UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LEXION MEDICAL, LLC
Petitioner

v.

SURGIQUEST, INC.
Patent Owner

Case No. Unassigned
Patent 9,095,372

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C §§ 311-319 AND 37 C.F.R. § 41.100 ET. SEQ. OF CLAIMS 1–11 OF U.S. PATENT NO. 9,095,372

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1013	U.S. Patent No. 5,431,676 to Dubrul et al.

I. INTRODUCTION

Lexion Medical, LLC ("Lexion" or "Petitioner") requests institution of *inter partes* Review ("IPR") and cancellation of Claims 1–11 of U.S. Patent No. 9, 095,372 ("'372 Patent") as unpatentable pursuant to 35 U.S.C. § 311(b).

Petitioner asserts that there is a reasonable likelihood that the challenged claims are unpatentable and requests review of, and cancellation of, the challenged claims under 35 U.S.C. § 103.

II. MANDATORY NOTICES, STANDING, AND FEES

A. Mandatory Notices

1. Notice of Each Real Party in Interest

Real Party in Interest: The real party in interest is Lexion Medical, LLC.

2. Notice of Related Matters.

Related Matters: The '372 patent claims priority from U.S. Application No. 14/268,408, which is currently pending.

In addition, on July 28, 2016, patent owner SurgiQuest, Inc. and its parent company ConMed Corporation filed a complaint in the Eastern District of New York (Case No. 6:16-cv-944-DNH/ATB) alleging infringement of the '372 patent by Lexion. Ex. 1012. SurgiQuest and ConMed served the complaint on Lexion on August 5, 2016, and the suit is pending.

3. Notice of Lead and Back-up Counsel

Lead Counsel: Lead Counsel is Brian Oaks (Reg. 44,981) and backup counsel is David G. Wille (Reg. No. 38,363), each of Baker Botts L.L.P.

4. Notice of Service Information

Service Information: Baker Botts L.L.P., 98 San Jacinto Blvd., Suite 1500, Austin, Texas 78701; phone: (512) 322-5470; fax: (512) 322-3621. Petitioner consents to service by electronic mail at: Lexion_372IPR@bakerbotts.com. A Power of Attorney is filed concurrently herewith under 37 C.F.R. § 42.10(b).

B. Certification of Grounds for Standing

Petitioner certifies that the ’372 Patent is available for IPR. Petitioner is not barred or estopped from requesting IPR of the ’372 Patent.

C. Fees

The Office is authorized to charge any fees that become due in connection with this Petition to Deposit Account No. 02-0384.

III. OVERVIEW OF THE '372 PATENT

A. Technology Background and Overview of the '372 Patent

The '372 patent describes "trocar" devices used in laparoscopic surgery. Ex. 1001, 1:45–52; Ex. 1003, ¶¶ 70–82. A trocar, which is a hollow, spike-like device, is inserted into the abdominal cavity of a patient to provide a channel through which surgical instruments can be inserted. *Id.*, 7:65–8:2; *see also*, *e.g.*, *id*. Fig. 5 (trocar with instrument inserted through center); Ex. 1003, ¶ 74–82.

To create room within the abdominal cavity, laparoscopic procedures "commonly involve filling or 'insufflating' the abdominal … cavity with a pressurized fluid, such as carbon dioxide" gas "so that the surgeon has an open interior space in which to work." Ex 1001, 1:53–56, 2:2–3; *see also* Ex. 1003, ¶¶ 71–72, 81. The '372 patent states that "insufflation can be carried out by a trocar equipped to deliver insufflation" gas from a gas source. Ex. 1001, 1:56–57. Specifically, a trocar both delivers gas to inflate the patient's abdomen and provides a port through which instruments can be introduced into the patient's abdominal cavity. Ex. 1003, ¶ 75. An illustration of a laparoscopic procedure with multiple trocars inserted into the insufflated abdomen is shown below:

See also Ex. 1003, ¶ 70.

By October 10, 2008, the filing date of the provisional application to which the '372 patent claims priority, laparoscopic surgery using trocars and conditioned insufflation gas had been known for many years. Ex. 1001, [60]; Ex. 1003, ¶¶ 73, 81. For example, a 1995 U.S. patent to Ott. et al. describes a "Method and Apparatus for Conditioning Insufflation Gas for Laparoscopic Surgery" involving the use of a trocar to deliver a heated, humidified insufflation gas to a patient for surgery. Ex. 1006, 1:11–15, 1:66–2:4. A May 11, 2004 patent filed on July 28, 2000 to Ott similarly discloses a "Perforated Trocar Sleeve and Method of Use" for delivering insufflation gas during surgery. Ex. 1008, 1:13–16, 1:9–2:20

(describing laparoscopic surgery, trocars, and insufflation). Similarly, a U.S. patent to Spearman et al. filed on June 12, 2003 describes a "Medical Gas Humidification System" used for "conditioning a gas so that when the conditioned gas is delivered to a body cavity it prevents or minimizes additional trauma" during surgery. Ex. 1010, 1:5–9.

Against this background, the '372 patent claims a particular configuration of trocar for delivery of conditioned or humidified insufflation gas. Specifically, the '372 patent claims a type of multi-lumen trocar, meaning a trocar made of at least two concentric tubes, with a central channel or lumen for the introduction of a surgical instrument and a separate chamber (called an "insufflation conduit") formed between the two tubes to deliver insufflation gas (which is humidified in the claimed invention). *See, e.g.*, Ex. 1001, Cl. 1; Ex. 1003, ¶¶ 83–85. The trocar claimed in the '372 patent allegedly differs from prior art trocars in that the end of the insufflation conduit is closed, such that gas only exits the insufflation conduit through a plurality of holes on the exterior sides of the trocar, rather than through the end of the trocar. *See* Ex. 1002, 434, 438–35. As discussed further below, however, dual-lumen trocars with closed insufflation chambers were well-known by the time of the alleged invention, as were trocars with a plurality of lateral (radial) apertures, which are also recited in the claims of the '372 Patent.

B. File History of the '372 Patent

The application leading to the '372 patent was filed as a continuation. Ex. 1001, [63]; Ex. 1003, ¶ 86.

The examiner rejected the claims as obvious in view of Ott '479 (Ex. 1008) and Spearman (Ex. 1010) in a first office action, finding that Ott '479 disclosed most limitations of the pending claims, while Spearman disclosed humidification of insufflation gas. Ex. 1002, 385–86; Ex. 1003, ¶ 87.

In response, the applicant amended the claims. *Id.*, 408. The examiner, however, then issued a final office action finding the amended claims obvious over Ott '479 in view of Spearman and another reference. Ex. 1002, 418–425; Ex. 1003, ¶ 87.

To overcome the rejection, the applicant amended the claims "to structurally clarify the device …" with the language "wherein the distal end portion of the outer tubular member and the distal end portion of the inner tubular member cooperate to enclose the insufflation conduit …." *Id.*, 434, 438–35; Ex. 1003, ¶ 88. A Notice of Allowance followed. *Id.*, 448; Ex. 1003, ¶ 88.

In a contemporaneous Examiner-Initiated Interview Summary, the Examiner noted that an updated search had revealed a new reference, U.S. 2006/0184095 ("Ott '095," Ex. 1009). Ex. 1002, 457; Ex. 1003, ¶ 89. The examiner noted that Ott '095 "appears to anticipate at least the structural aspects of the claims as amended on May 1, 2015," apparently referring to the similar dual-lumen trocar

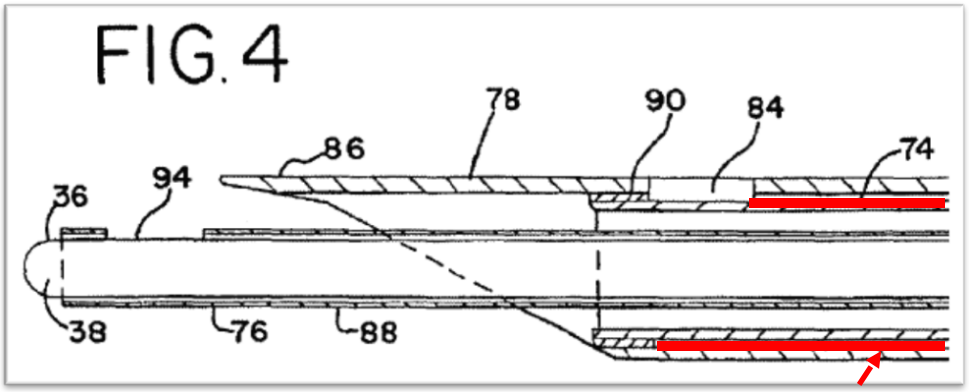
with a plurality of lateral apertures disclosed by Ott '095. *Id.*; Ex. 1009, Fig. 1. However, the examiner agreed with the applicant that Ott '095 did not expressly disclose that the end of the insufflation conduit was enclosed, and thus permitted the claims to issue. Ex. 1002, 457; Ex. 1003, ¶ 89.

IV. SUMMARY OF PRIOR ART

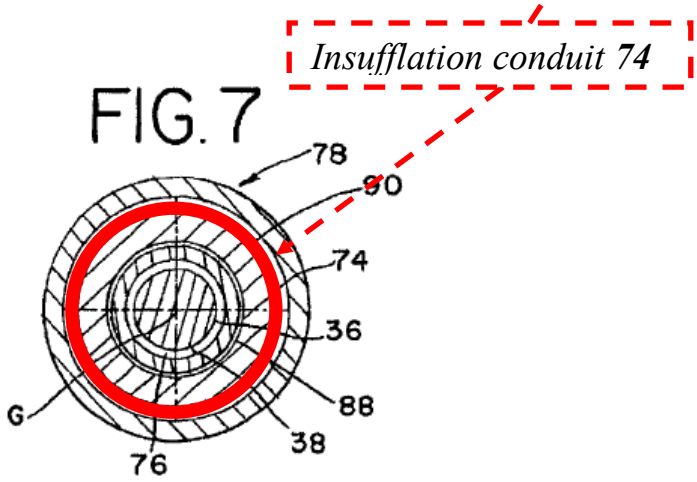
A. Mantell

United States Patent No. 6,905,489 (Ex. 1005, "Mantell") discloses a laparoscopic insertion device (such as a trocar or a so-called "Verres needle") that can be used to insufflate a patient for laparoscopic surgery, while also permitting insertion of a surgical instrument into the patient's body cavity. Ex. 1005, 1:6–10, 1:61–2:7, 8:56–9:2; Ex. 1003, ¶ 93. Figures 1–7 show aspects of one embodiment, while the remaining figures show similar embodiments differing primarily in the number of gases or instruments that may be used simultaneously. *See* Ex. 1005, 3:12–60 (describing Figs. 1–18) Ex. 1003, ¶ 94.

More particularly, Mantell discloses a dual-lumen Verres needle for use with insufflation gas. As shown in annotated Figures 2 and 4 below, Mantell has a first lumen (insufflation conduit **74**) formed between the outer tubular housing and the concentric inner tubular member. The inner member also defines a second or central lumen. As shown in Figure 4, a surgical instrument consisting of a needle cannula **88** and obturator **38** c inserted through the central lumen into the patient.



Ex. 1005, Fig. 7 (annotated):



Ex. 1005, Fig. 4 (excerpt), Fig. 7, 6:11–15, 5:23–26; Ex. 1003, ¶ 95. The insufflation conduit **74** is closed at the end using silver solder, so as to force insufflation gas to exit the insufflation conduit only through the lateral aperture **84**, rather than through the central lumen or the end of the trocar. *Id.*, 6:29–35, 8:64–66; Ex. 1003, ¶ 96.

Mantell thus discloses the feature primarily relied upon by the applicant to overcome the prior art—an insufflation conduit closed at the distal end, forcing gas to exit from a lateral aperture. Mantell lacks explicit disclosure of only two limitations of the challenged claims: a *plurality* of lateral apertures (as opposed to

the single lateral aperture shown in Figure 4) and that the insufflation gas used is conditioned (humidified or heated). As discussed below, however, these two elements or design choices were well-known in the art. Moreover, while Mantell's illustrated embodiment is a Verres needle, Mantell explicitly teaches, "For example, the present invention can be applied to other insertion devices, such as trocars, . . ." Ex. 1005, 10:59–63. Thus, Mantell explicitly teaches the use of the dual lumen arrangement discussed above for a trocar as well as a Verres needle. Ex. 1003, ¶ 97.

Mantell issued on June 14, 2005, and is at least § 102(b) prior art. Mantell was not considered during prosecution of the '372 Patent. Ex. 1003, ¶ 98.

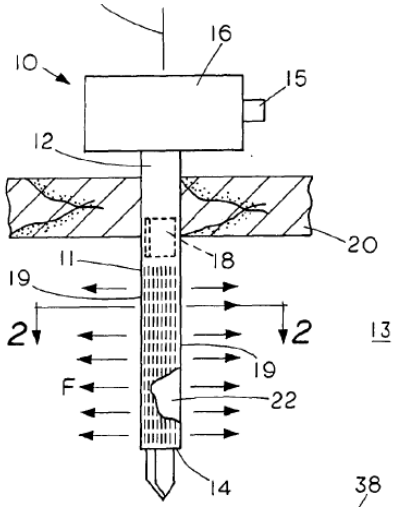
B. Ott '095

Like Mantell, U.S. Patent Application Publication No. US 2006/0184095 A1 to Ott ("Ott '095") discloses a dual-lumen trocar with a central lumen and a separate insufflation conduit to deliver insufflation gas. Ott '095 also explicitly discloses a plurality of lateral or radial apertures for the dispersion of the insufflation gas from the insufflation conduit into a patient. Ex. 1009, Fig. 1, Fig. 2, ¶¶ 9, 16, 18–20; Ex. 1003, ¶ 99.[1] As shown below in Figure 1, for example, the

[1] Ott '095 sometimes refers to the outer housing of the disclosed surgical access device as a "trocar sleeve." The term "trocar" is commonly used to collectively refer to the combination of a cutting instrument together with a sleeve or access

trocar is inserted through tissue layer **20** into a patient's peritoneum, with a cutting instrument inserted through the trocar's central lumen and exiting distal end **14**. Insufflation gas is simultaneously supplied via inlet port **15** to the insufflation conduit (shown in cutaway, and defined between outer housing **11** and concentric inner tubular member **22**). Gas exits the insufflation conduit through the plurality of lateral apertures (the lateral gas flow indicated by arrows).

FIG. 1



Ex. 1009, Fig. 1 (excerpt). Ott '095 thus expressly discloses each limitation of the

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port. The cutting instrument is referred to as an "obturator" but it is sometimes also referred to as a "trocar." Ex. 1003, ¶ 101; *see also* Ex. 1001, 1:62–2:3 (explaining that the surgical incisions are "typically made with the trocar devices themselves" and after insertion, "the trocar allows access for instruments" and further that "[t]ypical trocars often provide means to insufflate the abdominal cavity.").

challenged claims with two exceptions: that the end of the insufflation conduit is enclosed, and that the gas used is humidified. Again, however, these two elements or design choices were well-known in the art. Ex. 1003, ¶¶ 102–03.

Although Ott '095 appears to be silent as to whether the end of the insufflation conduit is enclosed, the arrows on Figure 1 depicting gas flow only show gas flowing laterally, not distally from the end. In addition, Ott '095 discloses a second embodiment in Figures 3 and 3A consisting of a single-lumen trocar with a fully sealed distal end. Like Figure 1, the arrows in Figures 3 and 3A also depict gas flow through lateral apertures. Thus, rather than teach away from sealing the end of the insufflation conduit, Ott '095 suggests through its second embodiment that sealing the end of the insufflation conduit would be advantageous with regard to lateral gas flow. Enclosing the insufflation conduit of the dual-lumen trocar in Figure 1 would lead to the predictable result of enhancing lateral gas flow through the lateral apertures of the dual-lumen trocar. *See* Ex. 1003, ¶ 100.

Ott '095 incorporates by reference United States Patent No. 6,733,479 (Ex. 1008, "Ott '479"), which also discloses a perforated trocar sleeve with multiple radial apertures for the dispersion of insufflation gas into a patient. *See* Ex. 1009, ¶8; *see also* Ex. 1008, 1:13–16, 3:34–52, 4:10–13; Ex. 1003, ¶ 104. Ott '095 further references the specific teachings of Ott '479 concerning avoiding a

dangerous "jet streaming" effect caused by a restricted flow of gas out of a trocar lacking multiple lateral apertures, which can damage tissue. Ex. 1009, ¶ 8; Ex. 1003, ¶ 105.

Ott '095 was filed on February 15, 2005 and published on August 17, 2006, and is at least § 102(b) prior art. Ex. 1003, ¶ 106.

C. Ott '474

United States Patent No. 5,411,474 (Ex. 1006, "Ott '474") discloses a method and system for delivering heated, humidified insufflation gas to a trocar for laparoscopic surgery—the limitation of the challenged claims not expressly disclosed in Mantell and Ott '095. Ex. 1006, 1:8–15, 5:42–47, 10:49–51, 10:60–62; *see also* Ex. 1007; Ex. 1003, ¶ 107. Ott '474 issued on May 2, 1995, and is at least § 102(b) prior art. Ott '474 was not considered during prosecution of the '372 Patent. Ex. 1003, ¶ 107.

V. CLAIM CONSTRUCTION

Pursuant to § 42.100(b), and solely for purposes of this review, Petitioner construes the claim language such that claim terms are given their broadest reasonable interpretation ("BRI").[2] For terms not specifically listed below,

[2] Petitioner reserves the right to seek different claim constructions in a different forum that applies more narrow standards of proof and analysis (*e.g.*, litigation applying the *Phillips* standard).

Petitioner interprets them for purposes of this review in accordance with their plain and ordinary meaning under the required BRI standard.

A. Level of Skill in the Art

A POSITA would have had a bachelor's degree in mechanical engineering, biomedical engineering, or a related field and three to five years of practical experience designing medical devices. A person of ordinary skill in the art could also include a surgeon with three to five years of experience with laparoscopic surgery and some experience with developing medical devices used in laparoscopic surgery. A person with less education, but more relevant practical experience, may also meet this standard. Exhibit 1003, ¶¶ 68–69.

B. "conditioned insufflation gas"

Claims 7–11 include the term "conditioned insufflation gas." As described by the '372 patent, "conditioned" insufflation gas can be insufflation gas that is heated or humidified. *See, e.g.*, Ex. 1005, 7:62–65. Similarly, Claim 10 specifies that "the conditioned insufflation gas is humidified insufflation gas," while Claim 11 specifies that "the conditioned insufflation gas is heated insufflation gas." Thus, the BRI of "conditioned insufflation gas" includes, at a minimum, insufflation gas that has been heated, humidified, or both. Ex. 1003, ¶¶ 91–92. Although "conditioned insufflation gas" may include additional meanings , no further construction is needed for purposes of this IPR, given the clear disclosures

of the prior art (discussed below)..

VI. THERE IS A REASONABLE LIKELIHOOD THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: The Combination of Mantell, Ott '474, and Ott '095 Renders Claims 1–11 Obvious Under 35 U.S.C. § 103

As explained below, Mantell discloses a surgical access device teaching each limitation of the challenged claims with two exceptions: that the insufflation gas is humidified, and that the gas is discharged from a plurality of apertures, rather than a single aperture. But those conventional elements were well known in the prior art by the time of the '372 patent, including as shown in Ott '474 (humidification of insufflation gases) and Ott '095 (use of multiple apertures to discharge insufflation gases). When considered together with the knowledge of a POSITA, Mantell, with Ott '474 and Ott '095, render each claim of the '372 patent obvious under 35 U.S.C. § 103. Ex. 1003, ¶ 108.

Moreover, Ott '095 itself also discloses a surgical access device teaching each limitation of the challenged claims with two exceptions: that the insufflation gas is humidified, and that the end of the insufflation conduit is enclosed. But again, those conventional elements were well known in the art by the time of the '372 patent, including as shown in Ott '474 (humidification of insufflation gases, as noted above) and Mantell (insufflation conduit with enclosed end). For that reason, too, each claim of the '372 patent is obvious. Ex. 1003, ¶ 109.

1. A POSITA would have been motivated to combine Mantell with Ott '474 and Ott '095

A POSITA would have been motivated to combine insufflation trocars (such as those taught in Mantell and Ott '095) with the insufflation gas heating and humidification system, and the resulting heated and humidified gas, taught by Ott '474. Ex. 1003, ¶ 110. As discussed below, a POSITA would have been motivated to combine these references whether Mantell is viewed as the primary reference, in combination with Ott '095 and Ott '474, or whether Ott '095 is viewed as the primary reference, in combination with Mantell and Ott '474.

a) A POSITA would have been motivated to use a trocar (Mantell or Ott '095) with conditioned gas (Ott '474)

First, as discussed above, Mantell expressly discloses various designs and uses of a surgical access or insertion device, such as a trocar, for use with insufflation gas. Ex. 1005, 10:59–62 ("For example, the present invention can be applied to other insertion devices, **such as trocars**, where the trocar is inserted into an opening of an animal, such as a human patient … ") (emphasis added); *id.*, 2:8–9 (describing "Verres needles and trocars" as types of "insertion devices"; *id.* 1:61–2:7 (describing similarities of Verres needles and trocars as types of insertion devices); Ex. 1003, ¶ 111. Even if Mantell does not disclose a trocar with the dual-lumen configuration, the dual lumen Verres needle disclosed by Mantell together with the teachings at column 10, lines 59-62 would make it obvious to use the

dual-lumen configuration taught by Mantell in a trocar. *See id.*. Mantell further discloses that his insertion device can be used to deliver various types of insufflation gas to a patient. Ex. 1005, 7:29–31 ("an insufflation gas is then directed into the abdomen"); *id.*, 5:66–67 ("The stopcocks **54** and **72** preferably are attached to supplies (not shown) for two isolated fluids."). Mantell also teaches the gas or fluid can be conditioned, such as with aerosolized medication. *Id*., 6:4–7; Ex. 1003, ¶ 111.

Similarly, Ott '095 discloses a trocar to deliver insufflation gas to a patient which has an inlet port for connection to a separate gas supply. *See, e.g.*, Ex. 1009, ¶ 21 (describing discharge of gas "from an external source" through the trocar); *id.*, ¶¶ 5–7 (describing the use of gas, including gas conditioned with "other substances, which may include drugs and anesthetics," to insufflate patient). Ex. 1003, ¶ 112.

Ott '474, discloses a gas heating and humidification system that can be used with various surgical access devices, explicitly including trocars. Ex. 1006, 9:18–22 ("The filtered and temperature/humidity conditioned gas **29** passes directly to a connector **26, designed to attach to a conventional trocar** used to inflate the peritonea or other such gas delivery device for the particular medical procedure.") (emphasis added). Ott '474 thus contains an express teaching that its gas heating and humidification system and the resulting heated and humidified insufflation gas

disclosed in Ott '474 should be used with trocar or surgical insertion devices, such as those disclosed in Mantell and Ott '095. Ex. 1003, ¶ 113. In any event, the choice of whether to use cold dry gas, heated gas, or heated and humidified gas is simply a matter of design choice and the preferences of an individual surgeon. *See id*.

In addition, at the time of the alleged invention, it was known in the art that use of heated and humidified insufflation gas had advantages compared to unheated, dry insufflation gas. Ex. 1003, ¶ 114. For example, Ott '474 recognized that "medical grade carbon dioxide, the most prevalent gas used for laparoscopy, contains 200 parts per million or less of water vapor." Ex. 1006, 2:34–36. "The extreme lack of moisture in the insufflation gas can lead to drying of exposed tissue surface within the abdomen, and to the possibility of adhesion formation within the peritoneal cavity." *Id.*, 2:36–41, 1:66–2:2 ("Newly developed insufflators and ancillary devices have recognized this problem and have attempted to correct it by adding heat to the gas stream before it enters the delivery system which directs the gas to the trocars …"); *see also, e.g.*, Ex. 1010, 1:34–43 (recognizing "the additional trauma from … medical gas … at an improper insufflation temperature or if the medical gas is to[o] dry when the medical gas is delivered to the body cavity"); Ex. 1011 (US 2005/0137529), ¶ 47.

Because the use of heated and humidified insufflation gas had known

advantages, a POSITA would have been motivated to combine the heating and humidification system taught by Ott '474 with the surgical access device as taught by Mantell or Ott '095 to obtain the benefits associated with heated and humidified gas. *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007) (concluding that "a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); Ex. 1003, ¶ 115. The structures and functions required to use conditioned (*e.g.*, heated and humidified) gas were well known, and a POSITA would have been capable of combining a gas heating or humidification system with a surgical access device already having a gas input (such as the trocars taught by Mantell and Ott '095) with predictable results. *Id.*, ¶ 116. In any event, the use of heated and/or humidified gas is simply a matter of design choice—*i.e.*, it is one recognized option for a surgeon to use for laparoscopic surgery. *See id*. ¶¶ 117–18.

A POSITA would be further motivated to combine Mantell with Ott '474 because of Mantell's teaching that the trocar disclosed therein can be used in combination with numerous different types of fluids or instruments, including with devices for "moisture infusion." Ex. 1005, 8:53–54 (table listing "moisture infusion" as a use); *id.*, 7:55–56 (surgical access device can be used with "humidification devices"); *id.*, 8:57 ("multiple fluids" can be delivered with device); Ex. 1003, ¶ 119. A POSITA would thus have been motivated to combine

the gas heating and humidification system disclosed by Ott '474 with the trocar disclosed by Mantell for this additional reason as well. *See id.* ¶¶ 119–20.

b) A POSITA would have been motivated to combine Mantell and Ott '095

(1) A POSITA would be motivated to modify the device of Mantell to include Ott '095's plurality of apertures

As noted above, Mantell explicitly discloses a surgical access device (both a Verres needle and trocar) having at least one lateral aperture to deliver the insufflation gas into the patient. *See, e.g.*, Ex. 1005, Fig. 4. Ott '095 teaches that gas exiting an aperture can cause a "jet streaming effect" that is "known to damage tissues and/or organs of the body[.] Ex. 1009, ¶ 8; *see also* Ex. 1008, 2:51–56 (air exiting trocar is "is oftentimes formed into a 'jet' stream **18** of highly concentrated flow rate at a relatively high fluid velocity. This in turn defines an impact site for the tissues/organs impinged by the jetted fluid, and also limits the dispersion of the agents contained within the fluid stream within the body cavity."). This "jet streaming" can cause "severe heat loss" to body tissues and organs. Ex. 1009, ¶ 9; *see also* Ex. 1008, 2:57–61, 5:60–66 (further describing ill effects); Ex. 1003, ¶ 121.

Ott '095 discloses that a solution to these problems is to use a *plurality* of apertures to laterally discharge gas from a surgical access device, which "effectively distribute[s] the gases at velocities, which are below the threshold of

the 'jet streaming effect.'" Ex. 1009, ¶8; *see also* Ex. 1008, 6:11–16 (plurality of trocar apertures "allows for the efficient and effective distribution of the fluid throughout the body cavity, and at a reduced pressure because of the plurality of openings **29** provided … rather than forcing the fluid to exit the body member only at the distal end."). Ott '095 teaches that multiple apertures address the jet streaming problem in the context of dual-lumen trocars (such as the surgical access device disclosed by Mantell). *See* Ex. 1009, Fig. 1; *id.*, ¶ 20 (noting that instruments in the lumen "will not have any effect on flow conditions through the trocar sleeve since the fluid flow is independent of conditions in [the lumen]"); *see also id.*, ¶10; Ex. 1003, ¶ 122.

Because the use of a plurality of apertures in a separate lumen to disperse insufflation gas had well-known advantages, with regard to trocars generally and with regard to dual-lumen trocars specifically, a POSITA would have been motivated to supplement the single lateral aperture of Mantell with the plurality of apertures as taught by Ott '095 to obtain the benefits associated with the use of multiple apertures, such as reducing tissue damage due to jet streaming , more efficient insufflation gas distribution, and better dispersion of agents within the gas.. *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007) (reasoning that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same

way, using the technique is obvious unless its actual application is beyond that person's skill."); Ex. 1003, ¶ 123. The plurality of apertures in Ott '095 function identically when incorporated into the device disclosed by Mantell, and it would have been within the skill of a POSITA to add multiple apertures to the single aperture of Mantell with predictable results. *Id.*, ¶ 124.

(2) A POSITA would also be motivated to modify the device of Ott '095 to include Mantell's enclosed insufflation conduit

As noted above, like Mantell, Ott '095 discloses a dual-lumen trocar. However, the dual-lumen trocar taught by Ott '095 does not expressly disclose that the distal end of the insufflation conduit is sealed or enclosed. However, Mantell teaches that an advantageous feature in dual-lumen trocars (such as the trocar disclosed by Ott '095) is to enclose the distal end of the insufflation conduit formed between the outer wall of the trocar and the inner wall. As described by Mantell, the end of the insufflation conduit is sealed with silver solder. *See* Ex. 1005, 6:21–23, 6:66–7:6, Fig. 4. As a result of this sealing, the insufflation chamber and the central lumen "are isolated from one another so they are permanently not in fluid communication with one another." *Id.*, 7:4–6. Thus, Mantell discloses that the sealed end permits isolated introduction of one gas through the insufflation chamber, while another gas or instrument is provided through the central lumen without impacting the first gas dispersed from the

insufflation conduit. *See id.*, 8:56–9:2, 8:6–20; Ex. 1003, ¶ 125.

Ott '095 similarly discloses a dual-lumen trocar and teaches that a goal is to avoid activity in the central lumen affecting gas dispersion from the insufflation conduit. *See* Ex. 1009, ¶ 8 (isolation desirable because in a single-lumen trocar "manipulation of an instrument such as a surgical device within the trocar sleeve … might block off a substantial portion of the trocar sleeve thereby increasing velocity … until the jet streaming velocity is exceeded"); *see also id.*, ¶¶10, 23. Given Ott '095's goal of isolating the central lumen from the insufflation conduit, a POSITA would thus also be motivated to modify Ott '095 to enclose the end of the insufflation conduit at the distal end in order to further isolate the central lumen from the insufflation conduit, as taught in Mantell. Ex. 1003, ¶ 126. The sealed insufflation conduit end disclosed in Mantell would function identically when incorporated into the Ott '095 device, and a POSITA would have been capable of supplementing Ott '095 with the sealed end with predictable results. *Id.*, ¶ 127–28.

c) A POSITA would be motivated to combine Mantell, Ott '474, and Ott '095

For at least the reasons described above, a POSITA would be motivated to combine Mantell, Ott '474, and Ott '095. Ex. 1003, ¶ 129. A POSITA would be motivated to combine the dual-lumen trocar disclosed by Mantell and the dual-lumen trocar taught by Ott '095 to obtain at least the benefits of multiple apertures for gas delivery (which may reduce jet streaming, better disperse the gas, and/or

agents within the gas) and the benefits of an enclosed insufflation conduit end. Likewise, for the reasons described above regarding the known advantages of heated and humidified gas, Ott '474's express teaching that its system should be combined with trocars, and its common inventorship with Ott '095, would be equally applicable to a modified trocar (such as the trocar of Mantell supplemented with the multiple apertures of Ott '095, or the trocar of Ott '095 supplemented with the enclosed insufflation conduit end of Mantell). Accordingly, a POSITA would be motivated to combine such a modified trocar with a system for heated and humidified gas as taught by Ott '474. Ex. 1003, ¶ 129.

2. Mantell, Ott '474, and Ott '095 Disclose Each Element of Claims 1–11.

a) Claim 1

Claim 1[pre].[3] Mantell discloses a surgical access device for use in laparoscopic surgery. *See, e.g.*, Ex. 1005, 1:6–10; Ex. 1003, ¶ 130. Ott '095 likewise discloses a surgical access device. *See, e.g.*, Ex. 1009, ¶ 10. Trocars and trocar sleeves are both surgical access devices. Also, while Mantell's illustrated embodiments concern Verres needles, the explicit teaching in Column 10 of Mantell that the invention can be used for trocars is an explicit teaching of the dual

[3] Petitioner contends that the preambles of each of the challenged claims are non-limiting, but are nonetheless disclosed by the prior art.

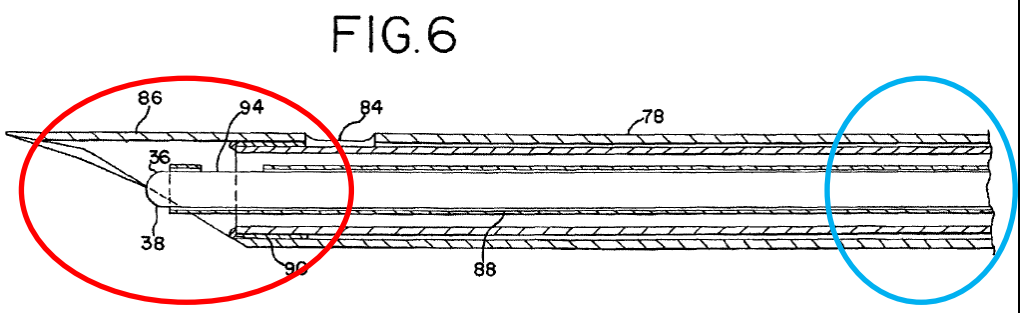
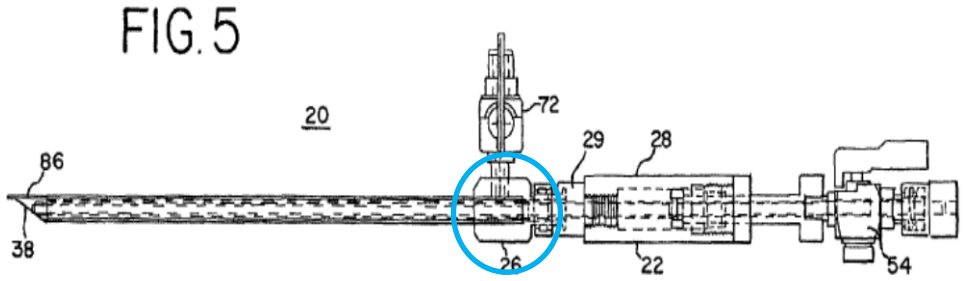
lumen design for trocars. Ex. 1003, ¶ 130. In the alternative, it suggests to persons skilled in the art to use the design for trocars, making the design an obvious choice for trocars, Verres needles, or other surgical access devices. *Id*.

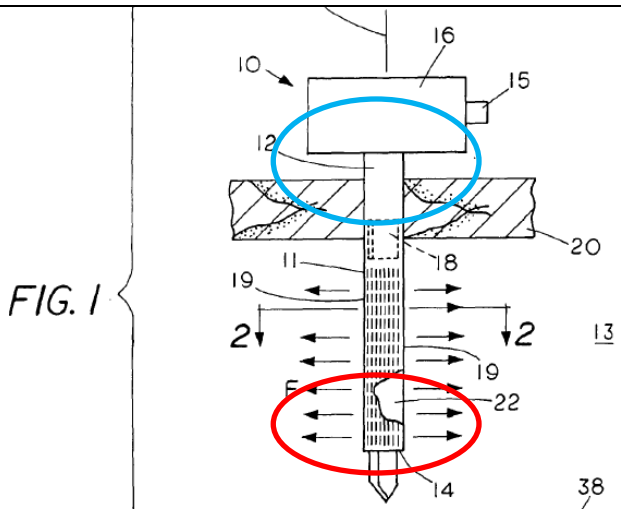
1[pre]. A surgical access device comprising:	**Mantell:** Ex. 1005, 1:6–10: "The present invention relates generally to instruments for laparoscopic surgery. In particular, it relates to an improved laparoscopic surgical instrument that can simultaneously perform multiple tasks and procedures independent of one another"; *id.* 10:59–63 "… the present invention can be applied to other insertion devices, such as trocars, where the trocar is inserted into an opening of an animal, such as a human patient …" *See also* Ex. 1005, Fig. 1, Fig. 4, Fig. 5. **Ott '095:** Ex. 1009, ¶¶1, 10 ("The present invention is a trocar sleeve for insufflating the body cavity …"), Fig. 1, Fig. 2.

Claim 1[a-1]. Mantell discloses an elongated outer tubular member having a proximal end and a distal end. Mantell's outer housing **78** is cylindrical (*i.e.*, tubular) in shape and elongated. Ex. 1005, 4:27–29, Figs. 1, 2, 4–7; Ex. 1003, ¶ 131. In addition, as shown below in annotated Figure 6, the elongated tubular outer housing of Mantell has a proximal end (not explicitly shown in Figure 5 but the direction of that end is circled in blue and the end itself is shown in Figure 5) opposed to a distal end (circled in red). Ex. 1005, Fig. 6; Ex. 1003, ¶ 131.

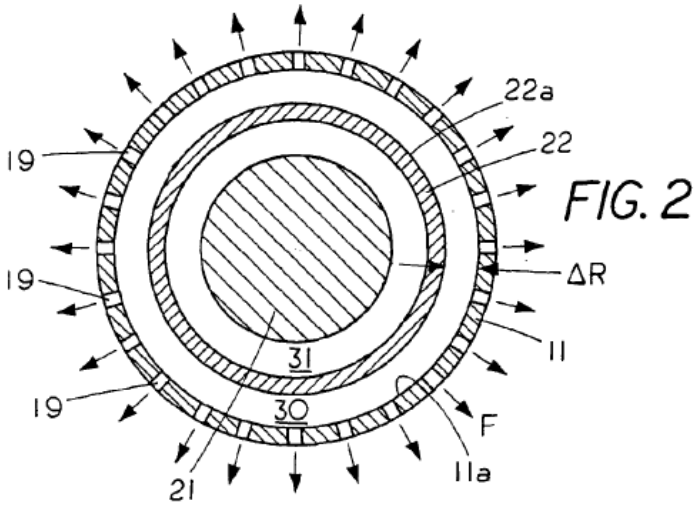
Similarly, Ott '095 discloses an elongated outer tubular member having

opposed proximal and distal ends. Ex. 1009, Fig. 1, ¶¶ 18–20. Ex. 1003, ¶ 132.

1[a-1]. a) an elongated outer tubular member having opposed proximal and distal end portions and having a longitudinal axis extending therethrough;	**Mantell:** Ex. 1005, Fig. 6 (annotated):  *See* Ex. 1005, 4:27–29: "As shown in FIGS **1**, **2** and **4**–**7**, the housing **78** is substantially cylindrical/annular in shape …."; *id.* 4:33–38: "The opening 80 is approximately 0.24 inches from a proximal end of the housing **78.** The housing **78** has a second opening **84** formed approximately 4.09 inches from the opening **80** and further includes a needle **86** formed at a distal end thereof." Ex. 1005, Fig. 5 (annotated):  *See also* Ex. 1005, Fig. 1, Fig. 4, Fig. 5. **Ott '095:** Ex. 1009, Fig. 1 (annotated excerpt):



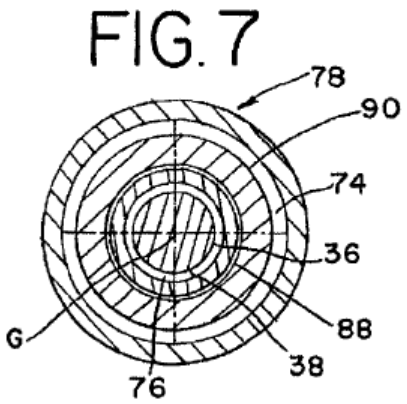
Ex. 1009, Fig. 2:

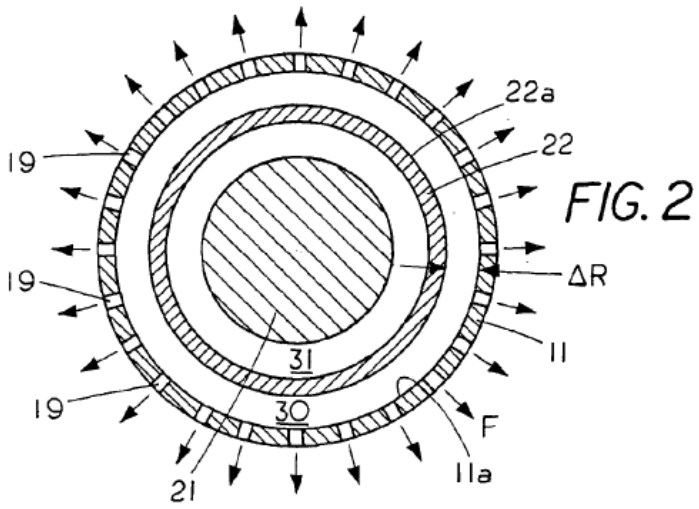


See Ex. 1009, ¶18: "**FIG. 1** shows trocar sleeve sleeve **10** in a partial cut away view. The trocar sleeve includes a housing **16**. Attached to the housing is an inlet port **15**. A cylindrical member or tube **11** is attached to the housing and is formed about a central longitudinal axis A_x of the trocar sleeve. The cylindrical member 11 has a proximal end **12** and spaced distally therein is a distal end **14**. A spaced plurality of apertures **19** is defined within the exterior of the body surface of the cylindrical member **11**."; *id.*, ¶ 19–20.

Claim 1[a-2]. Mantell discloses that a longitudinal axis extends throughout the device, and that the outer and inner housings are arranged in a concentric

manner around that axis. Ex. 1005, Fig. 1, Fig. 7 (cross-section of device), 6:23–26; Ex. 1003, ¶ 133. Similarly, Ott '095 teaches the same with regard to the surgical access device disclosed therein. *See* Ex. 1009, Fig. 2 (cross-section of device), ¶¶ 18–19; Ex. 1003, ¶ 133.

1[a-2]. a) an elongated outer tubular member having opposed proximal and distal end portions and having a longitudinal axis extending therethrough;	**Mantell:** Ex. 1005, Fig. 7:  *See* Ex. 1005, 6:23–26: "As shown in FIG. **7**, the housing **78** and the wall **90** are concentric about a common axis G so that the annular chamber **74** is concentric about axis G as well." *See also* Ex. 1005, Fig. 1. **Ott '095:** Ex. 1009, Fig. 2:

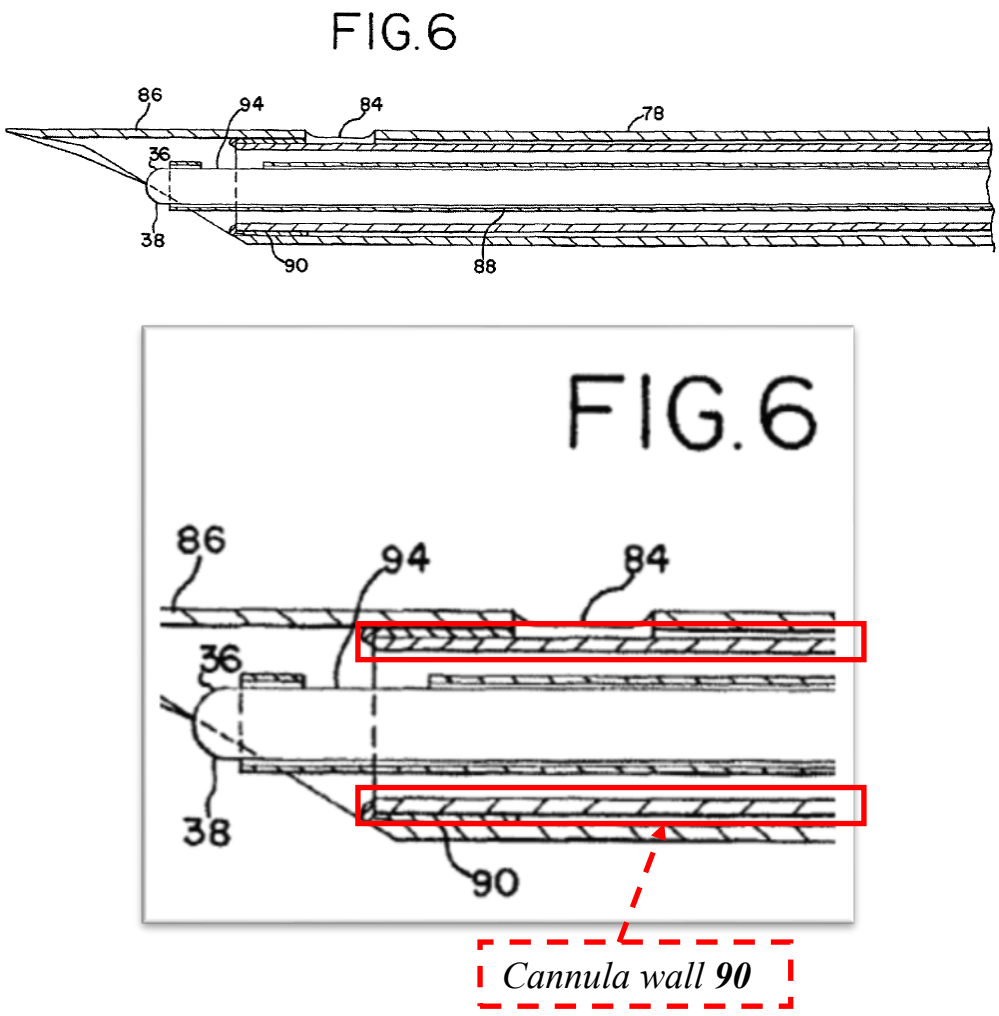


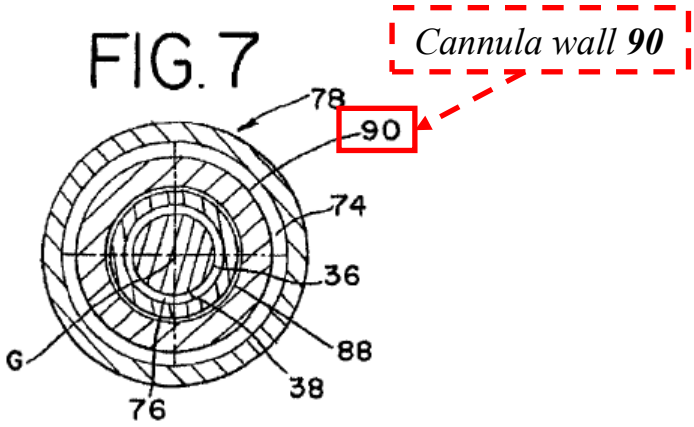
Ex. 1009, ¶ 18 ("A cylindrical member or tube **11** is attached to the housing and is formed about a central longitudinal axis A_x of the trocar sleeve."; *id.*, Fig. 1.

Claim 1[b-1]. As shown below in annotated Figure 6, Mantell discloses that elongated cannula wall **90** extends within outer tubular member **78** and has similarly opposed proximal and terminal end portions. Ex. 1005, Fig. 4, Fig. 5, Fig. 6.; Ex. 1003, ¶ 134. In addition, as shown below in annotated Figure 7, Mantell discloses that cannula wall **90** is cylindrical in shape (*i.e.*, tubular) and is arranged coaxially within outer tubular member **78.** Ex. 1005, Fig. 7, 6:15–16; Ex. 1003, ¶ 134.

As shown in Figure 2 below, Ott '095 likewise discloses an inner tubular member (**22**) having opposed proximal and distal end portions that is arranged coaxially within the outer tubular member (**11**) of the Ott device. *See* Ex. 1009, Fig. 2 (coaxial arrangement); Fig. 1 (cutaway showing inner member **22** extending

in elongated member such that opposed proximal and distal ends exist); *id.*, ¶ 20; Ex. 1003, ¶ 135.

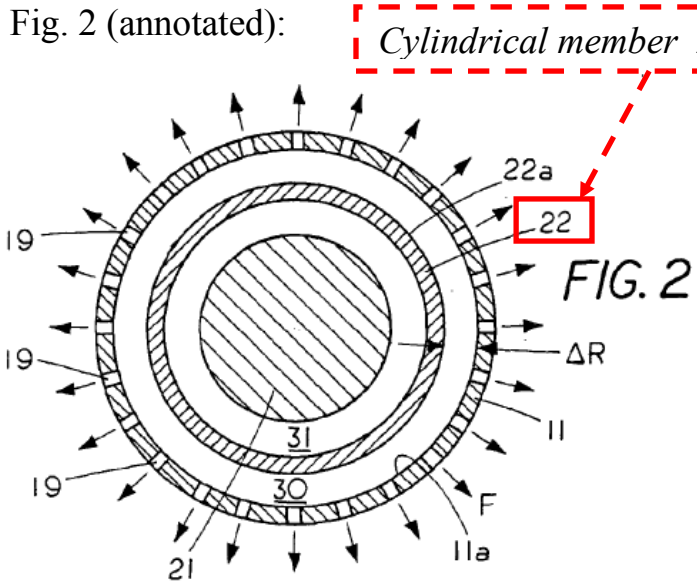
1[b-1]. b) an elongated inner tubular member having opposed proximal and distal end portions and being arranged coaxially within the outer tubular member, the inner tubular member defining a central lumen for introduction of a surgical instrument therethrough;	**Mantell:** Ex. 1005, Fig. 6 (annotated and enlarged):  *See* Ex. 1005, 6:15–16: "The cannula wall **90** is annular/cylindrical in shape having a length of approximately 4.562 inches …." Ex. 1005, Fig 7 (annotated):



See, e.g., Ex. 1005, 6:23–26: "As shown in FIG. **7**, the housing **78** and the wall **90** are concentric about a common axis G so that the annular chamber **74** is concentric about axis G as well."

Ott '095:

Ex. 1009, Fig. 2 (annotated):



Ex. 1009, ¶ 19: "Within the cylindrical member **11** and attached to the housing **16** is a cylindrical member or tube **22** having a sidewall **22a** which is impervious or substantially impervious to fluid flow therethrough."; *id.*, Cl. 3: "The trocar sleeve of claim 1 where said first member is coaxial with said second member."); *id.*, Fig. 1.

Claim 1[b-2]. Mantell discloses that the inner tubular member (*i.e.*, the

cannula wall **90**) defines a central lumen for introduction of a surgical instrument therethrough. As shown below in Figure 6 in red annotation, a central lumen is defined by the inner tubular member **90**, which is coaxially arranged within the outer tubular member (housing) **78**. Ex. 1005, Fig. 4, Fig. 6, Fig. 7; Ex. 1003, ¶ 136. The central lumen is for introduction of a surgical instrument therethrough. Ex. 1003, ¶ 136; Ex. 1005, 8, ll. 5-55 (infusing gas/tool entry combination). For example, as shown below in annotated Figure 6, a surgical instrument (the combination of inner needle cannula **88** and obturator **38)** is inserted through the central lumen defined by inner tubular member **90**. Ex. 1005, Fig. 6, 4:47–50; 5:27–31; Ex. 1003, ¶ 136. Although Figure 6 shows an inner needle cannula and an obturator inserted, Mantell also teaches that various other surgical instruments can also be inserted through the center of the device, such as "fluid pumps," "portable suction pumps," "graspers, scissors, electro-surgical tools, suction/irrigation wands, regular or mini endoscopes," among others. Ex. 1005, 7:49–58, 8:23–57 (listing additional possibilities); Ex. 1003, ¶ 136.

Patent Owner may argue that because obturator **38** is removable, inner needle cannula **88** rather than inner tubular member **90** defines the central lumen. However, this is incorrect for several reasons. *See* Ex. 1003, ¶¶ 137–40. First, inner needle cannula **88** and obturator **38** effectively form one moveable surgical instrument, which is inserted in Mantell's central lumen. For example, Mantell

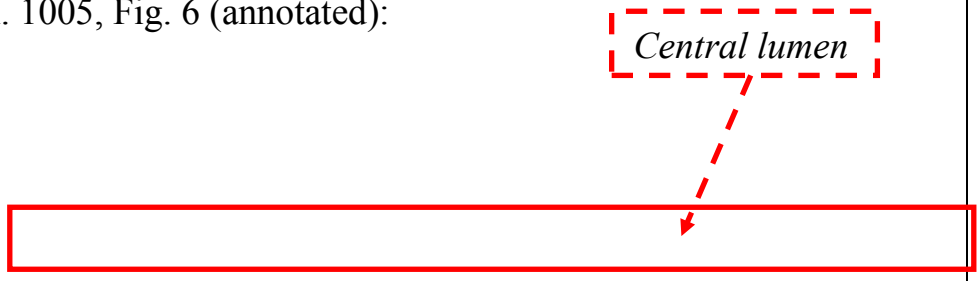
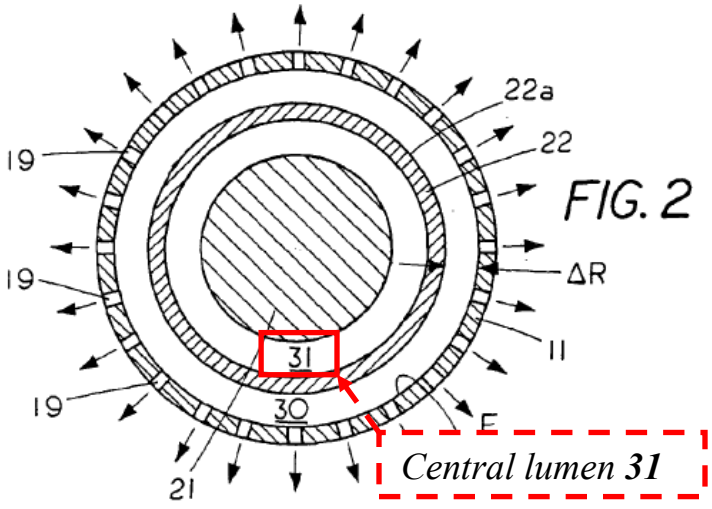
teaches that the inner needle cannula **88** is moveable within the central lumen created by inner tubular wall **90**. *See, e.g.*, Ex. 1005, 5:44–51. The obturator **38** is physically joined to, and thus moves together with, the inner needle cannula: "Since the obturator **38** is mechanically joined to the cannula wall **88**, the obturator **38** also moves to the extended position once the needle **86** enters the target area." Ex. 1005, 7:22–24. Although the obturator could be removed, it need not be. *Id.*, 7:30–32. The moveable combination of inner needle cannula **88** and obturator **38** thus form a surgical instrument inserted in the central lumen. Ex. 1003, ¶ 137.

Second, the inner needle cannula alone is also a surgical instrument introduced through the central lumen of inner tubular wall **90** because it performs surgical functions independent of the main body of the trocar/Verres needle taught by Mantell. For example, inner needle cannula **88** is attached to a separate stopcock **54**, such that it can be used to deliver drugs, for example, into a patient independent of the gas delivered through the insufflation conduit of the larger device. Ex. 1005, 6:43–46, 6:46–51, 8:50; Ex. 1003, ¶ 138. Thus, even if the combination of the inner needle cannula and obturator were not considered a single surgical instrument, Mantell's inner needle cannula is a surgical instrument introduced through the central lumen. Ex. 1003, ¶ 138.

Third, Mantell discloses that the inner tubular member **90** defines a central lumen for introduction of a surgical instrument regardless of whether the inner

needle cannula is considered a surgical instrument or the obturator is removeable. Specifically, Claim 1 is a "comprising" claim, which "creates a presumption that the recited elements are only a part of the device," such that "the claim does not exclude additional, unrecited elements." *Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l*, 24 F.3d 1336, 1348 (Fed. Cir. 2001). Mantell discloses a surgical instrument (such as obturator **38** or the other surgical instruments described above) at the center of the lumen defined by cannula wall **90.** Ex. 1003, ¶ 139. The presence of an additional concentric object (inner needle cannula **88**) around such a surgical instrument cannot negate Mantell's disclosure of the claimed element. In any event, if the needle cannula/obturator is not considered a single surgical instrument, an additional concentric object (inner needle cannula **88**) partially surrounding a surgical instrument (*e.g.* obturator 38) does not affect the fact that the surgical instrument (*e.g.* obturator 38) is still in the central lumen defined by cannula wall **90**. Ex. 1003, ¶ 139.

Finally, in addition to Mantell's disclosure of this element, Ott '095 also expressly discloses that the inner tubular member **22** defines a central lumen **31** for introduction of a surgical instrument therethrough. *See, e.g.*, Ex. 1009, Fig. 2; Fig. 1(showing cutting instrument inserted through device); *id.* ¶¶ 20, 21; *see also* Ex. 1003, ¶140. Ott '095 combined with Mantell renders this claim limitation obvious for this reason as well.

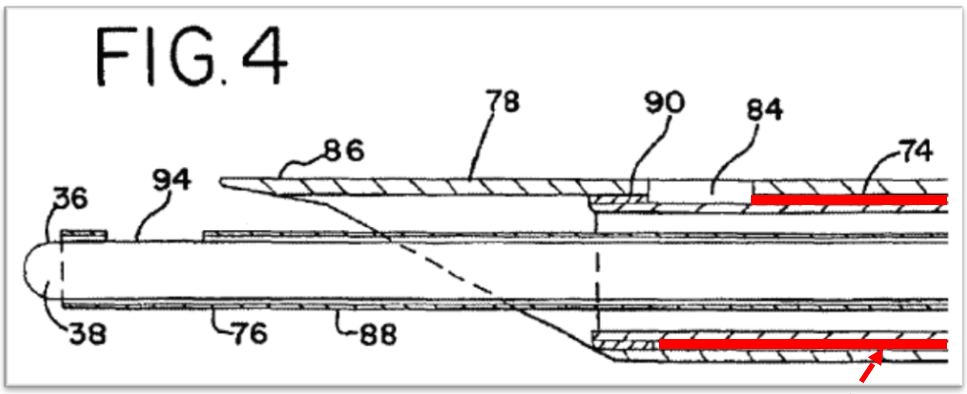
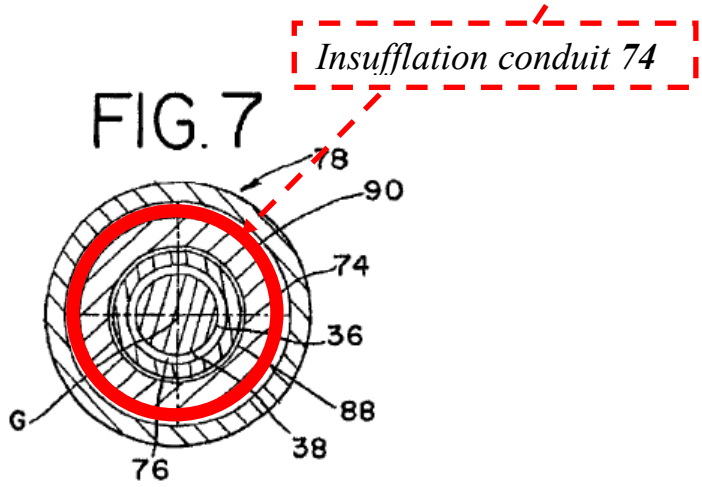
1[b-2]. b) an elongated inner tubular member having opposed proximal and distal end portions and being arranged coaxially within the outer tubular member, the inner tubular member defining a central lumen for introduction of a surgical instrument therethrough;	**Mantell:** Ex. 1005, Fig. 6 (annotated):  Ex. 1005, 4:47–50: "As shown in FIGS. **1**, **2** and **4–6**, the inner needle cannula wall **88** is inserted into the interior of the housing **78** and has a distal end that is near the distal end of the housing **78**."; *id.*, 5:27–31: "With the obturator **38** positioned within the inner needle cannula wall **88** and the housing **78**, the Verres needle **20** allows for both the obturator **38** and the inner needle cannula wall **88** to be movable relative to the housing **78** from an extended position to a retracted position and vice versa."; *id.*, 7:22–24; *id.*, 7:44–58: "In another mode of operation during insufflation via chamber **74**, the other chamber **76** can be adapted to receive a medical instrument by the open stopcock **54** and removing the obturator **38** when access to that space is required. Possible medical instruments that can be fed into chamber **76** into the abdomen are: . . . [LISTING INSTRUMENTS]. **Ott '095:** Ex. 1009, Fig. 2 (annotated): 

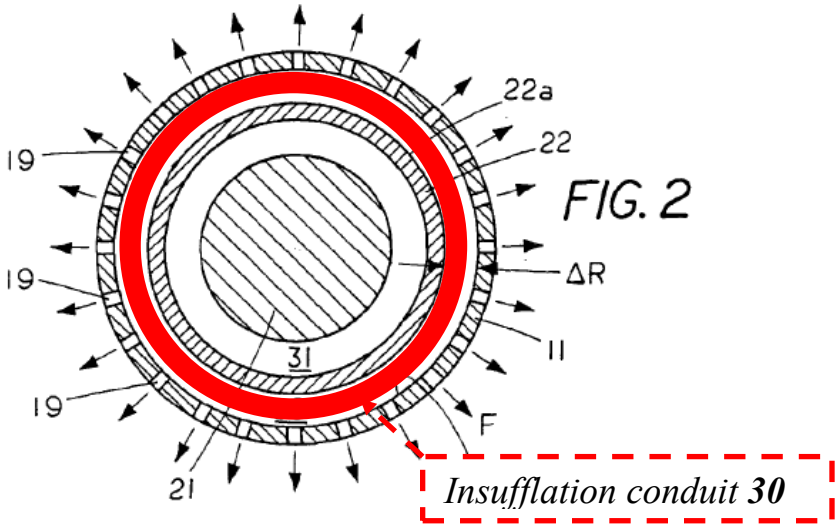
	Ex. 1009, ¶ 20: "Positioned within lumen **31** of cylindrical member **22** is the instrument comprising trocar **21**, which is shown occupying a central portion of the lumen **31**."; *id.* ¶21: "Thus regardless of whether an instrument is present in lumen **31** or whether an instrument is manipulated in lumen **31**. . . ." *id.* ¶20: The lumen **31** is used for manipulating the instruments and is isolated from the annular chamber **30**. That is, the lumen **31** is not used to deliver the insufflation gas to the patient any consequently manipulation of the surgical device **21** within the lumen **31** does not have any effect on the flow through the annular chamber **30** and hence through the radial apertures **19**."

Claim 1[c-1]. As shown below in annotated Figures 4 and 7, Mantell discloses an insufflation conduit **74** defined between the outer tubular member (housing **78**) and the inner tubular member (cannula wall **90**). Ex. 1005, Fig. 4, Fig. 6, Fig. 7; Ex. 1003,¶ 141. Mantell further discloses that insufflation fluid is introduced through stopcock **72** such that it flows through insufflation conduit **74**, out opening **84**, and into the body cavity of the patient. Ex. 1005, 6:29–34, Fig. 1, Fig. 2, Fig. 4, Fig. 5, Fig. 8; Ex. 1003, ¶ 141.

In addition to Mantell's disclosure of this element, Ott '095 also discloses that an insufflation conduit **30** is defined between inner tubular member **22** and outer tubular member **11.** Ex. 1009, Fig. 2, ¶¶ 20–21; Ex. 1003, ¶ 142.

1[c-1] c) an insufflation conduit defined between the inner and outer tubular members in	**Mantell:** Ex. 1005, Fig. 4 (annotated excerpt):

communication with a source of humidified insufflation gas; and	 Ex. 1005, Fig. 7 (annotated):  Ex. 1005, 6:13–15:"The annular chamber **74** is defined as the space between the housing **78** and a cannula wall **90**."; *id.* 6:29–34: "In operation, the stopcock **72** is opened so that a fluid is received by the opening **82** and delivered into the opening **80** of the housing **78**. The fluid then flows into the chamber **74** and exits out of the opening **84** of the housing and the annular space **74** between housing **78** and wall **90** and flows into a target area, such as a body cavity or abdomen." Ex. 1005, 7:35–39: (insufflation gas supplied via chamber **74**) **Ott '095:** Ex. 1009, Fig. 2 (annotated):



Ex. 1009, ¶ 20: "Located concentrically within cylindrical member **11** is a further elongated tube or cylindrical member **22** having the sidewall **22***a* impervious to fluid flow with sidewall **22a** spaced from inner sidewall **11***a* of tube **11** to form an annular chamber **30** for fluid to flow therethrough.…" ; *id.*: "The lumen **31** is used for manipulating the instruments and is isolated from the annular chamber **30**."

Ex. 1009, ¶21 (insufflating fluid, 'F', which may be gas, delivered to patient through annular fluid flow chamber 30)

Claim 1[c-2]. Mantell discloses that the insufflation conduit is in communication with a source of insufflation gas, and Ott '474 discloses that insufflation gas may be humidified. Ex. 1003, ¶ 143.

Specifically, Mantell discloses that insufflation conduit **74** communicates with a source of insufflation fluid, such that fluid is delivered through stopcock **72** through chamber **74** to exit opening **84** into a patient's peritoneum. *See, e.g.*, Ex. 1005, 6:29–34. Mantell's insufflation fluid may be "either a gas or a liquid." *Id.*, 6:9–10; Ex. 1003, ¶ 144; *see also* Ex. 1005, 1:39–41.

Ott '474 discloses "heating, humidifying and filtering insufflation gasses at a point immediately prior to passage of the gases into the patient." *See* Ex. 1006, 1:12-15, 3:30–35 ("The disadvantages of the prior art are overcome by the present invention which provides a high-efficiency apparatus for heating, **humidifying** and filtering gas, thus allowing the gas to be delivered to the patient at an accurate temperature **while also properly humidified** and filtered …") (emphases added). As discussed above, Section IV.C *supra*, Ott '474 further teaches the use of humidified gas in laparoscopic surgery. *See, e.g.*, Ex. 1006, 10:60–62. Moreover, Ott '474 teaches that humidified gas may be used with trocars. Ex. 1006, 9:18–22. This includes the trocar disclosed by Mantell (or the trocar that is obvious in light of Mantell's disclosure of a dual lumen Verres needle that he then says is applicable to trocars). Ex. 1005, 10:59–60; *see also* Ex. 1003, ¶ 145.

Mantell and Ott '474, when combined as discussed above in Section VI.A.1.(a), thus disclose an insufflation conduit in communication with a source of humidified insufflation gas, rendering this claim limitation obvious. Ex. 1003, ¶ 146.

In addition, Ott '095 also discloses that insufflation conduit **30** is in communication with a source of insufflation gas. *See, e.g.*, Ex. 1009, ¶ 21. For the same reasons described above and in Section VI.A.1.(a), *supra*, Ott '474 discloses that the gas may be humidified. Accordingly, this claim limitation is obvious for

this reason as well. Ex. 1003, ¶ 147. Also, Ott '095, as discussed above, discloses that the insufflation gas may include an anesthetic and that suggests a humidified gas as well.

1[c-2] c) an insufflation conduit defined between the inner and outer tubular members in communication with a source of humidified insufflation gas; and	**Mantell:** Ex. 1005, 6:13–15:"The annular chamber 74 is defined as the space between the housing 78 and a cannula wall 90."; *id*. 6:29–34: "In operation, the stopcock **72** is opened so that a fluid is received by the opening **82** and delivered into the opening **80** of the housing **78**."; *id.*, 6:9–10; *id.*, 8: 53–54 ("moisture infusion"); *id.*, 5:66–67. Ex. 1005, 7:35–39: (insufflation gas supplied via chamber **74**) **Ott '474:** Ex. 1006, 1:11–15; *id*., 3:30–35: "The disadvantages of the prior art are overcome by the present invention which provides a high-efficiency apparatus for heating, humidifying and filtering gas, thus allowing the gas to be delivered to the patient at an accurate temperature while also properly humidified and filtered and without the use of AC voltage."); *id.*, 2:36–39; *id.*, 3:30–35 ; *id*., Fig. 1 & 4:35–41: "Fig. **1** is a schematic view of a gas treatment apparatus … connected to an insufflator at one end and a means for delivering the gas to a patient at the opposite end, and being broken away at the heating and humidifying chamber to show the heating element within the chamber[.]"; *id.*, 9:18–22. Ex. 1006, 9:18-22: "The filtered and temperature/humidity conditioned gas **29** passes directly to a connector **26**, designed to attach to a conventional trocar used to inflate the peritonea or other such gas delivery device for the particular medical procedure." **Ott '095**:

	Ex. 1009, ¶21: "The fluid 'F' is delivered under pressure from an external source via inlet port **15**, travels through the annular fluid flow chamber **30** and is discharged at below a 'jet streaming velocity' through the plurality of apertures **19** as indicated by the arrows."; *id.*, Fig. 2; Fig. 1. Ex. 1009, ¶21: (insufflating fluid, 'F', which may be gas, delivered to patient through annular fluid flow chamber 30)

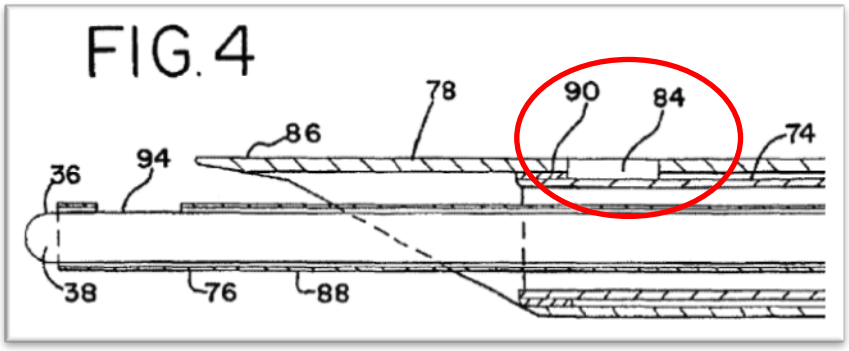
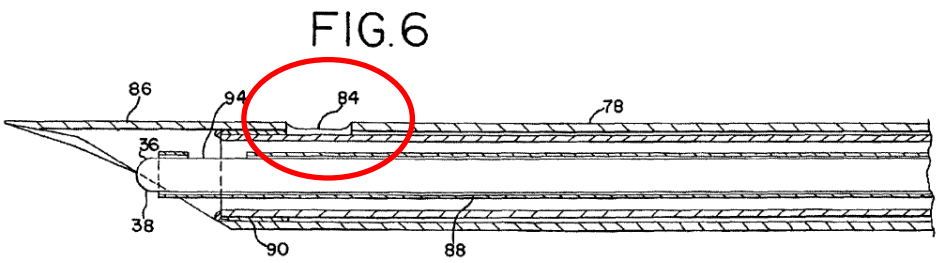
Claim 1[d-1]. As shown below in annotated Figures 4 and 6, Mantell discloses an aperture **84** extending through the outer surface of the distal portion (*i.e.*, needle end) of the tubular outer housing **78.** Ex. 1005, Fig. 4, Fig. 6, 4:35–37; Ex. 1003, ¶ 148. In addition, Mantell discloses that the aperture **84** is in fluid communication with insufflation conduit **74**, as is also shown in Figures 4 and 6. Mantell further discloses that insufflation gas flows from a gas source through insufflation conduit **74** to aperture **84**, and then into the body cavity or abdomen of the patient. Ex. 1005, 6:29–36: "The fluid then flows into the chamber **74** and exits out of the opening **84** of the housing and the annular space **74** between housing **78** and wall **90** and flows into a target area, such as a body cavity or abdomen."; Ex. 1003, ¶ 148.

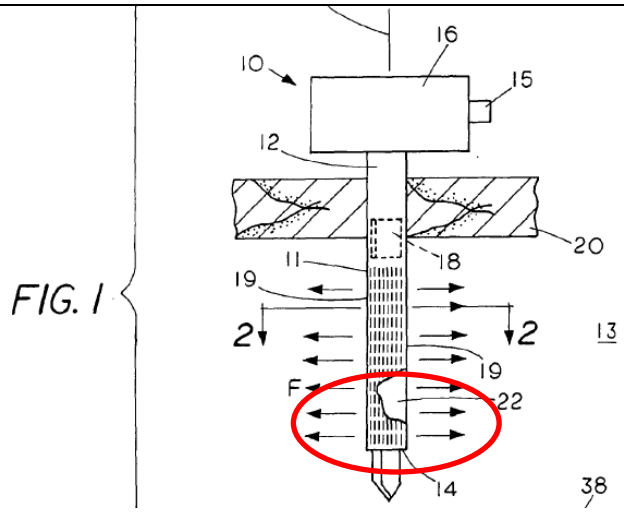
To the extent it would not be an obvious design choice from Mantell's disclosure to use a *plurality* of such apertures, that element is explicitly disclosed by Ott '095. As shown by the red annotations below, for example, excerpted Figure 1 of Ott '095 discloses a plurality of apertures in the side of the exterior tubular member of a dual-lumen trocar laterally discharging insufflation gas into

the peritoneum of a patient, while Figure 2 of Ott '095 shows an cut-away view of the plurality of apertures in communication with the insufflation conduit **30**. Ex. 1009, Fig. 1, Fig. 2, ¶ 18 ("A spaced plurality of apertures **19** is defined within the exterior of the body surface of the cylindrical member **11**. The plurality of apertures **19** are regularly spaced from one another and extend at least partially from the distal end **14** toward the proximal end **12** of the trocar sleeve."), ¶16, ¶ 21 (describing gas from plurality of apertures in Fig. 2); *see also* Ex. 1003, ¶ 149. Mantell, when modified to include the plurality of apertures of Ott '095, as described *supra* in Section VI.A.1.(b)(1), thus renders this claim limitation obvious.

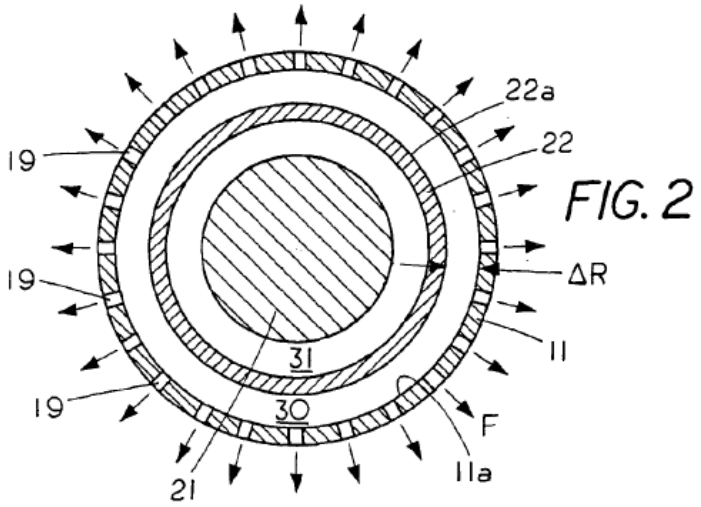
Although Mantell in combination with Ott '095 thus renders this claim limitation obvious, Ott '095 itself also discloses this limitation, as described above. *See, e.g.*, Ex. 1009, Fig. 2 (showing gas flow between insufflation conduit 30 and lateral apertures), Fig. 1 (showing flow into peritoneum), ¶¶ 18, 21; Ex. 1003, ¶ 150. Thus, the device of Ott '095 modified to include the enclosed insufflation conduit, as discussed above in Section VI.A.1.(b)(2) and below with regard to element 1[e], renders this claim limitation obvious. *See id.*

1[d-1] d) a plurality of apertures extending through an outer surface of	**Mantell:** Ex. 1005, Fig. 4 (annotated excerpt):

the distal portion of the outer tubular member in fluid communication with the insufflation conduit and configured to laterally discharge humidified insufflation gas from the insufflation conduit into the peritoneum of a patient,	 Ex. 1005, Fig. 6 (annotated):  *See also, e.g.*, Ex. 1005, 4:35–37: "The housing **78** has a second opening **84** formed approximately 4.09 inches from the opening **80** and further includes a needle **86** formed at a distal end thereof."; *id.*, 6:29–36. Ex. 1005, 7:35–39: (insufflation gas supplied via chamber **74**) **Ott '095:** Ex. 1009, Fig. 1 (annotated excerpt):



Ex. 1009, Fig. 2:



Ex. 1009, ¶ 18: "A spaced plurality of apertures **19** is defined within the exterior of the body surface of the cylindrical member **11**. . . ."; *id*., ¶ 16: "creating an opening within the body that extends through many layers of tissue **20**, which include skin, fat, muscle and pre-pleural or pre-peritoneal in either the thoracic or abdominal cavities, respectively"; *id*., ¶ **21**: "The fluid 'F' is delivered under pressure from an external source via inlet port **15**, travels through the annular fluid flow chamber 30 and is discharged at below a jet streaming velocity" through the plurality of apertures **19** as indicated by the arrows."

Ex. 1009, ¶21: (insufflating fluid, 'F', which may be gas, delivered to patient through annular fluid flow chamber 30)

	See also Ex. 1008 (incorporated by reference in Ex. 1009), 5:14–17; *id*., 3:41–44; *id.*, 6:11–16: "This construction allows for the efficient and effective distribution of the fluid throughout the body cavity, and at a reduced pressure because of the plurality of openings **29** provided along the body member, rather than forcing the fluid to exit the body member only at its distal end."; *id*., 7:27–32.

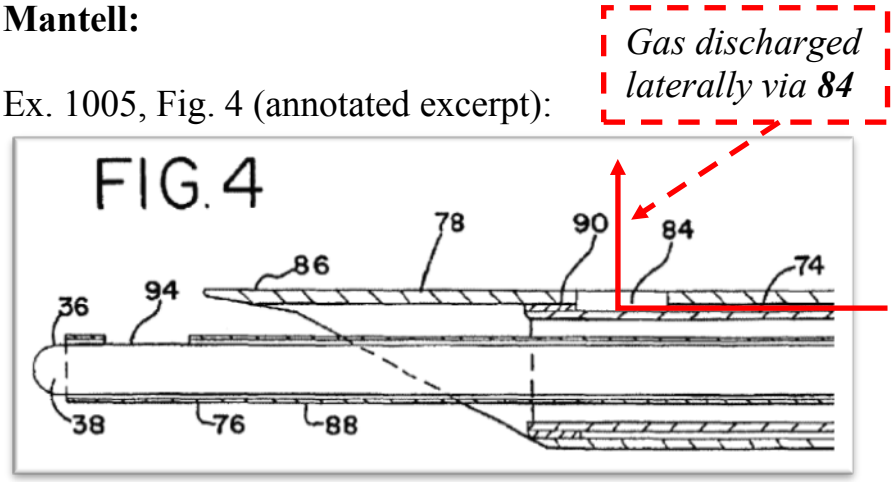
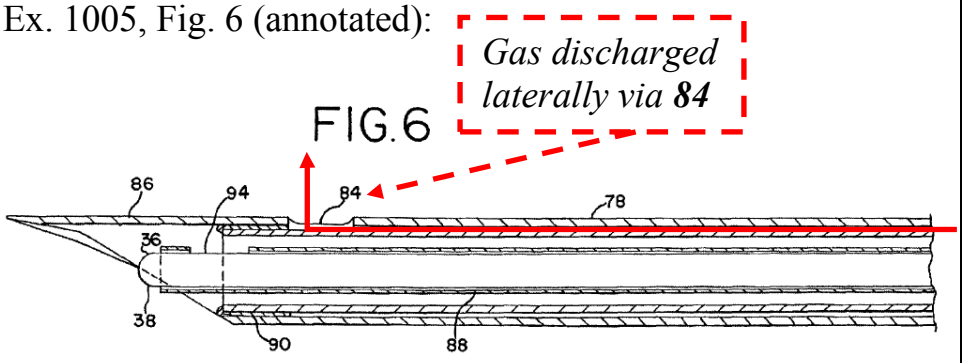
Claim 1[d-2]. As shown below in annotated Figures 4 and 6, Mantell discloses that aperture **84** is configured so as to laterally discharge gas[4] from insufflation conduit **74** into a patient's body, rather than axially through the distal end of the device. Ex. 1005, Fig. 4, Fig. 6; Ex. 1003, ¶ 151.

Mantell further discloses that the gas disclosed by aperture **84** from insufflation conduit **74** may be discharged into a patient's peritoneum. Ex. 1003, ¶ 152. Conduits **74** and **76** terminate in the same target area or body cavity. *See, e.g.*, Ex. 1005, 8:57–58: "[T]he isolated chambers **74** and **76** allow for multiple fluids to be conveyed to a target area."; *id.*, 8:57–66 (describing other uses for **74**

[4] As discussed *supra* with regard to claim element 1[c-2], that the insufflation gas can be conditioned (humidified and/or heated) is obvious in light of Ott '474 and the skill of a POSITA. For the sake of brevity, that explanation is not repeated again each time humidified or conditioned insufflation gas is referenced in the claims, but should be understood to apply equally throughout this petition. Instead, the discussion in Section V.B and VI.A.1.(a) is incorporated by reference.

and **76**'s simultaneous termination in the same target area or cavity). Mantell also discloses that the target area or body cavity can be a patient's peritoneum. For example, one mode of operation disclosed by Mantell is measuring pressure in the peritoneum using conduit **76**, while using insufflation conduit **74** to simultaneously supply gas to the same abdominal cavity. Ex. 1005, 7:38–43; Ex. 1003, ¶ 152.

As described above with regard to element 1[d-1], Ott '095 also discloses this limitation. *See, e.g.*, Ex. 1009, Fig. 2 (showing lateral gas flow), Fig. 1 (showing flow into peritoneum), ¶¶ 18, 21; Ex. 1003, ¶ 153.

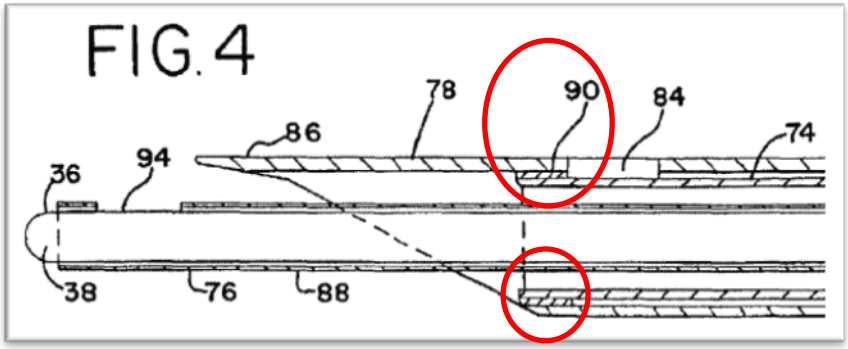
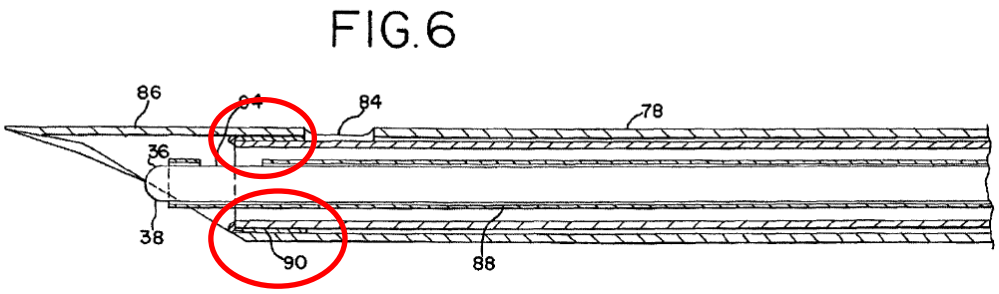
1[d-2] d) a plurality of apertures extending through an outer surface of the distal portion of the outer tubular member in fluid communication with the insufflation conduit and configured to laterally discharge humidified insufflation gas from the insufflation conduit into the peritoneum of a patient,	**Mantell:** Ex. 1005, Fig. 4 (annotated excerpt):  Ex. 1005, Fig. 6 (annotated):  *See also, e.g.*, Ex. 1005, 6:29–36: "In operation, the stopcock **72** is opened so that a fluid is received by the opening **82** and delivered into the opening **80** of the housing **78**. The fluid then flows into the chamber **74** and exits out of the opening **84** of the housing and the annular space **74** between housing **78** and wall **90** and flows into a target area, such as a body cavity or abdomen. Thus, the opening **84** is in fluid communication with a target area."; *id.*, 7:34–39. Ex. 1005, 7:35–39: (insufflation gas supplied via chamber **74**) **Ott '095:** Ex. 1009, Fig. 2 (showing lateral gas flow), Fig. 1 (showing flow into peritoneum); *id.* ¶¶ 18, 21.

	Ex. 1009, ¶21: (insufflating fluid, 'F', which may be gas, delivered to patient through annular fluid flow chamber 30) See chart for claim element 1[c-2] with respect to the teaching of the gas being humidified.

Claim 1[e]. As shown below in annotated Figures 4 and 6, Mantell discloses that the distal end portions of outer tubular member **78** and inner tubular member **90** are sealed together with silver solder so as to cooperate to enclose the insufflation conduit **74**. Ex. 1005, Fig. 4, Fig. 6, 6:19–23; Ex. 1003, ¶ 154. Mantell further teaches that because the insufflation conduit is enclosed in this manner, gas can only exit insufflation conduit **74** through the aperture **84**, and not through the central lumen or chamber **76** (which, unlike chamber **74**, is in fluid communication with the central lumen). *See, e.g.*, Ex. 1005, 6:66–7:6 ("[T]he chambers **74** and **76** are isolated from one another so they are permanently not in fluid communication with one another."), 6:7–9 (same); Ex. 1003, ¶ 154.

This limitation would also be obvious when viewed from the perspective of the Ott '095 reference. Although Ott '095 does not expressly disclose that the distal end of the insufflation conduit **30** is enclosed, that disclosure is expressly made by Mantell as discussed above. Moreover, Ott '095 does disclose sealing the end of the trocar with lateral apertures in the embodiment of Figure 3. For the reasons discussed in Section VI.A.1.(b)(2), a POSITA would be motivated to modify Ott '095 to realize the benefit of Mantell's enclosed insufflation conduit in

the similar dual-lumen trocar disclosed by Ott '095. Thus, this limitation would be disclosed when Ott '095 and Mantell are combined in this manner. Ex. 1003, ¶ 155.

1[e] wherein the distal end portion of the outer tubular member and the distal end portion of the inner tubular member cooperate to enclose the insufflation conduit such that the humidified insufflation gas is discharged only from the plurality of apertures.	**Mantell:** Ex. 1005, Fig. 4 (annotated):  Ex. 1005, Fig. 6 (annotated):  Ex. 1005, 6:19–23: "In particular, silver solder is applied to the housing **78** and wall **90** distally of the opening **84**. Silver solder is also applied to the housing **78** and wall **90** proximally of opening **82**. The silver solder seals the chamber **74** at distal and proximal ends thereof."); *id*. 6:66–7:6: "When both stopcock **54** and **72** are open at the same time, the fluids associated with the stopcocks flow within the Verres needle **20** do not intermingle within the needle **20** since the annular walls **78** and 90 do not define a volume of space that is common with any volume of space defined by the annular walls **36** and **88**. Accordingly, the chambers **74** and **76** are isolated from one another so they are permanently not in fluid communication with one another."; *id*., 6:7–9: "In accordance with the present invention, the two fluids are

	permanently not in fluid communication with one another." **Ott '095** : Ex. 1009, Fig. 1, Fig. 2, Fig. 3. Ex. 1009, ¶23: "FIG. 3A is a partial cut away view of the cylindrical member 41 revealing an end member 48 blocking the end of cylindrical member 41 to provide a closed end of trocar sleeve 40 . . ."

As shown above, Mantell, combined with Ott '474 and Ott '095 (or, viewed conversely as Ott '095 combined with Ott '474 and Mantell), discloses each element of Claim 1 of the '372 patent, and thus renders Claim 1 obvious under 35 U.S.C. § 103. Ex. 1003, ¶ 156.

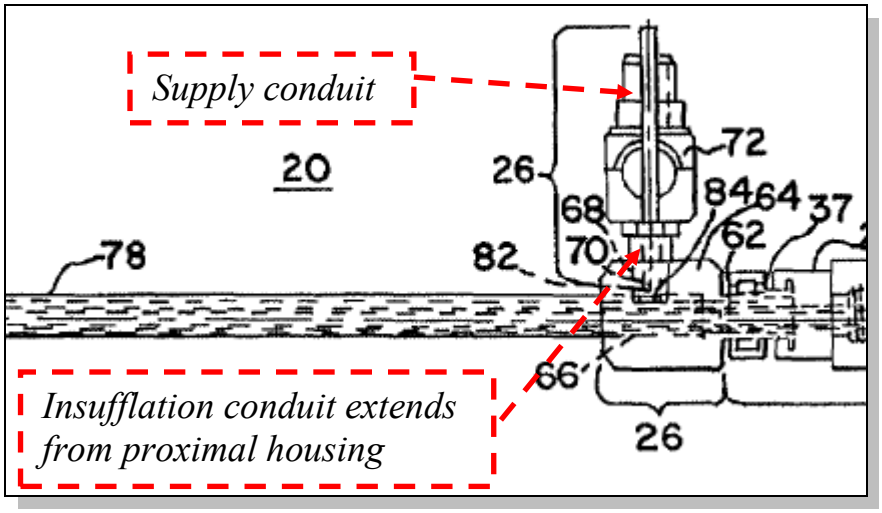
b) Claim 2

Claim 2. Claim 2 depends from Claim 1. The discussion above concerning Claim 1 is incorporated herein by reference. As shown below in excerpted Figures 1 and 5, Mantell further discloses that the insufflation conduit **74** extends from a housing at the proximal portion of the surgical access device, the housing in communication with a supply conduit to facilitate supply of the humidified[5] insufflation gas to the insufflation conduit. Specifically, insufflation conduit **74** extends from the device housing via aligned openings **80**/**82** in fluid port section **26** at the proximal portion of the trocar, in communication with a supply conduit defined by stopcock **72**, which stopcock is attached to a source of insufflation gas.

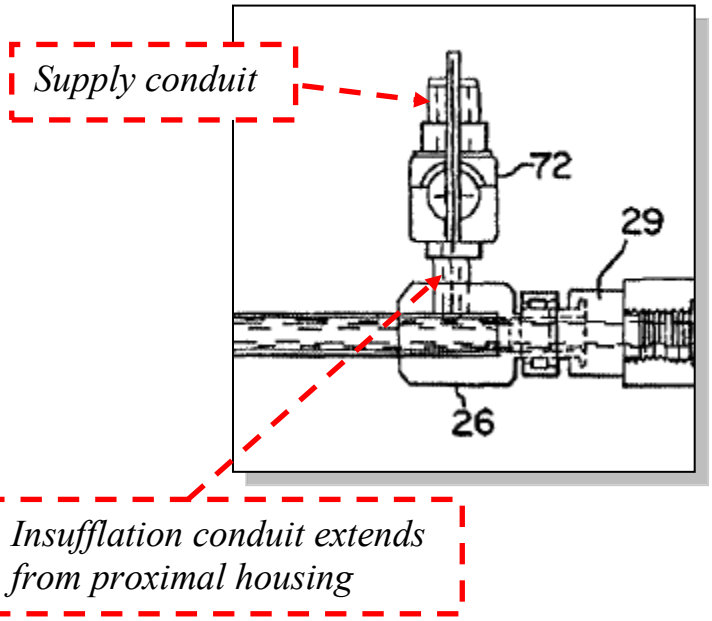
[5] With regard to humidification, *see* n.4, *supra.*

Ex. 1005, Fig. 1, 5:66–67 ("The stopcocks **54** and **72** preferably are attached to supplies (not shown) for two isolated fluids."); Ex. 1003, ¶ 157.

A similar disclosures exists in Ott '095. Specifically, as shown below in Figure 1, insufflation conduit **30** extends from the housing, which is in communication with an inlet port **15** to communicate with an external source of insufflation gas. Ex. 1009, Fig. 1, Fig. 2, ¶18–20; Ex. 1003, ¶ 158.

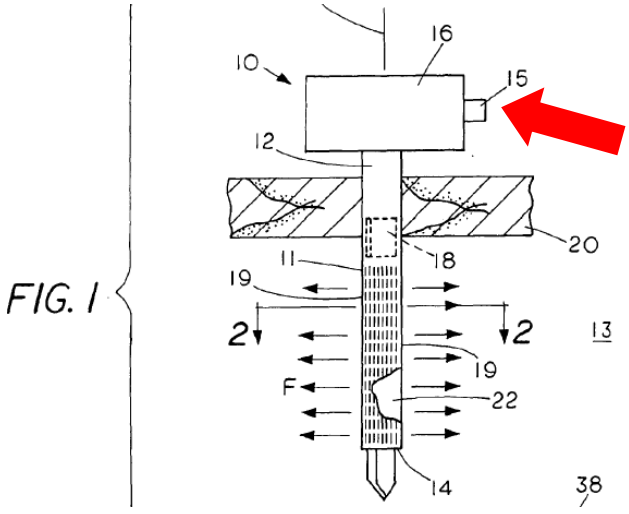
[2]. The surgical access device of claim 1, wherein the insufflation conduit extends from a housing at the proximal portion of the surgical access device, the housing in communication with a supply conduit to facilitate supply of the humidified insufflation gas to the insufflation conduit.	**Mantell:** Ex. 1005, 4:31–33: "The housing **78** has a 0.093 inch diameter opening **80** that is aligned with an opening **82** of the fluid port section **26**."); *id*., 6:29–36: "In operation, the stopcock **72** is opened so that a fluid is received by the opening **82** and delivered into the opening **80** of the housing **78**. The fluid then flows into the chamber **74** and exits out of the opening **84** of the housing and the annular space **74** between housing **78** and wall **90** and flows into a target area, such as a body cavity or abdomen." Ex. 1005, 7:35–39: (insufflation gas supplied via chamber **74**) Ex. 1005, Fig. 1 (annotated excerpt): 

Ex. 1005, Fig. 5 (annotated excerpt):



Ott '095:

Ex. 1009, Fig. 1 (annotated excerpt):



	Ex. 1009, Fig. 1, Fig. 2; *id.*, ¶18: "Attached to the housing is an inlet port **15**."; *id.*, ¶20: "The fluid 'F' is delivered under pressure from an external source via inlet port **15**, travels through the annular fluid flow chamber **30** and is discharged at below a 'jet streaming velocity' through the plurality of apertures **19** as indicated by the arrows." Ex. 1009, Fig. 2, *id.*, ¶20: "FIG. 2 shows a cross section view revealing the outer elongated tube or cylindrical member **11** having the apertures **19** therein. Located concentrically within cylindrical member **11** is a further elongated tube or cylindrical member **22** having the sidewall **22** a impervious to fluid flow with sidewall **22** a spaced from inner sidewall **11** a of tube **11** to form an annular chamber 30 for fluid to flow therethrough." Ex. 1009, Fig. 2.; *id*., ¶21: (insufflating fluid, 'F', which may be gas, delivered to patient through annular fluid flow chamber 30) See chart for claim element 1[c-2] with respect to the teaching of the gas being humidified.

c) Claim 3

Claim 3. Claim 3 depends from Claim 1 and adds that the gas source is external. The discussion above concerning Claim 1 is incorporated herein by reference. Mantell further teaches that the source of humidified insufflation gas is external to the surgical access device. Specifically, at least the embodiment depicted in Figures 1, 2, and 5 of Mantell and the embodiments depicted in Figures 8, 10, 11, 14, 15, 17, and 18 show stopcocks for connection to a separate source of humidified[6] insufflation gas. *See, e.g.*, Ex. 1005, 6:29–36: "In operation, the

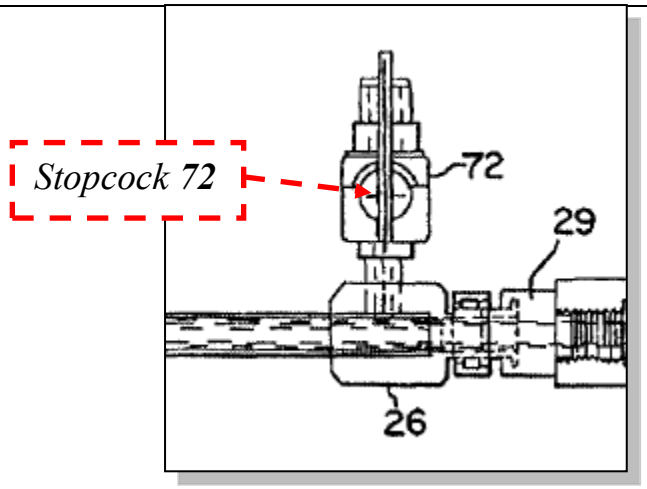
[6] With regard to humidification, *see* n.4, *supra.*

stopcock **72** is opened so that a fluid is received by the opening **82** and delivered into the opening **80** of the housing **78**. The fluid then flows into the chamber **74** and exits out of the opening **84** of the housing and the annular space **74** ….", Fig. 1, 2, 5; Ex. 1003, ¶ 159. That separate source is necessarily external to the surgical access device, as it is connected via a stopcock that controls access to the internal delivery mechanism of the surgical access device. Ex. 1003, ¶ 159. Mantell also teaches that detachable insufflation gas supplies were well known in the prior art. *See, e.g.*, Ex. 1005, 1:39–41.

Ott '095 also expressly discloses that the gas source is external. Ex. 1009, ¶ 21 ("The fluid 'F' is delivered under pressure from an external source via inlet port **15** …); Ex. 1003, ¶ 160.

In addition, as discussed regarding element 1[c-2] *supra*, Ott '474 is directed to an external source of humidified gas that is "designed to attach to a conventional trocar," and thus also discloses this element. Ex. 1006, 9:18–22; Ex. 1003, ¶ 161.

[3]. The surgical access device of claim 1, wherein the source of humidified insufflation gas is external to the surgical access device.	**Mantell:** *See, e.g.*, Ex. 1005, Fig. 5 (annotated excerpt):



See also Ex. 1005, 5:66–6:7 (emphasis added): "The stopcocks **54** and **72** *preferably are attached to supplies (not shown)* for two isolated fluids. Thus, the stopcocks **54** and **72** allow for two different fluids, to be supplied to the Verres needle **20**. For example, stopcocks **54** and **72** can be attached to *separate supplies of carbon dioxide*. In another embodiment, one of the stopcocks **54** can be attached *to a supply of carbon dioxide* while the other stopcock is attached to a supply of an aerosolized medication."; *id.*, 1:39–41 ("An insufflating gas then is delivered to the abdominal cavity from a gas supply *detachably connected* to the Verres needle …") (emphasis added).

Ott '474:

Ex. 1006, 9:18–22: "The filtered and temperature/ humidity conditioned gas **29** passes directly to a connector 26 designed **to** attach to a conventional trocar used to inflate the peritonea or other such gas delivery device for the particular medical procedure."; *see also id.*, Fig. 1, Fig. 2.

Ott '095:

Ex. 1009, ¶ 21; *see also* Ex. 1008 (incorporated by

	reference in Ex. 1009), 2:21–27 (emphasis added): "As the trocar is being inserted into the body cavity, a fluid … *from an external source*, which may be a gas or a liquid bearing drugs, anesthetics, or other substances … is commonly passed through the access port **11** and transported into the body cavity …." See the chart for claim element 1[c-2] with respect to the teaching of the gas being humidified.

d) Claim 4

Claim 4 is substantially identical to Claim 1, but written in system form. *See, e.g.*, Ex. 1012, ¶ 10 (patent owner stating that "Similar limitations [to claim 1] may be found in independent claim 4, which recites the invention as part of a system that includes the source of humidified gas …"); *see also* Ex. 1003, ¶ 162.

Claim 4 recites "a source of humidified insufflation gas in fluid communication with the insufflation conduit." As discussed in connection with Claim 1, Mantell discloses that the system therein includes a supply of insufflation gas in fluid communication with the insufflation conduit.[7] *See, e.g.*, Ex. 1005, 6:4–6 ("In another embodiment, one of the stopcocks **54** can be attached to a supply of carbon dioxide …"), 6:29–36, 1:39–41; Ex. 1003, ¶ 163. Similarly, Ott '095 discloses that the system therein includes a supply of insufflation gas in fluid communication with the insufflation conduit. *See, e.g.*, Ex. 1009, ¶¶ 6, 21; Ex. 1003, ¶ 163.

[7] With regard to humidification, see n.4, supra.

The remainder of Claim 4 is directed to a trocar assembly having the same structural characteristics as Claim 1. As discussed above, Mantell explicitly explains that its teachings can be applied to trocars. *See* Ex. 1005, 10:59–63; *see also* Ex. 1003, ¶ 164. And Ott discloses a dual-lumen trocar. Ex. 1003, ¶ 164. Although substantially similar to Claim 1, Claim 4 recites, in contrast to Claim 1, an "insufflation conduit therebetween that extends from the proximal end portion of the outer tubular member to the distal end portion of the outer tubular member." One of ordinary skill in the art would understand that the disclosures discussed above for Claim 1 also show that both Mantell and Ott meet this limitation.. *See, e.g., supra* Sections VI.A.2.(a)—VI.A.2.(b) and accompanying charts for claim element 1[c-1], 1[c-2], & Claim 2; Ex. 1003, ¶ 165. For example, Mantell describes fluid "flow[ing] into the [annular] chamber 74 and exit[ing] out of the opening 84 of the housing and the annular space 74 between housing 78 and wall 90 and flow[ing] into the target area, such as a body cavity or abdomen." Ex. 1005, 6:13–15, 6:29–34. Similarly, Ott '095 discloses "an annular chamber 30 for fluid to flow therethrough" defined by an "elongated tube or cylindrical member **22** having the sidewall **22***a* impervious to fluid flow with sidewall **22a** spaced from inner sidewall **ll***a* of tube **11,**" which is isolated from "lumen **31** [that] is used for manipulating the instruments." Ex. 1009, ¶¶ 20–21. Thus, one of ordinary skill in the art would understand that the disclosure of annular chambers in Mantell and

Ott ’095 that facilitate fluid flow in an isolated manner from the housing to the body cavity—as discussed with respect to Claim 1 above—discloses that the insufflation conduit extends from the outer tubular member’s proximal end portion to its distal end portion. Ex. 1003, ¶ 165.

Thus, for the reasons discussed in detail in connection with Claim 1, *see supra* Section VI.A.2.(a), Mantell, combined with Ott ’474 and Ott ’095 and the knowledge of a POSITA, discloses each element of Claim 4 of the ’372 patent, and thus renders Claim 4 obvious under 35 U.S.C. § 103. Ex. 1003, ¶ 166.

[4]. A system for delivering humidified insufflation gas, comprising: a) a trocar assembly having an elongated outer tubular member having opposed proximal and distal end portions and having a longitudinal axis extending therethrough and an elongated inner tubular member having opposed proximal and distal end portions and being arranged coaxially within the outer tubular member so as to form an insufflation conduit therebetween that extends from the proximal end portion of the outer tubular member to the distal end portion of the outer tubular member, the inner tubular member defining a central lumen for introduction of a surgical instrument therethrough, the insufflation conduit being in fluid communication with a plurality of apertures extending through an outer surface of the distal portion of the outer tubular member, and b) a source of humidified insufflation gas in fluid communication with the insufflation conduit, wherein humidified insufflation gas is laterally	**Mantell / Ott ’474 / Ott ’095:** *See supra* Claim 1. For the claim element of “an insufflation conduit therebetween that extends from the proximal end portion of the outer tubular member to the distal end portion of the outer tubular member,” *see supra* Claim element 1[c-1] and 1[c-2]; *see also supra* Claim 2.

discharged from the plurality of apertures into the peritoneum of a patient and wherein the distal end portion of the outer tubular member and the distal end portion of the inner tubular member cooperate to enclose the insufflation conduit such that the humidified insufflation gas is discharged only from the plurality of apertures.	

e) Claim 5

Claim 5. Claim 5 depends from Claim 4. The discussion above concerning Claim 4 is incorporated herein by reference. Ex. 1003, ¶ 167.

As shown below, Claim 5 is substantively identical to Claim 2, with the substitution of "trocar assembly" for "surgical access device." Ex. 1003, ¶ 168.

Claim 2	**Claim 5**
The surgical access device of claim 1, wherein the insufflation conduit extends from a housing at the proximal portion of the **surgical access device**, the housing in communication with a supply conduit to facilitate supply of the humidified insufflation gas to the insufflation conduit.	The system of claim 4, wherein the insufflation conduit extends from a housing at the proximal portion of the **trocar assembly**, the housing in communication with a supply conduit to facilitate supply of the humidified insufflation gas to the insufflation conduit.

For the same reasons discussed in detail above with regard to Claim 2, Mantell further discloses that the insufflation conduit **74** extends from a housing at the proximal portion of the trocar device, the housing in communication with a supply conduit to facilitate supply of the humidified[8] insufflation gas to the

[8] With regard to humidification of gas, *see* n.4, *supra.*

insufflation conduit. Specifically, insufflation conduit **74** extends from the device housing via aligned openings **80**/**82** in fluid port section **26** at the proximal portion of the trocar, in communication with a supply conduit defined by stopcock **72**, which stopcock is attached to a source of insufflation gas. Ex. 1005, Fig. 1, 5:66–67; Ex. 1003, ¶ 169. As discussed above, Mantell describes both "Verres needles and trocars" as types of "insertion devices" (*see* Ex. 1005, 2:8–9), and further describes the similarities of Verres needles and trocars as types of insertion devices. *See id.* 1:61–2:7. Regardless, even if Mantell does not disclose a trocar with the dual-lumen configuration, it would have been obvious to extend the teachings of Mantell's dual-lumen Verres needle to a dual-lumen trocar, particularly in view of Mantell's explicit teaching that "the present invention can be applied to other insertion devices, such as trocars." Ex. 1005, 10:59–63; Ex. 1003, ¶ 169. Similarly, as discussed in detail above with regard to Claim 2, Ott '095 likewise discloses this element.

f) Claim 6

Claim 6. Claim 6 depends from Claim 4. The discussion above concerning Claim 4 is incorporated herein by reference. Ex. 1003, ¶ 170.

Like Claim 3, Claim 6 adds the limitation that the source of humidified insufflation gas is external. For the same reasons discussed above with regard to Claim 3, Mantell teaches that the source of humidified insufflation gas is external

to the trocar assembly, as it is connected via a stopcock that controls access to the internal delivery mechanism of the surgical access device. *See, e.g.*, Ex. 1005, 6:29–36, Fig. 1, 2, 5; Ex. 1003, ¶ 171. Mantell discloses the trocar assembly, as discussed above. In addition, Mantell describes both "Verres needles and trocars" as types of "insertion devices" (*see* Ex. 1005, 2:8–9), and further describes the similarities of Verres needles and trocars as types of insertion devices. *See id.* 1:61–2:7. Even if Mantell does not disclose a trocar assembly, it would have been obvious to extend the teachings of Mantell's dual-lumen Verres needle to a dual-lumen trocar, particularly in view of Mantell's explicit teaching that "the present invention can be applied to other insertion devices, such as trocars." Ex. 1005, 10:59–63; Ex. 1003, ¶ 171. Similarly, as discussed above with regard to Claim 3, Ott '095 expressly discloses that the insufflation gas source is external. Ex. 1009, ¶ 21.

In addition, as discussed regarding Claim 3, Ott '474 is directed to an external source of humidified gas that is "designed to attach to a conventional trocar," and thus also discloses this element. Ex. 1006, 9:18–22; Ex. 1003, ¶ 172.

[6]. The system of claim 4, wherein the source of humidified a insufflation gas is external to the trocar assembly.	**Mantell / Ott '474 / Ott '095:** *See supra* Claim 3.

g) Claim 7

Claim 7. As shown below, Claim 7 is nearly identical to Claim 1, with the substitution of the word "conditioned" for "humidified" and "radially" for "laterally."[9] Ex. 1003, ¶ 173.

Claim 1	Claim 7
A surgical access device comprising:	A surgical access device comprising:
a) an elongated outer tubular member having opposed proximal and distal end portions and having a longitudinal axis extending therethrough;	a) an elongated outer tubular member having opposed proximal and distal end portions and having a longitudinal axis extending therethrough;
b) an elongated inner tubular member having opposed proximal and distal end portions and being arranged coaxially within the outer tubular member, the inner tubular member defining a central lumen for introduction of a surgical instrument therethrough;	b) an elongated inner tubular member having opposed proximal and distal end portion [sic] and being arranged coaxially within the outer tubular member, the inner tubular member defining a central lumen for introduction of a surgical instrument therethrough;
c) an insufflation conduit defined between the inner and outer tubular members in communication with a source of **humidified** insufflation gas; and	c) an insufflation conduit defined between the inner and outer tubular members in communication with a source of **conditioned** insufflation gas; and
d) a plurality of apertures extending through an outer surface of the distal portion of the outer tubular member in fluid communication with the insufflation conduit and configured to **laterally** discharge **humidified** insufflation gas from the insufflation conduit into the peritoneum of a patient,	d) a plurality of apertures extending through an outer surface of the distal portion of the outer tubular member in fluid communication with the insufflation conduit and configured to **radially** discharge **conditioned** insufflation gas from the insufflation conduit into the peritoneum of a patient,
wherein the distal end portion of the	wherein the distal end portion of the

[9] Claim element 7[b] contains an apparent typographical error, using "portion" for "portions" without altering the meaning of the claim. Ex. 1003, ¶ 173 n.4.

outer tubular member and the distal end portion of the inner tubular member cooperate to enclose the insufflation conduit such that the **humidified** insufflation gas is discharged only from the plurality of apertures.	outer tubular member and the distal end portion of the inner tubular member cooperate to enclose the insufflation conduit such that the **conditioned** insufflation gas is discharged only from the plurality of apertures.

See also Ex. 1012, ¶ 10; Ex. 1003, ¶ 174.

The only distinctions between Claims 1 and 7 are thus the limitations that "conditioned" gas be used and that there be apertures configured to "radially" discharge gas. Humidified gas is a type of "conditioned" gas. *See supra* Section V.B; *see also* Ex. 1003, ¶ 175. Ott '474's disclosure of humidified gas thus discloses this element as well. In addition, Ott '095 discloses that the gas can include drugs or anesthetics. Ex. 1009, ¶ 6. One of ordinary skill would understand that this amounts to conditioning the gas. Ex. 1003, ¶ 175. Mantell also teaches the gas or fluid can be conditioned, such as with aerosolized medication. Ex. 1005, 6:4–7. In addition, the limitation that the insufflation gas be "radially" discharged is disclosed by Mantell's disclosure of an aperture for the lateral discharge of gas from a tubular housing. Ex. 1003, ¶ 175. Likewise, Ott '095 expressly discloses radially discharging the conditioned insufflation gas from a plurality of apertures. *See, e.g.*, Ex. 1009, Fig. 2, ¶ 20 (describing "radial apertures **19**"), ¶ 21 ("radial fluid flow"); *see also* Ex. 1003, ¶ 175.

Thus, for the reasons discussed in detail in connection with Claim 1, *see supra* Section VI.A.2.(a), Mantell, combined with Ott '474 and Ott '095, discloses

each element of Claim 7 of the '372 patent, and thus renders Claim 7 obvious under 35 U.S.C. § 103. Ex. 1003, ¶ 176.

h) Claim 8

Claim 8. Claim 8 depends from Claim 7. The discussion above concerning Claim 7 (as well as Claims 2 and 5) is incorporated herein by reference. Ex. 1003, ¶ 177.

Claim 8 is substantively identical to Claim 2, with the substitution of "conditioned" for "humidified." For the same reasons discussed in detail above with regard to Claims 2 and 5, Mantell further discloses that the insufflation conduit **74** extends from a housing at the proximal portion of the surgical access device, the housing in communication with a supply conduit to facilitate supply of the conditioned[10] insufflation gas to the insufflation conduit.Ex. 1005, Fig. 1, 5:66–67; Ex. 1003, ¶ 178. Likewise, as discussed above with Claim 2, Ott '095 likewise discloses this element. Ex. 1009, Fig. 1; ¶¶ 18, 21.

i) Claim 9

Claim 9. Claim 9 depends from Claim 7. The discussion above concerning Claim 7 (and Claims 3 and 6) is incorporated herein by reference. Ex. 1003, ¶ 179.

Like Claims 3 and 6, Claim 9 adds the limitation that the source of

[10] With regard to conditioning or humidification of gas, *see* n.4, *supra.*

insufflation gas is external. For the same reasons discussed above with regard to Claims 3 and 6, Mantell discloses this element.[11] *See, e.g.*, Ex. 1005, 6:29–36, Fig. 1, 2, 5; Ex. 1003, ¶ 180.

Similarly, as discussed with regard to Claims 3 and 6, Ott '095 expressly discloses that the source of insufflation gas is external. Ex. 1009, ¶ 21; Ex. 1003, ¶ 181.

In addition, as discussed regarding Claims 3 and 6, Ott '474 is directed to an external source of conditioned (humidified and heated) gas that is "designed to attach to a conventional trocar," and thus also discloses this element. Ex. 1006, 9:18–22; Ex. 1003, ¶ 182.

j) Claim 10

Claim 10. Claim 10 depends from Claim 7 and adds that the insufflation gas is "humidified." The discussion above concerning Claim 7 is incorporated herein by reference. With regard to humidification, as discussed *supra* in connection with elements 1[c-2] and 7[c], Ott '474 is directed to a device for humidifying

[11] While Claims 3 and 6 refer to "humidified" insufflation gas, Claim 9 refers to "conditioned" insufflation gas. "Conditioned" insufflation gas includes "humidified" insufflation gas. *See supra* Sections V.B, VI.A.2.(c), and VI.A.2.(f); Ex. 1003, ¶ 180, n.6

insufflation gas and thus expressly discloses that the insufflation gas is be humidified. *See, e.g.*, Ex. 1006, 3:30–35; *see also* Ex. 1003, ¶ 183.

[10]. The surgical access device of claim 7, wherein the conditioned insufflation gas is humidified insufflation gas.	**Ott '474:** *See, e.g.*, Ex. 1006, 1:11–15; *id*., 3:30–35: "The disadvantages of the prior art are overcome by the present invention which provides a high-efficiency apparatus for heating, humidifying and filtering gas, thus allowing the gas to be delivered to the patient at an accurate temperature while also properly humidified and filtered and without the use of AC voltage."); *id.*, 2:36–39; *id.*, 3:30–35; *id*., Fig. 1 & 4:35–41; *id.*, 9:18–22.

k) Claim 11

Claim 11. Claim 11 depends from Claim 7 and adds that the insufflation gas is "heated." The discussion above concerning Claim 7 is incorporated herein by reference. Ott '474 further expressly discloses that the conditioned insufflation gas is heated insufflation gas. *See, e.g.*, Ex. 1006, 1:12–15 (invention "relates to a compact device for … **heating**, humidifying and filtering insufflation gas . . .") (emphasis added); Ex. 1003, ¶ 184.

[11]. The surgical access device of claim 7, wherein the conditioned insufflation gas is heated insufflation gas.	**Ott '474:** *See, e.g.*, Ex. 1006, 1:66–67; *id.*, 3:31–34 (emphasis added): "the present invention which provides a high-efficiency apparatus for **heating**, humidifying and filtering gas, . . ."; *id.*, 4:14–16; *id.*, 3:65–67; *id.*, 5:7–9; *id.*, 6:27–55.

VII. CONCLUSION

Petitioner respectfully requests that *inter partes* review of the '372 Patent be instituted and that Claims 1–11 be cancelled as unpatentable under 35 U.S.C. § 318(b).

Respectfully submitted,
BAKER BOTTS L.L.P.

December 21, 2016
Date

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petition, exclusive of the exempted portions as provided in 37 C.F.R. § 42.24(a), contains no more than 13,934 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(a). The word count was calculated by starting with Microsoft Word's total document word count and subtracting the words for the Table of Contents, the Exhibit List, the Mandatory Notices, the Certificate of Compliance, and the Certificate of Service.

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. §§ 42.6(e) and 42.105, the undersigned certifies that on the 21st day of December, 2016, a complete and entire copy of the **PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1–11 OF U.S. PATENT NO. 9,095,372 UNDER 35 U.S.C. § 311 and 37 C.F.R. § 42.100 *ET SEQ*** ("petition") was served on the patent owner at the correspondence address of record for the subject patent,

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via Express Mail or by means at least as fast and reliable as Express Mail.

In addition, the same were served upon prosecution counsel for the Patent Owner.

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because that is likely to effect service.

In accordance with § 42.51(b)(1), the undersigned certify that Petitioner is not aware of, and therefore does not provide any "relevant information that is inconsistent with a position advanced by petitioner[]."

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