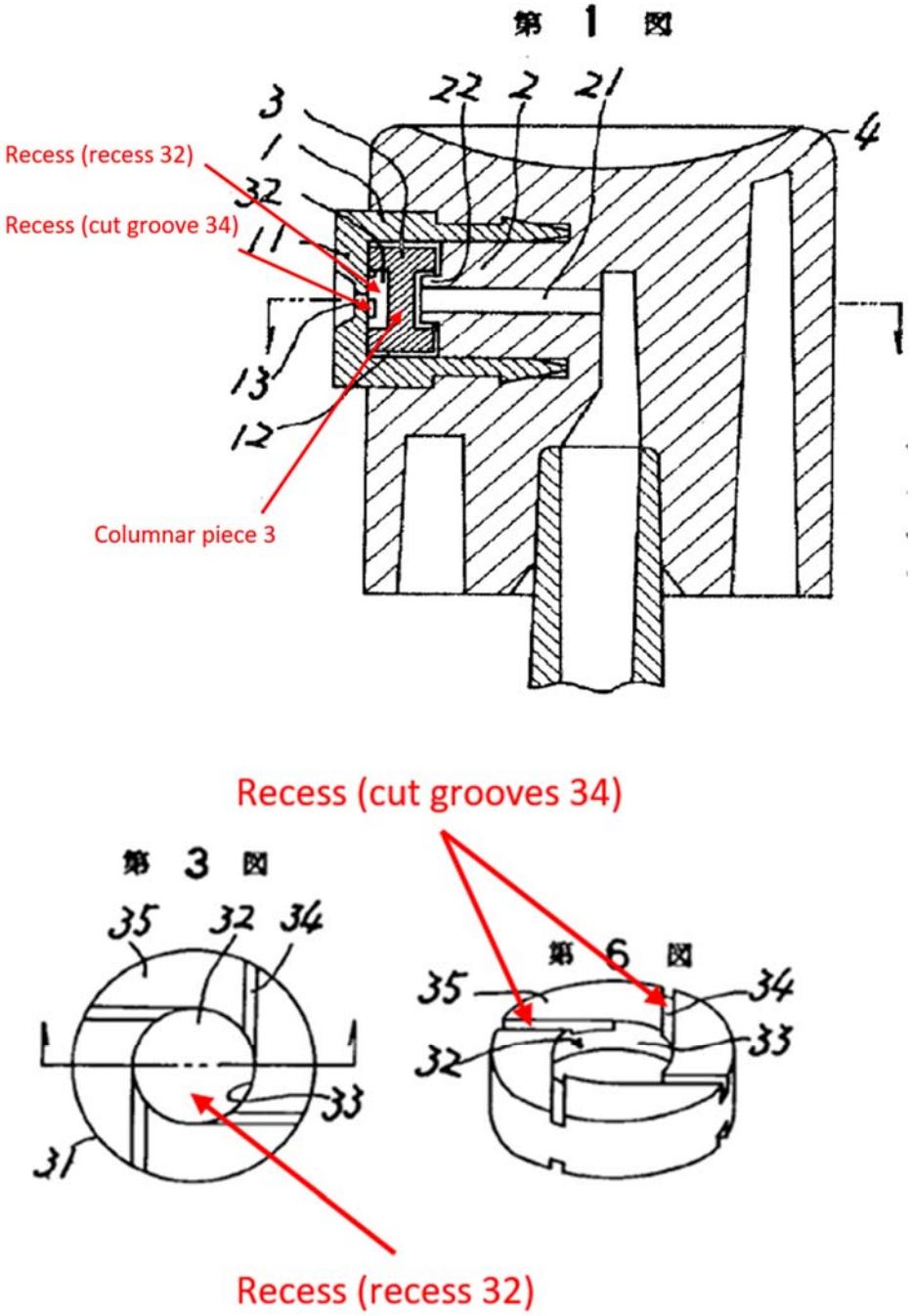
a. Claim elements 14[a]-14[d]

Spero discloses all of claim elements 14[a]-14[d]. The discussion of Spero in Section X.A.1 applies here under Ground II. (*See* Ex. 1003, ¶¶99-113, 150.)

b. It would have been obvious to include claim element 14[e] in Spero's system in view of the teachings of Kitabayashi

Replacing Spero's insert with the cylindrical spray nozzle insert taught by Kitabayashi creates a combination that meets all of the elements of claim 14. (*Id.*, ¶150.)

As discussed above, Spero's system includes spray regulator 104, which a POSA would recognize as an insert that is disposed within the mixing chamber 100 between the first and second component lumens and the outlet (spray aperture 94). (*See* Ex. 1005 (Spero) at Fig. 18; Ex. 1003, ¶151.)



(Ex. 1009 (Kitabayashi) at Figs. 1, 3, 6 (annotated).)

As seen in the figures above, Kitabayashi teaches a spray nozzle configuration that has a cylindrical insert with a recess in the proximal and distal ends of the insert,

and thus is an insert that includes a cylindrical member having a recess formed in a first end—*i.e.*, an end, in accord with Petitioner's proposed construction thereof. (*Id*. at 3¶¶3-4, Figs. 1, 3, 6.) In particular, Kitabayashi discloses a columnar piece 3 that includes a recess, in the form of centered recess 32 and cut grooves 34, in at least its distal end 35. (*Id*.) Further, as suggested by its name and shown in its depiction in Figs. 1, 3, and 6 above, the columnar piece 3 is cylindrical and thus is an insert that includes a "cylindrical member." Finally, when substituted for Spero's spray regulator, the Kitabayashi insert would be disposed in a mixing chamber between the first and second component lumens and the outlet, as discussed above.

(1) Motivation to Combine Spero and Kitabayashi

For similar reasons discussed in detail for the combination of Spero and Haber above in Ground I, which apply here in Ground II, a POSA would have been motivated to replace Spero's spray regulator 104 based on the teachings of Kitabayashi to improve both mixing and atomization of the components. (Ex. 1003, ¶152.)

Spero itself suggests that modifications could be made to its spray tip. (*Id*., ¶158.) Moreover, the use of an insert that includes a cylindrical member having a recess formed on an end thereof (such as Kitabayashi's insert) in a dual-component sprayer would provide no novel or unexpected results, but rather was among a number of well-known options within the skill of the art and was thus an obvious

matter of design choice. (*Id*., ¶¶117-119, 158.)

A POSA further would have recognized that the disclosed spray regulator 104 was a sub-optimal solution for achieving Spero's goals of thorough mixing and atomization of the components and that by incorporating the well-understood swirl atomizer geometry embodied by Kitabayashi's columnar piece 3, as other prior art dual-component applicators had done, the modified Spero spray tip would achieve these objectives more effectively and efficiently. (*Id*., ¶152.) The recess configuration in the Kitabayashi insert was well known to provide good vorticity and swirling, which were known to result in (1) thorough intimate mixing, and (2) good atomization, which, in turn, were known to result in less waste of components and a stronger, more uniform sealant layer, which (for the dual-component bioadhesives described in Spero) promotes wound healing. (*Id*., ¶¶153-156.)

Moreover, spray regulator 104 and Kitabayashi's columnar piece 3 are described as serving similar purposes, including at least aiding the formation of a spray. (*Id*., ¶157.)

(2) Reasonable Expectation of Success

For reasons similar to those discussed in detail in Ground I for the combination of Spero and Haber, which apply here in Ground II, a POSA would have had a reasonable expectation of success in combining the teachings of Spero and Kitabayashi. Replacing the spray regulator 104 in Spero based on the teachings

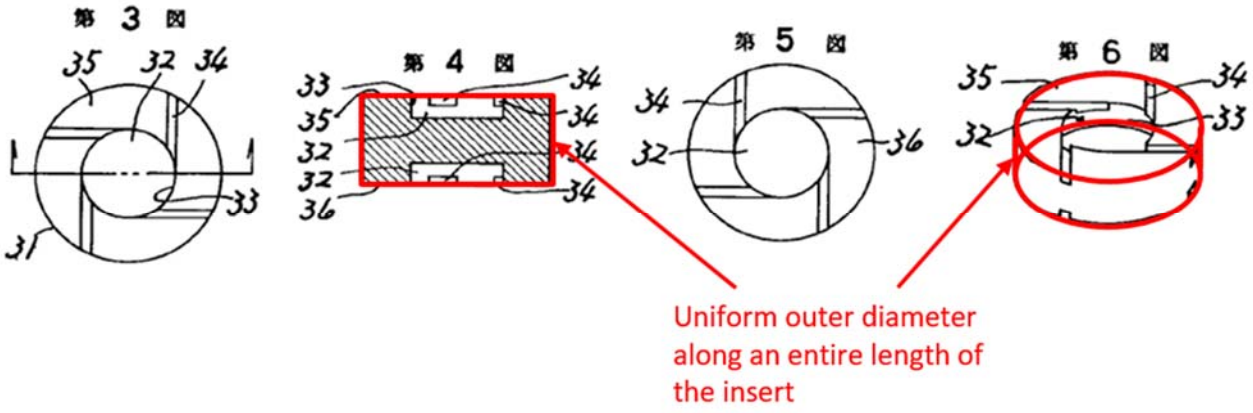
in Kitabayashi requires an understanding of only basic engineering principles and manufacturing techniques that were well within the grasp of a POSA. (Ex. 1003, ¶159.) Little to no modification of Spero's mixing chamber or to Kitabayashi's piece 3 would be necessary to substitute Kitabayashi's insert for spray regulator 104, as the elements are positioned in similar locations and the fluid flow path around the insert would be largely the same. (*Id*., ¶¶159-60, 165.) A POSA would understand that the insert should be placed in the mixing chamber such that its distal end abuts the distal wall of the chamber with the swirl chamber centered on the same axis as exit 94. (*Id*., ¶160.) Further, to the extent that any modifications to the interior of Spero's spray tip were necessary to accommodate the Kitabayashi insert and have it function as designed, a POSA could look to the chamber disclosed by Kitabayashi that houses the insert when adapting Spero's spray tip. (*Id*., ¶165.)

Further, because the effect of swirl atomizers, such as the Kitabayashi insert, were well known and because other prior art dual-component bioadhesive applicators employed similar swirl atomizer geometries to mix and atomize components, the results from combining Spero and Kitabayashi would have been predictable, and a POSA could have used well-known tools, such as prototype testing or computational fluid dynamics, to confirm that the expected improvements in mixing and atomization would be realized. (*Id*., ¶¶161-166.) A POSA thus would have a reasonable expectation of success—*i.e.*, a functional sprayer as disclosed by

Spero with improved mixing and atomization characteristics—in replacing spray regulator 104 according to the teachings of Kitabayashi. (*Id.*, ¶167.)

2. Dependent claim 15

Kitabayashi also discloses the additional limitation recited in dependent claim 15. As shown in Figures 3 through 6, the insert—columnar piece 3—has a uniform diameter along an entire length of the insert. In particular, columnar piece 3 is depicted as a cylinder of uniform diameter between its proximal end 36 and its distal end 35.



(Ex. 1009 (Kitabayashi) at Figs. 3-6 (annotated); Ex. 1003, ¶168.)

C. Ground III: Claims 14 and 15 are Obvious Under § 103 Over Capozzi

As discussed below and in Mr. Hattan's declaration, Capozzi in view of the knowledge of a POSA renders claims 14 and 15 obvious. (*See* Ex. 1003, ¶¶169-185.)

1. Independent claim 14

Capozzi discloses all of the limitations of claim 14 except for a recess formed

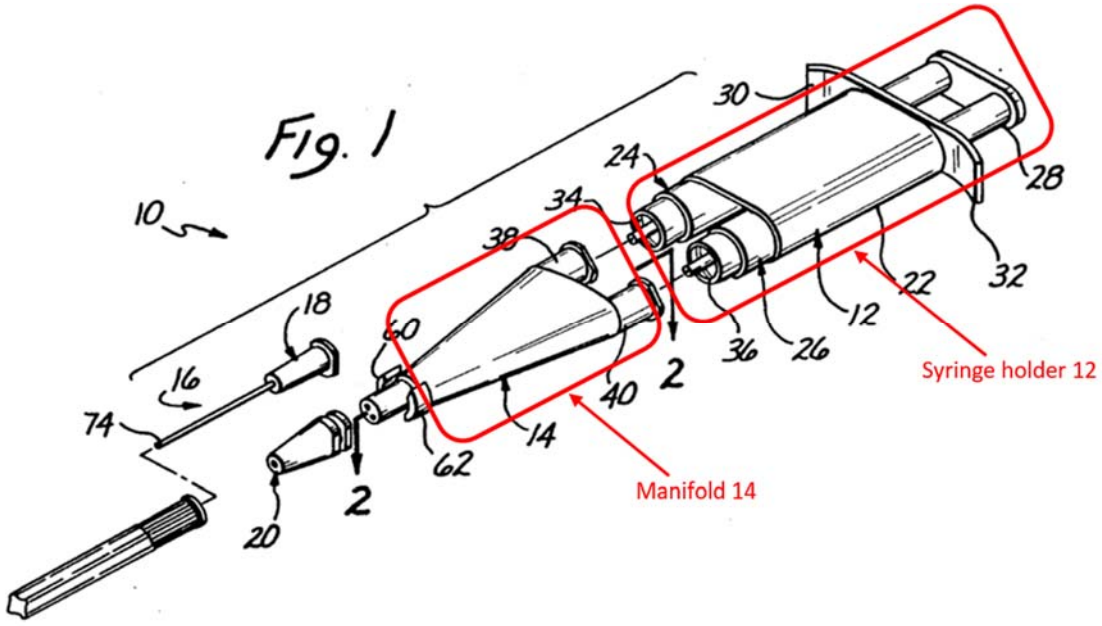
on a first end of an insert, which it renders obvious. (*See* Ex. 1003, ¶¶169-184.)

a. Capozzi discloses claim element 14[a]

To the extent the preamble is limiting, Capozzi discloses a "biological syringe system for delivering a first and second fluid in a mixed composition", satisfying this element. (Ex. 1011, Abstract.)

b. Capozzi discloses claim element 14[b]

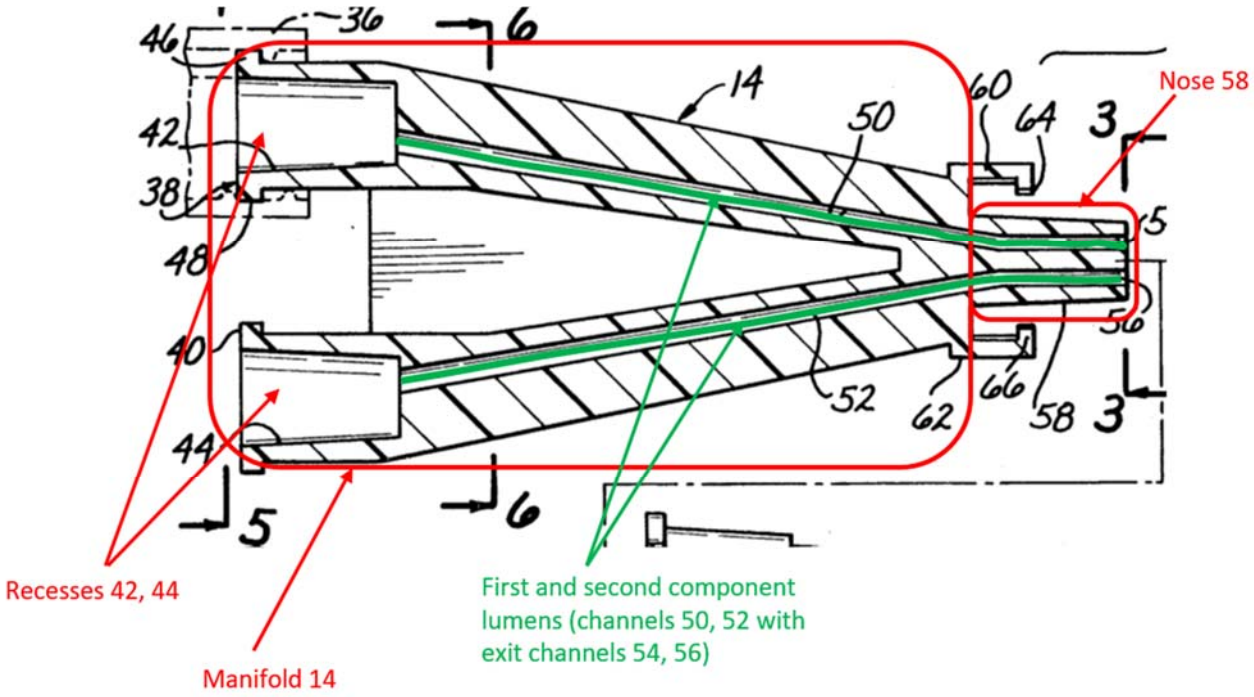
Capozzi's discloses providing "a first fluid" and "a second fluid" from corresponding syringes. (Ex. 1011, 2:49-56.) Additionally, Capozzi teaches syringe holder 12 that receives "two syringes 24 and 26." (*Id.* at 4:28-31.) Capozzi further discloses "manifold 14" that is "configured to detachably lock to the syringes." (Ex. 1011, 4:41-42.)



(*Id*. at Fig. 1 (annotated).) When the manifold is locked to syringes 24, 26, the

manifold 14 is operably engaged with the syringes, *i.e.*, the first and second sources of components.

Capozzi further discloses first and second component channels in the form of "channels 50 and 52" that "extend separately through the manifold" from recesses 42, 44 that receive the noses of the syringes. (*Id.*, 4:58-61.) Channels 50 and 52 extend through the manifold and fluidly communicate with exit channels 54 and 56, respectively, within the forward nose 58 that extends distally from the body of manifold 14. (*Id.*, 4:58-63.)

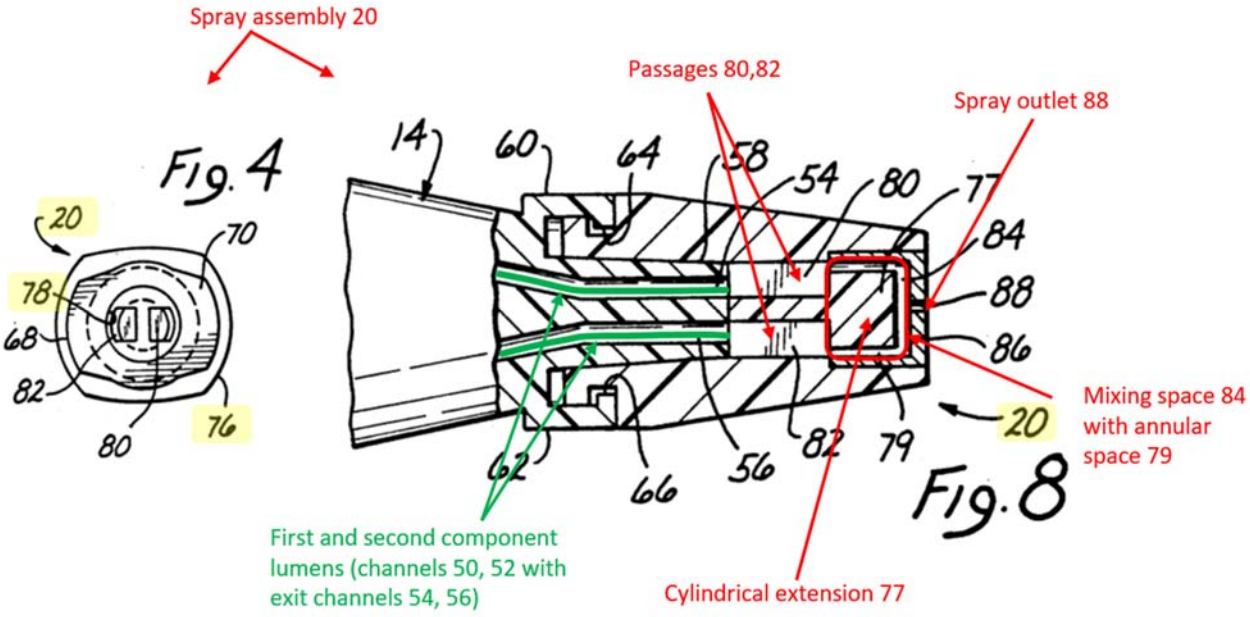


(*Id*. at partial Fig. 2 (annotated).) As shown above in annotated (partial) Figure 2, Capozzi thus discloses a first portion (*i.e.*, manifold 14 and nose 58) defining first and second component lumens (*i.e.*, channels 50, 52 with exit channels 54, 56

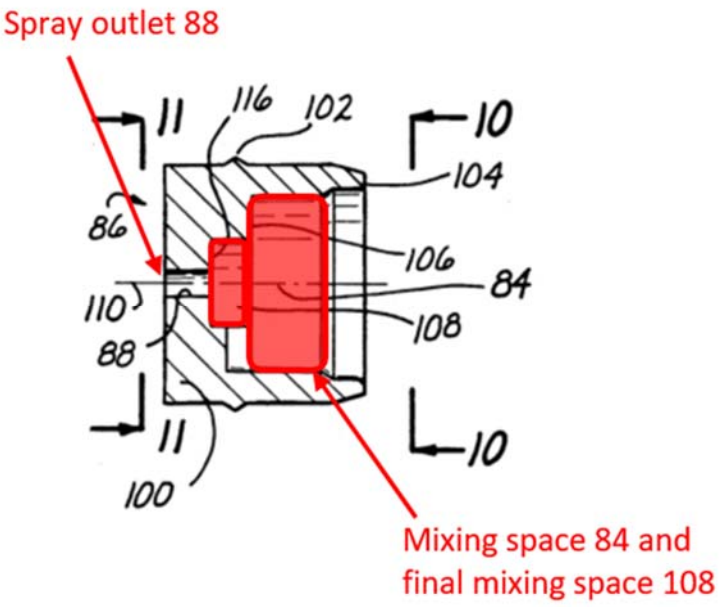
extending through manifold 14 and nose 58) each having proximal and distal ends (*i.e.*, proximal ends where they intersect with recesses 42, 44 and distal ends where they terminate at the distal end of nose 58) with the proximal ends being configured for fluid communication with first and second sources of components, respectively (*i.e.*, channels 50 and 52 are configured for fluid communication with first and second components in syringes 24 and 26 via communication with recesses 42, 44 that receive the noses of the syringes.)

c. Capozzi discloses claim element 14[c]

The system in Capozzi includes spray assembly 20, which includes body 76 with interior surface 78. (Ex. 1011, 5:24-27.) Interior surface 78 "meets and seals with the conical nose 58." (*Id.*, 5:25-27.) Body 76 further includes two passages 80, 82, which align with exit channels 54, 56, and carry the fluid components into mixing space 84 via annular space 79 formed around cylindrical extension 77. (*Id.*, 5:28-35, 6:48-55.) Cylindrical extension 77 is an insert that "extends into the mixing space 84," which is configured to receive this insert. (*Id.*, 6:48-51.) Some limited mixing of the components occurs in annular space 79. (*Id.*, 6:55-59.) Downstream of mixing space 84, body 76 has a final mixing space 108 that leads to spray outlet 88. (*Id*. at 6:19-21, 7:15-23, Figs. 8, 9.)



(*Id*. at Figs. 4, 8 (annotated).)



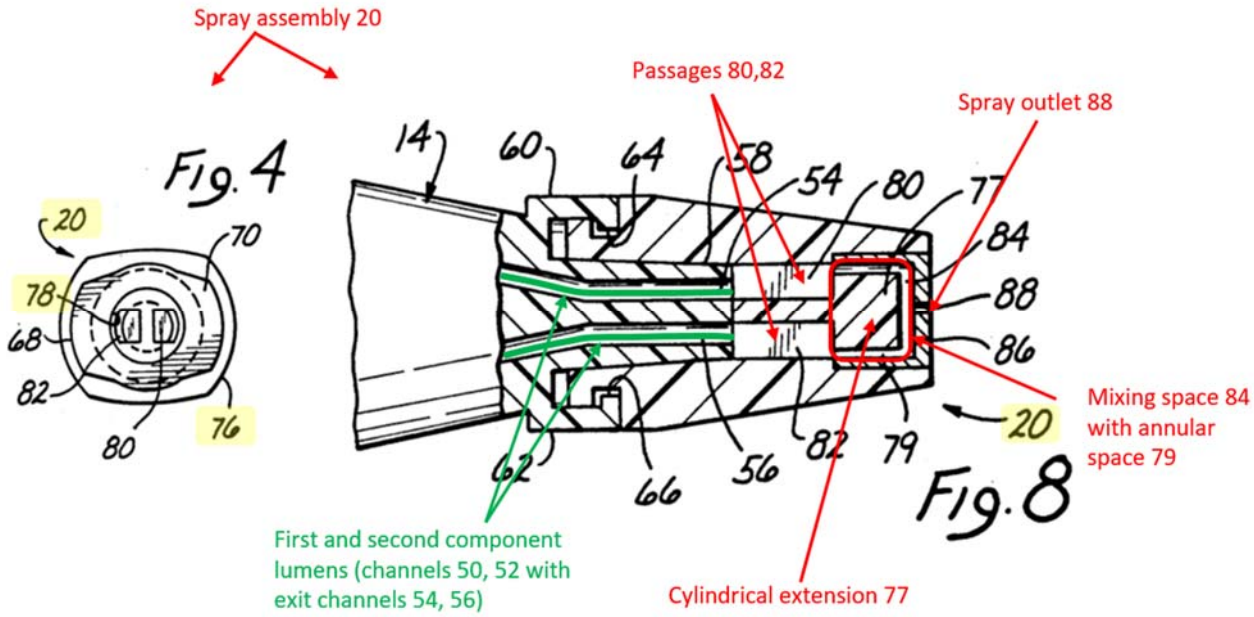
(*Id*. at Fig. 9 (annotated).)

Capozzi thereby discloses a second portion (*i.e.*, spray assembly 20) defining a mixing chamber (*i.e.*, mixing space 84 with final mixing space 108) with the distal

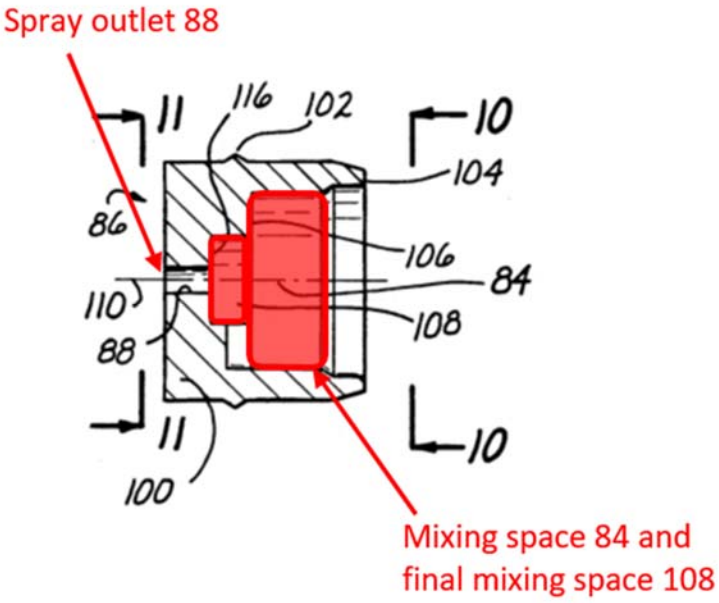
end of the first and second component lumens being in fluid communication with the mixing chamber (*i.e.*, the distal ends of the first and second component lumens in exit channels 54 and 56 are in fluid communication with mixing space 84 and final mixing space 108 via passages 80 and 82 and annular space 79 around cylindrical extension 77). (*See* Ex. 1003, ¶¶175-176.)

d. Capozzi discloses claim element 14[d]

Capozzi discloses that downstream of mixing space 84, body 76 has a final mixing space 108 that leads to spray outlet 88, where mixed fluid from mixing space 108 is ejected under pressure. (Ex. 1011 (Capozzi) at 6:19-21, 7:15-23, Figs. 8, 9.)



(*Id*. at Figs. 4, 8 (annotated).)

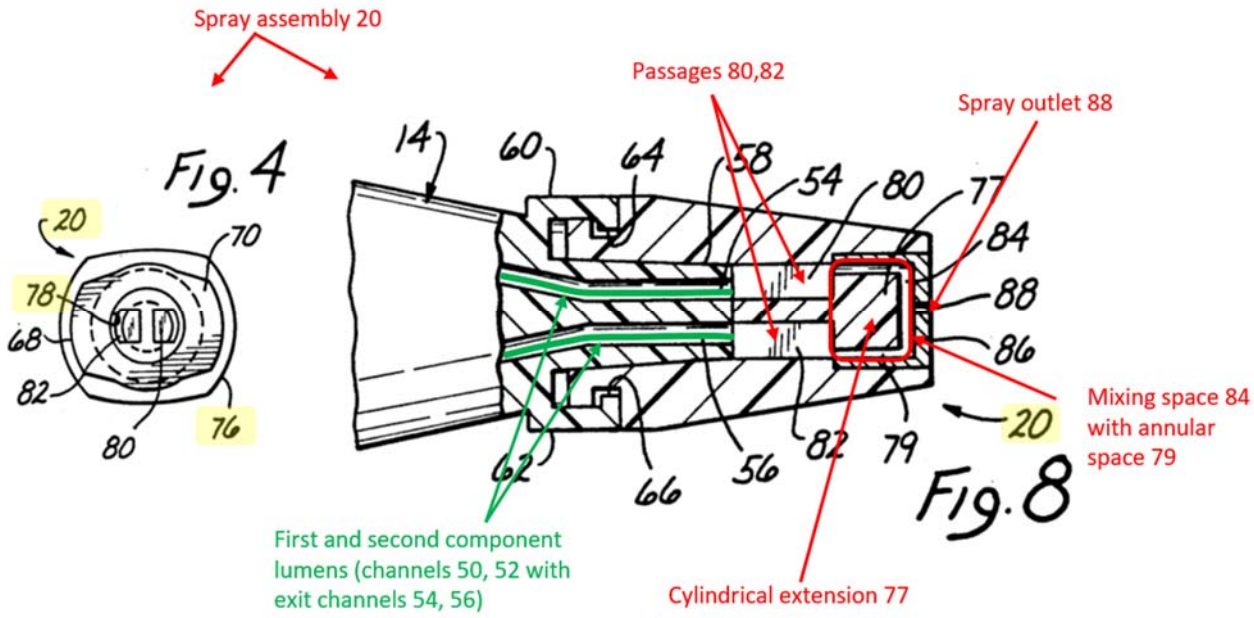


(*Id*. at Fig. 9 (annotated).) Capozzi thus discloses a third portion (*i.e.*, spray outlet 88) defining an outlet in fluid communication with the mixing chamber (*i.e.*, mixing space 84 and final mixing space 108).

e. Capozzi renders claim element 14[e] obvious

Capozzi discloses all parts of claim element 14[e], except for the recess on a first end of the insert, which it renders obvious. (Ex. 1003, ¶¶178-184.) Capozzi discloses cylindrical extension 77, which is an insert that serves to channel the flow through mixing space 84. Cylindrical extension 77 "extends into the mixing space 84" and forms annular cylindrical space 79 between its outer diameter and the adjoining inner wall of nozzle 86. (Ex. 1011 at 6:48-59.) As demonstrated by its name (cylindrical extension 77) and the fact that it, along with nozzle 86, form a "small annular cylindrical space 79," cylindrical extension 77 is an insert that

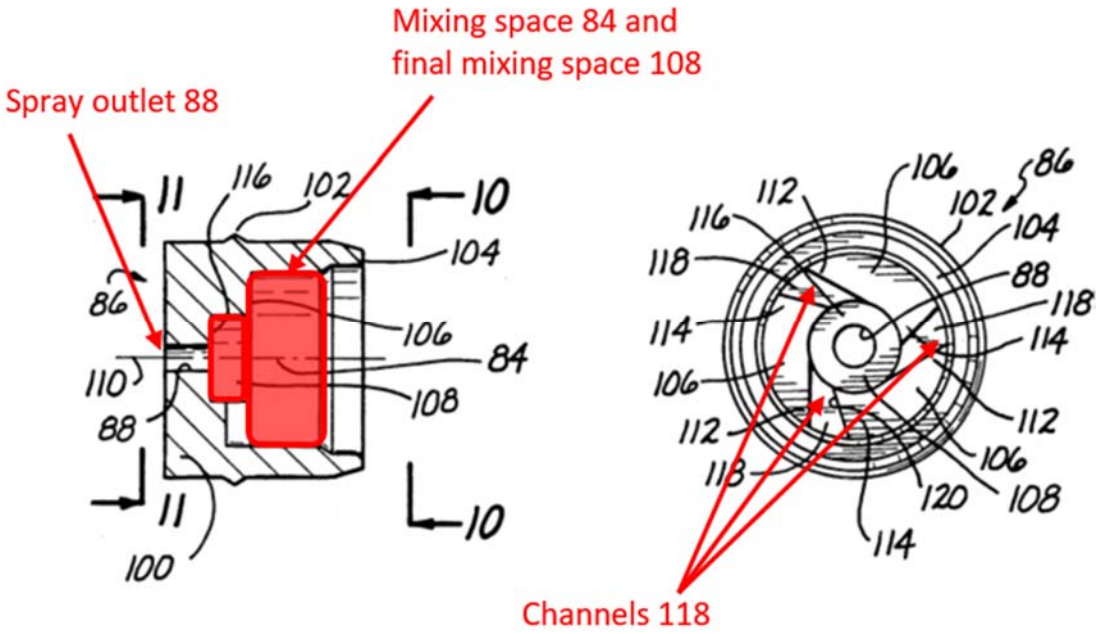
includes a cylindrical member.



(*Id*. at Figs. 4, 8 (annotated).) Capozzi thus discloses an insert (*i.e.*, cylindrical extension 77) disposed within the mixing chamber between the first and second component lumens and the outlet (*i.e.*, within mixing space 84) with the insert including a cylindrical member (*i.e.*, the cylindrical member portion of cylindrical extension 77, as depicted and described, that helps form annular cylindrical space 79).

Finally, although, Capozzi does not depict a recess on a first end of this insert, it would have been obvious to include a recess on the distal end of cylindrical extension 77. Capozzi provides that the nozzle wall (proximal to the distal end of the insert) contains recesses that form a swirl atomizer, *i.e.*, channels 118, that serve to direct the flow of material radially inward into final mixing space 108 in a

generally tangential direction to induce a swirling flow. (Ex. 1011 (Capozzi) at 7:3-23, Figs. 8-10.)



(*Id*. at Figs. 9-10 (annotated).)

It would have been obvious to a POSA that the fluid flow into channels 118 could be improved to create a faster swirling flow and thereby promote Capozzi's goals of thorough mixing and forming an atomized spray. (Ex. 1003, ¶¶180-182.) The obviousness of this modification would be informed by the knowledge of a POSA. (*Id*. at ¶¶24-50.) In particular, Capozzi discloses that distal face of cylinder 77 does not abut adjacent surfaces 106 of the spray nozzle 86 (*see* Figs. 8-9 above), leaving a continuous gap that creates an open path from the annular space 79 to the final mixing space 108 and exit orifice 88, thus allowing at least some of the

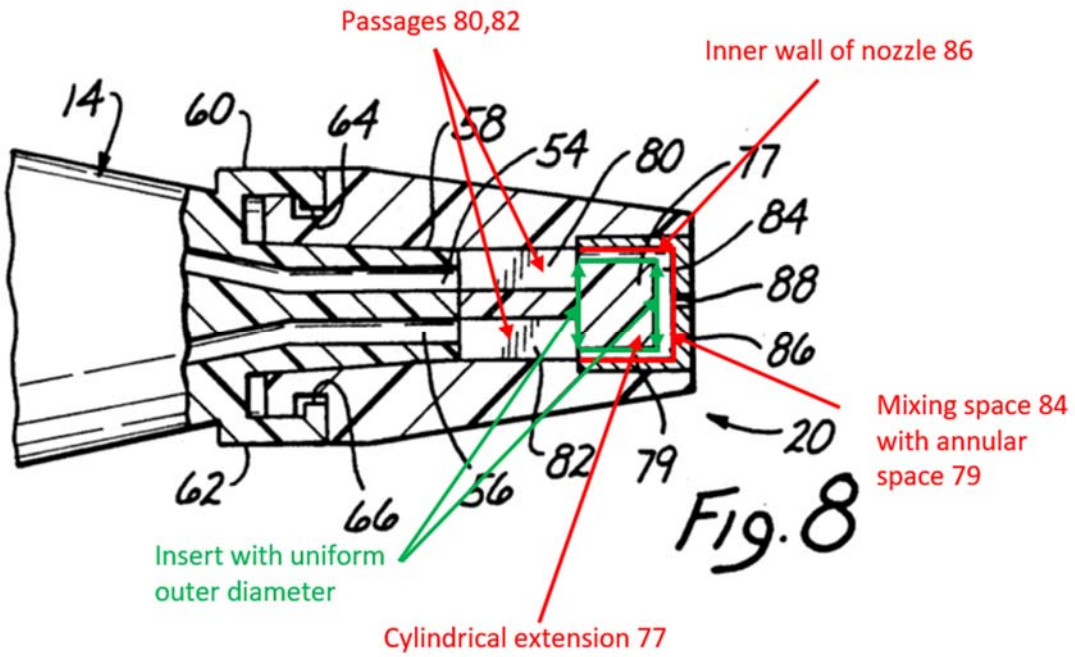
materials exiting the annular space 79 to bypass channels 118 and enter the swirl chamber directly. A POSA would be motivated to modify the fluid flow such that all of the flow passes through channels 118 to ensure that the tangentially intersecting flows are faster and create a stronger swirling flow within the final mixing space 108. (*Id*., ¶¶180-181.) A POSA would accomplish this modification simply by extending distal end of the cylindrical insert 77 so that it abuts the interior wall surfaces 106 of the nozzle 76. (*Id*., ¶181.)

Further, a POSA would have known that swirl inducing recesses of a simplex atomizer could be formed on either or both the distal end of an insert and on an adjacent surface of a nozzle assembly. (*Id*., ¶183.) It was not inventive or innovative to place the tangentially intersecting channels on the insert or on the adjoining nozzle wall, it was simply a routine design choice between two equally effective options. (*Id*.) So the radial channels 118 on the interior surface of the spray nozzle taught by Capozzi could be replaced (as a routine design choice between two options) by similar channels placed on Capozzi's cylindrical extension 77, as these recesses would serve the same function—i.e., induce a swirling flow—when placed in either location. A POSA could choose to put the radial channels 118 (and a swirl chamber) on the cylindrical extension 77 for any number of reasons including potentially a desire to simplify the mold for the nozzle body or the possible use of different materials for the nozzle body and cylindrical extension, with the cylindrical

extension material being more conducive to forming radial channels 118. (*Id*.) Thus, Capozzi renders obvious an insert that includes a cylindrical member having a recess formed in a first end thereof.

2. Dependent claim 15

Capozzi also discloses the additional limitations recited in claim 15. As depicted in Figure 8, cylindrical extension 77 has an outer diameter that is uniform along an entire length of the insert—namely, the diameter of cylindrical extension is uniform from its proximal end where the distal ends of passages 80 and 82 terminate to its distal end that terminates within mixing space 84. Further, the annular cylindrical space 79 between its outer diameter and the adjoining inner wall of nozzle 86, which is also shown as having a uniform diameter, confirms the uniformity of the cylindrical insert's outer diameter. (Ex. 1011 at 6:48-59; Figs. 8, 9.)



(*Id*. at Fig. 8 (annotated).)

D. Ground IV: Claims 14 and 15 Are Obvious Under § 103 over Dodge in view of Haber

1. Independent claim 14

Dodge discloses all of the limitations of claim 14 except for an insert including a cylindrical member having a recess formed in a first end thereof, which is disclosed or rendered obvious by Haber, as discussed above. Further, a POSA would have been motivated to use Haber's insert, and a POSA would have had a reasonable expectation of success in doing so. (*See* Ex. 1003, ¶¶186-215.) The obviousness of this combination would be informed by the knowledge of a POSA. (*Id*. at ¶¶24-50.)

a. Dodge discloses claim element 19[a]

To the extent the preamble is limiting, Dodge discloses a dispenser and kit for

"multi-part tissue sealants or other multi-part compositions" that "require[e] mixing immediately prior to use," including dispensing tip 150 that "is constructed to afford mixing the first and second components of the tissue sealant or adhesive." (Ex. 1012, Abstract, 1:9, 10:20-21, 10:66-11:1.)

b. Dodge discloses claim element 19[b]

Dodge discloses "manifold 30" "adapted to fit over and pierce the first and second septums 32 and 44" of the first and second components—first and second carpules 22, 24 respectively. (*Id.*, 8:11-12, 7:10-12, 7:37-38, Figs. 10-12, 14.) Dodge further discloses first and second component channels in the form of "piercers 116A and 118A", each with a hollow central bore, that are fluidly coupled to "plenums 124, 126." (*Id.*, 9:7-9, 9:17-20, Figs. 10, 12.) Dodge further discloses "nozzle 78" that includes "passageways 128 and 130" that lead to "openings 108 and 110" that allow the components in the carpules to be dispensed separately. (*Id.*, 8:64-66, Fig. 10.) As shown in annotated Fig. 10, Dodge teaches that passageways 128, 130 are fluidly coupled to the central bores of piercers 116A, 118A and plenums 124, 126. (*Id.*, 9:17-20.)

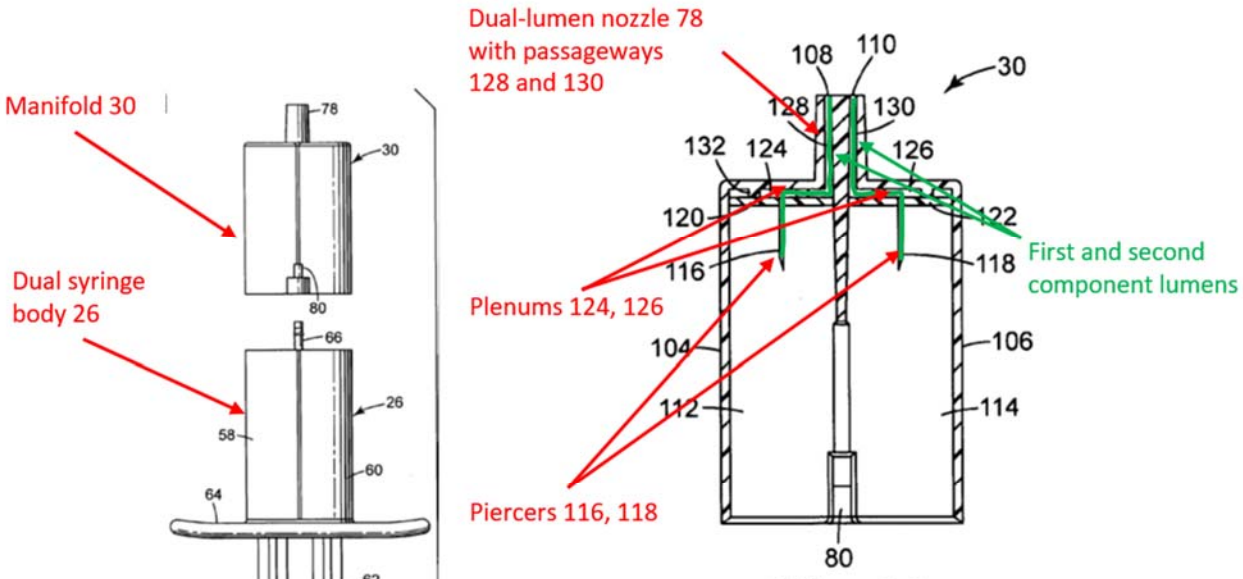


Fig. 1A

Fig. 10

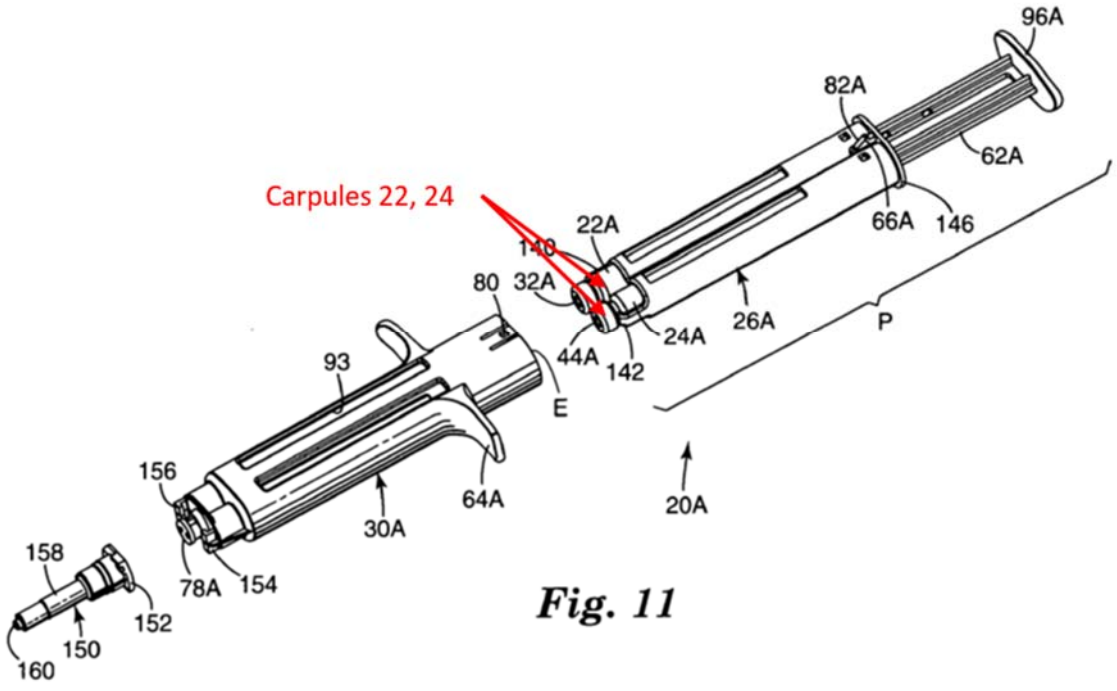


Fig. 11

(*Id*. at Figs. 1A, 10-11 (annotated).) Dodge thus discloses a first portion (i.e., manifold 30 and nozzle 78) defining first and second component lumens each having

proximal and distal ends (*i.e.*, the lumens defined by the central bore in piercers 116, 118 connected to plenums 124, 126 connected to passageways 128, 130, respectively) where the first and second component lumens are configured for fluid communication with respective first and second sources of component at their proximal ends (i.e., with the hollow bores at proximal ends of piercers 116 and 118 being configured for fluid communication with first and second carpules 22, 24, respectively.)

c. Dodge discloses claim element 19[c]

Dodge's dispenser includes dispensing tip 150 "that is sized and shaped to be fitted onto nozzle 78[]" and includes a barrel 158 with a static mixing element therein, and fluidic element 160 at the tip. (Ex. 1012, 10:15-24, Fig. 14.)

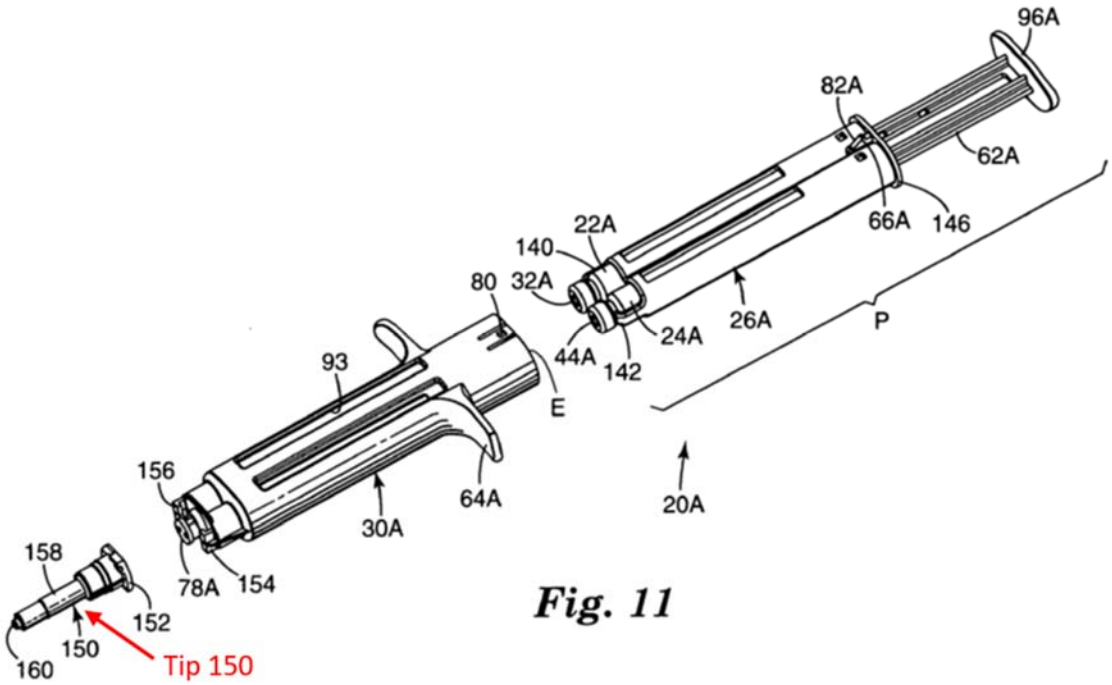


Fig. 11

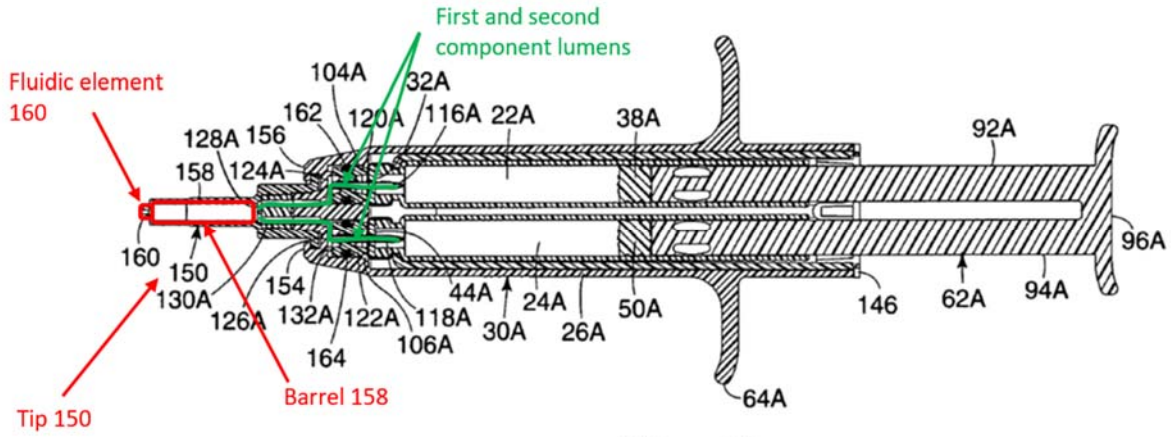


Fig. 12

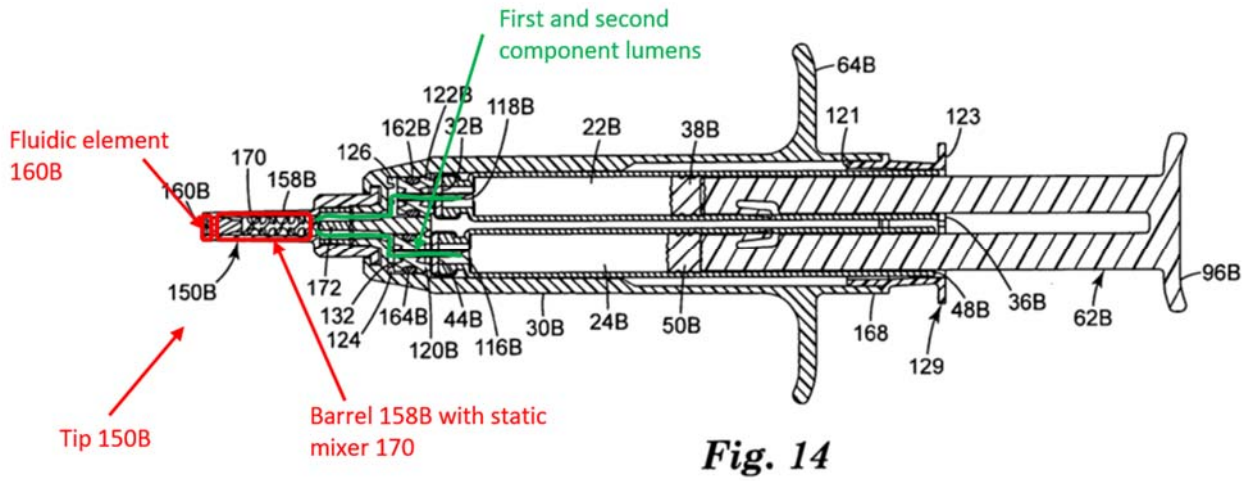


Fig. 14

(*Id*. at Figs. 11-12, 14 (annotated).) Dodge provides that once the components exit passageways 128A and 130A (*i.e*., the distal ends of the first and second component lumens, as discussed above), they can then begin mixing in the dispensing tip 150. (*Id*., 10:60-62.) Dodge discloses an insert—a static mixing element (static mixer 170)—to promote such mixing, placed within the chamber formed in barrel 158 of the dispensing tip. (*Id*., 12:47-48.) The static mixer assists

in mixing the two components within the dispensing tip before the components reach the fluidic element 160, where "a final mixing of the two liquid component [occurs] just before dispensing" through the dispensing tip orifice. (*Id.* 10:19-28, Figs. 12, 14.)

Dodge thus teaches a second portion defining a mixing chamber (*i.e.*, barrel 158 and fluidic element 160 within tip 150) with the distal end of the first and second component lumens being in fluid communication with the mixing chamber (*i.e.*, the exits of passageways 128 and 130 being in communication with the mixing chamber in barrel 158, allowing mixing of the components to occur within barrel 158).

d. Dodge discloses claim element 14[d]

As discussed above, the static mixer within barrel 158 assists in mixing the two components within the dispensing tip before the components reach the fluidic element 160, where "a final mixing of the two liquid component [occurs] just before dispensing" through the dispensing tip orifice. (*Id.* 10:22-28, Figs. 12, 14.) Dodge thus discloses a third portion defining an outlet (i.e., the disclosed "orifice" on dispensing tip 150 through which the mixed components are dispensed) in fluid communication with the mixing chamber.

e. It would have been obvious to include claim element 14[e] in Dodge's device in view of the teachings of Haber

As discussed above, Dodge discloses an insert (static mixer 170) disposed

within the mixing chamber between the first and second component lumens and the outlet (i.e., disposed within barrel 158 of mixing tip 150). Dodge does not expressly provide, however, that this insert include a cylindrical member having a recess formed in a first end thereof. Replacing Dodge's insert (static mixer 170) in view of the teachings of Haber meets this claim element, and thus this combination meets all of the elements of claim 14. (Ex. 1003, ¶187.) As explained in Section X.A.1 discussing Haber and its disclosures, which applies here under Ground IV, Haber discloses or renders obvious discloses a cylindrical insert with a recess in its distal end, and thus satisfies claim element 14[e]. (*See id.*, ¶¶114-116, 187, 195.)

(1) Motivation to Combine Dodge and Haber

A POSA would have been motivated to replace Dodge's static mixer 170 based on the teachings of Haber to improve mixing of the components, enhance atomization, and decrease the likelihood of the dispensing tip 150 clogging. (Ex. 1003, ¶196; *see also* Section X.B.1.b.(1) above.)

Dodge recites the objectives of achieving a uniform thickness in the applied sealant, preventing sealant run-off, applying sealant to hard to reach places (e.g., the underside of vessels), and minimizing the amount of sealant needed to coat a given area via a dispenser that mixes a multi-part adhesive prior to application to tissue. (*See* Ex. 1012 (Dodge) at 1:33-46, 1:55-2:14, 10:60-11:1; Ex. 1003, ¶197.) 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.)

Moreover, replacing Dodge's static mixer with Haber's swirl atomizer 40 would decrease the likelihood of clogging. As recognized by Dodge, mixing the two adhesive components causes them to "crosslink[] or cure[]", which results in clogging of the dispenser tip. (*See* Ex. 1012 (Dodge) at 14:32-41.) A POSA would have recognized that static mixer 170 would require a longer residence time for the two components than Haber's insert, and thus would have been motivated to use Haber's insert instead of static mixer 170 to decrease component residence time in the dispenser tip and decrease the likelihood of clogging the tip during component mixing. (Ex. 1003, ¶204.)

Finally, Dodge provides motivation to replace static mixer 170. Dodge states that "[m]ixing and channeling features may also be incorporated to enhance flow characteristics, thus permitting multiple sealant components, and simplifying and lower the cost of the tip assembly" and teaches that the dispensing tip "may be made

in accordance with, e.g., the teachings of" a book entitled Atomization and Sprays, which describes swirl atomizers generally, including those with inserts, and in particular, imparting swirl to fluid using swirl atomizers to achieve fine atomization and a fully developed spray. (Dodge at 2:17-20, 10:62-66; Ex. 1029 (Lefebvre) at 112-117; Ex. 1003, ¶205.) Accordingly, a POSA would have understood Dodge to suggest replacing static mixer 170 with, for example, an insert that forms a swirl atomizer, such as the one described in Haber, to achieve desired mixing and spray characteristics. (Ex. 1003, ¶205.) Such a modification would be an obvious matter of design choice within the skill in the art from a disclosed set of design choices coming from Dodge (via Lefebvre, Ex. 1029) itself. (*Id*.)

(2) Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in combining the teachings of Dodge and Haber because, as discussed above, Dodge provides that such a modification would be successful. Further, replacing the static mixer 170 in Dodge based on the teachings in Haber requires an understanding of only basic engineering principles and manufacturing techniques that were well within the grasp of a POSA. (Ex. 1003, ¶206.) Little to no modification of Dodge's mixing chamber within barrel 158 or to Haber's swirl atomizer 40 would be necessary to substitute Haber's insert for static mixer 170, as the elements are positioned in similar locations and the fluid flow path around the insert would be largely the same. (*Id*., ¶¶206,

212.) A POSA would understand that the insert should be placed in the mixing chamber such that its distal end abuts the distal wall of the chamber with the swirl chamber centered on the same axis as opening 160. (*Id*., ¶207.)

Further, because the effect of swirl atomizers, such as the Haber insert, were well known and because other prior art dual-component bioadhesive applicators employed similar swirl atomizer geometries to mix and atomize components, the results from combining Dodge and Haber would have been predictable, and a POSA could have used well-known tools, such as prototype testing or computational fluid dynamics, to confirm that the expected improvements in mixing and atomization would be realized. (*Id*., ¶¶208-213.) A POSA thus would have a reasonable expectation of success—*i.e.*, a functional sprayer as disclosed by Dodge with improved mixing and atomization characteristics—in replacing static mixer 170 according to the teachings of Haber. (*Id*., ¶214.)

2. Dependent claim 15

As discussed above in Section X.A.2., the combined teachings of Dodge and Haber also discloses or renders obvious the additional limitation recited in dependent claim 21. This discussion of Haber and its disclosures also applies here under Ground IV. Replacing Dodge's insert with the insert taught by Haber for the reasons discussed above would result in a device that contains an insert that includes a cylindrical member that has a uniform outer diameter along an entire length of the

insert and thus rendering dependent claim 15 obvious as well. (Ex. 1003, ¶¶146-148, 215.)

E. Ground V: Claims 14 and 15 Are Anticipated Under § 102 by Voegele

1. Independent claim 14

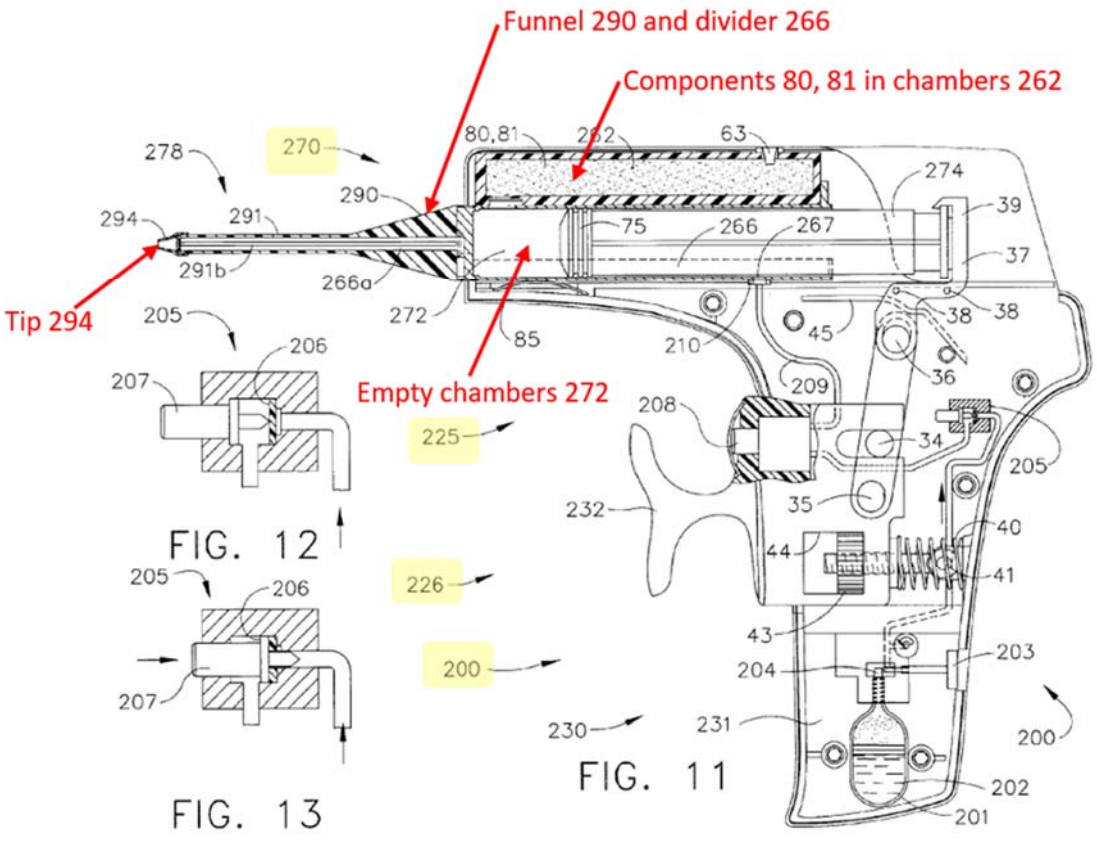
Voegele discloses each limitation in claim 14 and thus anticipates this claim. (*See* Ex. 1003, ¶¶216-223.)

a. Voegele discloses claim element 19[a]

To the extent the preamble is limiting, Voegele discloses an adhesive dispenser for "the mixing and dispensement of a dual component surgical adhesive onto tissue." (Ex. 1013 at Abstract, [0063], [0066], Figs. 11-17.)

b. Voegele discloses claim element 19[b]

Voegele discloses an "adhesive dispensing device 225" for dual-component adhesives that keeps the components separated until just before being applied that includes "adhesive components 80, 81" that are fed into cartridge body 261 that includes a pair of empty chambers 272 for holding these adhesive components. (*Id*. at [0003], [0063], [0066], Figs. 11-15.)



(*Id*. at Figs. 11-13 (annotated).)

Voegele further discloses "funnel 290" that attaches to the distal end of cartridge body 271" with a "pair of exit valves 279a and 279b" that operably connect the first and second sources of component in empty chambers 272 to funnel 290. (*See id*. at Fig. 15.) Further, a "divider 266 mounts within funnel 290 and separates adhesive components in funnel 290." (*Id.* at [0066], Figs. 15, 17.) Voegele further discloses "nozzle 278" has a "shaft 291 extending distally from funnel 290" that "has a first component passage 291a and a central gas passage 291b and a second component passage 291c extending longitudinally therethrough." (*Id.* [0066], Figs.

15-16.)

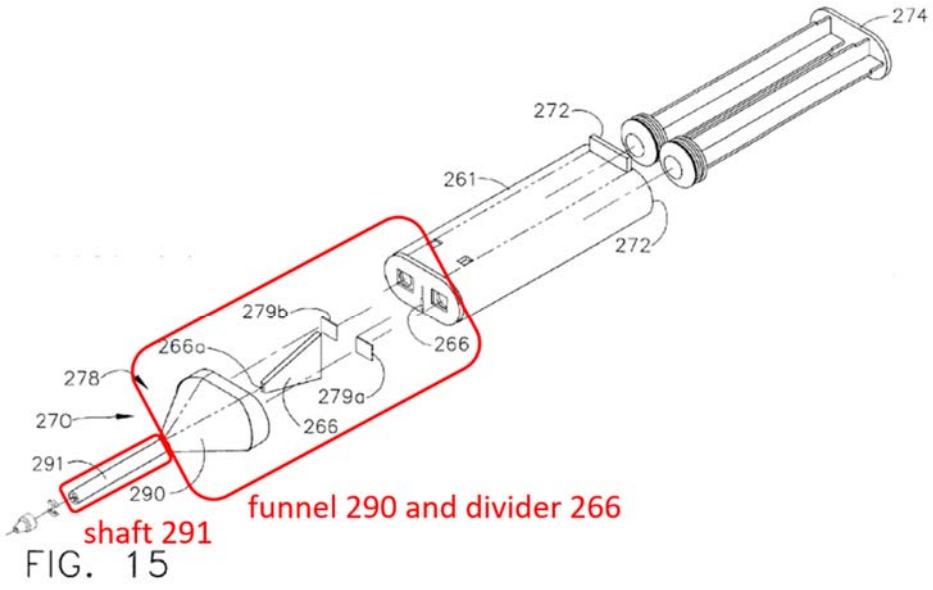


FIG. 15

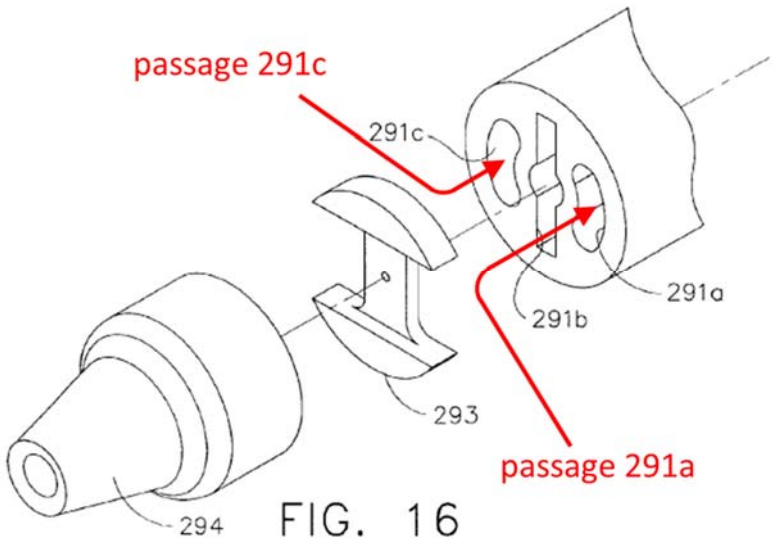


FIG. 16

(*Id*. at Figs. 15-16 (annotated).) As shown in annotated Figures 15 and 16 above, Voegele teaches that first component passage 291a and second component passage 291c are fluidly coupled to the respective first and second component channels

formed within funnel 290 by divider 266. Thus, Voegele discloses a first portion (*i.e.*, funnel 209 with divider 266 and shaft 291) defining first and second component lumens each having proximal and distal ends (*i.e.*, the lumens defined by the spaces within funnel 290 formed between divider 266 coupled to passages 291a and 291c, respectively) where the first and second component lumens are configured for fluid communication with respective first and second sources of component at their proximal ends (*i.e.*, with the first and second lumens within funnel 290 formed by divider 266 configured for fluid communication with the first and second sources of component in empty chambers 272 via exit valves 279a and 279b.)

c. Voegele discloses claim element 19[c]

As can be seen in annotated Fig. 16 below, Voegele's dispenser includes dispensing tip 294 that is designed to "attach to a distal end of shaft 291 to mix the gas and adhesive together as it is ejected from the tip." (Ex. 1013 at [0066], Figs. 11, 16.) Dispensing tip 294 is configured to receive mixer 293. (*Id*.)

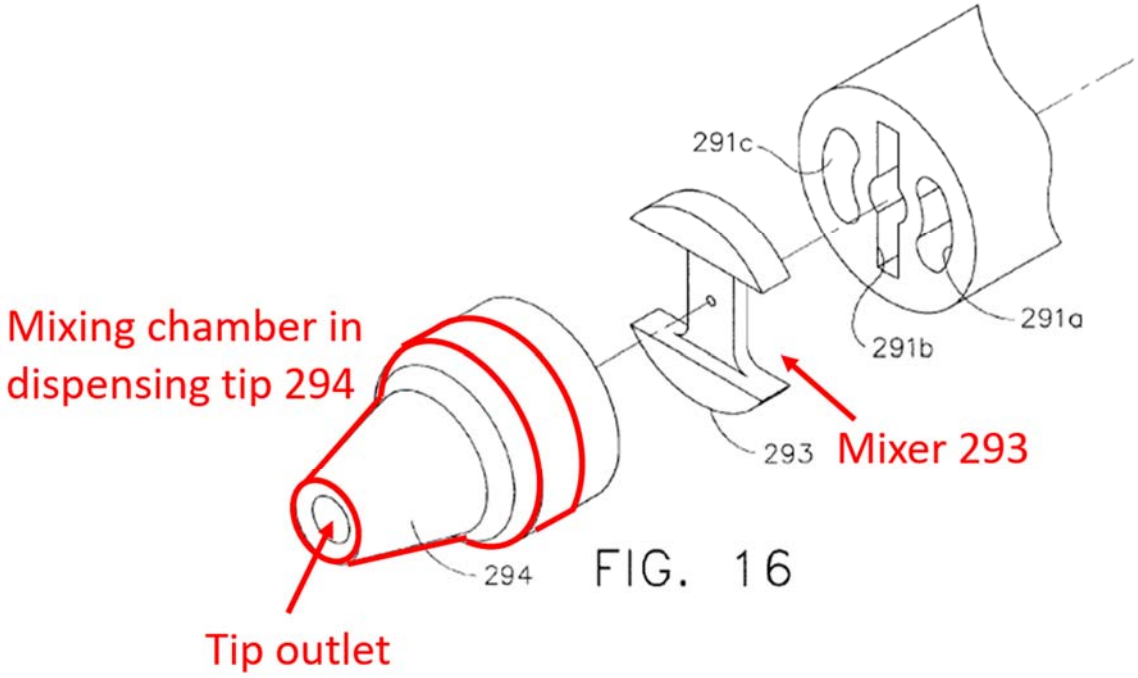
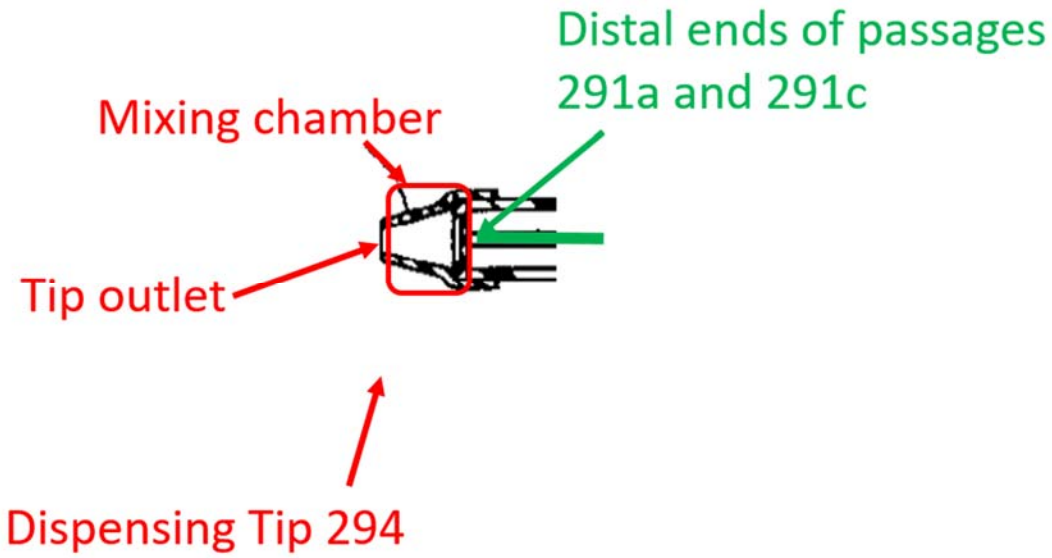


FIG. 16

(*Id*. at Fig. 16 (annotated).)



(*Id*. at partial Fig. 11 (annotated).) Voegele thus teaches a second portion defining a mixing chamber (*i.e.*, the portion of dispensing tip 294 that houses mixer 293 as

well as the conical portions of the tip) with the distal end of the first and second component lumens being in fluid communication with the mixing chamber (*i.e.*, the exits of passages 291a and 291c being in communication with the mixing chamber in dispensing tip 294, allowing mixing of the components to occur within the dispensing tip).

d. Voegele discloses claim element 14[d]

As shown in Figures 11 and 16 above, Voegele discloses an outlet to dispensing tip 294 that allows the mixed gas and adhesive components to be "ejected from the tip." (Ex. 1013 at [0066], Figs. 11, 16.) Voegele thus discloses a third portion defining an outlet (i.e., the disclosed outlet on dispensing tip 294 through which the mixed components are dispensed) in fluid communication with the mixing chamber.

e. Voegele discloses claim element 14[e]

As discussed above and shown in Figure 16 below, Voegele discloses mixer 293, which is an insert that is within distal end of the cylindrical cavity in tip 294. (Ex. 1013, [0066], Figs. 11, 16.) Also as depicted in Figure 16, mixer 293 has two cylindrical portions—the rounded top and bottom portions—and it has a recess on its distal end—i.e., an end, in accordance with Petitioner's proposed construction of this term. (*Id.* at Fig. 16.) The cylindrical portions of mixer 293 are depicted as allowing it to fit snugly within the interior cylindrical cavity of tip 294. (*See id.*; *see*

also id. at Fig. 11.)

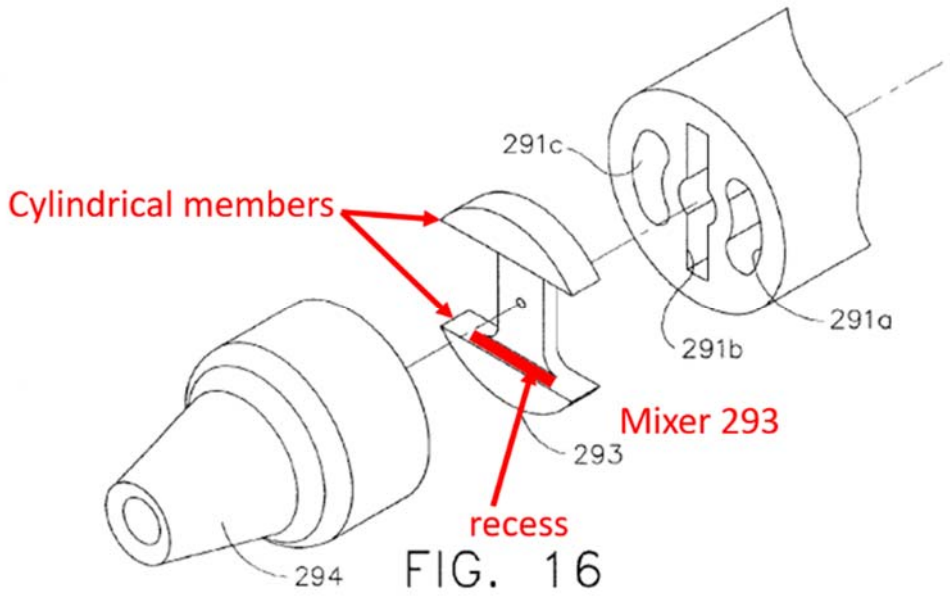


FIG. 16

(*Id*. at Fig. 16 (annotated); Ex. 1003, ¶221.) Voegele thus discloses an insert (*i.e.*, mixer 293) disposed within the mixing chamber between the first and second component lumens and the outlet (*i.e.*, disposed within dispensing tip 294 between the first and second component lumens 291a, 291c and the tip outlet), the insert including a cylindrical member (*i.e.*, the cylindrical portions at the top and bottom of mixer 293 as shown in Fig. 16) having a recess formed in a first end thereof (*i.e.*, a recess on an end (the distal end) of top and bottom cylindrical members as shown in Fig. 16).

2. Dependent claim 15

Voegele discloses the additional limitation recited in dependent claim 21. As shown in annotated Figure 16, the outer diameter of mixer 293 is uniform along an

entire length of the insert.

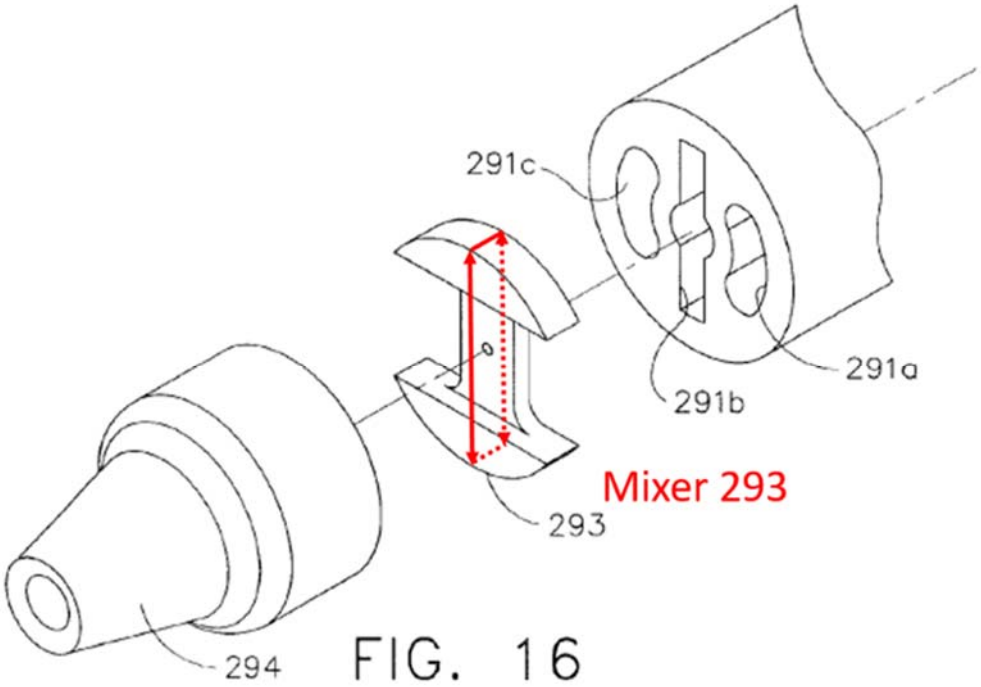
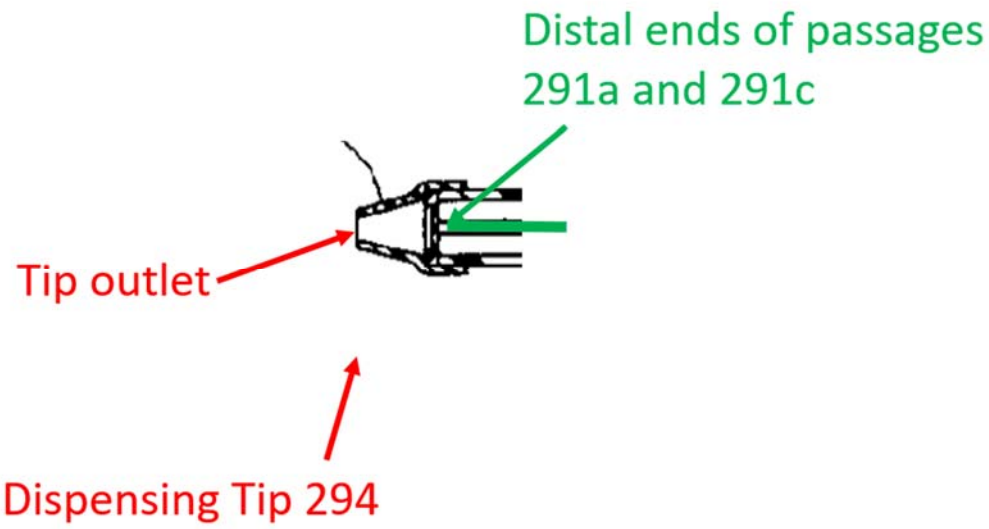


FIG. 16

(*Id*. at Fig. 16 (annotated).) Mixer 293 is depicted as being configured to fit snugly within the distal end of the interior cylindrical cavity of tip 294, between the distal end of shaft 290 and where tip 294 first begins to taper towards the tip outlet, which further confirms the uniformity of mixer 293's diameter along the cylindrical portions of the insert.



(*See id*. at partial Fig. 11 (annotated).) Voegele thus discloses the applicator assembly of claim 14 wherein an outer diameter of the insert (*i.e.*, the outer diameter between the cylindrical portions of mixer 293) is uniform along an entire length of the insert (*i.e.*, from the proximal to the distal ends of the insert).

F. NO SECONDARY INDICIA OF NON-OBVIOUSNESS

Petitioner is not aware of any evidence of any secondary indicia of non-obviousness having a nexus to the alleged claimed invention. Petitioner reserves the right to respond to evidence of secondary indicia of non-obviousness identified by Patent Owner.

XI. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of claims 14 and 15 of the ’021 patent, and a finding that the claims are unpatentable, based on the grounds presented herein.

Dated: May 21, 2018

Respectfully submitted,

By: /Orion Armon/
Orion Armon
Reg. No. 65,421
Counsel for Petitioner
HYPERBRANCH MEDICAL TECHNOLOGY, INC.

CERTIFICATE OF COMPLIANCE WITH WORD COUNT LIMITS

Pursuant to 37 C.F.R. § 42.24(d), I certify that this Petition complies with the type-volume limits of 37 C.F.R. § 42.24(a)(1)(i). According to the word processing system used to prepare it, this Petition contains 12,964 words, excluding parts that are exempted by 37 C.F.R. § 42.24(a).

Dated: May 21, 2018

By: /Orion Armon/
Orion Armon
Reg. No. 65,421
Counsel for Petitioner
HYPERBRANCH MEDICAL TECHNOLOGY, INC.

CERTIFICATE OF SERVICE

I hereby certify pursuant to 37 C.F.R. §§ 42.6(e) that a complete copy of:

- Petition;
- Exhibits 1001 – 1053; and
- this Certificate of Compliance with Word Count
- this Certificate of Service

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and being served via Federal Express, upon the Patent Owner at the address provided by Confluent Surgical, Inc. as its principal place of business in a related litigation:

CONFLUENT SURGICAL, INC.
311 ENTERPRISE DRIVE
PLAINSBORO, NJ 08536

and being served via Federal Express, upon counsel for Confluent Surgical, Inc. as provided below. As a courtesy, electronic versions of the foregoing materials will also be made available for counsel for Confluent Surgical, Inc. sometime shortly after their submission to the USPTO.

YOUNG CONAWAY STARGATT &TAYLOR LLP	Robert F. Altherr, Jr. Christopher B. Roth

Karen L. Pascale (#2903) [kpascale@ycst.com] James L. Higgins (#5021) [jhiggins@ycst.com] Rodney Square 1000 North King Street Wilmington, DE 19801 Telephone: (302) 571-6600	**BANNER &WITCOFF, LTD.** 1100 13th Street NW Suite 1200 Washington, DC 20005 Telephone: (202) 824-3000 John P. Iwanicki **BANNER &WITCOFF, LTD.** 28 State Street, Suite 1800 Boston, MA 02109 Telephone: (617) 720-9600 Jason S. Shull **BANNER &WITCOFF, LTD.** 10 S. Wacker Drive, Suite 3000 Chicago, IL 60606 Telephone: (312) 463-5000

Dated: May 21, 2018

By: /Orion Armon/
Orion Armon
Reg. No. 65,421
Counsel for Petitioner
HYPERBRANCH MEDICAL TECHNOLOGY, INC.